USE OF THE RE-AIM FRAMEWORK: TRANSLATING RESEARCH TO PRACTICE WITH NOVEL APPLICATIONS AND EMERGING DIRECTIONS

EDITED BY: Russell E. Glasgow, Samantha M. Harden, Bridget Gaglio, Borsika Adrienn Rabin, Marcia G. Ory, Matthew Lee Smith and Paul A. Estabrooks

PUBLISHED IN: Frontiers in Public Health

frontiers Research Topics

frontiers

ISSN 1664-8714
ISBN 978-2-88971-181-9
DOI 10.3389/978-2-88971-181-9

About Frontiers

Frontiers is more than just an open-access publisher of scholarly articles: it is a pioneering approach to the world of academia, radically improving the way scholarly research is managed. The grand vision of Frontiers is a world where all people have an equal opportunity to seek, share and generate knowledge. Frontiers provides immediate and permanent online open access to all its publications, but this alone is not enough to realize our grand goals.

Frontiers Journal Series

The Frontiers Journal Series is a multi-tier and interdisciplinary set of open-access, online journals, promising a paradigm shift from the current review, selection and dissemination processes in academic publishing. All Frontiers journals are driven by researchers for researchers; therefore, they constitute a service to the scholarly community. At the same time, the Frontiers Journal Series operates on a revolutionary invention, the tiered publishing system, initially addressing specific communities of scholars, and gradually climbing up to broader public understanding, thus serving the interests of the lay society, too.

Dedication to Quality

Each Frontiers article is a landmark of the highest quality, thanks to genuinely collaborative interactions between authors and review editors, who include some of the world's best academicians. Research must be certified by peers before entering a stream of knowledge that may eventually reach the public - and shape society; therefore, Frontiers only applies the most rigorous and unbiased reviews.
Frontiers revolutionizes research publishing by freely delivering the most outstanding research, evaluated with no bias from both the academic and social point of view. By applying the most advanced information technologies, Frontiers is catapulting scholarly publishing into a new generation.

What are Frontiers Research Topics?

Frontiers Research Topics are very popular trademarks of the Frontiers Journals Series: they are collections of at least ten articles, all centered on a particular subject. With their unique mix of varied contributions from Original Research to Review Articles, Frontiers Research Topics unify the most influential researchers, the latest key findings and historical advances in a hot research area! Find out more on how to host your own Frontiers Research Topic or contribute to one as an author by contacting the Frontiers Editorial Office: frontiersin.org/about/contact

USE OF THE RE-AIM FRAMEWORK: TRANSLATING RESEARCH TO PRACTICE WITH NOVEL APPLICATIONS AND EMERGING DIRECTIONS

Topic Editors:
Russell E. Glasgow, University of Colorado Hospital, United States
Samantha M. Harden, Virginia Tech, United States
Bridget Gaglio, Patient Centered Outcomes Research Institute, United States
Borsika Adrienn Rabin, University of California, San Diego, United States
Marcia G. Ory, Texas A&M University, United States
Matthew Lee Smith, Texas A&M University, United States
Paul A. Estabrooks, University of Nebraska Medical Center, United States

Citation: Glasgow, R. E., Harden, S. M., Gaglio, B., Rabin, B. A., Ory, M. G., Smith, M. L., Estabrooks, P. A., eds. (2021). Use of the RE-AIM Framework: Translating Research to Practice With Novel Applications and Emerging Directions. Lausanne: Frontiers Media SA. doi: 10.3389/978-2-88971-181-9

Table of Contents

USE OF RE-AIM IN CLINICAL SETTINGS

EMERGING DIRECTIONS IN THE APPLICATION OF RE-AIM

frontiers in Public Health

EDITORIAL
published: 11 June 2021
doi: 10.3389/fpubh.2021.691526

Editorial: Use of the RE-AIM Framework: Translating Research to Practice With Novel Applications and Emerging Directions

*Paul A. Estabrooks[1], Bridget Gaglio[2], Russell E. Glasgow[3], Samantha M. Harden[4], Marcia G. Ory[5,6], Borsika Adrienn Rabin[7] and Matthew Lee Smith[5,6]**

[1] Department of Health Promotion, University of Nebraska Medical Center, College of Public Health, Omaha, NE, United States, [2] Clinical Effectiveness and Decision Science, Patient-Centered Outcomes Research Institute, Washington, DC, United States, [3] Dissemination and Implementation Science Program of Adult & Child Consortium for Health Outcomes Research & Delivery Science (ACCORDS), Department of Family Medicine, School of Medicine, University of Colorado, Aurora, CO, United States, [4] Physical Activity Research and Community Implementation, Human Nutrition, Foods, and Exercise, Virginia Tech, Blacksburg, VA, United States, [5] Center for Population Health and Aging, Texas A&M University, College Station, TX, United States, [6] Department of Environmental and Occupational Health, School of Public Health, Texas A&M University, College Station, TX, United States, [7] Herbert Wertheim School of Public Health and Human Longevity Science, UC San Diego, San Diego, CA, United States

Keywords: RE-AIM, planning, evaluation, dissemination, implementation, research, practice

Editorial on the Research Topic

Use of the RE-AIM Framework: Translating Research to Practice With Novel Applications and Emerging Directions

Edited and reviewed by:
Stefania Salmaso, Independent Researcher, Rome, Italy

***Correspondence:**
Matthew Lee Smith
matthew.smith@tamu.edu

Specialty section:
This article was submitted to Public Health Education and Promotion, a section of the journal Frontiers in Public Health

Received: *06 April 2021*
Accepted: *26 April 2021*
Published: *11 June 2021*

Citation:
Estabrooks PA, Gaglio B, Glasgow RE, Harden SM, Ory MG, Rabin BA and Smith ML (2021) Editorial: Use of the RE-AIM Framework: Translating Research to Practice With Novel Applications and Emerging Directions. Front. Public Health 9:691526. doi: 10.3389/fpubh.2021.691526

INTRODUCTION

In 2019, we initiated a call for papers to contribute to a Frontiers of Public Health Research Topic on the use of the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) Framework. In part, the Research Topic was intended to celebrate 20 years of planning and evaluation using RE-AIM and underscore new research directions. More importantly, we saw the need to document how the framework continues to be adapted, evolve, and provide opportunities in emerging areas. Of key importance is speeding research-practice translation and studying the process that leads to more efficient movement of evidence-based principles, programs, and policies into sustained community and clinical practice. What follows is an overview of the excellent submissions we received that document lessons learned, adaptations, and innovative uses of RE-AIM, as well as highlight the framework's potential to advance science, quality of practice, and population health.

The Research Topic and resulting papers are grouped into four sections: (a) *Introduction*; (b) *Use of RE-AIM in Community Settings*; (c) Use of RE-AIM in Clinical Settings; and (d) *Emerging Directions in the Application of RE-AIM*. The *Introduction* section kicks off the collection with a paper led, fittingly, by (Glasgow, Harden et al.), on how the RE-AIM Framework has evolved over the 20 years since the seminal American Journal of Public Health (Glasgow, Vogt et al.) article was published in 1999. This is accompanied by an insightful commentary from Dr. Kurt Stange that highlights the value of using RE-AIM and its contextual extension, the Practical, Robust, Implementation, and Sustainability Model (PRISM) to "shine light on multilevel context" and solve real world problems, such as advancing health equity, in a meaningful and sustained way (Stange). We round out the *Introduction* with two papers summarizing goals, resources, benefits of

application, and future directions for RE-AIM by members of the National RE-AIM Workgroup (Smith and Harden, Harden et al.). These papers, along with the RE-AIM website (www.re-aim.org), provides readers with current definitions, examples, and resources for applying RE-AIM.

The second and third sections of the Research Topic are the *Use of RE-AIM in Community Settings* and the *Use of RE-AIM in Clinical Settings*, respectively. Papers in these sections include international studies focused on physical activity promotion in Brazil (Benedetti et al.) and work environment improvements in Denmark (Munch et al.). There are exceptional exemplars across these sections (Balis and Strayer; Balis et al.; Ball et al.; Wilcox et al.) to guide readers about the application of RE-AIM when planning, implementing, and/or evaluating specific interventions intended to improve effectiveness on participant health outcomes. There are also some thoughtful manuscripts illustrating qualitative and mixed methods approaches, and one applying RE-AIM in an iterative fashion to support ongoing improvements in implementation (Ball et al.; Kwan et al.; Glasgow et al.; Prusaczyk et al.). Finally, these sections conclude with an informative article about how to integrate an additional implementation science theory with RE-AIM constructs (King et al.).

Our Research Topic concludes with a collection of papers that reflect *Emerging Directions in the Application of RE-AIM*. Two studies and a commentary, focus on applications of RE-AIM (Baumann) in the areas of environmental health (Quinn et al.) and health policy (Toyserkani et al.). They provide interesting and novel adaptations that offer opportunities for replication and further evolution of the framework. This section, and the entire Research Topic, concludes with two papers that provide extensions to RE-AIM. One integrates Proctor's et al. conceptualization of implementation outcomes (Reilly et al.), and the other integrates PRISM and RE-AIM factors to advance sustainability and health equity (Shelton et al.). The papers in this section are strong examples of how RE-AIM can be conceptualized, re-conceptualized, and expanded to address and resolve. As called out in the Introductory commentary by Stange, these papers astutely address the wicked problems affecting the health and equity in our society by taking the path that creates and supports a high, robust, and sustained level of public health around the world.

It is our hope that this collection of papers provides concrete examples and guidance about how RE-AIM can be used to advance science and improve the public health impact in our communities, both nationally and internationally.

AUTHOR CONTRIBUTIONS

All authors contributed to the conceptualization of the manuscript and its content. All authors contributed to the full manuscript as well as reviewed and approved the final version of the manuscript.

FUNDING

MO and MS contributions supported through ACL SUSTAIN for Better Health and Health Care for Older Adults 90CS0065-01. PE contributions supported by Great Plains IDEA CTR U54 GM115458- 01. GCP contributions supported by American Heart Association 18PRE34060136. REG contributions partially supported by IMPlementation to Achieve Clinical Transformation (IMPACT): the Colorado Training Program from the NIH K12 HL137862, the Eastern Colorado VA Geriatric Research Education and Clinical Center, and NCI grant P50 CA244688. BR contributions partially supported by Center of Excellence in Stress and Mental Health at the San Diego VA and the UC San Diego ACTRI Dissemination and Implementation Science Center.

ACKNOWLEDGMENTS

The authors would like to acknowledge all members of the National Working Group on RE-AIM Planning and Evaluation Framework (www.re-aim.org).

Disclaimer: All statements in this report, including its findings and conclusions, are solely those of the authors and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors, or Methodology Committee.

Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

frontiers in Public Health

MINI REVIEW
published: 29 March 2019
doi: 10.3389/fpubh.2019.00064

RE-AIM Planning and Evaluation Framework: Adapting to New Science and Practice With a 20-Year Review

Russell E. Glasgow[1]*, *Samantha M. Harden*[2], *Bridget Gaglio*[3], *Borsika Rabin*[1,4], *Matthew Lee Smith*[5,6,7], *Gwenndolyn C. Porter*[8], *Marcia G. Ory*[5,6] and *Paul A. Estabrooks*[8]

[1] Dissemination and Implementation Science Program of ACCORDS, Department of Family Medicine, School of Medicine, University of Colorado, Aurora, CO, United States, [2] Physical Activity Research and Community Implementation, Human Nutrition, Foods, and Exercise, Virginia Tech, Blacksburg, VA, United States, [3] Patient-Centered Outcomes Research Institute, Washington, DC, United States, [4] Department of Family Medicine and Public Health, School of Medicine, University of California, San Diego, La Jolla, CA, United States, [5] Center for Population Health and Aging, Texas A&M University, College Station, TX, United States, [6] Department of Environmental and Occupational Health, School of Public Health, Texas A&M University, College Station, TX, United States, [7] Department of Health Promotion and Behavior, College of Public Health, The University of Georgia, Athens, GA, United States, [8] Department of Health Promotion, College of Public Health, University of Nebraska Medical Center, Omaha, NE, United States

OPEN ACCESS

Edited by:
Dan J. Graham, Colorado State University, United States

Reviewed by:
Melissa Bopp, Pennsylvania State University, United States
Deborah Paone, Independent Researcher, United States

***Correspondence:**
Russell E. Glasgow
russell.glasgow@ucdenver.edu

Specialty section:
This article was submitted to Public Health Education and Promotion, a section of the journal Frontiers in Public Health

Received: *09 January 2019*
Accepted: *05 March 2019*
Published: *29 March 2019*

Citation:
Glasgow RE, Harden SM, Gaglio B, Rabin B, Smith ML, Porter GC, Ory MG and Estabrooks PA (2019) RE-AIM Planning and Evaluation Framework: Adapting to New Science and Practice With a 20-Year Review. Front. Public Health 7:64. doi: 10.3389/fpubh.2019.00064

The RE-AIM planning and evaluation framework was conceptualized two decades ago. As one of the most frequently applied implementation frameworks, RE-AIM has now been cited in over 2,800 publications. This paper describes the application and evolution of RE-AIM as well as lessons learned from its use. RE-AIM has been applied most often in public health and health behavior change research, but increasingly in more diverse content areas and within clinical, community, and corporate settings. We discuss challenges of using RE-AIM while encouraging a more pragmatic use of key dimensions rather than comprehensive applications of all elements. Current foci of RE-AIM include increasing the emphasis on cost and adaptations to programs and expanding the use of qualitative methods to understand "how" and "why" results came about. The framework will continue to evolve to focus on contextual and explanatory factors related to RE-AIM outcomes, package RE-AIM for use by non-researchers, and integrate RE-AIM with other pragmatic and reporting frameworks.

Keywords: RE-AIM, evaluation, external validity, dissemination, implementation

INTRODUCTION

The RE-AIM framework (1) was developed to address the issue that the translation of scientific advances into practice, and especially into public health impact and policy, have been slow and inequitable (2–6). RE-AIM and other models (7) have helped balance the traditional focus on internal over external validity. Unique features of RE-AIM include an explicit focus on issues, dimensions, and steps in the design, dissemination, and implementation process that can either facilitate or impede success in achieving broad and equitable population-based impact.

The seminal RE-AIM paper (1) has been cited over 2,800 times, and the RE-AIM framework has been applied to study planning or evaluation in over 450 publications (7). RE-AIM is one of the most frequently used frameworks for planning and evaluation of grant applications at most of

the leading U.S. health and medical research agencies (8) and has been used widely (nationally and internationally) (9, 10) and across populations, settings, and health conditions (11–24). Generally, RE-AIM does seem to translate and be useful in the different countries and cultures in which use has been reported. Some international applications include low- and middle-income countries (25) including Australia (26–30), the Netherlands (31–34), and Brazil (35, 36). One interesting application was the use of RE-AIM to help plan and evaluate interventions to reduce the use of coal-fired indoor cook stoves in Africa (37). In this article, we summarize the history of the RE-AIM framework, discusses current applications of RE-AIM for research and practice, and outline opportunities for future application.

HISTORICAL PERSPECTIVES

The dimensions of the RE-AIM framework were originally introduced to encourage scientists to be more transparent and consider internal and external validity across pilot, efficacy, effectiveness, demonstration, and translational research (23, 38). Most peer reviewed publications previously emphasized efficacy, leaving researchers, and practitioners with little information about the generalizability of the intervention context, implementation personnel and conditions, and findings. The main goal from its conception was to improve assessment and reporting along the five RE-AIM dimensions, not necessarily intervening to improve all dimensions (see **Table 1**).

The RE-AIM dimensions include reach (R), effectiveness (E), and maintenance (M)–which operate at the individual-level (i.e., those who are intended to benefit), and adoption (A), implementation (I), and maintenance (M), which focus on the staff and setting levels. Setting-level RE-AIM factors are often multi-level and address context and external validity issues important to population impact. For example, settings may include clinics, schools, or worksites nested within communities or larger systems, and within these settings are nested clinicians, teachers, or human resources staff responsible for implementation.

All RE-AIM dimensions are complex, but implementation currently has the most indices. It focuses on fidelity to an intervention: the extent to which the program is implemented consistently across different settings, staff, and patients. It also includes adaptations made (58) and costs from multiple stakeholder perspectives (59). Maintenance has indices at the individual- (long-term effectiveness) and setting-level (sustainability after original research funded is completed).

The framework's operational components have been increasingly applied over the years. For example, in the past, studies reported participant characteristics that differed between study conditions or between those retained and those lost to follow-up. However, studies using RE-AIM compared the representativeness of individuals who enrolled in a study to the characteristics of the intended population. These comparisons used in RE-AIM studies increased understanding about access, awareness, appropriateness, and likely generalizability of recruitment strategies and intervention approaches.

In the past, clinical effectiveness research focused relatively narrowly on physiologic outcomes. RE-AIM expanded this focus to multiple factors that impact *public health*. This approach to assessing broader impacts aided in understanding comprehensive effects of a program on quality of life, including unintended consequences (e.g., increasing health inequity or the social stigma of labeling someone with a chronic condition).

There have been several literature reviews on use of RE-AIM (11, 42, 52, 60–62). The most comprehensive reviews have spanned the literature from 2000 to 2012 or 2015 (10, 42, 52). Notably, these reviews of different content areas reached similar conclusions: that adoption and maintenance, as well as representativeness across individual- and organizational-levels, were reported far less frequently. They identified frequent issues with confusing different dimensions, in particular reach (at the individual-level) and adoption (at the setting-level). These observations are not limited to the United States alone.

To enhance development and application of the framework, several scientists contributed to a RE-AIM research consortium funded by the Robert Wood Johnson Foundation (63–66). This work led to the development of a website, www.re-aim.org, in 2004 (64). The website serves as a repository of various resources and tools including self-quizzes, checklists, figures, tables, measures, tips for using RE-AIM, and increasingly, other social media tools. These are available to facilitate the operationalization and application of RE-AIM across diverse interventions, settings, and populations. To enhance a dialogue within the broader research community, monthly webinars are held about RE-AIM related issues; archived recordings are available on the website (www.re-aim.org).

FROM PAST TO PRESENT

Below, we summarize five general areas currently being examined using RE-AIM (**Table 1**). The first is to understand and maximize the potential of RE-AIM to assess adaptations prior to, during, and after program implementation (54, 55, 67). Adaptations naturally occur during the implementation of programs (68). Mittman et al. (69) suggest that instead of ignoring or suppressing this phenomenon, we should find ways to document and assess these changes. Recent Patient-Centered Outcomes Research Institute (PCORI) Methodology Standards (70) suggest that adaptations should be systematically documented. RE-AIM has great potential to provide guidance about documenting adaptations. It can also provide guidance about how to evaluate the impact of these adaptations, as well as their purpose (58). RE-AIM has been used to expand the widely known Stirman framework (71) on adaptations with additional components to address "who, what, why, where, and when" questions (67). RE-AIM considers adaptations in a longitudinal, multi-method, and multi-level manner and includes data collection at multiple time points and from multiple stakeholders, using multiple data collection approaches (54, 55, 67).

Second, there has been a recent focus on more qualitative RE-AIM assessments. Most evaluations and uses of the framework have emphasized descriptive or quantitative data, often focusing

TABLE 1 | The RE-AIM dimensions: definitions, evolution, and examples from the literature.

Dimension	Definition	Historical perspectives	Current issues and outcomes	Future directions
Reach Click here for more information	The absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative, intervention, or program. Reasons for not participating Click here for information on improving reach, such as: *"How do I reach the targeted population with the intervention?"*	- Reporting on demographic characteristics - Comparison between participants in different study conditions and between those who stayed in the intervention and those lost to follow-up - Unknown as to the degree to which those in the intervention were similar to the target audience	- Description of target audience (including a best estimate denominator) - Comparison of sample to the target audience (representativeness) - Use of a number of factors to best calculate the proportion reached (39) - Some use of qualitative methods to understand "why and how"	- Use of reach implementation strategies to improve access, awareness, and appropriateness of intervention to meet the target audience needs - More focus on recruitment strategies (and interventions) to directly address health equity (2) - Reach as an outcome target for dissemination trials.
Examples from the Literature	- Worksite wellness intervention started with a brief health survey of all participating worksites; participants were not informed that there may be a future worksite intervention. Results indicated that, once offered the worksite wellness intervention, "employees from higher income households, with higher education levels and health literacy proficiency were significantly more likely to participate in the program (p's < 0.01)" (40). - Community health promotion intervention for African American and Hispanic or Latina women. Investigators found that African Americans were more likely to not meet eligibility criteria and that the Hispanic/Latina women were more likely to drop out. There were no significant differences by city or recruitment method. In addition, at the end of the study participants "overrepresented higher educated, wealthier, and older women" (41).			
Effectiveness Click here for more information.	The impact of an intervention on important outcomes, including potential negative effects, quality of life, and economic outcomes. Heterogeneity of effects and reasons for success or lack of such Click here for information on improving effectiveness, such as: *"How do I know my intervention is effective?"*	- Reported subjective or objective measure related to the primary outcome (e.g., change in diet, smoking cessation, physical activity behavior, or biomarker such as hemoglobin A1c) - Exclusive focus on average overall effect and often one single outcome	- Still reporting primary outcomes; - Some studies are also measuring quality of life (QOL) and unintended consequences (42) - More emphasis on subgroup effects	- Need greater attention to QOL, unintended consequences, and systems impacts - For those participants who do experience an unintended consequence, more information on proposed "next steps." - Relationships among multiple outcomes and relationship of context to RE-AIM outcomes
Examples from the Literature	• In a community adaptation of a trial, body image satisfaction was measured as a secondary outcome of a child's weight loss intervention. Almost half of the overweight children [$n = 16$ of the 34 (47%)] exhibited a decrease in body dissatisfaction at 6 months compared with baseline (43). However, five children (15%) had an increase in body image dissatisfaction. • Diabetes self-management support web assisted program effectiveness outcomes included improvements in quality of life, but no unintended negative consequences were measured (44).			
Adoption Click here for more information.	The absolute number, proportion, and representativeness of: a) settings; and b) intervention agents (people who deliver the program) who are willing to initiate a program. Reasons for adoption or non-adoption Click here for information on improving adoption, such as: *"How do I develop organizational support to deliver my intervention?"*	- Limited to no information on rates and representativeness of *staff* and settings that participate - Reporting only on these settings and staff who participate	- More studies reporting setting level adoption rates - Few studies reporting representativeness at the setting level - Few reporting on multi-level adoption issues - Somewhat greater use of qualitative measures	- Need to better understand contextual factors related to adoption - Need more information on multiple setting level characteristics [e.g., organizational culture and climate (45)] - Development of guides and tools to help users enhance adoption (and other RE-AIM outcomes)
Examples from the Literature	• Full RE-AIM evaluation of a 10 week school-based nutrition education program for third graders. Adoption was measured at the third-grade classroom level. Thirty-nine percent of all third-grade classrooms across all public schools in the targeted state participated. No information on representativeness of the schools that did or did not participate (46). • Print materials tailored for Korean American women: adoption was a secondary outcome and interviews were used for adoption level data. Qualitative adoption results included that the print materials were easy to include and that this contributed to adoption (47).			

(Continued)

TABLE 1 | Continued

Dimension	Definition	Historical perspectives	Current issues and outcomes	Future directions
Implementation Click here for more information.	At the setting level, implementation refers to the intervention agents' fidelity to the various elements of an intervention's protocol, including consistency of delivery as intended and the time required. Also includes adaptations made and the costs of implementation. At the individual level, implementation refers to clients' use of the intervention and implementation strategies. Click here for information on improving implementation, such as: *"How do I ensure the intervention is delivered properly?"*	- Limited or no information on time, costs and resources needed to complete intervention components well and over-time. - Only fidelity reported, never adaptations	- Increased attention to strategies to improve implementation of an intervention - Improvements on standardized measures for capturing implementation fidelity. - Much recent attention to adaptations - Limited links of implementation quality, adaptations and impacts to other RE-AIM outcomes	- Need greater uptake of implementation measurement protocols (48) - Multi-method assessments of implementation and adaptation - Multi-level and practical assessments of costs and combining implementation cost with proportion of participants benefiting from intervention - More understanding of reasons for adaptations and high/low levels of implementation - Rapid, iterative use of RE-AIM assessments to guide adaptations
Examples from the Literature	• A pragmatic, mixed-methods, quasi-experimental study across five community hospitals. Three hospitals received the nurse-administered Tobacco Tactics intervention and two received usual care. Intervention was streamlined, user friendly, etc. and resulted in nurses increased provision of advice to quit, counseling, medications, handouts, and DVD (all $p < 0.05$) when compared to control (49). • A community-based implementation trial of a cancer educational intervention was offered to 14 African American churches. Community health advisors were trained in a Traditional classroom setting or via the Web. Implementation outcomes included adherence, dosage, and quality. Implementation was strong across both conditions (all churches fully completing the workshops), but Traditional churches took more time to complete the workshops than the Web-based group. Notably, "other implementation outcomes were comparable between both the Traditional and Technology groups ($p > 0.05$)," which showed promise for using "web-based methods to disseminate and implement evidence-based interventions in faith-based settings" (50). • A community-wide, technology-facilitated weight-loss program was implemented in Colorado and reached over 30,000 overweight or obese community residents. Implementation costs were derived using payer invoices and combined with the reach (number of participants) and effectiveness (proportion of participants to achieve a 5% weight loss) to determine cost per participant with a clinically meaningful weight loss. Costs varied based upon participant characteristics (representativeness) in that African American participants saw a lower cost per clinically meaningful weight loss due to a higher retention and success rate while costs per participant remained relatively constant (51).			
Maintenance (individual and organizational) Click here for more information.	The extent to which: a) behavior is sustained 6 months or more after treatment or intervention; and b) a program or policy becomes institutionalized or part of the routine organizational practices and policies. Includes proportion and representativeness of settings that continue the intervention and reasons for maintenance, discontinuance or adaptation Click here for information on improving maintenance, such as *"How do I incorporate the intervention so that it is delivered over the long term?"*	- Long term outcomes seldom reported - RE-AIM somewhat arbitrarily selected 6 months post intervention as default (1) - Ongoing challenge of relapse after intervention is withdrawn - Previous helicopter research: Unknown system-level impacts beyond the study lifespan	- Limited data on outcomes post intervention (with no intervention contact) - High attrition from post program to 6 month follow up unless there are intervention "contacts" - Most maintenance data reported relate to other dimensions - For example, those who *maintained* the behavior were more likely to exhibit certain characteristics - Improvements in collaborating with end-users to enhance intervention fit and sustainability - Proportion of settings still delivering intervention remains the most commonly reported metric within this dimension (52)	- Ongoing intervention is often needed to sustain impact - Need strategies for relapse prevention within large-scale interventions [-] Greater understanding of factors leading to sustainment - Partnership with intended delivery system is ubiquitous with successful institutionalization (53) - Need pragmatic measures and systems-level buy in to ensure that relevant data are collected beyond the "research" phase (54, 55) - Need more understanding of dynamic, complex multi-level factors related to sustainment
Examples from the Literature	• *S*etting level: To reduce depression outcomes in primary care, a collaborative-care management strategy called Community Based Outpatient Clinics (CBOCs) was deployed in the Department of Veterans Affairs. Eleven sites engaged in the study, and once funds were withdrawn, 91.9% (10/11) continued to apply the CBOCs approach (56). • *S*etting level: Evaluation of continued implementation of a new computer-based intervention tool for lifestyle intervention in primary health care, 2 years after its introduction. Clinics either had explicit (e.g., theory-based training and support) or implicit (e.g., non-theory-based introduction with no ongoing support) strategies for tool use. Units with explicit strategies were more successful at the onset of the intervention, but over 24 months, those effects were mitigated (57).			

on key aspects such as the percentage of potentially eligible persons or settings that participate. A qualitative focus as presented by Holtrop et al. (72) can enhance understanding about what happened as well as the "how" and the "why."

Third, we recognized the need for more pragmatic uses of the framework rather than trying to comprehensively assess all RE-AIM dimensions in all applications, especially when not having many evaluation resources (67, 73). All studies or evaluations, and particularly those without large evaluation budgets, do not need to assess all components of RE-AIM. Rather, they should address those components most valued and appropriate for their particular question, setting, stakeholders, and stage of research. An *a priori* decision should be made, however, to select the dimensions on which to focus for evaluation and on which to use for planning and improvement (i.e., beyond the evaluation scope). In some cases, the decision to capture all five dimensions is made *a priori* to understand individual impacts, contextual implications, and feasibility of ongoing data collection. This is demonstrated in two recent applications of RE-AIM before, during, and after program implementation—and on limited funds (74, 75). Both applications highlighted the need for stakeholder buy-in (54) and operationalization (67) of each dimension that holds value for these stakeholders.

Fourth, assessment of costs, from the perspective of multiple stakeholders and across the various RE-AIM dimensions, is another area of emphasis (5). Building upon earlier work by Ritzwoller et al. (76), recent RE-AIM cost assessments have focused on the multilevel nature of implementation, different stakeholder perspectives, and cost estimates for replicating a program or policy in different settings. Rhodes et al. (59) have provided templates to assess costs at the patient-, staff-, clinic-, and organizational-levels. Costs to deliver programs are associated with activities to address and enhance each RE-AIM dimension (**Figure 1**). In the future, we anticipate more consistent reporting of costs and burden and more frequent comparative effectiveness research about cost-effective methods to enhance value and various RE-AIM dimensions.

Finally, Glasgow et al. (77) have recently advocated for an extension of RE-AIM concepts and dimensions, termed an Expanded CONSORT Figure to enhance transparent reporting, and potentially, replication. The goal is to expand the CONSORT reporting criteria required for randomized studies (78) to (a) include factors related to setting and staff level participation and representativeness, which begin before individual participants are recruited, and (b) extend the temporal focus beyond the end of a study. The expanded CONSORT figure and a related downloadable template summarize issues of exclusion and inclusion criteria for settings (e.g., communities or healthcare networks) and delivery staff, [e.g., evaluating the percent and characteristics of settings and staff that participate or do not (adoption)], reasons for participation or non-participation, and intervention sustainability after project support ends (79).

Based on these observations, we have developed a new RE-AIM figure to highlight the various changes to the model, as well as new emphases, including explicit inclusion of costs and adaptations, as shown in **Figure 1**. The figure also emphasizes key multi-level contextual factors (both the internal and external context) that influence RE-AIM outcomes as discussed below. Two crosscutting issues are: (a) that it is critical that there is alignment across setting and context, the intervention and implementation strategies; and (b) it is important to include qualitative assessments to determine how and why various RE-AIM outcomes are produced.

WHAT WILL THE FUTURE BRING?

With the historical context and current application of RE-AIM in mind, we outline five future directions for researchers and practitioners interested in using RE-AIM.

First, there have been recent calls to more explicitly describe strategies and context (80, 81) as well as test mediating relationships between implementation strategies and implementation outcomes (82). We also see this as an emerging area for RE-AIM. The most well-articulated attempt to do this so far is the Practical, Robust, Implementation, and Sustainability Model (PRISM) (83, 84) that focuses on specific contextual factors from external macro-level factors such as policies, guidelines, and incentives, to more local organizational-level factors. It focuses on the fit between the characteristics of an intervention (i.e., Rogers' constructs of relative advantage, complexity, compatibility, observability, trialability, and cost) (85) and the particular intervention and implementation system. A somewhat unique factor of PRISM is its focus on enhancing setting-level maintenance characteristics by addressing the "implementation and sustainability infrastructure"—including job requirements, ongoing audit and feedback, and institutionalization of intervention activities (84, 86).

Second, mixed-methods should be used across framework components to identify explanatory processes across RE-AIM dimensions. To date, quantitative measures alone have been insufficient to strongly predict dissemination (reach and adoption), implementation, and maintenance outcomes. Using mixed-methods approaches can help identify factors that are causally related to different RE-AIM outcomes in different situations (72). Qualitative information integrated with newer predictive modeling approaches should provide more detailed guidance about actions that can be taken to enhance outcomes by addressing empirically-derived causal relationships.

Third, we encourage more iterative applications of RE-AIM and use of the framework during the implementation period, not just for initial planning and summative evaluation. Rapid, iterative use and analysis of brief practical measures of RE-AIM factors can inform adaptations (55, 66, 71). In brief, RE-AIM can be used as part of a participatory approach (Estabrooks et al., under review), to determine which dimensions should be assessed, described, or targeted for intervention. For example, a recruitment strategy may need to be adapted over the life-course of an intervention (to improve reach) or a new training strategy may be employed (to improve adoption and implementation). While often examined and interpreted independently, these adaptations can work together to be empirically robust and practically meaningful.

Another issue to be addressed is use of RE-AIM by non-researchers and groups such as state health programs or

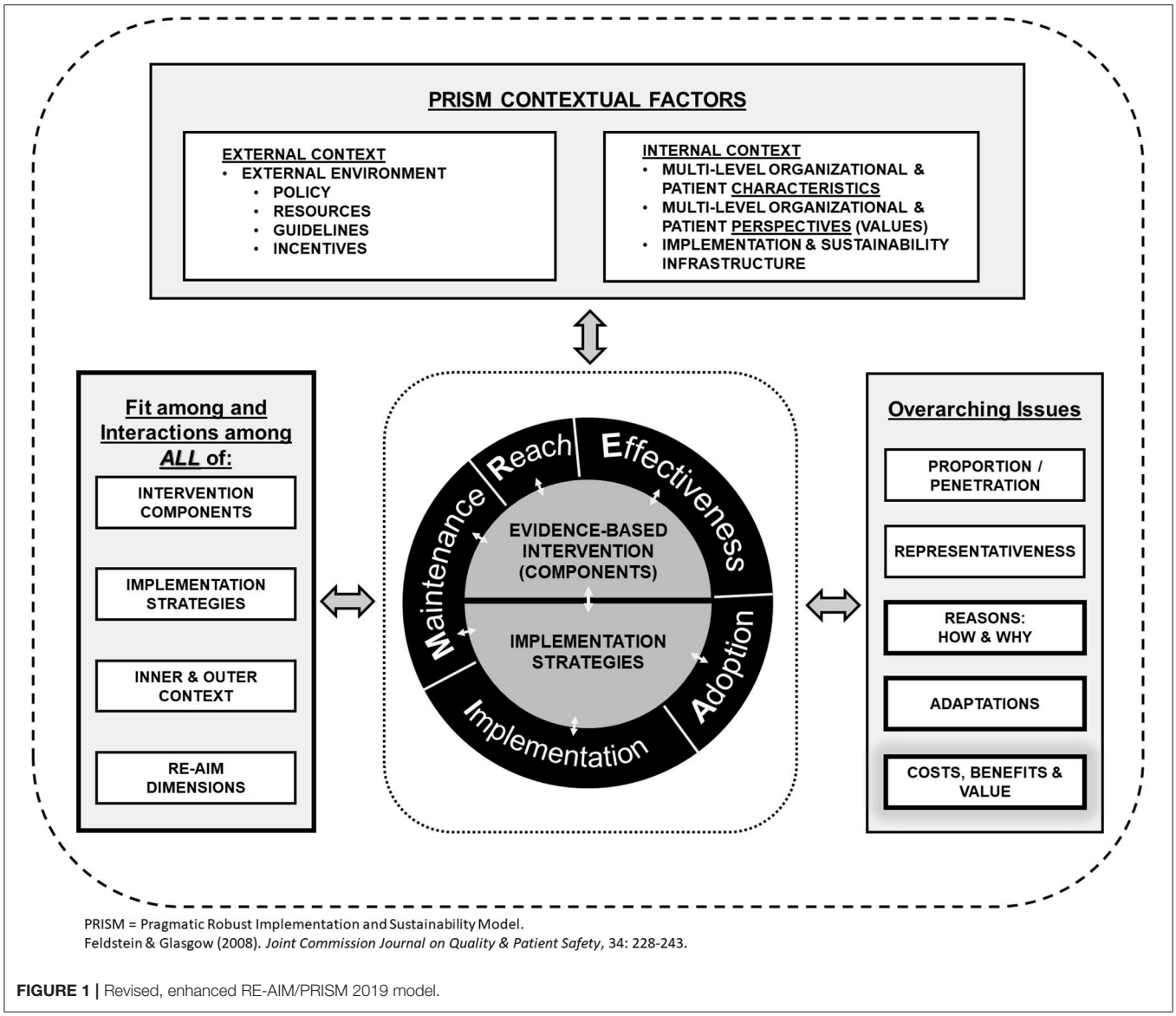

FIGURE 1 | Revised, enhanced RE-AIM/PRISM 2019 model.

program evaluators without substantial funds (grants/contracts). Using RE-AIM in low-resource and real-world settings can be challenging but successful (2). Preliminary findings assessing such use are that RE-AIM is used widely, and seems to be relatively intuitive, but there are challenges implementing it at a detailed level and assessing all components. The development of user-friendly tools and aids using human centered design, as well as more examples of the application of RE-AIM for such users is an important future direction.

Finally, we think there is great opportunity for RE-AIM to be used in combination with other approaches such as the Pragmatic Explanatory Continuum Indicator Summary (PRECIS) model (87, 88), where RE-AIM factors can be combined with the PRECIS-2 dimensions to determine how pragmatic a study is and how generalizable it is likely to be. Such use is illustrated in a recent systematic review by Luoma et al. (89), who demonstrated how reviews can simultaneously summarize effectiveness (using Cochrane-type criteria) and pragmatism (using a combination of PRECIS-2 and RE-AIM factors). RE-AIM and its Expanded CONSORT extension could also be integrated with the Standards for Reporting Implementation Studies (StaRI) (90) or other dissemination and implementation (D&I) research reporting criteria.

CONCLUSION

RE-AIM has been applied in research and practice for 20 years. Although its original components have remained, much has been modified and evolved to address emerging issues such as adaptation and dissemination costs. We expect that RE-AIM will continue to evolve to better address and enhance its original purpose—to increase the prevalence of relevant research that can be applied broadly across a wide variety of populations and

settings to achieve a large, equitable, and replicable public health impact. We invite researchers and practitioners to contribute to the expanded use of RE-AIM before, during, and after intervention delivery.

AUTHOR CONTRIBUTIONS

All authors listed have made a substantial, direct and intellectual contribution to the work, and approved it for publication.

FUNDING

The authors would like to acknowledge funding support for author contributions: MO and MS contributions supported through ACL SUSTAIN for Better Health and Health Care for Older Adults 90CS0065-01. PE contributions supported by Great Plains IDEA CTR U54 GM115458- 01. GP contributions supported by American Heart Association 18PRE34060136. RG contributions partially supported by IMPlementation to Achieve Clinical Transformation (IMPACT): the Colorado Training Program from the NIH K12 HL137862, and the Eastern Colorado VA Geriatric Research Education and Clinical Center.

ACKNOWLEDGMENTS

The authors would like to acknowledge all members of the National Working Group on RE-AIM Planning and Evaluation Framework (www.re-aim.org). A brief You Tube video related to the content in this paper is available at: https://www.youtube.com/watch?v=thpAniodvQU&t=3s&list=PLIM7iq2xw8VwTlvd7wVud0ET-uAbfT8hf&index=2.

REFERENCES

1. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health*. (1999) 89:1322–7. doi: 10.2105/AJPH.89.9.1322
2. Glasgow RE, Askew S, Purcell P, Levine E, Warner ET, Stange KC, et al. Use of RE-AIM to address health inequities: application in a low-income community health center-based weight loss and hypertension self-management program. *Transl Behav Med*. (2013) 3:200–10. doi: 10.1007/s13142-013-0201-8
3. Gaglio B, Phillips SM, Heurtin-Roberts S, Sanchez MA, Glasgow RE. How pragmatic is it? lessons learned using PRECIS and RE-AIM for determining pragmatic characteristics of research. *Implement Sci*. (2014) 9:96. doi: 10.1186/s13012-014-0096-x
4. Glasgow RE, Nelson CC, Strycker LA, King DK. Using RE-AIM metrics to evaluate diabetes self-management support interventions. *Am J Prev Med*. (2006) 30:67–73. doi: 10.1016/j.amepre.2005.08.037
5. Estabrooks PA, Allen KC. Updating, employing, and adapting: a commentary on what does it mean to "employ" the RE-AIM model. *Eval Health Prof*. (2013) 36:67–72. doi: 10.1177/0163278712460546
6. Estabrooks PA, Glasgow RE. Translating effective clinic-based physical activity interventions into practice. *Am J Prev Med*. (2006) 31 (4 Suppl.):S45–56. doi: 10.1016/j.amepre.2006.06.019
7. Tabak RG, Khoong EC, Chambers DA, Brownson RC. Bridging research and practice: models for dissemination and implementation research. *Am J Prev Med*. (2012) 43:337–50. doi: 10.1016/j.amepre.2012.05.024
8. Vinson C, Stamatakis K, Kerner J. Dissemination and implementation research in community and public health settings. In: Brownson RC, Colditz GA, Proctor EK, editors. *Dissemination and Implementation Research in Health; Translating Research to Practice*. Oxford, NY: Oxford University Press (2018). p. 355–70.
9. Shoup JA, Gaglio B, Varda D, Glasgow RE. Network analysis of RE-AIM framework: chronology of the field and the connectivity of its contributors. *Transl Behav Med*. (2015) 5:216–32. doi: 10.1007/s13142-014-0300-1
10. Kessler RS, Purcell EP, Glasgow RE, Klesges LM, Benkeser RM, Peek CJ. What does it mean to "employ" the RE-AIM model? *Eval Heal Prof*. (2013) 36:44–66. doi: 10.1177/0163278712446066
11. Galaviz KI, Harden SM, Smith E, Blackman KC, Berrey LM, Mama SK, et al. Physical activity promotion in Latin American populations: a systematic review on issues of internal and external validity. *Int J Behav Nutr Phys Act*. (2014) 11:77. doi: 10.1186/1479-5868-11-77
12. Kim AE, Towers A, Renaud J, Zhu J, Shea JA, Galvin R, et al. Application of the RE-AIM framework to evaluate the impact of a worksite-based financial incentive intervention for smoking cessation. *J Occup Environ Med*. (2012) 54:610–4. doi: 10.1097/JOM.0b013e31824b2171
13. Chen I, Money D, Yong P, Williams C, Allaire C. An evaluation model for a multidisciplinary chronic pelvic pain clinic: application of the RE-AIM framework. *J Obstet Gynaecol Can*. (2015) 37:804–9. doi: 10.1016/S1701-2163(15)30151-1
14. Ory MG, Altpeter M, Belza B, Helduser J, Zhang C, Smith ML. Perceived utility of the RE-AIM framework for health promotion/disease prevention initiatives for older adults: a case study from the U.S. evidence-based disease prevention initiative. *Front Public Health*. (2015) 2:143. doi: 10.3389/fpubh.2014.00143
15. Ory MG, Altpeter M, Belza B, Helduser J, Zhang C, Smith ML. Perceptions about community applications of RE-AIM in the promotion of evidence-based programs for older adults. *Eval Heal Prof*. (2015) 38:15–20. doi: 10.1177/0163278714542335
16. Aerts I, Cumps E, Verhagen E, Mathieu N, Van Schuerbeeck S, Meeusen R. A 3-month jump-landing training program: a feasibility study using the RE-AIM framework. *J Athl Train*. (2013) 48:296–305. doi: 10.4085/1062-6050-48.3.18
17. Altpeter M, Gwyther LP, Kennedy SR, Patterson TR, Derence K. From evidence to practice: using the RE-AIM framework to adapt the REACHII caregiver intervention to the community. *Dementia*. (2015) 14:104–13. doi: 10.1177/1471301213494499
18. Schwingel A, Gálvez P, Linares D, Sebastião E. Using a mixed-methods RE-AIM framework to evaluate community health programs for older latinas. *J Aging Health*. (2017) 29:551–93. doi: 10.1177/0898264316641075
19. Adams EJ, Chalkley AE, Esliger DW, Sherar LB. Evaluation of the implementation of a whole-workplace walking programme using the RE-AIM framework. *BMC Public Health*. (2017) 17:466. doi: 10.1186/s12889-017-4376-7
20. Brace AM, Padilla HM, DeJoy DM, Wilson MG, Vandenberg RJ, Davis M. Applying RE-AIM to the evaluation of FUEL your life : a worksite translation of DPP. *Health Promot Pract*. (2015) 16:28–35. doi: 10.1177/1524839914539329
21. Ward S, Chow AF, Humbert ML, Bélanger M, Muhajarine N, Vatanparast H, et al. Promoting physical activity, healthy eating and gross motor skills development among preschoolers attending childcare centers: process evaluation of the Healthy Start-Départ Santé intervention using the RE-AIM framework. *Eval Program Plann*. (2018) 68:90–8. doi: 10.1016/j.evalprogplan.2018.02.005
22. Glasgow RE, Gaglio B, Estabrooks PA, Marcus AC, Ritzwoller DP, Smith TL, et al. Long-term results of a smoking reduction program. *Med Care*. (2009) 47:115–20. doi: 10.1097/MLR.0b013e31817e18d1
23. Dzewaltowski DA, Estabrooks PA, Glasgow RE. The future of physical activity behavior change research: what is needed to improve translation of research into health promotion practice? *Exerc Sport Sci Rev*. (2004) 32:57–63. doi: 10.1097/00003677-200404000-00004

24. Estabrooks P, Dzewaltowski DA, Glasgow RE, Klesges LM. Reporting of validity from school health promotion studies published in 12 leading journals, 1996-2000. *J Sch Health*. (2003) 73:21–8. doi: 10.1111/j.1746-1561.2003.tb06554.x
25. Lee RE, Galavíz KI, Soltero EG, Rosales Chavez J, Jauregui E, Lévesque L, et al. Applying the RE-AIM conceptual framework for the promotion of physical activity in low-and middle-income countries. *Rev Lat Am Enfermagem*. (2017) 25:e2923. doi: 10.1590/1518-8345.1894.2923
26. Caperchione CM, Duncan M, Kolt GS, Vandelanotte C, Rosenkranz RR, Maeder A, et al. Examining an Australian physical activity and nutrition intervention using RE-AIM. *Health Promot Int*. (2015) 31:450–8. doi: 10.1093/heapro/dav005
27. O'Brien J, Finch CF. The implementation of musculoskeletal injury-prevention exercise programmes in team ball sports: a systematic review employing the RE-AIM framework. *Sports Med*. (2014) 44:1305-18. doi: 10.1007/s40279-014-0208-4
28. Koorts H, Gillison F. Mixed method evaluation of a community-based physical activity program using the RE-AIM framework: practical application in a real-world setting. *BMC Public Health*. (2015) 15:1102. doi: 10.1186/s12889-015-2466-y
29. Jenkinson KA, Naughton G, Benson AC. The GLAMA (Girls! Lead! Achieve! Mentor! Activate!) physical activity and peer leadership intervention pilot project: a process evaluation using the RE-AIM framework. *BMC Public Health*. (2012) 12:55. doi: 10.1186/1471-2458-12-55
30. Oldroyd JC, White S, Stephens M, Neil AA, Nanayakkara V. Program evaluation of the inner south community health oral health program for priority populations. *J Health Care Poor Underserv*. (2017) 28:1222–39. doi: 10.1353/hpu.2017.0107
31. Leenaars KE, Smit E, Wagemakers A, Molleman GR, Koelen MA. Exploring the impact of the care sport connector in the Netherlands. *BMC Public Health*. (2017) 17:813. doi: 10.1186/s12889-017-4830-6
32. Schaap FD, Dijkstra GJ, Finnema EJ, Reijneveld SA. The first use of dementia care mapping in the care for older people with intellectual disability: a process analysis according to the RE-AIM framework. *Aging Ment Health*. (2018) 22:912–9. doi: 10.1080/13607863.2017.1401582
33. Spook JE, Paulussen T, Paulissen R, Visschedijk G, Kok G, van Empelen P. Design rationale behind the serious self-regulation game intervention "balance it": overweight prevention among secondary vocational education students in the Netherlands. *Games Health J*. (2015) 4:387-400. doi: 10.1089/g4h.2014.0142
34. Boersma P, Van Weert JC, van Meijel B, van de Ven PM, Dröes RM. Study protocol Implementation of the Veder contact method (VCM) in daily nursing home care for people with dementia: an evaluation based on the RE-AIM framework. *Aging Ment Health*. (2017) 21:730–41. doi: 10.1080/13607863.2016.1154015
35. Baba CT, Oliveira IM, Silva AE, Vieira LM, Cerri NC, Florindo AA, et al. Evaluating the impact of a walking program in a disadvantaged area: using the RE-AIM framework by mixed methods. *BMC Public Health*. (2017) 17:709. doi: 10.1186/s12889-017-4698-5
36. Almeida FA, Almeida Brito F. Planning and evaluating health programs: contributions of the RE-AIM framework to Nursing. *Rev Lat Am Enfermagem*. (2014) 22:527–8. doi: 10.1590/0104-1169.0000.2447
37. Quinn AK, Bruce N, Puzzolo E, Dickinson K, Sturke R, Jack DW, et al. An analysis of efforts to scale up clean household energy for cooking around the world. *Energy Sustain Dev*. (2018) 46:1–0. doi: 10.1016/j.esd.2018.06.011
38. Estabrooks PA, Gyurcsik NC. Evaluating the impact of behavioral interventions that target physical activity: issues of generalizability and public health. *Psychol Sport Exerc*. (2003) 4:41–55. doi: 10.1016/S1469-0292(02)00016-X
39. Harden SM, Fanning J, Motl RW, McAuley E, Estabrooks PA. Determining the reach of a home-based physical activity program for older adults within the context of a randomized controlled trial. *Health Educ Res*. (2014) 29:861–9. doi: 10.1093/her/cyu049
40. You W, Almeida FA, Zoellner JM, Hill JL, Pinard CA, Allen KC, et al. Who participates in internet-based worksite weight loss programs? *BMC Public Health*. (2011) 11:709. doi: 10.1186/1471-2458-11-709
41. Lee RE, Reese-Smith JY, Mama SK, Medina AV, Wolfe KL, Estabrooks PA. Reach and representativeness of ethnic minority women in the health is power study: a longitudinal analysis. *Transl Behav Med*. (2017) 7:106–14. doi: 10.1007/s13142-016-0385-9
42. Harden SM, Gaglio B, Shoup JA, Kinney KA, Johnson SB, Brito F, et al. Fidelity to and comparative results across behavioral interventions evaluated through the RE-AIM framework: a systematic review. *Syst Rev*. (2015) 4:155. doi: 10.1186/s13643-015-0141-0
43. Perry RA, Golley RK, Hartley J, Magarey AM. The adaptation and translation of the PEACHTM RCT intervention: the process and outcomes of the PEACHTM in the community trial. *Public Health*. (2017) 153:154–62. doi: 10.1016/j.puhe.2017.08.009
44. Jaipakdee J, Jiamjarasrangsi W, Lohsoonthorn V, Lertmaharit S. Effectiveness of a self-management support program for Thais with type 2 diabetes: evaluation according to the RE-AIM framework. *Nurs Health Sci*. (2015) 17:362–9. doi: 10.1111/nhs.12198
45. Smith SN, Almirall D, Prenovost K, Goodrich DE, Abraham KM, Liebrecht C, et al. Organizational culture and climate as moderators of enhanced outreach for persons with serious mental illness: results from a cluster-randomized trial of adaptive implementation strategies. *Implement Sci*. (2018) 13:93. doi: 10.1186/s13012-018-0787-9
46. Dunton GF, Liao Y, Grana R, Lagloire R, Riggs N, Chou CP, et al. State-wide dissemination of a school-based nutrition education programme: a RE-AIM (Reach, Efficacy, Adoption, Implementation, Maintenance) analysis. *Public Health Nutr*. (2014) 17:422–30. doi: 10.1017/S1368980012005186
47. Maxwell AE, Jo AM, Chin SY, Lee KS, Bastani R. Impact of a print intervention to increase annual mammography screening among Korean American women enrolled in the National Breast and Cervical Cancer Early Detection Program. *Cancer Detect Prev. (*2008) 32:229–35. doi: 10.1016/j.cdp.2008.04.003
48. Breitenstein SM, Fogg L, Garvey C, Hill C, Resnick B, Gross D. Measuring implementation fidelity in a community-based parenting intervention. *Nurs Res*. (2010) 59:158–65. doi: 10.1097/NNR.0b013e3181dbb2e2
49. Duffy SA, Ronis DL, Ewing LA, Waltje AH, Hall S V, Thomas PL, et al. Implementation of the Tobacco Tactics intervention versus usual care in Trinity Health community hospitals. *Implement Sci*. (2016) 11:147. doi: 10.1186/s13012-016-0511-6
50. Santos SLZ, Tagai EK, Scheirer MA, Bowie J, Haider M, Slade J, et al. Adoption, reach, and implementation of a cancer education intervention in African American churches. *Implement Sci*. (2017) 12:36. doi: 10.1186/s13012-017-0566-z
51. Estabrooks PA, Wilson KE, McGuire TJ, Harden SM, Ramalingam N, Schoepke L, et al. A quasi-experiment to assess the impact of a scalable, community-based weight loss program: combining reach, effectiveness, and cost. *J Gen Intern Med*. (2017) 32:24–31. doi: 10.1007/s11606-016-3971-0
52. Gaglio B, Shoup JA, Glasgow RE. The RE-AIM framework: a systematic review of use over time. *Am J Public Health*. (2013) 103:e38–46. doi: 10.2105/AJPH.2013.301299
53. Glasgow RE, Vinson C, Chambers D, Khoury MJ, Kaplan RM, Hunter C. National Institutes of health approaches to dissemination and implementation science: current and future directions. *Am J Public Health*. (2012) 102:1274–81. doi: 10.2105/AJPH.2012.300755
54. Sweet SN, Ginis KAM, Estabrooks PA, Latimer-Cheung AE. Operationalizing the RE-AIM framework to evaluate the impact of multi-sector partnerships. *Implement Sci*. (2014) 9:74. doi: 10.1186/1748-5908-9-74
55. Harden SM, Smith ML, Ory MG, Smith-Ray RL, Estabrooks P, Glasgow R. RE-AIM in clinical, community, and corporate settings: perspectives, strategies, and recommendations to enhance public health impact. *Front Public Health*. (2018) 6:71. doi: 10.3389/fpubh.2018.00071
56. Fortney J, Enderle M, McDougall S, Clothier J, Otero J, Altman L, et al. Implementation outcomes of evidence-based quality improvement for depression in VA community based outpatient clinics. *Implement Sci*. (2012) 7:30. doi: 10.1186/1748-5908-7-30
57. Carlfjord S, Lindberg M, Andersson A. Sustained use of a tool for lifestyle intervention implemented in primary health care: a 2-year follow-up. *J Eval Clin Pract*. (2013) 19:327–34. doi: 10.1111/j.1365-2753.2012.01827.x
58. Rabin BA, McCreight M, Battaglia C, Ayele R, Burke RE, Hess PL, et al. Systematic, multimethod assessment of adaptations across four diverse health systems interventions. *Front Public Health*. (2018) 6:102. doi: 10.3389/fpubh.2018.00102

59. Jones Rhodes WC, Ritzwoller DP, Glasgow RE. Stakeholder perspectives on costs and resource expenditures: tools for addressing economic issues most relevant to patients, providers, and clinics. *Transl Behav Med*. (2018) 8:675–82. doi: 10.1093/tbm/ibx003
60. Akers JD, Estabrooks PA, Davy BM. Translational research: bridging the gap between long-term weight loss maintenance research and practice. *J Am Diet Assoc*. (2010) 110:1511–22, 1522-3. doi: 10.1016/j.jada.2010.07.005
61. Allen K, Zoellner J, Motley M, Estabrooks PA. Understanding the internal and external validity of health literacy interventions: a systematic literature review using the RE-AIM framework. *J Health Commun*. (2011) 16 (Suppl. 3):55–72. doi: 10.1080/10810730.2011.604381
62. Bull SS, Gillette C, Glasgow RE, Estabrooks P. Work site health promotion research: to what extent can we generalize the results and what is needed to translate research to practice? *Heal Educ Behav*. (2003) 30:537–49. doi: 10.1177/1090198103254340
63. Klesges LM, Estabrooks PA, Dzewaltowski DA, Bull SS, Glasgow RE. Beginning with the application in mind: designing and planning health behavior change interventions to enhance dissemination. *Ann Behav Med*. (2005) 29:66–75. doi: 10.1207/s15324796abm2902s_10
64. Dzewaltowski DA, Glasgow RE, Klesges LM, Estabrooks PA, Brock E. RE-AIM: evidence-based standards and a Web resource to improve translation of research into practice. *Ann Behav Med*. (2004) 28:75–80. doi: 10.1207/s15324796abm2802_1
65. Ory MG, Jordan PJ, Bazzarre T. The behavior change consortium: setting the stage for a new century of health behavior-change research. *Health Educ Res*. (2002) 17:500–11. doi: 10.1093/her/17.5.500
66. Glasgow RE, Bull SS, Gillette C, Klesges LM, Dzewaltowski DA. Behavior change intervention research in healthcare settings: a review of recent reports with emphasis on external validity. *Am J Prev Med*. (2002) 23:62–9. doi: 10.1016/S0749-3797(02)00437-3
67. Glasgow RE, Estabrooks PE. Pragmatic applications of RE-AIM for health care initiatives in community and clinical settings. *Prev Chronic Dis*. (2018) 15:170271. doi: 10.5888/pcd15.170271
68. Chambers DA, Norton WE. The adaptome: advancing the science of intervention adaptation. *Am J Prev Med*. (2016) 51:S124–31. doi: 10.1016/j.amepre.2016.05.011
69. Mittman B. *Evaluating Complex Interventions: Confronting and Guiding (Versus Ignoring and Suppressing) Heterogeneity and Adaptation*. PSMG Northwestern Grand Rounds webinar series. (2018) Available online at: http://cepim.northwestern.edu/psmg-archive/ (Accessed December 12, 2018).
70. Patient-Centered Outcomes Research Institute (PCORI). *Methodology Standards*. (2019) Available online at: https://www.pcori.org/sites/default/files/PCORI-Methodology-Standards.pdf
71. Stirman SW, Miller CJ, Toder K, Calloway A. Development of a framework and coding system for modifications and adaptations of evidence-based interventions. *Implement Sci*. (2013) 8:65. doi: 10.1186/1748-5908-8-65
72. Holtrop JS, Rabin BA, Glasgow RE. Qualitative approaches to use of the RE-AIM framework: rationale and methods. *BMC Health Serv Res*. (2018) 18:177. doi: 10.1186/s12913-018-2938-8
73. Stoutenberg M, Galaviz KI, Lobelo F, Joy E, Heath GW, Hutber A, et al. A pragmatic application of the RE-AIM framework for evaluating the implementation of physical activity as a standard of care in health systems. *Prev Chronic Dis*. (2018) 15:E54. doi: 10.5888/pcd15.170344
74. Balis LE, Strayer III TE, Ramalingam N, Harden SM. Beginning with the end in mind: contextual considerations for scaling-out a community-based intervention. *Front Public Health*. (2018) 6:357. doi: 10.3389/fpubh.2018.00357
75. Harden SM, Ramalingam NS, Breig SA, Estabrooks PA. Walk this way: our perspective on challenges and opportunities for extension statewide walking promotion programs. *J Nutr Educ Behav*. (2019). doi: 10.1016/j.jneb.2018.12.010. [Epub ahead of print].
76. Ritzwoller DP, Sukhanova A, Gaglio B, Glasgow RE. Costing behavioral interventions: a practical guide to enhance translation. *Ann Behav Med*. (2009) 37:218–27. doi: 10.1007/s12160-009-9088-5
77. Glasgow RE, Huebschmann AG, Brownson RC. Expanding the CONSORT figure: increasing transparency in reporting on external validity. *Am J Prev Med*. (2018) 55:422–30. doi: 10.1016/j.amepre.2018.04.044
78. Moher D. CONSORT: an evolving tool to help improve the quality of reports of randomized controlled trials. *JAMA*. (1998) 279:1489–91. doi: 10.1001/jama.279.18.1489
79. Glasgow R, Huebschmann A, Brownson R. *Expanded CONSORT Figure for Planning and Reporting D & I Research*. (2018) Available online at: http://www.re-aim.org/expanded-consort-figure-for-planning-and-reporting-d-i-research/ (Accessed December 13, 2018).
80. Proctor E, Silmere H, Raghavan R, Hovmand P, Aarons G, Bunger A, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Adm Policy Ment Health*. (2011) 38:65–76. doi: 10.1007/s10488-010-0319-7
81. Proctor E, Powell B, McMillen J. Implementation strategies: recommendations for specifying and reporting. *Implement Sci*. (2013) 8:139. doi: 10.1186/1748-5908-8-139
82. Lewis CC, Klasnja P, Powell BJ, Lyon AR, Tuzzio L, Jones S, et al. From classification to causality: advancing understanding of mechanisms of change in implementation science. *Front Public Health*. (2018) 6:136. doi: 10.3389/fpubh.2018.00136
83. Feldstein A, Glasgow R. A practical, robust implementation and sustainability model (PRISM) for integrating research findings into practice. *Jt Comm J Qual Patient Saf*. (2008) 34:228–43. doi: 10.1016/S1553-7250(08)34030-6
84. Liles EG, Schneider JL, Feldstein AC, Mosen DM, Perrin N, Rosales AG, et al. Implementation challenges and successes of a population-based colorectal cancer screening program: a qualitative study of stakeholder perspectives. *Implement Sci*. (2015) 10:41. doi: 10.1186/s13012-015-0227-z
85. Rogers EM. *Diffusion of Innovations*. New York, NY: Free Press of Glencoe; (1962)
86. Beck A, Bergman DA, Rahm AK, Dearing JW, Glasgow RE. Using implementation and dissemination concepts to spread 21st-century well-child care at a health maintenance organization. *Perm J*. (2009) 13:10. doi: 10.7812/TPP/08-088
87. Thorpe KE, Zwarenstein M, Oxman AD, Treweek S, Furberg CD, Altman DG, et al. A pragmatic-explanatory continuum indicator summary (PRECIS): a tool to help trial designers. *J Clin Epidemiol*. (2009) 62:464–75. doi: 10.1016/j.jclinepi.2008.12.011
88. Loudon K, Treweek S, Sullivan F, Donnan P, Thorpe KE, Zwarenstein M. The PRECIS-2 tool: designing trials that are fit for purpose. *BMJ*. (2015) 350:h2147. doi: 10.1136/bmj.h2147
89. Luoma KA, Leavitt IM, Marrs JC, Nederveld AL, Regensteiner JG, Dunn AL, et al. How can clinical practices pragmatically increase physical activity for patients with type 2 diabetes? A systematic review. *Transl Behav Med*. (2017) 7:751–72. doi: 10.1007/s13142-017-0502-4
90. Pinnock H, Barwick M, Carpenter CR, Eldridge S, Grandes G, Griffiths CJ, et al. Standards for Reporting Implementation Studies (StaRI) Statement. *BMJ*. 356:i6795. doi: 10.1136/bmj.i679

Disclaimer: All statements in this report, including its findings and conclusions, are solely those of the authors and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors, or Methodology Committee.

Conflict of Interest Statement: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

frontiers in Public Health

GENERAL COMMENTARY
published: 03 July 2020
doi: 10.3389/fpubh.2020.00245

Commentary: RE-AIM Planning and Evaluation Framework: Adapting to New Science and Practice With a 20-Year Review

Kurt C. Stange [1,2,3]*

[1] Center for Community Health Integration, Research and Development for Community Health and Integrated, Personalized Care, Cleveland, OH, United States, [2] Center for the Advancement of Primary Health Care for the Public Good Scholar, The Institute for Integrative Health, Cleveland, OH, United States, [3] Department of Family Medicine and Community Health, Population and Quantitative Health Sciences, Oncology and Sociology, Case Western Reserve University, Cleveland, OH, United States

Keywords: RE-AIM framework, interventions, evaluation, program planning, evidence-based

A Commentary on

RE-AIM Planning and Evaluation Framework: Adapting to New Science and Practice With a 20-Year Review
by Glasgow, R. E., Harden, S. M., Gaglio, B., Rabin, B., Smith, M. L., Porter, G. C., et al. (2019). Front. Public Health 7:64. doi: 10.3389/fpubh.2019.00064

OPEN ACCESS

Edited by:
Katherine Henrietta Leith, University of South Carolina, United States

Reviewed by:
Larry Kenith Olsen, Logan University, United States

***Correspondence:**
Kurt C. Stange
kcs@case.edu

Specialty section:
This article was submitted to Public Health Education and Promotion, a section of the journal Frontiers in Public Health

Received: *17 April 2020*
Accepted: *20 May 2020*
Published: *03 July 2020*

Citation:
Stange KC (2020) Commentary: RE-AIM Planning and Evaluation Framework: Adapting to New Science and Practice With a 20-Year Review. Front. Public Health 8:245. doi: 10.3389/fpubh.2020.00245

INTRODUCTION

As a boy, Charles Marlow, in Conrad's *Heart of Darkness*, is drawn to explore "blank space of delightful mystery" on the map of Africa. By the time he's old enough to take on the adventure, the blank space now has river names on it, and he's charmed by the uncoiled snake of a river that promises an easy path into what has become "a place of darkness."

As young investigators, we typically begin with a desire to map, and perhaps to conquer, blank spaces of delightful mystery. We steam boldly up the mighty waterways of well-traveled theory and methods that take us toward the heart of darkness. If we're adventurous, we ignore our advisors' advice and trundle up a tributary. But mostly, we stick to the main channels. We colonize without understanding. Through our colonization, we see the barriers to our dominance, while our theories and methods leave us blind to the motivating delights that await understanding in the murky context.

For more than two decades, the RE-AIM framework (1) has been a bonfire in the decontextualized darkness of health improvement interventions for which rigor is defined by the tenets of internal validity. By providing a framework for also paying attention to external validity, RE-AIM offers a lens for refracting and widening the laser focus of reductionist research to shine light on the multilevel factors that influence health and health care. Its extension to PRISM (2, 3) provides the methods and framework for assessing additional contextual factors essential for researchers who want to illuminate the real world impact of health interventions. Recent applications that use RE-AIM iteratively go even further in trying to make implementation science more rapid and relevant (to stakeholders), and aligned with recognition that context is dynamic, and our models, evaluations and interventions need to evolve as contextualized understanding advances (4).

TABLE 1 | Two paths to taking on a complex problem in health or health care.

Stepping stone along the path	Path to short-term career success	Path to make a difference for a wicked problem
Pilot study	Discover *the answer*.	Assess *complex interactions*
Hypothesis	Linear causality	Complex, multilevel causality
Funding	Likely	Unlikely
Intervention	RCT	Adaptive RCTs, interrupted time series…
Assessment	Quantitative	Quantitative & qualitative
Outcome	Decontextualized *answer* proven or disproved!	*Understanding* of complex interacting factors + early insight into what might work in what situation
Dissemination & Implementation	Call for simple dissemination	Call for iterative implementation & shared, contextualized learning
Speaker circuit	Bask in the glory of having *the answer*	Very little audience for a complex answer
Effect on the field	Frustration that things don't replicate, and we don't know why	*Continued learning* of how the system works and what the lever points are in different evolving situations
Next step	Move on to *the next big thing* while the complex problem gets worse	Incremental change until the a tipping point is reached, resulting in *progress on the complex problem*
Tenure	Granted	Denied
Relevant literary quotation	"The horror! The horror!" Joseph Conrad, *Heart of Darkness*	"A mosaic is a conversation with time." Terry Tempest Williams, *Finding Beauty in a Broken World*

AN INVESTIGATOR'S PATH

The **Table 1** on the next page shows two possible trajectories for a junior investigator's pathway—from pilot study to tenure. The path on the left is a tried and true trail to success by focusing on a narrowly-configured problem. It ignores the messiness that is the focus of RE-AIM. The other path, on the right, has more short-term risks. It probably is a bad career move. But is has the potential to make a difference in the wicked problems facing health and health care (5). It considers the multilevel contextual factors addressed by RE-AIM and PRISM.

The path to short-term career success is the hero's journey to find ***the answer***. A pilot study identifies a single promising mechanism. The hypothesis of simple, linear cause and effect is easy to explain, and appeals to reviewers and funders. Testing the hypothesis uses the gold standard method of a clinical trial—and all the messy contextual factors are washed from view by the miracle of randomization, allowing the investigator to isolate the effect of a single factor in the rarified group of people willing to leave their intervention choice up to a coin flip. The quantitative assessment of an outcome that can be easily measured leads to simple story of what needs to be implemented and disseminated more widely in the now ***evidence-based intervention***. The possible dead end on this pathway is the dreaded null trial, and the lack of contextual understanding can leave the investigator floundering as to a next step. But a positive trial leads to fame by proposing a simple answer to a complex problem, and the focused research and funding record make an easy case for tenure. It is a while before systematic reviews of dozens of similar trials that have launched other careers lead to the conclusion of "great heterogeneity of treatment effect. More research is needed." By the time it becomes apparent that the lack of contextual information in such trials makes it impossible to do more than speculate on what that next research should be, the investigator is on to ***the next big thing***.

The parallel path toward making a difference for a wicked problem attempts at the outset to ***assess complex multilevel causality***. It often involves less easy-to-explain research designs such as interrupted time series, and often integrates quantitative and qualitative methods. This research approach challenges the zeitgeist of rigor as rigid adherence to *a priori* hypotheses—by trying to capture inductive, participatory learning along the way. These studies are challenging to fund because they threaten an easily-ordered worldview. But when interventions show an effect, such studies gather sufficient contextualizing information to be able to do more than speculate on what might work in different situations. And if no treatment effect is identified, their contextualized understanding points the way toward new interventions, iterative implementation, and shared, ***contextualized learning*** that represent how knowledge of complex systems actually advances. These kind of results seldom lead to early acclaim, but continued learning of how the system works, and what the lever points are in different evolving situations, leads to incremental change in a learning community, until a tipping point is reached, resulting in real progress on the complex problem.

I have followed both these pathways in my career—brandishing the first path, secreting the second. I mentor many junior investigators who want to do more than look under the lamppost. They want to peer into the heart of darkness of wicked problems. I have to advise them to frame their research around the narrative in the left column of the **Table 1**, while trying to develop the story on the right.

The path on the left is the better career move. It garners the external markers of success that allow the work to continue. The trick in doing this stealth research, is to not be sucked into the illusion that reductionist success is the real goal.

I have managed to be successful by telling the story on the left while living the one on the right. That success has included tenure, many invitations to speak and to influence, sustained funding, appointment as a distinguished university professor, and membership in the National Academy of Medicine. I have been sustained by tremendous colleagues who have played this game together, sustaining each other in the narrative on the right, while living the lie on the left. But I wonder how much more could have been accomplished had we been able to tell the real story all along. I don't want the next generation to have to live the lie, but rather, to overtly track the truth of complex systems.

DISCUSSION

Our natural human hunger for the simple story makes it challenging to take on the more multifaceted plot line. But RE-AIM and PRISM help us to tell the real story. They shine light on multilevel context from the outset, rather than as an afterthought. Assessing that context means that we can take on the real problems affecting the health and equity of our society, rather than their decontextualized, reductionist shadows.

Let's mainstream the narrative that RE-AIM and PRISM allow us to tell. If we do, we will make much faster progress on what matters.

The alternative? The horror. The horror.

AUTHOR CONTRIBUTIONS

The author confirms being the sole contributor of this work and has approved it for publication.

REFERENCES

1. Glasgow RE, Harden SM, Gaglio B, Rabin B, Rabin ML, Porter GC, et al. RE-AIM planning and evaluation framework: adapting to new science and practice with a 20-year review. *Front Public Health.* (2019) 7:64. doi: 10.3389/fpubh.2019.00064
2. Feldstein AC, Glasgow RE. A practical, robust implementation and sustainability model (PRISM) for integrating research findings into practice. *J Comm J Qual Patient Saf.* (2008) 34:228–43. doi: 10.1016/s1553-7250(08)34030-6
3. McCreight MS, Rabin BA, Glasgow RE, Ayele RA, Leonard CA, Gilmartin HM, et al. Using the Practical, Robust Implementation and Sustainability Model (PRISM) to qualitatively assess multilevel contextual factors to help plan, implement, evaluate, and disseminate health services programs. *Transl Behav Med.* (2019) 9:1002–11. doi: 10.1093/tbm/ibz085
4. Chambers DA, Glasgow RE, Stange KC. The dynamic sustainability framework: addressing the paradox of sustainment amid ongoing change. *Implement Sci.* (2013) 8:117. doi: 10.1186/1748-5908-8-117
5. Haynes A, Garvey K, Davidson S, Milat A. What can policy-makers get out of systems thinking? Policy partners' experiences of a systems-focused research collaboration in preventive health. *Int J Health Policy Manage.* (2020) 9:65–76. doi: 10.15171/ijhpm.2019.86

Conflict of Interest: The author declares that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

frontiers in Public Health

PERSPECTIVE
published: 10 January 2020
doi: 10.3389/fpubh.2019.00390

National Working Group on the RE-AIM Planning and Evaluation Framework: Goals, Resources, and Future Directions

Samantha M. Harden[1], Thomas Edward Strayer III[1,2], Matthew Lee Smith[3,4,5], Bridget Gaglio[6], Marcia G. Ory[3,4], Borsika Rabin[7,8,9], Paul A. Estabrooks[10] and Russell E. Glasgow[8,9]*

[1] Physical Activity Research and Community Implementation, Human Nutrition, Foods, and Exercise, Virginia Tech, Blacksburg, VA, United States, [2] Translational Biology, Medicine, and Health, Virginia Tech, Blacksburg, VA, United States, [3] Center for Population Health and Aging, Texas A&M University, College Station, TX, United States, [4] Department of Environmental and Occupational Health, School of Public Health, Texas A&M University, College Station, TX, United States, [5] Department of Health Promotion and Behavior, College of Public Health, University of Georgia, Athens, GA, United States, [6] Clinical Effectiveness and Decision Science Program, Patient-Centered Outcomes Research Institute, Washington, DC, United States, [7] Department of Family Medicine and Public Health, School of Medicine, University of California, San Diego, San Diego, CA, United States, [8] Adult and Child Consortium for Outcomes Research and Delivery Science Dissemination and Implementation Science Program and The Department of Family Medicine, School of Medicine, University of Colorado-Anschutz Medical Campus, Aurora, CO, United States, [9] Eastern Colorado QUERI and GRECC Programs, University of Colorado- Anschutz Medical Campus, Aurora, CO, United States, [10] College of Public Health, University of Nebraska Medical Center, Omaha, NE, United States

OPEN ACCESS

Edited by:
Colette Joy Browning, Federation University, Australia

Reviewed by:
Iffat Elbarazi, United Arab Emirates University, United Arab Emirates
Claudia Meyer, Royal District Nursing Service Institute, Australia

***Correspondence:**
Samantha M. Harden
harden.samantha@vt.edu

Specialty section:
This article was submitted to Public Health Education and Promotion, a section of the journal Frontiers in Public Health

Received: *03 November 2019*
Accepted: *03 December 2019*
Published: *10 January 2020*

Citation:
Harden SM, Strayer TE III, Smith ML, Gaglio B, Ory MG, Rabin B, Estabrooks PA and Glasgow RE (2020) National Working Group on the RE-AIM Planning and Evaluation Framework: Goals, Resources, and Future Directions. Front. Public Health 7:390. doi: 10.3389/fpubh.2019.00390

The National Working Group on RE-AIM Planning and Evaluation Framework (herein Workgroup) was established in 2004 to support the application of the framework and advance dissemination and implementation science (D&I). Workgroup members developed and disseminated products and resources (and continue to do so) to advocate for consistent application of RE-AIM and allow for cross study comparisons. The purpose of this paper is to summarize key Workgroup activities, products, and services (e.g., webinars, consultations, planning tools) and enhance bidirectional communication between the Workgroup and RE-AIM users. The ultimate goal of this work is to serve as a forum for dissemination to improve the balance between RE-AIM user demand (needs) and the currently limited RE-AIM Workgroup supply (consultation and resources) to demonstrate and expand the utility of RE-AIM as a D&I planning and evaluation framework. A summary of resources is provided as well as specific examples of how the Workgroup has been responsive to user needs.

Keywords: dissemination, implementation, resources, application, synopsis

INTRODUCTION AND HISTORY

Dissemination and implementation (D&I) research is designed to facilitate integration of research into practice and policy and study the process by which this occurs (1). D&I science includes a number of models, theories, frameworks (herein models) to guide D&I science activities that have become much more prominent in recent years (2, 3). However, researchers often struggle operationalizing these models in their work (3). Resources and guidance are needed to support both researchers and practitioners to apply D&I models to their work in a meaningful way. In response to this need, a number of training programs were developed to support immersion in

D&I models, methods, and measures (4). These trainings typically combine in person and virtual meetings, mentorship, reading lists, and webinars. Evaluations of these trainings have been positive, but they have limited resources (i.e., mentors, funding, time) and therefore, limited reach among people who wish to apply D&I models in practice. To respond to these demands, several research groups provide a suite of materials to introduce and guide the use of specific D&I models (5–8). The suite of options typically showcases websites, webinars, static materials, and opportunities for consultation (7).

This suite of D&I model resources should have capabilities to reach and be useful to a large number of researchers and, of equal or greater importance, be understandable and useable for practitioners and healthcare teams. These resources should also provide user support to ensure adoption, consistent application of ideas, and, when necessary, appropriate adaptation of model implementation. This paper is centered on one of the most frequently used (9–11) D&I models, RE-AIM (reach, effectiveness, adoption, implementation, and maintenance) (12) and the various activities conducted since 2004 to provide general and tailored guidance and support for the operationalization of RE-AIM.

RE-AIM was developed in the late 1990s with the intent to support the translation of research to practice and policy, to improve the impact of health promotion and prevention efforts (4, 9, 12–14). The RE-AIM website, initially funded by the Robert Wood Johnson Foundation, was developed in 2004 to enhance understanding and transparency of the framework, provide application resources and address commonly asked questions (8). The website has consistently included RE-AIM-relevant papers, presentations, definitions, and checklists. Over the years, interactive materials have been developed including self-quizzes with feedback and suggestions, webinar viewings, and RE-AIM calculators. With limited funding, the website has been continuously supported by RE-AIM investigators, called the National Working Group on RE-AIM Planning and Evaluation Framework (herein the Workgroup). Members of the Workgroup consist of senior investigators who have applied RE-AIM since its inception and early career researchers who studied and applied RE-AIM in graduate school. This Workgroup is similar to other research or professional networks; membership is not exclusive but rather driven by shared tasks and mission (15–17).

The purpose of this paper is to summarize key activities, products, and services (e.g., webinars and planning tools) that the Workgroup offers. By doing so, Workgroup members invite RE-AIM users to provide feedback and recommend additional resources that could contribute to advancing D&I science. Some key efforts of the Workgroup are summarized including: (1) website resources, evolution, and future directions; (2) papers, presentations, and webinars; and (3) consultation experiences and offerings (e.g., grant consultations, trainings, and practice facilitation). It is our intent to connect those applying RE-AIM in clinical, corporate, or community settings with necessary resources, and also inspire others to apply the model, share new applications, and communicate additional needs. The ultimate goal is to serve as a forum for dissemination (18) to improve the balance between RE-AIM user demand (needs) and the RE-AIM Workgroup supply (offerings) to promote usefulness of RE-AIM as a D&I planning and evaluation framework.

GOALS OF THE WORKGROUP

The mission of the RE-AIM Workgroup is to implement a robust and evolving framework to advance science, enhance practice, and influence policy through collaboration and training. In addition to collaborative research to advance RE-AIM, members provide guidance for its use (particularly as related to its evolution in response to new settings, purposes, opportunities, data, and challenges) (9), In a recent summary of the RE-AIM framework over its 20 year history (9), published by the Workgroup, a number of suggestions for future use of RE-AIM were put forth. These included (1) enhanced reporting and evaluation of implementation context and strategies; (2) application of mixed-methods research designs; (3) more rapid and iterative use of RE-AIM; and (4) combining RE-AIM with other relevant D&I and pragmatic frameworks and approaches such as the Pragmatic Explanatory Continuum Indicator Summary (PRECIS-2) model (19, 20). These suggestions were, in part, in response to the needs of RE-AIM users shared with members of the Workgroup—via email, in person conversations, or website requests. By way of example, one Workgroup member recently consulted on a project reviewing physical activity self-management for patients with spinal cord injury that applied both PRECIS-2 and RE-AIM (21). This led to development of a new data extraction tool, discussions among co-authors on the nuances of the RE-AIM framework, and swift responses to peer review journal manuscript reviewer comments. To further reporting and evaluation, two members of the Workgroup completed a study to qualitatively identify and assess the planning, implementation, evaluation, and dissemination using RE-AM and the Practical Robust Implementation and Sustainability Model (PRISM) extension of the framework across four health services intervention projects in the Veterans health administration setting. PRISM is a contextual expansion of the RE-AIM framework which includes theoretical constructs hypothesized to be predictive of each of the RE-AIM dimensions. The constructs include intervention characteristics, recipient characteristics, implementation and sustainability infrastructure, and external environment domains (22, 23). Results of the Veterans health administration projects pointed to the need to engage key stakeholders, assess how an intervention "fits" the targeted system, and to adjust/adapt over time and for different settings as keys for the success of dissemination and implementation efforts (23). An ongoing effort of a sub-group of Workgroup members is using a protocol to apply RE-AIM iteratively to inform adaptations during the implementation of health services interventions across four health services research projects. This effort starts with periodic evaluative reflections by the implementation team for the project including ratings on the importance of and progress on the various RE-AIM dimensions. This exercise is followed by the selection of and goal setting around one to two RE-AIM dimensions that are most

important at the given time of the project and could benefit most from improvement. Examples include the selection of and goal setting on RE-AIM dimensions of (a) "reach," with activities identified as better specification of target audience or eligible population at each implementation site, outreach to sites to assess barriers for increasing recruitment of eligible participants; and (b) "effectiveness," to align original implementation and clinical outcomes to better match changed organizational priorities.

RESOURCES AND ACTIVITIES SUPPORTED BY THE WORKGROUP

Overview of the RE-AIM Website

The purpose of the Workgroup website (www.RE-AIM.org) (8) is to support and connect those in need of explanation or resources to apply the RE-AIM framework. Specifically, the Workgroup website introduces the framework and supports implementation researchers and practitioners with guidance on application and reporting of framework dimensions. The site contains a collection of tools as well as contextual and measurement considerations when using RE-AIM in implementation research (see **Figure 1** for illustration of website homepage). For example, it has a full description of each RE-AIM dimension, the methods to conduct research and planning for each, and publications about how these methodologies are applied. Finally, the website serves as an intermediary to connect users to other implementation resources such as the National Cancer Institute's Research-Tested Intervention Programs (RTIPs) and Implementation Science websites (24).

Who Is Using the Website?

Google analytics software was added to the RE-AIM site in January of 2015. Data are tracked to monitor the number of sessions started, unique users who access the website, the number of page views, average time for each session, and which pages have the most visits and downloads. From January 2015 to March of 2017, these data were reported quarterly, and since April of 2017, they have been reported monthly. In 2015, there were 3,387 unique users and 3,531 sessions initiated. The website usage has increased over time and in 2018, there were 32,793 unique users (36% increase from 2017) and 48,236 (31% increase from 2017) sessions. Since early 2017, the majority of the sessions, come from the United States (69%), followed by Australia (19%), United Kingdom (9%), Canada (9%), Netherlands (4%), and Germany (2%).

Page Visits

Most users start with the homepage (**Figure 1**), the "What is the RE-AIM framework?" page or the "Frequently Asked Questions" page. The next most frequently visited resources are the "Measures and Checklists" and "Applying the RE-AIM Framework" pages. Unfortunately, there are no current means to capture patterns/pathways of navigation of RE-AIM site users, though understanding this information could aid in improving the user experience.

Resources, Tools, and Guides

A variety of both static (stand-still, downloads) and interactive (listserv, webinars, planning tools) resources are provided on the site. The website includes links to other relevant D&I resources such as cfir.org (Consolidated Framework for Implementation Research website), reporting guidelines from CONSORT (25, 26), Standards for Reporting Implementation Studies (StaRI) Statement (27), and ways for site users to find evidence-based interventions [e.g., through Research Tested Intervention Programs (RTIPs)]. Another primary resource is the RE-AIM Planning and Evaluation Tool, which was iteratively developed to assist users from various sectors (e.g., research, public health, healthcare) to consider the RE-AIM dimensions and enhance implementation over time. Launched in June 2017, the updated planning tool is a portable document format (PDF) instrument organized to provide prompts for consideration related to common challenges to successful application of RE-AIM. The tool prompts users to consider to whom the initiative will appeal (Whom do you plan to reach and How do you define the intended beneficiaries?). For effectiveness, the planning tool prompts users to consider: "What might be the unintended consequences or outcomes? What has gone wrong in other similar initiatives?" An adapted version of these considerations is presented in a manuscript outlining the iterative use of RE-AIM before, during, and after intervention implementation (28). A detailed example of applying the planning tool across clinical, corporate, and community settings can be found in Harden et al. (28).

RE-AIM Publication Tracking and Repository

A graduate research assistant conducts a monthly PubMed search for "RE-AIM" so users can better understand the breadth, scope and content of RE-AIM publications. See **Figure 2** for the number of publications on RE-AIM, by year. In total, the RE-AIM framework has appeared in over 500 publications since its initial publication in 1999, with vastly enhanced publication rate beginning in 2009. The website includes a search feature for users to identify papers through keyword search, such as topic or target audience (e.g., physical activity, youth).

WEBINAR SERIES

The RE-AIM Workgroup and website also host and post recorded webinars featuring speakers that discuss the use of RE-AIM in research and in practice, and address questions from the audience. Each webinar is ∼1 h in duration, and usually follows the format of having a moderator introduce the topic, prepared remarks from the main speaker, reflections from other Workgroup members, and time for open audience questions and discussion. From 2015 to present, there have been 27 webinars with an average of 26 live audience attendees. One of the most popular webinars to date, was delivered in January of 2018. It was titled "Reflections from the field: RE-AIMers reflect on annual D&I meeting" (10th Annual Conference on the Science of Dissemination and Implementation in Health) with panelists

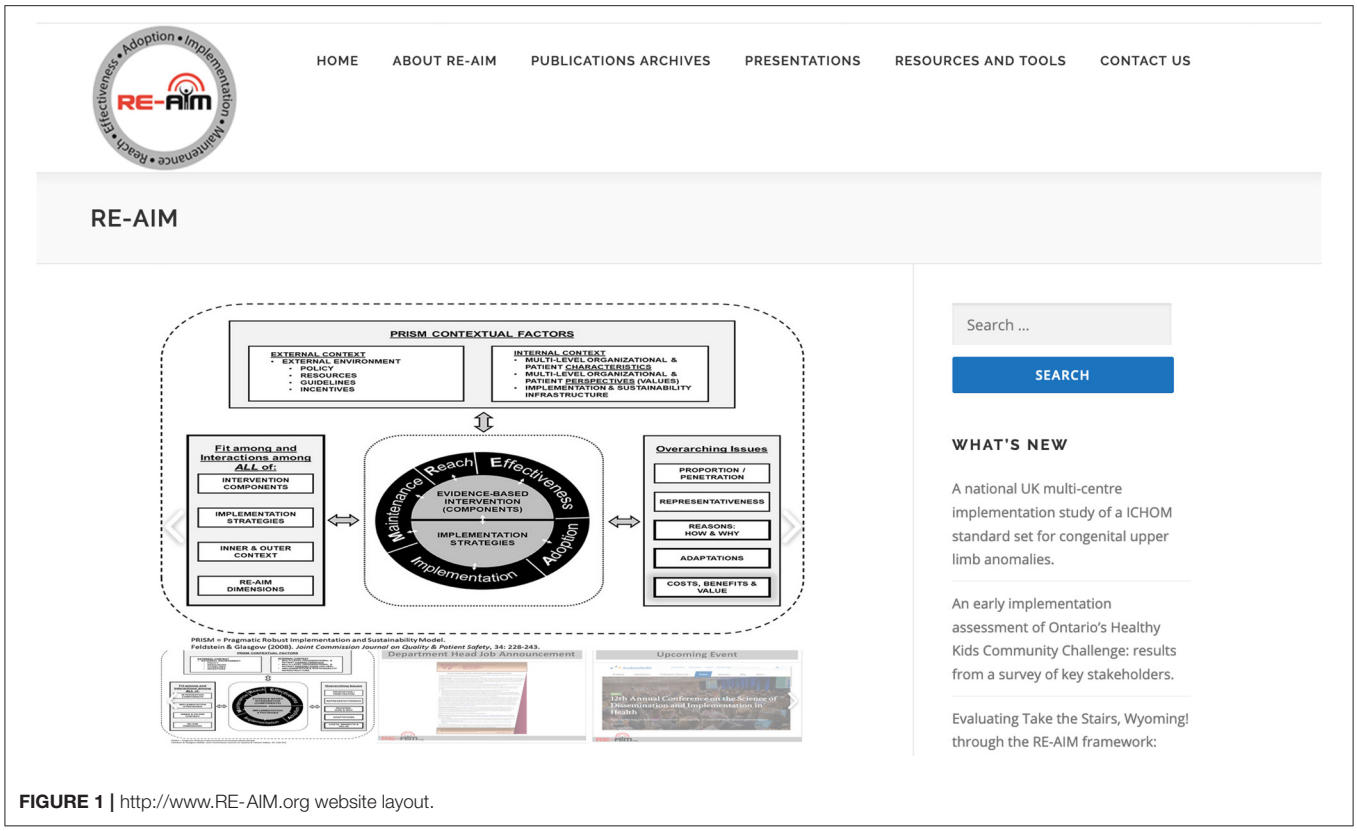

FIGURE 1 | http://www.RE-AIM.org website layout.

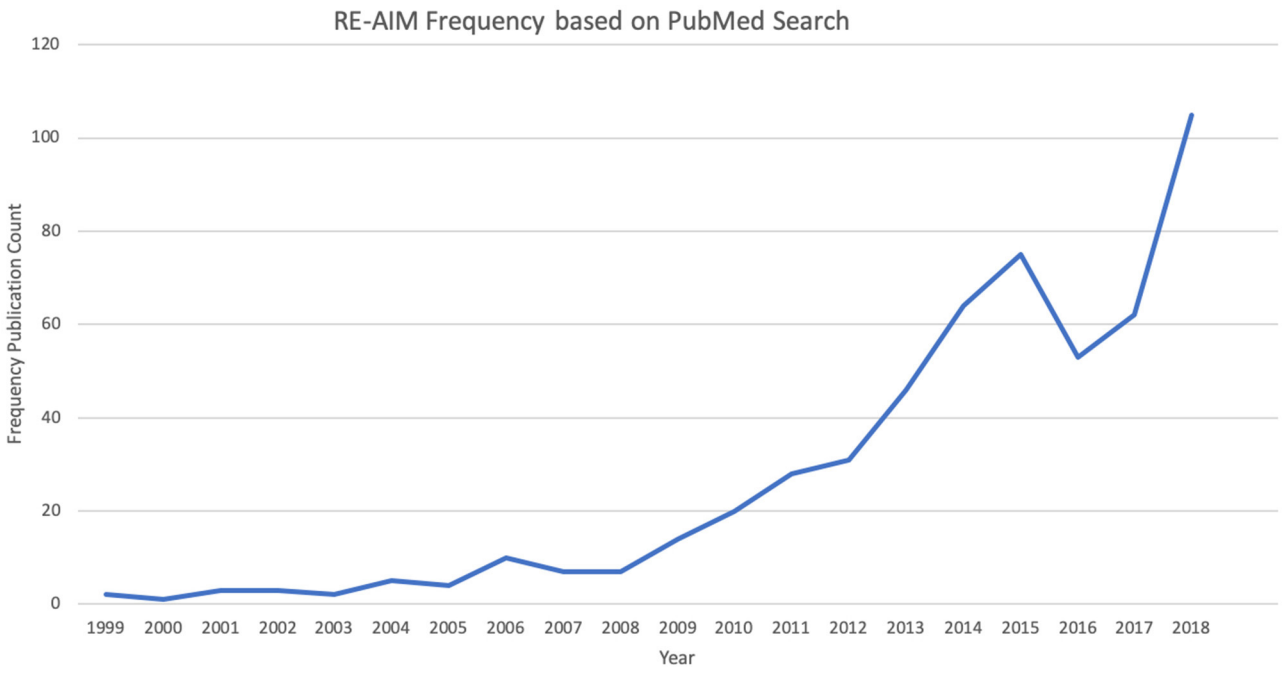

FIGURE 2 | Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) Framework Peer-Review Publications—frequency by year (1999–2018).

sharing their top lessons learned, experiences, and tips for the annual meeting.

CONSULTATION AND PRESENTATIONS

Members of the Workgroup have provided a number of tutorials and workshops on the application of RE-AIM for target outlets such as the Society of Behavioral Medicine (sbm.org) and American Public Health Association (apha.org), national non-profit and federal grantee meetings in aging and public health. Members of the Workgroup also provide educational workshops, guest lectures within the U.S. and internationally (in person or via the online platform Zoom) to a variety of audiences (e.g., undergraduate kinesiology students, graduate implementation science courses, grantee meetings, and professional forums with service organizations) and on-line technical assistance (please see website under the publications and presentations sections for examples of these efforts). While not unique to the RE-AIM framework specifically, many Workgroup members are included as co-investigators or consultants on grant proposals and funded projects to bolster the application of RE-AIM. An early example was the "adoption" of the RE-AIM framework by the Centers for Disease Control and Prevention Healthy Aging Research Network as a way of understanding the impact of promoting physical activity programs for older adults (29). Workgroup members have advised national funding agencies on the use of the RE-AIM framework leading to its recommended or required inclusion in the grant applications as well as technical assistance to grantees in its practical application (30).

PUBLICATIONS

Complementing the more than 500 publications referencing the RE-AIM framework, core Workgroup members have recently published two key collaborative summary papers. One paper, describes the past, present, and future application of the RE-AIM framework (9). The other describes the iterative application of RE-AIM in clinical, corporate, and community settings (28). Workgroup members have also collaborated on the application of RE-AIM in a multitude of research projects and publications and provided crosscutting resources including: (1) several literature reviews of use of RE-AIM in different content areas and settings (10, 13, 31, 32); (2) how to operationalize RE-AIM in pragmatic and more practitioner-friendly language of who, what, where, when, why, and how (13); (3) use of RE-AIM to evaluate statewide walking programs in Extension (33); and (4) editing a RE-AIM-based Research Topic in the journal Frontiers in Public Health.

This wide array of publications demonstrates the utility of the framework to address scientific questions across a variety of dissemination and implementation outcomes. Specifically, the framework has been used to guide the development and assessment of interventions that expand beyond simply improving effectiveness—to include an explicit focus on improving individual and organizational-level dissemination (34, 35) of evidence-based approaches (i.e., reach and adoption, respectively) and improving implementation quality, costs, and likelihood of organizational sustainability (36, 37). It is also possible to categorize publications by different levels on a translational research spectrum from efficacy (38), to effectiveness (39), to dissemination (35), to sustainability (40) across a variety of intervention types—program, policy, systems, and environmental changes (41–43). Indeed, the accumulation of literature demonstrating the utility of the framework matches the promise to improve planning, evaluation, and scientific advancement in health promotion of early RE-AIM articles (44–46).

FUTURE DIRECTIONS

Members of the National Working Group on RE-AIM Planning and Evaluation Framework are committed to advancing D&I science through the rigorous application of the framework and related approaches across a wide variety of research areas. This involves continuously evaluating the framework's utility for planning and assessing different interventions and implementation strategies, and in diverse populations and settings. We are also continuing to push the boundaries of the framework and test its scope of applicability, and are open to making modifications to address evolving issues (9). Such D&I work is notably complex, but critical to understand a program or policy's ability to be easily adopted and adapted, reach those most in need, ensure that it is delivered with fidelity, and that it can produce replicable and long-lasting individual and systems-level improvements.

Shoup and colleagues' network analysis of RE-AIM framework use commented that researchers publishing on RE-AIM were part of an "invisible college" (47). Since 2004, members of this well-connected RE-AIM college have worked to ensure that RE-AIM use is not restricted to a small set of individuals, but instead focused on sharing resources, experiences, and novel applications of the framework. The RE-AIM website and its offerings (webinars, consultations, tools, and resources) are one strategy to disseminate information and seek two-way communication with RE-AIM users. Researchers and practitioners are encouraged to contact the Workgroup regarding resources and needs through the Website (http://www.re-aim.org/contact/).

The Workgroup has focused on making RE-AIM accessible and adaptable across contexts including clinical, community, and other pragmatic settings (28). To accomplish this flexibility, the Workgroup is open to feedback through a variety of formats including contact tools on the RE-AIM website, active presence at conferences, webinars, and presentations.

To support the new research and practice directions summarized above (e.g., enhanced evaluation of contextual factors impacting RE-AIM dimensions; increased application of mixed-methods approaches; more rapid and iterative use of RE-AIM; and combining RE-AIM with other relevant D&I and pragmatic frameworks) we anticipate providing additional resources, application guides, new website features, and more concrete examples of new uses of RE-AIM.

We welcome reader input on these directions and resulting new resource needs. Designing features based on user feedback should enhance the usefulness of the framework and its website (48, 49).

CONCLUSIONS

This article summarizes progress by the RE-AIM Workgroup and the open-access resources that the workgroup has developed. The use of RE-AIM has moved beyond its original intent—to improve how programs are evaluated—to being a cornerstone for how programs and research are planned and evaluated, including the implementation phase. The continued popularity of RE-AIM can be attributed to the applicability of the core tenets of the RE-AIM framework across population and settings, its relative ease of use, and understandability to stakeholders (30). We do not see RE-AIM as static, but anticipate that the framework will continue to evolve based on advances in D&I science, to meet user needs and address new applications. For the last 10 years, Workgroup members have used limited resources to ensure that the RE-AIM framework is disseminated to researchers and practitioners. That said, there are ongoing opportunities to enhance the resources, tools and guides provided; therefore, through this paper and our mission, Workgroup members encourage users to take a proactive part in RE-AIM's continual evolution.

AUTHOR CONTRIBUTIONS

All authors contributed to the conceptualization of the manuscript and its content. All authors contributed to the full manuscript as well as reviewed and approved the final version of the manuscript.

FUNDING

RG's effort was partially supported by internal funds from the University of Colorado ACCORDS Dissemination and Implementation Science program. PE's time was partially supported by the National Institutes of Health Great Plains IDeA CTR U54GM115458. BR's effort was partially supported by the VA San Diego Center of Excellence in Stress and Mental Health.

REFERENCES

1. Estabrooks PA, Brownson RC, Pronk NP. Dissemination and implementation science for public health professionals: an overview and call to action. *Prev Chronic Dis*. (2018) 15:E162. doi: 10.5888/pcd15.180525
2. Tabak RG, Reis RS, Wilson P, Brownson RC. Dissemination of health-related research among scientists in three countries: access to resources and current practices. *BioMed Res Int*. (2015) 2015:179156. doi: 10.1155/2015/179156
3. Tabak RG, Khoong EC, Chambers DA, Brownson RC. Bridging research and practice: models for dissemination and implementation research. *Am J Prev Med*. (2012) 43:337–50. doi: 10.1016/j.amepre.2012.05.024
4. Glasgow RE. What does it mean to be pragmatic? Pragmatic methods, measures, and models to facilitate research translation. *Health Educ Behav Off Publ Soc Public Health Educ*. (2013) 40:257–65. doi: 10.1177/1090198113486805
5. EPIS Framework. *EPIS Framework*. Available online at: https://episframework.com/ (accessed July 5, 2019).
6. The Consolidated Framework for Implementation Research. *The Consolidated Framework for Implementation Research*. Available online at: https://cfirguide.org/ (accessed July 5, 2019).
7. Ford BS, Rabin B, Morrato EH, Glasgow RE. Online resources for dissemination and implementation science: meeting demand and lessons learned. *J Clin Transl Sci*. (2018) 2:259–66. doi: 10.1017/cts.2018.337
8. Dzewaltowski DA, Glasgow RE, Klesges LM, Estabrooks PA, Brock E. RE-AIM: evidence-based standards and a Web resource to improve translation of research into practice. *Ann Behav Med Publ Soc Behav Med*. (2004) 28:75–80. doi: 10.1207/s15324796abm2802_1
9. Glasgow R, Harden S, Gaglio B, Rabin B, Smith ML, Porter GC, et al. RE-AIM planning and evaluation framework: adapting to new science and practice with a twenty-year review. *Front Public Health*. (2019) 7:64. doi: 10.3389/fpubh.2019.00064
10. Gaglio B, Shoup JA, Glasgow RE. The RE-AIM framework: a systematic review of use over time. *Am J Public Health*. (2013) 103:e38–e46. doi: 10.2105/AJPH.2013.301299
11. Kessler RS, Purcell EP, Glasgow RE, Klesges LM, Benkeser RM, Peek CJ. What does it mean to "employ" the RE-AIM model? *Eval Health Prof*. (2013) 36:44–66. doi: 10.1177/0163278712446066
12. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health*. (1999) 89:1322–7. doi: 10.2105/AJPH.89.9.1322
13. Glasgow RE, Estabrooks PE. Pragmatic applications of RE-AIM for health care initiatives in community and clinical settings. *Prev Chronic Dis*. (2018) 15:E02. doi: 10.5888/pcd15.170271
14. Glasgow RE. RE-AIMing research for application: ways to improve evidence for family medicine. *J Am Board Fam Med*. (2006) 19:11–9. doi: 10.3122/jabfm.19.1.11
15. Manteiga AM, Eyler AA, Valko C, Brownson RC, Evenson KR, Schmid T. The impact of the physical activity policy research network. *Am J Prev Med*. (2017) 52:S224–7. doi: 10.1016/j.amepre.2016.10.018
16. Franz N, Stovall C, Owen M. The perceived value of an extension leadership network: enhancing personal and organizational effectiveness. *J Agric Educ Ext*. (2010) 16:433–43. doi: 10.1080/1389224X.2010.515066
17. Grills NJ, Robinson P, Phillip M. Networking between community health programs: a case study outlining the effectiveness, barriers and enablers. *BMC Health Serv Res*. (2012) 12:206. doi: 10.1186/1472-6963-12-206
18. Brownson RC, Eyler AA, Harris JK, Moore JB, Tabak RG. Getting the word out: new approaches for disseminating public health science. *J Public Health Manag Pract*. (2018) 24:102–11. doi: 10.1097/PHH.0000000000000673
19. Loudon K, Treweek S, Sullivan F, Donnan P, Thorpe KE, Zwarenstein M. The PRECIS-2 tool: designing trials that are fit for purpose. *BMJ*. (2015) 350:h2147. doi: 10.1136/bmj.h2147
20. Thorpe KE, Zwarenstein M, Oxman AD, Treweek S, Furberg CD, Altman DG, et al. A pragmatic-explanatory continuum indicator summary (PRECIS): a tool to help trial designers. *J Clin Epidemiol*. (2009) 62:464–75. doi: 10.1016/j.jclinepi.2008.12.011
21. Burke SM, Tomasone JR, Scime NV, Ma JK, Harden SM, Wolfe DL. Physical activity self-management interventions for adults with spinal cord injury: Part 2 – Exploring the generalizability of findings from research to practice. *Psychol Sport Exerc*. (2018) 37:286–95. doi: 10.1016/j.psychsport.2018.02.013
22. Feldstein AC, Glasgow RE. A practical, robust implementation and sustainability model (PRISM) for integrating research findings into practice. *Jt Comm J Qual Patient Saf*. (2008) 34:228–43. doi: 10.1016/S1553-7250(08)34030-6
23. McCreight M, Rabin B, Glasgow R, Ayele RA, Leonard CA, Gilmartin HM, et al. Using the Practical, Robust Implementation and Sustainability Model (PRISM) to qualitatively assess multilevel contextual factors to help plan,

implement, evaluate, and disseminate health services programs. *Transl Behav Med*. (2019) 9:1002–11. doi: 10.1093/tbm/ibz085
24. Research-Tested Intervention Programs: Home. Available online at: https://rtips.cancer.gov/rtips/index.do. (accessed March 30, 2018).
25. Boutron I, Altman DG, Moher D, Schulz KF, Ravaud P, CONSORT NPT Group. CONSORT Statement for randomized trials of nonpharmacologic treatments: a 2017 update and a CONSORT extension for nonpharmacologic trial abstracts. *Ann Intern Med*. (2017) 167:40–7. doi: 10.7326/M17-0046
26. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *Pilot Feasibility Stud*. (2016) 2:64. doi: 10.1186/s40814-016-0105-8
27. Pinnock H, Barwick M, Carpenter CR, Grandes G, Griffiths, CJ, Meissner P, et al. Standards for Reporting Implementation Studies (StaRI) Statement. *BMJ*. (2017) 356:i6795. doi: 10.1136/bmj.i6795
28. Harden SM, Smith ML, Ory MG, Smith-Ray RL, Estabrooks P, Glasgow R. RE-AIM in clinical, community, and corporate settings: perspectives, strategies, and recommendations to enhance public health impact. *Front Public Health*. (2018) 6:71. doi: 10.3389/fpubh.2018.00071
29. Belza B, Toobert D, Glasgow R. *RE-AIM for Program Planning: Overview and Applications*. Available online at: https://fromhungertohealth.files.wordpress.com/2013/02/re-aim_issue_brief.pdf (accessed March 11, 2019).
30. Ory MG, Altpeter M, Belza B, Helduser J, Zhang C, Smith ML. Perceived utility of the RE-AIM framework for health promotion/disease prevention initiatives for older adults: a case study from the U.S. evidence-based disease prevention initiative. *Front Public Health*. (2014) 2:143. doi: 10.3389/fpubh.2014.00143
31. Harden SM, Gaglio B, Shoup JA, Kinney KA, Johnson SB, Brito F, et al. Fidelity to and comparative results across behavioral interventions evaluated through the RE-AIM framework: a systematic review. *Syst Rev*. (2015) 4:155. doi: 10.1186/s13643-015-0141-0
32. Glasgow RE, McKay HG, Piette JD, Reynolds KD. The RE-AIM framework for evaluating interventions: what can it tell us about approaches to chronic illness management? *Patient Educ Couns*. (2001) 44:119–27. doi: 10.1016/S0738-3991(00)00186-5
33. Harden S, Ramalingam N, Breig S, Estabrooks P. Walk this way: our perspective on challenges and opportunities for extension statewide walking promotion programs. *J Nutr Educ Behav*. (2019) 51:636–43. doi: 10.1016/j.jneb.2018.12.010
34. Helmick MJ, Yaroch AL, Parks CA, Estabrooks PA, Hill JL. Utilizing the RE-AIM framework to understand adoption of nutrition policies at food pantries across the USA. *Transl Behav Med*. (2019) 9:1112–21. doi: 10.1093/tbm/ibz036
35. Kennedy S, Smith J, Estabrooks P, McKay H, Noetel M, Nathan N, et al. Scale-up and dissemination of a school-based resistance training program: RE-AIM evaluation of impact. *J Sci Med Sport*. (2019) 22:S22. doi: 10.1016/j.jsams.2019.08.174
36. Shaw RB, Sweet SN, McBride CB, Adair WK, Martin Ginis KA. Operationalizing the reach, effectiveness, adoption, implementation, maintenance (RE-AIM) framework to evaluate the collective impact of autonomous community programs that promote health and well-being. *BMC Public Health*. (2019) 19:803. doi: 10.1186/s12889-019-7131-4
37. Estabrooks PA, Smith-Ray RL, Dzewaltowski DA, Dowdy D, Lattimore D, Rheaume C, et al. Sustainability of evidence-based community-based physical activity programs for older adults: lessons from Active for Life. *Transl Behav Med*. (2011) 1:208–15. doi: 10.1007/s13142-011-0039-x
38. Yank V, Stafford RS, Rosas LG, Ma J. Baseline reach and adoption characteristics in a randomized controlled trial of two weight loss interventions translated into primary care: a structured report of real-world applicability. *Contemp Clin Trials*. (2013) 34:126–35. doi: 10.1016/j.cct.2012.10.007
39. Zoellner JM, You W, Hill JL, Brock DP, Yuhas M, Alexander RC, et al. A comparative effectiveness trial of two family-based childhood obesity treatment programs in a medically underserved region: rationale, design & methods. *Contemp Clin Trials*. (2019) 84:105801. doi: 10.1016/j.cct.2019.06.015
40. Scheirer MA, Santos SLZ, Tagai EK, Bowie J, Slade J, Carter R, et al. Dimensions of sustainability for a health communication intervention in African American churches: a multi-methods study. *Implement Sci*. (2017) 12:43. doi: 10.1186/s13012-017-0576-x
41. Lai J, Klag M, Shikako-Thomas K. Designing a program evaluation for a medical-dental service for adults with autism and intellectual disabilities using the RE-AIM framework. *Learn Health Syst*. (2019) 3:e10192. doi: 10.1002/lrh2.10192
42. Pawlowski CS, Schmidt T, Nielsen JV, Troelsen J, Schipperijn J. Will the children use it?—A RE-AIM evaluation of a local public open space intervention involving children from a deprived neighbourhood. *Eval Program Plann*. (2019) 77:101706. doi: 10.1016/j.evalprogplan.2019.101706
43. Economos CD, Anzman-Frasca S, Koomas AH, Bakun PJ, Brown CM, Brown D, et al. Dissemination of healthy kids out of school principles for obesity prevention: a RE-AIM analysis. *Prev Med*. (2019) 119:37–43. doi: 10.1016/j.ypmed.2018.12.007
44. Estabrooks PA, Gyurcsik NC. Evaluating the impact of behavioral interventions that target physical activity: Issues of generalizability and public health. *Psychol Sport Exerc*. (2003) 4:41–55. doi: 10.1016/S1469-0292(02)00016-X
45. Dzewaltowski DA, Estabrooks PA, Glasgow RE. The future of physical activity behavior change research: what is needed to improve translation of research into health promotion practice? *Exerc Sport Sci Rev*. (2004) 32:57–63. doi: 10.1097/00003677-200404000-00004
46. Glasgow RE, Klesges LM, Dzewaltowski DA, Estabrooks PA, Vogt TM. Evaluating the impact of health promotion programs: using the RE-AIM framework to form summary measures for decision making involving complex issues. *Health Educ Res*. (2006) 21:688–94. doi: 10.1093/her/cyl081
47. Shoup JA, Gaglio B, Varda D, Glasgow RE. Network analysis of RE-AIM framework: chronology of the field and the connectivity of its contributors. *Transl Behav Med*. (2015) 5:216–32. doi: 10.1007/s13142-014-0300-1
48. Hustak T, Krejcar O. Principles of usability in human-computer interaction. In: Park JJ, Jong H, Chao H-C, Arabnia H, Yen NY, editors. *Advanced Multimedia and Ubiquitous Engineering*. Lecture Notes in Electrical Engineering. Berlin; Heidelberg: Springer (2016). p. 51–7. doi: 10.1007/978-3-662-47895-0_7
49. Garett R, Chiu J, Zhang L, Young SD. A literature review: website design and user engagement. *Online J Commun Media Technol*. (2016) 6:1–14. doi: 10.29333/ojcmt/2556

Disclaimer: The statements presented in this publication are solely the responsibility of the author(s) and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors or Methodology Committee.

Conflict of Interest: Co-authors are members of the National Working Group on RE-AIM Planning and Evaluation Framework (www.re-aim.org).

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

frontiers in Public Health

OPINION
published: 18 February 2021
doi: 10.3389/fpubh.2021.599975

Full Comprehension of Theories, Models, and Frameworks Improves Application: A Focus on RE-AIM

Matthew Lee Smith[1,2]* *and Samantha M. Harden*[3]

[1] Center for Population Health and Aging, Texas A&M University, College Station, TX, United States, [2] Department of Environmental and Occupational Health, School of Public Health, Texas A&M University, College Station, TX, United States, [3] Physical Activity Research and Community Implementation, Human Nutrition, Foods, and Exercise, Virginia Tech, Blacksburg, VA, United States

OPEN ACCESS

Edited by:
Will R. Ross, Washington University School of Medicine in St. Louis, United States

Reviewed by:
Christopher Mierow Maylahn, New York State Department of Health, United States
Darrell Lee Hudson, Washington University in St. Louis, United States

***Correspondence:**
Matthew Lee Smith
matthew.smith@tamu.edu

Specialty section:
This article was submitted to Public Health Education and Promotion, a section of the journal Frontiers in Public Health

Received: *28 August 2020*
Accepted: *11 January 2021*
Published: *18 February 2021*

Citation:
Smith ML and Harden SM (2021) Full Comprehension of Theories, Models, and Frameworks Improves Application: A Focus on RE-AIM. Front. Public Health 9:599975. doi: 10.3389/fpubh.2021.599975

Keywords: RE-AIM, planning, evaluation, theory, model, framework, COVID-19

INTRODUCTION

Two decades after the introduction of the RE-AIM Framework (1), its utility for intervention planning and evaluation remains as relevant as ever. Applied widely across time, space, and discipline, RE-AIM has become a "household name" among researchers, practitioners, and government officials. For the last 20 years, this framework has structured funding initiatives, course curricula and trainings, and community and clinical efforts. RE-AIM has also been the focus of hundreds of published studies. However, despite RE-AIM's operationalized core elements and mainstream presence in research and practice communities (2), misconceptions about its application persist (3–5). Although RE-AIM was developed as a planning and evaluation framework, it is often inappropriately viewed narrowly for evaluation use only. Although its use for evaluation is valuable and highly recommended, the versatility of the RE-AIM framework is diminished when only envisioned for a single purpose. This article promotes the need for full comprehension of the framework to ensure it is appropriately used for its range of utility. Further, it encourages researchers and practitioners to proactively access the vast collection of RE-AIM resources in anticipation of potential challenges, disruptions, and delays caused by the COVID-19 pandemic.

ENCOURAGING FULL COMPREHENSION OF A FRAMEWORK

Dissemination and implementation science is an emergent field with a challenging taxonomy (6–8). The science itself stemmed from many fields (9), resulting in over 100 theories, models, and frameworks (TMF) with similar, yet distinct, constructs. Numerous attempts have been made to guide the understanding and selection of TMF (2, 10–12). In a recent scoping review by Esmail et al. (12), RE-AIM was miscategorized as an evaluation-only framework. This scoping, which resulted in a published exchange with the RE-AIM developers (4, 13) about where the confusion originated and who was accountable for misconceptions about the RE-AIM Framework. Regardless of this debate, we contend that the onus of contend that the onus of properly

using TMF remains with the scientists and practitioners who aim to apply TMF. For example, numerous studies have cited use of RE-AIM before, during, and after implementation, prior to the Esmail et al. (12) scoping review and after the 20-year RE-AIM review (4). Additionally, there is a vast collection of publicly-available RE-AIM resources compiled online to help researchers and practitioners comprehend and use the framework for all phases of research and practice [https://www.re-aim.org; (14)]. Resources include, but are not limited to, webinars, slide decks, definitions, guidance about measurement, and qualitative interview prompts. While these resources are encompassing and should be utilized by RE-AIM novices and experts alike, they also evolve alongside the needs of those in the field, new discoveries, trend shifts, and adversities.

PROVIDING STRUCTURE DURING THE COVID-19 PANDEMIC

These unprecedented times of the COVID-19 pandemic reinforce that efforts to develop, deliver, and evaluate public health initiatives require robust and flexible frameworks. The intermittent and area-specific lock-downs, shelter-in-place orders, and infection surges, coupled with newfound evidence about virus transmission and innovations for contact tracing and symptom identification, makes this pandemic the unfortunate, yet ideal, time to dispel misconceptions, and capitalize on RE-AIM's spectrum of iterative uses.

In response to COVID-19, many researchers and practitioners are curtailing their service provisions and limiting the physical contact needed for meaningful interactions between providers and clients (e.g., data collection, risk screening, educational efforts, and intervention delivery). While such disruptions are occurring for efforts across all age groups, many are pronounced among demographics at higher COVID-19 risk, such as older adults and those with chronic conditions. As such, there is an onslaught of new, non-conventional and translational efforts to meet the needs in our "new normal" (15, 16). Organizations like the Administration for Community Living, National Council on Aging, AARP Foundation, and Centers for Disease Control and Prevention have "answered the call" in our time of need to recommend strategies to alter person-to-person interactions to reduce COVID-19 exposure and transmission (17). However, despite "distanced connectivity" efforts (17), many researchers and practitioners are being challenged to take the "human" out of "human services" while maintaining a semblance of structured planning or evaluation. During the COVID-19 pandemic, the adoption of a flexible and robust planning and evaluation infrastructure is needed for optimized outputs and outcomes. However, TMF used during tentative times must be reactive to changes in the field and adaptable for rapidly evolving circumstances, unforeseen delays, and risk surges. Researchers and practitioners are encouraged to be simultaneously proactive and reactive when using the RE-AIM Framework during COVID-19 (and beyond), which includes a series of iterative reflective and active processes (assess, plan, do, evaluate, and report) at each temporal starting point (18).

In some instances, our recommendation for rapid, rigorous, and responsive efforts that apply RE-AIM to guide decision-making during the COVID-19 pandemic are already underway. The Test-to-Care Model underwent a rapid 3-week demonstration trial (19). Using program data, surveys, and informal interviews, this model was found to be feasible and acceptable for supporting patients from socioeconomically vulnerable populations during self-isolation and quarantine. In another example, New York City primary care facilities developed processes to guide patients through a video-delivered primary care practice appointment (20). The team applied RE-AIM and found significant differences in terms of reach and representativeness (i.e., patients were more likely to be younger adults, women, and have commercial insurance). Outside of these efforts, other research teams have adapted existing in-person interventions to be delivered via online platforms (17). The use of RE-AIM can guide decision-making about "what works" and "for whom it works" regarding new and existing interventions translated to meet demands during the COVID-19 pandemic. Utilizing RE-AIM, or other TMF, can also assist researchers and practitioners to identify changes in health-related outcomes and indicators over time and compare differences between interventions pre- and post-pandemic (in terms of their reach, adoption, implementation, effectiveness, and maintenance).

DISCUSSION

During the COVID-19 pandemic, thoughtful planning remains essential to the development and employment of meaningful initiatives and evaluation efforts. Despite persisting misconceptions about the RE-AIM by some (10, 12), the majority recognize the robust and versatile utility of this framework across the life course of research and practice initiatives (7, 8, 18, 21, 22). To reinforce the proper use of RE-AIM, we offer the following recommendations: [a] Be an active team member and proactively think through problems and solutions; [b] Use myriad available resources, not just the top-cited article in a quickly executed literature review; [c] When assuming the scientific role on a participatory team, incorporate strong and thoroughly vetted empirical knowledge; [d] When making decisions about how to adapt an intervention, use TMF (e.g., RE-AIM) to guide decisions before, during, and after implementation; [e] Be a wise consumer of TMF and utilize all high-quality resources available to ensure their use is optimized and appropriate; [f] Although we often need to make decisions rapidly, be responsive to evolving circumstances, and take action quickly, we must not lose sight of what is necessary and relevant. The quality or scientific rigor of research should not be lessened because we are working in "real-world" settings where things can be chaotic or messy. Rather, we suggest taking a deeper look into what it means to be robust or rigorous in our efforts. We contend that being rigorous does not make us rigid, and being flexible does not make us flippant.

Now, more than ever, we must attempt to be purposeful in our efforts to improve human health. We must capitalize

on known best practices and apply TMF capable of meeting our research and practice needs. TMF must be structured, yet remain flexible, and nimble. As researchers and practitioners using TMF, we must do our due diligence to understand the application of the framework, know its boundaries, and apply them appropriately. We must recognize the temporal iterations needed when initiatives reach critical decision points or are met with successes or challenges. The utility of the RE-AIM Framework lies with its robustness and vast application, despite misconceptions about it being inappropriately viewed narrowly for evaluation use only. Taking time to learn about the full scope of TMF is essential prior to their use in research or practice.

AUTHOR CONTRIBUTIONS

All authors listed have made a substantial, direct and intellectual contribution to the work, and approved it for publication.

REFERENCES

1. Glasgow RE, Harden SM, Gaglio B, Rabin B, Smith ML, Porter GC, et al. RE-AIM planning and evaluation framework: adapting to new science and practice with a 20-year review. *Front Public Health.* (2019) 7:64. doi: 10.3389/fpubh.2019.00064
2. Tabak RG, Khoong EC, Chambers DA, Brownson RC. Bridging research and practice: models for dissemination and implementation research. *Am J Prevent Med.* (2012) 43:337–50. doi: 10.1016/j.amepre.2012.05.024
3. Estabrooks PA, Allen KC. Updating, employing, and adapting: a commentary on what does it mean to "employ" the RE-AIM model. *Eval Health Prof.* (2013) 36:67–72. doi: 10.1177/0163278712460546
4. Glasgow RE, Estabrooks PA, Ory MG. Characterizing evolving frameworks: issues from Esmail et al. (2020) review. *Implement Sci.* (2020) 15:53. doi: 10.1186/s13012-020-01010-1
5. Kislov R, Pope C, Martin GP, Wilson PM. Harnessing the power of theorising in implementation science. *Implement Sci.* (2019) 14:103. doi: 10.1186/s13012-019-0957-4
6. Rabin BA, Brownson RC, Haire-Joshu D, Kreuter MW, Weaver NL. A glossary for dissemination and implementation research in health. *J Public Health Manag Pract.* (2008) 14:117–23. doi: 10.1097/01.PHH.0000311888.06252.bb
7. Bauer MS, Damschroder L, Hagedorn H, Smith J, Kilbourne AM. An introduction to implementation science for the non-specialist. *BMC Psychol.* (2015) 3:32. doi: 10.1186/s40359-015-0089-9
8. Shelton RC, Lee M, Brotzman LE, Wolfenden L, Nathan N, Wainberg ML. What is dissemination and implementation science? An introduction and opportunities to advance behavioral medicine and public health globally. *Int J Behav Med.* (2020) 27:3–20. doi: 10.1007/s12529-020-09848-x
9. Estabrooks PA, Brownson RC, Pronk NP. Dissemination and implementation science for public health professionals: an overview and call to action. *Prevent Chronic Dis.* (2018) 15:E162. doi: 10.5888/pcd15.180525
10. Nilsen P. Making sense of implementation theories, models and frameworks. *Implement Sci.* (2015) 10:53. doi: 10.1186/s13012-015-0242-0
11. Strifler L, Cardoso R, McGowan J, Cogo E, Nincic V, Khan PA, et al. Scoping review identifies significant number of knowledge translation theories, models, and frameworks with limited use. *J Clin Epidemiol.* (2018) 100:92–102. doi: 10.1016/j.jclinepi.2018.04.008
12. Esmail R, Hanson HM, Holroyd-Leduc J, Brown S, Strifler L, Straus SE, et al. A scoping review of full-spectrum knowledge translation theories, models, and frameworks. *Implement Sci.* (2020) 15:1–14. doi: 10.1186/s13012-020-0964-5
13. Esmail R, Hanson HM, Holroyd-Leduc J, Brown S, Strifler L, Straus SE, et al. Response to letter to the editor. *Implementat Sci.* (2020). doi: 10.1177/1941738113499730
14. Harden SM, Strayer III TE, Smith ML, Gaglio B, Ory MG, Rabin B, et al. National working group on the RE-AIM planning and evaluation framework: goals, resources, and future directions. *Front Public Health.* (2019) 7:390. doi: 10.3389/fpubh.2019.00390
15. Brownson RC, Burke TA, Colditz GA, Samet JM. Reimagining public health in the aftermath of a pandemic. *Am J Public Health.* (2020) 110:1605–10. doi: 10.2105/AJPH.2020.305861
16. Van Bavel JJ, Baicker K, Boggio PS, Capraro V, Cichocka A, Cikara M, et al. Using social and behavioural science to support COVID-19 pandemic response. *Nat Hum Behav.* (2020) 4:460–71. doi: 10.1038/s41562-020-0884-z
17. Smith ML, Steinman LE, Casey EA. Combatting social isolation among older adults in a time of physical distancing: the COVID-19 social connectivity paradox. *Front Public Health.* (2020) 8:403. doi: 10.3389/fpubh.2020.00403
18. Harden SM, Smith ML, Ory MG, Smith-Ray RL, Estabrooks PA, Glasgow RE. RE-AIM in clinical, community, and corporate settings: perspectives, strategies, and recommendations to enhance public health impact. *Front Public Health.* (2018) 6:71. doi: 10.3389/fpubh.2018.00071
19. Kerkhoff AD, Sachdev D, Mizany S, Rojas S, Gandhi M, Peng J, et al. Evaluation of a novel community-based COVID-19 'Test-to-Care' model for low-income populations. *PLoS ONE.* (2020) 15:e0239400. doi: 10.1371/journal.pone.0239400
20. Sinha S, Kern LM, Gingras LF, Reshetnyak E, Tung J, Pelzman F, et al. Implementation of video visits during COVID-19: lessons learned from a primary care practice in New York City. *Front Public Health.* (2020) 8:514. doi: 10.3389/fpubh.2020.00514
21. Gaglio B, Shoup JA, Glasgow RE. The RE-AIM framework: a systematic review of use over time. *Am J Public Health.* (2013) 103:e38–46. doi: 10.2105/AJPH.2013.301299
22. Kessler RS, Purcell EP, Glasgow RE, Klesges LM, Benkeser RM, Peek CJ. What does it mean to "employ" the RE-AIM model? *Eval Health Prof.* (2013) 36:44–66. doi: 10.1177/0163278712446066

Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

frontiers in Public Health

PERSPECTIVE
published: 17 December 2019
doi: 10.3389/fpubh.2019.00368

Evaluating "Take the Stairs, Wyoming!" Through the RE-AIM Framework: Challenges and Opportunities

Laura E. Balis[1]* *and Thomas Strayer III*[2]

[1] Division of Agriculture Cooperative Extension Service, University of Arkansas System, Little Rock, AR, United States,
[2] Center for Quality Aging, Vanderbilt University Medical Center, Nashville, TN, United States

Introduction: Health promotion delivery systems are increasingly being asked to implement policy, systems, and environmental interventions (PSEs). However, evaluating PSEs is challenging, especially in low-resource community settings. This paper describes the use of RE-AIM to evaluate a physical activity PSE delivered through University of Wyoming Extension and highlights challenges and opportunities in pragmatic, real-world program evaluation.

Methods: Extension health educators adapted a point-of-decision prompt intervention encouraging stairway use through posters, called Take the Stairs, Wyoming! *Reach* was assessed through estimates of daily traffic, *effectiveness* was assessed through opportunistic interviews, *adoption* was calculated as the number and proportion of sites that agreed to hang posters, *implementation* was calculated as the proportion of sites with a poster in place at a 2-weeks follow-up visit, and *maintenance* was assessed through 6-months opportunistic interviews (individual level) and proportion of sites with a poster in place (organizational level).

Results: Overall, the posters were widely *adopted* and most posters were *implemented* as intended. However, capturing *reach*, *effectiveness*, and *maintenance* was challenging, as health educators found the evaluation burdensome. Therefore, it was difficult to determine if the posters were effective at increasing physical activity levels.

Discussion: Suggestions are provided for capturing *reach*, *effectiveness,* and *maintenance* data in community settings. Future efforts are needed to create evaluation tools to pragmatically measure effectiveness of PSEs on changing behaviors, as well as to prioritize program evaluation in Extension.

Keywords: PSEs, RE-AIM, extension, evaluation, point-of-decision prompt, physical activity

OPEN ACCESS

Edited by:
Matthew Lee Smith,
Texas A&M University, United States

Reviewed by:
Jo Ann Shoup,
Kaiser Permanente, United States
Christopher Mierow Maylahn,
New York State Department of Health, United States

***Correspondence:**
Laura E. Balis
lbalis@uaex.edu

Specialty section:
This article was submitted to Public Health Education and Promotion, a section of the journal Frontiers in Public Health

Received: *17 September 2019*
Accepted: *19 November 2019*
Published: *17 December 2019*

Citation:
Balis LE and Strayer T III (2019) Evaluating "Take the Stairs, Wyoming!" Through the RE-AIM Framework: Challenges and Opportunities. Front. Public Health 7:368. doi: 10.3389/fpubh.2019.00368

INTRODUCTION

Health promotion delivery systems are increasingly being asked to implement policy, systems, and environmental interventions (PSEs). PSEs, such as creating or improving places for physical activity (1) and providing healthier food and beverages in schools (2), focus on changing the environment to support healthy behaviors. One system tasked with implementing PSEs is the nationwide Land-Grant University Cooperative Extension System (Extension). In Extension, campus-based specialists support county-based educators who deliver programs in agriculture, natural resources, 4-H/youth development, community development, and family and consumer science (3). Within

family and consumer science, Extension delivers health promotion programming addressing physical activity (since 2014) (4) and nutrition.

With its roots in home economics and agricultural education, Extension has a long history of implementing individual-level educational programs; however, implementing PSEs is a relatively new focus area. One driver of this change was the 2014 release of Cooperative Extension's National Framework for Health and Wellness, which outlined health promotion efforts based on the social-ecological model that included both "healthy and safe choices" and "healthy and safe environments" and identified PSEs as Extension priorities (5). Another factor is the Healthy, Hunger-Free Kids Act, which was released in 2010 and required the Supplemental Nutrition Assistance Program Education (SNAP-Ed, administered by Extension in some states) to implement comprehensive, multi-level interventions in addition to direct education (6). Lastly, funding opportunities available to Extension (e.g., Centers for Disease Control and Prevention grants) have shifted focus to increasing access to healthier foods and places for physical activity in an effort to create long-lasting health impacts (7).

Implementing PSEs in community settings has the potential for broad impacts on population health (1). However, evaluating PSEs can be challenging, as it is difficult to determine who is influenced by PSEs and track changes in their behavior. Evaluation of health promotion interventions (both PSEs and individual-level interventions) can be especially challenging in low-resource community settings (i.e., those that may not have funding or personnel dedicated to program evaluation) (8, 9). One challenge is that PSEs that were not designed and tested in community settings may include evaluations that are difficult to replicate (e.g., using many hours of observation pre- and post-intervention) (10). Adding to this challenge, interventions that are designed and evaluated in community settings as part of funded, researcher-initiated studies may also be difficult to replicate. Without funded research trials and dedicated evaluation staff, programs may not have the institutional support to be widely adopted and effectively evaluated, and consequently may not achieve the desired results (9).

Another challenge is that existing PSEs evaluation measures often only capture adoption and implementation at the organization level rather than measuring behavior change. For example, the PSEs listed in the SNAP-Ed Toolkit (a repository of practice-tested interventions used in SNAP-Ed) are primarily evaluated through indicators such as organizational-level adoption of nutrition or physical activity supports (11). The SNAP-Ed Evaluation Framework does include individual-level behavior change indicators; however, they are primarily designed to evaluate direct education (11).

While evaluating the impact of PSEs is difficult, it is necessary for stakeholder and funder accountability (12), as well as demonstrating the public value of federally funded programs, like Extension and SNAP-Ed (13). The reach, effectiveness, adoption, implementation, maintenance framework (RE-AIM) has been suggested for robustly evaluating PSEs (14), as well as for planning and evaluating Extension programs (15, 16). RE-AIM has been used for pragmatic program evaluation in community settings (8) and may help practitioners overcome the challenges to evaluating PSEs by providing a comprehensive evaluation framework. The purpose of this paper is to describe the use of RE-AIM as a planning and evaluation framework for a physical activity PSE delivered through University of Wyoming Extension (UWE).

METHODS

Setting and Intervention

In Wyoming, five county-based Extension health educators deliver programs in three initiative areas: healthy eating, active living, and food safety; each educator covers multiple counties. Additionally, Cent$ible Nutrition Program (CNP) educators are located in most counties and are federally funded to serve limited-resource audiences through SNAP-Ed and the Expanded Food and Nutrition Education Program (EFNEP). The Extension health educators identified a need for an intervention to increase physical activity levels that was feasible to implement with a small number of Extension health educators covering the state. Collections of evidence-based interventions were searched, and point-of-decision prompts, recommended by the Community Guide (the Community Preventive Services Task Force's list of evidence-based strategies and interventions) (10, 17) were selected. The prompts encourage stairway use through posters to increase physical activity levels (18–20). The posters were adapted to give them a more modern look (see **Figure 1**). UWE program funds were used to print posters for statewide dissemination.

Implementation Process and Research Design

The Extension health educators partnered with CNP educators to implement the intervention, titled Take the Stairs, Wyoming! As there was no database available listing all buildings with elevators in the state, each Extension health educator worked together with the CNP educator(s) in their area to identify businesses and organizations with elevators. Wyoming is a large, rural state with primarily small cities (95% of Wyoming cities have a population under 10,000); this made it possible for educators to identify buildings in their counties with elevators based on local knowledge.

Data were collected through an observational design. Both Extension health educators and CNP educators were asked to approach the identified businesses or organizations in their counties to hang the stairway posters and collect initial data (*reach* and *adoption*). After the initial visit, Extension health educators were responsible for completing data collection (*effectiveness*, *implementation*, and *maintenance*) through 2-weeks and 6-months follow-up visits. Educators were asked to implement the intervention between February and August 2018. The University of Wyoming Institutional Review Board approved this study.

RE-AIM Measures

Detailed aims and outcome measures for each RE-AIM dimension are described below and summarized in **Table 1**. Means and standard deviations of continuous variables and

FIGURE 1 | Take the Stairs, Wyoming! posters.

frequencies and proportions of nominal variables were calculated in SPSS (IBM, Version 25).

Reach

Each business or organization was asked to provide an estimate of daily traffic. For example, this could include average daily patrons at a library.

Effectiveness

Extension health educators conducted opportunistic interviews (i.e., using a convenience sample of all individuals who walked past the poster) (21) for 1 h at each poster site at a 2-weeks follow up visit. The opportunistic interviews consisted of three questions: (1) "Did you see the poster?," if yes, (2) "Did you feel that your behavior changed in response to the poster?," and, if yes, (3) "How did the posters change your behavior?" This evaluation measure was selected after reviewing evaluation methods of all the literature that was included in the Community Guide recommendation and was selected as the most feasible. The other studies included in the Community Guide used up to 9 h of pre- and post-implementation observations, which was determined not feasible due to competing demands on Extension health educators' time.

TABLE 1 | RE-AIM dimensions and measures.

Dimension	Aims and Outcome Measures
Reach: Number and proportion of individuals exposed to the PSE	Aim: To monitor and evaluate exposure rate Outcome Measure: Number of employees, building residents, clients, or daily traffic
Effectiveness: Impact on primary outcomes, quality of life, and unintended consequences	Aim: To confirm the effectiveness of the POD prompt posters at increasing stairway use Outcome Measure: Opportunistic interviews after 2 weeks
Adoption: Number, proportion, and representativeness of settings who deliver the intervention	Aim: To evaluate setting adoption rate Outcome Measure: Proportion and proportion of organizations/businesses that adopt the POD prompt posters
Implementation: Degree to which intervention was delivered as intended and the costs associated with continued delivery	Aim: To determine the degree to which POD prompt posters are delivered as intended Outcome Measure: Number of posters in place after 2 weeks
Maintenance: Long-term change in individual primary outcomes as well as extent to which delivery/ implementation is sustained over time	Aim: To determine the degree to which stairway use is sustained at least 6 months following intervention Outcome Measure: Opportunistic interviews after 6 months Aim: To determine the extent to which the posters are sustained after 6 months Outcome Measure: Number of posters in place after 6 months

Adoption

Adoption was calculated as the number and proportion of businesses and organizations that agreed to hang the posters.

Implementation

Implementation of the intervention (fidelity of posters implemented) was calculated as the proportion of sites that had a poster in place at the 2-weeks follow up visit to each poster site.

Maintenance

Maintenance was assessed at a 6-months follow up visit to each poster site through opportunistic interviews (individual level) and the proportion of sites that had a poster in place (organizational level).

RESULTS

Eight Extension personnel approached businesses and organizations to place stairway posters across the state: three Extension health educators, four CNP educators, and one campus-based Specialist within the Department of Agriculture and Applied Economics who volunteered to assist. Posters were placed in eight of the state's 23 counties.

Reach

At 38 of the 47 poster sites (81%), the estimated daily traffic was left blank or recorded as unknown, varies, not sure, or not available. Of the nine sites (19%) that did provide estimated daily traffic, an average of 99 ($SD \pm 127$) individuals per site were reached.

Effectiveness

Opportunistic interviews were conducted at 10 poster sites (21%). Across these sites, 42 interviews were conducted. Twenty-four interviewees (57%) responded "yes" to question one indicating that they had seen the poster. Of these twenty-four, eight (33%) responded yes to question two indicating that they felt their behavior had changed in response to the poster. Of those eight, five (63%) responded that they had taken the stairs more often (e.g., "I came in with bags and would have taken the elevator, but saw the sign and took the stairs."). Three (38%) indicated a change in their thoughts rather than their behavior (e.g., "It made me think twice about taking the elevator."). Of the 16 who indicated they had seen the posters but their behavior had *not* changed, 11 provided unsolicited feedback indicating that they already take the stairs (e.g., "I always take the stairs.") and three indicated that they had thought about changing their behavior (e.g., "I thought about it more seeing the poster."). See **Figure 2** for details.

These data were used to iteratively improve the intervention during the implementation phase (22). For example, when interviewees indicated that they had not seen the posters, this information provided an opportunity to place additional posters in locations that may have been more visible. This can be seen as a real-time adaptation to the intervention.

Adoption

A total of 32 businesses and organizations were asked for approval to hang a poster. Of these, all but two (94%) provided approval, and a total of 44 posters were placed. During 2-weeks follow-up visits to these buildings, three additional posters were placed for a total of 47 posters.

Implementation

Two-weeks follow-up visits were conducted at 42 of the original 44 poster sites; no additional follow-up visits were completed for the three additional posters placed during 2-weeks follow-up visits. Of the 42 follow-up visits completed, 29 posters (69%) were still in place. At two sites where the posters were no longer in place, staff reported the reason (e.g., the elevator was no longer working).

Maintenance

As no follow-up visits were conducted, maintenance was not able to be reported.

DISCUSSION

Overall, the posters were widely adopted by the businesses and organizations that were approached and most posters were implemented as intended (i.e., still in place after 2 weeks). However, capturing reach, effectiveness, and maintenance was challenging. Taken together, these results suggest that the posters may not have been effective at increasing levels of physical

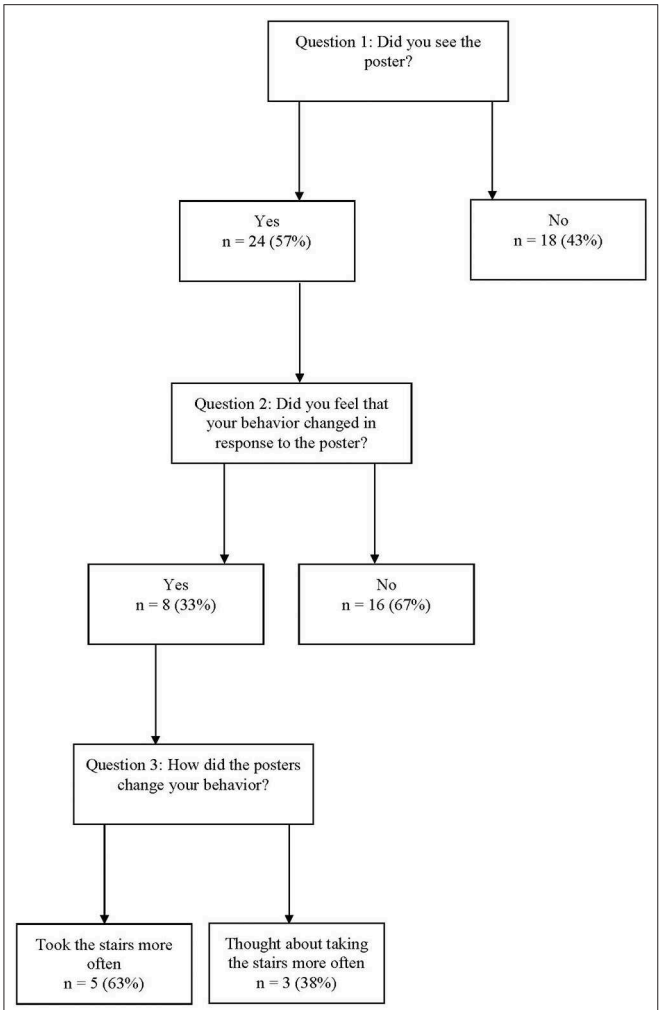

FIGURE 2 | Results of opportunistic interviews ($N = 42$).

activity through increased stair use, but it is difficult to determine due to the limited data. The challenges experienced with data collection as well as suggestions for improvement are presented.

Data Collection Challenges

Determining *reach* was difficult, as most staff at the participating businesses and organizations were unsure of daily traffic. Additionally, proportion and representativeness (e.g., age, gender) were not captured, so it is unknown if the intervention reached those most in need. While a limitation for impact, this type of barrier is not uncommon in pragmatic settings, as this study actively worked in organizations focused on their own daily activities rather than those specifically recruited for research (23).

As for *effectiveness*, there were multiple issues with data collection. Three Extension health educators and the Specialist completed the 2-weeks follow-up visits, but only two of them completed the opportunistic interviews. Via email, one who did not complete interviews reported that it was too time consuming and not a good use of her time. Of the two staff members who did complete opportunistic interviews, at four sites they were not completed as they were not able to obtain permission from staff at the business or organization. Additionally, at six of the sites where interviews were conducted, the interview period lasted for less than the prescribed 1 h; one Extension health educator reported that this was due to time constraints when traveling to distant sites. Of the 42 interviews that were completed, only five interviewees reported an actual change in behavior as a result of seeing the posters. Additionally, as the majority of interviewees who had seen the posters indicated that they already take the stairs, the targeted population may not have been reached through the poster intervention. In the future, a follow-up question for those who saw the poster but did not change their behavior may be useful to provide insight into improving effectiveness.

The issues faced in collecting effectiveness data also made collecting *maintenance* data challenging; if staff experience difficulty with data collection methods at the start of the intervention, it is likely that they will continue to struggle with completing evaluations 6 months or more post-program. No staff completed the prescribed 6-months follow-up visits, so no maintenance data were able to be reported.

Challenges in Evaluation

The barriers experienced in evaluating this PSE—especially effectiveness and maintenance data—are common among community organizations, as they often do not have the means to monitor impacts of PSEs on behavior change (14). Overall, more work is needed to evaluate PSEs in low-resource, community settings. Organizational changes, along with more feasible measures, could improve PSE evaluation in the future.

Need for Organizational Changes

One of the main barriers in this study was the lack of adherence to data collection by Extension health educators. Indeed, Extension struggles with program evaluation; collecting empirical data on behavior change as a program outcome is still relatively novel to the system (8, 9, 24, 25). In the case of PSEs, which are also fairly new to Extension and more difficult to evaluate than direct education interventions, matching evaluation methods to staff resources and expectations is key (Balis et al., under review). While this intervention was selected and planned by a fellow Extension health educator through a participatory approach (26–28), the evaluation was still considered a burden. This perception of evaluation as onerous highlights the need to change Extension culture to prioritize time spent evaluating programs rather than only time spent delivering programs. However, part of this burden must still remain on intervention developers to continuously consider the feasibility of the intervention's outcome measures.

Need for Feasible Measures

To improve data collection adherence, feasible measures that are less of a burden on staff need to be available. Intervention developers should consider including pragmatic, low-cost evaluation measures with their interventions for community organization staff to select. For example, with additional funding, infrared people counters or open/close sensors on

doors throughout adoption organizations are relatively low-cost solutions that could be used to collect pre- and post-intervention data. These types of measures reduce staff time while providing an estimate of people using stairs and also estimate (if placed at multiple levels) how many flights of stairs individuals will use. Additionally, they would provide an objective measure of physical activity rather than the subjective measure used in this study. These feasible, objective measures need to be tested and, if successful, included in program repositories (e.g., the SNAP-Ed toolkit and evaluation framework) (11) to be used by professionals in community-based organizations. Finally, engaging in partnerships may also reduce evaluation burden. For example, students could complete observations or interviews for research experience; however, this can present an obstacle for Extension interventions that are located throughout the state rather than clustered near campus. Partnering with the organizations and businesses that adopt stairway posters and training their staff to collect effectiveness and maintenance data (e.g., through systematic observations) could also result in better data completion (14). The intervention may have been improved by engaging these stakeholders during the planning process.

There were some limitations to this study, including small sample sizes and incomplete data collection. However, we believe that it is important to include these data in an effort to highlight the reality of real-world program implementation and evaluation. There have been calls from organizations such as the National Institute of Aging (29), funding announcements from the National Institute of Health (30), and commentary pieces from the New England Journal of Medicine (31) that all discuss the various important reasons for conducting pragmatic research. To summarize these points, the real world does not conform to the unrealistic expectations of a randomized-control trial, and while these trials are incredibly important during efficacy testing, it is equally important that intervention are adaptable to real-world uncontrolled settings. The barriers within this study highlight these pragmatic needs.

Overall, RE-AIM was a useful tool for both planning and evaluating this intervention; as recommended, it can also be used after delivery to iteratively refine the intervention (22). For example, for the next iteration, the needs of Extension health educators who did not adhere to data collection procedures can be considered to tailor the evaluation plan to better meet their needs or provide training and technical assistance. Additionally, future iterations could be adapted through RE-AIM to reach businesses and organizations with populations that do not already take the stairs (e.g., through engaging the organizations to complete pre-intervention observations).

Implications for intervention developers include providing PSE evaluation tools that go beyond assessing adoption and implementation and are feasible to use in low-resource community settings. Using pragmatic measures (32) could allow community organizations to confirm effectiveness of PSEs while also collecting data on the other RE-AIM dimensions to ensure these interventions work in the "real world."

DATA AVAILABILITY STATEMENT

The dataset analyzed during the current study is available from the corresponding author on reasonable request.

ETHICS STATEMENT

This study involving human participants was reviewed and approved by University of Wyoming IRB. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

AUTHOR CONTRIBUTIONS

LB conceived of the study, participated in its design and coordination, and led the manuscript preparation. TS contributed to data analysis and manuscript preparation. All authors read, contributed to, and approved the final manuscript.

ACKNOWLEDGMENTS

The authors would like to acknowledge Samantha Harden for her assistance with conceptualization.

REFERENCES

1. Kahn E, Ramsey L, Brownson RC, Heath GW, Howze EH, Powell KE, et al. The effectiveness of interventions to increase physical activity: a systematic review. *Am J Prev Med.* (2002) 22:73–107. doi: 10.1016/S0749-3797(02)00434-8
2. Hanks AS, Just DR, Wansink B. Smarter lunchrooms can address new school lunchroom guidelines and childhood obesity. *J Pediatr.* (2013) 162:867–9. doi: 10.1016/j.jpeds.2012.12.031
3. Franz NK, Townson L. The nature of complex organizations: the case of Cooperative Extension. *New Direct Eval.* (2008) 2008:5–14. doi: 10.1002/ev.272
4. United States Department of Agriculture. *The Farm Bill 2015*. Washington, DC: United States Department of Agriculture (2015). Available online at: http://www.usda.gov/wps/portal/usda/usdahome?navid=farmbill (accessed November 13, 2016).
5. Braun B, Bruns K, Cronk L, Kirk Fox L, Koukel S, Le Menestrel S, et al. *Cooperative Extension's National Framework for Health and Wellness*. Washington, DC: United States Department of Agriculture (2014).
6. United States Department of Agriculture. *Healthy, Hunger-Free Kids Act of 2010*. Washington, DC: United States Department of Agriculture (2010) Available online at: https://www.fns.usda.gov/school-meals/healthy-hunger-free-kids-act (accessed September 4, 2019).
7. Centers for Disease Control and Prevention. *High Obesity Program*. Washington, DC: Centers for Disease Control and Prevention (2019) Available online at: https://www.cdc.gov/nccdphp/dnpao/state-local-programs/hop-1809/high-obesity-program-1809.html (accessed September 13, 2019).
8. Balis LE, Strayer TE III, Ramalingam N, Harden SM. Beginning with the end in mind: contextual considerations for scaling-out a community-based intervention. *Front Pub Health.* (2018) 6:357. doi: 10.3389/fpubh.2018.00357

9. Balis L, Harden S. Scaling out a 4-H healthy meeting initiative: challenges in implementation and comprehensive evaluation. *J Nutrit Educ Behav.* (2019) 51:1020–4. doi: 10.1016/j.jneb.2019.05.288
10. Community Preventive Services Task Force. *The Community Guide*. Washington, DC: Community Preventive Services Task Force (2019). Available online at: https://www.thecommunityguide.org/ (accessed September 4, 2019).
11. United States Department of Agriculture. *SNAP-Ed Toolkit: Obesity Prevention Interventions and Evaluation Framework*. Washington, DC (2019). Available online at: https://snapedtoolkit.org/ (accessed September 4, 2019).
12. Fetsch RJ, MacPhee D, Boyer LK. Evidence-based programming: what is a process an Extension Agent can use to evaluate a program's effectiveness? *J Extens.* (2012) 50:5FEA2.
13. Franz N. The role of evaluation in determining the public value of Extension. *J Extens.* (2014) 52:4COM3.
14. King D, Glasgow R, Leeman-Castillo B. Reaiming RE-AIM: using the model to plan, implement, and evaluate the effects of environmental change approaches to enhancing population health. *Am J Public Health.* (2010) 100:2076–84. doi: 10.2105/AJPH.2009.190959
15. Balis L, John D, Harden S. Beyond evaluation: using the RE-AIM framework for program planning in Extension. *J Extens.* (2019) 57:2TOT1.
16. Downey LH, Peterson DJ, Donaldson J, Hardman A. An extension application of the RE-AIM evaluation framework. *J Extens.* (2017) 55:3IAW1.
17. Truman BI, Smith-Akin CK, Hinman AR, Gebbie KM, Brownson R, Novick LF, et al. Developing the guide to community preventive services—overview and rationale. *Am J Prev Med.* (2000) 18:18–26. doi: 10.1016/S0749-3797(99)00172-5
18. Task Force on Community Preventive Services. Recommendations to increase physical activity in communities. *Am J Prev Med*. (2002) 22:67–72. doi: 10.1016/S0749-3797(02)00433-6
19. Task Force on Community Preventive Services. Recommendation for use of point-of-decision prompts to increase stair use in communities. *Am J Prev Med*. (2010) 38:S290–1. doi: 10.1016/j.amepre.2009.10.031
20. Soler RE, Leeks KD, Buchanan LR, Brownson RC, Heath GW, Hopkins DH, et al. Point-of-decision prompts to increase stair use: a systematic review update. *Am J Prev Med*. (2010) 38:S292–300. doi: 10.1016/j.amepre.2009.10.028
21. Adams J, White M. A systematic approach to the development and evaluation of an intervention promoting stair use. *Health Educ J.* (2002) 61:272–86. doi: 10.1177/001789690206100308
22. Harden S, Smith M, Smith-Ray R, Ory M, Estabrooks P, Glasgow R. RE-AIM in clinical, community, and corporate settings: perspectives, strategies, and recommendations to enhance public health impact. *Front Public Health.* (2018) 6:71. doi: 10.3389/fpubh.2018.00071
23. Israel B, Eng E, Schulz A, Parker E. *Methods in Community-Based Participatory Research for Health*. San Francisco:Jossey-Bass (2005).
24. Harden SM, Ramalingam N, Breig S, Estabrooks P. Walk this way: our perspectives on challenges and opportunities for Extension statewide walking promotion programs. *J Nutrit Educ Behav*. (2019) 51:636–43. doi: 10.1016/j.jneb.2018.12.010
25. Balis L, Strayer T, Ramalingam N, Wilson M, Harden S. Open-access physical activity programs for older adults: a pragmatic and systematic review. *Gerontologist*. (2018) 59:e268–78. doi: 10.1093/geront/gnx195
26. Harden S, Johnson SB, Almeida F, Estabrooks P. Improving physical activity program adoption using integrated research-practice partnerships: an effectiveness-implementation trial. *Trans Behav Med.* (2017) 7:28–38. doi: 10.1007/s13142-015-0380-6
27. Johnson SB, Harden S, Estabrooks P. Uptake of evidence-based physical activity programs: comparing perceptions of adopters and nonadopters. *Trans Behav Med*. (2016) 6:629–37. doi: 10.1007/s13142-015-0371-7
28. Wilson ML, Strayer T III, Davis R, Harden, SM. Use of an integrated research-practice partnership to improve outcomes of a community-based strength-training intervention for older adults: reach and effect of lifelong improvements through fitness together (LIFT). *Int J Environ Res Pub Health*. (2018) 15:237. doi: 10.3390/ijerph15020237
29. Salive M. Pragmatic clinical trials: testing treatments in the real world. In: *Inside NIA: A Blog for Researchers*. Washington, DC: National Institute on Aging (2017). Available online at: https://www.nia.nih.gov/research/blog/2017/06/pragmatic-clinical-trials-testing-treatments-real-world (accessed September 12, 2019).
30. National Institutes of Health. *Pragmatic Research in Healthcare Settings to Improve Diabetes and Obesity Prevention and Care (R18 Clinical Trial Required)*. Washington, DC: National Institutes of Health (2019). Available online at: https://grants.nih.gov/grants/guide/pa-files/par-18-925.html (accessed September 12, 2019).
31. Ford I, Norrie J. Pragmatic trials. *N Eng J Med*. (2016) 375:454–63. doi: 10.1056/NEJMra1510059
32. Glasgow R. What does it mean to be pragmatic? Pragmatic methods, measures, and models to facilitate research translation. *Health Educ Behav.* (2013) 40:257–65. doi: 10.1177/1090198113486805

Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

frontiers in Public Health

ORIGINAL RESEARCH
published: 05 March 2020
doi: 10.3389/fpubh.2020.00048

Re-thinking Physical Activity Programs for Older Brazilians and the Role of Public Health Centers: A Randomized Controlled Trial Using the RE-AIM Model

Tânia Rosane Bertoldo Benedetti[1†], Cassiano Ricardo Rech[1], Lisandra Maria Konrad[1], Fabio Araujo Almeida[2*], Fabiana A. Brito[2], Wojtek Chodzko-Zajko[3] and Andiara Schwingel[3]*

[1] Sports Center, Federal University of Santa Catarina, Florianópolis, Brazil, [2] College of Public Health, University of Nebraska Medical Center, Omaha, NE, United States, [3] Department of Kinesiology and Community Health, University of Illinois at Urbana-Champaign, Urbana, IL, United States

OPEN ACCESS

Edited by:
Matthew Lee Smith,
Texas A&M University, United States

Reviewed by:
Pradeep Nair,
Central University of Himachal Pradesh, India
Cathy H. Gong,
Australian National University, Australia

***Correspondence:**
Tânia Rosane Bertoldo Benedetti
tania.benedetti@ufsc.br
Fabio Araujo Almeida
fabio.almeida@unmc.edu

†ORCID:
Tânia Rosane Bertoldo Benedetti
orcid.org/0000-0002-2035-5082

Specialty section:
This article was submitted to Public Health Education and Promotion, a section of the journal Frontiers in Public Health

Received: 27 September 2019
Accepted: 10 February 2020
Published: 05 March 2020

Citation:
Benedetti TRB, Rech CR, Konrad LM, Almeida FA, Brito FA, Chodzko-Zajko W and Schwingel A (2020) Re-thinking Physical Activity Programs for Older Brazilians and the Role of Public Health Centers: A Randomized Controlled Trial Using the RE-AIM Model. Front. Public Health 8:48. doi: 10.3389/fpubh.2020.00048

Background: Explored the role of public health centers in the delivery of physical activity programs to older Brazilians.

Methods: Total of 114 older adults (81% women) from public health centers across the city of Florianopolis, Brazil, were randomized into three groups: behavior change group ($n = 36$), traditional exercise group ($n = 52$), and control group ($n = 26$). The behavioral change group included 12 weekly meetings (2 h each). The traditional exercise group offered a 12-week exercise class. Individuals in the control group participated only in measurements. Program evaluation included a mixed-methods approach following the RE-AIM framework (reach, effectiveness, adoption, implementation, and maintenance). Trained interviewers conducted 12 focus groups and 32 interviews with participants in the program, professionals delivering the programs, community health workers, and local and city administrators overseeing public health centers. Participants completed health, quality of life, and fitness assessments at four time points.

Results: The study *reached* 11.5% of the eligible population in the community. Older adults' resistance to change and limited understanding of behavior change science by public health center staff hindered program reach. Physician encouraging patient participation and personal invitations by community health workers were perceived as favorable factors. Results of program *effectiveness and maintenance* suggest that behavior change strategies may be better suited than traditional exercise classes for decreasing sedentary time and increasing moderate-to-vigorous physical activity, as well as improving participants' quality of life. Only 14% of public health centers in the city adopted the programs. Heavy workload of health educators delivering the programs and limited physical space for program delivery were barriers for *adoption*. The fidelity of program delivery was high and indicates that the programs are culturally-appropriate for the Brazilian context and feasible for implementation by local health educators.

Conclusions: Our findings support the potential for dissemination of behavior change and traditional exercise programs to older adults through public health centers in Brazil.

REBEC: RBR-9pkxn2 (retrospectively registered) Register April 20, 2019.

Keywords: physical activity, community, intervention, RE-AIM, public health center, behavior change, sedentary behavior

BACKGROUND

Regular physical activity (PA) has been associated with maintenance and improvements in functional capacity and quality of life in older adults (1). Current guidelines suggest that older adults should strive to achieve 150 min/week of moderate-intensity aerobic activity, in addition to muscle-strengthening activities 2 days/week. Balance exercise is also recommended for many older adults as a way to prevent falls and fall-related injuries (2).

In Brazil, the 1990's were marked by an increase in physical activity promotion for older adults, when the Federal Government, States and Municipalities began subsidizing exercise classes to individuals for free or at low cost. The majority of these classes involved structured exercise programs (3) led by physical activity professionals or trained volunteers (4). In this article we refer to structured, instructor-led physical activity programs as "traditional" exercise programs. Common examples of traditional exercise programs include aerobics classes, aqua aerobics, team and individual sports, dance, and muscle-strengthening exercise. With an average of 30 older adult participants per class, these classes have the potential to help many older adults achieve the recommendation for PA, as they meet two to three times per week for an average of 60 min each time (4).

Despite the governmental efforts supporting the implementation of traditional exercise programs for older adults, PA participation remains disappointingly low across Brazil. For instance, the Brazilian national public health surveillance system (VIGITEL) assessments between 2011 and 2016 found no significant increases in leisure time PA, and reported that only 22% of adults 65 and older meet the recommendation for PA (5, 6). The surveys found that PA decreases with age and confirmed that Brazilian older adults are a vulnerable group for physical inactivity and related chronic diseases and conditions.

Research findings on the health impact of traditional exercise programs show that they are most effective when people participate regularly (7). Unfortunately, most older adults do not participate regularly in traditional exercise programs, which limits their effectiveness in increasing PA levels and providing health benefits. Additional limitations include low reach and high cost of these programs due to space, equipment and the need for instructor compensation (4). Although traditional exercise programs continue to be widely offered across Brazil, particularly at public universities, public health centers, and other public spaces, it is questionable whether or not this is a cost-effective strategy for PA promotion among older Brazilians (4).

In recent years significant attention has focused on the study of behavioral factors that increase the likelihood of an individual initiating and maintaining a regular program of exercise and PA. Research in this area suggests that incorporating a comprehensive behavioral management strategy in PA interventions can help maximize recruitment, increase motivation for exercise progression, and minimize attrition (8). Behavioral strategies include conversations about PA goals that are personally meaningful to individuals and help them find ways to make PA part of their lives (9).

The aging of society brings both opportunities and challenges for many low- and middle-income countries like Brazil. A new paradigm in health needs to be adopted, one that focuses on the prevention and management of chronic disease through healthy lifestyle strategies designed to maintain independent living and promote quality of life. In addressing this complex public health challenge, there is a need to bring community resources together and utilize systems that touch people's lives, including community and public health care settings. Public health centers, referred in this manuscript as HCs, are an example of a community health strategy sponsored by the government that has been Brazil's primary health care delivery strategy. Although most of the health services provided by HCs focuses on primary health care, prevention programs focusing on healthy lifestyles are increasingly being offered to communities.

In this article we describe our efforts to implement "Active Living Every Day," an evidence-based program conceived and broadly disseminated in the United States, that incorporates behavior change for the promotion of PA (10). The goal of this study was to evaluate the potential of public community health centers for the delivery of traditional exercise classes and behavioral change programs for the promotion of PA among older Brazilians. This evaluation was guided by the RE-AIM framework (11, 12).

METHODS

Under the Unified Health System (SUS), cities across Brazil support teams of multidisciplinary professionals at local HCs to provide health care at no cost to about 4,000 people living in each neighborhood or community. Each team has a physician, nurse, technical nurse, and, at least, five community health workers with some also including nutritionists and exercise specialists.

Abbreviations: PA, Physical activity (PA); HCs, Public health centers; SUS, Unified health system; TEG, Traditional exercise group; BCG, Behavioral change group; CG, Control group; FGs, Focal groups; BMI, Body mass index; SED, Sedentary behavior; LPA, Light physical activity, MVPA: Moderate-to-vigorous physical activity.

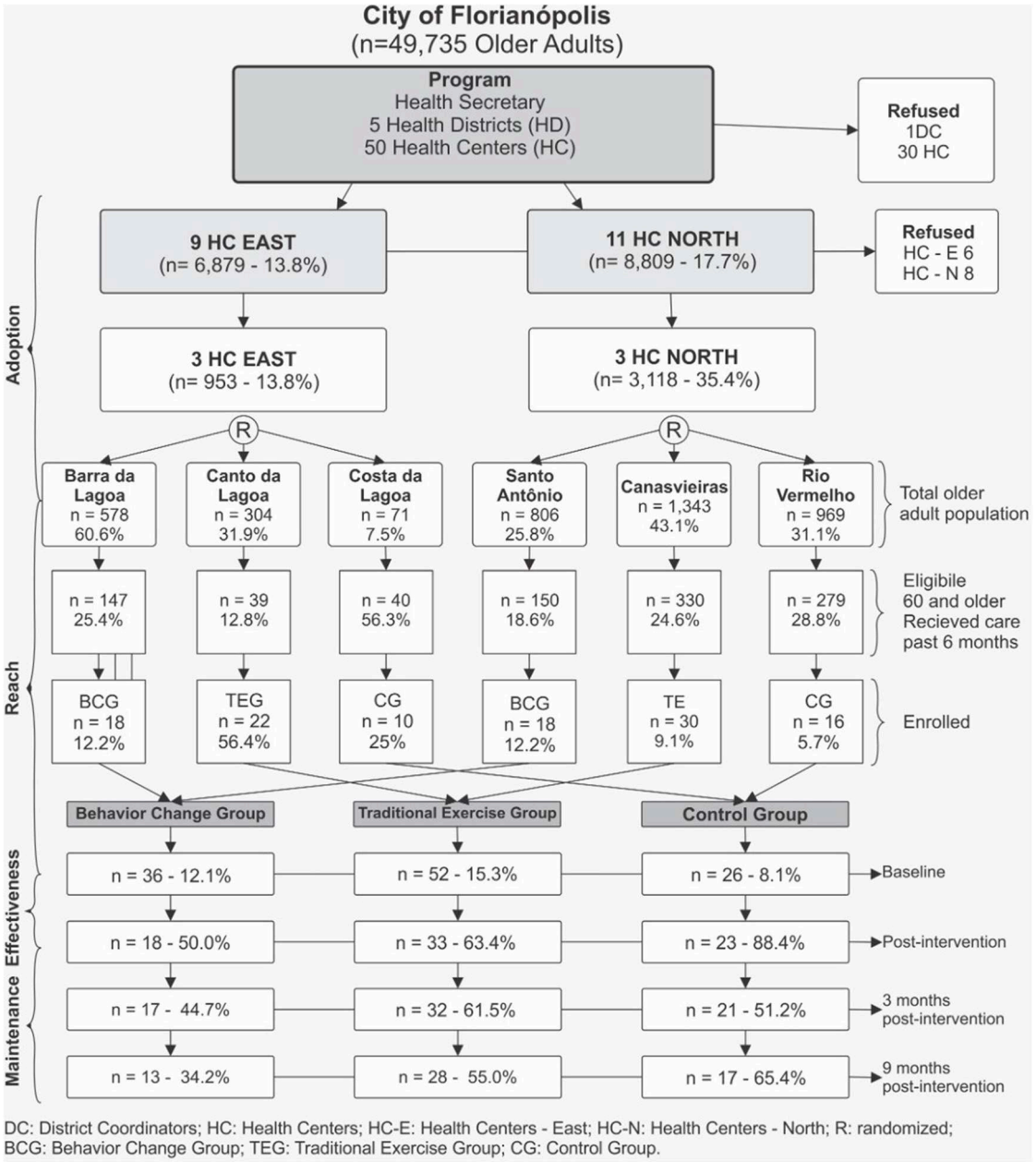

FIGURE 1 | Flow diagram of study participants in an intervention of health centers (HC). Florianopolis, Brazil, 2012.

This study took place in Florianopolis, Santa Catarina, a city with ∼500,000 inhabitants in Southern Brazil. In Florianopolis there are 50 *Public Health Centers (HC)* divided in five health districts. The implementation of our project started with an initial meeting where the study was presented to all five health district coordinators. Of those, two coordinators (districts North and East) demonstrated interest in participating in the study. A total of 20 HCs belonged to districts North ($n = 11$) and East ($n = 9$), but not all of them had the physical structure and human resources to offer the programs. Thus, a total of six HCs were involved in the study and randomized to one of three groups (Traditional Exercise Group—TEG, Behavioral Change Group—BCG, Wait List Control Group – CG) stratified by health district (see **Figure 1**).

PARTICIPANTS

Study participants were men and women aged 60 or older who had no severe physical and/or mental health impairments and had not participated in physical activity programs in the past 6 months. Exclusion criteria included: history of heart attack

and/or stroke in the past 6 months, cancer diagnosis and/or other severe medical conditions. Strategies to recruit participants included local media advertisements, flyer distribution, referrals by HC team members during medical appointments and home-visits by community health workers.

A total of 114 older adults were enrolled and assigned to one of three groups based on their home HC assignment: traditional exercise, behavior change, or waiting list control group. After initial group assignment, an orientation session to explain the study was offered to all interested older adults. Those interested in joining the program, completed the enrollment process, signed the informed consent and scheduled the appointment for baseline data collection. The protocols were approved by the ethics committee of the Federal University of Santa Catarina (CONEP n. 480560 and CEPSH n. 2387/2010).

GROUPS AND PROGRAM DESCRIPTION

Behavior Change Group (BCG)

The BCG participated in a behavioral change program that was adapted from "Active Living Every Day," or ALED (13). ALED is an evidence-based program conceived and broadly disseminated in the United States that assists individuals to become more physically active. ALED is structured into 12 weekly meetings of 1.5–2 h duration. The sessions follow a series of topics related to behavior change with the goal of achieving a more active lifestyle (**Table 1**). Meetings were conducted by nutrition or exercise science professionals already working at the HCs who received specific training to facilitate the program. An agreement was established with Human Kinetics®, copyright holder of ALED, for using the program in Brazil. It included training of program personnel, rights to adapt/translate ALED into Brazilian Portuguese. ALED was linguistically and culturally adapted by Benedetti et al. (4).

Traditional Exercise Group (TEG)

Participants in the TEG received a 12-week exercise class conducted at the local HCs. The classes were held three times per week for 60 min duration. The classes included a 5- to 10-min warm-up, 25 min of aerobic exercise at 50–80% of max. aerobic power, resistance training for 20 min, and a 5-min cool-down. Participants had their heart rate and ratings of perceived effort tracked throughout the sessions (14). Classes were led by exercise professionals employed by the HC.

TABLE 1 | Chapters of the Behavior Change Program—VAMOS—Brazil, 2012.

Active living every day program	
Week 1. Ready, Set, Go.	Week 7. Avoiding pitfalls.
Week 2. Finding new opportunities.	Week 8. Step by step.
Week 3. Overcoming challenges.	Week 9. Defusing stress.
Week 4. Setting goals and rewarding yourself.	Week 10. Finding new ways to be active.
Week 5. Gaining confidence.	Week 11. Positive planning.
Week 6. Enlisting support	Week 12. Making lasting changes.

Wait List Control Group (CG)

Individuals in the CG participated only in measurements, without any intervention. They were asked to continue their routine activities before the start of the study. At the completion of the 9-month post-randomization assessment they were offered participation in the TEG classes.

PROGRAM EVALUATION USING THE RE-AIM FRAMEWORK

We chose to conduct a comprehensive program evaluation including all dimensions of RE-AIM (11) using quantitative and qualitative data. Accordingly, we assessed reach (participation rate and representativeness), effectiveness (impact on health outcomes), adoption (interest in the program), implementation (consistency of delivery and costs), and maintenance (impact on long-term outcomes, continuing to offer the intervention over time). Our mixed-methods approach builds on successes of prior studies that have focused on program evaluation (15, 16). Trained research personnel conducted a total of 12 focus groups (FGs) and 32 interviews including: the director of the City Health Department, managers and the coordinators of HC/NASF Family Health Support Centers, coordinators of the health districts, exercise specialists and/or nutritionists working at the HCs, and other HC staff members such as community health agents; in addition to older adults participants in the program.

Reach

Described as the proportion of a target population that participates in an intervention (17). We assessed reach using quantitative data from recruitment, participation rate and representativeness of the population. To calculate participation rate, we used the number of participants attending the baseline assessment, divided by the number of individuals potentially eligible for the program. Additionally, barriers and facilitators of reach were assessed qualitatively. Interviews with HC personnel and city administrators sought to understand their perceptions about older adult participants, HCs, and program factors that could have influenced reach. Questions included: After the advertising of the project, how many older adults came in for the first meeting? How many older adults completed the entire baseline evaluation (e.g., physical test and answered the questionnaire)? How many older adults were engaged in the programs at a rate >75% of attendance? How many older adults dropped out the programs, meaning attending three or fewer sessions?

Effectiveness

Measured at the individual level and reflective of the success of an intervention in improving health outcomes (17). To assess effectiveness, health measurements and questionnaires were collected from participants by trained researchers at two time points (baseline and immediately post-intervention). Evaluation included a social-demographic survey, quality of life assessment, anthropometric measurements and PA participation. Additionally, we conducted focus groups (FGs) to understand participants' perceptions. Questions included: What did you

(participant) think of the program? What are your thoughts about program? How do you see your behavior (i.e., physical activity) after participating in the program? Do you think you are more physically active now? Has the program helped you to improve your lifestyle? How about your quality of life, did you perceive any changes?

Anthropometric Measurements

Weight was measured with the assistance of a medical weight scale. Height was measured with a stadiometer. Body mass index (BMI) scores were calculated and participants were classified as underweight (<18.5), normal weight (18.5–24.9) and overweight/obese (25.0 or more) (18).

Physical Activity

PA was assessed by GT3X and GT3X+ accelerometers and ActiLife® software was used to analyze the data. Each participant was instructed to use the accelerometer for 7 days in a row, removing it only to sleep, bathe or perform activities involving water. The device was attached to an elastic belt and fixed in the right side of the hip. Data were collected in a 30 Hz sample frequency and were analyzed using 60-s epochs. Periods with consecutive values of zero (with 2-min of spike tolerance) for 60 min or longer were interpreted as "accelerometer not worn" and excluded from the analysis (19). Physical activity data were included only when participants had accumulated a minimum of 10 h/day of recording, for at least 4 days, including one weekend day. The time spent in sedentary behavior (SED = 0–99 counts min^{-1}) (20), in light physical activity (LPA = 100–2,689 counts min^{-1}) and in moderate-to-vigorous physical activity (MVPA ≥ 2,690 counts min^{-1}) (21) was calculated adjusting to the valid days and wear time. It was also analyzed the total time spent in SED bouts and the time spent in MVPA bouts by the sum of minutes spent in SED and MVPA, respectively, in periods lasting ≥10 min.

Quality of Life

Quality of life was evaluated by WHOQOL BREF and OLD questionnaire (22, 23). The WHOQOL-BREF instrument comprises of 26 items, which measure the following broad domains: physical health, psychological health, social relationships, and environment. The WHOQOL-OLD questionnaire comprises of 24 items which measure the following domains: sensory abilities; autonomy; past, present and future activities; social participation; death and dying; and intimacy. Each domain provides an individual score. Additionally, an overall score was calculated for each instrument (WHOQOL BREF and OLD).

Adoption

Defined as the absolute number, proportion, and representativeness of settings and intervention agents who were willing to initiate a program (17). Adoption was evaluated using information from our database regarding the interest in adopting the programs, from regional district level through HC staff. We explored program adoption within hierarchical levels of the City Health Department using interviews and focus groups. Questions covered topics related to: What is your opinion about the program that was implemented in this health center in the last three months? How did the program change the health center routine? What do you think about the background and experience of the professionals in the health center and the degree to which they are confidently prepared to offer the program? Do the professionals in the health center have sufficient time available to deliver the program? What do you think was the most interesting aspect of the program? How do you see the benefits of the program? What do you think about the program cost?

Implementation

At the setting level, implementation refers to staff fidelity to the various elements of an intervention's protocol. This includes consistency of delivery as intended and the time and cost of the intervention (17). We followed the implementation strategies (e.g., training) suggested by the program developers of ALED. ALED's check-list include 24 questions regarding implementation covering topics such as program fidelity, instructor knowledge, classroom, schedule, participants attention, attendance, among others. Programs implementation was assessed twice at each program site by two independent observers. In addition, interviews and focus groups with HCs personnel sought to understand their perceptions about the program implementation. Questions included: What was like to teach the program? What was most difficult and challenging? What was easy? What do you think motivates participation of older adults?

Maintenance

Defined as the extent to which a program becomes institutionalized or part of routine organizational practices, maintenance also refers at the individual level to the long-term effects of a program on health outcomes (17). In our study, we focused on individual level maintenance. Similar data collection described in the effectiveness domain was carried out at 3 and 9 months after the intervention was concluded.

DATA ANALYSIS

The demographic characteristics of the sample are presented in **Table 2**. Reach was analyzed using two-way ANOVA and chi-square tests to compare participants to those who declined to participate for each group and each location. Adoption rates were assessed by calculating the number of HCs that were approached and those that agreed to participate; as well as by assessing the percentage of professionals that agreed to deliver the programs. Although there are a multitude of definitions for implementation, for the purposes of the analyses, we focus on participation and adherence. As such, implementation rates were calculated by determining the proportion of participants completing at least 75% of program. Effectiveness and Maintenance were analyzed following procedures for clustered randomized control analysis. The generalized linear mixed model for repeated measures was used to conduct individual level outcome analysis and controlled the following characteristics as covariates (sex, age,

TABLE 2 | Participants' baseline characteristics by group.

Variable	BCG	TEG	CG	Overall	Dif
Total number of participants *n* (%)	**36 (31.6)**	**52 (45.6)**	**26 (22.8)**	**114 (100)**	
Demographic variables					
Age, mean (SD)	69.7 (6.9)	71.3 (7.3)	67.2 (5.8)	69.8 (7.0)	0.055[a]
Female, %	75.0	82.7	84.6	80.7	0.556[b]
Education level, %					0.139[b]
No studied	5.7	7.8	3.8	6.3	
Elementary school	51.4	68.6	76.9	65.2	
High school	20.0	13.7	19.2	17.0	
Higher	22.9	9.8	0.0	11.6	
Marital status, % married	65.7	52.9	46.2	55.4	0.189[b]
Monthly household income, %					0.267[b]
<2 salaries	27.8	34.6	50.0	36.0	
3–4 salaries	44.4	44.2	42.3	43.9	
More than 4 salaries	27.8	21.2	7.7	20.2	
Occupation, %					0.007[b]**
Retiree and/or pension	72.2	48.1	80.8	63.2	
Active works	27.8	51.7	19.2	36.8	
Health/behavior variables					
Health Status, %					0.669[b]
Good	52.8	44.2	53.8	49.1	
Fair	47.2	51.9	42.3	48.2	
Weak	0.0	3.8	3.8	2.6	
Disease, %					0.845[b]
Arthrosis	13.9	5.8	11.5	9.6	
Heart Disease	25.0	28.8	19.2	25.4	
High Blood Pressure	38.9	44.2	50.0	43.9	
BMI, Mean (SD)	27.4 (4.5)	28.4 (5.5)	27.8 (3.0)	27.9 (4.7)	0.609[a]
Weight, %					0.233[b]
Normal weight	47.2	34.6	53.8	43.0	
Overweight/obese	52.8	65.4	46.2	57.0	
PA Level (min/week) (SD)					
Sedentary time	498.5 (113.6)	529.8 (107.3)	522.8 (86.7)	518.3 (105.3)	0.391[a]
Light PA	315.5 (96.1)	301.6 (93.5)	292.8 (57.6)	304.1 (87.6)	0.600[a]
Moderate/vigorous PA	28.8 (24.2)	16.2 (17.9)	25.2 (26.1)	22.2 (22.6)	0.026[a]*

*BCG, Behavior Change Group; TEG, Traditional Exercise Group; CG, Control Group. *p < 0.05, **p < 0.01.*
[a]Anova One Way (factor group).
[b]Chi-square test.
The average of AFMV and occupation (ANOVA analysis) were larger in traditional groups than in the control groups (p < 0.005).
Florianopolis, Brazil, 2012 (n = 114).

schooling, sedentary time and PA in baseline). Additionally, variables with significant differences between groups (**Table 2**) were also included in the model as covariates. The Sidak *post-hoc* test was used to compare difference between groups at different assessment points. We used intention-to-treat (ITT) analysis to keep all participants with non-missing baseline outcome measurements.

Two Portuguese-speaking investigators transcribed the interviews and focus groups and checked them for accuracy. Transcript analysis was conducted in Portuguese. Deductive thematic analysis was conducted to identify themes/quotes within the RE-AIM model. A team of bicultural native Brazilian-Portuguese and English speakers translated the quotations through a translation/back-translation process to ensure semantic equivalence across languages (24, 25). This team reviewed each quotation for conceptual and normative equivalence (adapting and dropping items as needed to address cultural fit and social norms).

RESULTS

Table 2 presents participant ($n = 114$) characteristics at baseline. Findings show a similarity among demographic and health variables across the three groups (BCG, TEG, CG). Average age was 69.8 years, the majority were women (80.7%) with high school education or less (88.5%). Approximately, 57% were overweight or obese with an average BMI of 27.9 kg/m^2. There was a high prevalence of chronic diseases with 43.9% reporting

high blood pressure and 25.4% heart disease. The only significant difference among groups at baseline was regarding occupation and MVPA, where participants in the traditional group were more likely to be working and were found to be engaged in less moderate/vigorous PA.

Reach

Results are shown in **Figure 1**. Among the 4,071 older adults across the six HCs, 985 individuals (24.2%) were considered eligible for the study. A total of 114 individuals completed the baseline assessment, representing a reach of 11.5%. Overall 49% of participants attended at least 75% of all sessions with disengagement occurring mostly in the first three weeks of the study (42%). TEG showed highest reach (15.3%) followed by BCG (12.1%) and CG (8.1%), respectively. Several barriers affecting the program's reach were identified. System's level instabilities that often lead to inconsistent support for health services was a common barrier mentioned in interviews. This issue was captured in this quote from a community health worker recruiter for the study: "*We were having a lot of turbulence in the unit [HC], we almost could not get involved. It was soon after that we were without the doctor. And, after then, the doctor went on vacation, so for me it was a very hard time to work.*" (CCS BL). Another barrier deals with older adults' resistance to change. A community health worker described "*Older adults struggle with new things…they fear if we invite them for something new, they are scared…*" (ACS ST). A final barrier for recruitment was lack of staff familiarity with behavior change programs. Innovative and new to most staff in the HCs, the program was relatively difficult to explain and to understand. A community health worker described this concern when saying "*Very often the team could not understand the concept of the program [referring to the behavior change program]*" (PEFI).

On the other hand, several facilitators for reach were identified. Doctors and other health professionals encouraging patient participation was viewed as favorable in interviews. One community health worker noted "*The involvement of the health team was very important*" (PNS CAN). In addition, the program materials were perceived to be attractive by participants. An older adult participant said "*It was very good [referring to the program recruitment material], because for me it was essential, you know why I do not live without it [laughs] that motivates you there...*" (BP3). Distribution of flyers and personal invitations were effective ways to reach participants. This was illustrated by a community health worker who stated "*We have a definite demand of people attending the center, we are capable of attending a defined number, but by word of mouth the information gets through and we will always have someone else attending, so I believe there would be greater attendance, a bigger group*" (PNS ST).

Effectiveness and Maintenance

Table 3 reports the statistical summary of outcomes for physical activity behavior, BMI, quality of life over a 12-month period comparing the three groups (BCG, TEG, and CG). There was a reduction in sedentary behavior after the intervention for BCG ($P < 0.05$). This result was maintained at 3- and 9-month post-intervention evaluations ($P < 0.01$). Participants in the BCG increased their MVPA behavior at post program assessment, and maintained their physical activity participation levels at 3-month post-intervention. Neither the TEG, nor the CG, increased their MVPA, experiencing significant declines in MVPA over time ($P < 0.05$). No difference was observed among groups and no time effect was observed in BMI. Participants in the BCG showed significant improvements in quality of life (WHOQOL-*Brief*) at 9-month post-intervention relative to baseline ($P < 0.031$).

Analysis of the interviews and focus groups suggest that many of the participants perceived positive changes in themselves as a result of participating in the study. One participant in the BCG stated "*I needed to be physically active, I thought that I was limited by my illness, but I want to reach program targets and, I started walking more*" (12 BLP). Participants also described their appreciation with regard to the program effectiveness. "*Oh, I learned a lot with the program, mainly the walking activities, it was also good to know the number of steps we take, this device (pedometer) is great*" (P1).

The satisfaction with results achieved was noted by a participant with cardiovascular disease and obesity, as follows: "*(…) I started to take the program seriously (...) the activities are important, today I feel satisfied with my weight loss, some people lost five, ten and after until twenty kilos (refer the lose weight), a little every day, I am very satisfied* (14 BLP)".

Adoption

The program was approved by the director of City Health Department and by the management of NASF (Family Health Support Centers). Three of the five health districts declined to participate due to prior commitments or no interest in the study. Of the 18 health centers located in the two participating HDs, six agreed to participate in the study. Reasons for non-participation included health educators declining to participate for work or health reasons ($n = 5$), HCs with insufficient physical space to offer the programs ($n = 5$) and, HC professionals simply declining to participate (**Figure 1**).

These following quotations illustrate the heavy workload reported by the health center teams: "*The staff in this center is already over committed, they cannot handle extra activities*" (ACS BL); "*Everybody is busy an d overworked*" (ACS ST); "*I cannot let the staff dedicate eight hours per week to the program during the training period when the program is focused on only twenty or thirty people and our demand is much greater than that and they must take care of others areas*" (G2).

Implementation

Two researchers with expertise in RE-AIM and the ALED program assessed program implementation twice in each study site. The evaluation for all items under analysis achieved an average of 98% fidelity. The estimated cost per participant for 3 months in the BCG program was R$ 65 (about U$ 30) and the TEG was R$ 50 per month (about U$ 23). Overall, 47% of TEG participants attended at least 75% of the sessions compared to 27.3% of their BCG counterparts. When managers were questioned regarding the cost of the programs, they found it to be

TABLE 3 | Estimated mean change in physical activity behavior.

Outcome variable	Mean (SE)			*P*-Value		
	BCG	TEG	CG	BCG vs. CG	TEG vs. CG	BCG vs. TEG
INTENT-TO-TREAT						
Change in sedentary behavior, min/day						
At 3 months	−14.3 (56.3)*	−4.1 (62.2)	−25.6 (77.9)**	0.999	0.634	0.987
At 6 months	−16.6 (46.0)**	16.4 (97.9)*	−0.6 (80.1)	0.954	0.103	0.010*
At 12 months	−10.9 (59.9)**	4.2 (78.6)	−26.7 (68.3)**	0.976	0.216	0.520
Change in light PA, min/day						
At 3 months	−1.9 (30.3)	3.2 (57.9)	21.1 (40.5)	0.334	0.453	0.987
At 6 months	19.1 (40.1)	−4.7 (51.3)	41.4 (70.5)	0.278	0.007*	0.435
At 12 months	2.4 (42.6)	−15.0 (52.6)	10.1 (56.2)	0.855	0.068	0.588
Change in MVPA, min/day						
At 3 months	4.8 (14.1)*	3.8 (23.9)	−1.2 (21.0)	0.469	0.555	0.988
At 6 months	−0.2 (17.8)	−2.7 (10.5)	−5.2 (15.1)*	0.357	0.789	0.646
At 12 months	0.6 (18.0)	−3.6 (9.8)*	−4.9 (20.3)*	0.219	0.965	0.168
Change in BMI, kg/m^2						
At 3 months	−0.1 (0.3)	−0.1 (0.7)	0.2 (0.5)	0.644	0.419	0.765
At 6 months	0.1 (0.5)	−0.1 (1.2)	0.1 (0.7)	0.765	0.536	0.234
At 12 months	0.1 (0.5)	−0.1 (0.8)	0.3 (1.1)	0.578	0.021*	0.346
Change in WHOQOL brief						
At 3 months	2.2 (5.4)	2.4 (6.9)	1.5 (8.9)	0.467	0.876	0.865
At 6 months	1.3 (7.9)	1.4 (7.2)	0.8 (9.6)	0.534	0.423	0.234
At 12 months	3.0 (7.8)*	1.0 (6.6)	1.7 (10.3)	0.986	0.456	0.765
Change in WHOQOL old						
At 3 months	2.4 (7.3)	1.5 (6.9)	2.7 (10.1)	0.943	0.965	0.942
At 6 months	2.4 (7.3)	1.4 (6.3)	4.4 (10.8)	0.673	0.897	0.761
At 12 months	2.3 (7.8)	−0.1 (7.3)	2.9 (11.0)	0.996	0.767	0.611
COMPLETE CASES						
Change in sedentary behavior, min/day						
At 3 months	−26.0 (75.2)*	−5.4 (78.3)	−29.3 (82.6)*	0.371	0.918	0.010*
At 6 months	−27.2 (57.4)**	62.6 (130.9)	4.9 (74.9)	0.494	0.103	0.020*
At 12 months	−16.7 (98.5)**	−4.3 (83.8)	−21.6 (64.7)*	0.567	0.308	0.057
Change in Light PA, min/day						
At 3 months	−26.0 (17.2)	−5.4 (13.6)	−29.3 (17.6)	0.999	0.619	0.748
At 6 months	−27.2 (14.3)	62.6 (23.1)	4.9 (16.3)	0.375	0.256	0.027*
At 12 months	−16.7 (31.1)	−4.3 (15.8)	−21.6 (15.7)	0.967	0.970	0.698
Change in MVPA, min/day						
At 3 months	8.7 (4.1)*	1.5 (2.5)	−1.3 (4.5)	0.010*	0.762	0.023*
At 6 months	−2.8 (6.1)	−4.4 (2.3)	−3.9 (3.1)	0.083	0.245	0.087
At 12 months	2.0 (8.4)*	−6.4 (2.3)*	−2.1 (5.0)	0.069	0.546	0.013*
Change in BMI, kg/m^2						
At 3 months	−0.5 (0.1)	−0.1 (0.1)	0.2 (0.1)	0.883	0.997	0.998
At 6 months	0.1 (0.2)	−0.2 (0.2)	0.1 (0.2)	0.996	0.876	0.965
At 12 months	0.1 (0.2)	−0.2 (0.1)	0.5 (0.3)	0.679	0.786	0.987
Change in WHOQOL brief						
At 3 months	4.4 (1.6)	4.1 (1.5)	1.7 (1.9)	0,678	0.564	0.998
At 6 months	2.9 (2.7)	3.1 (1.4)	1.6 (1.9)	0.996	0.876	0.896
At 12 months	3.7 (2.2)*	2.1 (1.5)	2.2 (2.5)	0.987	0.787	0.976
Change in WHOQOL old						
At 3 months	4.8 (2.3)	2.5 (1.6)	3.0 (2.1)	0.987	0.645	0.654
At 6 months	5.0 (2.4)	2.1 (1.4)	4.9 (2.3)	0.675	0.786	0.876
At 12 months	2.3 (3.4)	−0.7 (1.9)	1.9 (2.8)	0.986	0.876	0.054

*BCG, Behavior Change Group; TEG, Traditional Exercise Group; CG, Control Group. *p < 0.05, **p < 0.01 Adjusted.*
BMI, quality of life over a 12-month period. Florianópolis, Brazil, 2012.

expensive, as shown by the following quotes: "*. . . it is expensive, considering what is financially available from the government to each person, what is given to the cities, the fixed minimum wage, which is very low, the program is expensive. . .*" (G1). "*We would have to quit a program like "Floripa Ativa" or the walking group to include this new program. . .*" (PEF3).

DISCUSSION

This study evaluated the role of public health centers (HC) in the promotion of physical activity programs among older Brazilians, and compared the impact of two program strategies, behavioral change and traditional exercise. The RE-AIM framework was used to ground the evaluation of our programs. This framework has been previously used to evaluate programs offered in real-world settings (16, 26, 27). The use of RE-AIM in this study represents an innovation in public health program evaluation in Brazil. As stated by Glasgow, the knowledge generated by the RE-AIM goes beyond literal translational research, and supports program adaptations to various cultures and populations (11).

Our analysis investigated the reach, efficacy, adoption, implementation, and maintenance of RE-AIM components by collecting qualitative and quantitative data from program participants and partners at the organizational level. Our findings reveal both strengths and areas for improvement of the program strategies, and identified important factors associated with the utilization of public health centers in such initiatives.

Results revealed a limited *reach* of the programs offered at public health centers, with participation levels of about 12% of the older adult population. This finding suggests that future studies should seek to understand better older adults' resistance to change, and to develop culturally-sensitive strategies to overcome these barriers to reach. A systematic review published by Franco et al. (28) on barriers and facilitators to physical participation among activity older adults revealed that some individuals believe that physical activity is unnecessary or even potentially harmful. Others recognize the benefits of physical activity, but report a range of barriers to physical activity participation. The authors describe the importance of raising awareness of the benefits, educating about incorrect perceptions regarding the risks of physical activity, and improving environmental and financial access to physical activity opportunities. While building on the status and respect paid to leaders in public health centers to promote reach, such as doctors encouraging patient participation and personal invitations from community health workers.

The reach *and representativeness* of our program could be improved with a stronger level of support from administrators responsible for the planning and scheduling of health services, so that the programs become less susceptible to systems-level instabilities. *While program participants presented very similar demographic characteristics of non-participants, the program was only offered to 2 participating health districts, so with three health district coordinators declining participation, it led to 30 HCs never having the opportunity to hear about the program. The* complex operational problems in SUS/HCs have been previously documented (29) and the solutions require multi-faceted public health actions. *Reach and representativeness could be improved by greater buy-in from operational leaders and changes throughout the system to increase the number of health districts offering the program.*

Results of the program *effectiveness* and *maintenance* assessments reveal trends favoring behavior change strategies over traditional exercise classes. Behavior change programs were more successful in decreasing sedentary time and increasing moderate-to-vigorous physical activity, as well as improving participants' quality of life. Overall, participants perceived positive changes in themselves as a result of participating in the programs. They reported satisfaction with program results, improved awareness of the importance in being active, and were able to find opportunities to be active in daily routines. The effectiveness of the behavior change program (ALED) is consistent with the study by Baruth et al. (30) who reported clinically meaningful improvements in performance-based measures of physical functioning. Dunn et al. (10) also noted that a behaviorally based lifestyle physical activity intervention can significantly increase physical activity levels. They concluded that health care professionals who counsel their patients about physical activity can provide options beyond traditional fitness center–based recommendations.

Our results regarding program maintenance were promising, as many improvements post-intervention persisted in follow up. This is an important finding as maintenance has often been an overlooked dimension of RE-AIM and a common limitation of programs' evaluation. Galaviz et al. (24) describe important methodological limitations to the assessment of maintenance, such as the low participation of subjects in follow-up measurements.

We had an overall 14% rate of program *adoption* by public health centers. This is somewhat disappointing, considering the efforts by program developers in building partnerships with stakeholders across all hierarchical levels within the local health system. Our findings suggest that several organizational level factors hindered greater adoption of the programs, including heavy workload of health professionals delivering the program and limited physical space for program delivery. Without question, adoption depends on the commitment of local health teams. Schrader et al. (31) raised concerns about workload of health teams in Brazil that prevent them from engaging in activities beyond the typical assignment. King (32) underscored the importance of health care providers promoting physical activity interventions for older adults. However, the culture of managing chronic diseases at health care centers in Brazil is often associated with more traditional medical or pharmaceutical approaches including drug prescription (33). A deconstruction of these health care settings is necessary to engage patients and health professionals in health promotion and improve adoption of such programs.

The fidelity of program delivery was high and indicates that both programs are culturally- appropriate for the Brazilian context and feasible to be *implemented* by local health educators. Results showed that training of staff members was adequate and effective. As Brazil is lacking evidence-based behavior change programs for older adults, disseminating US-developed health programs, such as ALED, seems a viable option. Liu et al. have supported similar efforts in China (34). Additional implementation factors examined in this study included the

cost of program implementation, which placed traditional exercise classes at an advantage over behavior change programs. However, regardless of program type, administrators of public health centers reacted negatively to any additional cost that the programs added to their budgets or for participants. This is clearly an implementation issue that requires further attention. Finally, both intervention groups showed relatively high disengagement rates (BCG 50% vs. TEG 37%) with individuals in the BCG presenting lower rates of overall attendance (27 vs. 47%). Nevertheless, our effectiveness and maintenance results showing greater sedentary behavior, MVPA, and quality of life improvements in BCG, suggests that the behavioral modification strategies (tailored goal setting, self-monitoring, action planning, feedback) presented at the on-site meetings and throughout the written materials may have had the desired impact in helping individuals engage in healthful behaviors even when not attending sessions. These results are not unlike current literature on lifestyle modification interventions where a recent review on factor associated with adherence to lifestyle modification programs for weight management found adherence rates to vary from 20 to 80% of participants attending three or less sessions (35). Clearly, attendance continues to be a challenge for these types of programs and future studies should continue to explore strategies to improve overall attendance rates. In particular, the use of automated tracking tools (i.e., Fitbit, pedometers) have shown some early promise (36). Translating research into policy and practice is both a need and a challenge. As described by Oelke et al. (37) there are many barriers to disseminating and using research results in the Brazilian health care setting, including little involvement of key stakeholders and lack of partnerships between researchers and knowledge-users in research process, low research budgets and limited support by funding agency policies.

CONCLUSION

While participant attendance remains a challenge, this study supports the potential for dissemination of behavior change and traditional exercise programs to older adults through public health centers in Brazil. Our study advances the health literature by examining individual- and system-level factors associated with the promotion of physical activity in this aging society.

DATA AVAILABILITY STATEMENT

The datasets generated for this study are available on request to the corresponding author.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by the ethics committee of the Federal University of Santa Catarina (CONEP n. 480560 and CEPSH n. 2387/2010). The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

TB designed the research. FA guided on the design and statistical analyses. CR analyzed the data. LK, FB, WC-Z, and AS contributed to data collection and interpretation of findings. TB, CR, LK, FA, FB, WC-Z, and AS wrote the manuscript and TB had primary responsibility for final content. All authors contributed to the manuscript editing, read, and approved the final manuscript.

FUNDING

This research was supported by the Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq. Edital Universal 14/2012. Processo n. 475.075/2012) and Lemann Institute for Brazilian Studies, University of Illinois at Urbana-Champaign (US-Brazil Collaborative Research Grants, 2011). The University of Nebraska Medical Center provided the funds to pay for the article processing fees.

REFERENCES

1. Chodzko-Zajko WJ, Proctor DN, Fiatarone Singh MA, Minson CT, Nigg CR, Salem GJ et al. American College of Sports Medicine position stand. Exercise and physical activity for older adults. *Med Sci Sports Exerc*. (2009) 41:1510–30. doi: 10.1249/MSS.0b013e3181a0c95c
2. US Department of Health and Human Services. *2018 Physical Activity Guidelines Advisory Committee. Physical Activity Guidelines Advisory Committee Scientific Report*. Washington, DC, United States (2018). Available online at: https://health.gov/paguidelines/second-edition/report/pdf/pag_advisory_committee_report.pdf (accessed February 10, 2019).
3. Mazo GZ, Lopes MA, Benedetti TRB. *Atividade Física e o Idoso: Concepção Gerontológica*. 3rd ed. Porto Alegre: Sulina (2009).
4. Benedetti TRB, Schwingel A, Gomez LSR, Chodzko-Zajko W. Programa "VAMOS" (Vida Ativa Melhorando a Saúde): da concepção aos primeiros resultados. *Rev Bras Cineantropom Desempenho Hum*. (2012) 14:723–37. doi: 10.5007/1980-0037.2012v14n6p723
5. Brasil, Ministério da Saúde, Secretaria de Vigilância em Saúde, Departamento de Vigilância e Agravos não Transmissíveis e Promoção da Saúde. *VIGITEL Brasil 2016: Vigilância de Fatores de Risco e Proteção Para Doenças Crônicas por Inquérito Telefônico: Estimativas Sobre Frequência e Distribuição Sociodemográfica de Fatores de Risco e Proteção Para Doenças Crônicas nas Capitais dos 26 Estados Brasileiros e no Distrito Federal em 2016*. Brasília: Ministério da Saúde (2017) 159 p.
6. Brasil, Ministério da Saúde, Secretaria de Vigilância em Saúde, Departamento de Vigilância e Agravos não Transmissíveis e Promoção da Saúde. *VIGITEL Brasil 2011: Vigilância de Fatores de Risco e Proteção Para Doenças Crônicas por Inquérito Telefônico*. Brasília: Ministério da Saúde (2012). 132 p.
7. Gonçalves LHT, Petroski EL, Nassar SM, Schwingel A, Chodzko-Zajko W. Aging in Brazil: physical activity, socioeconomic conditions, and diseases among older adults in southern Brazil. *J Appl Gerontol*. (2008) 27:631–40. doi: 10.1177/0733464808319710
8. Cress ME, Buchner DM, Prohaska T, Rimmer J, Brown M, Macera C, et al. Best practices for physical activity programs and behavior counseling in older adult populations. *J Aging Phys Act*. (2005) 13:61–74. doi: 10.1123/japa.13.1.61

9. Pratt M. Benefits of lifestyle activity vs structured exercise. *JAMA*. (1999) 281:375–6. doi: 10.1001/jama.281.4.375
10. Dunn AL, Marcus BH, Kampert JB, Garcia ME, Kohl HW, Blair SN. Comparison of lifestyle and structured interventions to increase physical activity and cardiorespiratory fitness: a randomized trial. *JAMA*. (1999) 281:327–34. doi: 10.1001/jama.281.4.327
11. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health*. (1999) 89:1322–7. doi: 10.2105/AJPH.89.9.1322
12. Almeida FA, Brito FA, Estabrooks PA. Modelo RE-AIM: tradução e adaptação cultural para o Brasil. *REFACS*. (2013) 1:6–16. doi: 10.18554/refacs.v1i1.602
13. Bors P, Dessauer M, Bell R, Wilkerson R, Lee J, Strunk SL. The active living by design national program: community initiatives and lessons learned. *Am J Prev Med*. (2009) 37(6 Suppl. 2):S313–21. doi: 10.1016/j.amepre.2009.09.027
14. Borg GA. Psychophysical bases of perceived exertion. *Med Sci Sports Exerc*. (1982) 14:377–81. doi: 10.1249/00005768-198205000-00012
15. Greene JC. *Mixed Methods in Social Inquiry*. San Francisco, CA: Jossey-Bass (2007).
16. Schwingel A, Gálvez P, Linares D, Sebastião E. Using a mixed-methods RE-AIM framework to evaluate community health programs for older latinas. *J Aging Health*. (2017) 29:551–93. doi: 10.1177/0898264316641075
17. Glasgow RE, Hiss RG, Anderson RM, Friedman NM, Hayward RA, Marrero DG, et al. Report of the health care delivery work group: behavioral research related to the establishment of a chronic disease model for diabetes care. *Diabetes Care*. (2001) 24:124–30. doi: 10.2337/diacare.24.1.124
18. World Health Organization. *Obesity: Prevenig and Managing the Global Epidemic*. Geneva: World Health Organization (2000).
19. Choi L, Liu Z, Matthews CE, Buchowski MS. Validation of accelerometer wear and nonwear time classification algorithm. *Med Sci Sports Exerc*. (2011) 43:357–64. doi: 10.1249/MSS.0b013e3181ed61a3
20. Freedson PS, Melanson E, Sirard J. Calibration of the computer science and applications, inc. accelerometer. *Med Sci Sports Exerc*. (1998) 30:777–81. doi: 10.1097/00005768-199805000-00021
21. Sasaki JE, John D, Freedson PS. Validation and comparison of ActiGraph activity monitors. *J Sci Med Sport*. (2011) 14:411–16. doi: 10.1016/j.jsams.2011.04.003
22. Fleck MP, Louzada S, Xavier M, Chachamovich E, Vieira G, Santos L, et al. Aplicação da versão em português do instrumento abreviado de avaliação da qualidade de vida "WHOQOL-bref". *Rev Saúde Pública*. (2000) 34:178–83. doi: 10.1590/S0034-89102000000200012
23. Fleck MP, Chachamovich E. Trentini C. Desenvolvimento e validação da versão em Português do módulo WHOQOL-OLD. *Rev Saúde Pública*. (2006) 40:785–91. doi: 10.1590/S0034-89102006000600007
24. Behling O, Law KS. *Translating Questionnaires and Other Research Instruments: Problems and Solutions*. Thousand Oaks, CA: Sage Publications (2000).
25. Santo RM, Ribeiro-Ferreira F, Alves MR, Epstein J, Novaes P. Enhancing the cross-cultural adaptation and validation process: linguistic and psychometric testing of the Brazilian-Portuguese version of a self-report measure for dry eye. *J Clin Epidemio*. (2015) 68:370–8. doi: 10.1016/j.jclinepi.2014.07.009
26. Galaviz KI, Harden SM, Smith E, Blackman KCA, Berrey LM, Mama SK, et al. Physical activity promotion in Latin American populations: a systematic review on issues of internal and external validity. *Int J Behav Nutr Phys Act*. (2014) 17:77. doi: 10.1186/1479-5868-11-77
27. Glasgow RE, Estabrooks PE. Pragmatic applications of RE-AIM for health care initiatives in community and clinical settings. *Prev Chronic Dis*. (2018) 15:R2. doi: 10.5888/pcd15.170271
28. Franco MR, Tong A, Howard K, Sherrington C, Ferreira PH, Pinto RZ et al. Older people's perspectives on participation in physical activity: a systematic review and thematic synthesis of qualitative literature. *Br J Sports Med*. (2015) 49:1268–76. doi: 10.1136/bjsports-2014-094015
29. Massuda A, Hone T, Leles FAG, Castro MC, Atun R. The Brazilian health system at crossroads: progress, crisis and resilience. *BMJ Glob Health*. (2018) 3:e000829. doi: 10.1136/bmjgh-2018-000829
30. Baruth M, Wilcox S, Wegley S, Buchner DM, Ory MG, Phillips A, et al. Changes in physical functioning in the active living every day program of the active for life initiative. *Int J Behav Med*. (2011) 18:199–208. doi: 10.1007/s12529-010-9108-7
31. Schrader G, Palagil S, Padilha MAS, Noguez PT, Thofehrn MB, Pai DD. Trabalho na Unidade Básica de Saúde: implicações para a qualidade de vida dos enfermeiros. *Rev Bras Enferm*. (2012) 65:222–8. doi: 10.1590/S0034-71672012000200004
32. King AC, Interventions to promote physical activity by older adults. *J Gerontol*. (2001) 56A(Special Issue II):36–4. doi: 10.1093/gerona/56.suppl_2.36
33. Nogueira ALG, Munari DB, Fortuna CM, Santos LF. Pistas para potencializar grupos na Atenção Primária à Saúde. *Rev Bras Enferm*. (2016) 69:964–71. doi: 10.1590/0034-7167-2015-0102
34. Liu M, Belza B, Zhang X. Considerations when disseminating american-developed, evidence-based health promotion programs in china. *J Gerontol Nurs*. (2015) 41:3–4. doi: 10.3928/00989134-20150511-01
35. Leung AWY, Chan RSM, Sea MMM, Woo J. An overview of factors associated with adherence to lifestyle modification programs for weight management in adults. *Int J Environ Res Public Health*. (2017) 14:922. doi: 10.3390/ijerph14080922
36. Grock S, Ku Jh, Kim J, Moin T. A review of technology-assisted interventions for diabetes prevention. *Curr Diab Rep*. (2017) 17:107. doi: 10.1007/s11892-017-0948-2
37. Oelke ND, Lima MADS, Acosta AM. Knowledge translation: translating research into policy and practice. *Rev Gaúcha Enferm*. (2015) 36:113–7. doi: 10.1590/1983-1447.2015.03.55036

Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

frontiers in Public Health

ORIGINAL RESEARCH
published: 03 December 2020
doi: 10.3389/fpubh.2020.502106

Nation-Wide Dissemination of a Digital Checklist to Improve Work Environment in the Eldercare Sector in Denmark

Pernille Kold Munch[1], *Marie Birk Jørgensen*[2], *Helene Højberg*[1] and *Charlotte Diana Nørregaard Rasmussen*[1]*

[1] National Research Centre for the Working Environment, Copenhagen, Denmark, [2] Health and Safety, Municipality of Copenhagen, Copenhagen, Denmark

In this study, we evaluated the dissemination of a digital checklist for improving implementation of work environment initiatives in the Danish eldercare sector. We evaluated the impact of the checklist using the RE-AIM framework. Initiated in 2016, researchers and relevant stakeholders were responsible for disseminating the checklist to all workplaces in the eldercare sector in Denmark through a national campaign. The checklist guided the user to define an action plan to implement, and the checklist covered 11 implementation concept points that should be addressed to reach full implementation of the action in focus. One year after the launch of the campaign almost all municipalities in Denmark had visited the website hosting the checklist (96%), 17% of individual workers within the eldercare responding to a union survey was reached, 4% ($n = 199$) of all eligible eldercare workplaces in Denmark and 8% of all nursing homes had adopted the checklist. Of the workplaces that used the checklist, 46% typed an action in the checklist. There were 13% of the first time users that used the checklist twice and 29% of the actions were revised (maintenance) after working with the implementation. Finally, the workplaces that had used the checklist showed a higher prioritization of work environment compared to workplaces not using the checklist both at baseline and at follow up. In conclusion, this study employing various strategies, including a 1-year national campaign to disseminate a checklist shows potential to impact implementation of work environment initiatives in the Danish eldercare sector. While dissemination is satisfactory and likely to increase further with time, more efforts is needed to ensure maintenance.

Keywords: re-aim, campaign, workplace, reach, adoption, maintenance, implementation, evaluation

OPEN ACCESS

Edited by:
Matthew Lee Smith,
Texas A&M University, United States

Reviewed by:
Thomas Edward Strayer III,
Vanderbilt University Medical Center, United States
Ninfa Peña-Purcell,
Texas A&M University, United States

****Correspondence:***
Charlotte Diana Nørregaard Rasmussen
cnr@nfa.dk

Specialty section:
This article was submitted to Public Health Education and Promotion, a section of the journal Frontiers in Public Health

Received: *01 October 2019*
Accepted: *12 November 2020*
Published: *03 December 2020*

Citation:
Munch PK, Jørgensen MB, Højberg H and Rasmussen CDN (2020) Nation-Wide Dissemination of a Digital Checklist to Improve Work Environment in the Eldercare Sector in Denmark. Front. Public Health 8:502106. doi: 10.3389/fpubh.2020.502106

INTRODUCTION

Currently many countries are facing shortage of healthcare workers, and the trends are forecasted to continue (1). In addition, the demographic changes in the Western World mean that there will be more elderly people with need for care. Thus, there is a great need for healthcare workers being healthy and fit to care for the elderly. Both the physical and psychosocial work environment is important factors for maintaining a healthy and fit workforce (2). Thus, several initiatives have been introduced in Denmark to improve the work environment among eldercare workers

(3–6). The effect of work environment initiatives has often been reported in the scientific literature (7) and effective evidence-based work environment intervention studies among eldercare workers are available (3, 4, 6). A major limitation is the emphasis on efficacy and effectiveness of the initiatives, with little attention paid to the overall public health impact, which takes into account the dissemination potential of the initiative—the extent to which the initiative can be delivered to a large number of people and sustained over time.

There is a huge challenge in translation of policies and research knowledge into practice (8). Many factors can influence whether the translation of research knowledge into practice is successful and whether policies or evidence based practices are accepted and used by the target users (9). Dissemination of research findings is an important step to bridge the gap between research and practice. Effective dissemination strategies include formative research to customize dissemination strategies to fit audience needs and preferences (10). Distribution strategies should focus on ensuring that messages and materials from research reach intended audiences by use of multicomponent dissemination strategies, e.g., mailings, websites, publications, webinar or in-person presentations, interpersonal connections, and mass media among others (10, 11). To be most effective, distribution should engage the channels that intended audiences already trust and access for information (10). Thus, in a recent initiative in Denmark, a checklist was developed in collaboration with key stakeholders, to guide the implementation of work environment initiatives in eldercare sector workplaces. Given that the checklist is sector-specific for work environment initiatives, and developed through systematic collaboration between research and practice, it is likely to have high utility and impact. However, to evaluate the impact it is important to examine when, why, and how the checklist is spread to the Danish eldercare sector, in particular nursing homes and homecare.

A commonly used framework in the evaluation of public health impact of health promotion interventions is the RE-AIM framework (12–15). The RE-AIM model offers a useful framework for assessing the overall public health impact (12). The model focuses on five evaluation dimensions: reach (i.e., proportion of the target population that participated), efficacy (i.e., success rate at changing desired outcomes), Adoption (i.e., proportion of target settings involved), implementation (i.e., extent to which the program was delivered as intended), and maintenance (i.e., extent to which the program becomes a part of the routine) (12). The RE-AIM framework has been used in various fields including the evaluation of clinical guidelines implementation (12, 16, 17). To expand knowledge in the area on implementation and dissemination of work environment initiatives the five dimensions in the RE-AIM framework will be investigated.

To ensure effective interventions and to improve the work environment in the future, knowledge of the dissemination strategies, the workplace adoption, the reach of employees, the implementation and maintenance of these initiatives are important. The aim of this study is therefore to evaluate the dissemination and reach, adoption, implementation, maintenance, and effectiveness of the checklist to improve implementation of work environment initiatives among eldercare workers in Denmark.

MATERIALS AND METHODS

Study Setting and Population

The study setting is the eldercare sector in Denmark, and more specifically nursing homes and homecare settings. In Denmark, there are ∼5,000 workplaces within the eldercare sector that employ about 100,000 eldercare workers in total.

Dissemination

Dissemination Object—A Digital Checklist

We developed a digital checklist in collaboration with key stakeholders, which was connected to a specific developed website (can be accessed on *www.MEDvirknu.dk)*. The users (primarily the occupational health and safety (OHS) groups) can use it in their work environment practice when implementing new routines, projects, or initiatives (termed an "action" in the checklist) to improve the work environment. The development and content of the checklist has earlier been described in details (18, 19). In brief, the checklist is an interactive digital platform and has 11 implementation concept points (implementation concept points related to implementation, e.g., involvement of relevant employees, supervisor support, allocation of resources, etc.). First, the user has to log in with their affiliation, and then choose the action they want to implement. The next step is to go through the checklist, check the implementation concept points they have covered already and pick the implementation concept point in the checklist which they want to focus on to fulfill implementation. After having gone through all the points of the checklist, it is possible to print a diploma, tips and a letter. The diploma works as a process document and includes the work environment action, the implementation concept points already covered, and the implementation concept point to focus further on to make sure the implementation of the work environment action is fulfilled. A supplement to the diploma is tips covering how to begin and continue the work with the chosen implementation concept point and the letter describes in detail the checklist, the work environment action and the implementation concept points and is used for circulation in the management or among other local stakeholder groups to inform them of the action and the implementation progress.

Dissemination Strategy

To promote the checklist, we planned a national campaign, focusing at the eldercare sector and specifically the nursing homes. The campaign consisted of digital elements (videos, newsletters, social media, etc.), oral presentations (workshops, train-the-trainer, training, and conferences) and paper elements (printed checklist as postcards, magnets, letters, and magazines). The researchers and stakeholders primarily drove the campaign. The campaign was running for 1 year, starting the 4th of September 2017 ending 3rd of September 2018. The website remains open, regardless of the ended campaign.

Design

In this prospective observational study, we used a range of quantitative data collection approaches to accomplish the study aims. We used the RE-AIM framework to investigate the impact of the checklist. Reach is an individual-level measure of the participation, and will be investigated by the proportion of eldercare workers who know the checklist and the characteristics of those who know the checklist compared to a reference group (union members who didn't answer, that they have gained knowledge of the checklist during the campaign (answered no or don't know). In addition to this, reach will be measured as number of unique visitors to the online checklist website (day to day activity, accumulated activity, and geographical position) during the campaign. Effectiveness will be evaluated in respect to whether the prioritization of the work environment among workplaces that know the checklist has changed. Adoption is an organizational-level measure of the representativeness of the setting, and will be investigated by the proportion of workplaces who adopt the checklist (create an account and log into the online checklist website) and their characteristics. Implementation refers to the extent to which an intervention is delivered as intended (dissemination) and will be measured at individual level as whether the eldercare workers has seen a diploma at their workplace. At the organizational level, implementation will be measured as workplace activity at the online checklist website. Maintenance is the extent to which the programme becomes a part of the routine at the workplace and will be evaluated by return/revised actions (repeated use of the checklist). See protocol paper for further details (18).

Data Collection and Outcomes

We used multiple data sources to report reach, effectiveness, adoption, implementation and maintenance. The data sources included data from a large union survey, the checklist website, the Central business Register (CVR—contains information about all registered workplaces in Denmark) and Google Analytics. See **Figure 1** for detailed data collection points before, during and after the campaign.

Union Survey

The third largest trade union in Denmark (FOA), organize ∼180,000 members primarily in the public sector. Members can voluntarily sign-up to receive a questionnaire 4–6 times a year. Union members can register and drop out as they want, making the population an open cohort. The union survey is sent to ∼7,500 union members each time. For each round of the survey, we embedded campaign-specific questions in the questionnaire and the following background information on each member was collected: age, gender, position of trust (OHS representative, employee representative, OHS representative and employee representative or no position of trust) and manager (yes/no), information on employer (municipality or an self-governing institution, private/private resident, region, state, or other/don't know) and workplace (temporary agency, treatment/district psychiatry, home care, social psychiatry, school, rehabilitation, hospital, nursing home, special area, handicap assistant, or other).

Reach was assessed with the questions: "do you know the campaign (MEDvirk)? (Yes, no or don't know)," "where have you heard of the campaign (MEDvirk)? (network, OHS representative, colleagues, the Danish Working Environment Authority, employer/sector association, the Sector-Specific Work Environment Community Organization for Public and Welfare workplaces, trade union (FOA), website/newsletter, conference or similar, flyer, other or don't know/don't remember) (you can answer more than one))." The union members were invited to

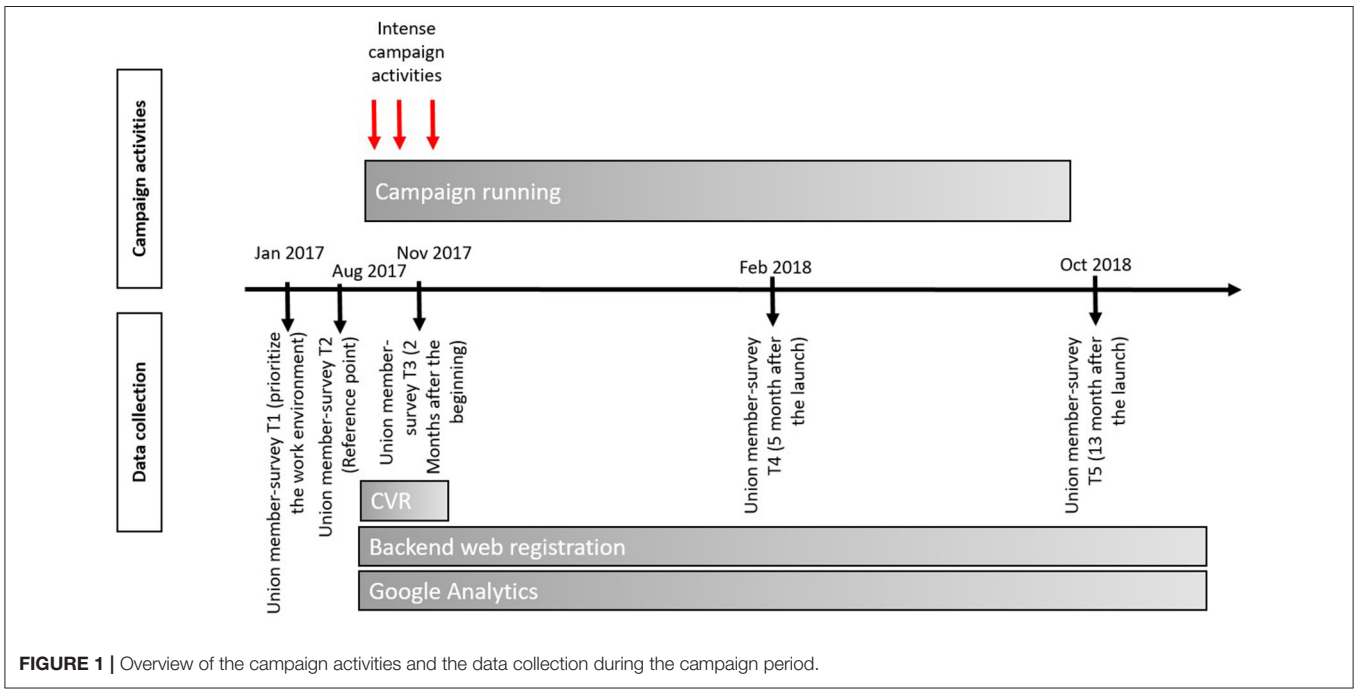

FIGURE 1 | Overview of the campaign activities and the data collection during the campaign period.

answer these questions just after the launching of the campaign (T3: 17th to 28th of November 2017), 5 months after the launching (T4: 2th to 14th of February) and after the campaign finished (T5: 12th to 31th of October 2018). Further before the campaign started, it would have been impossible to know the checklist and to establish a reference point we invited the union members before the campaign started (T2: 21th to 31th of August 2017) to answer the same questions as a control.

Implementation was assessed with the question: "have you seen this diploma at your workplace? (yes, no or don't know)" (showing a picture of the diploma). The union members were then invited to answer the question just after the launching of the campaign (T3: 17th to 28th of November 2017), 5 months after the launching (T4: 2th to 14th of February) and after the campaign finished (T5: 12th to 31th of October 2018). Again as a control, the union members were invited to answer the same question before the campaign started (T2: 21th to 31th of August 2017).

Furthermore, in the last union survey and in an additional union survey from January 2017 (T1) we included a question to evaluate *effectiveness*: "does your workplace in general prioritize the work environment? (to a very great extent, to a great extent, to some extent, to a small extent, not at all or don't know)." See protocol paper for overview of the data collection and timeline (18).

The Checklist Website

From the checklist website, we used user-specific information from each visitor and work environment action. User data were copied from "www.MEDvirknu.dk" user database and pasted into an ".xlsx" file. Copied Metrics were "user name," "municipality," "workplace name," and "unique company identification (p-Number)." All actions were downloaded as an ".xlsx" file (incorporated function in the backend of the website), including "municipality," "workplace name," "unique company identification (p-Number)," "email," "unique user-id," "date for created action," "number of visits," "number of actions," "action," "date for edit," "print," and "answers to the 11 checkpoints."

To assess *adoption and maintenance* both dataset were filtered to only include users/actions from 4th of September 2017 until and including the 3rd of September 2018. Additionally, data were filtered via user names and/or email to remove project developer, internal and project associate users created to highlight the checklist to potential users. The unique company identification (p-number) at the user-specific dataset was linked to information from the CVR to evaluate the representativeness and characteristics of adopters. The CVR dataset from "www.datacvr.virk.dk/data/" was filtered to include all possible eldercare workplaces in Denmark (including hospitals, home care, nursing home, 24-h care center (mental- or physical disability or children and adolescents) or others based on main and secondary sector (4,899 different eldercare workplaces in Denmark). The information contained in the CVR is: size (number of employees in intervals [<49 (small) 50–199 (medium) >200 (large)]), type of workplaces (nursing home, home care, hospital, etc.), age (date for founding of the workplace), and geographical position of the workplaces [municipalities (region)].

To assess *implementation*, we coded actions into the following different categories: physical surroundings, physical exposure, psychological exposure, training during working hours, organization, other or not usable.

Google Analytics

The website "www.MEDvirknu.dk" was associated with a Google Analytics account. We downloaded day-by-day history as ".xlsx" files from this account, between and including 4th of September 2017 and 3rd of September 2018. The metrics downloaded were "date," "segment," "users," and "bounce rate." "Users" indicate unique visitors, and will be used as a measure for reach. Furthermore, month-by-month geographical data on city level was also downloaded as ".xlsx" files from the google analytics account, from and including 4th of September 2017 and 31st of August 2018. Google Analytics determine geographical location by the active users' IP-address. The metrics downloaded were "date-interval," "segment," "users," "city," "month," and "year."

User segment for both data downloads were limited to users from the geographical location of Denmark. Month by month geographical data were linked to a dataset from Statistics Denmark including all cities in Denmark with more than 200 citizens and the belonging municipality (98 municipalities in Denmark).

The activity at the checklist website was used to evaluate *reach* (number of unique visitors to the online checklist website (day to day activity, accumulated activity, and geographical position) during the campaign) and the activity after different dissemination activities.

Analyses

To test for differences between the workplaces that use the checklist (adopters) and workplaces that do not use the checklist (non-adopters) we performed ANOVA and *t*-test. To test for differences between the union members who know the checklist (reached) and union members who do not know the checklist (non-reached) we performed ANOVA and *t*-test.

Union members who answered that they knew the campaign or had seen the diploma before the start were excluded in the analysis. For the analysis of where the members have heard of the campaign, each time a union member has participated in the survey and knows the campaign, the answer is included in the analysis (minimum once and maximal three times).

For the effectiveness evaluation the inclusion criteria were: participation in T1 and T5. We excluded respondents who answered "don't know" and respondents who knew the campaign before campaign start (T2). Respondents who knew the campaign was based on T3, T4, and T5. To investigate the prioritizing of work environment before the campaign started and after the campaign, we performed a repeated ANCOVA with time (T1 and T5) as the within-participants factor, and the between-participants factor (knows the campaign) as the dependent variable. We adjusted for age and gender.

RESULTS

Dissemination

Table 1 provides an overview of the dissemination activities to promote the checklist over a period of 12 months. The dissemination activities included digital elements, physical appearance as e.g., oral presentations, campaign materials, and printed elements. The checklist and all the activities were in Danish. Approximately 55,000 people were subscribed to receive the newsletters by the different partner organizations where the checklist was promoted and more than 500 people participated in oral presentations or training sessions (physical presence). There were more than 26,000 likes on partner organizations' Facebook who shared the checklist, the campaign video or articles about the checklist. Paper elements (a letter, printed checklist, and magnets) were sent to 1,079 nursing homes, 627 home care units, and 98 different administrative departments of the municipalities.

In **Table 1**, the number of potential reached and the actual reached can be seen. Within each activity, we estimated the potential reach. For the digital elements potential reach included likes, followers and subscribers. For the physical presence potential, reach included participants. In addition, the number of adopting workplaces can be seen from the different dissemination methods used to promote the checklist. This provides an overview of the effect of the different dissemination strategies. **Table 1** shows that oral presentations and meetings may be good strategies to reach people. Several times we reached a high proportion of the potential reached during oral presentations and training sessions (physical presence) compared to dissemination actions using digital elements, As an example, the 6th of September we held an oral presentation for around 250 participants (the same day we also had a training session for around 90–100 participants), resulting in 154 visits. The 27th of September we shared the checklist on Facebook with a potential reach of around 17,000 and a newsletter was sent to almost 10,000, resulting in 153 (237) visits.

In **Table 2**, an overview of where the respondents have heard of the campaign during the 1-year campaign is presented. During the campaign, 1,168 respondents answered the question (response rate 99.7% of all who indicated to know the checklist). Almost 60% have heard of the campaign from the trade union FOA, more than 30% from their OHS representative and around 20% have heard of it from colleagues or network.

Reach (Organizational Level)

Unique Visitors

From 4th of September 2017 until 3rd of September 2018, we had 3,644 unique visitors to the website hosting the digital checklist (average of 10 unique visitors per day during the 364 campaign days). Within the first 3 months, we had 2,277 unique visitors to the website (average of 25 unique visitors per day during the first 3 months). The number of unique visitors peaked within the first couple of months; within the last 6 months of the campaign, 571 unique visitors visited the website (average of 3 unique visitors per day during the last 6 months). The bounce percentage, i.e., percentage of visitors leaving the website after only viewing one page, was 30% ($n = 1{,}089$). After the campaign period and until September 2019 people still visited the website, however the unique number of visitors decreased after the campaign period (average of 2 unique visitors per day after the campaign). **Figure 2** gives an overview of the monthly and total number of visitors on the website during and after the campaign.

Geographic Location

Within the 1st month of the campaign, visitors from 82 different municipalities in Denmark were reached (84%). Within the same period, 39 municipalities were reached with at least five unique visitors from each of the 39 municipalities. This number was unchanged for the rest of the campaign period. After 3 months, 89 different municipalities in Denmark were reached (91%). After 1 year, visitors from 94 different municipalities in Denmark were reached (96%) (data not shown).

Adoption

In total, 534 visitors ($n = 15\%$ of unique visitors) created an account and logged in to the website (adopters). Within the 12 months of the campaign, visitors from 88 different municipalities created an account and logged in to the website (from 56 visitors we had no information about municipality). Top three adopting municipalities were all placed in Zealand (10% of all eligible workplaces were located in Copenhagen, 8% in Frederiksberg, and 7% in Ringsted).

Of the 534 created accounts, 230 of the accounts were linked to a target p-number, from 199 different workplaces (from 1 to 7 accounts per workplace) and defined as eligible workplaces, meaning that 4% of all possible eldercare workplaces in Denmark adopted the checklist. A special focus within the dissemination strategy was the nursing homes. Of 1,089 nursing homes, 88 nursing homes adopted the checklist, corresponding to 8%. Of the 199 identified workplaces, the users came from 74 different municipalities within Denmark (data not shown). There were 304 of the created accounts that were without a p-number, and defined as ineligible workplaces (from other sectors than the eldercare sector). Some of the adopting ineligible workplaces were from unidentified eldercare workplaces, however a large amount were from other sectors (schools, administrations, municipality, childcare, the Danish Working Environment Authority, and trade union). See **Figure 3**, for a flow diagram of possible adopters, adopters, and use of the checklist.

In **Table 3**, characteristics of the workplaces that adopted the checklist and workplaces that did not adopt the checklist are presented. A significant higher proportion of workplaces that adopted the checklist were placed in the capital region, were more often nursing home, home care, or hospital, medium sized workplaces or founded before year 2000 compared to workplaces that did not adopt the checklist.

Reach—Individual Level (Knowledge of the Campaign)

Seven thousand three hundred and fifty-four union members from the Social and Health Service Sector were invited to participate in the survey before the campaign started—2,574 answered (response rate 35%). There were 181 survey members who responded that they knew the checklist before the campaign

TABLE 1 | Dissemination activities to promote the checklist (MEDvirknu.dk) during the 1-year campaign.

Timing	Dissemination Action	Reach		Adopting			
		Potential		Eligible workplaces		Ineligible workplaces	
	Digital elements	Reached/n[d]	Reached/n[e]	Workplaces/n[e]	Actions/n[e]	Workplaces/n[e]	Actions/n[e]
04-Sep-17	Checklist shared on the project group's own LinkedIn profiles	NA	111 (298)	0 (7)	0 (9)	4 (10)	4 (11)
	Article about the checklist on the Sector-Specific Work Environment Community Organization for Public and Welfare workplaces ()	NA					
	News about the checklist on the Danish Knowledge Center for Work Environments webpage	NA					
	Special newsletter about the checklist to those subscribed to receive the Danish Knowledge Center for Work Environment's newsletter	21,000 subscribed[a]					
	News about the checklist shared on the project leader's (researcher) LinkedIn profile (Danish and English)	669 followers[b]					
05-Sep-17	Checklist shared on The Danish Working Environment Authorities' LinkedIn	4,189 followers[b]	187 (341)	7 (12)	9 (16)	6 (39)	7 (41)
	Online article in the sector-based magazine "Pleje" (care) about the checklist	NA					
	News about the checklist at the National Research Center for the Working Environment's official website (www.nfa.dk)	NA					
07-Sep-17	Newsletter about the checklist to those subscribed to receive The National Research Center for the Working Environment's newsletter	4,100 subscribed[a]	92 (132)	1 (2)	1 (2)	5 (8)	5 (8)
	News about the checklist on a Facebook page generated in the development process of the checklist, primarily targeted at workers in the eldercare sector with the aim of sharing knowledge on how to create a good work environment (The page is named "SKAB JER")	253 Facebook likes[b]					
14-Sep-17	Checklist shared on "FOA Vejle's" Facebook (sub-group within the large union within the sector)	411 Facebook-likes[b]	36 (80)	1 (1)	1 (1)	2 (7)	3 (8)
15-Sep-17	Checklist shared on The National Research Center for Working Environment's Facebook page	1,448 Facebook likes[c]	44 (49)	0 (0)	0 (0)	5	5 (5)
27-Sep-17	Newsletter about the checklist to those subscribed to receive the Sector-Specific Work Environment Community Organization for Public and Welfare workplaces	9,876 subscribed[a]	153 (237)	3 (7)	3 (7)	3 (4)	3 (5)
	Checklist shared on "Godt arbejdsmiljø"s (good working environment) Facebook group (associated with the Sector-Specific Work Environment Community Organization for Public and Welfare workplaces)	16,888 Facebook-likes[b]					
28-Sep-17	Newsletter about the checklist to those subscribed to receive The Danish Working Environment Authorities' newsletter	20,000 subscribed[a]	84 (108)	4 (4)	4 (4)	1 (1)	2 (2)

(Continued)

TABLE 1 | Continued

Timing	Dissemination Action	Reach		Adopting			
		Potential		Eligible workplaces		Ineligible workplaces	
	Digital elements	**Reached/n[d]**	**Reached/n[e]**	**Workplaces/n[e]**	**Actions/n[e]**	**Workplaces/n[e]**	**Actions/n[e]**
	Repost of "Godt Arbejdsmiljø"s Facebook post, on "SKAB JER"s Facebook	253 Facebook-likes[b]	24 (36)				
10-Oct-17	Campaign movie about the checklist shared on "SKAB JER" Facebook page	253 Facebook-likes[b]/4,400 views of the campaign movie[c]	23 (54)	0 (0)	0 (1)	0 (0)	0 (0)
10-Oct-17	Campaign movie about the checklist shared on The National Research Center for Working environments' Facebook page	1,448 Facebook-likes[c]/4,400 views of the campaign movie[c]					
19-Oct-17	Checklist shared on "SKAB JER"s Facebook page	253 Facebook-likes[b]	12 (38)	0 (0)	0 (0)	0 (1)	0 (1)
19-Oct-17	Campaign movie about the checklist shared on The Danish schools for nursing aides' Facebook	2,793 Facebook-likes[b]					
24-Oct-17	Campaign movie about the checklist shared on "Godt arbejdmsiljø"s (good working environment) Facebook	16,888 Facebook-likes[b]	31 (47)	0 (0)	0 (0)	0 (1)	0 (1)
14-Nov-17	Newsletter about the checklist to those subscribed to receive the Sector-Specific Work Environment Community Organization for Public and Welfare workplaces newsletter	9,876 subscribed[a]	88 (123)	1 (1)	1 (1)	3 (3)	3 (3)
07-Dec-17	Newsletter about the checklist to those subscribed to receive Danish physiotherapists' newsletter	NA	43 (65)	0 (0)	0 (0)	0 (0)	0 (0)
	Internal newsletter about the checklist to employees in the Ministry of Employment	NA					
15-Jan-18	Article about the checklist shared on topic-specific Facebook page regarding interventions for musculoskeletal health at public workplaces, published and edited by a section under the Ministry of Employment	18,477 Facebook-likes[b]	11 (20)	0 (0)	0 (0)	0 (0)	0 (0)
30-Jan-18	Repost of the Sector-Specific Work Environment Community Organization for Public and Welfare workplaces article on "SKAB JER"s Facebook	253 Facebook-likes[b]	42 (72)	0 (0)	0 (0)	2 (2)	3 (3)
30-Jan-18	News at the Sector-Specific Work Environment Community Organization for Public and Welfare workplaces website (www.arbejdsmiljoweb.dk) - interview with the project leader	NA					
14 May-18	Checklist shared on "Godt arbejdsmiljø"s (good working environment) Facebook	16,888 Facebook-likes[b]	28 (87)	0	0 (0)	0 (1)	0 (0)
15 May-18	Checklist shared on "Godt arbejdsmiljøs" (good working environment) Facebook	16,888 Facebook-likes[b]	59 (73)	1 (1)	1 (1)	1 (1)	1 (1)
	Physical presence	Participants/*n*	Reached/n[f]	Workplaces/n[f]	Actions/n[f]	Workplaces/n[f]	Actions/n[f]
05-Sep-17	Oral presentation of the checklist at the yearly Working Environmental Conference organized by the Local Government Denmark (central organization of all Danish municipalities), with representatives from most of the Danish municipalities	≈100 participants	187	7	9	6	7

(Continued)

TABLE 1 | Continued

Timing	Dissemination Action	Reach		Adopting			
		Potential		Eligible workplaces		Ineligible workplaces	
	Digital elements	**Reached/n[d]**	**Reached/n[e]**	**Workplaces/n[e]**	**Actions/n[e]**	**Workplaces/n[e]**	**Actions/n[e]**
06-Sep-17	Oral presentation at a conference for local work environment representatives within the eldercare sector—organized by the sector-specific work environment Community Organization for Public and Welfare workplaces	≈250 participants	154	5	7	33	34
	Training in use of the website and checklist of all Danish Working Environment Authority inspectors within the elder care sector	≈90–100 participants					
21-Sep-17	Oral presentation of the checklist at the trade union for eldercare workers—FOA—for employee representatives situated at regional union offices (i.e., coordinators and advisors of local employee representatives at workplaces)	NA	40	6	6	4	4
5-Oct-17	Oral presentation for the Working Environment Authorities employee club of therapists (typically inspectors) (project leader promoting the checklist)	≈40 participants	46	6	6	13	13
25-Oct-17	Oral presentation at the yearly conference for teachers in the common labor parties' school for work environment that trains work environment representatives in Denmark.	NA	16	0	0	1	1
26-Oct-17	Oral presentation at the yearly conference for teachers in the common labor parties' school for work environment that trains work environment representatives in Denmark.	NA	11	0	0	0	0
22-Nov-17	Theme-day for work environment groups in eldercare sections in a municipality	≈80 participants	53	13	14	8	7
28-Nov-17	Oral presentation at the work environment conference for work environment consultants and other occupational health and safety representatives (not sector-specific)	52 participants	47	0	0	2	2
22-Jan-18	Instruction and facilitation of usage of the checklist for work environment groups in a municipality	13 participants	14	3	7	1	1
22-Mar-18	Network meeting for OSH representative (not sector-specific)	≈40 Participants	40	6	6	23	26
	Articles in magazines	Circulation/*n*					
5-Sep-17	Article about the checklist in the magazine "Arbejdsmiljø" (Working Environment), which covers working environment and is distributed by a section under the Ministry of Employment	6,600					
29-Sep-17	Article about the checklist in the magazine "Pleje" (Care)	7,944					
17-Apr-18	Article about the checklist in the magazine "Arbejdsmiljø" (Working Environment)	6,600					
	Campaign materials	Views/*n*					
10 Oct-17	Campaign movie published	717 views[b]					
9 Oct-17	Introduction movie of the checklist published	695 views[b]					

(Continued)

TABLE 1 | Continued

Timing	Dissemination Action	Reach		Adopting			
		Potential		Eligible workplaces		Ineligible workplaces	
	Digital elements	**Reached/n[d]**	**Reached/n[e]**	**Workplaces/n[e]**	**Actions/n[e]**	**Workplaces/n[e]**	**Actions/n[e]**
	Paper elements	Sent out/*n*					
Dec-17	Letter, 5 × postcards and one magnet	1,079 nursing homes and 627 home care					
	Letter and 3 × postcard	98 different administrative departments of the municipalities					

Data collected per: [a]5 Apr 2017, [b]18 Dec 2018, and [c]3 Jan 2019 NA, not available [d]Number of followers/subscribed and [e]Number of reached/adopting workplaces/actions the day, the digital element occurred (Number of reached/adopting workplaces/actions the day, the activity occurred + the day after the digital element occurred), [f]Number of reached/adopting workplaces/actions the day, the dissemination activity occurred.

For digital elements, you can see the reach and adopting workplaces and actions for the day of the activity and the day after. For other dissemination elements, you can see the reach and adopting workplaces and actions.

TABLE 2 | Overview of where the survey-members have heard of the campaign.

Knowledge of the checklist (*N* = 1.168)

	N	**%**
Trade union (FOA)	681	58
OHS representative	400	34
Network	233	20
Colleagues	214	18
Website/newsletter	196	17
Brochure/flyer	83	7
Don't know/remember	79	7
The Sector-Specific Work Environment Community Organization for Public and Welfare workplaces	73	6
The Danish Working Environment Authority	47	4
Employer/sector association	46	4
Conference	31	3
Other	30	3
Answers	2.113	–

OHS, Occupational Health and Safety.

started (143 union members participated in the following three rounds and were excluded) and 152 had seen the diploma before the campaign started (123 union members participated in the following three rounds). Two months after the launch of the campaign 7,917 union members were invited to participate in the survey−2,891 answered (response rate 37%). Five months after the launch, 7,875 union members were again invited−2,877 answered (respond rate 37%). Finally, after the campaign finished (13 months after the launch), 8,399 union members were invited−3,055 answered (respond rate 36%). before, during and after the campaign, 5,118 unique union members participated in the survey. During and after the campaign, 4,692 unique union members answered the question. of these, 17% ($n = 754$), of the union members answered at least once, that they have gained knowledge of the checklist during the campaign and were considered reached. However, given that the total number of eldercare workers are ∼100,000, the reach of total eldercare workers in Denmark can be considered to be 0.8%. Two months after the launch of the campaign, 9% ($n = 252$) of the union members were reached. Five months after the launch, 13% ($n = 367$) of the union members were reached and after 13 months (after the campaign finished), 13% ($n = 380$) of the union members were reached.

In **Table 4**, characteristics of reached and non-reached union members are presented (characteristics from the first time the respondent was reached). Overall, the characteristics are similar. However, a higher (non-significant) proportion of the reached had a position of trust than the non-reached.

Implementation

Organizational Level

Of the 199 eligible workplaces (in total 230 accounts, meaning some workplaces created more than one account), that created an account on the website, 92 workplaces (46%) defined an action and 12 (13%) workplaces defined a second action. Overall 108 different actions were defined. However, a higher proportion of the users who created an account from ineligible workplaces defined an action, compared to users from eligible workplaces. **Table 5** shows the types of actions defined by eligible workplaces. The most common action was related to improvements in the physical surroundings and the least common action was change in the physical exposures.

Figure 4 shows how frequent workplaces checked that the implementation concept point was already in place or not, by the time the workplaces filled in the checklist. The three implementation concept points which were most frequently already in place by the time the workplaces filled in the checklist were "*does the supervisor support the action*?," "*does the action deal with what's* "*top of mind*" *among the employees*?" and "d*oes the action deal with an everyday problem*?" The two implementation concept points, which were most frequently not in place, was "h*ave you involved all relevant employees*?" and "h*ave resources been allocated?*"

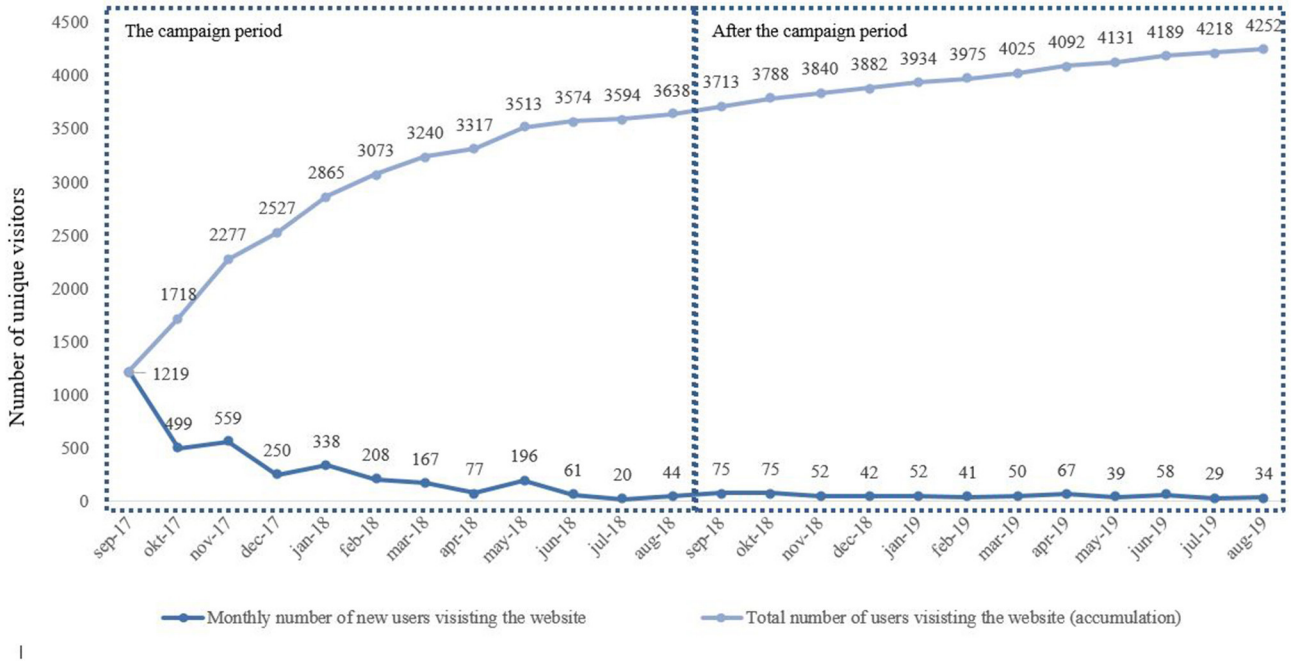

FIGURE 2 | Overview of the accumulated and monthly Danish visitors during the campaign period and after the campaign period.

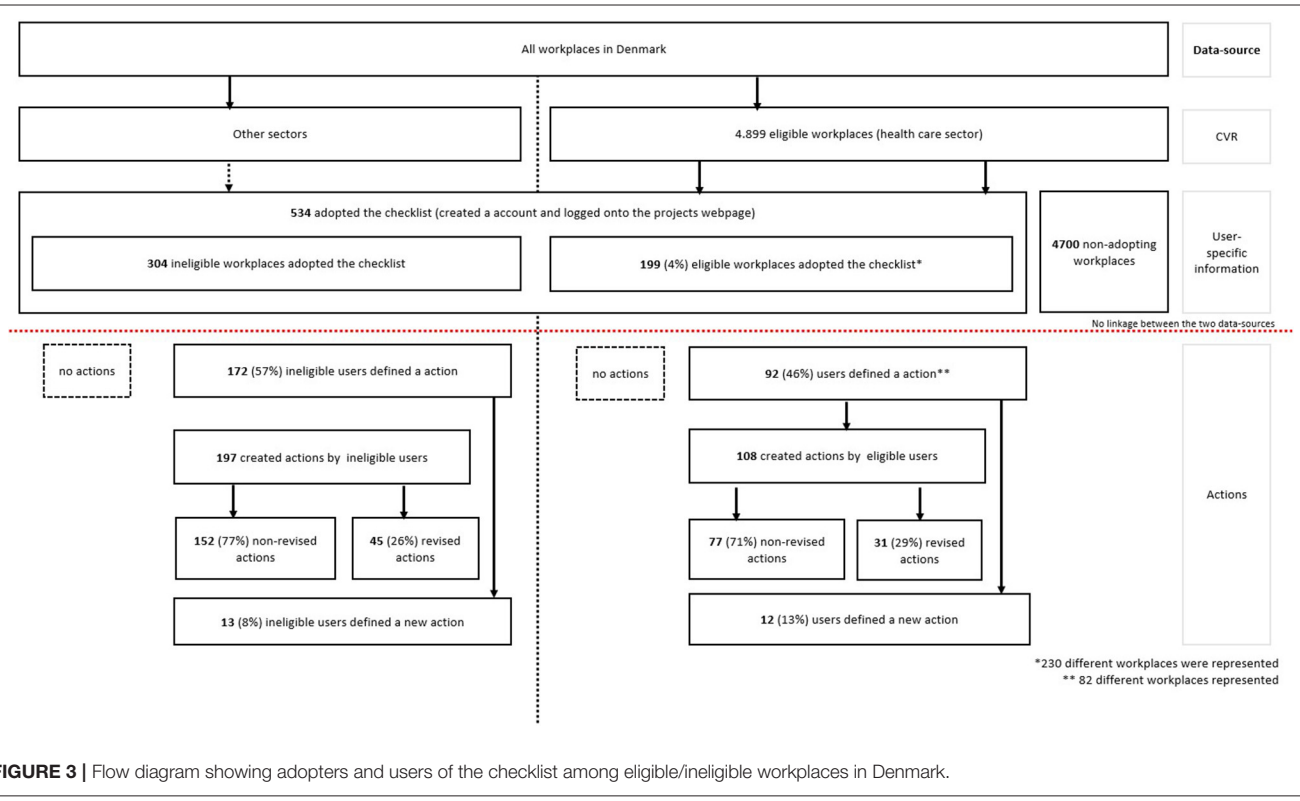

FIGURE 3 | Flow diagram showing adopters and users of the checklist among eligible/ineligible workplaces in Denmark.

Individual Level

Table 6 shows the distribution of printed diplomas, letters and tips by non-revised and revised actions. A higher proportion of users who revised their action printed the diploma, letter and tips, compared to the non-revised actions. During and after the campaign, 4,569 unique union members answered the question whether they had seen the diploma at their workplace. Of these, 17% ($N = 762$) answered at least once, that they had seen the

TABLE 3 | Characteristics of the workplaces who adopted and did not adopt the checklist.

Characteristic of the workplace	Adopting workplaces ($N = 199$)		Non-adopting workplaces ($N = 4,700$)		Differences adopting/non-adopting workplaces
Geographical position (regions)	***N***	**%**	***N***	**%**	***p*-value**
North Jutland	22	11	684	15	0.011
Central Jutland	40	20	1,060	23	
The Southern part of Denmark	44	22	1,058	23	
Zealand	30	15	849	18	
Capital	63	32	1,049	22	
Type of workplace (based on main sector)					0.000
Nursing home	88	44	1,001	22	
Home care	33	17	571	12	
Hospital	21	11	242	5	
24-h care center (mental disability)	22	11	1,048	23	
24-h care center (physical disability)	9	5	285	6	
24-h care center (children and young)	1	1	453	10	
Other	25	13	1,100	24	
Size of workplace (Employees)*					0.000
Small	62	35	2,257	65	
Medium	91	51	1,127	32	
Large	24	14	104	3	
Missing	22	–	1,212	–	
Size of workplace (fulltime employees)*					0.000
Small	83	47	2,610	75	
Medium	73	41	802	23	
Large	21	12	76	2	
Missing	22	–	1,212	–	
Workplace start-up					0.000
Before 2000	101	51	1,584	34	
2000–2010	44	22	1,191	25	
After 2010	54	27	1,925	41	

*in 2015

diploma at their workplace. Two months after the campaign started 8% ($N = 210$) had seen the diploma at their workplace, 5 months after the campaign started, 15% ($N = 429$) had seen the diploma at their workplace and after the campaign finished, 12% ($N = 343$) had seen the diploma at their workplace.

Maintenance

There were 31 (29%) of the actions that were revised (see **Figure 3**). Of the workplaces who defined an action, a higher proportion of the users who were employed at eligible workplaces returned to the website and defined a new action, compared to users from ineligible workplaces. From eligible workplaces a higher proportion of the users revised their action. For eligible workplaces who revised their action, 35% revised the action the same day, 20% revised their action within 1 week, 16% revised their action within 30 days (and more than 7 days), and the remaining 29% revised after 30 days (maximum 202 days after the action were created). **Table 5** shows revised actions defined by eligible workplaces.

Effectiveness

The unadjusted and adjusted (for gender and age) mean rating of the prioritization of the work environment for reached and non-reached union members, before the campaign started (baseline) and after the campaign, remained the same (0.35) and there was no significant group by time effect. However, there was a significant difference between the reached and non-reached union members. In general, reached union members were employed at workplaces, where the prevention of the work environment were prioritized to a higher degree, compared to non-reached union members (<0.001).

DISCUSSION

We evaluated the dissemination of a checklist for improving implementation of work environment initiatives in the Danish eldercare using the RE-AIM framework. One year after the launch of the campaign, almost all municipalities in Denmark

TABLE 4 | Characteristic of the Union (FOA) survey-members who were "reached" before the campaign started (and therefor excluded), reached during the campaign and not reached.

Characteristic of FOAs survey-members	Reached before the campaign started (*N* = 181)		Reached (*N* = 754)		Non-reached (*N* = 3.795)		Differences between reached/non reached
	N	%	*N*	%	*N*	%	*p*-value
Gender (women)	164	91	691	92	3.466	91	0.779
Age (years (SD years))	52.5 (9.0)		50.1 (10.2)		49.7 (10.3)		0.461
Manager (yes)	7	4	6	1	54	1	0.168
Position of trust							0.070
No position of trust	113	62	512	68	3,272	86	
Employee representative	43	24	121	16	318	8	
OHS representative	24	13	117	16	187	5	
OHS representative and employee representative	1	1	4	1	18	0	
Employer							0.116
Municipality or an self-governing institution	142	78	627	83	3.082	81	
Region	29	16	93	12	530	14	
Private/private resident	7	4	26	3	151	4	
State	1	1	0	0	5	0	
Other/don't know	2	1	7	1	24	1	
Missing	–	–	2	–	3	–	
Workplace							0.885
Nursing home	72	40	321	43	1,591	42	
Home care	48	27	210	28	1,083	29	
Hospital	22	12	58	8	339	9	
Other	39	22	165	22	782	21	

OHS, Occupational Health and Safety.
The number and percent or mean and standard deviation (SD) are presented.

TABLE 5 | Categories of actions and revised actions defined by eligible workplaces, listed according to frequency (high-low).

Action	Actions by eligible workplaces		Revised actions by eligible workplaces	
	N	%	*N*	%
Physical surroundings (e.g., use of assistive devices/reduce noise)	25	23	7	23
Physical exposure (e.g., reduce lift/awareness of pain)	11	10	5	16
Psychological exposure (e.g., reduce workload/no bullying)	14	13	6	19
Training during working hours (e.g., cardio/elastic training)	15	14	4	13
Organization (e.g., meeting/communication/collaboration/education/information)	20	19	4	13
Other (e.g., improve the work environment/starting different processes)	17	16	4	13
Not usable	6	6	1	3
Total	108	100	31	100

had visited the website (96%). Among all eligible workplaces, 4% of eligible workplaces actually adopted the checklist covering 8% of all nursing homes in Denmark. In the following, we will discuss whether this is a satisfying number of adopters, what affected the adoption percentage, and whether adopters succeeded with implementation.

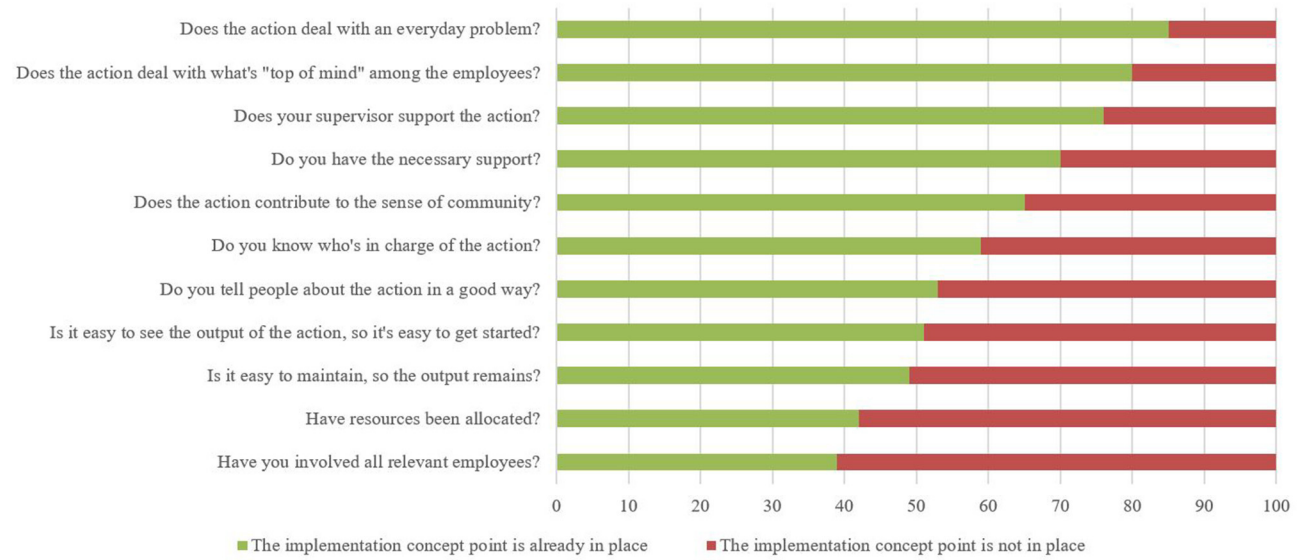

FIGURE 4 | The distribution of workplaces where the implementation concept point was already in place or not in place by the time they filled in the checklist by eligible workplaces (high to low).

TABLE 6 | Distribution of printed diploma, letter and tips by non-revised and revised actions by eligible workplaces.

	Non-revised actions ($n = 77$)		Revised actions ($n = 31$)	
	N	**%**	***N***	**%**
Print				
Diploma	36	47	26	84
Letter	15	19	12	39
Tips	29	38	15	48

The Impact of Different Dissemination Strategies

Due to several activities at the same time, it is not possible to isolate the impact of each activity separately. However, one of our main findings regarding dissemination of the checklist was that physical presence at workplaces, at sector-specific conferences and at meetings was an effective way to reach the target population. This is emphasized in our data, as the three municipalities adopting the checklist the most, are also the municipalities we visited the most during the campaign. Andersen and colleagues found that workplace visits affected the number of website visits that are in line with our findings (21). The strategy was that the OHS representatives and employee representatives at the workplaces would disseminate the knowledge about the checklist further to the rest of the employees in their respective workplaces (22). Our findings show, that we succeeded in doing this, as the trade union FOA and OHS representatives are the most frequent sources from which the respondents have heard of the checklist. Further, network and colleagues were the third and fourth highest ranked sources. This is in accordance with previous findings that the channels that intended audiences already trust and access for information is crucial (10). It seems like the dissemination strategy was successful in terms of covering Denmark geographically. A year after the campaign started, we succeeded in reaching 96% of the municipalities in Denmark.

Reached Eldercare Workers

The campaign reached 17% of the respondents from the union survey—this corresponds to a reach of 17,000 eldercare workers nationwide, if assuming that the survey is representative. Another national campaign in Denmark targeting public-sector employees with a mixture of networking activities, workplace visits, and a mass media outreach with topics related to job and body (e.g., musculoskeletal pain, movement and work), also reached 17% of their target population over a period of 3 years (21). Although previous findings also suggests that campaigns using internet and social media seem to reach workplace-based audiences, how to best reach the employees who are audiences for OHS information remains a challenge (23, 24).

Among the sample of reached employees, employees with a position of trust (OHS or employee representatives) were over-represented. Further, the reached employees were employed at workplaces where they reported the work environment to be more highly prioritized than non-reached employees reported. A highly prioritized work environment effort may indicate good organization around the work environment practice. The checklist is highly adaptable to fit in line with a well-organized and structural work environment practice, and this

may explain our reach of employees from workplaces with higher prioritization. For example, for the checklist to be useful, the workplaces should be quite aware what actions they aim to implement and why. Furthermore, previous studies have shown that workplace readiness for change is a strong indicator for a successful implementation of workplace health programs (25). A good work environment practice may also cultivate the readiness for change. To target workplaces where the work environment is less prioritized may require a special focus on preparation and creating organizational readiness to work with work environment issues and a special focus in the dissemination strategy.

Which Workplaces Use the Checklist and How?

The campaign disseminated the checklist to all regions in Denmark, and 199 workplaces adopted the checklist, corresponding to 4% of all eligible workplaces in Denmark. A special focus within the dissemination strategy was the nursing homes. Of 1,089 nursing homes, 88 nursing homes adopted the checklist, and corresponding to 8%.

While 4% is a low fraction, we consider 199 workplaces and 8% of all nursing homes in Denmark in action after a campaign quite a success. If all 199 workplaces get an actual output of the checklist, this is likely to affect ∼4,000 employees' work environment positively. Considering the fact that the campaign was merely motivating—with no incitements or legal requirements, and the fact that it was a relatively low financed campaign merely financed by research funding, the dissemination and workplace adoption rate was successful. It is even likely, that having continued the intense campaign of the first 3 months for a longer period, and supporting this with more good examples of implementation, could have increased dissemination further. However, the biggest issue regarding gaining impact of this campaign does not seem to be the dissemination—but in the implementation and maintenance.

Developing both the content and the concept of the checklist with much user and stakeholder involvement, higher implementation rates than 46% of the adopters could likely have been expected. Furthermore, a relatively low number of the adopters (13%) used the checklist twice, indicating, that the incentives for returning to the checklist were not strong enough. However, we have data showing that the use of the checklist was broad in scopes [both physical and psychosocial work environment challenges were addressed (see **Table 5**)] and the workplaces generally reported to be lacking several of the implementation concept points to reach full implementation, both of which may explain the relatively low implementation rate. Regarding the broadness in scope,—this is in line with the aim of the checklist a possible explanation for this is the complexity of multiple work demands resulting in many different work environment challenges. Rasmussen et al. (26) find a similar trend among the same target population. Regarding the implementation concept points lacking among the users, most actions were supported by the supervisor, in line with what was "top on mind" among employees and dealt with an everyday problem (27, 28). These are three highly relevant implementation concept points to cover early in an implementation process. Particularly the implementation concept point of supervisor support has been shown to be important for implementation of workplace initiatives (20, 29). However, to become successful with the implementation of a new action it is important to work with all 11 implementation concept points (19), and none of the workplaces had all implementation concept points covered. Still, the majority of the adopters did not return to the checklist. One reason may be that they did cover the remaining implementation concept points after the first usage of the checklist, but did not have the incitements to fill in the checklist again. Another potential explanation for the lack of returning users may be found in those implementation concept points that the workplaces generally did not cover by the first time of usage. For example, lack of resources allocated was one of the most frequent implementation concept points not dealt with by the first usage. Lack of resources may disrupt the entire progress of the implementation and thus explain the low number of returning users (30). Another implementation concept point with low coverage was the involvement of all relevant employees (31). Involvement of many employees in participatory processes is shown to be highly demanding on organizations and may have disrupted further implementation (26). Overall, it is likely, that some workplaces found usage of the checklist and actually obtained the implementation, they expected. However, it is also likely, that some implementation processes were disrupted due to the checklist making the workplaces aware of the high demands for implementation of new habits. Ultimately, the checklist may help workplaces quit unrealistic actions and focus on smaller, more implementable actions.

What Is the Effectiveness?

Considering the relatively low implementation of the checklist, it would be unrealistic to expect a large effect. Furthermore, those who were reached by the campaign scored higher at baseline on the prioritization of the work environment compared to those not reached. At follow-up, both groups reported a non-significant decrease in prioritization of the work environment. Data from a national Danish work environment survey conducted in 2012, 2014, 2016, and in 2018 also reporting the prioritizing of the work environment from the eldercare sector indicate the same overall decreasing of the prioritizing in the period (32). Overall, it is challenging to disentangle the effect of behavioral interventions in observational designs, as the effectiveness and *real life* impact of the intervention (in this project the effect of using the checklist in implementing new routines in the work environment) is highly sensitive to so many factors that cannot be directed in an evaluation, particularly not when implementation is low.

Strengths and Limitations

We used all five components in the RE-AIM framework to evaluate the impact of the checklist, which is a strength of the study. Evaluation of a dissemination project like this is complex, and therefore the RE-AIM framework was the best suited framework for guiding the evaluation. Because of the complexity it is difficult to separate the effect of all the activities

and therefore the overall impact as stated earlier is also difficult to highlight as one final quantity. A strength of the study was the systematic dissemination strategy using a large variation of dissemination channels, and to ensure a sustainable change we involved a broad range of relevant stakeholders in the eldercare sector. The involvement of stakeholder resulted in a large support for the campaign activities, large dissemination, but insufficient implementation. Finally, another strength of this study was the use of multiple data sources not only using self-reported data.

Limitations are that we were unable to evaluate "offline" usage of the checklist, which was also part of the campaign. Furthermore, campaign intensity was highest in the first 3 months and the evaluation time was only 12 months. Prolonging the intense campaign activities and the evaluation period and supporting the maintenance/returning users would have increased the relevance of effect evaluation and a more full impact evaluation. Another limitation is, that the many different dissemination strategies couldn't be measured. This could have actually made the results appear less robust than they might have been. A limitation for adoption, is that we could not connect all 534 accounts to a specific workplace to see whether they all were eligible workplaces. So this means that our adoption might be underestimated. In addition to this, users who are reported as reached could actually also be those who are reported in adoption. Adoption is meant to represent organizational uptake of the tool. However, with one registered user in one organization, the data cannot reveal whether the user represents the entire organization (i.e., cooperating with other members of the health and safety organization) or if the user operates singlehandedly. This means that our measure of adoption may be biased—both possibly underestimated because all users couldn't be matched to a certain workplace, but also likely overestimated as a measure of adoption, because some users may not have implemented the tool organizationally. Our study of adoption should therefore be considered in the light of this limitation.

Implications

This study contributes to the field of research to practice or knowledge translation. First, it constitutes an example of how to disseminate and translate research knowledge to a relatively large fraction of the nursing homes in Denmark. Furthermore, it gives input on what the implementation concept points that may hinder implementation in the eldercare workplaces are. Finally, it maps out useful communication channels in the sector and topics for action that are top of mind in the adopting workplaces. Disemmination strategies are difficult to track and measure. Future research should consider innovative ways to track user-journeys between dissemination efforts and usage, i.e., through interviews of the users or by various kinds of digital footprints.

CONCLUSION

In conclusion, this study shows that a 1-year stakeholder-supported national campaign can disseminate knowledge to a large number of workplaces in the Danish eldercare sector. Useful dissemination channels are those, which the target population already trusts, and access for information. Implementation of the checklist was not satisfactory, and good implementation may require a certain level of organizational readiness for change. Usage of the checklist may reveal that implementation is more demanding than expected by Danish eldercare workplaces.

DATA AVAILABILITY STATEMENT

The datasets generated for this study are available on request to the corresponding author.

INFORMED CONSENT

By law, no informed consent is needed when using survey data.

ETHICS STATEMENT

Ethical review and approval was not required for the study on human participants in accordance with the local legislation and institutional requirements. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

AUTHOR CONTRIBUTIONS

PM handled the data and did the analyses, drafted the first version of the manuscript, and wrote the final version of the manuscript. MJ acquired funding for the project, designed the study, and participated in discussions around the study, and critically revised the manuscript. HH designed the study and participated in discussions around the study, and critically revised the manuscript. CR acquired funding for the project, designed the study, and critically revised the manuscript. All authors have read and approved the manuscript. All authors contributed to the article and approved the submitted version.

FUNDING

This study was funded by the Danish Working Environment Research Fund (33-2016-03 20165101121). The funders had no role in study design, data Collection and analysis, decision to publish, or preparation of the manuscript.

ACKNOWLEDGMENTS

The authors thank Peter Rasmus Hendriksen, MSc, for his contribution with data extraction in Google Analytics, and all the involved stakeholders and workplaces who contributed to the development and dissemination of the checklist in the study. Also, the authors thank the scientific advisory board consisting of Richard H. Osborne, Lydia Kwak, Irene Jensen, Laura Linnan, and Ole Henning Sørensen. Further, we want to give a special thank to the Trade Union FOA who provided us with data from their member survey.

REFERENCES

1. Campbell JDG, Buchan J, Pozo-Martin F, Guerra Arias M, Leone C, Siyam A, et al. *A Universal Truth: No Health Without a Workforce*. Forum Report TGFoHRfH, editor: Geneva, Global Health Workforce Alliance and World Health Organization (2013).
2. Andersen L, Villadsen E, Clausen T. Influence of physical and psychosocial working conditions for the risk of disability pension among healthy female eldercare workers: prospective cohort. *Scand J Public Health.* (2019) 48:460–7. doi: 10.1177/1403494819831821
3. Larsen AK, Holtermann A, Mortensen OS, Punnett L, Rod MH, Jorgensen MB. Organizing workplace health literacy to reduce musculoskeletal pain and consequences. *BMC Nurs.* (2015) 14:46. doi: 10.1186/s12912-015-0096-4
4. Aust B, Rugulies R, Finken A, Jensen C. When workplace interventions lead to negative effects: learning from failures. *Scand J Public Health.* (2010) 38(3 Suppl):106–19. doi: 10.1177/1403494809354362
5. Nielsen K. Review article: how can we make organizational interventions work? Employees and line managers as actively crafting interventions. *Hum Relat.* (2013) 66:1029–50. doi: 10.1177/0018726713477164
6. Rasmussen CD, Holtermann A, Mortensen OS, Sogaard K, Jorgensen MB. Prevention of low back pain and its consequences among nurses' aides in elderly care: a stepped-wedge multi-faceted cluster-randomized controlled trial. *BMC Public Health.* (2013) 13:1088. doi: 10.1186/1471-2458-13-1088
7. Robroek SJ, van Lenthe FJ, van Empelen P, Burdorf A. Determinants of participation in worksite health promotion programmes: a systematic review. *Int J Behav Nutr Phys Act.* (2009) 6:26. doi: 10.1186/1479-5868-6-26
8. Dugan AG, Punnett L. Dissemination and implementation research for occupational safety and health. *Occup Health Sci.* (2017) 1:29–45. doi: 10.1007/s41542-017-0006-0
9. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci.* (2009) 4:50. doi: 10.1186/1748-5908-4-50
10. Leeman J, Birken SA, Powell BJ, Rohweder C, Shea CM. Beyond "implementation strategies": classifying the full range of strategies used in implementation science and practice. *Implement Sci.* (2017) 12:125. doi: 10.1186/s13012-017-0657-x
11. McCormack L, Sheridan S, Lewis M, Boudewyns V, Melvin CL, Kistler C, et al. Communication and dissemination strategies to facilitate the use of health-related evidence. *Evidence Rep Technol Assess.* (2013) 213:1–520. doi: 10.23970/AHRQEPCERTA213
12. Glasgow R, Vogt T, Boles S. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health.* (1999) 89:1322–7. doi: 10.2105/AJPH.89.9.1322
13. Glasgow RE. eHealth evaluation and dissemination research. *Am J Prev Med.* (2007) 32(5 Suppl):S119–26. doi: 10.1016/j.amepre.2007.01.023
14. Cocker K, Cardon G, Bennie JA, Kolbe-Alexander T, Meester F, Vandelanotte C. From evidence-based research to practice-based evidence: disseminating a web-based computer-tailored workplace sitting intervention through a health promotion organisation. *Int J Environ Res Public Health.* (2018) 15:1049. doi: 10.3390/ijerph15051049
15. Van Acker R, De Bourdeaudhuij I, De Cocker K, Klesges LM, Cardon G. The impact of disseminating the whole-community project '10,000 Steps': a RE-AIM analysis. *BMC Public Health.* (2011) 11:3. doi: 10.1186/1471-2458-11-3
16. Carlfjord S, Andersson A, Bendtsen P, Nilsen P, Lindberg M. Applying the RE-AIM framework to evaluate two implementation strategies used to introduce a tool for lifestyle intervention in Swedish primary health care. *Health Promot Int.* (2012) 27:167–76. doi: 10.1093/heapro/dar016
17. Farris RP, Will JC, Khavjou O, Finkelstein EA. Beyond effectiveness: evaluating the public health impact of the WISEWOMAN program. *Am J Public Health.* (2007) 97:641–7. doi: 10.2105/AJPH.2005.072264
18. Rasmussen CDN, Højberg H, Larrsen AK, Munch PK, Osborne R, Kwak L, et al. Evaluation and dissemination of a checklist to improve implementation of work environment initiatives in the eldercare sector: Protocol for a prospective observational study. *JMIR Res. Protoc.* (2020) 9:e16039. doi: 10.2196/16039
19. Hojberg H, Rasmussen CDN, Osborne RH, Jorgensen MB. Identifying a practice-based implementation framework for sustainable interventions for improving the evolving working environment: hitting the moving target framework. *Appl Ergonomics.* (2018) 67:170–7. doi: 10.1016/j.apergo.2017.10.001
20. Jeon YH, Luscombe G, Chenoweth L, Stein-Parbury J, Brodaty H, King M, et al. Staff outcomes from the caring for aged dementia care resident study (CADRES): a cluster randomised trial. *Int J Nurs Stud.* (2012) 49:508–18. doi: 10.1016/j.ijnurstu.2011.10.020
21. Andersen LL, Geisle N, Knudsen B. Can beliefs about musculoskeletal pain and work be changed at the national level? Prospective evaluation of the Danish national Job & Body campaign. *Scand J Work Environ Health.* (2018) 44:25–36. doi: 10.5271/sjweh.3692
22. Hasle P, Seim R. New roles for the OHS representatives - from employee representation to problem-solving. In: Broberg O, Fallentin N, Peter H, Jensen PL, Kabel A, Larsen ME, editors. *Proceedings : 11th International Symposium on Human Factors in Organisational Design and Management (ODAM) & 46th Annual Nordic Ergonomics Society (NES) Conference*. Copenhagen: International Energy Agency, IEA (2014).
23. Sublet V, Spring C, Howard J. Does social media improve communication? *Evaluating the NIOSH science blog. Am J Ind Med.* (2011) 54:384–94. doi: 10.1002/ajim.20921
24. Hudson H, Hall J. Value of social media in reaching and engaging employers in Total Worker Health. *J Occup Environ Med.* (2013) 55(12 Suppl):S78–81. doi: 10.1097/JOM.0000000000000035
25. O'Connor EJ, Fiol CM. Creating readiness and involvement. *Physician Exec.* (2006) 32:72–4.
26. Rasmussen CDN, Lindberg NK, Ravn MH, Jorgensen MB, Sogaard K, Holtermann A. Processes, barriers and facilitators to implementation of a participatory ergonomics program among eldercare workers. *Appl Ergonomics.* (2017) 58:491–9. doi: 10.1016/j.apergo.2016.08.009
27. Barbosa A, Nolan M, Sousa L, Figueiredo D. Supporting direct care workers in dementia care: effects of a psychoeducational intervention. (2015) 30:130–8. doi: 10.1177/1533317514550331
28. Figueiredo D, Barbosa A, Cruz J, Marques A, Sousa L. Empowering staff in dementia long-term care: towards a more supportive approach to interventions. *Educ Gerontol.* (2013) 39:413–27. doi: 10.1080/03601277.2012.701105
29. Jeon YH, Simpson JM, Li Z, Cunich MM, Thomas TH, Chenoweth L, et al. Cluster randomized controlled trial of an aged care specific leadership and management program to improve work environment, staff turnover, and care quality. *J Am Med Dir Assoc.* (2015) 16:629.e19–28. doi: 10.1016/j.jamda.2015.04.005
30. Baumann A, Holness DL, Norman P, Idriss-Wheeler D, Boucher P. The Ergonomic Program Implementation Continuum (EPIC): integration of health and safety–a process evaluation in the healthcare sector. *J Safety Res.* (2012) 43:205–13. doi: 10.1016/j.jsr.2012.07.003
31. van der Meer EW, Boot CR, Twisk JW, Coenraads PJ, Jungbauer FH, van der Gulden JW, et al. Hands4U: the effectiveness of a multifaceted implementation strategy on behaviour related to the prevention of hand eczema-a randomised controlled trial among healthcare workers. *Occup Environ Med.* (2014) 71:492–9. doi: 10.1136/oemed-2013-102034
32. The National Research Center for the Working Environment. Occupational safety and health in Denmark (2018). Available online at: https://arbejdsmiljodata.nfa.dk/

Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

frontiers in Public Health

ORIGINAL RESEARCH
published: 14 May 2020
doi: 10.3389/fpubh.2020.00171

The Faith, Activity, and Nutrition (FAN) Dissemination and Implementation Study: 24-Month Organizational Maintenance in a Countywide Initiative

Sara Wilcox[1,2*], *Ruth P. Saunders*[1,3], *Danielle Jake-Schoffman*[4] *and Brent Hutto*[1]

[1] *Prevention Research Center, Arnold School of Public Health, University of South Carolina, Columbia, SC, United States,* [2] *Department of Exercise Science, Arnold School of Public Health, University of South Carolina, Columbia, SC, United States,* [3] *Department of Health Promotion, Education, and Behavior, Arnold School of Public Health, University of South Carolina, Columbia, SC, United States,* [4] *Department of Health Education and Behavior, College of Health and Human Performance, University of Florida, Gainesville, FL, United States*

OPEN ACCESS

Edited by:
Matthew Lee Smith, Texas A&M University, United States

Reviewed by:
Pradeep Nair, Central University of Himachal Pradesh, India
Junfeng Wang, University of Illinois at Springfield, United States

***Correspondence:**
Sara Wilcox
wilcoxs@mailbox.sc.edu

Specialty section:
This article was submitted to Public Health Education and Promotion, a section of the journal Frontiers in Public Health

Received: *29 January 2020*
Accepted: *20 April 2020*
Published: *14 May 2020*

Citation:
Wilcox S, Saunders RP, Jake-Schoffman D and Hutto B (2020) The Faith, Activity, and Nutrition (FAN) Dissemination and Implementation Study: 24-Month Organizational Maintenance in a Countywide Initiative. Front. Public Health 8:171. doi: 10.3389/fpubh.2020.00171

Introduction: Despite the important role that faith-based organizations can play in eliminating health disparities, few studies have focused on organizational change and maintenance of interventions in this setting, making their long-term impact unknown. This study reports 24-month maintenance of the Faith, Activity, and Nutrition (FAN) program in a southeastern county. Previously reported findings of reach, adoption, implementation, and effectiveness are also summarized.

Methods: Church coordinators from 35 intervention churches (97% predominantly African American) located in a rural, medically underserved county in South Carolina were interviewed at baseline (2015), and 12- and 24-months post-training regarding implementation of physical activity (PA) and healthy eating (HE) components of the FAN program. Guided by the RE-AIM framework, organizational maintenance was defined as church coordinator-reported 24-month implementation of the four FAN components (providing opportunities, setting guidelines/policies, sharing messages, engaging pastor). Repeated measures analyses (mixed models) examined change in implementation over time. Churches were also classified as maintainers, non-sustained implementers, and low implementers for each FAN component. Statistical analyses were conducted in 2019.

Results: Church coordinators reported significantly greater implementation of both PA and HE FAN components at 12 and 24 months compared to baseline (medium to large effects). The percentage of churches classified as maintainers ranged from 21 to 42 and 27 to 94% across PA and HE components, respectively. Most churches (58% for PA, 97% for HE) were maintaining at least one FAN component at 24 months.

Conclusions: These promising findings position FAN well for the national implementation study now underway.

Trial Registration: This study is registered at www.clinicaltrials.gov NCT02868866.

Keywords: RE-AIM, physical activity, nutrition, community, faith-based, maintenance, sustainability

INTRODUCTION

Most U.S. adults (70.6%) report a Christian affiliation, and around 36% report attendance at religious services at least once per week (1, 2). Faith-based settings are a viable setting for health promotion efforts, but a number of gaps in the literature limit the ability to scale-up programs for wider dissemination. For example, only 9% of studies in a recent review reported implementation fidelity (3), and studies examining the sustainability or maintenance of intervention effects are rare. Furthermore, most interventions focus on individual rather than organizational (church) level outcomes. Faith, Activity, and Nutrition (FAN) is an evidence-based program designed to help churches make policy, systems, and environmental change to support physical activity (PA) and healthy eating (HE). Based on its significant impact on improving church attendees' PA and dietary change, FAN is indexed in the National Cancer Institute's Research Tested Intervention Programs (4) and is cited as a promising intervention in the Rural Health Information Hub (5). Most recently we undertook the FAN dissemination and implementation (D&I) study in two phases. In the first phase of the FAN D&I study, we partnered with a county coalition to offer FAN to all churches in a county in South Carolina. In the second phase of the FAN D&I study, we partnered with a large religious denomination and offered FAN to all churches of that denomination in the state. Phase 1 is the focus of this paper.

The FAN D&I study was guided by the RE-AIM framework (6). Phase 1 of the study included an examination of each component of the framework. The primary goal of this paper is to report the 24-month maintenance of FAN in intervention churches participating in Phase 1. A secondary goal of the paper is to summarize previously published findings from the other RE-AIM components in Phase 1—reach, effectiveness, adoption, and implementation—so that readers have a full understanding of how the full RE-AIM framework was applied in this study and the major findings. The reader is referred to previous papers for more details regarding adoption, reach, effectiveness, and 12-month implementation of FAN; (7, 8) recruitment, training, and implementation of the trainings and technical assistance by community health advisors; (9) and barriers and facilitators to 12-month implementation (10).

MATERIALS AND METHODS

Design

Phase 1 of the FAN D&I study was a group-randomized trial and an academic-community partnership (7). The study was conducted in Fairfield County, South Carolina (23,956 residents) (11), a medically underserved and health professional shortage area (12). A high proportion of residents are Black/African American (59.1%), and 21.2% of residents live in poverty (11, 13).

All churches ($N = 132$) in the county were invited to participate in the study. Enrolled churches ($N = 59$) were randomized to either an intervention ($n = 39$) or control (delayed intervention, $n = 20$) condition. The delayed intervention control churches were trained 12-months after intervention churches were trained and after effectiveness measurements were taken. This delayed treatment design allowed us to compare intervention to control churches on 12-month implementation and effectiveness. This design was also deemed acceptable by the community who viewed 1 year as a realistic time to wait for the full training. However, because the delayed intervention control group was trained and had 1 year of implementation at the 24-month follow up assessment, it was not possible to compare intervention to true control churches at 24 months. As a result, this paper examines whether the implementation outcomes seen at 12 months, which were significantly different than measurements taken at 12 months in control churches, were maintained in the intervention churches at the 24-month assessment. As reported elsewhere (7), 97% of intervention churches had predominantly Black/African American members, 42% had <50 regular attendees, and the most common religious denominations were Baptist (46%), non-denominational or independent (26%), AME/AME Zion (11%), and Pentecostal (8%).

FAN Intervention

FAN is an evidence-based program that helps churches to create policy, systems, and environmental changes to support increased PA and HE in members. It was developed using a community-based participatory research approach in which church leaders, church lay representatives, and university staff and faculty collaborated to develop, implement, and evaluate the program (14). Guided by Cohen's structural model of health behavior (15), FAN's four structural components are to provide opportunities, set guidelines (policies), engage pastors, and share messages for PA and HE. As described elsewhere (7, 8), the university collaborated with community organizations in Fairfield County, SC to identify and train community health advisors who, in turn, delivered trainings, and provided technical assistance to churches (9).

Each participating church formed a committee, led by a church coordinator (liaison with the research staff and responsible for coordinating the implementation efforts in the church). Church committees attended a 1 day training where they were guided through an active "assessment and planning" process that was organized according to the four structural components of FAN. While there was a set of activities that all churches were asked to implement (i.e., distribute bulletin inserts or handouts, share messages during worship services about PA and HE, distribute educational materials, create a FAN bulletin board to display PA and HE materials to congregants, and suggest guidelines/policies that the pastor could set), churches had flexibility to choose specific activities within each of the structural components so that the activities matched the culture, norms, and preferences of their congregations. Each church committee created and submitted a plan and budget for how program components would be implemented in their church (this plan was started during the in-person training), and implemented the program in their church over the next 12 months with technical assistance from a community health advisor. Trainings, technical assistance, and program materials emphasized the scriptural relevance of physical health from a Christian tradition without reference to specific denominations or doctrines.

Community health advisors provided brief monthly telephone support for 12 months after training (4 calls to the pastor, 8 calls to the church coordinator). Research staff also emailed the pastor and church coordinator monthly program materials, provided at training, as a reminder to use them. Near the end of the first year of the study, the community health advisor encouraged churches to create a revised plan for implementing FAN activities in the upcoming year. The core set of activities described previously (e.g., distributing bulletin inserts or handouts) remained the same, but consistent with the underlying philosophy and approach of FAN, and consistent with the assessment and planning process used during training, churches were encouraged to assess what was working well, what could be improved, and what was not working with regard to increasing opportunities, messages, pastor support, and setting guidelines (policies) for PA and HE, and to make necessary adjustments to meet these goals and also keep their activities fresh and engaging for members. This consistency over time in approach and intervention components and goals ensured that churches adhered to the essential program elements. During the second year of the program, research staff emailed the pastor and church coordinator once per month with new materials to share with their congregations (a bulletin insert that tied a health message to Scripture, educational materials, and a website).

Data Collection Procedures

We collected implementation data from church coordinators, rather than conducting on-site observations, for two main reasons. First, the logistics of collecting data on-site for such a large number of participating churches were prohibitive. Second, components of our ecological intervention were meant to be embedded before, during, and after church events and meetings, making it very difficult to capture the range of activities over a period of even a week during an on-site observation. It is noteworthy that member reports of the church environment were quite consistent with reports from church coordinators in our examination of 12-month implementation (7, 8), making us confident in the validity of church coordinator reports.

Baseline, 12, and 24-month telephone interviews with church coordinators were conducted by the Survey Research Laboratory at the University of South Carolina using a computer-aided telephone interviewing system. Interviewers received specialized training for this study prior to data collection. Interviews were conducted from September 2 to October 28, 2015 at baseline; September 6 to November 3, 2016 at 12 months; and September 21 to December 19, 2017 at 24 months. Three out of 39 intervention churches did not attend training and one additional intervention church withdrew after training. Twelve-month interviews were conducted with 35 (89.7%) church coordinators. Twenty-four-month interviews were conducted with 33 (84.6%) church coordinators. At 24 months, three of these were completed via a paper-and-pencil survey because the church coordinators were not available for a telephone interview.

Measures

Implementation measures of the FAN components (15) were based on the guiding conceptual model (8) and were adapted from the implementation measures used in our prior FAN study (16). All measures were reviewed by community partners to ensure clarity and acceptability. PA implementation was assessed with 10 items-−1 for guidelines (policies), 4 for opportunities (2 focused on integrating PA into existing church events, 1 on offering PA programs, and 1 on sharing information about free or low-cost PA opportunities in the community), 1 for pastor support (sharing messages during services), and 4 for messages (church bulletins, bulletin board, person other than pastor sharing messages during services, sharing messages at church meetings, and events). HE implementation was assessed with 9 items-−2 for guidelines (policies) (fruit and vegetables), 2 for opportunities (fruit and vegetables), 1 for pastor support (sharing messages during services), and 4 for messages (same channels as described for PA). Mean scores were calculated for multi-item scales, and composite scores for PA and HE were computed, each representing the average of the four components. Each item was rated on a 4-point Likert scale, where, depending on the question, 1 indicated "rarely or never" or "not at all," 2 indicated "very little" or "every few months," 3 indicated "some of the time" or "about monthly," and 4 indicated "almost all of the time" or "about weekly." For the guideline (policy) questions, a score of 3 indicated that the guideline was partially in place whereas a 4 indicated it was fully in place.

The criteria for evidence of acceptable implementation (12 months) was set a priori at 3 or 4 out of 4. Although we did not set an a priori criteria of acceptable implementation for maintenance (24 months), for the current analysis we use the same level of evidence as we did for 12 months (i.e., 3 or 4 out of 4).

For each of the four components, churches were categorized as maintainers if they met the criteria for maintenance at 24 months, non-sustained implementers if they met the criteria for implementation at 12 months but were below the criteria for maintenance at 24 months, and low implementers if they were below the criteria for implementation at 12 months and below the criteria for maintenance at 24 months.

Data Analyses

We tested differences in implementation scores among early intervention churches over time with repeated measures regression models using mixed linear models (SAS PROC MIXED). When the time effect was significant, we examined pairwise least square mean differences from baseline to 12 months, baseline to 24 months, and 12 to 24 months. We calculated effect sizes (Cohen's *d*) from baseline to 12 months and baseline to 24 months. We also categorized the pattern of meeting implementation and maintenance criteria for each church over time, and described the proportion of churches classified as maintainers, non-sustained implementers, and low implementers for each intervention component. Finally, we reported the percentage of churches maintaining four, three, two, one, or zero of the structural components of FAN for PA and HE, and the percentage of churches who either maintained or improved relative to baseline for four, three, two, one, or zero of these components.

RESULTS

Reach, Adoption, Implementation, and Effectiveness

Phase 1 reach, adoption, implementation, and effectiveness results have been published in prior papers. The results are summarized here so that readers have a fuller understanding of how the full RE-AIM framework was applied in this study and the key findings.

Reach and Adoption

All 132 churches in the county were invited to participate in the study. As reported previously (7), FAN was adopted by 42% of these churches and reached at least 42% of regular church attendees and at least 15% of residents in the county. Churches with predominantly black/African American congregations and those who participated in an earlier tobacco-free county initiative were significantly more likely to adopt FAN. Church size and church denomination were not related to adoption. When compared to county-level data, the sample of church attendees from adopting churches were more likely to be 65 years of age or older, obese, women, and African American.

Implementation

Implementation in this study was studied at two levels. First, we studied the fidelity of delivering the intervention to the church committees (9). Second, we studied the degree to which church committees implemented the intervention (FAN) as intended in their churches (7, 8).

Three community health advisors were recruited and trained to deliver the church committee trainings and technical assistance calls to church coordinators and pastors, and a paper describing this process and findings is available (9). One community health advisor resigned prior to implementing any of the duties due to unforeseen scheduling conflicts. The remaining two community health advisors trained 142 church committee members from 36 intervention churches and 60 church committee members from 18 control churches. In the post-training evaluation, church committees positively rated how well the training prepared them to put the program into place. University staff who observed the trainings rated nearly complete coverage of all content areas and rated factors such as the community health advisors' ability to engage participants very positively. A high percentage of calls (>90%) were delivered, and calls averaged around 7 min in duration (9). Thus, fidelity to delivering the intervention was high.

Two papers have reported the churches' 12-month implementation of the four structural components of FAN (7, 8). In a sample of 1,308 church members (811 from intervention and 497 from control churches), members from intervention churches reported significantly greater implementation then members from control churches of PA opportunities, PA and HE messages, and pastor support for PA and HE at 12-months, with implementation of HE opportunities approaching statistical significance (7). The magnitude of these differences was large, ranging from d = 0.96 to 1.22. Consistent with member reports, church coordinators from intervention churches also reported significantly greater changes from baseline to 12 months in implementation than church coordinators from control churches for PA opportunities, PA and HE messages, pastor support for PA and HE, and guidelines for PA and HE (8). The magnitude of differences in these changes ranged from d=0.50 to 1.60 (except for opportunities for vegetables which did not differ over time by group as both groups scored high at baseline).

Effectiveness

Finally, the effectiveness of the intervention on member outcomes has been reported (7). Surveys conducted with members of intervention (n = 811) and control churches (n =

TABLE 1 | Change in physical activity and healthy eating implementation from baseline to 12 months and baseline to 24 months (N = 39 churches).

	LSM (SE)				Effect size (d)		*p* values			
	BL	12 M	24 M	BL SD	BL-12 M	BL-24 M	Time	BL-12 M	BL-24 M	12–24 M
PHYSICAL ACTIVITY										
Composite score	1.70 (0.10)	2.77 (0.10)	2.24 (0.11)	0.52	2.04	1.02	<0.0001	<0.0001	<0.0001	<0.0001
Guidelines	1.95 (0.16)	2.83 (0.17)	2.27 (0.17)	0.75	1.18	0.43	<0.0001	<0.0001	0.0539	0.0012
Opportunities	1.81 (0.10)	2.71 (0.11)	2.31 (0.11)	0.66	1.35	0.75	<0.0001	<0.0001	0.0002	0.0024
Pastor support	1.49 (0.14)	2.84 (0.14)	2.24 (0.15)	0.76	1.79	0.99	<0.0001	<0.0001	<0.0001	0.0009
Messages	1.59 (0.12)	2.70 (0.12)	2.12 (0.12)	0.72	1.54	0.74	<0.0001	<0.0001	<0.0001	<0.0001
HEALTHY EATING										
Composite score	2.30 (0.09)	3.15 (0.09)	2.72 (0.09)	0.55	1.56	0.77	<0.0001	<0.0001	<0.0001	<0.0001
Guidelines	2.27 (0.16)	3.23 (0.17)	2.83 (0.17)	0.87	1.10	0.65	<0.0001	<0.0001	0.0014	0.0252
Opportunities	3.31 (0.11)	3.59 (0.11)	3.56 (0.11)	0.71	0.40	0.35	<0.0001	0.0003	0.0016	0.6774
Pastor support	1.82 (0.14)	2.87 (0.15)	2.18 (0.15)	0.90	1.17	0.40	<0.0001	<0.0001	0.0441	0.0003
Messages	1.79 (0.12)	2.86 (0.12)	2.28 (0.12)	0.78	1.37	0.63	<0.0001	<0.0001	0.0003	<0.0001

LSM, least square mean; SE, standard error; BL, baseline; 12 M, 12 months; 24 M, 24 months; SD, standard deviation.

Results are from a repeated measures analysis. Possible scores for each area of implementation can range from 1 to 4, with 4 indicating greater implementation. Cohen's d calculated as 12-month (24-month) least square mean minus baseline least square mean divided by baseline standard deviation.

TABLE 2 | Baseline, 12 and 24-month implementation scores and church categorization of 24-month maintenance status for physical activity components.

	Guidelines				Opportunities				Pastor Support				Messages			
Church	**BL**	**12 M**	**24 M**	**Cat**	**BL**	**12 M**	**24 M**	**Cat**	**BL**	**12 M**	**24 M**	**Cat**	**BL**	**12 M**	**24 M**	**Cat**
A	2.00	**3.00**			1.75	2.50			1.00	2.00			1.00	1.75		
B	2.00	**3.00**	**3.00**	M	1.75	2.50	2.25	LI	2.00	**3.00**	2.00	NSI	1.50	2.50	2.00	LI
C	1.00	2.00	1.00	LI	1.75	1.50	1.50	LI	1.00	**3.00**	1.00	NSI	1.00	1.75	1.00	LI
D	3.00	**4.00**			1.75	**3.25**			4.00	**4.00**			1.25	**3.50**		
E	2.00	**4.00**	2.00	NSI	3.75	**3.25**	**3.50**	M	1.00	**3.00**	1.00	NSI	3.25	**3.50**	**3.25**	M
F	2.00	**3.00**	1.00	NSI	2.00	2.00	1.50	LI	1.00	**3.00**	**3.00**	M	1.50	2.25	1.50	LI
G	2.00	2.00	1.00	LI	1.50	**3.50**	1.00	NSI	1.00	1.00	1.00	LI	1.25	2.50	1.50	LI
H	3.00	**4.00**	**3.00**	M	2.25	2.75	2.50	LI	3.00	2.00	2.00	LI	1.75	2.50	2.00	LI
I	2.00	**3.00**	2.00	NSI	1.25	1.75	1.50	LI	1.00	2.00	1.00	LI	1.00	1.50	1.00	LI
J	3.00	**3.00**	1.00	NSI	1.50	2.75	1.50	LI	1.00	**3.00**	1.00	NSI	1.00	2.50	1.00	LI
K	2.00	**3.00**	2.00	NSI	2.00	**3.00**	1.75	NSI	1.00	**3.00**	**3.00**	M	2.33	2.50	2.25	LI
L	1.00	1.00	1.00	LI	1.50	2.75	2.75	LI	1.00	**3.00**	1.00	NSI	1.50	**3.00**	1.50	NSI
M	3.00	**4.00**	**4.00**	M	1.50	**3.50**	**3.50**	M	2.00	**3.00**	**3.00**	M	1.00	**3.00**	2.75	NSI
N	2.00	1.00	2.00	LI	2.75	2.25	2.00	LI	2.00	**3.00**	2.00	NSI	1.50	2.75	1.75	LI
O	2.00	**3.00**	**4.00**	M	2.00	2.25	2.50	LI	2.00	**3.00**	2.00	NSI	1.50	2.75	1.50	LI
P	1.00		1.00	LI	1.75	2.25	2.00	LI	1.00	1.00	1.00	LI	1.00	**3.25**	1.00	NSI
Q	3.00	**4.00**	**4.00**	M	1.50	**3.25**	**3.25**	M	1.00	**3.00**	**4.00**	M	3.00	**3.25**	**4.00**	M
R	1.00	1.00	1.00	LI	1.25	2.75	1.00	LI	2.00	**3.00**	1.00	NSI	1.75	2.75	1.50	LI
S		**4.00**	**4.00**	M	3.00	**3.25**	2.50	NSI	1.00	**3.00**	**4.00**	M	3.00	2.75	2.50	LI
T	2.00	**4.00**	**3.00**	M	2.50	2.75	**3.00**	M	2.00	**3.00**	**3.00**	M	2.75	**3.00**	**3.50**	M
U	3.00	**3.00**	**4.00**	M	2.75	**3.50**	**3.50**	M	1.00	**4.00**	**4.00**	M	3.00	**3.25**	**3.25**	M
V	2.00	1.00	2.00	LI	1.00	2.25	2.00	LI	1.00	2.00	2.00	LI	1.50	1.75	1.00	LI
W	1.00	2.00	**3.00**	M	1.50	**3.00**	**3.75**	M	1.00	**4.00**	**3.00**	M	1.00	2.75	**3.00**	M
X	3.00	**4.00**	**3.00**	M	1.00	**3.25**	2.50	NSI	3.00	**3.00**	**3.00**	M	1.50	**3.00**	2.50	NSI
Y	1.00	**4.00**	1.00	NSI	2.00	2.67	2.50	LI	2.00	**3.00**	**4.00**	M	1.75	2.25	**3.25**	M
Z	3.00	**4.00**	**3.00**	M	3.00	2.67	2.50	LI	2.00	**4.00**	2.00	NSI	3.00	**3.25**	2.75	NSI
AA	1.00	2.00	2.00	LI	1.75	2.50	2.00	LI	1.00	**3.00**	2.00	NSI	1.00	**3.00**	1.75	NSI
BB	2.00	1.00	1.00	LI	1.25	2.00	2.25	LI	1.00	**3.00**	2.00	NSI	1.00	2.75	1.50	LI
CC	2.00	**4.00**	**4.00**	M	1.50	**3.25**	**3.50**	M	1.00	**3.00**	**4.00**	M	1.25	**3.25**	**4.00**	M
DD	2.00	**3.00**	**3.00**	M	1.75	**3.00**	2.75	NSI	1.00	2.00	2.00	LI	1.25	**3.25**	2.75	NSI
EE	1.00	**4.00**	**3.00**	M	1.00	2.75	2.00	LI	1.00	**3.00**	2.00	NSI	1.00	2.75	2.25	LI
FF	2.00	**3.00**	2.00	NSI	1.50	**3.00**	2.00	NSI	1.00	**3.00**	1.00	NSI	1.00	2.25	1.75	LI
GG	2.00	**3.00**	2.00	NSI	1.00	2.25	1.50	LI	1.00	2.00	1.00	LI	1.00	1.75	1.00	LI
HH	2.00	2.00	1.00	LI	2.50	2.50	2.25	LI	2.00	**4.00**	**3.00**	M	1.25	**3.25**	2.25	NSI
JJ	1.00	2.00	1.00	LI	1.25	2.50	1.75	LI	1.00	2.00	2.00	LI	1.00	2.75	1.75	LI

BL, baseline; 12 M, 12-month assessment; 24 M, 24-month assessment; Cat, maintenance category.

Boldface indicates church met criteria for implementation or maintenance categorization. Maintainers (M) scored 3+ at 24 M. Non-Sustained Implementers (NSI) scored 3+ at 12 M but below 3 for 24 M maintenance. Low Implementers (LI) scored below 3 at 12 and 24 M.

497) revealed that significantly fewer members of intervention churches were inactive as compared to members of control churches at 12 months. Fruit and vegetable intake, PA self-efficacy, and HE self-efficacy were also higher in members from intervention churches, although these differences were not statistically significant, but were similar in magnitude to results from our earlier and larger effectiveness trial (17).

Physical Activity Maintenance

As shown in **Table 1**, statistically significant time effects were found for all PA components and for the implementation composite score. Church coordinators reported significantly greater implementation at 12 months compared to baseline for all PA components. They also reported significantly greater implementation at 24 months compared to baseline for the PA composite score, messages, opportunities, and pastor support. For PA guidelines (policies), the increase from baseline to 24 months approached statistical significance ($p = 0.05$). Scores at 24 months were significantly lower than scores at 12 months for all PA components. Effect sizes across components ranged from 1.18 to 2.04 from baseline to 12 months (large changes) and 0.43 to 1.02 from baseline to 24 months (medium to large changes).

Table 2 presents the PA implementation scores, by church, at the three time points, and their maintenance classification. A total of 42% of churches were classified as maintainers for guidelines (policies), 21% for opportunities, 36% for pastor support, and 21% for messages. Non-sustained implementers made up 24% of churches for guidelines (policies), 18% of churches for opportunities, 39% of churches for pastor support, and 24% of churches for messages. Finally, low implementers made up 33% of churches for guidelines (policies), 61% for opportunities, 24% for pastor support, and 55% for messages.

Table 3 presents the percentage of churches who met criteria for maintenance as well as the percentage of churches who either met criteria or showed improvements relative to baseline on four, three, two, one, and zero components of PA. Fifteen percent of churches were classified as maintainers on all four components, 3% on three components, 12% on two components, 27% on one component, and 42% on none of the components. Finally, 30% of churches met criteria or maintenance or improved relative to baseline on four components, 15% on three components, 18% on two components, 27% on one component, and 9% on none of the components.

Healthy Eating Maintenance

Statistically significant time effects were found for all HE components and for the HE composite score (**Table 1**). Church coordinators reported significantly greater implementation at 12 and 24 months compared to baseline, indicating that at 24 months, they were significantly above baseline levels. While these increases were sustained from 12 to 24 months for the HE opportunities, scores at 24 months were significantly lower than scores at 12 months for the other HE components and for the HE composite score. Effect sizes ranged from 0.40 to 1.56 from baseline to 12 months (medium to large changes) and 0.35–0.77 from baseline to 24 months (small to medium changes).

As shown in **Table 4**, 52% of churches were classified as maintainers for HE guidelines (policies), 94% for opportunities, 36% for pastor support, and 27% for messages. Non-sustained implementers made up 30% of churches for guidelines (policies), 3% of churches for opportunities, 42% of churches for pastor support, and 33% of churches for messages. Finally, low implementers made up 18% of churches for guidelines (policies), 3% for opportunities, 21% for pastor support, and 39% for messages.

Table 5 presents the percentage of churches who met criteria for maintenance as well as the percentage of churches who either met criteria or showed improvements relative to baseline on four, three, two, one, and zero components of HE. Twenty-four percent of churches were classified as maintainers on all four components, 6% on three components, 27% on two components, 39% on one component, and 3% on none of the components. Finally, 33% of churches met criteria or maintenance or improved relative to baseline on four components, 30% on three components, 24% on two components, 12% on one component, and 0% on none of the components.

TABLE 3 | The number and percentage of churches that met criteria for maintenance and the percentage of churches that either met criteria for maintenance or showed an improvement at 24 months relative to baseline, by number of FAN physical activity components.

	Met criteria for maintenance		Met criteria for maintenance or showed an improvement from baseline to 24 months	
Number of FAN physical activity components	**Churches, *n***	**Churches, %**	**Churches, *n***	**Churches, %**
4	5	15.2	10	30.3
3	1	3.0	5	15.2
2	4	12.1	6	18.2
1	9	27.3	9	27.3
0	14	42.4	3	9.1

DISCUSSION

This study's focus on organizational change and sustainability contributes to the faith-based (and other organizational) interventions literature, as well as to dissemination and implementation research and process evaluation literatures. Our focus on organizational change, consistent with the structural model of health behavior, (15) rather than on individual behavior change, makes FAN distinct in the faith-based literature (18–20). The intervention, developed using a community-based participatory research approach, (14) was designed to increase church capacity, with the goal of fostering sustainable changes in the church setting.

While there are examples of faith-based interventions that are based on ecological models, (21–26) the policy, systems, and environmental changes are rarely a central focus of the intervention, and organizational outcomes are measured infrequently. Even fewer faith-based interventions have examined program sustainability. In the North Carolina Black Churches United for Better Health Study (49 churches), (25) member behavior change (fruit and vegetable intake) was found to be maintained over a 2-year period in intervention vs. control churches, and although organizational maintenance was targeted in the intervention, it was not systematically examined.

The FAN D&I study used the RE-AIM framework to study adoption through maintenance. RE-AIM has been applied to a variety of topic areas and settings. Literature reviews consistently conclude that organizational maintenance is reported at lower levels than the other dimensions of RE-AIM. For example, Antikainen et al. (27) found that among theory-based PA intervention studies, organizational maintenance was reported in only 5% ($n = 3$) of studies. The reporting of organizational maintenance in childhood and youth PA, diet, and obesity studies has also been low (28–31). Harden et al.'s systematic review of behavioral interventions found that there was insufficient data to determine the average organizational maintenance for the 82 interventions included (32). A recent 20-year review of studies using RE-AIM concluded that there are limited data

TABLE 4 | Baseline, 12 and 24-month implementation scores and church categorization of 24-month maintenance status for healthy eating components.

	Guidelines				Opportunities				Pastor Support				Messages			
Church	**BL**	**12 M**	**24 M**	**Cat**	**BL**	**12 M**	**24 M**	**Cat**	**BL**	**12 M**	**24 M**	**Cat**	**BL**	**12 M**	**24 M**	**Cat**
A	2.00	**4.00**			3.50	**4.00**			1.00	2.00			1.25	2.50		
B	2.00	**3.00**	**3.00**	M	3.00	**3.50**	**3.00**	M	2.00	**3.00**	2.00	NSI	1.50	**3.00**	2.00	NSI
C	3.00	2.00	**3.00**	M	3.50	**3.50**	**4.00**	M	2.00	**3.00**	2.00	NSI	1.25	2.75	1.25	LI
D	2.50	**4.00**			4.00	**4.00**			1.00	**3.00**			1.25	**3.00**		
E	2.00	**3.00**	2.00	NSI	3.50	**3.00**	**3.00**	M	1.00	**3.00**	1.00	NSI	3.25	**3.50**	**3.00**	M
F	2.00	**4.00**	**4.00**	M	3.50	**4.00**	**4.00**	M	2.00	**3.00**	**3.00**	M	1.50	**3.00**	2.00	NSI
G	1.50	**3.50**	1.00	NSI	3.00	**3.50**	**4.00**	M	1.00	**3.00**	1.00	NSI	1.50	2.50	1.50	LI
H	2.00	**4.00**	2.50	NSI	3.00	**4.00**	**4.00**	M	2.00	2.00	**3.00**	M	2.50	2.75	2.75	MLI
I	2.50	**3.00**	2.50	NSI	2.00	**3.00**	**3.00**	M	1.00	2.00	2.00	LI	1.25	1.25	1.25	LI
J	3.00	**4.00**	**4.00**	M	3.50	**4.00**	**4.00**	M	2.00	**4.00**	1.00	NSI	1.00	2.75	1.00	LI
K	2.00	**3.00**	2.00	NSI	3.50	**3.00**	**3.00**	M	1.00	**4.00**	1.00	NSI	2.25	2.75	2.25	LI
L	1.00	1.00	1.00	LI	3.50	**4.00**	**3.50**	M	1.00	**3.00**	1.00	NSI	2.00	**3.25**	2.25	NSI
M	2.50	**4.00**	**4.00**	M	3.50	**4.00**	**4.00**	M	3.00	**3.00**	2.00	NSI	2.25	**3.25**	2.50	NSI
N	2.00	1.00	1.50	LI	4.00	**4.00**	**3.50**	M	2.00	**3.00**	1.00	NSI	1.75	2.75	2.25	LI
O	2.00	**3.50**	**4.00**	M	3.00	**3.00**	2.50	NSI	3.00	**3.00**	2.00	NSI	1.75	2.75	1.50	LI
P	1.00	**4.00**	**3.50**	M	3.50	**3.50**	**3.50**	M	1.00	**4.00**	1.00	NSI	1.00	**3.75**	2.00	NSI
Q	4.00	**4.00**	**4.00**	M	4.00	**4.00**	**4.00**	M	3.00	**3.00**	**4.00**	M	3.50	**3.25**	**4.00**	M
R	3.00	**3.50**	2.00	NSI	4.00	**3.50**	**4.00**	M	2.00	2.00	2.00	LI	2.75	2.50	2.50	LI
S	4.00	**4.00**	**4.00**	M	4.00	**4.00**	**4.00**	M	1.00	**3.00**	**3.00**	M	3.25	2.25	**3.00**	M
T	2.50	**4.00**	**4.00**	M	3.00	**4.00**	**4.00**	M	2.00	**3.00**	**3.00**	M	3.00	**3.50**	**3.50**	M
U	3.50	**4.00**	**4.00**	M	3.50	**3.50**	**3.50**	M	2.00	**4.00**	**4.00**	M	3.00	**3.50**	**3.00**	M
V	2.00	1.00	1.50	LI	3.00	**4.00**	**3.50**	M	1.00	2.00	1.00	LI	1.25	1.75	1.50	LI
W	1.00	**4.00**	**4.00**	M	3.50	**4.00**	**4.00**	M	2.00	**3.00**	**4.00**	M	1.00	2.25	**3.25**	M
X	2.50	**3.50**	**4.00**	M	4.00	**4.00**	**4.00**	M	3.00	**3.00**	**3.00**	M	2.25	**3.00**	2.25	NSI
Y	1.00	1.00	1.00	LI	3.50	**4.00**	**4.00**	M	1.00	1.00	2.00	LI	1.00	2.00	1.75	LI
Z	3.50	**4.00**	**3.50**	M	3.00	**3.00**	**3.00**	M	3.00	**4.00**	**3.00**	M	3.25	**3.50**	**3.25**	M
AA	1.50	2.00	2.00	LI	4.00	**4.00**	**4.00**	M	1.00	2.00	2.00	LI	1.25	**3.25**	2.00	NSI
BB	2.00		2.50	LI	4.00	**4.00**	**4.00**	M		**3.00**	2.00	NSI	1.33	**3.67**	1.50	NSI
CC	2.00	**4.00**	**4.00**	M	3.00	**3.50**	**4.00**	M	1.00	**3.00**	**3.00**	M	1.75	2.75	**3.75**	M
DD	2.50	**3.50**	**4.00**	M	2.50	**3.50**	**4.00**	M	1.00	2.00	**3.00**	M	1.00	**3.50**	**3.00**	M
EE	3.00	**4.00**	2.50	NSI	3.00	**4.00**	**3.00**	M	1.00	**3.00**	2.00	NSI	1.25	**3.25**	1.75	NSI
FF	3.00	**4.00**	**4.00**	M	4.00	**4.00**	**4.00**	M	2.00	**3.00**	1.00	NSI	1.25	2.25	1.50	LI
GG	2.00	**3.00**	2.50	NSI	1.50	1.00	1.50	LI	1.00	2.00	1.00	LI	1.00	2.00	1.50	LI
HH	4.00	**4.00**	2.00	NSI	3.50	**4.00**	**3.50**	M	3.00	**3.00**	**3.00**	M	1.50	**3.00**	2.75	NSI
JJ	2.50	**3.00**	1.00	NSI	3.50	**3.50**	**3.50**	M	1.00	2.00	2.00	LI	1.00	**3.50**	2.50	NSI

BL, baseline; 12 M, 12-month assessment; 24 M, 24-month assessment; Cat, maintenance category.
Boldface indicates church met criteria for implementation or maintenance categorization. Maintainers (M) scored 3+ at 24 M. Non-Sustained Implementers (NSI) scored 3+ at 12 M but below 3 for 24 M maintenance. Low Implementers (LI) scored below 3 at 12 and 24 M.

on outcomes after interventions end (33). Our study not only reported organizational maintenance using distinct criteria, but also reported the maintenance of each intervention component using a continuous scale, avoiding the "all or nothing" view of maintenance, as recommended by Scheirer et al. (34).

Our findings are encouraging. This paper summarized the positive and meaningful findings previously reported for reach, adoption, implementation, and effectiveness in this study. With regard to maintenance, although mean implementation scores of the majority of PA and HE components decreased from 12 to 24 months, churches had significantly higher implementation at 24 months than they did at baseline, with effect sizes ranging from $d = 0.35$ to 1.02 (most were medium to large). Furthermore, 21–42% of churches were classified as maintainers across the four PA components, and 27–94% across the HE components. Fifteen percent of churches were classified as maintainers on all four PA components, and 24% were classified as maintainers on all four healthy heating components. Most churches maintained at least one FAN component. Furthermore, when considering the percentage of churches that were either classified as maintainers or showed an improvement from baseline to 24 months, 30% of churches did so for all four PA components and 33% for all

TABLE 5 | The number and percentage of churches that met criteria for maintenance and the percentage of churches that either met criteria for maintenance or showed an improvement at 24 months relative to baseline, by number of FAN healthy eating components.

	Met criteria for maintenance		Met criteria for maintenance or showed an improvement from baseline to 24 months	
Number of FAN healthy eating components	**Churches, *n***	**Churches, %**	**Churches, *n***	**Churches, %**
4	8	24.2	11	33.3
3	2	6.1	10	30.0
2	9	27.2	8	24.2
1	13	39.4	4	12.1
0	1	3.0	0	0.0

four HE components, with the majority of churches showing improvements on at least two of the PA and HE components.

Several factors likely contributed to sustained improvements relative to baseline at 24 months. First, FAN is a flexible program organized around core elements rather than a rigid curriculum. Churches were enabled to select activities from within the conceptual model that fit their church culture, demographics, customs, and resources. Second, the intervention was developed in partnership with church leaders and lay members using a community-based participatory research approach, was consistent with the idea of designing for dissemination (35), and resulted in a good fit with church practices and beliefs. Third, churches received a year of technical assistance telephone calls to help support program implementation (9) which has been shown to be important for organizations implementing evidence-based programs (36). Community health advisors, and not research staff, delivered the training and technical assistance to churches, resulting in meaningful changes in member and organizational outcomes (7, 8), and an approach that is likely to be more cost-effective.

For PA, using categorical outcomes, the greatest maintenance was of guideline (policy) changes and pastor support for PA. Maintenance of opportunities and messages were the lowest, likely because fewer than half of the churches met criteria for high implementation at 12 months for these two components. In contrast, for HE, maintenance of opportunities was the highest, with most churches providing members fruit and vegetables when food was served. HE policies was the second most frequently maintained component, with maintenance of pastor support of PA and HE messages the lowest. An earlier analysis of qualitative data from our study showed that resistance to change was among the most common barriers to implementation that pastors and church coordinators reported, whereas leader support was an important enabler (10). Because many churches provide meals and snacks to members, it might have been easier to make modifications to an existing practice rather than add a completely new activity (PA).

It was also notable that the percentage of churches categorized as "non-sustained implementers" was relatively high for some of the components of FAN. These were churches that met criteria for high implementation at 12 months, but no longer met the criteria at 24 months. For example, across the PA components, these percentages ranged from 18% (opportunities) to 39% (pastor support), and across the HE components, these percentages ranged from 3% (opportunities) to 42% (pastor support). It might be that the criteria for implementation were too stringent for some components and perhaps not realistic in the faith-based setting whose main focus is on the spiritual well-being of members. For example, it is probably not realistic that pastors include messages about PA and HE at least monthly or that the church distribute PA and HE materials at this frequency over time. Rather, it might be more important and realistic for members to hear and see messages frequently for a shorter period of time and then continue to hear and see messages over time, but less frequently, to reinforce the importance of PA and HE. Adjusting the threshold of acceptable implementation would have yielded substantially more favorable maintenance findings, and our future projects will reconsider what constitutes both meaningful and realistic implementation. However, we opted to use our a prior definition for 12-month implementation and apply this same criteria at 24-months for this paper. FAN's focus is on organizational change which is challenging and may require more time and technical assistance to produce and maintain relative to individual level change. Identifying which churches are more likely to need greater assistance is an important next step for research in this area.

There are several limitations to this study. First, we were reliant on church coordinator reports of implementation at all time points and were unable to do on-site observations. Although we cannot rule out social desirability biases, our implementation data as reported by church coordinators and perceived by members has been congruent, both in this Phase of the study (7, 8) and in a previous study of FAN (16, 17). Second, we did not collect in-depth information regarding the specific policy, systems, and environmental changes made, as was done by Boutain et al. (37). Future studies should focus on the factors that enabled some churches to successfully maintain all or parts of FAN. Third, we did not have a control group for comparison for maintenance. Our study design used a delayed-intervention control group, and the control group was trained 1 year after the intervention group. As reported in earlier papers, (7, 8) we demonstrated differences between intervention and control churches on implementation and effectiveness outcomes at 12 months, but we could not make these comparison for maintenance, as we did not have a control group unexposed to the intervention for 24 months.

This study also has several strengths. First, it is one of the largest faith-based interventions conducted to date (59 churches randomized; 39 in the intervention group). Only 4 of the 39 intervention churches did not participate in subsequent interviews. Church coordinator interview completion was high at 12 (35/39) and 24 months (33/39). We assessed implementation at three time points (baseline, 12, 24 months), allowing us to examine patterns over time. Furthermore, it is the only study, to our knowledge, to assess organizational maintenance in this

setting. Finally, this study is unique in its reporting of each component of the RE-AIM framework.

CONCLUSION

In this county-wide dissemination of an evidence-based program, delivered to churches by community health advisors, we found that PA and HE implementation increased significantly from baseline to 12 months and from baseline to 24 months, and these increases were medium to large in magnitude. We also found that most churches maintained at least one component of FAN at 24 months. These promising findings position FAN well for the national implementation study now underway.

DATA AVAILABILITY STATEMENT

The datasets generated for this study will not be made publicly available. The dataset generated and analyzed during the current study is not publicly available due to concerns about confidentiality with the limited number of participating churches in a specific geographical region. Requests for data and data analyses will be considered and honored if they do not duplicate work conducted or underway by our team and appear reasonable. Requests to access the datasets should be directed to SW, wilcoxs@mailbox.sc.edu.

ETHICS STATEMENT

The study involved human participants and was reviewed and approved by the University of South Carolina Institutional Review Board and was granted exempt status. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

AUTHOR CONTRIBUTIONS

SW, RS, and BH were involved in writing the grant proposal and conceptualizing the study. DJ-S participated in enrolling churches. SW, RS, and DJ-S selected study measures and developed the church visit protocol. SW was involved in making day-to-day decisions on the project, with community input. BH and SW conducted data analyses. SW drafted the manuscript. All authors substantially reviewed and edited the manuscript.

FUNDING

This study was supported by Cooperative Agreement Number U48DP005000 from the Centers for Disease Control and Prevention. The funding agency did not have a role in selecting the study design or methods. The research presented in this paper is that of the authors and does not reflect the official views of the Centers for Disease Control and Prevention.

ACKNOWLEDGMENTS

We wish to thank each participating church, especially the church coordinators and pastors, for their participation in this study. We also appreciate the contributions of Fairfield Forward (formerly the Fairfield Community Coordinating Council), the Pastor Health Advisors, and the Community Health Advisors. Finally, we thank students and staff in the University of South Carolina Prevention Research Center who contributed to conducting this study.

REFERENCES

1. Pew Research Center. *America's Changing Religious Landscape*. (2015). Available online at: https://www.pewforum.org/2015/05/12/americas-changing-religious-landscape/ (accessed August 13, 2019).
2. Pew Research Center US. *Public Becoming Less Religious*. (2015). Available online at: https://www.pewforum.org/2015/11/03/u-s-public-becoming-less-religious (accessed June 28, 2019).
3. Yeary KH, Klos LA, Linnan L. The examination of process evaluation use in church-based health interventions: a systematic review. *Health Promot Pract*. (2012) 13:524–34. doi: 10.1177/1524839910390358
4. National Cancer Institute, Research-Tested Intervention Programs (RTIPs). *The Faith, Activity, and Nutrition (FAN) Program*. Available online at: https://rtips.cancer.gov/rtips/programDetails.do?programId=10977999 (accessed August 13, 2019).
5. Rural Health Information Hub. *Rural Health Models and Innovations, Faith, Activity, and Nutrition*. (2018). Available online at: https://www.ruralhealthinfo.org/project-examples/1011 (accessed April 25, 2019).
6. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health*. (1999) 89:1322–27. doi: 10.2105/AJPH.89.9.1322
7. Wilcox S, Saunders RP, Kaczynski AT, Forthofer M, Sharpe PA, Goodwin C, et al. Faith, activity, and nutrition randomized dissemination and implementation study: countywide adoption, reach, and effectiveness. *Am J Prev Med*. (2018) 54:776–85. doi: 10.1016/j.amepre.2018.02.018
8. Saunders RP, Wilcox S, Jake-Schoffman DE, Kinnard D, Hutto B, Forthofer M, et al. The faith, activity, and nutrition (FAN) dissemination and implementation study, phase 1: implementation monitoring methods and results. *Health Educ Behav*. (2019) 46:388–97. doi: 10.1177/1090198118818235
9. Sharpe PA, Wilcox S, Kinnard D, Condrasky MD. Community health advisors' participation in a dissemination and implementation study of an evidence-based physical activity and healthy eating program in a faith-based setting. *J Commun Health*. (2018) 43:694–704. doi: 10.1007/s10900-018-0473-5
10. Bernhart JA, Dunn CG, Wilcox S, Saunders RP, Sharpe PA, Stucker J. Church leaders' barriers and facilitators before and after implementing a physical activity and nutrition intervention. *Health Educ Res*. (2019) 34:188–99. doi: 10.1093/her/cyy051
11. United States Census Bureau. *American FactFinder*. (2010). Available online at: https://factfinder.census.gov/faces/nav/jsf/pages/community_facts.xhtml (accessed December 13, 2017).
12. US Department of Health and Human Services. *Health Resources and Services Administration Tools*. (2018). Available online at: https://datawarehouse.hrsa.gov/tools/tools.aspx (accessed February 13, 2018).
13. United States Census Bureau. *Quick Facts*. (2010). Available online at: https://www.census.gov/quickfacts/ (accessed July 12, 2017).
14. Wilcox S, Laken M, Parrott AW, Condrasky M, Saunders R, Addy CL, et al. The faith, activity, and nutrition (FAN) program: design of a participatory research intervention to increase physical activity and improve dietary habits in African American churches. *Contemp Clin Trials*. (2010) 31:323–35. doi: 10.1016/j.cct.2010.03.011

15. Cohen DA, Scribner RA, Farley TA. A structural model of health behavior: a pragmatic approach to explain and influence health behaviors at the population level. *Prev Med*. (2000) 30:146–54. doi: 10.1006/pmed.1999.0609
16. Saunders RP, Wilcox S, Baruth M, Dowda M. Process evaluation methods, implementation fidelity results and relationship to physical activity and healthy eating in the faith, activity, and nutrition (FAN) study. *Eval Program Plann*. (2014) 43:93–102. doi: 10.1016/j.evalprogplan.2013.11.003
17. Wilcox S, Parrott A, Baruth M, Laken M, Condrasky M, Saunders R, et al. The faith, activity, and nutrition program: a randomized controlled trial in African-American churches. *Am J Prev Med*. (2013) 44:122–31. doi: 10.1016/j.amepre.2012.09.062
18. Bopp M, Peterson JA, Webb BL. A comprehensive review of faith-based physical activity interventions. *Am J Lifestyle Med*. (2012) 6:460–78. doi: 10.1177/1559827612439285
19. Tristao Parra M, Porfirio GJM, Arredondo EM, Atallah AN. Physical activity interventions in faith-based organizations: a systematic review. *Am J Health Promot*. (2018) 32:677–90. doi: 10.1177/0890117116688107
20. Florez KR, Payan DD, Palar K, Williams MV, Katic B, Derose KP. Church-based interventions to address obesity among African Americans and latinos in the United States: a systematic review. *Nutr Rev*. (2019) 78:304–22. doi: 10.1093/nutrit/nuz046
21. Allicock M, Campbell MK, Valle CG, Carr C, Resnicow K, Gizlice Z. Evaluating the dissemination of body & soul, an evidence-based fruit and vegetable intake intervention: challenges for dissemination and implementation research. *J Nutr Educ Behav*. (2012) 44:530–38. doi: 10.1016/j.jneb.2011.09.002
22. Pinsker EA, Enzler AW, Hoffman MC, Call KT, Amos S, Babington-Johnson A, et al. A community-driven implementation of the body and soul program in churches in the twin cities, minnesota, 2011-2014. *Prev Chronic Dis*. (2017) 14:E26. doi: 10.5888/pcd14.160386
23. Resnicow K, Campbell MK, Carr C, McCarty F, Wang T, Periasamy S, et al. Body and soul. A dietary intervention conducted through African-American churches. *Am J Prev Med*. (2004) 27:97–105. doi: 10.1016/j.amepre.2004.04.009
24. Arredondo EM, Elder JP, Haughton J, Slymen DJ, Sallis JF, Perez LG, et al. Fe en accion: promoting physical activity among churchgoing latinas. *Am J Public Health*. (2017) 107:1109–15. doi: 10.2105/AJPH.2017.303785
25. Campbell MK, Motsinger BM, Ingram A, Jewell D, Makarushka C, Beatty B, et al. The north Carolina black churches united for better health project: intervention and process evaluation. *Health Educ Behav*. (2000) 27:241–53. doi: 10.1177/109019810002700210
26. Hardison-Moody A, Yao J. Faithful families, thriving communities: bridging faith and health through a state-level partnership. *Am J Public Health*. (2019) 109:363–68. doi: 10.2105/AJPH.2018.304869
27. Antikainen I, Ellis R. A RE-AIM evaluation of theory-based physical activity interventions. *J Sport Exerc Psychol*. (2011) 33:198–214. doi: 10.1123/jsep.33.2.198
28. Jang M, Chao A, Whittemore R. Evaluating intervention programs targeting parents to manage childhood overweight and obesity: a systematic review using the RE-AIM framework. *J Pediatr Nurs*. (2015) 30:877–87. doi: 10.1016/j.pedn.2015.05.004
29. McGoey T, Root Z, Bruner MW, Law B. Evaluation of physical activity interventions in youth via the reach, efficacy/effectiveness, adoption, implementation, and maintenance (RE-AIM) framework: a systematic review of randomised and non-randomised trials. *Prev Med*. (2015) 76:58–67. doi: 10.1016/j.ypmed.2015.04.006
30. McGoey T, Root Z, Bruner MW, Law B. Evaluation of physical activity interventions in children via the reach, efficacy/effectiveness, adoption, implementation, and maintenance (RE-AIM) framework: a systematic review of randomized and non-randomized trials. *Prev Med*. (2016) 82:8–19. doi: 10.1016/j.ypmed.2015.11.004
31. Schlechter CR, Rosenkranz RR, Guagliano JM, Dzewaltowski DA. A systematic review of children's dietary interventions with parents as change agents: application of the RE-AIM framework. *Prev Med*. (2016) 91:233–43. doi: 10.1016/j.ypmed.2016.08.030
32. Harden SM, Gaglio B, Shoup JA, Kinney KA, Johnson SB, Brito F, et al. Fidelity to and comparative results across behavioral interventions evaluated through the RE-AIM framework: a systematic review. *Syst Rev*. (2015) 4:155. doi: 10.1186/s13643-015-0141-0
33. Glasgow RE, Harden SM, Gaglio B, Rabin B, Smith ML, Porter GC, et al. RE-AIM planning and evaluation framework: adapting to new science and practice with a 20-year review. *Front Public Health*. (2019) 7:64. doi: 10.3389/fpubh.2019.00064
34. Scheirer MA, Dearing JW. An agenda for research on the sustainability of public health programs. *Am J Public Health*. (2011) 101:2059–67. doi: 10.2105/AJPH.2011.300193
35. Brownson RC, Jacobs JA, Tabak RG, Hoehner CM, Stamatakis KA. Designing for dissemination among public health researchers: Findings from a national survey in the United States. *Am J Public Health*. (2013) 103:1693–99. doi: 10.2105/AJPH.2012.301165
36. Durlak JA, DuPre EP. Implementation matters: a review of research on the influence of implementation on program outcomes and the factors affecting implementation. *Am J Community Psychol*. (2008) 41:327–50. doi: 10.1007/s10464-008-9165-0
37. Boutain DM, McNees M. Moving together in faith health collaborative. Initiating policy, systems, and environmental changes for childhood obesity prevention by engaging six faith-based organizations. *Fam Community Health*. (2013) 36:248–59. doi: 10.1097/FCH.0b013e31829315b1

Conflict of Interest: SW, RS, and BH were supported during the preparation of this article by a cooperative agreement from the Centers for Disease Control and Prevention (U48DP005000).

The remaining author declares that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

frontiers in Public Health

ORIGINAL RESEARCH
published: 10 December 2018
doi: 10.3389/fpubh.2018.00357

Beginning With the End in Mind: Contextual Considerations for Scaling-Out a Community-Based Intervention

Laura E. Balis[1,2]*, *Thomas E. Strayer III*[3], *NithyaPriya Ramalingam*[3] and *Samantha M. Harden*[1]

[1] Department of Human Nutrition, Foods, and Exercise, Virginia Tech, Blacksburg, VA, United States, [2] Extension, University of Wyoming, Lander, WY, United States, [3] Translational Biology, Medicine, and Health, Department of Human Nutrition, Foods, and Exercise, Virginia Tech, Blacksburg, VA, United States

Introduction: A number of effective physical activity programs for older adults exist, but are not widely delivered within community settings, such as the Cooperative Extension System. The purpose of this paper was to determine if an evidence-based intervention (EBI) developed in one state Extension system could be scaled-out to a new state system.

Methods and results: The RE-AIM (reach, effectiveness, adoption, implementation, maintenance) framework was used to guide an iterative evaluation of three translational stages. Stage 1: Before program adoption, Extension health educators were surveyed and interviewed to assess physical activity programming perceptions and factors that may influence their decision to attend training or deliver the program in practice. Results indicated that a virtual, scalable training protocol would be necessary and that training needed to include hands-on instruction and be catered to those who were less confident in physical activity program delivery. Stage 2: Training attendees were surveyed pre- and post-training on factors related to the adoption-decision making process and contacted post-training to assess program delivery status. Training did not influence perceptions of the program, intent to deliver, or confidence in delivering the program. Stage 3: During program implementation, the program was evaluated through the RE-AIM framework by surveying across three key stakeholder groups: (1) program participants, (2) potential delivery personnel, and (3) Extension administrators. Findings indicate that the program has the potential to reach a large and representative proportion of the target audience, especially in rural areas. However, adoption and implementation rates among Extension health educators and community partners were low and data collection for effectiveness, implementation, and maintenance was a challenge.

Conclusion: Overall, the results indicate initial struggles to translating and evaluating the program in a large, rural state. Implications for practice include making system-level changes to increase physical activity program adoption rates among Extension health educators and improve data collection and program evaluation through this community-based organization. More work is needed to identify infrastructure support and capacity to scale-out EBIs.

Keywords: RE-AIM, physical activity, cooperative Extension system, implementation science, translation

OPEN ACCESS

Edited by:
Melody Goodman,
New York University, United States

Reviewed by:
Cassandra Arroyo,
Barnes-Jewish Hospital, United States
Anna J. DeRuyter,
Washington University in St. Louis, United States
Deborah Paone,
Independent Researcher, Minneapolis, United States

***Correspondence:**
Laura E. Balis
lbalis@uwyo.edu

Specialty section:
This article was submitted to Public Health Education and Promotion, a section of the journal Frontiers in Public Health

Received: *28 August 2018*
Accepted: *21 November 2018*
Published: *10 December 2018*

Citation:
Balis LE, Strayer TE III, Ramalingam N and Harden SM (2018) Beginning With the End in Mind: Contextual Considerations for Scaling-Out a Community-Based Intervention. Front. Public Health 6:357. doi: 10.3389/fpubh.2018.00357

INTRODUCTION

Delivering (and sustaining) evidence-based interventions (EBI) in community practice is challenging. One challenge is that delivery personnel have to select an intervention and ensure its fit within the mission, values, and resources of the system they are delivering (1). County-based delivery personnel in the land-grant university Cooperative Extension Service (Extension) have the autonomy to select open-access (i.e., open to all, without restriction due to sex, socioeconomic status, or, more notably, health condition) interventions for their county residents (2). One target audience for whom Extension professionals provide services is older adults. As only 12% of this population is meeting physical activity recommendations, and new efforts within Extension are geared toward promoting physical activity (3–5), it is necessary to understand existing programs, their impacts, and how to scale-out interventions (6) across Extension state systems. Scale-out is "a deliberate effort to broaden the delivery of an EBI. Scale-out is an extension of scale-up and uniquely refers to the deliberate use of strategies to implement, test, improve, and sustain an EBI as it is delivered to new populations and/or through new delivery systems that differ from those in effectiveness trials." [(6) p. 3].

One way that Extension has been challenged at scale-out is that rather than scaling core elements of "what works," new or unique programs are introduced to the system. This is evidenced by a recent systematic review of open-access physical activity interventions for older adults which found that 17 unique open-access physical activity programs were offered by Extension professionals (7). In addition to duplicated efforts, both the fidelity to the underlying evidence-based program principles and the impact of these open-access interventions on older adult physical activity levels is underreported (7).

In order for this process of scale-out to be successful, information about how and why the intervention works is needed, as much as whether the intervention worked or not (6, 8, 9). Notably, there are three types of scale-out: EBI scaled-out to (1) the same population through a different system, (2) different population, same delivery system, and (3) different population and different delivery system (6). However, while the national Extension system is "one delivery system," the structure of each state may be somewhat unique. In addition, while "older adults" may be one population, older adults from one state may experience different barriers and facilitators to program adherence when compared to older adult population in a different state. Therefore, the degree to which an EBI can be scaled-out from one state Extension system to another is difficult to discern.

One way to understand scale-out of EBI from one state system to another is to use pragmatic data collection. Pragmatism focuses on "issues and data relevant for making decisions and taking action [(10), p.257]." This type of evaluation is especially useful in community settings that may not have substantial research funding, and can move beyond evaluating intervention effectiveness and determine for whom, where, when, why, and how an intervention is working in a given context (11). The RE-AIM (reach, efficacy, adoption, implementation, maintenance) framework can be used to systematically capture perceptions, decision making, and impacts (8, 9, 12, 13).

Using these key considerations, researchers and practitioners can iteratively engage to reflect on successes and failures related to adoption and implementation through a participatory approach (1). Collecting pragmatic measures within a participatory approach is crucial to understand how and why an evidence-based intervention may be delivered outside of the context in which it was developed. Taken together, the research question was: Can an EBI developed in one state Extension system be scaled-out to a new state system? Capturing this context-driven work is essential to understanding why and how interventions are adopted, implemented, and maintained within delivery systems so they can be scaled-out to reach broader populations.

MATERIALS AND METHODS

Design

As recently proposed by members of the National Working Group on RE-AIM Planning and Evaluation Framework (14), the RE-AIM framework was applied across three stages of implementation: before adoption, during adoption, and during program implementation; herein called the scaling-out process. First, before the program was adopted, a mixed-methods design based on RE-AIM was used to capture perceptions of Extension health educators who could deliver the program in practice. Second, during program adoption, a pre- and post-training survey based on RE-AIM adoption was used to understand delivery personnel's adoption-decision making process. Finally, as the program was implemented, it was comprehensively evaluated through RE-AIM, including pre/post and cross-sectional measures, depending on outcome.

In addition to the planning and evaluation framework, an adapted participatory process model was used to guide this work. **Figure 1** [adapted from Estabrooks et al. (15)] details the contextual considerations that influenced each stage of the process. Notably, there were challenges in visually representing the iterative process of contextual considerations and responses. While the work here is presented in stages, it is important to note that these processes are continuous steps in order to ensure that the researchers, Extension health educators, and community partners engaged in a reflective and action-oriented manner. This study was approved by the University of Wyoming (stage 1) and Virginia Tech (stages 2 and 3) Institutional Review Boards.

Setting

Wyoming is a large, rural state with a small population (579,315). Ten Extension health educators cover the state's 23 counties and the Wind River Indian Reservation (by stage 2 of this research, only six health educators were employed in the state). These educators have a broad reach, interacting with over 40,000 participants per year. In Wyoming, there is no Extension health or physical activity specialist. When a new county-based Extension health educator (with a background in physical activity promotion and research) was hired by University of Wyoming Extension (UWE), the educator contacted the Virginia

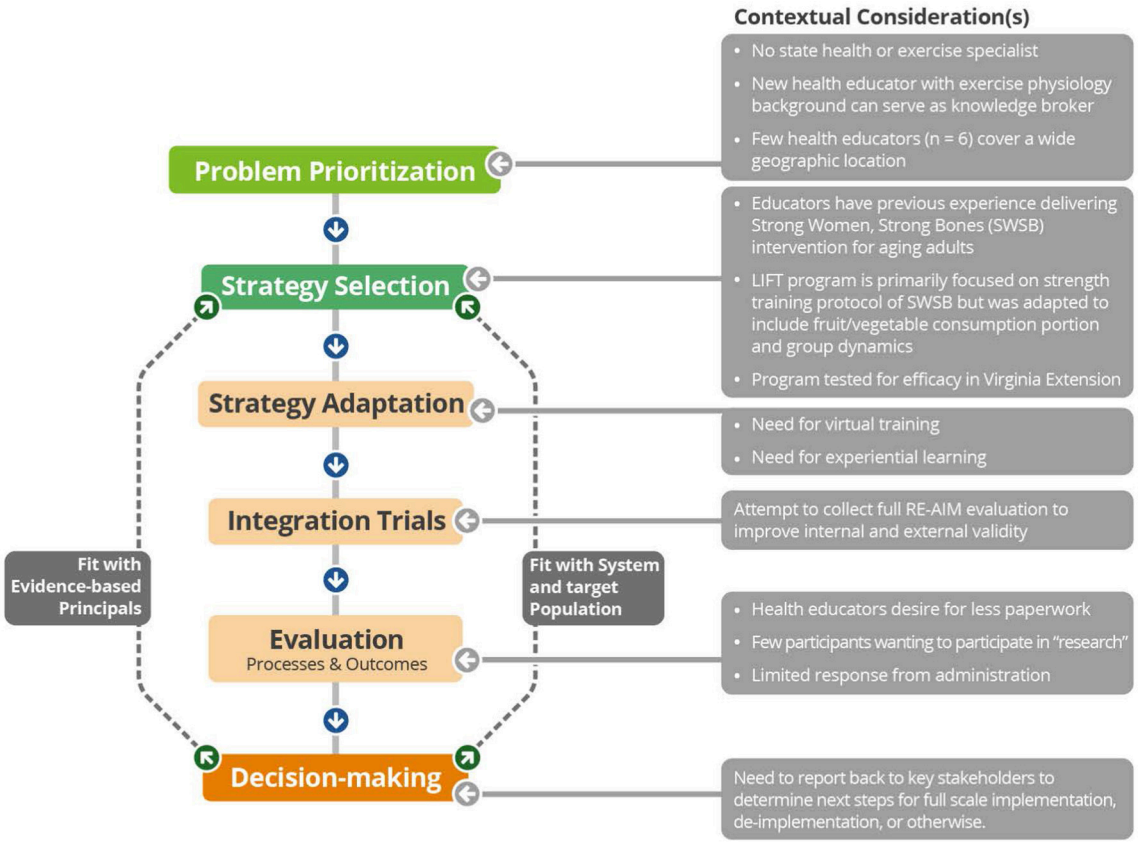

FIGURE 1 | Integrated research-practice partnership model with contextual considerations leading to translational solutions.

Cooperative Extension (VCE) Exercise Specialist to inquire about potential research partnerships. The new county-based Extension health educator served as a knowledge broker (i.e., an intermediary between researchers and stakeholders who facilitates knowledge transfer between these parties) (16). In alignment with the integrated research-practice process (IRPP) model, this setting and work identified that the lack of a health specialist and the small number of Extension health educators covering the state were problems to be addressed in order to successfully implement a physical activity intervention (see **Figure 1**: problem prioritization).

Program Development and Description

Lifelong Improvements through Fitness Together (LIFT) (17, 18) was adapted from two programs: Stay Strong Stay Healthy (19) and Activity for the Ages (20). LIFT combines the evidence-based behavioral strategies (goal setting, self-monitoring, and group dynamics) from Activity for the Ages with the evidence-based strength training protocol from Stay Strong Stay Healthy (18) and Strong Women, Strong Bones (also delivered by Extension professionals) (21). Since LIFT was adapted and tested specifically in Virginia, it was unknown whether the packaged LIFT program could be scaled-out to a new Extension state system (see **Figure 1**: strategy selection).

STAGE 1: BEFORE ADOPTION

Before offering a LIFT training, the exercise specialist and UWE knowledge broker conducted a pragmatic concurrent, transformative mixed-methods [i.e., equal emphasis on the quantitative and qualitative findings (22)] study. To aid in replicability, the survey and interview guide can be found in Appendices A and B. Briefly, 67% of the eligible Extension health educators completed the online survey. Overall, participants were middle-aged Caucasian females; more demographic characteristics are displayed in **Table 1**. Health educators reported a range of comfort for delivering physical activity (from moderately to very comfortable). While none of the Extension health educators were currently delivering physical activity programs, three (50%) were thinking about offering a physical activity program (contemplation phase) (23). Finally, most of the survey respondents ($n = 5$) indicated that they would be interested in receiving training (either in person or via webinar) on delivery and evaluation of the LIFT program.

Thematic coding of the two interviews yielded 349 meaning units reporting perceived barriers ($n = 115$ meaning units) and facilitators ($n = 157$) for delivering physical activity programs and types of programs delivered ($n = 71$). See **Table 2** for coding, frequencies, and example meaning units. For barriers,

TABLE 1 | Extension health educator characteristics compared to LIFT training participant characteristics.

Demographics	Extension health educators ($N = 6$)	LIFT training participants ($N = 7$)
	Mean (±SD)	**Mean (±SD)**
Age	50 (±17.8)	46 (±15.0)
	N (%)	**N (%)**
GENDER		
Female	6 (100)	5 (71)
Male	0 (0)	2 (29)
RACE		
White	5 (83)	5 (71)
Other race	1 (17)	2 (29)
ETHNICITY		
Non-Hispanic	4 (67)	7 (100)
Hispanic	0 (0)	0 (0)
Not sure	2 (33)	0 (0)
EDUCATION LEVEL		
Some college	0 (0)	4 (57)
Bachelor's degree	2 (33)	1 (14)
Graduate degree	4 (67)	2 (29)
HEALTH SELF-RATING		
Excellent	3 (50)	2 (29)
Very good	2 (33)	1 (14)
Good	1 (17)	2 (29)
Fair	0 (0)	2 (29)

interviewees expressed that their workload was too high to incorporate additional types of programming and their focus was on nutrition. They also mentioned that delivering the Strong Women, Strong Bones program (which was previously implemented through UWE) was too time consuming. As for facilitators, interviewees had positive perceptions of physical activity recommendations and benefits and had enjoyed the Strong Women, Strong Bones training. Community partners were mentioned as a source of physical activity program delivery. While a lack of facilities came up as a barrier, the presence of facilities (e.g., schools, fairgrounds, and walking paths) was also mentioned as a facilitator. Finally, regarding types of programs delivered, interviewees indicated that they were not currently delivering any physical activity programs. Rather, physical activity was promoted through incorporating topics, such as "sit less, move more" in other programming.

STAGE 2: DURING ADOPTION (TRAINING)

Based on the results of Stage 1, the research team decided that there was a need for a scalable training protocol (i.e., one that was feasible across the entire 97,818 square miles of Wyoming) designed to target Extension health educators who were less confident in delivering physical activity programs and include hands-on instruction and teach-back. LIFT training was created as a 4 h "live" virtual format based on evidence-based methods on training (24, 25), learner-centered teaching (26), and program adoption rates (27). Training included detailed descriptions of program principles and opportunities for experiential learning (e.g., practicing and receiving feedback on the exercises and fitness assessments). Additionally, the training was made available to Extension health educators' community partners (e.g., staff from senior centers and other health organizations) to promote a delivery model that would address the time requirement barrier; Extension health educators were encouraged to attend training with their community partners so they could offer support with implementation and evaluation. See **Figure 1**: strategy adaptation.

In alignment with Extension practices, pragmatic recruitment and feedback methods (e.g., listserv email invites and post-training surveys) were used. Nine participants completed the initial LIFT training in September 2017: the knowledge broker, one Extension health educator, and seven community partners (including one retired Extension health educator). Following this training, additional community partners expressed interest in the training, and the research team offered another training in December 2017 to four community partners.

Of the thirteen total training participants, nine (69%) completed surveys. Of the seven who completed pre-training surveys, trainees were predominantly middle-aged Caucasian females. All participants (100%) were very or completely confident in meeting physical activity recommendations. While all participants (100%) reported high physical activity levels through the International Physical Activity Questionnaire (IPAQ), only 57% reported meeting strength training guidelines. Pre-training, participants agreed that they intended to deliver LIFT and to include LIFT in a plan of work; mean values were both 4.00 (+0.707). The Wilcoxon signed-rank test showed that post-training surveys did not detect a statistically significant change in intent to deliver LIFT ($Z = 0.000$, $p = 1.000$) or inclusion of LIFT in a plan of work ($Z = -0.447$, $p = 0.655$).

The program characteristic that influences the adoption-decision making process of highest importance was "The program has been successful when tested in community settings" (mean rating of 4.00 = very important). While the majority of the factors (73%) had a mean rating between 3.00 and 3.99 (moderately important), four factors rated as only "somewhat important": "I do not feel that the program is part of my job responsibility," "I do not feel comfortable delivering the program," "I am not physically active, so do not feel comfortable delivering a physical activity program," and "I do not have the expertise that is needed to deliver the program." By February 2018 (5 months after the first training and 2 months after the second), three LIFT programs were being delivered through UWE, and the comprehensive evaluation was initiated. Due to this low initial implementation rate, a survey for trainees who both did and did not implement the program was added to the measures for adoption.

STAGE 3: DURING IMPLEMENTATION

Participants and Recruitment

The final step in this research was to evaluate both the individual-level impact and the system-level delivery of LIFT through the RE-AIM framework. The evaluation included three levels

TABLE 2 | Qualitative results of Extension health educators' perceptions of physical activity programs ($n = 2$ interviewees).

Theme	Subtheme (n = meaning units)	Category (n = meaning units)	Example meaning unit
Perceived barriers to delivering physical activity programs	Educator personal factors ($n = 51$)	Workload ($n = 17$)	And we never can say, "oh If I add this I can let that other thing go so pretty soon it's like so much that that you don't do the new stuff [programming]."
		Difficulty meeting physical activity recommendations ($n = 12$) Strength training ($n = 7$) physical activity ($n = 5$)	And so I think again you'd just have to ahh try to work that [strength training] into your routine every day and I don't.
		Lack of confidence ($n = 9$)	Because you don't feel as comfortable yet so you stick with the old stuff [programming].
		Lack of communication with colleagues ($n = 6$) Out of state colleagues ($n = 3$) Local colleagues ($n = 3$)	That I don't know. I don't have any, I guess I don't have any idea on what's going on elsewhere [physical activity programming in other states].
		Lack of interest in training ($n = 5$)	Personally, no [I wouldn't be interested in a training or certification for physical activity].
		Other influential characteristics ($n = 3$) Age ($n = 1$) Lack of training ($n = 1$) Unfamiliar with facilities ($n = 1$)	Well I think probably my biggest barrier is I'm getting old.
	Organizational structure ($n = 27$)	Job focus area ($n = 14$)	I have to concentrate a lot on um cooking and nutrition through cooking and that's sort of just where I went.
		Lack of organizational support ($n = 6$)	So I do know…. we don't think that's [delivering Strong Bones] quite the best use of our time.
		Multiple areas served ($n = 5$)	So there's five counties [that I'm employed in].
		Single-county programming ($n = 3$)	But I do a lot of little individual programing within my area too.
	Program factors ($n = 25$)	Time required ($n = 10$)	For that one [Strong Bones]… it's time consuming you know.
		Heavy weights required ($n = 4$)	Another thing was we had hand held weights and carrying those little guys around I mean they're heavy.
		Costs ($n = 3$)	…because of how much it costs you know for the gas because when we go to other counties the university reimburses us for fuel and that was you know a pretty big commitment the 2 days a week as far as financial.
		Travel ($n = 3$)	That's a tough life you know to keep going back and forth.
		Community partners not available to deliver ($n = 2$)	I just couldn't seem to find a volunteer and the senior center didn't have enough staff to commit to it [delivering Strong Bones].
		Participant recruitment ($n = 2$)	And so once you kind of do something you have to not do it for a while because probably everyone that was interested did it the first go round so you need to kind of wait and a few years and get a new bunch of people that might be interested.
		Lack of variety ($n = 1$)	The one thing I know by the end of the 8 weeks the people were getting tired because they were of the same exercises, it was the exact, you know it would be like doing an aerobics class with the exact same routine for 8 weeks. And so with that one you know I don't think we changed.

(Continued)

TABLE 2 | Continued

Theme	Subtheme (n = meaning units)	Category (n = meaning units)	Example meaning unit
		Maintenance of physical activity ($n = 1$)	Whether they stick with it or not is you know is another issue.
	Facilities ($n = 10$)	Lack of facilities ($n = 4$)	We don't have like a YMCA or a rec center.
		Lack of space ($n = 3$)	But you know that was when I did it [Strong Bones] … I had in the building I have we have a conference room so you'd have to move all the tables and chairs and then put them all back.
		Facility operating hours ($n = 3$)	The weight room we have a great facility it's just such limited hours.
	Weather ($n = 2$)	Winter weather ($n = 1$)	But I think one of our biggest barriers that we face is um our weather is not conducive to um outdoor stuff. In the winter it's cold and snowy and icy and the wind is blowing. So if you don't have a place to do that inside it makes it really hard. And winter, I mean a lot of times by the first of October till may were in winter, you know.
		General weather ($n = 1$)	But I think weather is a huge thing for us.
Perceived facilitators to delivering physical activity programs	Educator personal factors ($n = 61$)	Positive perception of physical activity ($n = 22$)	I've always just believed it's really good for your health.
		Aerobic activity recommendation ($n = 7$)	
		Active lifestyle ($n = 5$)	
		Belief that older adults need physical activity ($n = 4$)	
		Need for strength training ($n = 2$)	
		Strength training ($n = 2$)	
		Health benefits ($n = 1$)	
		Ease of meeting recommendations ($n = 1$)	
		Types of activities used to meet physical activity recommendations ($n = 8$)	Well I just try to set time, 5 days a week, you know I exercise, um my walking partner has just started going south for the winter, but we would usually do like 2 days in the gym.
		Walking ($n = 5$)	
		Exercise bike ($n = 2$)	
		Gym ($n = 1$)	
		Positive perception of physical activity programming ($n = 7$)	We've always felt it's important and if we can speak about it and add a little tidbit here and there that's good so I think we're coming along with having an actually subcommittee that's maybe gonna bring forth some programs or help strengthen that area [physical activity] you know by whichever tactic they take.
		Strategies used to meet physical activity recommendations ($n = 6$)	I also have like a Garmin, Fitbit whatever you want to call it, so that helpful, reminds me to move, it reminds me to you know how far I have walked, so.
		Fitbit for motivation ($n = 3$)	
		Habit ($n = 1$)	
		Working around weather ($n = 1$)	
		Creativity ($n = 1$)	
		Peer influence ($n = 4$)	So I think they [younger educators] are all very excited and they're trying to get us older ones on board, so.
		Positive perception of Strong Bones program ($n = 3$)	Um, You know that little handheld weight program with um, Strong Women was easy.
		Confidence ($n = 2$)	Um I would say, like do you want a rating scale, I'd say fairly confident [in successfully delivering physical activity programming].
		Knowledge of physical activity recommendations ($n = 1$)	I know kids have a different recommendation.

(Continued)

TABLE 2 | Continued

Theme	Subtheme (n = meaning units)	Category (n = meaning units)	Example meaning unit
	Organizational factors ($n = 38$)	Initiative team ($n = 11$) Need team buy-in ($n = 6$) Programs should be chosen as a team ($n = 3$) Willing to deliver programs chosen by team ($n = 2$)	Because if you don't, there's so few of us, there's what like 10 if we're fully staffed, and I think we're down to seven maybe or eight now, and so there's so few of us so in order to get the kind of impacts you need to all buy into the same thing.
		Issue team ($n = 7$) New active living team ($n = 4$) Issue team structure ($n = 3$)	And for the first time we actually have an issue team that deals with physical activity.
		Job performance evaluation ($n = 6$)	But um they [superiors] you know want us to be out teaching and educating.
		Organizational support ($n = 4$)	We have a very progressive person as our nutrition and food safety administrator and I think she would be really behind this, so.
		Organizational change ($n = 3$)	And so whoever takes over my position will be 100% nutrition and food safety.
		Role in Extension ($n = 2$)	I am a nutrition and food safety educator.
		Age difference ($n = 2$)	I think the young ones, we're kind of divided right now, there's three of us that I would consider in the older group (laughing) and the rest of them are all very young.
		Educators value physical activity ($n = 2$)	You know I think we all [Wyoming Extension health educators] realize physical activity is very important.
		Need for program evaluation ($n = 1$)	And then you know we'll have our evaluations ready and go from there.
	Physical activity training ($n = 31$)	Past training ($n = 16$) Training components ($n = 9$) Programs trained on ($n = 5$) Perceptions of training ($n = 2$)	[I enjoyed Strong Bones training] cause there were some of the exercises I wasn't sure if I was doing them exactly right or not you know.
		Desire for training ($n = 11$) Desired training components ($n = 5$) Belief in importance of training ($n = 3$) Program type ($n = 2$)	Maybe having to um do some of the program in front of some of the rest of us. Um hands on as far as that goes.
		Need for resources ($n = 1$)	
		Current training methods ($n = 4$)	So basically what I keep up with is you know if I find a webinar that's interesting.
	Community partners ($n = 14$)	Delivery support ($n = 11$)	That we could work with someone in our community and get that [physical activity program] delivered.
		Partnerships with local organizations ($n = 3$)	Yes. Yes, I do [generally have partnerships with the senior center].
	Facilities ($n = 9$)	School ($n = 3$)	Um, I think that's one thing, our school makes it easy, like, we can use their hallways, and we try to do things sometimes in conjunction with the schools.
		Fairground ($n = 2$)	And we try to have things here at our fair grounds, for like if we have a 4-H event we have a basketball hoop here and we're gonna install horseshoe ends, and so we are trying to do some things that encourage physical activity.

(Continued)

TABLE 2 | Continued

Theme	Subtheme (n = meaning units)	Category (n = meaning units)	Example meaning unit
		Walking path ($n = 2$)	Having a place to do it um you know we have some bike paths well we have a walking bike path which is good.
		Playground ($n = 1$)	And we do have really nice playgrounds in town, so it's easy to like have a 4-H activity maybe at the park where the kids can use the equipment that we have.
		Pool ($n = 1$)	Um, we just got, one thing is we just got a brand new swimming pool so the kids are excited, we have tried to incorporate going to the pool into our 4-H activities.
	Program factors ($n = 4$)	Resources available ($n = 2$)	And some people would have their own weights and some wouldn't so that's why we always had weights with us that we carried so that if someone didn't have their own we would provide them with some if I can remember them right the weights were from like one or two pounds up to maybe 10 just those little hand held dumbbells.
		Target audience interest ($n = 2$)	And every year we have to reprint those [walking program] maps for everyone to use 'cause they like them so much, so that's been kind of a cool thing we did.
Types of programs delivered	Physical activity programs delivered ($n = 32$)	Past programs delivered ($n = 18$)	We've [in the past] done things like have a treasure hunt where they [4-H kids] have to follow a treasure map and count their steps and find the treasure.
		Program adaptation ($n = 11$)	And then probably have to make some adjustments. Because even if it is a program from another state, we like to "Wyomingize" it make it for our clientele so it's successful.
		Needs assessment methods ($n = 3$)	Um we have a focus group (pause) system of um clientele assessment that we use um we meet in different counties every year and then we get the various county reports plus a statewide summary we use.
	Methods of promoting physical activity ($n = 17$)	Dissemination methods ($n = 9$)	So I tried to get the word out [on physical activity] vs. doing it with them in a class.
		Physical activity topics delivered ($n = 8$)	I mean with my, I do a variety of projects so for example at the senior center my last topic was sit less move more.
	Program target audience ($n = 11$)	Older adults ($n = 4$)	Uh elderly I'm guessing they [Strong Bones participants] were oh probably 60 and up.
		Adults ($n = 3$)	We've had anyone from 20 to probably 75 [in Dining with Diabetes].
		Diabetics and their caretakers ($n = 3$)	And some of them are like the wife of someone with diabetes.
		All age groups ($n = 1$)	Um my primary I don't know I do everything from youth through seniors.
	Nutrition/food safety programs delivered ($n = 6$)	Current programs delivered ($n = 3$)	Um just trying to think what else we've done recently. I do a lot of food preservation, but there's really no physical activity portion to that.
		Past programs delivered ($n = 3$)	Um we've done Dining with Diabetes here numerous times here.
	Programs not delivered ($n = 5$)	Not currently doing physical activity programs ($n = 4$)	I think the lack of not having anything real formal since the Strong Women, you know the Body Works program, we haven't really had anything formal since that, it's been quite a few years, maybe even more 3 years.
		Not currently doing physical activity in nutrition programs ($n = 1$)	Um it you know I do um nothing specific [nutrition programs that include physical activity] at the moment.

TABLE 3 | RE-AIM dimensions and measures.

Dimension	Aims and outcome measures
Reach: Number, proportion, and representativeness of LIFT older adult participants	**Aim:** To monitor and evaluate older adult participation rate **Outcome Measure:** Number of LIFT participants, demographic items through pre-program survey
Effectiveness: Impact on primary outcomes, quality of life, and unintended consequences	**Aim:** To confirm the effectiveness of LIFT at improving functional fitness and increasing physical activity levels **Outcome Measure:** Functional Fitness Assessments, International Physical Activity Questionnaire through pre- and post-program surveys
Adoption: Number, proportion, and representativeness of settings and staff who deliver the intervention	**Aim:** To monitor and evaluate Extension health educator and community partner adoption rate; to understand factors influencing adoption **Outcome Measure:** Number of Extension health educators and community partners implementing LIFT, demographic items through pre-training survey; acceptability, appropriateness, and feasibility of LIFT through follow-up survey
Implementation: Degree to which intervention was delivered as intended	**Aim:** To determine the degree of fidelity to which LIFT is delivered by Extension health educators and community partners **Outcome Measure:** Process evaluations
Maintenance (system level): Extent to which delivery/ implementation is sustained over time	**Aim:** To evaluate administrator support of LIFT **Outcome Measure:** Acceptability, appropriateness, and feasibility of LIFT through follow-up survey

of respondents in an attempt to collect data on all RE-AIM dimensions: *reach* and *effectiveness* (LIFT participants), *adoption* and *implementation* (delivery personnel, i.e., both Extension health educators and community partners), and system-level *maintenance* (UWE administrators). LIFT participants were recruited through senior centers (including participants in Strong Bones programs), newspaper articles, flyers, and word of mouth. Extension health educators and community partners were contacted via email after the LIFT training to complete a brief online survey. Extension administrators ($N = 3$) were also contacted via email to complete a brief online survey.

Data Collection and Analysis

Data were collected on all RE-AIM dimensions except for individual-level maintenance, which was outside the scope of this work (see **Figure 1**: integration trials). Measures for each dimension were as follows (see **Table 3** for detailed aims and outcome measures):

Reach

LIFT participants completed baseline surveys including demographic items used to calculate reach (proportion and representativeness).

Effectiveness

The pre- and post-program surveys included IPAQ items to assess whether participants were meeting physical activity recommendations (28). A validated seven-item test associated with performing everyday activities independently (29) was completed at baseline and post-program, as an additional outcome of LIFT is improving functional fitness.

Adoption

The primary adoption indicator was the total number and representativeness of those trained on LIFT program (including both Extension health educators and community partners). In addition, all those eligible to deliver the LIFT program were asked to complete a survey assessing: (1) acceptability, appropriateness, and feasibility (30) of implementing LIFT (on a 5-point Likert scale; 1-completely disagree, 5-completely agree), and (2) their current stage of change category (23) based on the 6-point scale of 1- "I am not considering delivering LIFT in my county at all" to 6- "I have been delivering LIFT for 6 months of more." Demographic items were not included to create a short survey that decreased respondent burden.

Implementation

This was assessed through process evaluations designed for delivery personnel to self-report the extent to which the program was delivered as intended and capture adaptations made during program delivery. The process evaluations contained five categories: warm-up activity, group-dynamics strategy, exercises, cool down, and overall program delivery.

Maintenance

As a proxy measures for system-level maintenance, administrator perceptions were sought related to: (1) acceptability, appropriateness, and feasibility (30) of LIFT; (2) the importance of RE-AIM factors for LIFT [e.g., "The program has potential to attract/recruit a group of participants that is representative of the residents of Wyoming (reach); LIFT has been previously tested in community settings (effectiveness): 1-not at all important, 5-very important], and (3) whether they supported educators in delivering LIFT (yes or no with reasons why or why not). Demographic items were also not included in this survey.

Means and standard deviations of continuous variables and frequencies and proportions of nominal variables were calculated for the overall sample. Representativeness was calculated by comparing demographics (age, gender, race, ethnicity, education level, and work status) of LIFT participants to all older adults (age 65 and older) in Wyoming (city or county level census

TABLE 4 | LIFT participant characteristics compared to older adults (age 65+) in Wyoming.

Demographics	LIFT Participants (N= 18)	Older Adults in Wyoming
	Mean (±SD)	Mean
Age	67.8 (±4.9)	73
	N (%)	N (%)
GENDER		
Female	18 (100)	45,921 (52)
Male	0 (0)	41,891 (48)
RACE		
White	18 (100)	84,488 (96)
Other race	0 (0)	3,324 (4)
ETHNICITY		
Non-Hispanic	18 (100)	83,649 (95)
Hispanic	0 (0)	4,163 (5)
EDUCATION LEVEL		
High school graduate or some college	11 (61)	51,814 (64)
Bachelor's degree or higher	7 (39)	19, 854 (25)
WORK STATUS		
Not in the labor force (retired, disabled/unable to work, or homemaker)	16 (89)	64,001 (79)
Employed	2 (11)	16,222 (20)
BMI		
Overweight or obese	14 (78)	1,077 (64)
Normal weight	4 (22)	603 (36)

data was not available) (31). As raw data was not available for education level or work status, frequencies were calculated by using census data percentages and totals. Representativeness of BMI was calculated by comparing LIFT participants to the sub-sample of older adults in Wyoming (age 65 and older) who were selected and responded to the Behavioral Risk Factor Surveillance System (BRFSS) survey. A one-sample *t*-test was used to compare mean age; Fisher's exact test was used to compare categorical variables due to the small sample size.

Results

Reach

Forty-eight participants attended the LIFT classes. However, only 37 individuals agreed to the research portion of this work. Of the 37 who agreed to be research participants, 18 completed pre-program surveys. These participants had a mean (±SD) age of 67.8 (±4.9) years, were predominantly retired (78%), and were Caucasian females (100%). Participants had a mean (±SD) BMI of 29.9 (±7.0) with seven (39%) classified as obese, seven (39%) classified as overweight, and four (22%) classified as normal weight. For each of the three delivery locations, proportion of LIFT participants was calculated as 17 out of 1,480 adults age 65 or older (1%) in Lander, 12 out of 35 (34%) in Pavillion, and 8 out of 281 (3%) in Guernsey. When comparing the representativeness of LIFT participants to older adults in Wyoming, there were no significant differences in terms of race ($p = 1.000$), ethnicity ($p = 1.000$), employment status ($p = 1.000$), education level ($p = 0.297$), and BMI ($p = 0.324$). There was a significant difference in age and gender: LIFT participants were younger ($t = -4.385$, $p = 0.000$) and more likely to be female ($p = 0.000$) (see **Table 4**).

Effectiveness

Of the 37 LIFT research participants, 10 completed both pre- and post-program functional fitness assessments. There was a statistically significant increase in the 30 s chair stand test ($t = -2.673$, $p = 0.028$) and no significant difference in any of the other tests (balance station, 30 s arm curl, 2 min step test, chair sit and reach, back scratch, and eight food up and go). As only five participants completed both pre- and post-program surveys, changes in physical activity levels were not included in this report.

Adoption

Proportion of delivery agents was calculated for both Extension health educators and community partners. Of the six Extension health educators employed at the time who were invited to the training, one delivered LIFT for an adoption rate of 17%. Of the two Extension health educators who attended training, one delivered LIFT for an adoption rate of 50%. However, the other Extension health educator who attended training indicated through the follow-up email 2 months post-training that she was planning on delivering LIFT but had not yet scheduled a session; she also recruited community partners to attend the second LIFT training and assisted one of the community partners with completing evaluations when she delivered the program.

Of the eleven community partners who attended training, two delivered LIFT for an adoption rate of 18%. Representativeness of those who delivered LIFT compared to those who attended the training but did not deliver LIFT was not calculated, as demographic data from the pre-training survey was only available for one of the educators who delivered LIFT.

Demographics of those invited to attend LIFT training (the six Extension health educators) were compared to the demographics of those who attended LIFT training (both Extension health educators and community partners) and completed the pre-training survey (see **Table 1**). Due to the small sample sizes, representativeness was not calculated.

One of the 13 training attendees and none of the four Extension health educators who did not attend training completed follow-up surveys. Due to the low response rate, survey results are not included.

Implementation

One of the two eligible delivery personnel completed process evaluations. One other educator completed the process evaluations, but these data were not eligible for inclusion in analysis as she was also the knowledge broker (i.e., a research team member with the potential to bias responses) (32). Results from the one educator indicated that the program was overall delivered as intended 100% of the time, although adaptations were made to program components: the warm-up was delivered with 63% fidelity, group dynamics-based activities 75%, strength training exercises 100%, and cool-down 69%. Due to the small sample size, these data should be interpreted with caution.

Maintenance

One of the three administrators completed the surveys; due to the low response rate, administrator survey results are also not included.

Discussion

Results of this work indicated initial struggles in scaling-out a previously tested Extension EBI to Wyoming Extension. All three stages were equally important in capturing the challenges and facilitators of the LIFT EBI scale-out; however, a lack of compliance with data completion (see **Figure 1**: evaluation processes and outcomes) highlights challenges of a pragmatic approach to data collection (e.g., without large funds for systematic evaluation). This is notable as the researchers were also from within the Extension system, and therefore, aligned evaluation with standards of practice. Therefore, translational solutions (**Figure 1**) are yet to be determined. However, there were notable observations and implications, by stage, to be shared.

Stage 1: Before Adoption

In order to improve physical activity program adoption rates among Extension health educators, system-wide changes are needed. While it appears that the UWE organizational structure supports physical activity programming (e.g., interviewees mentioned a newly developed Active Living issue team tasked with choosing physical activity programs to deliver), educators face barriers to adopting these programs, including role clarity, traditional delivery models, and organizational culture.

Physical activity is not explicitly included as a focus area of Extension health educators' work. Including "physical activity promotion" in Extension health educators' job descriptions and changing position titles to be more inclusive of physical activity could help educators prioritize physical activity programming and de-implement other work duties that are not evidence-based (33). In addition, physical activity programming is fairly new as an Extension target area and Extension educators (in both health and other disciplines) not aware of this change may not support physical activity programming among their colleagues. Interviewees also mentioned a lack of communication with colleagues, both those on their initiative team as well as educators in neighboring states, which makes program dissemination difficult (34). Future work should investigate the usefulness of a dissemination network of Extension state specialists that assists educators in staying informed of evidence-based physical activity promotion efforts taking place nationwide (34).

In addition to role clarity within the system, Extension professionals need guidance on how to leverage volunteers and community members to engage participants across a disperse region. That is, novel approaches for program delivery may be necessary to increase the penetration of an intervention across a state system, particularly a large rural one. For example, interview respondents mentioned time required for program delivery as a barrier to Strong Women, Strong Bones (and LIFT requires a similar time commitment); adaptations to the delivery model may encourage adoption. They also mentioned a lack of funds to cover fuel to reach geographically disparate communities. A train-the-trainer delivery model may help Extension health educators to adopt the program and then turn it over to community partners, as has been done by Washburn and colleagues for their version of LIFT (35). To address lack of time as a barrier, Extension health educators also need training on evidence-based programming; this training could encourage them to adopt existing structured, evidence-based programs instead of developing their own programming (36). Future studies should explore the effects on program adoption rates when these system-level changes are made.

Finally, the culture of the organization and the state can also affect physical activity program adoption. Wyoming is a politically conservative state with an individualistic and independent culture. This culture can impede health promotion efforts, as observed in the tobacco control efforts of the 2000s: "We are independent, we're rugged, we'll smoke if we want to, and do not want any government folks trying to tell us how to live healthier and live longer" (37). This belief can be a barrier to adoption of any program with health behavior change as an outcome. To encourage adoption of physical activity interventions, it may be necessary to shift this mindset within the system.

Stage 2: During Adoption

Although perceptions of the LIFT training were positive, participating in training did not change attendees' predictors of implementation, stage of change, or positive intent to deliver both the LIFT program and physical activity programming in general. This may be because those who attended already planned on delivering LIFT (e.g., intent to incorporate physical activity into existing programming and intent to deliver LIFT both had a mean rating of 4 (agree) both before and after training). As these are the top predictors of program implementation, it was

expected that program implementation rates following training would be high. However, only 2 months had passed since the second LIFT training, so it is possible that those who attended training will deliver LIFT once they have determined a location, community partners, etc., as intent to deliver LIFT was high post-training. The optimal length of time post-training to assess implementation status is unknown; other studies of Extension-delivery physical activity programs have assessed delivery status after 1 year (Ramalingam et al., in preparation) or annually for 5 years (38). Overall, through this iterative work, attempts were made to include perceptions of delivery agents to "begin with the end in mind (39)"; however, in this study, these efforts to align the intervention with the pull of the system (40) did not lead to strong adoption or implementation. More work is needed to determine what factors would lead to higher implementation rates.

More work is needed to understand the adoption-implementation gap among community partners that occurred following the LIFT training. Training attendees had positive perceptions of the training and intentions to deliver LIFT post-training. Without responses to the follow-up survey, it is difficult to understand perceptions of the program or implementation barriers that occurred. Future research on system-level changes to promote physical activity programming through Extension, training on evidence-based programming for Extension health educators, physical activity program delivery methods that decrease educator time commitment, and barriers to community partner program implementation are needed to address low adoption and implementation rates.

Stage 3: During Implementation

Extension is an open-access entity that values pragmatic outcomes; stringent collection of empirical data is more novel to this system and its personnel. Therefore, the magnitude of effect and fit of LIFT within the system is yet to be determined. Furthermore, it was difficult to determine if the program was implemented with fidelity; changes are needed to encourage or incentivize collecting these data from delivery personnel (41, 42). While self-report process evaluations seem easy and manageable, observations may be necessary to monitor program delivery. However, these observations require intense resources (travel, time), so the longevity of this approach may not be feasible. Future work is needed to determine how to train for and monitor high quality delivery.

Although effectiveness, adoption, and implementation data were challenging to collect, there were positive outcomes in terms of reach. First, LIFT demonstrated a strong reach among eligible older adults, particularly in small communities (e.g., 34% of older adults (12 participants) from one community participated). In terms of representativeness, LIFT participants were more likely to be female; however, this is also not surprising as the Wyoming Extension system had previously delivered Strong Women, Strong Bones (21). The program was eventually called "Strong Bones" to be more inclusive but more females participated. One advantage of LIFT is that it is available and promoted to both men and women, similar to the Stay Strong, Stay Healthy program of Extension in Missouri and, more recently, Kansas (19, 43). Although previous research demonstrated that older adults prefer to exercise with other older adults (44, 45), new research shows that gender-segregated classes do not produce better adherence or physical activity outcomes when compared to classes of similar age but mixed-gender (46). From a practical perspective, some older adults may prefer gender segregated classes (44), but LIFT will continue to be offered to all aging adults due to its open-access policy (7).

Limitations

The most prominent limitation of this work is the small sample size for empirical data. However, in pragmatic settings large sample sizes are not always available; the purpose of this work was to report process and outcome data in order to aid in replicability and understanding the process of scaling an intervention that was adapted specifically for Extension. Due to low survey response rates, perceptions of LIFT that influence adoption and system level maintenance were not captured. These data may have offered insight into reasons for LIFT not being adopted and implemented (e.g., low perceived acceptability, appropriateness, or feasibility among community partners, Extension health educators, or UWE administrators) and predicted institutionalization of the program. Future work should consider other methods of collecting data to determine perceptions of LIFT and potentially adapt the program to improve adoption and implementation rates. The sample sizes for each portion of this study were small as they were limited by the organization structure of UWE (i.e., only three administrators and six Extension health educators serve the entire state). However, these educators have a large reach, as they cover the entire state and are tasked with providing community-based education to all Wyomingites.

Finally, strategies to partner with delivery personnel could have been better used to enhance buy-in and ensure a good fit between LIFT and UWE as a delivery system (47). The research team did not fully employ an IRPP in UWE, as the LIFT program was developed through an IRPP in VCE. As there were challenges with translating LIFT from Virginia to Wyoming, in the future employing a new, state-specific IRPP is recommended to address potential program adaptations and enhance program sustainability.

This is the first study to follow the scaling-out of an Extension intervention for Extension professionals by Extension professionals that did not include place-based adaptations. For example, Sequin et al. used Extension as a dissemination model for the Strong Women, Strong Bones intervention but were not Extension professionals themselves (48). In another example, a statewide walking program was translated to a new state but the state made place-based adaptations before launching the intervention (1, 49). Reports like this one are needed to show the challenges, successes, and next steps to translating evidence-based interventions across state lines within the national system as well as to other community-based entities that partner with Extension.

CONCLUSION

Applying a planning and evaluation framework (e.g., RE-AIM) has the potential to improve transparency and translation of best practices into community settings. However, many settings do not have the resources to capture these iterative, pragmatic data. The results of this study suggest that system-level changes are needed to increase physical activity program adoption rates among Extension health educators, reduce system-level barriers (e.g., role clarity, lack of time or transportation funds), and leverage partnerships to ensure programs can reach those most in need of intervention. Collecting ongoing effectiveness data will be a challenge, and pragmatic ways to indicate a public health impact need to be developed (and match systems' capacity, interest, and value). These improvements in community-based and community-driven data collection may improve reach, effectiveness, adoption, implementation, and maintenance of interventions within Extension.

AVAILABILITY OF DATA AND MATERIALS

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

AUTHOR CONTRIBUTIONS

LB and SH conceived of the study, and participated in its design and coordination. LB led the manuscript preparation. NR contributed to data collection and analysis. TS contributed to data analysis. All authors read, contributed to, and approved the final manuscript.

SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2018.00357/full#supplementary-material

REFERENCES

1. Harden S, Johnson SB, Almeida F, Estabrooks P. Improving physical activity program adoption using integrated research-practice partnerships: an effectiveness-implementation trial. *Transl Behav Med.* (2017) 7:28–38. doi: 10.1007/s13142-015-0380-6
2. United States Department of Agriculture. *Civil Rights Compliance Review Guide: Extension Programs*. Washington, DC; n.d. Available online at: https://agsci.psu.edu/diversity/civil-rights-compliance-training/civil-rights-compliance-review-guide-extension-programs
3. United States Department of Agriculture. *The Farm Bill 2015*. Washington, DC (2015). Available online at: https://nifa.usda.gov/farm-bill
4. United States Department of Agriculture. *NIFA Strategic Plan FY2014–FY2018 2015*. Washington, DC (2015). Available online at: https://nifa.usda.gov/resource/nifa-strategic-plan-fy2014-fy2018
5. Braun B, Bruns K, Cronk L, Kirk Fox L, Koukel S, Le Menestrel S, et al. *Cooperative Extension's National Framework for Health and Wellness*. Washington, DC: United States Department of Agriculture (2014).
6. Aarons G, Sklar M, Bustanski B, Benbow N, Hendricks Brown C. "Scaling-out" evidence-based interventions to new populations or new health care delivery systems. *Implement Sci.* (2017) 12:111. doi: 10.1186/s13012-017-0640-6
7. Balis L, Strayer T, Ramalingam N, Wilson M, Harden S. Open-access physical activity programs for older adults: a pragmatic and systematic review. *Gerontologist*5 (2018) gnx195. doi: 10.1093/geront/gnx19
8. Whitelaw N. System change and organizational capacity for evidence-based practices: lessons from the field. *Generations J Am Soc Aging* (2010) 34:43–50.
9. Wilcox S, Dowda M, Leviton LC, Bartlett-Prescott J, Bazzarre T, Campbell-Voytal K, et al. Active for life: final results from the translation of two physical activity programs. *Am J Prev Med.* (2008) 35:340–51. doi: 10.1016/j.amepre.2008.07.001
10. Glasgow R. What does it mean to be pragmatic? Pragmatic methods, measures, and models to facilitate research translation. *Health Educ Behav.* (2013) 40:257–65. doi: 10.1177/1090198113486805
11. Glasgow R, Estabrooks P. Pragmatic applications of RE-AIM for health care initiatives in community and clinical settings. *Prev Chron Dis.* (2018) 15:1–7. doi: 10.5888/pcd15.170271
12. Glasgow R, Vogt T, Boles S. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health* (1999) 9:1322–7.
13. Glasgow RE, Nelson CC, Strycker LA, King DK. Using RE-AIM metrics to evaluate diabetes self-management support interventions. *Am J Prev Med.* (2006) 30:67–73. doi: 10.1016/j.amepre.2005.08.037
14. Harden S, Smith M, Smith-Ray R, Ory M, Estabrooks P, Glasgow R. RE-AIM in clinical, community, and corporate settings: perspectives, strategies, and recommendations to enhance public health impact. *Front Public Health* (2018) 6:71. doi: 10.3389/fpubh.2018.00071
15. Estabrooks P, Harden S, Almeida F, Hill J, Johnson S, Greenaward M. Translating evidence-based principles into sustained programs through integrated research practice partnerships. *Exerc Sport Sci Rev.* (forth coming).
16. Bornbaum C, Kornas K, Peirson L, Rosella L. Exploring the function and effectiveness of knowledge brokers as facilitators of knowledge translation in health-related settings: a systematic review and thematic analysis. *Implement Sci.* (2015) 10:162. doi: 10.1186/s13012-015-0351-9
17. Wilson ML, Strayer T, Davis R, Harden SM. Informed adaptations of a strength-training program through a research-practice partnership. *Front Public Health* (2018) 6:58. doi: 10.3389/fpubh.2018.00058
18. Wilson ML, Strayer III T, Davis R, Harden SM. Use of an integrated research-practice partnership to improve outcomes of a community-based strength-training intervention for older adults: reach and effect of lifelong improvements through fitness together (LIFT). *Int J Environ Res Public Health* (2018) 15:237. doi: 10.3390/ijerph15020237
19. Ball S, Gammon R, Kelly P, Cheng A-L, Chertoff K, Kaume L, et al. Outcomes of stay strong, stay healthy in community settings. *J Aging Health* (2013) 25:1338–97. doi: 10.1177/0898264313507318
20. Estabrooks P, Fox E, Doerksen S, Bradshaw M, King A. Participatory research to promote physical activity at congregate-meal sites. *J Aging Phys Act.* (2005) 13:121–44. doi: 10.1123/japa.13.2.121
21. Nelson M, Wernick S. *Strong Women Stay Young*. New York, NY: Bantam Books (1997).
22. Creswell J, Plano Clark V. *Designing and Conducting Mixed Methods Research*. Los Angeles, CA: Sage (2011).
23. Prochaska J, DiClemente C. *The Transtheoretical Approach: Crossing Traditional Boundaries of Change*. Homewood, IL: Dorsey Press (1984).
24. Proctor E, Landsverk J, Baumann A, Mittman B, Aarons G, Brownson R, et al. The implementation research institute: training mental health implementation researchers in the United States. *Implement Sci.* (2013) 8:105.doi: 10.1186/1748-5908-8-105
25. Nebeker C, Lopez-Arenas A. Building research integrity and capacity (BRIC): an educational initiative to increase research literacy among community health workers and promotores. *J Microbiol Biol Educ.* (2016) 17:41–5. doi: 10.1128/jmbe.v17i1.1020
26. Weimar M. *Learner-Centered Teaching: Five Key Changes to Practice*. San Francisco, CA: Jossey-Bass (2013).

27. Salas E, Tannenbaum S, Kraiger K, Smith-Jentsch K. The science of training and development in organizations: what matters in practice. *Psychol Sci Public Interest* (2012) 13:74–101. doi: 10.1177/1529100612436661
28. Craig C, Marshall A, Sjostrom M, Bauman A, Booth M, Ainsworth B, et al. International physical activity questionnaire: 12-country reliability and validity. *Med Sci Sports Exerc.* (2003) 35:1381–95. doi: 10.1249/01.MSS.0000078924.61453.FB
29. Rikli R, Jones CJ. Development and validation of a functional fitness test for community-residing older adults. *J Aging Phys Act.* (1999) 7:129–61.
30. Weiner B, Lewis C, Stanick C, Powell B, Dorsey C, Clary A, et al. Psychometric assessment of three newly developed implementation outcome measures. *Implement Sci.* (2017) 12:108. doi: 10.1186/s13012-017-0635-3
31. United States Census Bureau. *American Fact Finder 2016*. Washington, DC (2016). Available online at: https://factfinder.census.gov/faces/nav/jsf/pages/community_facts.xhtml?src=bkmk#
32. McCambridge J, Witton J, Elbourne D. Systematic review of the Hawthorne effect: new concepts are needed to study research participation effects. *J Clin Epidemiol.* (2014) 67:267–77. doi: 10.1016/j.jclinepi.2013.08.015
33. Harden S, Lindsay A, Everette A, Gunter K. Systematic review of physical activity objectives in extension strategic plans: findings and implications for improved public health impact. *J Ext.* (2016) 54.
34. Strayer III T, Kennedy L, Balis L, Ramalingam N, Wilson M, Harden SM. Cooperative extension gets moving, but how? Exploration of extension health educators' sources and channels for information-seeking practices. *BMC Health Serv Res.* (forth coming).
35. Washburn L, Cornell C, Phillips M, Felix H, Traywick L. Strength training in community settings: impact of lay leaders on program access and sustainability for rural older adults. *J Phys Act Health* (2014) 11:1408–14. doi: 10.1123/jpah.2013-0007
36. Peña-Purcell N, Bowen E, Zoumenou V, Schuster E, Boggess M, Manore M, et al. Extension professional's strengths and needs related to nutrition and health programs. *J Ext.* (2012) 50.
37. The Center for Tobacco Policy Research. *The Wyoming Profile: A Review of Wyoming's Tobacco Prevention & Control Program*. St. Louis, MO: Saint Louis University Prevention Research Center (2003).
38. Estabrooks PA, Bradshaw M, Dzewaltowski DA, Smith-Ray RL. Determining the impact of Walk Kansas: applying a team-building approach to community physical activity promotion. *Ann Behav Med.* (2008) 36:1–12. doi: 10.1007/s12160-008-9040-0
39. Klesges L, Estabrooks P, Dzewaltowski D, Bull S, Glasgow R. Beginning with the application in mind: designing and planning health behavior change interventions to enhance dissemination. *Ann Behav Med.* (2005) 29:66–75. doi: 10.1207/s15324796abm2902s_10
40. Lavis JN, Lomas J, Hamid M, Sewankambo NK. Assessing country-level efforts to link research to action. *Bull World Health Organ.* (2006) 84:620–8. (41): doi: 10.2471/BLT.06.030312
41. Ahn S, Smith ML, Altpeter M, Belza B, Post L, Ory MG. Methods for streamlining intervention fidelity checklists: an example from the chronic disease self-management program. *Front Public Health* (2015) 2:294. doi: 10.3389/fpubh.2014.00294
42. Lambert JD, Greaves CJ, Farrand P, Cross R, Haase AM, Taylor AH. Assessment of fidelity in individual level behaviour change interventions promoting physical activity among adults: a systematic review. *BMC Public Health* (2017) 17:765. doi: 10.1186/s12889-017-4778-6
43. K-State Research and Extension. *Stay Strong, Stay Healthy*. Manhattan, KS: Kansas State University (2018). Available online at: https://www.k-state.edu/staystrong/
44. Beauchamp M, Carron A, McCutcheon S, Harper O. Older adults' preferences for exercising alone versus in groups: considering contextual congruence. *Ann Behav Med.* (2007) 33:200–6. doi: 10.1080/08836610701310037
45. Dunlop W, Beauchamp M. Birds of a feather stay active together: a case study of an all-male older adult exercise program. *J Aging Phys Act.* (2013) 21:222–32. doi: 10.1123/japa.21.2.222
46. Beauchamp M, Dunlop W, Ruissen G, Estabrooks P, Harden S, Wolf S, et al. GrOup based physical Activity for oLder adults (GOAL) randomized controlled trial: exercise adherence outcomes. *Heath Psychol.* (forthcoming).
47. Israel B, Eng E, Schulz A, Parker E. *Methods in Community-Based Participatory Research for Health*. San Francisco, CA: Jossey-Bass (2005).
48. Seguin RA, Heidkamp-Young E, Kuder J, Nelson ME. Improved physical fitness among older female participants in a nationally disseminated, community-based exercise program. *Health Educ Behav.* (2012) 39:183–90. doi: 10.1177/1090198111426768
49. Johnson SB, Harden S, Estabrooks P. Uptake of evidence-based physical activity programs: comparing perceptions of adopters and nonadopters. *Transl Behav Med.* (2016) 6:629–37. doi: 10.1007/s13142-015-0371-7

Conflict of Interest Statement: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

frontiers in Public Health

ORIGINAL RESEARCH
published: 22 November 2019
doi: 10.3389/fpubh.2019.00345

RE-AIM in the Real World: Use of the RE-AIM Framework for Program Planning and Evaluation in Clinical and Community Settings

Bethany M. Kwan[1], Hannah L. McGinnes[1], Marcia G. Ory[2], Paul A. Estabrooks[3], Jeanette A. Waxmonsky[1] and Russell E. Glasgow[1]*

[1] Department of Family Medicine and the Adult and Child Consortium of Health Outcomes Research and Delivery Science, University of Colorado Anschutz Medical Campus, Aurora, CO, United States, [2] Center for Population Health and Aging, Texas A&M University, College Station, TX, United States, [3] Department of Health Promotion, College of Public Health, University of Nebraska Medical Center, Omaha, NE, United States

Background: The RE-AIM framework has been widely used in health research but it is unclear the extent to which this framework is also used for planning and evaluating health-related programs in clinical and community settings. Our objective was to evaluate how RE-AIM is used in the "real-world" and identify opportunities for improving use outside of research contexts.

Methods: We used purposive and snowball sampling to identify clinical and community health programs that used RE-AIM for planning and/or evaluation. Recruitment methods included surveys with email follow-up to funders, implementers, and RE-AIM working group members. We identified 17 programs and conducted structured in-depth interviews with key informants ($n = 18$). Across RE-AIM dimensions, respondents described motivations, uses, and measures; rated understandability and usefulness; discussed benefits and challenges, strategies to overcome challenges, and resources used. We used descriptive statistics for quantitative ratings, and content analysis for qualitative data.

Results: Program content areas included chronic disease management and prevention, healthy aging, mental health, or multiple, often behavioral health-related topics. During planning, most programs considered reach ($n = 9$), adoption ($n = 11$), and implementation ($n = 12$) while effectiveness ($n = 7$) and maintenance ($n = 6$) were considered less frequently. In contrast, most programs evaluated all RE-AIM dimensions, ranging from 13 programs assessing maintenance to 15 programs assessing implementation and effectiveness. On five-point scales, all RE-AIM dimensions were rated as easy to understand (Overall $M = 4.7 \pm 0.5$), but obtaining data was rated as somewhat challenging (Overall $M = 3.4 \pm 0.9$). Implementation was the most frequently used dimension to inform program design ($M = 4.7 \pm 0.6$) relative to the other dimensions (3.0–3.9). All dimensions were considered similarly important for decision-making (average $M = 4.1 \pm 1.4$), with the exception of maintenance ($M = 3.4 \pm 1.7$). Qualitative corresponded to the quantitative findings in that RE-AIM was reported to be a

OPEN ACCESS

Edited by:
Melody Goodman,
New York University, United States

Reviewed by:
Hueiming Liu,
George Institute for Global Health, Australia
Helaine Mary Alessio,
Miami University, United States

****Correspondence:***
Bethany M. Kwan
bethany.kwan@cuanschutz.edu

Specialty section:
This article was submitted to Public Health Education and Promotion, a section of the journal Frontiers in Public Health

Received: *19 August 2019*
Accepted: *31 October 2019*
Published: *22 November 2019*

Citation:
Kwan BM, McGinnes HL, Ory MG, Estabrooks PA, Waxmonsky JA and Glasgow RE (2019) RE-AIM in the Real World: Use of the RE-AIM Framework for Program Planning and Evaluation in Clinical and Community Settings. Front. Public Health 7:345. doi: 10.3389/fpubh.2019.00345

practical, easy to understand, and well-established implementation science framework. Challenges included understanding differences among RE-AIM dimensions and data acquisition. Valuable resources included the RE-AIM website and collaborating with an expert.

Discussion: RE-AIM is an efficient framework for planning and evaluation of clinical and community-based projects. It provides structure to systematically evaluate health program impact. Programs found planning for and assessing maintenance difficult, providing opportunities for further refinement.

Keywords: RE-AIM, dissemination and implementation, program planning, evaluation, pragmatic

INTRODUCTION

With the proliferation of evidence-based programs for improving population health, there is a greater concern with promoting the dissemination and implementation (D&I) of health programs (1). It is important to evaluate if these programs are being used, implemented as intended, and having the expected impact on health outcomes, to ensure we are investing in the best available programs and strategies (2). There have been numerous calls for more comprehensive use of dissemination and implementation science models, theories, and frameworks (3–5) to help understand how programs work, inform future interventions, and provide generalizable knowledge. To date, most assessments of the use of frameworks have been in research settings (6). This is also true of the RE-AIM framework, use of which in research grants and publications has been well-documented (7–9). There has been far less evaluation of use of RE-AIM in non-research settings. Such use is especially appropriate for RE-AIM, which is designed to be a pragmatic model (10).

We define "non-research" projects as programs and interventions intended for local quality or health improvement rather than generalizable knowledge (e.g., instituting evidence-based practices to improve patient outcomes vs. pursuing patterns of patient changes to advance a scientific question). Research may use random assignment to control conditions and be intended to establish efficacy or effectiveness. In contrast, non-research uses –which as discussed here, include quality improvement (QI), program or product evaluation, and demonstration projects. QI and program evaluations may have greater opportunity for adaptations and iterative refinement of protocols and intervention delivery. In both research and non-research contexts, the value of RE-AIM is in adding information on issues that are often not considered, such as outcomes involving representativeness and generalizability. Yet it is not known the extent to which and how RE-AIM is used for non-research purposes.

RE-AIM is a planning and evaluation model that addresses five dimensions of individual- and setting-level outcomes important to program impact and sustainability (11): Reach, Effectiveness, Adoption, Implementation, and Maintenance. Reach refers to the absolute number, proportion, and representativeness of individuals who participate in a given intervention or program. Effectiveness is the impact of an intervention on important outcomes and includes negative effects, quality of life, and economic outcomes. Adoption is the absolute number, proportion, and representativeness of settings and intervention agents who initiate a program. Implementation refers to the intervention agents' fidelity to and adaptations of an intervention and associated implementation strategies, including consistency of delivery as intended and the time and costs. Lastly, maintenance is the extent to which a program or policy becomes institutionalized or part of the routine organizational practices and policies. Within the RE-AIM framework, maintenance also applies at the individual level, and has been defined as the long-term effects of a program on outcomes after 6 or more months after intervention contact.

Systematic reviews of the research literature on RE-AIM have found that certain dimensions (effectiveness, implementation) are evaluated and reported more often than other dimensions (reach, adoption, maintenance)—with the primary underreporting in describing the representativeness of individuals and settings, maintenance of effects, costs, and sustained program implementation (7). To our knowledge, the only reported assessment of the use of RE-AIM in non-research settings has been in a series of articles coordinated by Ory et al. on use in aging and health programs (12). In an article on perceived utility of the RE-AIM framework (13), program implementers and administrators in 27 states were interviewed about use of RE-AIM as a guiding framework to plan, deliver and evaluate state-level delivery of a national evidence-based prevention initiative directed toward older adults. Findings suggested high perceived utility by key community stakeholders in using the RE-AIM framework in national initiatives for older adults. Although RE-AIM was viewed as a useful planning, implementation, and evaluation tool, uptake was not universal across all dimensions, and difficulty was reported in applying the framework as a whole. A major conclusion from this study was the need for more tailored resources and technical assistance, something that the National Working Group on RE-AIM Planning and Evaluation Framework (www.re-aim.org) has been addressing (14, 15). Additionally, this paper called for additional assessments of the use of the RE-AIM framework in other funding initiatives as part of a quality assurance process to understand roll-out of evidence-based programming.

To understand the application of RE-AIM in non-research settings across different content areas, populations and settings, we designed a study to assess experience (understandability and usefulness) and methods and resources used to apply all five RE-AIM dimensions for program planning, evaluation, decision-making and improvement in non-research settings.

MATERIALS AND METHODS

Design

This is a cross-sectional, retrospective mixed-methods evaluation of use of RE-AIM for program planning and evaluation in clinical and community settings. We identified eligible programs and representatives using purposive and snowball sampling. We administered structured interviews to program representatives to assess both qualitative perceptions and quantitative ratings of the usability and usefulness of RE-AIM. Open-ended questions were used to elaborate upon and explain quantitative ratings, consistent with an explanatory concurrent mixed methods design. Study procedures were approved by the Colorado Multiple Institutional Review Board in June 2018.

Participants and Eligibility

Our goal was to interview 15–20 representatives from projects or programs that used RE-AIM for planning and/or evaluation in clinical or community settings. Eligibility criteria for interviewees included a lead or supportive role in the local planning, implementation, and/or evaluation of a health-related program or intervention (e.g., program director) and self-reported use of RE-AIM.

Sample Identification and Recruitment

It is challenging to review and evaluate non-research use of models and theories (13). There are no repositories or databases such as PubMed or federal grants to search, and publications in the academic literature or gray literature are rare. Therefore, pragmatic methods such as purposive and snowball sampling (asking those interviewed for recommendations of other potential participants) can be used. This makes it difficult, however, to establish a denominator or response rate.

We used multiple strategies to identify and recruit interviewees. First, we developed a brief survey sent to contacts at agencies that we had reason to believe had funded, conducted, or organized health-related programs designed primarily for local QI or community health impact (purposive sampling). Agencies included health foundations, health systems, state health departments, and national health agencies in the U.S and internationally. We targeted both agencies and individuals known to us (experienced RE-AIM scholars) to have required or encouraged use of RE-AIM for planning or evaluation of supported projects, as well initiatives in which use of RE-AIM was unknown. The identified contact persons from target agencies were sent an email with a survey link. Those that did not reply after 10 days were sent a reminder e-mail.

The survey asked, "Have any of your grantees ever actually used RE-AIM, in whole or in part, as a program planning or evaluation framework for one or more health-related programs or initiatives?" Respondents indicated how many programs or initiatives had used RE-AIM, and described projects that "Primarily aimed to improve the health or well-being of a specific community or population" and had used RE-AIM. With respondents' permission, we followed up via email to request introductions or contact information for representatives from relevant projects.

Names of representatives from relevant projects were also obtained through personal contacts, PubMed and Google Scholar searches, emails to the RE-AIM working group, and nomination by RE-AIM researchers and interviewees (snowball sampling). Literature search terms included "RE-AIM," "health" and "evaluation"; we reviewed abstracts to identify potentially eligible projects, and emailed lead authors.

In total, we emailed 95 people with invitations to complete the survey (for agency representatives) and/or participate in the interview (for program representatives; some people represented both). Many were multiple potential contacts for the same program. Of the 35 surveys completed, 19 reported their grantees had used RE-AIM; 14 indicated they would provide introductions to project representatives. Of the 17 interviews conducted, 8 resulted from contacts identified by those who were sent the survey, 1 resulted from nominations from other interviewees, 2 resulted from emails to the RE-AIM working group, and 2 resulted from personal contacts. Four of the interviewees were co-authors on this paper, who are experienced evaluators and had used RE-AIM for eligible projects. All but one interview was conducted by a trained research assistant; one was conducted by the lead author.

Outcomes and Data Collection Tools

Data were collected using a structured interview guide (**Supplementary Material**). Additionally, we requested copies of any public documents, project summaries, and reports involving the RE-AIM framework on their project. Participants reported if they had ever been involved in a "non-research" project that used RE-AIM, in whole or in part, as a program design or evaluation framework; if they had been involved in more than one such project, they were asked to consider the most recent project for the remainder of the interview. We audio recorded the interviews, and kept detailed notes. We appended our notes after the interview by reviewing the recordings.

Quantitative Outcomes

For each RE-AIM dimension, participants reported whether they used the dimension for initial planning or program design, evaluation, or both, and described how they measured or otherwise operationalized the dimension. Additional details about measurement/operationalization were gathered from written reports or documents provided by the interviewee. Interviewees rated usability and usefulness of the five RE-AIM dimensions using 5-point Likert-type scales: "Dimension was easy to understand" (1 very difficult – 5 very easy); "Getting the data to assess this dimension was easy" (1 very difficult – 5 very easy); "Did consideration of this dimension inform initial program design?" (1 not at all – 5 extremely); "Was consideration

of this dimension important for decision making during the program?" (1 not at all – 5 extremely).

Qualitative Outcomes

Open-ended questions in the interview guide addressed the following topics:

- Description of the health program, project, or initiative, its intended audience and outcomes, and its origin and funding;
- Rationale, purpose and funding for use of RE-AIM;
- Experience with and methods used to apply the five RE-AIM dimensions;
- Receipt and nature of consultation, published guidance, online resources, training, and technical assistance; and
- Recommendations for improvement in the model itself and guidance materials.

Analyses

Quantitative Analyses

For quantitative ratings, we calculated descriptive statistics including means, medians, standard deviations and ranges for 16 (of 17) interviews. One interview was excluded from the quantitative analysis as it covered use of RE-AIM for a series of projects, rather than a single project, and hence was not comparable for quantitative analyses.

Qualitative Analyses

For qualitative data, the research assistant who conducted the interviews organized her notes into a case-based matrix by topic (project health topic and setting, program and RE-AIM use funders, RE-AIM impact and usefulness, challenges, overcoming challenges, use of educational resources, and recommendations for improvement). Another team member coded the data within each topic area and identified themes. We used a qualitative descriptive approach to content analysis (16). All 17 interviews were included in the qualitative analysis.

RESULTS

Description of the Sample and Use of RE-AIM

As shown in **Table 1**, the interviews represented a diverse group of projects and organizations. The interview participants were most often from universities (62%), especially schools of public health. Project locations where programs were conducted were primarily in community or public healthcare settings—and not associated with research funding. Programs were located in the U.S (Colorado, Maine, Georgia, Wyoming, Texas, Alaska, Nebraska, Washington State, national programs), and outside the U.S (Guadalajara, Amsterdam). Projects addressed several different content areas, and most (71%) focused on prevention or management of multiple health conditions or behaviors. Funding came from several sources, with the most frequent being U.S. public health funders such as the Centers for Disease Control and Prevention (CDC) or state health departments. It is notable that 6 programs had either had no funding or combined funding from multiple sources, and 2 were internally funded. Finally, these programs made modest use of RE-AIM resources, including www.re-aim.org (9 programs) or formal training or consultation (7 programs).

TABLE 1 | Characteristics of organizations and projects interviewed.

Organization type	No. of 16
U.S. university	8
Government (non-research agency)	3
Foreign university	2
Research evaluation center	2
Non-profit organization	1
Project content area	
Multiple	6
Chronic disease or aging	5
Prevention	4
Mental health	1
Funding source	
CDC or state health	6
National health organization	4
Internal or none	3
Multiple	3
RE-AIM resources used	
www.re-aim.org	9
Consultation	7

TABLE 2 | Use of RE-AIM dimensions for planning and evaluation (no. of 16 possible).

RE-AIM dimension	Planning	Evaluation
Reach	9	14
Effectiveness	7	15
Adoption	11	14
Implementation	12	15
Maintenance	6	13

Table 2 summarizes which RE-AIM dimensions were addressed in each program, for planning or evaluation. Respondents reported RE-AIM was used more comprehensively for evaluation than for planning. Organizational factors such as adoption and implementation were used most frequently for planning while individual factors such as reach and effectiveness were used less frequently. In terms of evaluation, all dimensions were reportedly used in most programs.

Tables 3, **4** summarize exemplar projects' application of RE-AIM in Clinical and Community Settings, respectively.

Quantitative Ratings of RE-AIM Dimensions

Table 5 summarizes respondent ratings on the five RE-AIM dimensions for: perceptions of ease of use, ease of data acquisition, use in program design decisions, and importance for decision making. All domains were rated as easy to understand (4.3 or higher on the 5 point scale), with few differences across dimensions. Obtaining data was rated as moderate across

TABLE 3 | Definitions and measures for RE-AIM applications in a clinical setting.

	Clinical setting case study
Project type	• Clinical project to ensure exercise is addressed in routine medical care
Why use RE-AIM?	• Used RE-AIM for evaluation purposes. • Used as part of a process evaluation. • Also used to shape interventions and projects.
Reach	• Defined as type of patients reached by the intervention, including characteristics of patients and how generalizable to the target population for the program. • Measures: Patient demographic information.
Effectiveness	• Defined as expected or perceived outcomes by clinicians. • Examined the difference between intervention effectiveness and implementation effectiveness. • Measures: Questionnaires and in-depth interviews with the clinicians.
Adoption	• Defined as what sorts of departments are willing to use the new intervention and what sorts of clinical/staff are willing to use it • Measures: Questionnaires and in-depth interviews with clinicians. Demographic data based on field notes, talking to people in recruitment.
Implementation	• Defined as clinician adherence to protocols for implementation and intervention. • Measures: Questionnaires, interviews, and observations.
Maintenance	• Defined as intended use after evaluation at the clinician level, including recommendations for others to use the intervention and anticipated benefits other settings. • Measures: Questionnaires and interviews.

dimensions (average of 3.4), but somewhat more difficult for maintenance. The largest difference across dimensions was on the rating of "informed program design,' on which Implementation was rated more highly than the other dimensions (4.7 of 5 vs. 3.0–3.9 for all other dimensions). All dimensions, except maintenance (3.4/5) were reported to be important for decision making (all >4/5).

Qualitative Themes

We identified themes related to the usefulness of RE-AIM for real-world projects, including its impact on planning and usefulness for evaluation and program refinements over time, challenges in using RE-AIM and strategies for overcoming those challenges, resources used for learning about and applying RE-AIM, recommendations for improvement, and how use of RE-AIM is funded.

RE-AIM Impact and Usefulness

RE-AIM was reported to be a useful organizing framework or "roadmap" for planning (impact and usefulness theme 1). An interviewee explained, "[RE-AIM] provides a nice roadmap with all the components of program development that you need to consider." RE-AIM helps to ensure consideration of adoption, implementation and sustainability, reaching the right audiences, and ensuring you have been clear about who will benefit and expected outcomes, as well as potential unintended consequences (e.g., attending to reach and potential health disparities). An

TABLE 4 | Definitions and measures for RE-AIM application in a community setting.

	Community setting case study
Project type	• Older Adults Community Living: Fall prevention and exercise programs
Why use RE-AIM?	• Used RE-AIM as a framework for evaluation. • Used RE-AIM to describe dissemination for a regional project.
Reach	• Defined as types of people who participated in the prevention programs, and assessment of who was more likely to participate in each of two exercise programs. • Also defined as extent to which programs were covering all counties in their service area, covering the hotspots or places within certain miles of a hospital or well-known health clinic, or whether areas were missing. • Used to help an organization when they were making a decision about what programs best suited their population, whether it was by age category, by income level, or education level. • Measures: Participant, Host site, and Program leader surveys (pretest posttest) including demographics, such as gender, race, income level of participants as well as who did not participate and who were missing, over 2 years. Geocoding using zip codes to evaluate the site and how many people they served.
Effectiveness	• Given a focus on disseminating evidence-based falls prevention programs, there was less concern about the effectiveness. • Defined as quality assurance throughout the project, attitudes toward perceived effects on falls efficacy at end of the program. • Fidelity check as part of quality assurance, making sure that the program is working as intended. • Measures: Quality assurance check-ins and survey measures on falls efficacy and falls risk factors and ensured that outcomes were matching up with national outcomes as a fidelity check.
Adoption	• At the organizational level, defined as characteristics of organizations and implementation sites, including those invited to participate and their organizations; and reasons for adoption or non-adoption. • At the participant level, defined as characteristics of those who participated, who was hesitant and reasons for hesitations. • Measures: Survey and anecdotal information; the collection of the host information form and the population that they served. Collected the zip code location of the sites to garner information about the population served, where they were located, if they received any government funding, and how each site was set up.
Implementation	• Defined as program attendance and the number of programs or classes offered, and having quality assurance measures (such as using a checklist) in place to ensure fidelity to program protocol. • Measures: Individual level surveys to measure program attendance and the number of programs or classes offered, using attendance logs and completion logs. Fidelity observations for new program leaders.
Maintenance	• At the individual level, maintenance defined as evidence on sustaining benefits and participants' intentions to continue the program. • At the site level, sustainability defined as evidence of organizations embedding these programs into their routine operations and budgets. • Measures: Questionnaires and interviews with organization representatives.

TABLE 5 | Ratings of RE-AIM dimensions on ease of understanding and getting data; consideration for design and decision making.

RE-AIM dimension	Easy to understand	Ease of getting data	Considered in program design	Important for decision making
	M (SD)	M (SD)	M (SD)	M (SD)
Reach	4.3 (0.8)	3.5 (1.1)	3.5 (1.6)	4.0 (1.4)
Effectiveness	4.7 (0.6)	3.4 (1.3)	3.9 (1.6)	4.1 (1.4)
Adoption	4.2 (0.9)	3.7 (1.2)	3.9 (1.3)	4.1 (1.3)
Implementation	4.7 (0.5)	3.4 (1.1)	4.7 (0.6)	4.2 (1.3)
Maintenance	4.4 (0.8)	3.1 (1.1)	3.0 (1.4)	3.4 (1.7)
Overall	4.7 (0.5)	3.4 (0.9)	3.6 (1.6)	3.6 (0.8)

Each item measured on a scale of 1 ("very difficult" or "not at all") to 5 ("very easy" or "extremely") scale.

interviewee described the value of the "reach" dimension for attending to health equity, "It was a moral imperative to check in on what we were doing.… We wanted to use this to inform, how can we reach those vulnerable populations, how can we reach rural populations, how can we reach those disadvantaged or untouched sectors of the community."

RE-AIM was reported to help with focusing on context and setting, and implications for what works in "real life" (impact and usefulness theme 2). Specifically, understanding who is or isn't adopting or delivering the program well, what's required for sustainability, and making refinements to the program over time to ensure overall quality. Finally, RE-AIM was described as a practical, familiar, easy to understand and well-established D&I framework (impact and usefulness theme 3). One interviewee indicated, "if you are wanting a framework or conceptual model, this is a good one" since many people are familiar with it and it's fairly straightforward, and helpful for coordinating and communicating with program implementers. Furthermore, "I'm from the public health field and it's always nice to have a framework, theory or model on which you base your decisions on. So that was a big value-add for me was to have an established D&I framework that was known in the field and highly applicable to our project."

RE-AIM Challenges

Interviewees reported challenges with understanding the differences among the RE-AIM components (challenges theme 1). Notably, respondents reported that there are "fuzzy boundaries" between adoption and implementation, adoption and reach, and reach and effectiveness (e.g., which dimension it is when the outcome is number served). A respondent noted, "I just think that distinguishing between when does somebody move from being an adopter to an implementer, I find that a fuzzy boundary." There can be lack of clarity on the unit of analysis (e.g., participant vs. system/organization), as well as defining terms and figuring out relevance to a specific program. For example, in a program focused on recruiting staff members to deliver a program to parents, the staff participation would be the measure of *adoption* and parents contacted the measure of *reach*. Second, there can be difficulty with data acquisition, as in a source of data exists but access was slow or limited (challenges theme 2). Specifically, it was especially hard to get electronic health records (EHR) data that allowed linking patients over time to track clinical outcomes longitudinally. One person summarized the problem as, "Electronic health records are not set up to extract the data for these [RE-AIM] measures." As in research and evaluation in general, interviewees struggled to schedule interviews with busy staff and providers, and often found participants did not want to spend a lot of time answering questions. A parallel data challenge theme concerns when a source of data doesn't exist (challenge theme 3); this includes getting denominator data to estimate reach and adoption, knowing who does not get into a program, getting demographic data for characterizing sites and participants, and measuring maintenance. For example, "Often there is no denominator known, so you want to describe our reach but don't know your full population so you cannot say if you did well on reach." Finally, interviewees reported practical and logistical issues with RE-AIM evaluations—likely not specific to RE-AIM itself, but to the nature of evaluation (challenge theme 4). These issues included few resources, changing organizational priorities, staff turnover, and frustration that it can take a long time to see impact at the patient level.

Overcoming Challenges

To overcome challenges, interviewees reported that being flexible and adapting the approach over time to best fit your needs and purpose was helpful (overcoming challenges theme 1) but also resulted in modifications to RE-AIM definitions. One participant described this as "the way we're interpreting it (adoption) is probably not pure RE-AIM so we might be taking some liberties because … you're usually looking at adoption as sort of the analog to reach, what sort of percentage of all the eligible health systems that you approached actually signed on to do it. Respondents noted the liberal use of RE-AIM while focusing on one's purpose: "The way we used some of the reach data as a metric for taking a look at fidelity and seeing if, for example, one clinic is really falling short." Some reported using a trial and error approach to methods and measures, being open to changing methods over time, and going back and forth with sites to figure out what will work from a measurement perspective. For instance, "In terms of maintenance … we had to expand beyond the cancer center to include all hospital inpatients." In addition, interviewees suggested putting in the effort for careful planning up front (overcoming challenges theme 2). Specifically, spending time at the beginning to define your terms, develop relationships

with sites and participants, and figure out what's realistic at the outset for both evaluation and for the program (e.g., what are realistic numbers for reach?). For instance, "Getting the data all depends on the previous steps. How you use it, how you define it, and what methods. It's worth spending a lot of time on designing that part so it's easy to collect." Finally, interviewees advised learning more about the RE-AIM dimensions and how they have been applied in other real-world projects (overcoming challenges theme 3). This can help clarify definitions—such as one interviewee who reported that reading examples helped to clarify that adoption refers to the provider or setting level or that maintenance can refer to the organization level as well as the individual level.

Educational Resources

Interviewees reflected upon their use of the website, trainings or formal education, consultation or technical assistance, and publications to learn about and guide application of RE-AIM. Most interviewees were familiar with the website and had used or visited it in the past (14). They found it useful for finding definitions of terms and finding publications on RE-AIM (e.g., for examples and materials used in previous projects). Sources of training and formal education included graduate coursework (e.g., public health programs, D&I courses); lectures, conference presentations and webinars; and workshops from RE-AIM experts. They recommend promoting existing resources like recorded webinars so that others can benefit from them. Consultation and technical assistance included brief discussions to in-depth collaboration with RE-AIM experts, having RE-AIM experts walk them through the website, as well as peer-to-peer and internal organizational expertise in RE-AIM. Publications found to be most useful to guide understanding and applying RE-AIM in non-research settings included the original 1999 paper (11), the pragmatic applications in clinical and community settings paper (10), RE-AIM systematic review (7), RE-AIM for environmental change and health paper (17), the practical, robust implementation and sustainability model (PRISM) paper (18), and the use of RE-AIM for chronic illness management research paper (19).

Recommendations

To help promote ease of use of RE-AIM for community and clinical programs, interviewees had several recommendations for RE-AIM developers. First, highlight real-world projects on the RE-AIM website that do a good job linking measures to the constructs and giving concrete examples. Describe tools and measures that can be adapted—especially for measuring and distinguishing reach (especially denominators), adoption and maintenance. For instance, it is helpful "To have some good examples of tools people use to capture some of the dimensions especially those that are a little bit harder to capture like the maintenance piece for institutions or the adoption aspect." Emphasize that RE-AIM can be used pragmatically by only assessing constructs that are a priority for your stakeholders and/or aligning RE-AIM constructs with metrics stakeholders care about. This allows practice settings to plan strategies that can address each RE-AIM dimension without feeling obligated to collect data across all dimensions. Users of the framework can benefit from clarifying when RE-AIM (vs. another framework) may be most applicable. For example, "I think now that there are so many frameworks out there I think it's just helpful to understand... how is RE-AIM different, when is it appropriate to use RE-AIM, when is appropriate to use other frameworks.… It's still pretty driven toward the research community, but it can be used outside of the research community." Interviewees asked for better placing RE-AIM in context by explaining how RE-AIM factors influence and relate to each other, and formally integrating contextual factors and consideration of facilitators and barriers to adoption, implementation and maintenance into RE-AIM.

Funding RE-AIM in Community and Clinical Settings

Finally, interviewees described funding sources for applying RE-AIM, which sometimes differed from the funding for the program itself. Sources included federal grants, national agencies, internal health system funds (especially those at academic health centers and integrated health systems), foundations, state health departments, and commercial companies. The type or degree of support included small allocations from internal funds or carved out from larger grants, seed grants and case studies specifically geared toward evaluation, "leftover money" at the end of the year, or work done as part of regular employment or job duties.

DISCUSSION

Although challenging to identify programs using RE-AIM in non-research settings, our multiple recruitment approaches identified 17 non-research programs in "real world" clinical and community settings that had used RE-AIM for planning and/or evaluation. These programs included funders as well as universities, and government and community organizations. Our mixed methods assessment of RE-AIM use revealed that most RE-AIM dimensions have been used and found to be useful for planning and evaluation across diverse content areas, programs and settings. Qualitative findings show that RE-AIM is a well-known and easy to explain organizing framework or "roadmap" for planning, especially with regard to encouraging consideration of context and setting, and implications for what works in "real life." These results are complementary to the more quantitative reviews that have been conducted on the formal research literature on use of RE-AIM. For instance, Vinson et al. found it to be one of the most frequently used implementation science frameworks in research grant proposals (20).

However, in contrast to the literature on research using RE-AIM, the program members interviewed for this report tended to use all RE-AIM dimensions for evaluation (7, 9, 21). In particular, these non-research users used Adoption and Maintenance dimensions in 100% and 75% of their applications, respectively, rates higher than reporting on these dimensions in the research literature. Key informants indicated that they used fewer of the dimensions during the planning period than the evaluation period. Of note, effectiveness and maintenance were considered in fewer than half of the program planning processes. It may be that when selecting programs for implementation the

stakeholders began planning for implementation of evidence-based interventions—and as such felt that planning for adoption and implementation factors were the most important to address in planning to ensure the evidence-based approach would achieve the same magnitude of effect.

Some of the most frequent challenges to applying RE-AIM identified in these real-world applications were the same as those identified in the research literature, namely difficulty distinguishing Reach from Adoption, and specifying denominators for measures of Reach (10, 22). Despite consistent endorsement of RE-AIM as easy to understand or explain to program implementers, the nuances among dimensions can be—as one interviewee said—"tricky" to distinguish in practice. Further, despite the high use of all dimensions in evaluation across programs, there were challenges in proactive data collection—both from existing sources and gathered directly from participants. This suggests that even when using RE-AIM for planning, operationally evaluating each dimension can be complex.

It is informative to compare our results to those of Ory et al. (13) who evaluated use of RE-AIM for a larger number of settings ($n = 27$ states, with multiple delivery channels in each state) that were all part of one large national project to enhance physical activity. Similar to that report, we found that most RE-AIM dimensions were rated as relatively easy to understand and that RE-AIM was used consistently for both planning and evaluation. This stands in contrast to the research literature, in which RE-AIM has been used much more often for evaluation, despite documented successes in applying it for planning (23). The Ory et al. evaluation focused more on general experience applying RE-AIM using the framework as a whole, while our study delves into more specific evaluation of the use and helpfulness of the various RE-AIM dimensions in variety of different program areas (13).

We identified a number of themes related to challenges in using RE-AIM and strategies for overcoming those challenges in real-world settings. Most of the challenges reported are not unique to planning and evaluation of "real-world" programs—even research projects struggle with understanding RE-AIM dimensions, acquiring high-quality, longitudinal data, and maintaining commitment from staff and leadership. Similarly, as with any program evaluation, program planners and evaluators should engage stakeholders early in the process to ensure mutual agreement on defining outcomes of interest and establishing feasible measures and data sources for those outcomes. Strategies for overcoming challenges specifically aligned with using RE-AIM for non-research projects include being flexible and adapting the RE-AIM measures and priorities over time to best fit local and emergent needs and purpose. Program evaluation has more flexibility in this regard than does research.

Overall, RE-AIM appears to be applicable in non-research settings and to be helpful for pragmatic use (10) in projects that do not have large evaluation budgets. Respondents to our interview made moderate use of various resources on RE-AIM, including www.re-aim.org, but felt that more specific training in its use and case examples of how it has been applied in other non-research projects would be beneficial.

One notable recommendation for RE-AIM developers was to explicitly integrate RE-AIM with factors related to context and setting. This in fact has been done—the Pragmatic, Robust Implementation and Sustainability Model (PRISM) is an emerging D&I science framework that focuses on multiple factors related to context and setting (18, 24) that impact RE-AIM outcomes, but this expansion is not widely known. Such factors include the external environment, organizational and patient/recipient characteristics, and the implementation and sustainability infrastructure. For example, Liles et al. found that use of PRISM facilitated adoption of a new colorectal cancer screening intervention (24). In general, the PRISM framework focuses on contextual factors related to RE-AIM outcomes. While maintenance (at the setting level) in RE-AIM is defined as continuation after 6 months or longer following completion of funding support, newer conceptualizations of sustainability and the "implementation and sustainability infrastructure" component of PRISM focus on longer term sustainability.

Limitations and Next Steps

This study has limitations including lack of a tightly defined sampling due to lack of searchable databases of non-research applications of RE-AIM (or other D&I frameworks). Although our records show we attempted to contact 95 people, which led to 17 interviews (16 of which reflected distinct programs), it was not possible to calculate a true response rate. There is no clear denominator for those eligible to participate. While this study includes a relatively small sample of informants, the interviews spanned 16 distinct programs and initiatives across a variety of health domains and clinical contexts. As is typical of qualitative research, we focused more on depth of understanding experiences with RE-AIM rather than breadth (25). Strengths of the study include its focus on pragmatic, non-research application and the mixed methods assessment. Unfortunately, the small number of interviewees precluded comparisons on RE-AIM use among programs with different types of funding or from different geographic locations. Future research is recommended to replicate and extend these findings at a future time to assess longitudinal trends, and development and evaluation of more specific training strategies for applying RE-AIM.

CONCLUSIONS

RE-AIM can be a useful organizing framework or "roadmap" for planning and evaluation of implementation of health programs in clinical and community settings, especially given it helps focus on contextual and setting factors that have implications for what works in "real life." As a practical, familiar, and easy to understand D&I framework, it is a good choice for a planning or evaluation framework in real-world settings. RE-AIM is generally not seen as an alternative to more traditional program evaluation methods, focusing on effectiveness, but as a way to broaden and contextualize results, with a focus on population impact (15). Projects using RE-AIM are not immune to the usual challenges of planning and evaluation, including data acquisition and availability, lack of resources, and changing priorities and staffing over time. It can also be difficult to understand the

nuances and distinctions among the 5 RE-AIM dimensions, and figure out how each dimensions applies and can be measured in a given context.

To address these challenges, those planning to use RE-AIM may benefit from reading key papers on pragmatic application of RE-AIM (8–10) and not just the original 1999 paper; reviewing examples on the RE-AIM.org website; and seeking out consultations from experts. Then, be realistic about what can be done to measure RE-AIM dimensions, and be flexible to change over the course of the project in how RE-AIM is used. Finally, RE-AIM can serve as a tool for organizing and informing decision making before, during, and after program implementation. Specifically, funders can include RE-AIM as an expectation in grant applications to help systematically collect information on health program impact across multiple grantees (26). Additionally grantee organizations or evaluators can use RE-AIM as a tool for understanding what is working/not working within their programs and use this information to plan for quality improvement activities as well as long-term program sustainability.

DATA AVAILABILITY STATEMENT

The datasets for this study can be requested from the corresponding author with appropriate approvals.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by the Colorado Multiple Institutional Review Board. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

AUTHOR CONTRIBUTIONS

BK, RG, MO, PE, and JW contributed to the conceptualization of the project, study design and development of data collection materials, and recruited participants. BK and HM prepared IRB documents and collected data. BK, HM, and RG analyzed the data. BK and RG drafted the manuscript, and all authors edited and approved the final draft.

FUNDING

This project did not have extramural funding. NCI grant # 1P50CA244688-01 partially supported RG participation. PE time was supported in part by the National Institutes of Health (Great Plains IDeA CTR U54GM115458). BK time was partially supported by NIH/NCATS Colorado CTSA Grant Number UL1 TR002535. Contents are the authors' sole responsibility and do not necessarily represent official NIH views. The University of Colorado School of Medicine provided support for student assistants.

ACKNOWLEDGMENTS

The authors wish to acknowledge the contributions of Ms. Kate Ytell for her assistance with this project. We offer our thanks to the participants in this project.

SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2019.00345/full#supplementary-material

REFERENCES

1. Brownson RC, Colditz GA, Proctor EK. *Dissemination and Implementation Research in Health: Translating Science to Practice*. Oxford University Press (2018). doi: 10.1093/oso/9780190683214.001.0001
2. Woolf SH. The meaning of translational research and why it matters. *JAMA*. (2008) 299:211. doi: 10.1001/jama.2007.26
3. Tabak RG, Khoong EC, Chambers DA, Brownson RC. Bridging research and practice: models for dissemination and implementation research. *Am J Prevent Med*. (2012) 43:337–50. doi: 10.1016/j.amepre.2012.05.024
4. Nilsen P. Making sense of implementation theories, models and frameworks. *Implement Sci*. (2015) 10:53. doi: 10.1186/s13012-015-0242-0
5. Sales A, Smith J, Curran G, Kochevar L. Models, strategies, and tools. Theory in implementing evidence-based findings into health care practice. *J Gen Intern Med*. (2006) 21(Suppl. 2):S43–9. doi: 10.1111/j.1525-1497.2006.00362.x
6. Estabrooks PA, Brownson RC, Pronk NP. Dissemination and implementation science for public health professionals: an overview and call to action. *Prev Chronic Dis*. (2018) 15:E162. doi: 10.5888/pcd15.180525
7. Gaglio B, Shoup JA, Glasgow RE. The RE-AIM framework: a systematic review of use over time. *Am J Public Health*. (2013) 103:e38–46. doi: 10.2105/AJPH.2013.301299
8. Harden SM, Smith ML, Ory MG, Smith-Ray RL, Estabrooks PA, Glasgow RE. RE-AIM in clinical, community, and corporate settings: perspectives, strategies, and recommendations to enhance public health impact. *Front Public Health*. (2018) 6:71. doi: 10.3389/fpubh.2018.00071
9. Kessler RS, Purcell EP, Glasgow RE, Klesges LM, Benkeser RM, Peek CJ. What does it mean to "employ" the RE-AIM model? *Eval Health Prof*. (2013) 36:44–66. doi: 10.1177/0163278712446066
10. Glasgow RE, Estabrooks PE. Peer reviewed: pragmatic applications of RE-AIM for health care initiatives in community and clinical settings. *Prevent Chron Dis*. (2018) 15:170271. doi: 10.5888/pcd15.170271
11. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health*. (1999) 89:1322–7. doi: 10.2105/AJPH.89.9.1322
12. Ory MG, Smith ML. Research, practice, and policy perspectives on evidence-based programing for older adults. *Front Public Health*. (2015) 3:136. doi: 10.3389/fpubh.2015.00136
13. Ory MG, Altpeter M, Belza B, Helduser J, Zhang C, Smith ML. Perceived Utility of the RE-AIM Framework for Health Promotion/Disease Prevention Initiatives for older adults: a case study from the U.S. Evidence-based disease prevention initiative. *Front Public Health*. (2015) 2:143. doi: 10.3389/fpubh.2014.00143
14. Dzewaltowski DA, Glasgow RE, Klesges LM, Estabrooks PA, Brock E. RE-AIM: evidence-based standards and a Web resource to improve translation of research into practice. *Ann Behav Med*. (2004) 28:75. doi: 10.1207/s15324796abm2802_1
15. Glasgow RE, Harden SM, Gaglio B, Rabin B, Smith ML, Porter GC, et al. RE-AIM planning and evaluation framework: adapting to new science

and practice with a 20-year review. *Front Public Health*. (2019) 7:64. doi: 10.3389/fpubh.2019.00064
16. Hsieh H-F, Shannon SE. Three approaches to qualitative content analysis. *Qual Health Res*. (2005) 15:1277–88. doi: 10.1177/1049732305276687
17. King DK, Glasgow RE, Leeman-Castillo B. Reaiming RE-AIM: using the model to plan, implement, and evaluate the effects of environmental change approaches to enhancing population health. *Am J Public Health*. (2010) 100:2076–84. doi: 10.2105/AJPH.2009.190959
18. Feldstein AC, Glasgow RE. A practical, robust implementation and sustainability model (PRISM) for integrating research findings into practice. *Joint Commission J Q Patient Saf*. (2008) 34:228–43. doi: 10.1016/S1553-7250(08)34030-6
19. Glasgow RE, McKay HG, Piette JD, Reynolds KD. The RE-AIM framework for evaluating interventions: what can it tell us about approaches to chronic illness management? *Patient Educ Counsel*. (2001) 44:119–27. doi: 10.1016/S0738-3991(00)00186-5
20. Vinson CA, Stamatakis K, Kerner J. Dissemination and implementation research in community and public health settings. *Dissemination Impl Res Health*. (2018) 2018:355–70. doi: 10.1093/oso/9780190683214.003.0021
21. Harden SM, Gaglio B, Shoup JA, Kinney KA, Johnson SB, Brito F, et al. Fidelity to and comparative results across behavioral interventions evaluated through the RE-AIM framework: a systematic review. *Syst Rev*. (2015) 4:155. doi: 10.1186/s13643-015-0141-0
22. Stoutenberg M, Galaviz KI, Lobelo F, Joy E, Heath GW, Hutber A, et al. A Pragmatic Application of the RE-AIM framework for evaluating the implementation of physical activity as a standard of care in health systems. *Prevent Chron Dis*. (2018) 15:E54. doi: 10.5888/pcd15.170344
23. Klesges LM, Estabrooks PA, Dzewaltowski DA, Bull SS, Glasgow RE. Beginning with the application in mind: designing and planning health behavior change interventions to enhance dissemination. *Ann Behav Med*. (2005) 29:66–75. doi: 10.1207/s15324796abm2902s_10
24. Liles EG, Schneider JL, Feldstein AC, Mosen DM, Perrin N, Rosales AG, et al. Implementation challenges and successes of a population-based colorectal cancer screening program: a qualitative study of stakeholder perspectives. *Implement Sci*. (2015) 10:41. doi: 10.1186/s13012-015-0227-z
25. Pope C, Mays N. Qualitative research: reaching the parts other methods cannot reach: an introduction to qualitative methods in health and health services research. *BMJ*. (1995) 311:42–5. doi: 10.1136/bmj.311.6996.42
26. Green LA, Cifuentes M, Glasgow RE, Stange KC. Redesigning primary care practice to incorporate health behavior change: prescription for health round-2 results. *Am J Prevent Med*. (2008) 35:S347–9. doi: 10.1016/j.amepre.2008.08.013

Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

frontiers in Public Health

ORIGINAL RESEARCH
published: 22 January 2020
doi: 10.3389/fpubh.2019.00419

Implementation and Sustainability of a Pharmacy-Led, Hospital-Wide Bedside Medication Delivery Program: A Qualitative Process Evaluation Using RE-AIM

Beth Prusaczyk[1], Amanda S. Mixon[2] and Sunil Kripalani[2]*

[1] Department of Medicine, Washington University School of Medicine, St. Louis, MO, United States, [2] Department of Medicine, Vanderbilt University Medical Center, Nashville, TN, United States

OPEN ACCESS

Edited by:
Samantha M. Harden, Virginia Tech, United States

Reviewed by:
Armin D. Weinberg, Baylor College of Medicine, United States
Renae L. Smith-Ray, Walgreens, United States

****Correspondence:***
Beth Prusaczyk
beth.prusaczyk@wustl.edu

Specialty section:
This article was submitted to Public Health Education and Promotion, a section of the journal Frontiers in Public Health

Received: *02 September 2019*
Accepted: *30 December 2019*
Published: *22 January 2020*

Citation:
Prusaczyk B, Mixon AS and Kripalani S (2020) Implementation and Sustainability of a Pharmacy-Led, Hospital-Wide Bedside Medication Delivery Program: A Qualitative Process Evaluation Using RE-AIM. Front. Public Health 7:419. doi: 10.3389/fpubh.2019.00419

Background: Few studies of hospital-based implementation assess sustainability or collect formal implementation outcomes, in part because the emphasis is often on initial adoption and rapid cycles of improvement. The purpose of this process evaluation was to assess the implementation of a pharmacy-led, hospital-wide program and contribute to the literature by collecting formal implementation outcomes, including sustainability.

Methods: This was a qualitative process evaluation of a program that delivers discharge medications and related education to hospitalized patients' bedside prior to discharge. Semi-structured interviews were conducted with the program's key stakeholders to assess the program's implementation barriers and facilitators as well as its potential for sustainability. An interview guide was created based on the RE-AIM constructs of Reach, Adoption, Implementation, and Maintenance. Effectiveness was not assessed due to an ongoing effectiveness evaluation by another team. Each interview was coded by two independent coders and any discrepancy was adjudicated by a third, independent coder.

Results: Twelve stakeholders were approached and all agreed to be interviewed. Related to providers' decisions to *adopt* the program, key themes emerged around the different priorities of nurses and physicians, which has implications for how program leadership promoted the program to these different stakeholder groups. Key *implementation* barriers included the nature of hospital provider rotations and turnover, which led to confusion on who could use the program and to whom providers should direct program-related questions. Key *implementation* facilitators included the enthusiasm of program staff and identified champions on the units. Themes related to *maintenance* or sustainability included the need to continually generate buy-in and educate providers about the program and allowing program staff and leadership to remain nimble and adapt their operations to meet evolving needs.

Conclusions: The results suggest that in an environment in which rapidly achieving improvement is often the focus more than maintaining that improvement, strategies to achieve successful implementation may not be sufficient to achieve successful sustainment. New strategies are likely needed to address the unique barriers to sustaining a program once initial adoption and implementation is complete.

Keywords: implementation, hospital, sustainability, RE-AIM, qualitative

INTRODUCTION

Bedside medication delivery programs, commonly referred to as "meds to beds" or "meds in hand," involves delivering discharge medications to hospitalized patients' bedside prior to discharge and often includes a medication education component (1, 2). This intervention, or program, can be provided by hospital pharmacies, on-site affiliated outpatient pharmacies, or third-party retail pharmacies. In this study, the specific program was conceptualized and initiated by the on-site hospital-affiliated outpatient pharmacy as a quality improvement initiative for the purpose of improving patients' transition from hospital to home.

These programs have been shown to significantly reduce 30-day hospital readmissions (in one study the reduction was greater among older adult patients) (1) and emergency department visits (2). Although not empirically tested, hospitals also report that these programs increase the number of patients actually obtaining their discharge medications by removing common barriers related to payment and transportation, increase patient satisfaction, and reduce costs (3, 4).

To our knowledge, there has been no study of the implementation of these programs. A recent systematic review of the barriers and facilitators to the implementation of hospital-based interventions by Geerligs and colleagues found that the barriers and facilitators fell into three domains: system-, staff-, and intervention-level (5). System-level barriers and facilitators included the physical structure/environment, resources, culture, and external pressures such as reporting guidelines and regulations. At the staff level they included awareness, attitudes, commitment, role identity, skills, ability, and confidence. Intervention-level barriers and facilitators included the ease of integration, strength of the evidence, and available support. The authors found that there was considerable interaction between the domains as well (5). For example, a response to an intervention-level barrier (lack of flexibility) might influence a staff-level facilitator (confidence in ability to deliver the intervention with fidelity) which in turn might affect the system (a change in culture).

However, the authors also noted a number of areas in which the included studies fell short. First, few studies addressed sustainability thus it was unclear how the barriers and facilitators to initial implementation impacted long-term sustainability (5). Similarly, a majority of studies included in the review assessed implementation only anecdotally and did not collect formal implementation outcome data, making it hard to generalize across different studies (5).

The current study addresses these limitations by evaluating the implementation of a pharmacy-led, hospital-wide intervention 3 years after implementation and using RE-AIM (6) to guide the collection of implementation outcome data, including sustainability. Definitions of sustainability, or maintenance, vary, and include constructs such as those related to the passage of time, funding support, or the presence of workplace policies on the intervention. For the purpose of this study, we used the passage of time as our criterion for sustainability and, consistent with the definition of Maintenance from the RE-AIM framework, we assessed sustainability at least 6 months after initial implementation of the intervention (6).

METHODS

Setting

This study was conducted at Vanderbilt University Medical Center. Vanderbilt University Hospital (VUH) has 834 beds, 36 nursing units, and provides a variety of services including medical, surgical, and specialty care. The hospital-affiliated, on-site outpatient pharmacy serves the adult hospital for discharge prescriptions, as well as all outpatient clinics at the medical center.

Intervention

The Meds to Beds program, launched in March of 2016, fills the patients' discharge medications and delivers them to their hospital bedside, where education about their medications is also provided. Through the program, the pharmacy processes patients' insurance (just as a third-party pharmacy would) and, if the patient cannot pay for their medications, utilizes appropriate discount or charity programs to assist patients in covering the costs. Ideally, the inpatient providers (physicians or nurses) send patients' discharge medication prescriptions to the pharmacy as soon as those orders are written, and the pharmacy processes those orders and delivers the medications to the patients' bedsides as soon as possible. On average, it takes the pharmacy approximately 2 h from the time they receive the orders to process them and deliver the medications. However, as we will discuss below, this ideal process is not always feasible.

The program was initially provided to only a few units on a few services (e.g., a single unit on surgery, a single unit on medicine) but within 6 months expanded to the entire hospital. The program has designated full-time staff including pharmacy technicians and pharmacists. In the beginning pharmacists delivered the medications and provided the education, but as the program expanded the increased demand caused program

leadership to adapt the program. With this adaptation, pharmacy technicians now deliver the medications and use a tablet computer to facilitate a two-way video call between the patient in the hospital room and a program pharmacist in the pharmacy to provide education. The program is "opt-out," where patients are able to choose not to use the program or the hospital pharmacy if they prefer to use an outside pharmacy.

Design

We used the RE-AIM framework to guide our evaluation. RE-AIM stands for Reach, Effectiveness or Efficacy, Adoption, Implementation, and Maintenance (6) RE-AIM was the appropriate framework because of its applicability to an evaluation effort and its specificity of constructs. This specificity also addresses the gap found in Geerligs' review that studies of hospital-based interventions failed to collect generalizable implementation outcomes.

We conducted brief, semi-structured interviews with various program stakeholders and hospital providers. We structured our interview guide around Reach, Adoption, Implementation, and Maintenance. A separate effectiveness study was being conducted at the same time as this implementation evaluation; therefore, we chose not to measure program effectiveness in the current study.

Participants

We worked with program leadership to identify key stakeholders in the implementation of the program to approach for interviews. These included pharmacy and nursing leadership, program staff, physicians, and nurses. We also utilized snowball sampling techniques, asking interviewees for the names and information of others they thought we should speak to. All identified stakeholders were employees of Vanderbilt University Medical Center. This project was reviewed by the Institutional Review Board at Vanderbilt University Medical Center and was deemed a quality improvement project evaluation and not human subjects research thus informed consent was not obtained from the providers.

Data Collection

The program was adopted (i.e., launched) in March 2016 and was fully implemented hospital-wide by October 2016. Data collection for this evaluation took place over a 5-month period from November 2017 to March 2018, beginning approximately 21 months after adoption and 13 months after implementation was complete. Semi-structured interviews were conducted by a single interviewer (author BP). A structured interview guide based on the RE-AIM framework was used and is available (see **Supplementary Material File 1**). For the purposes of this study, the operationalization of the RE-AIM constructs were adapted and these adaptations can be seen in the codebook (see **Supplementary Material file 2**). Specific questions about how the program was "pitched" to the interviewee, the barriers and facilitators to implementation, any adaptations made to the program since it began, and factors impacting the program's sustainability were included. The interviews were conducted in-person and lasted approximately 30 min. Because these interviews often occurred in patient-care settings they were not audio recorded for privacy reasons. However, the interviewer took detailed and extensive notes during and immediately after the interview.

Data Coding and Analysis

A codebook was created based on RE-AIM. This codebook was created by author BP and sent to authors ASM and SK for input. Clarifications and additional detail was added to the codebook based on their input. The purpose of this codebook was to define the constructs of the RE-AIM framework and to guide coders in assigning text to one of the four constructs (Reach, Adoption, Implementation, Maintenance).

BP and AM then independently coded each interview to identify blocks of text that represented one of the four constructs. The results of this first round were reviewed and any discrepancy was adjudicated by SK. Then BP and AM conducted a more detailed second round of coding to identify specific themes within these blocks of text. The results of this second round were discussed by BP, AM, and SK, and consensus was reached on the emergent themes.

RESULTS

A total of 12 interviews were conducted. The two program leaders who assisted in identifying stakeholders were interviewed in addition to one representative from pharmacy operational leadership, one representative from nursing operational leadership, one pharmacy supervisor, one program supervisor, one program pharmacist, one inpatient unit pharmacist (not affiliated with the program), two attending physicians (one of whom was a champion of the program when it began), and two nurses. These nurses were specifically "patient flow nurses" which is a type of nurse at the hospital tasked with facilitating timely and quality discharges.

Reach

A key facilitator to the *reach* of the program was the program being "opt-out," meaning only when patients expressed wishes to not use the program did they actually not receive it.

> *"The opt-out model is extremely important. The patient is sick, the caregiver is in the room tapping their foot, and everyone just wants to go home." – Pharmacy Administrator*

In turn, stakeholders noted that the main reason patients declined to use the program was when they had a strong, personal relationship with their hometown pharmacy.

> *"If they want to go to their local pharmacy that's fine but if the default is they get the medications here, at least they have it in their hand when they leave and they don't ultimately come back." – Pharmacy Administrator*

> *"Patients who have a local, independent pharmacy are "ride or die" with their pharmacy because the pharmacist there knows their history and knows their families so they will often decline (the program)."– Inpatient Unit Pharmacist (not affiliated with the program)*

Adoption

A common theme discussed related to providers decision to adopt the program was that stakeholders have not just different priorities but competing priorities. This was apparent when interviewees discussed how the program was "pitched" to them or how they pitched it to others. Depending on what the actual or perceived priorities were of a stakeholder group, the pitch changed and in some cases these priorities were mutually exclusive. For example, priorities for attending physicians were related to the comprehensiveness of the program and the services—medication education and assistance with payment—it provides to their patients.

> "*It was described that patients would get pharmacy education around their medications and previously I think it was an assumption on the nursing staff part that physicians did counseling and the physicians thought the nurse or pharmacy did the counseling so it didn't happen. With Meds to Beds it was actually guaranteed that the pharmacist would do it.*" – *Attending 1*

These additional services may be priorities for physicians because they recognize their potential effect on reducing readmissions, which was also stated as a priority for physicians.

> *"For physicians it is all about readmissions and why readmissions occur—patients not getting prescriptions filled, reasons why they don't get prescriptions filled. And how we help with those things."* – *Program Pharmacy Supervisor*

However, the provision of these additional services takes additional time, which was in conflict with the priorities of nurses. A key quality metric on which nursing units are monitored is what time patients actually leave the hospital.

> *"[I tell the nurses] it will help decrease your work[load] and make your discharges quicker."* – *Patient Flow Nurse 1, describing how she sells the program to other nurses*

Likewise, if nurses prioritize expedient discharges but patients leave too quickly without receiving appropriate arrangements and counseling, this could conflict with best practices for reducing readmissions.

Implementation

Another instance where competing priorities related to the timing of discharge presented was during the implementation of the program. One of the most frequently cited barriers to implementation was the amount of time it took to deliver the medications. Physicians and nurses reported that the medications were often delivered later than they would prefer which delayed discharge.

> *"I think some people didn't buy into it because they thought it would delay discharge. What do we do if their [the patient] ride is there but they don't have their meds? Do we reprint the prescriptions and let them go? Or spend extra time to call pharmacy and see when the meds will be there? Even now I still think about timing."* – *Attending*

The program staff and leadership were made aware of this complaint from providers early during implementation and attempted to address the barrier by requesting that providers order their discharge medications as early as possible. The program often received patients' medication orders in the morning (usually mid-morning after team rounds) for a same-day, afternoon discharge. The pharmacy, on average, takes 2 h after receiving the prescription orders to process and deliver the medications. In order to get the medications delivered sooner, the program asked that providers send the orders to the pharmacy as soon as possible.

> *"If there's a way to just start sending prescriptions down sooner that would be helpful. Sometimes they send them down the day before but it's at the end of the day at 6:29 p.m. And I mean, did you just now decide that patient was going home tomorrow? So if they could send the prescriptions down in real time that would help."* – *Program Supervisor*

However, providers expressed concern about sending the orders sooner.

> *"There was a fear in the beginning that if you sent the prescriptions down a day early, is the patient going to get them? Will they actually appear the next day?"* – *Attending 1*

> *"And this will just be impossible on different services. On a teaching services the intern isn't going to prescribe until they've rounded with the attending. It's just not going to happen. So that won't ever happen early."* – *Attending 2*

This tension—providers wanting the medications sooner but not always being able to follow the proposed solution of sending the orders sooner—is another example of not just different stakeholder' priorities but of conflicting priorities in which no "silver-bullet" solution exists.

Another recurring theme across the interviews was the challenge of implementing a program in an environment with complicated care structures and frequent planned and unplanned staff changes. VUH does not have geographic localization for most medical services, where physicians on a given rotation see all of their patients in the same hospital unit or location (exceptions include contained units like the Intensive Care Unit or Geriatrics). Instead, the hospital has a structure where physicians admit patients across different units and floors. The nursing staff is unit-based, however.

In addition to this unique structure, attendings, residents, and interns commonly rotate on and off teaching services at 2-week intervals. Attendings on non-teaching services rotate more frequently, usually every 5 days or so. Also, not unique to VUH is the typical, unanticipated staff turnover that all hospitals experience across all staff members.

The unique structure of VUH, the typical physician rotation schedule, and turnover of providers and staff were reported to have significant impact on the implementation of the program. First, program leaders and staff said the structure made the decision about where to begin rolling out the program difficult. If they decided to go with a physician-based rollout around

specific medical or surgical teams, then it became challenging for the nurses, who were unit-based. Because the nurses on a single unit cared for the patients of numerous physicians, they had to remember which physicians were assigned the program and therefore which patients could receive the program. The alternative—a service- or unit-based rollout—would be challenging to physicians because they would have to remember which units were assigned the program and therefore which patients on their service they could enroll in the program based on what unit the patient was on.

"Every unit has a different process for discharge. We went live on 7 North [service] because they had some familiarity with the Meds to Beds process then we went to the Riven [Hospitalist] Services. But Riven is everywhere with certain beds on certain units. So we had to pull back and rethink." – Program Leader

"There was a big decision about which service to approach first. Do we go floor by floor? We started with one service spread across all these floors. Then communication and education with providers were really difficult."– Program Pharmacy Supervisor

The program leaders reported that they quickly learned their initial plan to start with one hospital service and slowly rollout the program sequentially to others was not feasible due to the reasons mentioned above (physicians had to remember which units and therefore which patients were eligible for the program).

"They tried to roll out the program too quickly when they didn't have the staff. And then it was taking too long to get scripts and if the nurses have one bad experience or don't know who to contact they will write off the program as not useful. They don't have time to try things more than once." – Patient Flow Nurse 1

These challenges led the program to scale-up hospital-wide shortly after starting.

"So we decided to roll out to everywhere and then go around and educate everyone. Because not being live on all floors was causing problems." – Program Leadership

It was this next phase of implementation—educating providers about the program—where providers' rotations and staff turnover caused challenges, according to multiple interviewees. Education about the program to providers included in-person instruction delivered by program staff to providers and reminder materials such as posters and flyers posted around the unit.

"The hospital has high turnover, residents come through, and suddenly no one knows about us." – Program pharmacist

"I would like to go to each unit and find the person who is going to—just someone who I can explain the program to and clear up any misconceptions. Because some people think they can't start the process until the patient is ready to discharge and I want them to know they can start it much earlier. But you know you have new residents coming in and out and they are hearing about the program from someone else and it's not the full story."– Program Supervisor

"Residents need formal, in-depth education on the program from their attendings. If it's someone from the program delivering it, then it just seems like is a vendor wanting the residents to use their service."– Patient Flow Nurse 1

These comments highlight the challenges that presents to a program that is implemented hospital-wide.

Despite these significant barriers to implementation, interviewees also noted two major facilitators: patient flow nurses and the positive attitudes of the program staff.

Patient flow nurses are nurses hired for the specific purpose of facilitating patients' discharges, including ensuring the patients' hospitalizations and discharges are timely and high quality. While the hospital did not begin employing patient flow nurses because of the Meds-to-Beds program, their hiring did coincide with the program's rollout, with patient flow nurses starting only a few months after the program began. Multiple program staff commented on the importance of patient flow nurses in the program's implementation and future sustainability.

"We got patient flow nurses about a year in and that made a huge difference. One of their chief goals is to get fast discharge. The hospital implementing them was a lucky break for the program. "– Program Pharmacy Supervisor

"The PFNs [Patient flow nurses] are great. They have our backs and they have similar barriers in their jobs. The perception is that Meds to Beds is taking too long but Pharmacy doesn't know when the physician wants the patient to go home. The PFN helps with that and gets the prescriptions sent the night before."– Program Leadership

"The relationships between the (program) coordinator and the PFN [are] critical."– Program Supervisor

Likewise, many interviewees who did not work directly for the program cited the positive attitudes of the pharmacy program staff as an important facilitator to successful implementation.

"The enthusiasm from staff stuck out to me. I'm sure they had a lot of challenges on their end but my impression was that it was a lot of work but I never got the impression they didn't have time for me or my patient. There was always someone to answer the phone. It never rang and rang and rang. They never appeared overwhelmed. It would have been a big barrier if there was a 'you're in the queue' attitude or a 'we're just trying to get through the day.' But they always had a positive attitude."– Attending

"I also liked that they were pretty available from the get-go. They started with very reasonable hours. It was impressive. They weren't just available during business hours. I just liked that it was comprehensive to start. It was a complete package. A lot of pilot programs start small and build up and it takes a long time. (The Program) bit off a big chunk and they delivered. It was also great the speed at which they expanded. It was rapid. They expanded very quickly."– Attending

"The two (program) pharmacists at the beginning were extremely helpful. We knew that they would do what was right for the patients and they could trust them them…The pharmacists were super responsive, helpful, and would work hard for our patients."– Attending

"The (program) pharmacy was really good about listening to each PFN and listening to what works and what doesn't work and adapting."– Patient Flow Nurse

Maintenance

Each stakeholder was asked if they believed the program was sustainable and what needed to happen to bolster its sustainability. Numerous stakeholders cited the need to continually educate hospital providers about the program in order for it to be sustained.

"I think you always have to change to sustain. You can't take your finger off the pulse. You always have to keep reselling and re-educating and keep the communication lines open. I think they've done a good job in the pharmacy doing this but it has to continue—getting input from stakeholders, listen to them, and give feedback."– Nursing Administration.

"We can't have sustainability without progress. We must continue to actively market the program, keep constant communication and education going. Still need to 'make a presence' though. (The Hospital) has high turnover, residents come through, and suddenly no one knows about us."– Program pharmacist.

"The education is on autopilot for people who are already using the program but for new residents, thorough education needs to take place." – Patient Flow Nurse.

In addition to the need for recurring education and outreach, stakeholders cited the need for more resources such as staff and physical space to support the program long-term.

"With more volume, more demand for staff, new staff means training, training is hard in a busy pharmacy location so training sometimes fall to wayside, which can cause staff issues. It's helpful that we hired pharmacist manager and tech coordinator to oversee staff. I don't know if we needed them in the beginning. They may not have been necessary. It was when more staff were hired that the need for oversight was needed." – Program Pharmacist

"Training takes a lot of time, too. We've had major staffing changes. We have to be prepared for those changes, though, and make a comprehensive training plan. But even that means having staff available to do that." – Program Leadership

"The physical space of the pharmacy is important. It's very challenging to get a physical workflow in order. "Everything has to be like McDonald's. Everything moves in a certain order." We have that now but if they change our space that will be a problem. We're constantly trying to improve things and find ways to make things better. We have no bureaucratic red tape to go through in terms of changing our physical space. We have good autonomy. But to hire more staff and get more space, we need approval. It's not sustainable if administration doesn't listen to the issues we're bringing up. When your team is asking for certain things…"– Program Pharmacist

"We have to find space dedicated to Meds to Beds. We have reworked, and reworked, and triple worked our space over time to make it more streamlined and efficient." – Program Leadership

Other

The results thus far represent common themes across the interviews and key points are summarized in **Table 1**. However, some stakeholders made points that, while not made by others, we believe are important and unique contributions to understanding the implementation of hospital-wide programs. These comments can be grouped into two categories: (1) unanticipated structural or policy challenges and (2) advice for others implementing programs in the hospital setting.

Unanticipated Structural or Policy Challenges

Pharmacy operational leadership noted that when adaptations needed to be made to the program, even though they were in a position to authorize such adaptations, the implementation of those adaptations was dependent upon others. In reference to a decision to start using the tablet computers to deliver the education to patients rather than in-person:

"We want to do education. We have to do it. But we have people running all over the hospital. So [program leadership] asked, 'Why can't we use an iPad?' I thought it was a great idea. What took a long time, though, was getting the device compliant with HIPAA and PHI. We approved the idea quickly and then it took a long time to actually implement it."– Pharmacy Administrator

In reference to a request from program leadership for more physical office space:

"[Program leadership] brought me the idea about how they were running out of space but could remodel the store room in the pharmacy relatively easily. And that was a quick decision because I just said 'Go do it'." – Pharmacy Administrator

Certain classes of medications also presented unique challenges that were unanticipated.

"The controlled substances were an issue before [the new EMR] because they required a paper prescription and there were issues with printing, because the printers were tied to the units but I may be printing a prescription on one unit for a patient on another unit and then I have to get that paper prescription from the other unit, sign it, then find a tube [the pneumatic tube system that physically sends a paper prescription that had to be hand-signed to the pharmacy]."– Attending

"Patients who get prescriptions [from the hospital] for narcotics must fill those prescriptions in Tennessee so for out-of-state patients, they can't get it filled at home. So [the program] helps get them filled in Tennessee."– Patient Flow Nurse

"There have been issues with narcotics and blood thinners in the past so the medications were being delivered to the nursing station

TABLE 1 | Summary of key findings by RE-AIM construct.

Construct	Finding	Quotes
Reach	The opt-out model was a facilitator to patients using the program.	*"The opt-out model is extremely important. The patient is sick, the caregiver is in the room tapping their foot, and everyone just wants to go home." – Pharmacy Administrator*
Effectiveness	Not assessed	
Adoption	Stakeholders have different and specifically competing priorities.	*"For physicians it is all about readmissions and why readmissions occur–patients not getting prescriptions filled, reasons why they don't get prescriptions filled. And how we help with those things." – Program Pharmacy Supervisor* *"[I tell the nurses] it will help decrease your work[load] and make your discharges quicker." – Patient Flow Nurse 1, describing how she sells the program to other nurses*
Implementation	Structure of hospital beds/units/providers made educating providers about program difficult.	*"Every unit has a different process for discharge. We went live on 7 North [service] because they had some familiarity with the Meds to Beds process then we went to the Riven [Hospitalist] Services. But Riven is everywhere with certain beds on certain units. So we had to pull back and rethink." – Program Leader* *"So we decided to roll out to everywhere and then go around and educate everyone. Because not being live on all floors was causing problems." – Program Leadership*
Maintenance	Education of providers also necessary for sustainment	*"The education is on autopilot for people who are already using the program but for new residents, thorough education needs to take place."* – Patient Flow Nurse *"We can't have sustainability without progress. We must continue to actively market the program, keep constant communication and education going. Still need to 'make a presence' though. (The Hospital) has high turnover, residents come through, and suddenly no one knows about us."* – Program pharmacist

but that caused downstream problems because the patients have to be notified that their meds have arrived and have to be educated and some patients were then getting upset that they weren't allowed to leave or have their medications. In other instances the patients were going to jail after discharge and telling them where their meds were was causing problems because the [police] officers didn't want them to know they were going to be discharged and then going to jail."– Unit-Based Clinical Pharmacist

Advice for Others Implementing Hospital-Wide Programs

Every interviewee was asked what advice they had for others who are planning to implement a program hospital-wide.

"I think they have to get stakeholders early so they understand their perspectives. They need to know who the stakeholders are even. The pharmacy didn't know who to get, who to bring in. So finding someone who can match up the right stakeholders with the project, know who does what roles and who they should talk to. Because you have to have the ability to pitch to key institutional stakeholders. It makes a huge difference."– Attending

"In future roll-outs, just rip the band-aid off and realize that you're going to experience some kickback but have enough staff—too many staff is not a bad thing—to handle that. " – Unit-Based Clinical Pharmacist

"You have to set clear expectations with nurses and physicians. Because if they think something is going to take 30 minutes and you don't tell them otherwise then when it takes longer you look like you failed." – Program Supervisor

"In the future, if we're rolling out a new initiative my advice would be to get a champion in administration, sell them on it, then have that trickle down effect. It has to be a top-down approach. Sure, there will be growing pains but it's going to take a lot of selling and talking to the same people over and over again. We need to be a permanent fixture on the floors." – Program Pharmacy Supervisor

DISCUSSION

We found considerable interaction between the different levels of implementation barriers and facilitators, consistent with the findings of Geerligs and colleagues (5). The tension between physicians and nurses on what they prioritized about the program demonstrates this interaction. The program appealed to physicians because they believed it provided their patients with important services such as education about their medications and logistical or financial assistance in getting their medications. This staff-level desire to provide quality care interacted with the system-level desire to reduce readmissions. In this instance, this interaction was beneficial. The staff-level facilitator was in agreement with the system-level facilitator—providing quality care can reduce readmissions (7). However, our results also demonstrated when these interactions can be in conflict. The program appealed to nurses because they believed it would help them discharge patients faster (because the program would provide the medication education to the patient). This staff-level facilitator is in conflict with the system-level desire to reduce readmissions because discharging patients too quickly is associated with readmissions (8).

Another example of the interaction between system-, staff-, and intervention-level barriers and facilitators is the challenge of rolling out the program hospital-wide. The hospital structure and staff fluctuations represented structural barriers to implementation which conflicted with the intervention-level barrier of needing to provide detailed education to providers so they understood the program. The intervention required that program staff provide thorough instructions and

education to providers who would be using the program, but the structure of the hospital nursing units and medical services made this difficult. This need to provide detailed education on a continual basis for implementation and sustainability purposes is especially pertinent within the context of continuing medical education (CME). In its most recent strategic plan, the Accreditation Council for Continuing Medical Education noted its plan to evolve CME to include not just clinicians but other members of the healthcare team as well the healthcare institution as a whole (9). Given the interdisciplinary nature of an intervention such as the one discussed here, there is likely an opportunity to incentivize or bolster education around the program by coupling it with CME. This could also improve the tracking and evaluation of implementation outcomes because participation would be better recorded.

This study is also significant because of the inclusion of sustainability data, something Geerling and colleagues noted many hospital-based implementation studies did not examine. At the time of data collection, the program had been operating hospital-wide for more than 2 years, which provided a unique opportunity to study the sustainability of a program in a hospital, where a version of a program may generally be more short-lived due to the use of rapid-cycle quality improvement methods (e.g., Plan-Do-Study-Act cycles). We collected sustainability data with the Maintenance construct of the RE-AIM framework. In the interviews we found that the points interviewees believed were most critical to the sustainability of the program were to address or mitigate the cited implementation barriers and continue or bolster the implementation facilitators. For example, the timing of medication delivery was the most commonly cited barrier to implementation and was cited as an ongoing issue. When asked about what the program needs to do in order to be sustained, not surprisingly many interviewees said the timing issue needed to be resolved. Likewise, when asked what the program "had going for it" in terms of sustainability many interviewees said the positive attitudes of the program staff and the effective communication between providers and the program staff. These were also cited as facilitators to implementation.

This relationship between barriers and facilitators and sustainability has multiple implications. First, it suggests that how programs address barriers is important not just for implementation but also sustainability, which is consistent with other findings (10). This also suggests that, despite interviewees reporting that if the program fails once some providers will not give it a second try, providers will indeed continue to use the program even if a commonly cited barrier remains. This may be because the facilitators to implementation—the positive attitudes of program staff and the effective communication between providers and the program—was also ongoing and thus balanced out the ongoing barrier. However, because the timing barrier was cited as a potential impediment to sustainability, it is unclear how long this "grace period" for barriers will continue.

The last important finding we will discuss is how counterintuitive the program's rollout was. Existing guidance found in the quality improvement and implementation science literature suggests that programs should be rolled out in phases, starting with small-scale change working up to system-wide rollout (11). While this program attempted to do this, the leadership quickly learned that the sequential rollout was causing so much confusion and difficulty that they had to go straight to system-wide rollout. The system-wide rollout presented different challenges because there was suddenly an overwhelming demand for the program, which put strain on program staff. These results suggest that others who are planning to implement hospital-based programs may benefit from considering the pros and cons to a sequential vs. system-wide rollout ahead of time rather than assuming a sequential rollout is the most appropriate plan.

This study is not without limitations. First, this was part of a small-scale evaluation project which placed certain restrictions on the data collection procedures including what data were collected, how they were collected, and the number of interviews conducted. However, we believe our close relationship with the two program leaders in identifying key stakeholders to interview and our rigorous data analysis process help to mitigate this limitation. Second, given the important adaptation to the program that had to be made involving pharmacy technicians, it is a limitation that a pharmacy technician was not interviewed. Because we were not aware of this important adaptation until the data analysis phase, we could not go back to collect more data from this important stakeholder group.

CONCLUSION

This study begins to fill two gaps in the implementation literature: it includes assessment of sustainability in hospital settings and sheds light on the implementation of pharmacy-led, bedside medication delivery interventions which are growing in popularity. Results indicate that there are unique challenges both to implementation in a hospital setting and that barriers and facilitators present during early implementation phases may not be resolved and yet the program can still continue for an extended period of time. However, it is unknown how long the program can sustain with unaddressed barriers and facilitators. More work is needed to better understand the relationship between implementation and sustainability and the results of this study can serve as guidance for this future work.

DATA AVAILABILITY STATEMENT

The datasets generated and analyzed during the current study are not publicly available due concerns about confidentiality with the limited number of participants but are available from the corresponding author on reasonable request.

ETHICS STATEMENT

This project was reviewed by the Institutional Review Board at Vanderbilt University Medical Center (called the Human Research Protections Program) and was determined not to be human subjects research (it was deemed a quality improvement project instead) thus informed consent was not required.

AUTHOR CONTRIBUTIONS

BP and SK conceptualized the study. BP collected all data. BP, AM, and SK analyzed the data, interpreted the results, and contributed to the writing of the manuscript. All authors read and approved the final manuscript.

FUNDING

BP was funded by an institutional training award from AHRQ (T32 HS26122-01).

ACKNOWLEDGMENTS

We would like to acknowledge Rusty Catlin and Melissa Patton for their assistance with this study.

SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2019.00419/full#supplementary-material

REFERENCES

1. Kirkham HS, Clark BL, Paynter J, Lewis GH, Duncan I. The effect of a collaborative pharmacist-hospital care transition program on the likelihood of 30-day readmission. *Am J Heal Pharm*. (2014) 71:739–45. doi: 10.2146/ajhp130457
2. Hatoun J, Bair-Merritt M, Cabral H, Moses J. Increasing medication possession at discharge for patients with asthma: the meds-in-hand project. *Pediatrics*. (2016) 137:e20150461. doi: 10.1542/peds.2015-0461
3. Buckley B. *Meds-to-Beds Yields $2.5M Profit, Boosts Pt Satisfaction*. Pharmacy Practice News (2016). Available online at: https://www.pharmacypracticenews.com/Article/PrintArticle?articleID=38885 (accessed February 4, 2019).
4. Coughlin M. *Calculating the Value of Meds-to-Beds*. ScriptPro (2017). Available online at: https://www.scriptpro.com/blog/calculating-value-meds-beds/ (accessed February 4, 2019).
5. Geerligs L, Rankin NM, Shepherd HL, Butow P. Hospital-based interventions: a systematic review of staff-reported barriers and facilitators to implementation processes. *Implement Sci*. (2018) 13:36. doi: 10.1186/s13012-018-0726-9
6. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health*. (1999) 89:1322–7.
7. Kripalani S, Theobald CN, Anctil B, Vasilevskis EE. Reducing hospital readmission rates: current strategies and future directions. *Annu Rev Med*. (2014) 65:471–85. doi: 10.1146/annurev-med-022613-090415
8. Auerbach AD, Kripalani S, Vasilevskis EE, Sehgal N, Lindenauer PK, Metlay JP, et al. Preventability and causes of readmissions in a national cohort of general medicine patients. *JAMA Intern Med*. (2016) 176:484–93. doi: 10.1001/jamainternmed.2015.7863
9. Accreditation Council for Continuing Medical Education. *ACCME Strategic Plan 2018–2021*. Chicago, IL: Accreditation Council for Continuing Medical Education (2018).
10. Campbell S, Pieters K, Mullen KA, Reece R, Reid RD. Examining sustainability in a hospital setting: case of smoking cessation. *Implement Sci*. (2011) 6:108. doi: 10.1186/1748-5908-6-108
11. Stetler CB, Mittman BS, Francis J. Overview of the VA Quality Enhancement Research Initiative (QUERI) and QUERI theme articles: QUERI series. *Implement Sci*. (2008) 3:8. doi: 10.1186/1748-5908-3-8

Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

frontiers in Public Health

ORIGINAL RESEARCH
published: 15 May 2020
doi: 10.3389/fpubh.2020.00169

A Qualitative Evaluation of the Pain Management VA-ECHO Program Using the RE-AIM Framework: The Participant's Perspective

Sherry Ball[1], Krysttel Stryczek[1], Lauren Stevenson[1], Rene Hearns[1], David H. Au[2], P. Michael Ho[3] and David C. Aron[1]*

[1] Louis Stokes Cleveland VA Medical Center (LSCVAMC), Cleveland, OH, United States, [2] VA Puget Sound Health Care System, Seattle, WA, United States, [3] Rocky Mountain Regional VA Medical Center (RMRVAMC), Aurora, CO, United States

Introduction: Veterans frequently seek chronic pain care from their primary care providers (PCPs) who may not be adequately trained to provide pain management. To address this issue the Veterans Health Administration (VHA) Office of Specialty Care adopted the Specialty Care Access Network Extension for Community Healthcare Outcomes (VA-ECHO née SCAN-ECHO). The VA-ECHO program offered training and mentoring by specialists to PCPs and their staff. VA-ECHO included virtual sessions where expertise was shared in two formats: (1) didactics on common pain conditions, relevant psychological disorders, and treatment options and (2) real-time consultation on patient cases.

Materials and methods: VA-ECHO participants' perspectives were obtained using a semi-structured interview guide designed to elicit responses based on the RE-AIM (reach, effectiveness, adoption, implementation, and maintenance) framework. A convenience sampling was used to recruit PCPs and non-physician support staff participants. Non-physicians from rural VHA sites were purposively sampled to gain diverse perspectives.

Findings: This qualitative study yielded data on each RE-AIM domain except reach. Program reach was not measured as it is outside the scope of this study. Respondents reported program effectiveness as gains in knowledge and skills to improve pain care delivery. Effective incorporation of learning into practice was reflected in respondents' perceptions of improvements in: patient engagement, evidenced-based approaches, appropriate referrals, and opioid use. Program adoption included how participating health care systems selected trainees from a range of sites and roles to achieve a wide reach of pain expertise. Participation was limited by time to attend and facilitated by institutional support. Differences and similarities were noted in implementation between hub sites. Maintenance was revealed when respondents noted the importance of the lasting relationships formed between fellow participants.

Discussion: This study highlights VA-ECHO program attributes and unintended consequences. These findings are expected to inform future use of VA-ECHO as a means to establish a supportive consultation network between primary and specialty care providers to promote the delivery evidence-based pain management practices.

Keywords: pain management, continuing education, tele-mentoring, primary care, specialty care

OPEN ACCESS

Edited by:
Borsika Adrienn Rabin, University of California, San Diego, United States

Reviewed by:
Erin Finley, South Texas Veterans Health Care System (STVHCS), United States
Iffat Elbarazi, Abu Dhabi University, United Arab Emirates

****Correspondence:***
Sherry Ball
sherry.ball@va.gov

Specialty section:
This article was submitted to Public Health Education and Promotion, a section of the journal Frontiers in Public Health

Received: *22 November 2019*
Accepted: *20 April 2020*
Published: *15 May 2020*

Citation:
Ball S, Stryczek K, Stevenson L, Hearns R, Au DH, Ho PM and Aron DC (2020) A Qualitative Evaluation of the Pain Management VA-ECHO Program Using the RE-AIM Framework: The Participant's Perspective. Front. Public Health 8:169. doi: 10.3389/fpubh.2020.00169

INTRODUCTION

Most Veterans receive primary care relatively close to home at Veterans Healthcare Administration (VHA) community-based outpatient clinics (CBOCs) where access to specialty care, such as for chronic pain, is greatly needed but limited. Although pain is documented in approximately 50 percent of primary care visits at VHA facilities (1), primary care providers (PCPs) are not adequately trained to provide pain care (2). In response, the VHA has promoted initiatives designed to train and support PCPs working in CBOCs to provide chronic pain care.

The specialty care access network extended community healthcare outcomes (VA-ECHO; née SCAN-ECHO) program is an initiative implemented in 2010 to improve specialty care access, This initiative focuses on VA sites with limited specialty care resources. The program, adapted from Project ECHO® (3), offers PCPs training on the delivery of routine specialty care at their respective CBOCs. Training sessions are led virtually by a multidisciplinary specialty care team typically located at an urban VHA medical center (hub site) and simultaneously attended via teleconferencing by 10 or more PCPs from multiple VHA spoke sites, either CBOCs or rural VHA medical centers. Sessions include a didactic presentation on a series of specialty-related topics, live consultation with a specialist team, and the opportunity to learn from fellow PCP participants' consultations. At each session a PCP typically presents a case and obtains feedback from the specialty team. Participants have the opportunity to ask follow-up questions in real time and to discuss treatment options and challenges with other participants. When needed, the PCP can obtain follow-up consultation(s) at a future session(s). Sessions are recurring with different cases and topics covered at each session. Hub sites were able to design their own program, curriculum, and participation expectations. Presentation topics fit into the following categories: pain etiology, comorbidities, psychology (Post Traumatic Stress Disorder, anxiety, etc.), medications etc., as well as, guidelines on treatments, evaluation, and management. Over time relationships between specialty and primary care providers can be fostered through regularly scheduled teleconferencing sessions. Our objective was to evaluate this program to inform the expansion and implementation of pain management.

MATERIALS AND METHODS

This evaluation used qualitative methods to explore program participants' experiences with providing pain care. This work was approved, supported, and funded by the VHA Office of Specialty Care and the Office of Rural Health as an evaluation study. Our goals included understanding and improving implementation of VA-ECHO. This work was deemed quality improvement and exempt from Institutional Review Board oversight. The Louis Stokes Cleveland Department of Veterans Affairs Research and Development Committee waived the requirement for the ethical approval for this study because the project was designed and implemented for the purposes of improving internal VA processes in support of the VA mission in accordance with the national legislation and the institutional requirements.

Employee unions reviewed and approved the interview guide before initiating participant recruitment. Participation was voluntary and responses are kept anonymous.

Participants and Setting

We obtained attendance data from four active VA-ECHO Pain Management programs (Hub sites). Two of the four hub sites were excluded due to incomplete participation data, such as missing participant contact information. The remaining two hub sites (Hub A and B) were selected for participant sampling based on confirmation of attendee's name, VHA email, spoke site location in VHA databases. Programs were designed to include a case presentation at each session. One site used a video-teleconferencing format and the other an audio-teleconferencing system with a chat box for entering written comments or questions. Both held regular weekly sessions (with some breaks, i.e., for holidays) spanning over at least 1 year. We sampled past and current VHA PCPs, ancillary providers, and clinical support staff who attended programs offered by the selected Hub sites. Participants' spoke sites were identified, including urban and rural VHA Medical Centers and CBOCs, and participants from rural facilities (serving a patient population composed of 50 percent or greater rural Veteran population according to VHA administrative data) and non-physicians were purposively sampled to obtain diverse perspectives. Participants with non-VHA email addresses (i.e., university affiliates) and those who were no longer employed with the VHA were excluded.

Data Collection

We contacted 537 program participants by VHA email to participate in a telephone interview. Twenty-three contacts responded to decline the interview invitation, citing lack of interest in participating in the interview, not having time to participate, or incorrect information about their program participation. Six contacts accepted the invitation but did not complete scheduling. All other invitations were assumed to be declined if contacts were non-responsive. From May 2018 through September 2018, we completed 26 interviews with program participants (**Table 1**), including 20 females and six males. Fifteen respondents practiced at a rural facility. Three respondents had experience with both Hub programs. Six interviews were completed with respondents reporting limited experience with the program, including those who discontinued attendance after a few sessions or reported no attendance. The qualitative team ensured reflexivity by acknowledging and identifying their assumptions and existing knowledge about VA-ECHO pain management program during regular team meetings (4).

A semi-structured interview guide (see Supplementary Appendix) informed by RE-AIM (5) and past evaluation work (6, 7) was used to gather detailed descriptions and examples of respondents' experiences with the VA-ECHO pain management program. The interview guide included open-ended questions and semi-structured probes for uniform data collection of key topics and allowed exploration of unanticipated themes generated by respondents. Probes using respondents' verbatim words or phrases were used to elicit additional details and

TABLE 1 | Program participant interviews by provider type.

Provider type	Program participants	Limited/No program participation
Physicians	7	3
Physician assistants	2	0
Nurse practitioners	3	0
Registered dieticians	2	0
Pharmacists/Clinical pharmacists	4	1
Nurses	0	2
Other non-physicians	2	0

to ensure understanding of the respondent perspective rather than relying on the team's assumed knowledge. The interview guide was adapted according to the respondent's role and experience with the program (8, 9). For respondents with limited or no experience with the program, interviews focused on barriers and facilitators to program attendance, and access to pain management consultation and resources. Interviews lasted approximately 30 min.

Interviews were conducted by trained and experienced qualitative interviewers (SB, LS, and KS). All three female interviewers are research scientists who collectively have over 20 years of VHA health services and quality improvement experience and have been working together on the evaluation of specialty care initiatives for over 4 years. Interviews were audio-recorded and transcribed verbatim by Transcription Outsourcing, LLC. ATLAS.ti® software was used for data management, coding and analysis. We collected and analyzed data concurrently. Data were analyzed using iterative deductive content analysis applying *a priori* codes (**Table 2**) using RE-AIM (5) and inductive content analysis using open and unstructured coding to capture data that did not fit into *a priori* categories. The qualitative team met weekly to review data and reach consensus on interpretation of themes and findings. Findings were aggregated across sites and respondent types for each RE-AIM domain.

TABLE 2 | RE-AIM a priori constructs.

Domain	Operational definition	Findings
Reach	The number of patients expected or shown to reap the main benefit from the program	Beyond the scope of this paper
Effectiveness[1]	How participation in the program improved the attendees' ability to provide quality patient care	Attendees reported gaining multidisciplinary knowledge and increased job satisfaction, improved self-efficacy in communicating with, providing care for, offering resources to patients, reduced opioid prescribing, and referring patients with chronic pain
Adoption	A description of the program attendees, their roles, and how they learned about the SCAN-ECHO program	Attendees were PCPs and support staff in primary care; informed about program from local leaders or from professional conferences
Implementation	How *spokes* sites implemented SCAN-ECHO at their sites, including barriers and facilitators to participation How *hub* sites organized the content and format of the SCAN-ECHO program and sessions	Participation in the program was possible when local leadership supported session attendance by allowing schedules to be blocked and offering continued education credit Hub sites implemented programs using different delivery platforms (video and/or audio only) and with different attendance expectations (regular attendance expected or no expectations). Didactic sessions covered a similar range of topics
Maintenance	How participants continue to use knowledge and skills obtained from the SCAN-ECHO program	Attendees continued to learn from program by continued attendance or continued interaction with fellow attendees or program leaders

[1] *Effectiveness measured at PCP level, not patient outcomes.*

Findings

Reach

The goal of the VA ECHO pain management program was to improve pain care for patients. Our work focused on how program participants and how they gained knowledge to improve patient care through learning and mentorship. Thus, Reach, defined as the number of patients expected or shown to reap the main benefit from the program, was beyond the scope of our work.

Effectiveness

Consistent with a focus on the provider level and not patient outcomes, effectiveness is reported as the extent to which providers gained skills and knowledge in pain management. Most respondents reported that the program provided a level of multidisciplinary knowledge that was not included in prior medical education and training. This training improved their knowledge of treatment options and their ability to communicate with specialists and to make better and more timely referrals. Many respondents reported having few local pain resources (i.e., pain specialist or alternative medicine providers) to address their questions before participating in the program. Respondents noted a reduction in opioid prescribing with VA-ECHO participation.

> *It was kind of changing the conversation and changing the approach, how we approach, you know, somebody with comorbid psychological conditions that are overlapping, … it was just really a plethora of information being provided that I can really apply in dealing with my patients that have pain.*
>
> Nurse Practitioner, Rural Medical Center

I think patients are getting referred more quickly to the specialist that's going to give them the most benefit for what they have wrong with them. I think the physicians that have been through it make decisions faster about these things. I think also, it stops so many inappropriate consults that other physicians have to deal with, whether they wind up seeing the patient or not, they still have to review the consult and make some determination. And that takes up people's time needlessly. So, I think it's helped on many levels.

Physician, Urban Medical Center

…and I found it to be very helpful facility wide. I noticed just changes in prescribing patterns in the physicians that participated, I noticed the referrals to pain management were more appropriate, some patients had more of a workup, the providers were, actually, trying to figure out the etiology of their pain before sending them somewhere. They wound up going to the more appropriate specialist.

Physician, Leadership, Urban Medical Center

Many providers reported increased empowerment and confidence in their ability to provide pain care. The connection of providers through VA-ECHO made them feel they are not facing the challenges of providing pain care alone. Some respondents commented that participation improved their job satisfaction.

I really feel like I've operated independently on this island with no assistance for a while and very uncomfortable and frustrated and so forth with no direction. Having now gotten to participate in SCAN-ECHO, …I'm starting to see the benefits of it, just being able to talk about it week after week after week. You develop so much more of a comfort in here that other people are facing the absolute same things you face in your clinics every day. And, you are able to gain insight from other providers on how they do things, and why they do that. It's just started to allow me to focus on pain as something other than a pain to myself as a provider.

Physician, Urban CBOC

*It has helped me dramatically deal with the tremendous sea change in practice and practice expectation and what is good practice. And it helped me to deal with resistance in patients and to deal with resistance in VA providers, and VA administrators saying "that's not the way we do it, that's not gonna' work", sort of the consistent messaging became my voice. It was so important for me to learn. I am really grateful [*for this opportunity*] for letting me learn and letting me fail a little.*

Clinical Pharmacist, Rural Medical Center

Learning how to talk to patients specifically about use of opioids was emphasized as a skill that was valued and well-suited for this platform. However, another provider mentioned that when they stop opioids, or refuse to provide opioids for pain management, patients sometimes seek care elsewhere and don't return to that VHA provider.

… I don't dread my pain patients if they come in. You run the list in the morning and there's a sense of dread to some degree on some folks. So, I feel like that's less, I don't feel that way as much, there's still a few, but I feel like I have more control, or more of an idea of how to, how to even talk to them and address their pain treatment.

Physician, Urban CBOC

There's been some patients who basically some stop coming once you stop their narcotics. Now, that's not surprising; that's happened to all of us. I don't know if that's unintended. I think a small portion of patients, that will be the case, they will go somewhere else.

Physician, Urban CBOC

Adoption

Respondents at spoke sites included a variety of roles and clinical backgrounds, including physician and non-physician PCPs (i.e., physician assistants, nurse practitioners) and direct care support staff. Who participated depended upon the current needs of primary care at spoke sites. Spoke site leadership directed and encouraged staff to attend VA-ECHO sessions. Respondents reported they were expected to bring information and skills back to their site to provide new knowledge or better support for existing services.

The plan was to have one provider from each of the CBOCs. We especially wanted the more rural CBOCs [that] *we felt were the most important, because we had a lot more issues with opioid prescribing in those areas and not much support. The patients would have to come all the way to the main facility to see a pain management specialist. So, we made sure that the furthest away CBOCs each had a physician that attended, that was approved to attend it. Chief just blocked out that time in their schedule for the entire year and everyone knew; it's happening, and everything was fine.*

Physician, Urban Medical Center

*Most of the primary care don't participate unless their staffing a case, but because that [*presenting a case*] was made part of my job per say. It just is.*

Non-physician, Urban Medical Center

Implementation

Limited time was reported as a barrier to attendance. However, supervisory and institutional support were identified to mitigate this barrier. Support was leveraged from Chiefs of Staff and other supervisors to encourage providers at spoke sites to attend. Many respondents reported that having their schedules blocked during VA-ECHO sessions was the key for consistent attendance. Respondents reported they were more likely to attend when continuing education credit was offered or when VA-ECHO sessions were scheduled at times when providers were more likely to be available such as during lunch time in their respective time zone.

We have a couple, one or two, primary care providers that participate regularly and come down regularly because we can get CEUs from them as well.

Non-physician, Urban Medical Center

One spoke site discontinued participating in the program after realizing the program did not fit their needs. Some non-prescribers felt the program was less suited to them in that a large portion of the program content was related to opioid prescribing practices.

> *It [*attending VA-ECHO*] didn't work out for us and I wish there was a little bit less focus on opiates, you know, not using opiates, but the format I think of the SCAN remote videoing in and it's a good, I like it. I think it could be really great if rolled out well, led by somebody with kind of a broader view of the landscape.*
>
> Physician, Rural Medical Center

> *If they [*VA-ECHO sessions*] are in those block times, I can participate and make efforts to meet with some of my peers, but usually our pain scope is very limited. For example, we are limited to offer opioids. Opioids are restricted for my scope, but we can refer on pain clinic.*
>
> Nurse Practitioner, Urban Medical Center

One Hub site used video teleconferencing with no more than 15 attendees per session and the other Hub site used an audio only format allowing 100 or more to participate in a session. For some, utilization of a video format allowing attendees to see each other during each session was an initial deterrent, but after attending a few sessions participants began enjoying the video component and saw the advantage of being able to see fellow participants. Discussion was a key component of both formats.

> *It was really it was nice to see the team, the pain management providers and get to know their faces and be able to ask them questions directly. Especially as a new provider, totally new to the VA it allowed me to be a little bit more comfortable with that particular specialty.*
>
> Physician Assistant, Urban CBOC

> *I think that there's less of a group discussion on the Adobe platform [audio only] in some respects. There's a larger participation because it's not a direct video conversation. A lot of people can certainly put in their two cents on the chat.*
>
> Non-physician, Rural Medical Center

In addition to the didactic component of the VA-ECHO sessions, case presentations were also integral. Although only a few of our respondents had presented a case at VA-ECHO, respondents felt that understanding and observing how others treated chronic pain in the VHA helped them learn how to incorporate chronic pain treatment into their practice. Respondents with experience practicing outside the VHA mentioned differences in treatment practices present between the private sector and VHA, adding that VA-ECHO helped them understand VHA practices and available resources.

> *I was able to learn how the pain management providers thought through chronic pain at the VA, just because it's very different here at the VA than outside the VA. And so, it was good to see the cases that presented were consistent with your treatment plan. It was good to see the consistency of care and how I guess intentional they were with each of their patients. It was also helpful to see what resources the VA had to treat pain, more than just medication like the chiropractic care and the alternative modalities and things like that.*
>
> Physician Assistant, Urban CBOC

Maintenance

Many respondents continued to consult with fellow participants and specialists regarding pain care after completing the 1 year program. Some respondents continued regular or intermittent participation beyond a year in one or more Pain VA-ECHO programs depending on providers' interest, perception of learning potential, and schedule availability. One respondent reported their participation ended despite their interest to continue because of perceived competing priorities for the use of clinical time resulted in the loss of institutional support for program attendance.

Respondents also expressed improved job satisfaction. A desire to have and be a part of a support system where participants could contribute to a greater effort to improve pain management on a national level project was cited as a motivating force to attend the program.

> *I think that you know we really felt the program to be enormously helpful here. All the providers that went through it enjoyed it and learned things and looked forward to it every week. It was good. It built comradery among people that otherwise wouldn't interact, other than "why did they send me that consult? That's not appropriate." So, it's really good. There was no level that it wasn't a positive thing. It was just positive across the board. It was great. Everyone should do it.*
>
> Physician, Urban Medical Center

> *. . . sometimes in rural clinics or even in urban clinics where people are so busy they hardly ever leave their offices, it can be great to work together on a case or think through a case in a safe space; you're not with someone who is your boss or someone who is your superior.*
>
> Clinical Pharmacist, Rural Medical Center

Continued contact with other participants and specialists to ask questions rather than sending numerous consults is another way some individuals hoped to continue to use what they learned in the program. Relationships between fellow participants and with specialists developed during participation, facilitated providers utilizing their connection to other provider participants for advice on difficult cases, or reaching out to specialists outside of the VA-ECHO sessions for advice.

> *I can call* [specialist from program A] *or* [B] *or whoever you know if I've got a patient issue, because I don't have a provider here right now, so if I've got an issue that I really need* [to be*] addressed, and I can't find somebody around to do* [it]*, then I can call* [program A] *and say 'Hey* [specialist X]*, can you give me input on this? Do I need to send this emergently somewhere or do I need to do whatever?' They're not just available during the SCAN, the video SCAN time. It's a long-term relationship.*
>
> Non-physician, Rural Medical Center

DISCUSSION

Utilization of the RE-AIM framework with qualitative inquiry (5) highlighted aspects of the VHA pain management VA-ECHO program consistent with other published evaluations. These findings support other studies in which respondents reported program *effectiveness* as improved referrals to specialists, skills, and knowledge of available resources and treatment options for Veterans with chronic pain (10–13). Many respondents reported that improved confidence enhanced their ability to talk to patients about their pain care. Respondents who were prescribers described increased comfort in reducing the use of opioids similar to other studies and as shown quantitatively (14–17). Some reported improved job satisfaction. This and former examinations of *adoption* identified program participants as primary care team members from a range of health care provider positions who critically needed and wanted this training (1–11, 14). The primary barrier to program *implementation* was time constraints, as has been noted in other studies (18). Aspects of program *implementation* were consistent with other programs including weekly didactics. Case discussions on highly relevant topics with the multidisciplinary team, and fellow PCPs facilitated learning and provided support to clinicians who otherwise had few interactions with other VHA PCPs or pain specialists (14, 19). Respondents noted that *maintenance* of knowledge and skills occurred through continued relationships and contact with the multidisciplinary specialty care team members and fellow clinicians. Continued widespread implementation of this program is likely to continue only when the benefits of participation to patient care are balanced with the pressure to see patients and do not conflict with patient care duties.

While efforts are underway to ensure fidelity to the original Project ECHO® model and to provide guidance for consistent replication (20), implementation of the VA-ECHO program and other ECHO-like models (21) is not standardized. Allowing individual VHA hub sites to design their own programs may produce a stronger program with more local buy-in but can make comparisons of programs challenging. Due to the limited availability and time of PCPs, future studies need to address necessary and sufficient components of the VA-ECHO training model. Efforts could then be made to apply this model in the most efficient and effective manner, and potentially increase participation. In other settings, other types of care models have been combined with VA-ECHO including asynchronous component and a patient participation component (22).

This program is designed to establish a mentor-mentee relationship between hub and spoke clinicians. Learning and relationship building are expected to be promoted when the specialty care team members possess good interpersonal skills and conduct sessions with professionalism. These qualifications are especially important to promote dialogue and open discussion using the video teleconferencing system and should be considered when building new programs.

This study has some limitations including the sole use of email contact for recruitment. Providers and staff receive a large volume of email making overlooking an email relatively prevalent. It may not have always been clear to all recipients why they were being contacted. Respondents agreeing to be interviewed had participated in established VA-ECHO programs and primarily reported on positive attributes of the program. Participants from other programs may have not responded to emailed interview requests. Due to these limitations and the fact that participation was restricted to VHA staff, findings may not be generalizable to non-VHA settings as the VHA is unique within the United States being the largest health care delivery system.

Recommendations and Future Studies

Future studies could examine retention rates for VA-ECHO participants and explore this program from the perspective of the patient. Consistent with prior studies (6, 7, 18) respondent participants in this study reported positive experiences with the program but how that may or may not influence retention has not been explored. Respondents shared that attendance was feasible when leadership was assured that their participation would not interfere with seeing patients, yet no participants reported monitoring clinic utilization for any potential effects. One spoke site discontinued participation in the program upon realizing that the program focus was not applicable to their specialized clinic. This site, as most, learned about the program by word of mouth. A better fit of participants could be obtained with a more formalized outreach. Finally, patients receiving pain care from providers participating in VA-ECHO were interviewed as part of the overall quality improvement evaluation and these findings will be reported separately.

CONCLUSION

This evaluation provides indications that the pain management VA-ECHO program is successful in meeting the needs of the primary care staff to improve pain care for Veterans. Tele-mentoring-based programs are growing in use to educate primary care staff. Based on respondents' comments, the program format fostered improvements in confidence, knowledge and skills as well as learning and implementation of critical soft skills specific to providing pain care to Veterans. The format, whether video-based or audio only, filled a critical gap in participants' education: Learning how to talk to patients about their pain care. More in-depth analysis of how providers learn to have those difficult conversations will require further investigation.

DATA AVAILABILITY STATEMENT

The datasets generated for this study are available on request to the corresponding author.

AUTHOR CONTRIBUTIONS

SB, KS, LS, and RH contributed to the study design, data collection, data analysis, and writing the manuscript. DAu, PH, and DAr were primarily responsible for the design of the larger evaluation of the VA-ECHO program and contributed to the writing of this manuscript.

FUNDING

This work was funded by the U.S. Department of Veterans Affairs (VA) Office of Rural Health (ORH), (visit www.ruralhealth.va.gov to learn more) and was conducted in cooperation with the Office of Specialty Care.

ACKNOWLEDGMENTS

We presented a portion of these data as a poster at the AcademyHealth Annual Conference on the Science of Dissemination & Implementation (Washington, D.C., 2018) and at the MetaECHO conference (Albequerque, New Mexico, 2019).

REFERENCES

1. Kerns RD, Otis J, Rosenberg R, Reid MC. Veterans' reports of pain and associations with ratings of health, health-risk behaviors, affective distress, and use of the healthcare system. *J Rehabil Res Dev*. (2003) 40:371–79. doi: 10.1682/JRRD.2003.09.0371
2. Mezei L, Murinson BB. Pain education in North American medical schools. *J Pain*. (2011) 12:1199–208. doi: 10.1016/j.jpain.2011.06.006
3. Arora S, Thornton K, Murata G, Deming P, Kalishman S, Dion D, et al. Outcomes of treatment for hepatitis C virus infection by primary care providers. *N Engl J Med*. (2011) 364:2199–207. doi: 10.1056/NEJMoa1009370
4. Palaganas EC, Sanchez MC, Molintas MP, Caricativo RD. Reflexivity in qualitative research: a journey of learning. *Q Rep*. (2017) 22:426–38. Retrieved from https://nsuworks.nova.edu/tqr/vol22
5. Holtrop JS, Rabin BA, Glasgow RE. Qualitative approaches to use of the RE-AIM framework: rationale and methods. *BMC Health Serv Res*. (2018) 18:177. doi: 10.1186/s12913-018-2938-8
6. Stevenson L, Ball S, Haverhals LM, Aron DC, Lowery J. Evaluation of a national telemedicine initiative in the veterans health administration: factors associated with successful implementation. *J Telemed Telecare*. (2018) 24:168–78. doi: 10.1177/1357633X16677676
7. Sayre GG, Haverhals LM, Ball S, Stevenson L, Battaglia C, Aron DC et al. Adopting SCAN-ECHO: the providers' experiences. *Healthcare*. (2017) 5:29–33. doi: 10.1016/j.hjdsi.2016.04.006
8. Hill CE, Knox S, Thompson BJ, Williams EN, Hess SA, Ladany N. Consensual qualitative research: an update. *J Couns Psychol*. (2005) 52:196–205. doi: 10.1037/0022-0167.52.2.196
9. Hill CE, Thompson BJ, Williams EN. A guide to conducting consensual qualitative research. *Couns Psychol*. (1997) 25:517–72. doi: 10.1177/0011000097254001
10. Jansen BDW, Brazil K, Passmore P, Buchanan H, Maxwell D, McIlfatrick SJ, et al. Evaluation of the impact of telementoring using ECHO© technology on healthcare professionals' knowledge and self-efficacy in assessing and managing pain for people with advanced dementia nearing the end of life. *BMC Health Ser Res*. (2018) 18:228. doi: 10.1186/s12913-018-3032-y
11. Furlan AD, Zhao J, Voth J, Hassan S, Dubin R, Stinson JN, et al. Evaluation of an innovative tele-education intervention in chronic pain management for primary care clinicians practicing in underserved areas. *J Telemed Telecare*. (2018) 25:484–92. doi: 10.1177/1357633X18782090
12. Ball S, Wilson B, Ober S, Mchaourab S. SCAN-ECHO for pain management: implementing a regional telementoring training for primary care providers. *Pain Med*. (2018) 19:262–68. doi: 10.1093/pm/pnx122
13. Eaton LH, Godfrey DS, Langford DJ, Rue T, Tauben DJ, Doorenbos AZ. Telementoring for improving primary care provider knowledge and competence in managing chronic pain: a randomised controlled trial. *J Telemed Telecare*. (2018) 27:1–8. doi: 10.1177/1357633X18802978
14. Katzman JG, Comerci G Jr., Boyle JF, Duhigg D, Shelley B, Olivas C, et al. Innovative telementoring for pain management: project ECHO pain. *J Contin Educ Health Prof*. (2014) 34:68–75. doi: 10.1002/chp.21210
15. Frank JW, Carey EP, Fagan KM, Aron DC, Todd-Stenberg J, Moore BA, et al. Evaluation of a telementoring intervention for pain management in the veterans health administration. *Pain Med*. (2015) 16:1090–100. doi: 10.1111/pme.12715
16. Zhou C, Crawford A, Serhal E, Kurdyak P, Sockalingam S. The impact of project ECHO on participant and patient outcomes: a systematic review. *Acad Med*. (2016) 91:1439–61. doi: 10.1097/ACM.0000000000001328
17. Katzman JG, Qualls CR, Satterfield WA, Kistin M, Hofmann K, Greenberg N, et al. Army and navy ECHO pain telementoring improves clinician opioid prescribing for military patients: an observational cohort study. *J Gen Intern Med*. (2018) 34:387–95. doi: 10.1007/s11606-018-4710-5
18. Ní Cheallaigh C, O'Leary A, Keating S, Singleton A, Heffernan S, Keenan E, et al. Hepatitis C outcomes research network. Telementoring with project ECHO: a pilot study in Europe. *BMJ Innov*. (2017) 3:144–51. doi: 10.1136/bmjinnov-2016-000141
19. Carlin L, Zhao J, Dubin R, Taenzer P, Sidrak H, Furlan A. Project ECHO telementoring intervention for managing chronic pain in primary care: insights from a qualitative study. *Pain Med*. (2018) 19:1140–46. doi: 10.1093/pm/pnx233
20. Katzman JG, Galloway K, Olivas C, McCoy-Stafford K, Duhigg D, Comerci G, et al. Expanding health care access through education: dissemination and implementation of the ECHO model. *Mil Med*. (2016) 181:227–35. doi: 10.7205/MILMED-D-15-00044
21. Fischer SH, Rose AJ, McBain RK, Faherty LJ, Sousa J, Martineau M. *Evaluation of Technology-Enabled Collaborative Learning and Capacity Building Models: Materials for a Report to Congress*. Santa Monica, CA: RAND Corporation (2019). Available online at: https://www.rand.org/pubs/research_reports/RR2934.html.
22. Wood BR, Mann MS, Martinez-Paz N, Unruh KT, Annese M, Spach DH, et al. Project ECHO: telementoring to educate and support prescribing of HIV pre-exposure prophylaxis by community medical providers. *Sex Health*. (2018) 15:601–5. doi: 10.1071/SH18062

Conflict of Interest: DAu receives remuneration from Novarits Inc. for participation on a data safety monitoring board. He serves as a Deputy Editor for the Annals of the American Thoracic Society and is a member of the Exam Committee for the American Board of Internal Medicine Pulmonary Board, for which he receives remuneration.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

frontiers in Public Health

COMMUNITY CASE STUDY
published: 12 June 2020
doi: 10.3389/fpubh.2020.00221

Pragmatic Application of the RE-AIM Framework to Evaluate the Implementation of Tobacco Cessation Programs Within NCI-Designated Cancer Centers

Heather D'Angelo[1], Alex T. Ramsey[2,3], Betsy Rolland[1,4], Li-Shiun Chen[2,3], Steven L. Bernstein[5], Lisa M. Fucito[6,7], Monica Webb Hooper[8†], Robert Adsit[9], Danielle Pauk[1], Marika S. Rosenblum[9,10], Paul M. Cinciripini[11], Anne Joseph[12], Jamie S. Ostroff[13], Graham W. Warren[14,15], Michael C. Fiore[9] and Timothy B. Baker[9]*

[1] Carbone Cancer Center, School of Medicine and Public Health, University of Wisconsin-Madison, Madison, WI, United States, [2] Department of Psychiatry, Washington University School of Medicine, St. Louis, MO, United States, [3] Alvin J. Siteman Cancer Center, Barnes-Jewish Hospital and Washington University School of Medicine, St. Louis, MO, United States, [4] Institute for Clinical and Translational Research, School of Medicine and Public Health, University of Wisconsin-Madison, Madison, WI, United States, [5] Yale Department of Emergency Medicine, Yale School of Medicine, New Haven, CT, United States, [6] Department of Psychiatry, Yale School of Medicine, New Haven, CT, United States, [7] Yale Cancer Center, Smilow Cancer Hospital at Yale-New Haven, New Haven, CT, United States, [8] Case Comprehensive Cancer Center, Case Western Reserve University, Cleveland, OH, United States, [9] Department of Medicine, Center for Tobacco Research and Intervention, School of Medicine and Public Health, University of Wisconsin-Madison, Madison, WI, United States, [10] Department of Research, William S. Middleton Memorial Veterans Hospital, Madison, WI, United States, [11] Department of Behavioral Sciences, University of Texas MD Anderson Cancer Center, Houston, TX, United States, [12] Department of Medicine, Masonic Cancer Center, University of Minnesota, Minneapolis, MN, United States, [13] Department of Psychiatry and Behavioral Sciences, Memorial Sloan Kettering Cancer Center, New York, NY, United States, [14] Department of Radiation Oncology, Hollings Cancer Center, Medical University of South Carolina, Charleston, SC, United States, [15] Department of Cell and Molecular, Pharmacology and Experimental Therapeutics, Hollings Cancer Center, Medical University of South Carolina, Charleston, SC, United States

OPEN ACCESS

Edited by:
Matthew Lee Smith, Texas A&M University, United States

Reviewed by:
Sapana R. Patel, Columbia University, United States
Kara Wiseman, University of Virginia, United States

***Correspondence:**
Heather D'Angelo
hdangelo@wisc.edu

†Present address:
Monica Webb Hooper, National Institute on Minority Health and Health Disparities, National Institutes of Health, Bethesda, MD, United States

Specialty section:
This article was submitted to Public Health Education and Promotion, a section of the journal Frontiers in Public Health

Received: *05 October 2019*
Accepted: *13 May 2020*
Published: *12 June 2020*

Citation:
D'Angelo H, Ramsey AT, Rolland B, Chen L-S, Bernstein SL, Fucito LM, Webb Hooper M, Adsit R, Pauk D, Rosenblum MS, Cinciripini PM, Joseph A, Ostroff JS, Warren GW, Fiore MC and Baker TB (2020) Pragmatic Application of the RE-AIM Framework to Evaluate the Implementation of Tobacco Cessation Programs Within NCI-Designated Cancer Centers. Front. Public Health 8:221. doi: 10.3389/fpubh.2020.00221

Tobacco cessation after cancer diagnosis leads to better patient outcomes. However, tobacco treatment services are frequently unavailable in cancer care settings, and multilevel implementation challenges can impede uptake of new programs. The National Cancer Institute (NCI) dedicated Cancer Moonshot funding through the Cancer Center Cessation Initiative (C3I) for NCI-Designated Cancer Centers to implement or enhance the implementation of tobacco treatment services. We examined a pragmatic application of the RE-AIM framework (reach, effectiveness, adoption, implementation, and maintenance) to evaluate tobacco treatment programs implemented within Cancer Centers funded through C3I. Using three C3I-funded Centers as examples, we describe how each RE-AIM construct was operationalized to evaluate the implementation of a wide range of cessation services (e.g., tobacco use screening, counseling, Quitline referral, pharmacotherapy) in this heterogeneous group of cancer care settings. We discuss the practical challenges encountered in assessing RE-AIM constructs in real world situations, including using the electronic health record (EHR) to aid in assessment. Reach and effectiveness evaluation required that Centers define the setting(s) where cessation services were implemented (to determine the "denominator"), enumerate the patient population, report current patient tobacco use, patient engagement in tobacco

treatment, and 6-month cessation outcomes. To reduce site heterogeneity, increase data accuracy, and reduce burden, reach was frequently captured via standardized EHR enhancements that improved the identification of current smokers and tobacco treatment referrals. Effectiveness was determined by cessation outcomes (30-day point prevalence abstinence at 6-months post-engagement) assessed through a variety of data collection approaches. Adoption was measured by the characteristics and proportion of targeted cancer care settings and clinicians engaged in cessation service delivery. Implementation was assessed by examining the delivery of tobacco screening assessments and intervention components across sites, and provider-level implementation consistency. Maintenance assessments identified whether tobacco treatment services continued in the setting after implementation and documented the sustainability plan and organizational commitment to continued delivery. In sum, this paper demonstrates a pragmatic approach to using RE-AIM as an evaluation framework that yields relevant outcomes on common implementation metrics across widely differing tobacco treatment approaches and settings.

Keywords: Tobacco treatment, Smoking Cessation, Cancer center, RE-AIM (Reach, Effectiveness, Adoption, Implementation and Maintenance), implementation

INTRODUCTION

Continued smoking after a cancer diagnosis has been associated with adverse outcomes, including overall and cancer specific mortality, and increased risk of developing a second primary cancer. Importantly, smoking cessation after a cancer diagnosis improves clinical outcomes (1, 2). Several national cancer organizations have developed recommendations for integrating tobacco treatment as a routine component of cancer care (3–6). All patients seen in cancer care should be consistently assessed for tobacco use, and if they are current users (usually past 30 day use), should be advised to quit, and/or referred to cessation treatment (6, 7). While the recommendations are clear for *what* to implement, there is little published on *how* to implement and evaluate tobacco treatment programs in cancer care settings (7). Despite the availability of the National Comprehensive Cancer Network (NCCN) (6) and other Clinical Practice Guidelines for Smoking Cessation, tobacco treatment services are often not a routine component of cancer care (8–10).

To address this gap in research-to-practice, the National Cancer Institute (NCI) dedicated Cancer Moonshot funding to enhance the capacity of NCI-Designated Comprehensive Cancer Centers to implement sustainable evidence-based tobacco treatment programs (11). The resulting Cancer Center Cessation Initiative (C3I) funded 42 NCI-Designated Comprehensive Cancer Centers ("Centers") to integrate tobacco treatment into cancer care. The C3I provides a unique opportunity to examine how tobacco treatment can be effectively implemented in cancer care. This study uses the RE-AIM framework (12) to evaluate how different tobacco treatment programs were implemented in diverse real-world clinical settings receiving the same level of supplemental funding (11).

RE-AIM has been used previously to evaluate tobacco treatment programs in healthcare settings (13, 14). However some elements of the framework, namely adoption, implementation, and maintenance, are often not reported (15, 16), and most published studies report on measures collected as part of a research study rather than a pragmatic application in multiple, diverse clinical settings. This paper provides examples of a pragmatic application of the RE-AIM framework to evaluate the implementation of real-world tobacco treatment programs in cancer care settings using simple, low burden measures easily gathered across clinical settings using electronic health records (EHRs) to aid in measurement (12, 17).

CANCER CENTER CESSATION INITIATIVE PRAGMATIC RE-AIM APPLICATION

The C3I funded 42 Cancer Centers from 28 states and the District of Columbia for 2 years to implement evidence-based tobacco treatment programs through a supplement to the Cancer Center Support Grant (11). The C3I Coordinating Center provides scientific and technical assistance to help Centers integrate tobacco treatment services into clinical care. The goals were to: (1) achieve consistent tobacco use screening and documentation for every patient; and (2) deliver evidence-based tobacco treatment to current smokers, ideally using the EHR to streamline referrals. Centers were free to choose evidence-based intervention components for their sites, including referrals to internal (e.g., counseling, medication) and external (e.g., Quitline) programs.

The C3I Coordinating Center, in collaboration with an expert panel of physicians, psychologists, and behavioral scientists with clinical and implementation expertise in smoking cessation for cancer patients, developed measures to evaluate progress amongst the C3I Centers. Measures were drawn from a pragmatic application of the RE-AIM framework and

intended to be low burden, actionable, sensitive to change, and broadly applicable to diverse cancer care settings (12). **Figure 1** shows the RE-AIM application to evaluate tobacco treatment program implementation, the evidence-based program components implemented, and the related implementation steps employed. Measures were designed to be compatible with existing EHR functionalityto generate data for evaluation. The Coordinating Center facilitated the sharing of best practices across C3I sites, and created a learning environment where sites meet every 6 months to discuss their successes and challenges, including reporting on the evaluation of their program implementation. Coordinating Center recommendations to the C3I Centers for how each RE-AIM measure might be interpreted and used is presented below.

Reach

Reach in C3I is defined as the proportion of current smokers seen in a cancer care setting who engaged or participated in an evidence-based tobacco treatment program. However, calculating reach is dependent upon the consistent identification of current smokers in the EHR (i.e., the denominator for reach) and upon the definition and documentation of patient engagement in an evidence-based tobacco treatment program (i.e., the numerator for reach). The following steps were offered to guide the assessment of reach by using the EHR to determine the numerator and denominator for the reach of tobacco treatment programs in cancer care settings. **Table 1** shows the results for three NCI-Designated Cancer Centers in C3I.

1. Define the setting where patients are assessed for tobacco use and identified as current smokers during their medical visit (e.g., the whole cancer center, or certain clinics).
2. Count unique patients seen in the setting during a specific period (e.g., 6 months). Each Center determined the type of visit in which tobacco use assessment would occur, such as during registration or nursing assessment, and were encouraged to include patients seen for cancer screening or treatment. The EHR reporting team may need to set up filters for selecting patient encounters and/or rules for counting visits. The aim is to select visits with clinician-patient interactions where tobacco use assessment and referrals should occur for current smokers.
3. Count the number of patients screened for tobacco use to determine the tobacco use assessment rate (number of patients screened/total number of patients).
4. Determine the number of current smokers by counting patients with a current smoking status. In the EHR a current smoking status could include: current every day smoker; current some days smoker; heavy smoker; or light smoker, but may vary depending on how the EHR is programmed. This number serves as the *denominator* for reach.
5. Among current smokers, count the number who engaged in at least one type of evidence-based tobacco treatment, and the number who engaged in each type of treatment offered at the Center. This serves as the *numerator* for reach. Each Center defined engagement depending on the services offered and following these guidelines for what constitutes engagement:
   a. counseling (in-person, phone, including brief advice to quit),
   b. connection to a Quitline, web-based, or text/mobile program via fax or eReferral, or
   c. cessation medications prescribed.

   If a program counts *acceptance* to receive treatment (e.g., to be referred to a Quitline) as engagement, reach should be defined as such. The number of smokers who were *offered* a program should be recorded separately from those who did engage. This could include the number of smokers who were offered enrollment in a counseling program (regardless of engagement), or the number who were given educational materials but were not connected with a program. The number of current smokers who declined to participate should be documented as a target for quality improvement.
6. Wherever possible, each Center should record patient demographics for current smokers and program participants to determine the representativeness of those reached. Many EHRs capture data on patient gender, race, ethnicity, age, and primary insurance type.

Effectiveness

Effectiveness is assessed by examining quit rates among those who participate in cessation treatment. In C3I, outcomes are assessed at 6-months post-engagement with one item; "When did you last smoke a cigarette (even one or two puffs)?," which allows for the calculation of both 7- and 30-day point prevalence abstinence rates. Documentation may occur in a separate database or within the EHR, although this may require additional programming. Follow-up assessments can be conducted in-person, via telephone, or through Quitline reports. In line with reach, effectiveness should be examined by patient sociodemographics and the type of tobacco treatment program used to explore variation in cessation outcomes.

Adoption

Setting level adoption is defined as the proportion of settings targeted for implementation that initiated the program. Adoption can be examined by organizational characteristics to understand local barriers. For example, are the administrative leaders in some settings hesitant to make changes to the EHR, or is there high staff turnover that makes clinical leadership hesitant to devote time to staff training? Provider level adoption can be assessed by documenting participation in training and tracking initiation of program components. Examining which implementation steps facilitated adoption (e.g., securing buy-in, provider trainings) should suggest how tobacco treatment can be enhanced at the setting and provider level.

Implementation

Level of implementation can be indexed by the quality and consistency of tobacco treatment service delivery. Examining provider level tobacco use screening, advice and referral rates can identify high- and low-performing providers, which can be used to focus additional training. Intervention fidelity can be assessed by examining the delivery

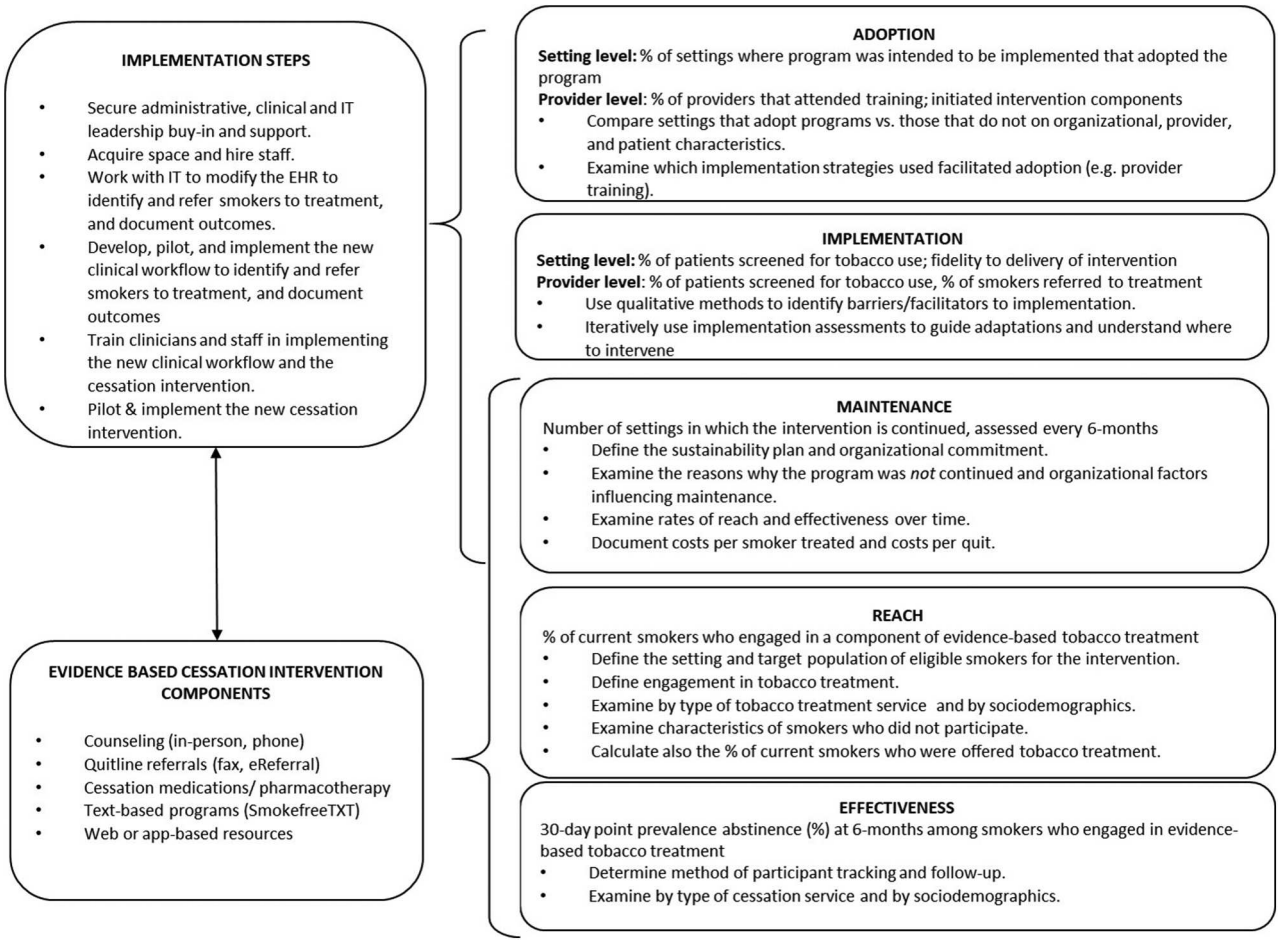

FIGURE 1 | RE-AIM application to evaluate tobacco treatment program implementation in cancer care, and the related implementation steps and evidence-based intervention components employed.

of intervention components, such as brief advice, counseling sessions delivered as intended, and whether medications were prescribed. Such information can be used to understand the sources of variation in intervention effectiveness: (i.e., is it the intervention or is it the level of implementation?) Qualitative methods, such as stakeholder interviews with patients, clinicians, and administrators can be used to examine barriers to implementation.

Maintenance

Maintenance can be defined as the degree to which rates of reach and effectiveness are sustained across time, as well as the potential for sustainability of the program. Defining the sustainability plan and securing organizational commitment to the program are key elements in estimating sustainability potential. After implementation, the number of settings in which the program is continued can be assessed, with a qualitative examination of the reasons programs were not maintained, with a comparison of maintained/not maintained settings on organizational, provider, and patient characteristics.

EXAMPLES OF RE-AIM APPLICATION AT C3I CANCER CENTERS

Washington University

Context

The EHR-enabled Evidence-based Smoking Cessation Treatment (ELEVATE) program developed at Washington University was implemented at the Siteman Cancer Center, which serves about 25,000 patients per year across rural and urban areas and medically underserved populations in multiple Midwestern states. The implementation of ELEVATE coincided with the launch of a new EHR platform at Washington University and BJC Healthcare system. ELEVATE leverages newly developed EHR modifications, including enhanced clinical workflows, Best Practice Alerts (BPAs), and automated referral systems to prescribe smoking cessation medications and provide counseling resources at the point-of-care (**Table 1**). Patients with a status of current smoker or a prescription for cessation medication are defined as "current smokers," which triggers a BPA prompting the clinician to deliver brief advice, prescribe medications, and refer patients to "light-touch" resources including the Quitline, SmokefreeTXT, and Smokefree smartphone apps.

TABLE 1 | Description of tobacco treatment programs at three NCI-Designated Cancer Centers funded through the Cancer Center Cessation Initiative.

	Washington University	**Yale University**	**Case Western Reserve University**
Setting (*s*)	Siteman Cancer Center, St. Louis, MO	Smilow Cancer Hospital, New Haven, CT and Smilow Cancer Care Centers throughout CT	University Hospitals Seidman Cancer Center, MetroHealth Cancer Center, Cleveland Clinic Taussig Cancer Center, Cleveland, OH[b]
Patients with visits to the setting[a], *N*	27,728	43,264	41,405
Patients screened for tobacco use[a], *N*	25,779	21,424	32,541
Patients identified as current smokers[a], *N*	3,224	3,882	4,316
Current smokers who engaged in at least one type of evidence-based cessation treatment[a], *N*	1,390	277	907
Tobacco treatment program components	ELEVATE (Electronic Health Record-Enabled Evidence-Based Smoking Cessation Treatment) • Deliver smoking cessation counseling (5A's) and pharmacotherapy at the point of care. • Enhance the EHR to identify and refer current smokers to the Quitline and SmokefreeTXT. • Training and video-based demonstrations and simulated patient scenarios with clinical care providers using test patients in the EHR. • Monthly provider performance data feedback, in comparison to department- and/or clinic-level data and clinical benchmarks.	Tobacco Treatment Service (TTS) at Smilow Cancer Hospital • In-person counseling program including medication management, and training providers. • Phone/tele-health counseling also delivered. • Smokers are also referred to SmokefreeTXT. • Monthly audit and feedback reports on Care Center performance are prepared and reviewed by the Tobacco Treatment Service and shared with Smilow Cancer Hospital and Care Center leadership.	Tobacco Intervention & Psychosocial Support (TIPS) Service • Face-to-face cognitive behavioral therapy combined with pharmacotherapy. • Tailored to cancer patients by including cancer-specific psychoeducation, emotional vulnerability content, and flexible intervention formats (e.g., in-clinic, telephone). • Caregivers and/or significant others may also be treated. • Smokers may also be referred to the SmokefreeTXT.
Smoker identification and referral method(s)	• Current smokers identified through the EHR during visit. • Patients with a current smoker status or documented as using a cessation medication will trigger a BPA that prompts the clinician to deliver counseling and pharmacotherapy at the point-of-care. • Referrals to the Quitline and SmokefreeTXT generated through the EHR.	• Current smokers identified through the EHR. • A list of current smokers sent to program staff who contact patients to schedule appointments. • eReferral to SmokefreeTXT is in development.	• Current smokers identified through the EHR during visit. Patients who indicate motivation to quit are referred via email, pager, or through eReferral (in select clinics). • Patients are contacted by TIPS staff for the initial assessment, treatment planning, and schedule for counseling appointments. • Patients may be signed up for SmokefreeTXT by program staff or may self-enroll. • Caregivers/significant others may be seen with the patient or contacted independently by program staff
EHR modifications implemented	Developed new clinical workflow, BPAs, and eReferral systems.	• Modified clinical workflow. • Enhanced the EHR to standardize tobacco use assessment. • eReferral sends prompt to Tobacco Treatment Service for current smokers.	• Standardized tobacco use assessments based on NCCN guidelines. • EHR provider notes generated to summarize tobacco treatment services delivered. • EHR eReferral generated to send patient information to TIPS

[a] *Reported for a 6-months period at 1 year post-implementation.*
[b] *Sum across the three healthcare systems.*

The ELEVATE program is supported by a bundled implementation strategy that includes: formal and informal training exercises through in-person and video-based demonstrations of ELEVATE module use, technical assistance and recommendations following live patient encounters and simulated patient scenarios with clinical care providers using test patients in the EHR, and monthly performance data feedback delivered to medical assistants and physicians that provides

data on assessment and treatment rates at the provider level and in comparison to department- and/or clinic-level data and clinical benchmarks. With the emphasis on data-driven quality improvement, provider-level assessment and treatment rates are expected to increase over time.

Reach

Smoking prevalence was 12.5% among patients screened for tobacco use who had at least one outpatient oncology clinic visit within a 6-month period (**Table 2**). Reach was defined as the proportion of current smokers who received either of the following types of tobacco treatment documented in the EHR within a 6-month period: active smoking cessation medication prescribed (i.e., medication rate) or brief cessation counseling (i.e., brief counseling rate). Before ELEVATE implementation, overall reach was 3.6%; after implementation, reach increased to 43.1%. Interest in counseling (i.e., counseling offer rate), and referral to phone-based, SMS text-based, and/or smartphone app-based counseling (i.e., counseling referral rate) were recorded separately from engagement.

Effectiveness

The EHR was used to assess current smoking status at 6-months post-tobacco treatment. This method relied on patients having an updated tobacco use status at 6-months after receiving tobacco treatment. Using this method, 67.2% of patients that received tobacco treatment had follow-up data available in the EHR in the following 6 months. Before ELEVATE was implemented, EHR data indicated that only 2.3% of patients treated for smoking had not smoked in the past 30 days at 6-months post-treatment. Following ELEVATE, 43.9% of smokers who received brief counseling, medications, or both and who had 6-month follow-up data documented in the EHR had not smoked in the past 30 days (29.5% using an intent to treat principle counting those lost to follow-up as current smokers). In contrast, only 7.6% of smokers who did *not* receive tobacco treatment reported they were no longer current smokers 6-months following their cancer center visit.

Adoption

At the setting level, all 21 outpatient oncology clinics in the Siteman Cancer Center adopted ELEVATE and initiated tobacco assessment and treatment services with the new point-of-care EHR module. At the provider level, at 1-year post-implementation, EHR data revealed that 99% of providers/clinic staff had initiated use of the new smoking status assessment, 79% initiated medication documentation, and 85% initiated the counseling referral components of ELEVATE, indicating high levels of adoption.

Implementation

The tobacco use assessment rate was 93% over a 6-month period 1 year after implementation. In contrast, the assessment rate was only 47.9% in the 5 months preceding the ELEVATE launch (18). Provider-level rates of assessment and treatment varied substantially. Over a 6 month period, 93% of medical assistants documented tobacco use assessment for at least 90% of patient encounters. During this time period, 51% of providers offered a counseling referral during at least half of their patient encounters.

Maintenance

Longer-term data on reach and effectiveness will be collected every 6-months. Sustainability is often driven by a favorable "implementation climate," characterized by the extent to which delivering tobacco treatment is expected, supported, and rewarded. We believe the training strategies, data transparency, and performance feedback will enhance maintenance, as will the tactical design of ELEVATE as a low-burden point-of-care decision support tool. The program utilizes an embedded cancer care team, with no plans to hire tobacco treatment specialists or additional staff. As a result, there are no discrete costs for dedicated personnel, and the cost per patient is $3, which promotes sustainability of the program.

Yale University

Context

The Tobacco Treatment Service (TTS) at Smilow Cancer Hospital in New Haven, CT was started in 2011 and expanded in 2017 after receiving C3I funding to include several Cancer Care Centers across Connecticut (**Table 1**). The TTS offers smoking cessation counseling (in-person, televideo, or phone-based), medication management, and referrals to the NCI SmokefreeTXT program. EHR modifications improved the identification and treatment of current smokers. Streamlining the EHR tobacco use assessment section was proposed, but would have required changes across the whole health system and therefore was not accepted at the organizational level. Due to this barrier, efforts were redirected toward revising the BPA to increase utilization. The previously existing BPA required multiple steps on the part of the provider and ordered a TTS referral only. Through feedback from providers and beta testing, the BPA was optimized to be less disruptive to clinical workflows, include all necessary steps and documentation in one click (i.e., diagnosis, after visit summary, smoking counseling note, and CPT billing code), and include the option to order tobacco pharmacotherapies (i.e., varenicline or nicotine patches and lozenges) using pre-populated fields based on the patient's current tobacco use.

Reach

EHR generated reports documented the number of current smokers, and the number who were referred to the TTS and/or prescribed cessation medication. The TTS received notification of patients referred to SmokefreeTXT via a separate reporting mechanism. Over a 6-month period after program implementation, smoking prevalence among those screened was 18%. Among the documented current smokers, reach for the Smilow Cancer Hospital and the Care Centers over 6 months was 7% (**Table 2**). Among those reached, 58.5% received in-person counseling, and 97.4% received medications.

Effectiveness

Participants who receive counseling from the TTS are offered follow-up visits after 6 months to assess and document current smoking status in the EHR. Follow-up can be challenging because some patients withdraw from the TTS,

TABLE 2 | Pragmatic application of RE-AIM to evaluate tobacco treatment program implementation at three NCI-Designated Cancer Centers funded through the Cancer Center Cessation Initiative.

RE-AIM construct	Evaluation measures[a]		Washington University Siteman Cancer Center	Yale University Smilow Cancer Hospital	Case Western Reserve University Case Comprehensive Cancer Center[c]
REACH	Smoking prevalence[b] Smokers reached with at least one evidence-based cessation treatment		12.5% 43.1% of smokers were prescribed cessation medications and/or received brief counseling at the point-of-care	18% 7% of smokers were prescribed cessation medications, referred to the TTS, and/or referred to SmokefreeTXT	21.1% 24.3% of smokers were prescribed cessation medications, referred to TIPS, and/or referred to SmokefreeTXT
EFFECTIVENESS	Assessment method		Tobacco use status from EHR for most recent visit during 6-months period post-treatment	Assessed at 6-months in person or via phone & documented in EHR	Assessed at 6-months in person or via phone and documented in EHR.
	6-month follow-up rate		67.2%	13.5%	54.4%
	30-day point prevalence abstinence	Counting patients lost to follow-up as smokers	29.5%	2.2%	19.5%,
		Among patients with follow-up data	43.9%	16.7%	35.1%
ADOPTION	Setting level adoption		21/21 outpatient oncology clinics over a 6-months implementation period.	Adopted at Smilow Cancer Center and 9/10 Care Centers over ∼8 months.	Adopted in 3/3 healthcare systems. One launched center-wide, two launched in thoracic and gynecological oncology clinics.
	Provider level adoption		99% providers initiated assessment, 79% initiated documentation of medication, 85% initiated offer of counseling referral.	Not assessed	Number of referring providers ($N = 64$) has increased by 25% over 1 year of implementation.
IMPLEMENTATION	Setting level tobacco use assessment rate		93%	49.5%	80%
	Provider-level tobacco use assessment rate		93% providers achieved ≥90% rate	Not assessed	Not assessed
	Implementation of key program components		Pharmacotherapy rate: 49% of providers achieve ≥20% rate; Counseling offer rate: 51% of providers achieve ≥50% rate	BPA utilization rates for referrals to the TTS, pharmacotherapy or both.	51% of referred patients received at least one component of the TIPS intervention.
MAINTENANCE	Sustainability plans/goals		• 6-months ongoing reach and effectiveness evaluation. • Incentivize care using data transparency and performance feedback. • Low-burden, low cost decision support tool for point-of-care use ($3 per patient).	Hiring another tobacco treatment specialist to maintain program at Care Centers. Billing for services using an APRN and expanding telehealth services. Integrating referrals into new patient onboarding by nurse navigators.	• Leverage initial success. • Generate new funding sources. • Reduce patient barriers to treatment (e.g. cost, transportation. • Identify 100% of smokers & reach at least 50% of smokers with treatment.

[a] *Reported for a 6-month period at 1-year post-implementation.*
[b] *Among patients screened for tobacco use.*
[c] *Average of three cancer healthcare settings.*
TTS, Tobacco Treatment Service; TIPS, Tobacco Intervention & Psychosocial Support.

appointment availability may not always align with patients' schedules, and there are limited resources to maintain contact. Among those who completed 6-month follow-up visits ($n = 30$ out of 223 participants), the 30-day point prevalence abstinence rate was 16.7% (2.2% using an intent to treat principle counting those lost to follow-up as current smokers) (**Table 2**).

Adoption

Programmatic adoption occurred in stages. The TTS program has been adopted at nine of 10 Smilow Cancer Care Settings in addition to the Smilow Cancer Hospital. One site declined to participate due to an established relationship with a smoking cessation program at another local hospital. Care Centers were visited by TTS staff to establish relationships with clinical and

administrative staff, which facilitated the adoption of the new clinical workflow. Adoption occurred over about 8 months, with two to three Care Centers added every 1 to 2 months. This gradual expansion allowed for piloting the BPA first in a few sites, revealing a need to modify the EHR to allow for referrals from RNs in addition to MDs and Advanced Practice Providers, and a need for educational meetings with nursing staff. A TTS "Champion" partner was identified at each Care Center to help integrate services into the center.

Implementation

Rates of tobacco use assessment and documentation are examined by clinical setting and by provider. The average tobacco use assessment rate for a 6-month period was 49.5% across settings, primarily because tobacco use assessment in the EHR is not mandatory. Reports are generated to show: (1) the number of times the BPA "fired," or appeared to a provider (2) the number of times the BPA "fired" and was acted on, and (3) the number of acted on BPA fires that included a referral to the TTS only, tobacco pharmacotherapy orders, or both. The data are then used to identify settings or providers with lower BPA utilization rates to provide feedback and troubleshoot barriers. For example, at one Care Center, low utilization was due to limited staffing following the departure of an oncologist. The remaining clinical staff were unable to devote substantial resources to implementing enhanced care for their patients who smoked, because their patient loads had increased.

Maintenance

Currently, one staff member provides counseling services at nine Care Centers on a rotating weekly schedule, traveling up to 900 miles per month. To maintain the program and increase capacity for treatment provided at each site, another full-time APRN was hired. As NCI grant funding comes to an end, Smilow Cancer Hospital will take over funding for the TTS providers, who will eventually bill for services. Additional maintenance efforts include expanding telehealth options and working with nurse navigators who onboard new cancer patients to integrate the TTS into the standard treatment offered at Smilow.

Case Western Reserve University

Context

Case Comprehensive Cancer Center (Case CCC) serves 15 counties in Northeast Ohio. In Cleveland, the most populous city in the catchment area, smoking prevalence (35%) and lung cancer mortality rates exceed national averages. Case CCC consists of Case Western Reserve University School of Medicine, University Hospitals Seidman Cancer Center (SCC), Cleveland Clinic Taussig Cancer Institute (TCI), and is closely affiliated with the county safety-net hospital, MetroHealth Cancer Center (MHCC). Together, these cancer centers see about 20,000 new cancer cases annually and comprise a complex clinical setting in which to implement change. Each health system sees a distinct patient population, with underserved and racial/ethnic minority cancer patients seen largely at MHCC. In 2017, the Tobacco Intervention and Psychosocial Support (TIPS) Service was implemented in all three health systems and was designed to address the unique needs of cancer patients and survivors.

Clinicians screen for tobacco use and identify current smokers using the EHR during new patient visits. The tobacco use assessment questions were standardized across the three healthcare settings based on NCCN guidelines (6). The provider note includes a field to assess tobacco use status and tobacco use history/nicotine dependence. For current users, readiness to quit is assessed; relapse risk is assessed among recent quitters/former smokers. EHR modifications included programming to generate provider notes to summarize services delivered. Current tobacco users who indicated willingness to quit within the next 4 weeks are referred to TIPS either via an EHR-based order for counseling, or via email/pager. Irrespective of their willingness to participate in counseling, patients have the option to be enrolled in SmokefreeTXT. TIPS delivers cessation counseling using cognitive behavioral therapy combined with FDA-approved pharmacotherapy. TIPS is tailored to cancer patients by including cancer-specific psychoeducation, content that addresses the emotional vulnerability of this population, and flexible intervention formats (e.g., in-clinic, telephone, combination). Caregivers, family members, and/or significant others who use tobacco products are eligible for TIPS, and may participate with the patient, or independently.

Reach

Reach was defined as the proportion of current smokers who participated in TIPS, enrolled in SmokefreeTXT, and/or were prescribed cessation medication. Over 6 months, the average prevalence of current smoking was 21.1% among those screened, and an average of 24.3% of smokers across the three sites received at least one type of tobacco treatment (**Table 2**). Pharmacotherapy was the most common treatment type (82.1%), followed by in-person counseling (10.2%). Of note, 98% of patients who received counseling or another intervention also received pharmacotherapy.

Effectiveness

Effectiveness is assessed at 6-months after TIPS engagement. Program staff contact patients to document their current smoking status via telephone or interview patients in person if they have a scheduled an appointment. An average of 54.4% of TIPS participants were reached at 6-months follow-up across the three healthcare settings, after 1 year of implementation. Challenges to follow-up include patients being unreachable by phone or not being scheduled for a clinic follow-up near the time of assessment. Among TIPS patients with follow-up data, average 30-days abstinence at 6-month post-treatment was 35.1% across the three sites. Using an intent-to-treat principle (assuming patients lost to follow-up were still smoking) there was an average 30-day abstinence rate of 19.5%.

Adoption

The TIPS program was adopted in all three Case CCC affiliated health systems. Two health systems focused the initial implementation in thoracic and gynecological oncology

clinics and the third opted for a center-wide launch. Pre-implementation program site leaders and clinical champions were instrumental to build clinical capacity, train staff, modify the EHR to standardize the assessment and documentation of tobacco use and treatment, and to integrate TIPS into the clinical workflow. Several implementation strategies facilitated the adoption of TIPS into the clinical workflow, including securing support from clinical and administrative leadership, operations staff, and IT specialists early in the process; seeking input from providers and staff during clinical division meetings and grand rounds; developing marketing strategies; and facilitating TIPS staff and medical team engagement. Initial provider engagement strategies have been encouraging, as the number of referring providers ($N = 64$) has increased by 25% over the past year with growing awareness of the service. Adoption challenges included securing adequate space, buy-in from providers with many competing responsibilities and limited time with patients, and the lengthy period to implement requested additions to the EHR.

Implementation

Implementation was assessed for the following elements key to delivering the TIPS program: tobacco use screening, provider referrals, and intervention delivery to smokers referred. The average rate of tobacco use assessment was 80%, which was negatively affected by EHR programming challenges at one of the hospitals (we anticipate the rate will increase). Over a 6-month period following implementation, 51.4% of patients referred to TIPS completed the tobacco history assessment and at least one intervention component of TIPS.

Maintenance

TIPS service adoption is ongoing in three cancer hospitals that serve Northeast Ohio, the first regional effort to address tobacco use in cancer care settings. To maintain TIPS, the goal is to leverage the initial success of the effort, sustain EHR modifications to facilitate assessment and referrals, develop new strategies to increase provider and patient engagement, generate funding sources, and examine strategies to reduce patient-level barriers (e.g., cost/copays, transportation). The sustainability goals are to identify 100% of current tobacco smokers (and recent quitters), maintain an overall program reach of at least 50% of eligible patients, and demonstrate abstinence rates that are at least comparable to published estimates.

DISCUSSION

Using case studies from three funded C3I Cancer Centers, this report describes the application of the RE-AIM framework and the operationalization of each construct to evaluate the implementation of a range of cessation services (e.g., counseling, Quitline) in cancer care settings. The RE-AIM measures proposed have implications for cancer care settings beyond NCI Cancer Centers. The measures are flexible enough to work in different settings and for different types of tobacco treatment programs but are robust enough to measure intended evaluation outcomes. The measures can be applied across different healthcare systems and EHR platforms. C3I Centers largely used the funding to enhance the EHR to identify and refer smokers to treatment (19). As a result, the examples described provide guidance on using the EHR to assess RE-AIM constructs to evaluate the implementation of tobacco treatment programs integrated into cancer care. Each Center identified common challenges to measuring RE-AIM, or "lessons learned," for other cancer care settings to be aware of when implementing tobacco treatment programs (**Table 3**).

TABLE 3 | Summary of challenges to the measurement of RE-AIM within three NCI-Designated Cancer Centers funded through the Cancer Center Cessation Initiative.

RE-AIM dimension	Challenges to measurement
Reach	Measurement relies on consistent documentation of patient smoking status and engagement in tobacco treatment services.
Effectiveness	Follow-up measures (at 6-months post engagement) are dependent upon patient availability and program staff and resources to maintain follow-up contacts.
Adoption	Measuring provider-level adoption is dependent upon program and organizational resources to track and obtain provider-specific reports from the EHR.
Implementation	Measuring the implementation of key program components is dependent on program resources to document and produce reports using the EHR.
Maintenance	Measuring maintenance and sustainability is dependent on the program's ability to measure the other RE-AIM dimensions. Reporting on each of these measures over time can help Cancer Centers understand the long term sustainability of their program.

Previous work has shown that systems level changes, including EHR modifications, for assessing and referring patients to treatment can result in increased tobacco use documentation and counseling referrals (20–23). The profiled Centers utilized the EHR to identify and refer smokers to tobacco treatment services and to evaluate reach. Measuring reach posed challenges. Documenting the denominator (the number of current smokers) relies both on the consistent documentation of smoking status, and a way to extract that information from the EHR. Measuring the numerator for reach requires defining and documenting program engagement. At Washington University, the numerator included patients prescribed cessation medication or who had received counseling at the point-of-care. At Yale and Case, the reach numerator included patients who participated in in-person or telephone counseling, SmokefreeTXT, and/or were prescribed cessation medication. Because the treatment offered differs, defining the numerator is critical when making cross site comparisons. Reach is likely greater at Washington University because cessation counseling is delivered at the point-of-care, while the others refer to a counseling program.

Measuring effectiveness posed a different set of challenges (e.g., low rates of smoking status ascertainment), which may limit information regarding quit rates (20). While assessment

of long-term smoking status is challenging, the EHR provides a highly efficient and cost-effective means of gathering follow-up data on patients receiving treatment. Each Center used the EHR to document tobacco use status at follow-up. However, Washington University utilized the EHR as the primary method to assess tobacco use with the patient's most recent visit at 6 months after tobacco treatment. The others used in-person or phone follow-up as the primary assessment. In reality, a combination of approaches may be necessary, where patients are contacted at follow-up to determine outcomes, but EHR-documented tobacco use status could be used when patients are not reached. Capturing the assessment of smoking outcomes in health system delivered programs is vital since reduced smoking prevalence is a key goal. Such data would yield meaningful outcomes upon which different implementation and intervention strategies can be compared.

In addition to reach and effectiveness, measuring implementation and adoption was facilitated by generating EHR reports for screening rates and provider-level program referrals. Two Centers provided monthly provider and clinic level performance data to show progress and identify areas for improvement. Non-adopting sites or providers may signal local barriers to initiation ranging from awareness, to self-perceived competence, to lack of supporting resources. Implementation strategies, such as staff training and practice facilitation, pairing non-adopting sites with mentor sites to share knowledge and resources, or identifying "champions" may be needed to address barriers and increase site- and provider-level adoption rates. Monthly data not only reflect adoption and implementation across providers and clinics, but also show trajectories that speak to maintenance. However, sites may be limited by organizational capacity to report back provider-level adoption and implementation metrics that may be useful for evaluation. The evaluation of provider level measures could be built into the EHR during program development, as making changes to the EHR after the fact is often challenging.

There are some limitations to this study. The RE-AIM application was examined within well-resourced Centers receiving funding to implement tobacco treatment services; however, it is unknown how readily less well-resourced cancer care settings without robust health informatics support could query the EHR to extract RE-AIM relevant data. The profiled Centers engaged in EHR modifications permitting efficient collection of evaluation measures, which may limit the adoption of this RE-AIM approach given significant resource requirements. Implementation at Washington University coincided with the launch of a new EHR platform allowing for more changes to the EHR than the other Centers. Data on reach and effectiveness were collected by patient sociodemographics; however, presenting this information was beyond the scope of this paper. Information on cost was not available, however cost data are being collected from C3I Centers and will be reported to inform program implementation in other cancer care settings. It is premature to report on the long-term maintenance of reach and effectiveness among programs overall and across different patient demographics. As programs mature, evaluation of demographics may facilitate the adoption of programs to better suit patient populations and is an important indicator of whether programs are equitably reaching all cancer patients who smoke.

Delivering tobacco treatment to cancer patients who smoke should be a routine and integrated part of cancer care (24). RE-AIM provides a framework for multilevel program evaluation to ensure patient benefit, provider performance, and organizational commitment. RE-AIM provides a vital component of an audit and feedback strategy by yielding performance data to inform normative comparisons, rewards, and encouragement to improve, along with existing resources and supports for the lower-performing groups. Conducting routine RE-AIM evaluations via the EHR allows program staff to rapidly identify gaps in care and address barriers with targeted strategies. A common RE-AIM approach to implementation assessment allows for trans-program comparisons to identify effective implementation and intervention strategies. The programs described provide tobacco treatment program staff working in cancer care settings with specific examples of measuring each RE-AIM dimension using the EHR to facilitate measurement. In summary, the measures demonstrate a pragmatic approach to using RE-AIM as an evaluation framework that yields relevant outcomes on common implementation metrics across widely differing tobacco treatment approaches and cancer care settings.

DATA AVAILABILITY STATEMENT

The datasets generated for this study are available on request to the corresponding author.

AUTHOR CONTRIBUTIONS

HD'A, BR, MF, and TB contributed to the conception and design of the study. HD'A wrote the first draft of the manuscript. AR, MW, LF, and SB wrote sections of the manuscript. All authors contributed to manuscript revision, read and approved the submitted version.

FUNDING

The C3I Coordinating Center was funded by the National Cancer Institute (ICF Contract #17GZSK0031). AR receives funding from NIH/NIDA K12 DA041449, NIH/NCI P30 CA091842-16S2, and a grant from the Foundation for Barnes-Jewish Hospital. L-SC receives funding from NIH/NCI P30 CA091842-16S2, NIH/NIDA R01 DA038076. JO received funding from NIH/NCI P30 CA008748-52S3. TB received funding from NIH/NCI P01 CA180945. MW received funding from Case Comprehensive Cancer Center Support Grant (5P30CA043703).

REFERENCES

1. U.S. Department of Health and Human Services. *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General*. US Department of Health and Human Services (2014).
2. Warren G, Simmons V. "Tobacco use and the cancer patient." in DeVita VT, Lawrence TS, and Rosenberg SA, editors. *Cancer Principles & Practice of Oncology, 11th edn*. New York, NY: Wolter Kluwer Health (2018). p. 388–401.
3. Morgan G, Schnoll RA, Alfano CM, Evans SE, Goldstein A, Ostroff J, et al. National Cancer Institute conference on treating Tobacco dependence at Cancer centers. *J Oncol Practice*. (2011) 7:178–82. doi: 10.1200/JOP.2010.000175
4. Toll BA, Brandon TH, Gritz ER, Warren GW, Herbst RS. Assessing Tobacco use by Cancer patients and facilitating cessation: an American Association for Cancer Research Policy Statement. *Clin Cancer Res*. (2013) 19:1941–8. doi: 10.1158/1078-0432.CCR-13-0666
5. Hanna N, Mulshine J, Wollins DS, Tyne C, Dresler C. Tobacco cessation and control a decade later: American society of clinical oncology policy statement update. *J Clin Oncol*. (2013) 31:3147–57. doi: 10.1200/JCO.2013.48.8932
6. Shields PG, Herbst RS, Arenberg D, Benowitz NL, Bierut L, Luckart JB, et al. Smoking cessation, version 1.2016, NCCN clinical practice guidelines in oncology. *J Natl Comprehens Cancer Netw*. (2016) 14:1430–68. doi: 10.6004/jnccn.2016.0152
7. Warren GW, Ward KD. Integration of tobacco cessation services into multidisciplinary lung cancer care: rationale, state of the art, and future directions. *Transl Lung Cancer Res*. (2015) 4:339. doi: 10.3978/j.issn.2218-6751.2015.07.15
8. Goldstein AO, Ripley-Moffitt CE, Pathman DE, Patsakham KM. Tobacco use treatment at the U.S. National Cancer Institute's designated Cancer centers. *Nicotine Tobacco Res*. (2013) 15:52–8. doi: 10.1093/ntr/nts083
9. Cooley ME, Poghosyan H, Sprunck-Harrild K, Winickoff JP, Edge SB, Emmons KM. Tobacco treatment implementation within 28 commission on cancer accredited programs in the Northeast region of the USA: a pilot study. *Transl Behav Med*. (2018) 8:706–13. doi: 10.1093/tbm/ibx024
10. Warren GW, Marshall JR, Cummings KM, Toll BA, Gritz ER, Hutson A, et al. Addressing tobacco use in patients with cancer: a survey of American Society of Clinical Oncology members. *J Oncol Practice*. (2013) 9:258–62. doi: 10.1200/JOP.2013.001025
11. Croyle RT, Morgan GD, Fiore MC. Addressing a core gap in Cancer care–the NCI moonshot program to help oncology patients stop smoking. *N Engl J Med*. (2019) 380:512. doi: 10.1056/NEJMp1813913
12. Glasgow RE, Estabrooks PE. Peer reviewed: pragmatic applications of RE-AIM for health care initiatives in community and clinical settings. *Prevent Chronic Dis*. (2018) 15:271. doi: 10.5888/pcd15.170271
13. Duffy SA, Ronis DL, Ewing LA, Waltje AH, Hall SV, Thomas PL, et al. Implementation of the Tobacco Tactics intervention versus usual care in Trinity Health community hospitals. *Implement Sci*. (2016) 11:147. doi: 10.1186/s13012-016-0511-6
14. Vidrine JI, Shete S, Cao Y, Greisinger A, Harmonson P, Sharp B, et al. Ask-Advise-Connect: a new approach to smoking treatment delivery in health care settings. *JAMA Intern Med*. (2013) 173:458–64. doi: 10.1001/jamainternmed.2013.3751
15. Gaglio B, Shoup JA, Glasgow RE. The RE-AIM framework: a systematic review of use over time. *Am J Public Health*. (2013) 103:e38–46. doi: 10.2105/AJPH.2013.301299
16. Harden SM, Gaglio B, Shoup JA, Kinney KA, Johnson SB, Brito F, et al. Fidelity to and comparative results across behavioral interventions evaluated through the RE-AIM framework: a systematic review. *Syst Rev*. (2015) 4:155. doi: 10.1186/s13643-015-0141-0
17. Glasgow RE, Harden SM, Gaglio B, Rabin BA, Smith ML, Porter GC, et al. RE-AIM planning and evaluation framework: adapting to new science and practice with a twenty-year review. *Front Public Health*. (2019) 7:64. doi: 10.3389/fpubh.2019.00064
18. Ramsey AT, Chiu A, Baker T, Smock N, Chen J, Lester T, et al. Care-paradigm shift promoting smoking cessation treatment among cancer center patients via a low-burden strategy, Electronic Health Record-Enabled Evidence-Based Smoking Cessation Treatment. *Transl Behav Med*. (2019). doi: 10.1093/tbm/ibz107. [Epub ahead of print].
19. D'Angelo H, Rolland B, Adsit R, Baker TB, Rosenblum M, Pauk D, et al. Tobacco treatment program implementation at NCI Cancer centers: progress of the NCI Cancer moonshot-funded Cancer center cessation initiative. *Cancer Prevent Res*. (2019) 12:735–40. doi: 10.1158/1940-6207.CAPR-19-0182
20. Boyle R, Solberg L, Fiore M. Use of electronic health records to support smoking cessation. *Cochrane Database Syst Rev*. (2014) 12:1–32. doi: 10.1002/14651858.CD008743.pub3
21. Thomas D, Abramson MJ, Bonevski B, George J. System change interventions for smoking cessation. *Cochrane Database Syst Rev*. (2017) 2:1–40. doi: 10.1002/14651858.CD010742.pub2
22. Adsit RT, Fox BM, Tsiolis T, Ogland C, Simerson M, Vind LM, et al. Using the electronic health record to connect primary care patients to evidence-based telephonic tobacco quitline services: a closed-loop demonstration project. *Transl Behav Med*. (2014) 4:324–32. doi: 10.1007/s13142-014-0259-y
23. Fiore M, Adsit R, Zehner M, McCarthy D, Lundsten S, Hartlaub P, et al. An electronic health record–based interoperable eReferral system to enhance smoking Quitline treatment in primary care. *J Am Med Inform Assoc*. (2019) 26:778–86. doi: 10.1093/jamia/ocz044
24. Fiore MC, D'Angelo H, Baker T. Effective cessation treatment for patients with cancer who smoke—the fourth pillar of cancer care. *JAMA Network Open*. (2019) 2:12264. doi: 10.1001/jamanetworkopen.2019.12264

Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

frontiers in Public Health

ORIGINAL RESEARCH
published: 27 May 2020
doi: 10.3389/fpubh.2020.00194

Making Implementation Science More Rapid: Use of the RE-AIM Framework for Mid-Course Adaptations Across Five Health Services Research Projects in the Veterans Health Administration

Russell E. Glasgow [1,2], Catherine Battaglia [3,4,5], Marina McCreight [6], Roman Aydiko Ayele [7] and Borsika Adrienn Rabin [8,9,10]*

[1] Department of Family Medicine, School of Medicine, University of Colorado, Aurora, CO, United States, [2] Director, Dissemination and Implementation Science Program, The Adult and Child Consortium for Health Outcomes Research and Delivery Science, School of Medicine, University of Colorado, Aurora, CO, United States, [3] School of Medicine, University of Colorado, Aurora, CO, United States, [4] Independent researcher, Aurora, CO, United States, [5] Department of Health System/Management and Policy, Colorado School of Public Health, University of Colorado Denver, Aurora, CO, United States, [6] Veterans Health Administration (VHA), Washington, DC, United States, [7] Seattle-Denver Center of Innovation, VA Eastern Colorado Health Care System, Denver, CO, United States, [8] Department of Family Medicine and Public Health, School of Medicine, University of California, San Diego, San Diego, CA, United States, [9] Seattle-Denver Center of Innovation, VA Eastern Colorado Health Care System, Denver, CO, United States, [10] Dissemination and Implementation Science Program, The Adult and Child Consortium for Health Outcomes Research and Delivery Science, School of Medicine, University of Colorado, Aurora, CO, United States

OPEN ACCESS

Edited by:
Marcelo Demarzo, Federal University of São Paulo, Brazil

Reviewed by:
Christopher Mierow Maylahn, New York State Department of Health, United States
Deborah Paone, Independent researcher, Minneapolis, United States

***Correspondence:**
Russell E. Glasgow
russell.glasgow@cuanschutz.edu

Specialty section:
This article was submitted to Public Health Education and Promotion, a section of the journal Frontiers in Public Health

Received: *07 January 2020*
Accepted: *29 April 2020*
Published: *27 May 2020*

Citation:
Glasgow RE, Battaglia C, McCreight M, Ayele RA and Rabin BA (2020) Making Implementation Science More Rapid: Use of the RE-AIM Framework for Mid-Course Adaptations Across Five Health Services Research Projects in the Veterans Health Administration. Front. Public Health 8:194. doi: 10.3389/fpubh.2020.00194

Introduction: Implementation science frameworks have helped advance translation of research to practice. They have been widely used for planning and *post-hoc* evaluation, but seldom to inform and guide mid-course adjustments to intervention and implementation strategies.

Materials and Methods: This study developed an innovative methodology using the RE-AIM framework and related tools to guide mid-course assessments and adaptations across five diverse health services improvement projects in the Veterans Health Administration (VA). Using a semi-structured guide, project team members were asked to assess the importance of and progress on each RE-AIM dimension (i.e., reach, effectiveness, adoption, implementation, maintenance) at the current phase of their project. Based on these ratings, each team identified one or two RE-AIM dimensions for focused attention. Teams developed proximal goals and implementation strategies to improve progress on their selected dimension(s). A follow-up meeting with each team occurred approximately 6 weeks after the goal setting meeting to evaluate the usefulness of the iterative process. Results were evaluated using both descriptive quantitative analyses and qualitative assessments from interviews and meeting notes.

Results: A median of seven team members participated in the two meetings. Qualitative and descriptive data revealed that the process was feasible, understandable and useful to teams in adjusting their interventions and implementation strategies. The RE-AIM

dimensions identified as most important were adoption and effectiveness, and the dimension that had the largest gap between importance and rated progress was reach. The dimensions most frequently selected for improvement were reach and adoption. Examples of action plans were summarizing stakeholder interviews for leadership, revising exclusion criteria, and conducting in-service trainings. Follow-up meetings indicated that teams found the process very useful and were able to implement the action plans they set.

Discussion: The iterative use of RE-AIM to support adjustments during project implementation proved feasible and useful across diverse projects in the VA setting. Building on this and related examples, future research should replicate these findings and further develop the methodology, as well as explore the optimal frequency and timing for these iterative applications of RE-AIM. More generally, greater focus on more rapid and iterative use of implementation science frameworks is encouraged to facilitate successful translation of research to practice.

Keywords: implementation science, frameworks, rapid, iterative, adaptation, RE-AIM, evaluation

INTRODUCTION

It is widely accepted that use of theory improves outcomes, understanding and generalization (1–3) within implementation science as well as other areas. There are many implementation science theories, models, and frameworks that have been used for various purposes (1–4). Our research group has developed, refined, and disseminated the RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework that has been widely used for evaluation and more recently, planning programs (5, 6). RE-AIM has been found to be useful for both researchers and practitioners (7–9) and for planning as well as end of project evaluations (6). However, with a few exceptions noted below and summarized in the discussion (10–14), to our knowledge, neither RE-AIM nor other implementation science models have been systematically used for, nor specific guidance provided, for mid-course corrections, or rapid assessment and feedback.

If implementation science is to have more impact in real world settings, it needs to become more rapid and iterative (15–17) to address the needs and time frame in which organizations need to make decisions. There have been recent advances in more rapid approaches to qualitative analyses (18–20) and discussion of integrating implementation science with quality improvement procedures to make it more rapid (21–23), but little use of implementation science models to help inform and guide such improvement and adaptations. Many studies track ongoing implementation efforts and report findings (24) using RE-AIM or other implementation science models and outcomes, but few have provided detailed guidance, reported results on or compared stakeholder perspectives on both priorities and progress over time, specific goals set and/or provided tools and resources that can be used by others. As detailed in the discussion, this study extends upon the important efforts above by providing more detail, and reporting application across different interventions, conditions and stages of multiple research projects.

Implementation science models such as Intervention Mapping (25), the Consolidated Framework for Implementation Research (CFIR) (26), RE-AIM (5, 6) and others have been used to plan and guide pre-implementation strategies, but in general, application of these models is not rapid enough to inform during-study adaptation (27). It is also well-documented that context also changes over time (28, 29), that adaptations occur with or without guidance and in ways that are either intervention congruent or not (27, 30), and that sustainment of outcomes almost always requires adaptations (31). Thus, it would help to have a systematic, framework-informed strategy to guide adaptations in response to emerging results and changing context. Such an approach would also be very congruent with and useful for learning health system approaches (32, 33). In summary, we think that rapid learning systems, as well as implementation science research in general, could benefit from systematic and integrated use of frameworks, methods, and iterative processes to evaluate interim progress, ensure that unintended consequences do not occur, and help guide appropriate adaptations.

The goals of this paper are to describe: (1) a team engagement and reflection process to identify RE-AIM dimensions that are most important and most in need of improvement at the current point in the project cycle in each of five Veterans Health Administration (VA) Health System improvement projects; (2) the use of this framework-driven procedure and related data to guide development and execution of an action plan to address key RE-AIM dimensions identified and facilitate mid-course adaptations; and (3) the feasibility and short-term usefulness of this iterative RE-AIM process and directions for future research and practice.

TABLE 1 | Characteristics of five health services research implementation studies.

	Patient reported health status assessment	Multimodal pain	Community transitions	Advanced care coordination	Rural transitions
Problem addressed	Lack of standardized reporting of patient health status in setting of cardiovascular procedure	Delivering multimodal pain care through tele-mentoring	Transitional care from non-network hospital to network primary care	Transitional care from non-VA community hospital-based emergency department (ED) to VA primary/specialty care	Care coordination for rural Veterans during and post-discharge from a tertiary VHA Medical Center back to their patient aligned care team
Setting	VHA Medical Center	VHA Medical Center, community-based outpatient clinics	VHA Medical Center, community-based outpatient clinics, community hospitals	VHA Medical Center, community-based outpatient clinics, community EDs	VHA Medical Center, community-based outpatient clinics
Intervention	To collect patient-reported health status information before and after percutaneous coronary intervention via an interactive voice response system, and to integrate use of the health status data into routine clinical care	Leveraging data to identify gaps in the use of multimodal pain care, and to train providers in best practices through tele-mentoring	Integrated, non-network hospital discharge care coordination program that includes nurse care coordination and health system changes, including dedicated phone and fax lines for non-network hospitals and Veteran care identification cards	Assess social determinants of health of all Veterans admitted to community ED and discharged home for follow-up care with VA primary/specialty care	A transitions nurse at the VHA Medical Center who prepares patient for discharge and obtains a follow-up appointment, communicates with the patient aligned care team site about the discharge care coordination, follows up with the patient within 48 h after discharge, and engages with the rural primary care provider and registered nurse to ensure continuity of care and information exchange
Implementation strategies	Audit and feedback; facilitation	Audit and feedback; facilitation	Audit and feedback; facilitation	Audit and feedback; facilitation	Audit and feedback; internal and external facilitation; modified rapid Process improvement workshop

MATERIALS AND METHODS

Setting and Description of the Projects

A detailed description of the project settings and the five interventions has been provided elsewhere (34–38) and is summarized in **Table 1**. Briefly, four interventions described in this paper emerged from the VA Triple Aim Quality Enhancement Research Initiative (QUERI) (https://www.queri.research.va.gov/) and a fifth VA initiative was funded through the VA Office of Rural Health. The five projects are diverse in the program focus area, clinical problem they address, research and implementation team involved, target population, and the intervention format and delivery. These projects involve different healthcare settings including hospitals, primary care, centralized VA offices, and community settings. The first project, Patient Reported Health Status Assessment, utilizes Interactive Voice Response technology to capture the pre- and post-procedural patient-reported health status for patients receiving elective catheterization laboratory procedures to inform clinical care (35). The second project, Multimodal Pain, addresses barriers and facilitators to multimodal pain care in the VA and designs and implements an intervention based on identified best practices to support primary care providers (38). The third project, Community Transitions, focuses on care coordination of Veterans admitted to non-VA community hospitals for inpatient care, and their transition back to VA primary care in a safe, patient-centered and timely manner (36). The fourth, project, Advanced Care Coordination, aims to improve care coordination for Veterans discharged from community emergency departments by addressing social determinants of health. The fifth project, Rural Transitions, is a proactive, personalized, nurse-led, and Veteran-centered intervention to improve access for rural Veterans to follow-up with their primary care teams following hospitalization at a larger urban VA Medical Center (37).

At the planning stage of each grant proposal and study, each team had specified key outcomes for the various RE-AIM dimensions. These were slightly modified by the primary investigators at baseline from the measures in their original QUERI proposal. **Table 2** provides a summary of the initially established RE-AIM measures by dimension for each project. Other members of the implementation team were not involved in this specification, and several had not yet been hired or assigned to the project at baseline.

Participants and Project Team Members

All implementation study team members from each project were included in the iterative RE-AIM process. We invited a diverse set of participants including the principal investigator, co-investigators, project coordinator, nurses, social workers, research analysts, and research assistants, who were all closely involved with the development, implementation, and evaluation of the interventions. An important aspect of this iterative

TABLE 2 | Operationalization of RE-AIM measures by projects.

	Patient-reported health status assessment	Multimodal pain	Community transitions	Advanced care coordination	Rural transitions
Reach	Number, proportion and representativeness of Veterans: • called by automated calls pre-procedure • who answered the automated calls pre-procedure • reached by automated calls 1 month post-procedure • who answered the automated calls 1 month post-procedure • reached by automated calls 6 months post-procedure • who answered the automated calls 6 months post-procedure Number, proportion and representativeness of cath labs who informed their Veterans of this program	Number, proportion, and representativeness of Veterans with chronic pain care who are seen by providers after providers receive the pain SCAN ECHO training	Number, proportion and representative-ness of Veterans reached by the CHTP program	Number, proportion, and representative-ness of Veterans reached by the ACC program	Number, proportion and representative-ness of Veterans enrolled in TNP Enrollment numbers Rurality GIS maps
Effectiveness	Number, proportion and representativeness of Veterans whose health status is captured and shared to their PCP/Cardiologist pre-procedure: • 1-month post-procedure • 6-months post-procedure • Number, proportion, and representative-ness of providers who utilize reported PROST • outcomes for treatment decision (follow through) • Number, proportion, and representative-ness of Veteran and provider satisfaction using PROST • Number, proportion, and representative-ness of Cath labs satisfaction using PROST	Number, proportion, and representativeness of provider satisfaction with the training (assessed qualitatively) Perception of skills assessment, confidence, perceived knowledge, provider attitude, behaviors Unintended/negative consequences, generalization effects (both positive and negative, at various levels) Assess care utilization using claims data 2 levels: intervention effectiveness, implementation strategy effectiveness	Number, proportion, and representativeness of Veterans: ER utilization after community hospital discharge [among those Veterans who interacted with our program] 30-days re-hospitalizations post community hospital discharge [among those Veterans who interacted with our program] Veteran satisfaction using IVR Veterans who had VA PCP assignment after d/c from community hospitals if no current PCP Veterans who reached out to us post re-hospitalization discharge [Veterans who received our letters]	ER utilization rate after ACC program interaction Veterans 30-day re-admission rate post ACC program interaction [among those Veterans who interacted with our program] Veteran and provider satisfaction with ACC (using IVR) Number, proportion, and representativeness of Veterans who utilized extra visits, services, consults or orders because of ACC involvement	30, 60, 90-days ED Visit Rate, 30-day hospital re-admission rate, death after 30, 60, 90 days 14-days PCP follow up Provider satisfaction Veteran satisfaction Voices of Veterans and providers Relational coordination
Adoption	Number, proportion, and representativeness of Cath labs who follow through suggested program implementation Level of engagement with the program Ability for the Cath labs to identify patients pre-procedure, and identifying ways to reach patients	Organizational factors associated with variation in adoption at various levels Number, proportion and representativeness of providers who received/completed the pain SCAN ECHO training Can you get the right people to participate? Why or why not? Ex.: Understand why we didn't get a high provider reach and what we did about that	Number, proportion and representativeness of community hospitals who inform us of Veteran admission—count this as adoption	Number of times community hospitals notify the ACC program of Veteran ED admission/discharge (specific method important: case manager, fax, phone call) Number and roles of VA providers ACC collaborates with, including any potential referrals	% referrals to CBOCs teams affiliated with TNP Provider satisfaction surveys Provider satisfaction interviews Adaptation interviews with TNs and champions

(Continued)

TABLE 2 | Continued

	Patient-reported health status assessment	Multimodal pain	Community transitions	Advanced care coordination	Rural transitions
Implementation	Implementation of core components of the intervention: number of times all or part of the core components are met for each patient Data capture Patient engagement and asking them to call Barriers and facilitators to implementation Adaptations and fidelity tracking Return on investment/cost	Number of SCAN ECHO sessions attended by providers Barriers and facilitators of implementation, contextual factors guided by PRISM Documenting implementation strategies delivery (ex., when and How A&F was delivered, how facilitation was delivered, etc. Economic evaluation Core components, intervention fidelity Adaptations tracking	Number, proportion and representativeness of times community hospitals notify the program of Veteran admission/discharge (specific method important: case manager fax, phone call) Implementation of core components: number of times all or part of the core components are met for each patient Number of medical records received and discharge summaries uploaded Number of follow-up appointments made Number of patients who had the full intervention completed Adaptations made Barriers and facilitators to implementation Cost of intervention Fidelity to the program intervention	Barriers and facilitators to implementation Return on investment/cost Tracking adaptions and fidelity to the program delivery	Theoretical Domain Framework (TNs and champions) Adaptations Tracking using modified Stirman Framework End of program assessment by Cohort 1 site champions Adaptation interviews with TNs and champions Mid-course process assessment Implementation costs; comparison of Cohorts 1 and 2 Final program interviews with Cohort 1 sites
Maintenance	Planned maintenance, including expansion to other sites Unplanned maintenance where VA internalizes program Develop toolkit that other programs can use to engage and implement PROST	Extent to which sites continue to have other providers participate in the SCAN ECHO program after completion of evaluation period Expansion of SCAN ECHO program to other VA sites	Rapid prototyping Local adaptability Intent to sustain	Local adaptability Rapid prototyping Program continuation after funding period ends	Return on investment analysis Program continuation after funding period ends Maintenance Interviews Exit Interviews (if needed)

RE-AIM process is that it gathered diverse perspectives on importance, progress, priorities, and goals. This helped the project team obtain greater team engagement and buy-in when implementing goals emerging from the iterative RE-AIM process.

All meetings were facilitated by one or two members of our QUERI Triple Aim implementation core (RG, CB, MM, BR). The structure of our Triple Aim QUERI Center is such that an Implementation Core team co-led by Drs. Glasgow and Rabin and coordinated by Ms. McCreight, functions as an overarching methodological and support unit advising all projects. Ms. McCreight also serves as liaison between the Implementation Core and individual projects, as she also plays roles on each project team.

Overview of Iterative RE-AIM Process

The iterative RE-AIM process was conducted separately for each project and involved four steps. Step 1 involved use of a regularly scheduled team meeting during which (a) the implementation science team members explained the purpose of and steps involved in the iterative RE-AIM process, and (b) the project team reviewed the initial operationalization of RE-AIM dimensions developed at the beginning of the project, and then (c) discussed the status of their project on the various RE-AIM dimensions. Step 2 took place at the conclusion of this meeting, in which team members were then asked separately and confidentially to provide ratings on each RE-AIM dimension in terms of (a) its importance at the present stage of the project and (b) their perception of progress to date on that dimension. Step 3 involved a second team meeting, also facilitated by members of the implementation science team, during which the team reviewed the ratings summarized from the individual rating sheets. A group engagement, reflection and discussion process was used to identify one to two key RE-AIM dimensions on which to focus and set specific, measurable, attainable, relevant and timely (SMART) goals (39), and action plans for these dimension(s). Finally, Step 4 involved a follow-up interview with the PI and project manager for each project regarding their progress on the implementation of the SMART goals, and collect data on the feasibility and usefulness of the iterative RE-AIM process.

Step 1: Team Meeting #1: Preparation and Initial Discussion

Each project team spent one of their regularly scheduled team meetings for this step. These meetings lasted approximately 1 h, involved all project team members and were facilitated by one or two members of the Implementation Core. The main activities for this meeting were:

1. Introduction/general overview and 5-min description of the purpose of the meeting and the iterative RE-AIM process.
2. Review of the pragmatic definition of each of the RE-AIM dimensions and how they had been operationalized for this project (**Table 2**).
3. General discussion of the status of the project as it related to the RE-AIM dimensions; and an explanation and distribution of a rating sheet to each team member asking about the importance of and progress on each RE-AIM dimension at the current point of their project. While PIs were familiar with these pragmatic RE-AIM definitions and operationalization plans, other members of the team were less or not at all familiar; and benefited from a discussion of these concepts.

Step 2: Ratings on the Importance of and Progress With the Different RE-AIM Dimensions

As a follow up to the first team meeting, team members were asked to fill out the above rating sheet (Appendix 1) independently between meetings. Two main questions were asked on the rating sheet: (a) how important is each dimension to this project at this time? and (b) how is the project doing on each dimension to date? Team members were asked to use a five-point Likert scale (1 = not important (or not satisfied); 2 = somewhat important or satisfied; 3 = important (or satisfied); 4 = moderately and 5 = extremely important or extremely satisfied). Participants were also encouraged to add comments or examples that supported their rating. For ratings of progress, teams were instructed to use both any objective data available (e.g., participation rates to that point for reach; fidelity checklist data for implementation), and their subjective impressions concerning improvement to date compared to the initially established project goals. Team members were asked to rate RE-AIM dimensions independently and confidentially to allow for unbiased, equal input from each member of the team.

Results from the surveys were analyzed between steps 2 and 3. These results were summarized for the team using simple statistics and visually displayed using histograms at the second team meeting. These histograms displayed the team's cumulative ratings in three different ways including median ratings and variability across raters (**Figure 1**) on (a) importance, (b) progress on each RE-AIM dimension, and (c) the gap comparing importance and progress ratings on each dimension (three figures per project). All de-identified comments made on the rating forms were added verbatim to the summary report and, presented to each team before meeting #2.

Step 3: Team Meeting #2: Review Ratings and Goal Setting/Action Planning

A second team meeting focused on review of the summary reports generated from the individual ratings; and goal setting/action planning based on these. During this one-hour session, the following activities were conducted:

1. Reiteration of the purpose of the iterative RE-AIM process and that day's meeting.
2. Distribution and facilitated team discussion of the summary visual displays of rating data and the open-ended comments. Each team member received a copy of both their own ratings and the team summary. The group sequentially reviewed and discussed each of the three displays of their results.
3. Team discussion of and decision on which RE-AIM dimensions should be identified for improvement at that stage of the project based on the information provided. Project teams were asked to agree on one to two RE-AIM dimensions to address at that project stage. We made an a priori decision to limit the focus at a given time point to one or two RE-AIM

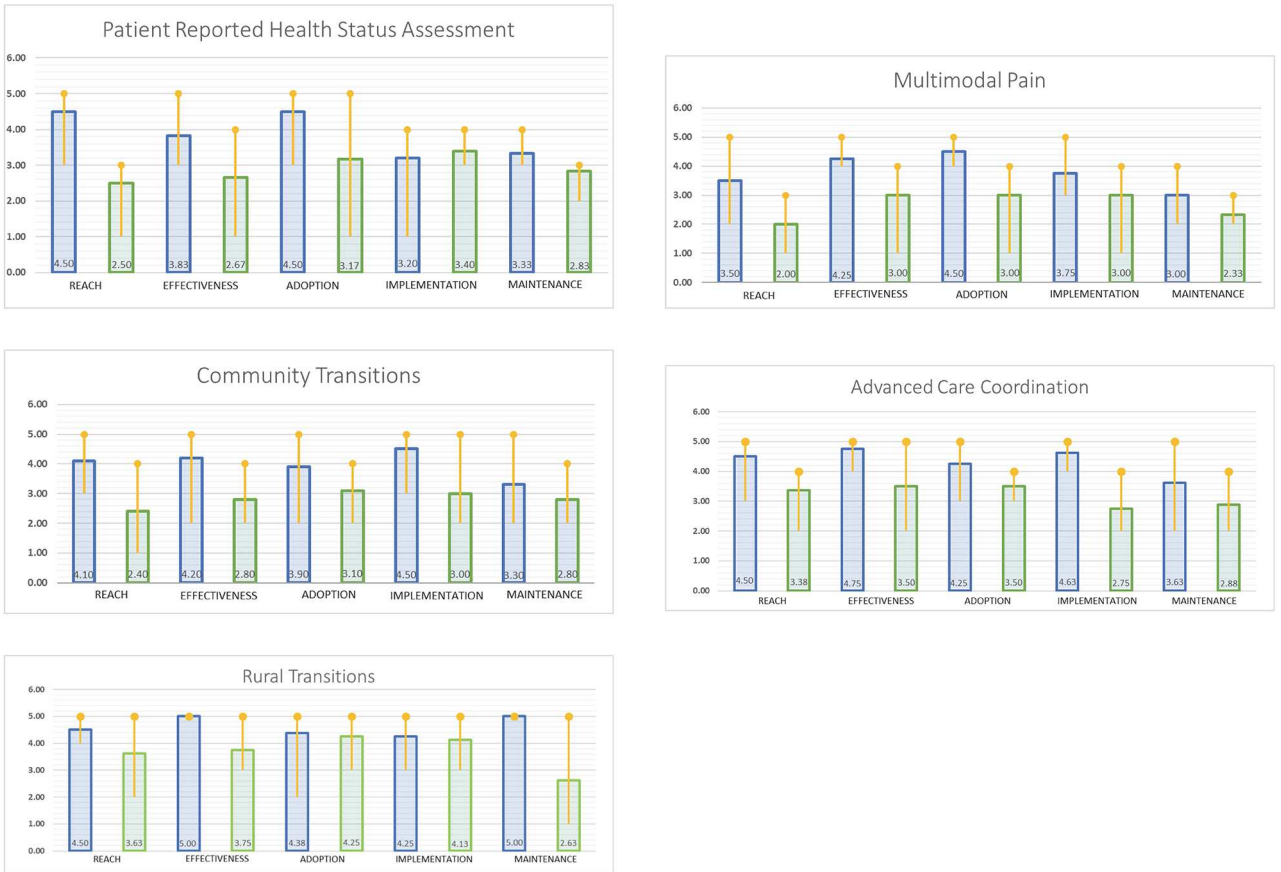

FIGURE 1 | Indicates the rating of the current importance of the RE-AIM dimensions. Indicates the rating of satisfaction with progress on the RE-AIM dimensions.

dimensions given limited resources and the multiple ongoing responsibilities and competing demands of various staff.

4. Goal setting and action planning for the selected RE-AIM dimension(s). Team members were asked to brainstorm possible strategies and specific activities they could use to improve their success on the relevant RE-AIM dimension(s). Then they were asked to create SMART goals and action plans. A template for SMART goal-setting (Appendix 2), and a list of sample action strategies to enhance each RE-AIM dimension were provided to the team. These plans specified which team members were going to do what actions by what date.

Field notes from team meetings were collected to document discussions as well as to record feedback and observations related to the iterative RE-AIM process. After the second meeting, one implementation core member (MM) completed any unfinished items based on the team discussion, and returned the team goal setting/action plan document to all team members within one week after the second team meeting.

Step 4: Follow-Up on RE-AIM Goals and Evaluation of the Process

For each team, a follow-up session was conducted with the PI and project coordinator approximately 6 weeks after the second meeting. During this 30-min debriefing meeting, data were collected about the team's progress on their SMART goals and intention to revise or continue work on these goals. We also collected ratings of and comments on the usefulness and level of implementation of the iterative RE-AIM process as well as recommendations for improvement (1—not at all; 3—somewhat; 5—extremely useful/completely implemented).

Data Analyses

Results were evaluated using both descriptive quantitative analyses and qualitative assessments from narrative data and meeting notes. We used matrix analysis (40) to describe and summarize narrative data from surveys and field notes to identify salient themes on each step of the iterative RE-AIM process and creation of the SMART goals and action plans. Matrix analysis is used to summarize qualitative data in a table of rows and columns, for comparison of coded data in cells and observe themes as they emerge. Data from the rating surveys (Step 2) were summarized using simple descriptive statistics (e.g., means and medians) and visual displays. This study was not considered research according to VA Office of Research Oversight policy 1058.05, therefore ethical review and approval was not required in accordance with the local legislation and institutional guidelines.

TABLE 3 | Information on participants by project.

	Patient-reported health status assessment	Multimodal pain	Community transitions	Advanced care coordination	Rural transitions
Current point of time in the project cycle at the time of the assessment	Implementation/ Expansion	Pre-implementation	Implementation/Expansion	Implementation/Expansion	Maintenance
Number of participants who completed the assessment (Step 2)	6	4	10	8	8
Number of participants in the discussion (Step 3)	7	4	9	6	9
Role descriptions	PI, project manager, quantitative lead, database programmer, qualitative lead, qualitative analysts	PI, PM, qualitative lead, RA	PI, PM, TN, SW, qualitative lead, qualitative analysts, health economist, clinical consultant	PI, PM, SW, qualitative analysts	PI, PM, RA, qualitative analysts, quantitative lead, quantitative analysts, database programmer

PI, principle investigator; PM, project manager; RA, research assistant; SW, social worker; TN, transitions nurse.

TABLE 4 | Average ratings of importance and progress by project.

Project		Patient-reported health status assessment	Multimodal pain	Community transitions	Advanced care coordination	Rural transitions	Average rating across all projects
RE-AIM dimension							
Reach	Average rating of importance	4.50	3.50	4.10	4.50	4.50	4.22
	Average rating of satisfaction with progress	2.50	2.00	2.40	3.38	3.63	2.78
Effectiveness	Average rating of importance	3.83	4.25	4.20	4.75	5.00	4.41
	Average rating of satisfaction with progress	2.67	3.00	2.80	3.50	3.75	3.14
Adoption	Average rating of importance	4.50	4.50	3.90	4.25	4.38	4.31
	Average rating of satisfaction with progress	3.17	3.00	3.10	3.50	4.25	3.40
Implementation	Average rating of importance	3.20	3.75	4.50	4.63	4.25	4.07
	Average rating of satisfaction with progress	3.40	3.00	3.00	2.75	4.13	3.26
Maintenance	Average rating of importance	3.33	3.00	3.30	3.63	5.00	3.65
	Average rating of satisfaction with progress	2.83	2.33	2.80	2.88	2.63	2.69

RESULTS

Table 3 provides a summary for each project of the current point of time in the project cycle, the number of team members participating, and the roles of participants in the team meetings. The results of the iterative RE-AIM assessment are described for each step of the process as outlined above. During Step 1 (meeting #1) there was a median of seven team members with diverse roles who participated in two team discussions (range= 4–10). Our observations indicated that there was active participation and general equity of discussion across team members. The process and RE-AIM dimensions were deemed understandable for team members, including those who were not directly involved in evaluation or specification of the initial RE-AIM measures.

There was variability in the RE-AIM dimensions identified as most important and on progress ratings across the different projects. **Table 4** summarizes ratings and identifies the most important dimension(s) and rated progress on each dimension by project team. There was a range of RE-AIM dimensions considered most important (Effectiveness, Reach, or Adoption). The Maintenance dimension was generally rated as less important, likely because most projects had not reached the maintenance phase of their project's life cycle.

TABLE 5 | RE-AIM Dimension(s) chosen for improvement and key phrases from project action plans by project.

Project name	RE-AIM dimension to focus on	SMART goals and action plans
Patient-reported health status assessment	Reach adoption	1. Conduct workflow assessments to learn where it would fit and how 2. Perform chart review to learn about actions taken after decline status note in the EMR
Multimodal pain	Effectiveness adoption	1. Effectiveness: summarize feedback from semi-structured interviews with providers and review for opportunities to improve program sessions; share the feedback with operational partners 2. Adoption: inform providers of the upcoming sessions 3. Engage/re-engage with program stakeholders for assistance and guidance
Community transitions	Reach	1. Conduct in-services with community hospital to educate about the program enrollment criteria 2. Interview other investigators about how they approach REACH in their projects 3. Consider giving out Veterans program cards pro-actively 4. Review and revise program exclusion criteria
Advanced care coordination	Reach	1. Schedule and conduct educational in-services in participating community hospitals 2. Program social worker to identify best practices of approach at each participating community hospital
Rural transitions	Reach maintenance	1. Review existing literature and plan to collect and analyze real-time return on investment-type data 2. Access operational data and performance measures to compare with program outcomes 3. Discuss with site champions about what leadership and stakeholders need to sustain the program

In terms of satisfaction with progress, teams generally rated Adoption and Implementation dimensions highest, with Reach usually receiving the lowest ratings. Combining these data resulted in a visual display of the "gap" between importance and progress, which was consistently the largest for the Reach dimension. **Figure 1** illustrates the team members' average score for importance and progress by project as well as the gap between importance and progress ratings.

Qualitative Results

Examples of participant comments written on the survey to support the ratings included:

- **REACH**: *Continue outreaching current hospitals and enrolling new ones when appropriate. Work on education with community providers on inclusion and exclusion criteria (Advanced Care Coordination project).*

  At this point, providers have just started to participate. Reach to Veterans is important, but we can't reach Veterans without reaching the providers first (Multimodal Pain project).
- **EFFECTIVENESS**: *It has been hard to measure effectiveness without reaching adequate amount of reach (Community Transitions project).*
- **ADOPTION**: *The success of the implementation also depends on the engagement and participation of the catheterization laboratory teams (Patient-Reported Health Status Assessment project).*
- **IMPLEMENTATION**: *<Rural Transitions> is making efforts to track and measure our implementation efforts and how effective each is (Rural Transitions project).*
- **MAINTENANCE**: *Much of maintenance is out of our hands-<Rural Transitions> has made many efforts to assist each site with maintenance; cost benefit analysis may strengthen this dimension (Rural Transitions project).*

Team Goals and Action Plans

Although there was variability, most teams selected Reach as one of the dimensions to target (**Table 5**). Three teams selected two RE-AIM dimensions to target and the other two focused solely on Reach. Teams most often chose reach and adoption dimensions as needing improvement. **Table 5** summarizes SMART goals and action plans developed for each RE-AM dimension the team selected. Examples of reach action plans were "re-engaging key stakeholders to solicit their ideas to reach more participants" and "revising participant exclusion criteria." An example of an adoption action plan was to conduct chart reviews to closely track adoption.

Field notes from meeting #2 revealed that team members were not surprised by the summary ratings of importance and satisfaction with progress on different RE-AIM dimensions, as they were consistent with their impressions of program challenges and priorities at that time. For example, the Rural Transitions project was beginning the dissemination phase and was largely focused on maintenance efforts; while Multimodal Pain and Patient-Reported Health Status Assessment teams were largely concerned with adoption prior to the assessment process. Additionally, team members discussed how potential improvements in one dimension (e.g., Reach) could lead to impacts on other dimensions (e.g., Effectiveness).

Follow-up assessment meetings were held on average 6 weeks after Meeting #2 with one meeting taking place 15 weeks after the group session due to PI availability. At the time of the follow up meeting, all teams had (a) completed specific SMART goals/action plans with accountabilities specified; and (b) implemented or attempted to implement this plan. Average ratings of the extent to which the plan was implemented was 3.88 on a 5 point scale (1= not at all; 3= somewhat; 5= completely). Teams rated the iterative RE-AIM assessment as being useful (average of 4.25 on the 5 pt. scale of usefulness; 1= not at all; 3= somewhat; 5 = extremely).

The teams were all satisfied with the iterative RE-AIM approach and pragmatic tools. They were implementing action plans based on SMART goals and waiting to evaluate the impact of these on the chosen RE-AIM dimensions. Four out of five project teams commented that it was too early to assess progress on the SMART goals/action plans; the fifth project interviewees reported that they could not move forward due to the exit of their operational partner. Additionally, teams suggested that it would be helpful to conduct the RE-AIM assessments throughout the project phases at regular intervals and suggested a 6-month interval. They felt that this process would help evaluate project progress, address program data collection challenges, and inform adaptations to interventions and implementation strategies. They commented that the focus may shift from one RE-AIM dimension to another over time, resulting in different ratings depending on context and project priorities.

Interviewees also shared lessons learned through the iterative RE-AIM assessment. These included that they were surprised and relieved that they would not need to focus on all the RE-AIM dimensions at once and that it was acceptable to prioritize different dimensions at different phases of the project. For example, Reach was a priority in the implementation/expansion phase and it was reasonable to prioritize Maintenance when the project was further along. Additionally, projects reported experiencing stalls during the implementation phase. The iterative RE-AIM assessment was felt to be useful to overcome barriers and to look for solutions to keep the projects moving forward.

DISCUSSION

The rapid and iterative RE-AIM assessment and action planning process was feasible and rated as useful for project teams. All five projects found the assessment and planning activities to be understandable and relevant. It is well-established in implementation science that adaptations are going to happen (27, 28, 30) and this approach provides one way to assist in making adaptations purposeful, conceptually based, and data-driven.

The review and reflection process involved was relatively efficient; conducted during two regularly scheduled team meetings and required very little participant work outside of these meetings. The RE-AIM assessment and adaptation process involved all team members and was effective in creating buy in and common goals. There was a balanced discussion and input from team members from a variety of positions and roles, thus supporting and enhancing team science processes (41). The activities were rated as useful and provided teams with a structured and systematic way to assess progress and share perceptions from their different perspectives. This reflection process has recently been reported (23) to be an important aspect of assessment processes that are valued by implementation teams and helpful to inform progress.

There was variability across teams as to which RE-AIM dimensions were most important at that stage in the study, but most felt that Maintenance was less important. While our implementation science team made the decision not intervene to guide discussion or priority setting, these results suggest the opportunity in future applications of this process to point out the importance of designing for sustainability (29, 31), rather than waiting till the end of the project. Most projects reported the least satisfaction with their progress on Reach; their ratings indicated this was the dimension on which there was the largest gap between what they originally planned and what they had achieved; and most teams included Reach as one of the RE-AIM dimensions targeted for mid-course improvement. This focus on Reach is important, both from a health equity perspective (whether the most vulnerable and highest need Veterans were participating), and in terms of population health impact, which cannot be substantial if only a small or unrepresentative portion of the targeted population is reached.

Consensus was achieved among different team members on their perspectives of relative importance and satisfaction with progress on different RE-AIM dimensions. The facilitator-led discussion was informative and useful for team members to hear each other's perspectives. Part of the success and positive ratings may have been because the investigators listened to all team members input and did not dominate the discussion (41). The process might not have been as productive with projects and teams that are more hierarchical. This activity seemed to be a good way to allow for some protected time for team reflection, and to address both progress to date and the longitudinally changing context (1, 29). More generally, the study of adaptions to interventions and implementation strategies during a project is still relatively new and there is not consensus on whether changes to a study protocol should be encouraged or just observed and documented (30).

Adaptations are going to occur whether investigators ignore them or even suppress information on their occurrence (30), thus it makes sense to help to make adaptations fidelity and conceptually consistent rather than haphazard (27). It is still critically important to carefully document and report both fidelity and adaptations for transparency and replication purposes (34, 42), and this mid-course assessment and correction process can help increase reporting on and transparency regarding adaptations.

Prior studies have included some of the elements of our approach in this report. Specifically, Paone (13) used RE-AIM to observe, document, and analyze the implementation experience, as well as the perceived value of and satisfaction with an evidence based program for spousal caregivers in 14 Minnesota organizations. Quarterly reports generated by the consultants provided narrative information on progress and barriers using a mixed-methods assessment of strategies using the five RE-AIM dimensions. In Kwan et al. (12) findings from initial quantitative analysis (e.g., low reach) informed topics for RE-AIM focused interviews and focus groups. In turn, findings from interviews and focus groups informed both practice process improvement and subsequent evaluation priorities. Quinn and colleagues (14) used existing literature and expert consultation to translate and iteratively adapt the RE-AIM framework across several stages of the NIH Clean Cooking Implementation Science case study project while also developing checklists to guide investigators at each stage. Hill and colleagues (11) pilot tested their adapted pediatric weight management intervention iChoose, in 3 iterative phases delivered initially by research partners, then co-delivered by research and community partners,

then delivered by community partners. The RE-AIM framework was used to plan and evaluate the iChoose intervention across all waves with assessments at baseline, post program (3 months), and follow-up (6 months). Finally, Forman et al. (10) used the RE-AIM QuEST formative evaluation to identify real-time implementation barriers and explain how implementation context may influence translation to additional settings.

Our iterative RE-AIM assessment and adaptation process is both similar to and different from more frequently used quality improvement (QI) methods (21, 22). Like QI, it is intended to assess progress and guide modifications that can be tested. Although iterative, it is much less rapid than most QI approaches, but it is conceptually based, and explicitly focuses on multiple implementation outcome dimensions important for population health and overall program success (5, 43). A similar, although purely qualitative approach has been suggested by Finley and colleagues in the form of periodic reflections (23).

This study extends related work using RE-AIM for similar purposes by having a more specific, primary and systematic focus on the iterative use of RE-AIM. It adds to the literature by detailing a specific, step by step protocol, using systematic goal-setting, independent ratings by various team members, reflecting on the assessment of both progress and priorities using a standard rating form, evaluating the (short term) impact of the resulting adaptations, and providing scales, guides and resource materials for others interested in this process.

This activity based on implementation science principles and outcomes is also one way to support and operationalize a learning health system (32, 33); and an approach that does not require many resources or much staff time. This is because of the focus on well-defined implementation outcomes and the relative intuitiveness and transparency of the RE-AIM model and measures (8). It is also a way to help teams discuss and focus on "value"- that is, to reflect on whether they are investing resources on and achieving results on what is important (within the confines of RE-AIM implementation outcomes). The observation that the focus might shift during the lifetime of a project is also a critical contribution.

This study has both strengths and limitations. Limitations include the relatively small number of teams and sample size; and that all were projects coordinated from one VA medical center. Also, at least some members of each team were familiar with and had used RE-AIM at the proposal stage. Future directions should include replication in other VAs and non-VA settings and projects that did not use RE-AIM in their initial proposal. This study did not include a control condition and there is clearly a need for more formal and empirical evaluation of the long-term impact of the process. Although the activity explicitly involved all implementation team members, it did not engage Veteran patients or operational leader partners. The iterative RE-AIM process appears helpful in directing mid-course adjustments, but we did not experimentally compare this process to other approaches such as QI or use of other implementation science frameworks. Future research should assess the impact of different timing and intensities of iterative assessments using comparative effectiveness designs and including formal cost analyses (44, 45).

Strengths of this paper include the novel idea of guiding adaptations through rapid and collaborative application of a widely used implementation science framework and the mixed methods assessment. The RE-AIM based evaluation was successfully implemented across five diverse projects, different content areas, at different points in their projects, and with different teams. The pragmatic approach seems to engage team members and appears to be replicable. Finally, our materials are publicly available in the Appendices.

CONCLUSIONS

The use of this RE-AIM based approach was feasible, relatively efficient and seemed to facilitate both engagement of team members having different roles, and mid-course adjustments. Similar rapid assessment and adaptation approaches could be conducted using other implementation science frameworks and comparing different frequencies and intensities of facilitation.

DATA AVAILABILITY STATEMENT

All datasets generated for this study are included in the article/supplementary material.

ETHICS STATEMENT

This study was not considered human subject research according to VA Office of Regulatory Oversight policy 1058.05 and was designated as quality improvement by the VA Office of Rural Health, therefore ethical review and approval was not required in accordance with the local legislation and institutional guidelines. This is because subjects were not individually randomized, no identifying data were collected from participants and the interventions were done system wide as part of regular care. Therefore, written informed consent for this study was not required in accordance with national legislation and institutional requirements.

AUTHOR CONTRIBUTIONS

RG and BR initially conceptualized the study. MM organized the database and performed the statistical analysis. RG wrote the first draft of the manuscript. All authors contributed to conception and design of the study, drafted sections of the text or tables and figures, contributed to manuscript revision, read, and approved the submitted version.

FUNDING

This material is based upon work supported by the Department of Veterans Affairs, Veterans Health Administration, Office of Research and Development/ Quality Enhancement Research Initiative [QUE 15-268] and Office of Rural Health [N19-FY14Q3-S0-P01240]. Additionally, a portion of Dr. RG's and BR's time was supported was supported by NCI CENTER GRANT # P50CA244688.

REFERENCES

1. Nilsen P. Making sense of implementation theories, models and frameworks. *Implement. Sci.* (2015) 10:53. doi: 10.1186/s13012-015-0242-0
2. Mitchell SA, Fisher CA, Hastings CE, Silverman LB, Wallen GR. A thematic analysis of theoretical models for translational science in nursing: mapping the field. *Nurs Outlook.* (2010) 58:287–300. doi: 10.1016/j.outlook.2010.07.001
3. Birken SA, Powell BJ, Shea CM, Haines ER, Alexis Kirk M, Leeman J, et al. Criteria for selecting implementation science theories and frameworks: results from an international survey. *Implement. Sci.* (2017) 12:124. doi: 10.1186/s13012-017-0656-y
4. Strifler L, Cardoso R, McGowan J, Cogo E, Nincic V, Khan PA, et al. Scoping review identifies significant number of knowledge translation theories, models, and frameworks with limited use. *J Clin Epidemiol.* (2018) 100:92–102. doi: 10.1016/j.jclinepi.2018.04.008
5. Glasgow RE, Harden SM, Gaglio B, Rabin B, Smith ML, Porter GC, et al. RE-AIM planning and evaluation framework: adapting to new science and practice with a 20-year review. *Front Public Health.* (2019) 7:64. doi: 10.3389/fpubh.2019.00064
6. Klesges LM, Estabrooks PA, Dzewaltowski DA, Bull SS, Glasgow RE. Beginning with the application in mind: designing and planning health behavior change interventions to enhance dissemination. *Ann Behav Med.* (2005) 29(Suppl):66–75. doi: 10.1207/s15324796abm2902s_10
7. Harden SM, Smith ML, Ory MG, Smith-Ray RL, Estabrooks PA, Glasgow RE. RE-AIM in clinical, community, and corporate settings: perspectives, strategies, and recommendations to enhance public health impact. *Front Public Health.* (2018) 6:71. doi: 10.3389/fpubh.2018.00071
8. Glasgow RE, Estabrooks PE. Pragmatic applications of RE-AIM for health care initiatives in community and clinical settings. *Prev Chronic Dis.* (2018) 15:E02. doi: 10.5888/pcd15.170271
9. Ory MG, Altpeter M, Belza B, Helduser J, Zhang C, Smith ML. Perceived utility of the RE-AIM framework for health promotion/disease prevention initiatives for older adults: a case study from the U.S. Evidence-Based Disease Prevention Initiative. *Front Public Health.* (2014) 2:143. doi: 10.3389/fpubh.2014.00143
10. Forman J, Heisler M, Damschroder LJ, Kaselitz E, Kerr EA. Development and application of the RE-AIM QuEST mixed methods framework for program evaluation. *Prev Med Rep.* (2017) 6:322–8. doi: 10.1016/j.pmedr.2017.04.002
11. Hill JL, Zoellner JM, You W, Brock DJ, Price B, Alexander RC, et al. Participatory development and pilot testing of iChoose: an adaptation of an evidence-based paediatric weight management program for community implementation. *BMC Public Health.* (2019) 19:122. doi: 10.1186/s12889-019-6450-9
12. Kwan BM, Chadha S, Hamer MK, Spagnolo D, Kee S. Mixed methods evaluation of a collaborative care implementation using RE-AIM. *Fam Syst Health.* (2017) 35:295–307. doi: 10.1037/fsh0000291
13. Paone D. Using RE-AIM to evaluate implementation of an evidence-based program: a case example from minnesota. *J Gerontol Soc Work.* (2014) 57:602–25. doi: 10.1080/01634372.2014.907218
14. Quinn AK, Neta G, Sturke R, Olopade CO, Pollard SL, Sherr K, et al. Adapting and operationalizing the RE-AIM framework for implementation science in environmental health: clean fuel cooking programs in low resource countries. *Front Public Health.* (2019) 7:389. doi: 10.3389/fpubh.2019.00389
15. Riley WT, Glasgow RE, Etheredge L, Abernethy AP. Rapid, responsive, relevant (R3) research: a call for a rapid learning health research enterprise. *Clin Transl Med.* (2013) 2:10. doi: 10.1186/2001-1326-2-10
16. Glasgow RE, Chambers D. Developing robust, sustainable, implementation systems using rigorous, rapid and relevant science. *Clin Transl Sci.* (2012) 5:48–55. doi: 10.1111/j.1752-8062.2011.00383.x
17. Peek CJ, Glasgow RE, Stange KC, Klesges LM, Purcell EP, Kessler RS. The 5 R's: an emerging bold standard for conducting relevant research in a changing world. *Ann Fam Med.* (2014) 12:447–55. doi: 10.1370/afm.1688
18. Palinkas LA, Zatzick D. Rapid Assessment Procedure Informed Clinical Ethnography (RAPICE) in pragmatic clinical trials of mental health services implementation: methods and applied case study. *Adm Policy Ment Health.* (2019) 46:255–70. doi: 10.1007/s10488-018-0909-3
19. U.S. Department of Health and Human Services National Cancer Institute. *National Cancer Institute. Qualitative Research in Implementation Science (QualRIS)*. Available online at: https://cancercontrol.cancer.gov/IS/docs/NCI-DCCPS-ImplementationScience-WhitePaper.pdf.
20. Hamilton AB, Finley EP. Qualitative methods in implementation research: An introduction. *Psychiatry Res.* (2019) 280:112516. doi: 10.1016/j.psychres.2019.112516
21. Berwick DM. The science of improvement. *JAMA.* (2008) 299:1182–4. doi: 10.1001/jama.299.10.1182
22. Shojania KG, Grimshaw JM. Evidence-based quality improvement: the state of the science. *Health Aff.* (2005) 24:138–50. doi: 10.1377/hlthaff.24.1.138
23. Finley EP, Huynh AK, Farmer MM, Bean-Mayberry B, Moin T, Oishi SM, et al. Periodic reflections: a method of guided discussions for documenting implementation phenomena. *BMC Med Res Methodol.* (2018) 18:153. doi: 10.1186/s12874-018-0610-y
24. Clinton-McHarg T, Yoong SL, Tzelepis F, Regan T, Fielding A, Skelton E, et al. Psychometric properties of implementation measures for public health and community settings and mapping of constructs against the consolidated framework for implementation research: a systematic review. *Implement Sci.* (2016) 11:148. doi: 10.1186/s13012-016-0512-5
25. Fernandez ME, Ruiter RAC, Markham CM, Kok G. Intervention mapping: theory- and evidence-based health promotion program planning: perspective and examples. *Front Public Health.* (2019) 7:209. doi: 10.3389/fpubh.2019.00209
26. Damschroder L, Hall C, Gillon L, Reardon C, Kelley C, Sparks J, et al. The Consolidated Framework for Implementation Research (CFIR): progress to date, tools and resources, and plans for the future. *Implement Sci.* (2015) 10:A12. doi: 10.1186/1748-5908-10-S1-A12
27. Wiltsey Stirman S, Baumann AA, Miller CJ. The FRAME: an expanded framework for reporting adaptations and modifications to evidence-based interventions. *Implement Sci.* (2019) 14:58. doi: 10.1186/s13012-019-0898-y
28. Chambers DA, Norton WE. The adaptome: advancing the science of intervention adaptation. *Am J Prev Med.* (2016) 51(4 Suppl 2):S124–31. doi: 10.1016/j.amepre.2016.05.011
29. Chambers DA, Glasgow RE, Stange KC. The dynamic sustainability framework: addressing the paradox of sustainment amid ongoing change. *Implement Sci.* (2013) 8:117. doi: 10.1186/1748-5908-8-117
30. Mittman B. Evaluating complex interventions: confronting and guiding (versus ignoring and suppressing) heterogeneity and adaptation. *PSMG Northwestern Grand Rounds webinar series.* (2018) Available from: cepim.northwestern.edu/psmg-archive/
31. Shelton RC, Cooper BR, Stirman SW. The sustainability of evidence-based interventions and practices in public health and health care. *Annu Rev Public Health.* (2018) 39:55–76. doi: 10.1146/annurev-publhealth-040617-014731
32. Deans KJ, Sabihi S, Forrest CB. Learning health systems. *Semin Pediatr Surg.* (2018) 27:375–8. doi: 10.1053/j.sempedsurg.2018.10.005
33. Kilbourne AM, Elwy AR, Sales AE, Atkins D. Accelerating research impact in a learning health care system: va's quality enhancement research initiative in the choice act era. *Med Care.* (2017) 55(Suppl 7):S4–S12. doi: 10.1097/MLR.0000000000000683
34. Rabin BA, McCreight M, Battaglia C, Ayele R, Burke RE, Hess PL, et al. Systematic, multimethod assessment of adaptations across four diverse health systems interventions. *Front Public Health.* (2018) 6:102. doi: 10.3389/fpubh.2018.00102
35. Bradley SM, Rumsfeld JS, Ho PM. Incorporating health status in routine care to improve health care value: the va patient reported health status assessment (PROST) system. *JAMA.* (2016) 316:487–8. doi: 10.1001/jama.2016.6495
36. Ayele RA, Lawrence E, McCreight M, Fehling K, Peterson J, Glasgow RE, et al. Study protocol: improving the transition of care from a non-network hospital back to the patient's medical home. *BMC Health Serv Res.* (2017) 17:123. doi: 10.1186/s12913-017-2048-z
37. Leonard C, Lawrence E, McCreight M, Lippmann B, Kelley L, Mayberry A, et al. Implementation and dissemination of a transition of care program for rural veterans: a controlled before and after study. *Implement Sci.* (2017) 12:123. doi: 10.1186/s13012-017-0653-1
38. U.S. Department of Veterans. *Affairs HSRaD Quality Enhancement Research Initiative (QUERI). Building Pain Management Expertise in VA Primary Care.* QUERI E-news. (2017). Available online at: https://www.queri.research.va.gov/qnews/feb17/default.cfm?QnewsMenu=article4.

39. Doran GT. There's a smart way to write managements's goals and objectives. *Manag Rev.* (1981) 70:35–6.
40. Averill JB. Matrix analysis as a complementary analytic strategy in qualitative inquiry. *Qual Health Res.* (2002) 12:855–66. doi: 10.1177/10432302012006011
41. Hall KL, Vogel AL, Huang GC, Serrano KJ, Rice EL, Tsakraklides SP, et al. The science of team science: a review of the empirical evidence and research gaps on collaboration in science. *Am Psychol.* (2018) 73:532–48. doi: 10.1037/amp0000319
42. Glasgow RE, Huebschmann AG, Brownson RC. Expanding the CONSORT figure: increasing transparency in reporting on external validity. *Am J Prev Med.* (2018) 55:422–30. doi: 10.1016/j.amepre.2018.04.044
43. Glasgow RE, Klesges LM, Dzewaltowski DA, Estabrooks PA, Vogt TM. Evaluating the impact of health promotion programs: using the RE-AIM framework to form summary measures for decision making involving complex issues. *Health Educ Res.* (2006) 21:688–94. doi: 10.1093/her/cyl081
44. Ritzwoller DP, Sukhanova A, Gaglio B, Glasgow RE. Costing behavioral interventions: a practical guide to enhance translation. *Ann Behav Med.* (2009) 37:218–27. doi: 10.1007/s12160-009-9088-5
45. Jones Rhodes WC, Ritzwoller DP, Glasgow RE. Stakeholder perspectives on costs and resource expenditures: tools for addressing economic issues most relevant to patients, providers, and clinics. *Transl Behav Med.* (2018) 8:675–82. doi: 10.1093/tbm/ibx003

Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

frontiers in Public Health

ORIGINAL RESEARCH
published: 03 March 2020
doi: 10.3389/fpubh.2020.00059

Planning for Implementation Success Using RE-AIM and CFIR Frameworks: A Qualitative Study

Diane K. King[1], Jo Ann Shoup[2], Marsha A. Raebel[2], Courtney B. Anderson[2], Nicole M. Wagner[2], Debra P. Ritzwoller[2] and Bruce G. Bender[3]*

[1] Center for Behavioral Health Research and Services, University of Alaska Anchorage, Anchorage, AK, United States, [2] Kaiser Permanente Colorado, Institute for Health Research, Denver, CO, United States, [3] Department of Pediatrics, National Jewish Health, Denver, CO, United States

OPEN ACCESS

Edited by:
Paul Estabrooks, University of Nebraska Medical Center, United States

Reviewed by:
Pradeep Nair, Central University of Himachal Pradesh, India
Warren G. McDonald, Methodist University, United States
Gwenndolyn Porter, University of Nebraska Medical Center, United States
Souheila AliHassan, Tawam Hospital, United Arab Emirates

***Correspondence:**
Diane K. King
dkking@alaska.edu

Specialty section:
This article was submitted to Public Health Education and Promotion, a section of the journal Frontiers in Public Health

Received: *19 August 2019*
Accepted: *17 February 2020*
Published: *03 March 2020*

Citation:
King DK, Shoup JA, Raebel MA, Anderson CB, Wagner NM, Ritzwoller DP and Bender BG (2020) Planning for Implementation Success Using RE-AIM and CFIR Frameworks: A Qualitative Study. Front. Public Health 8:59. doi: 10.3389/fpubh.2020.00059

Background: RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) and CFIR (Consolidated Framework for Implementation Research) dissemination and implementation frameworks define theory-based domains associated with the adoption, implementation and maintenance of evidence-based interventions. Used together, the two frameworks identify metrics for evaluating implementation success, i.e., high reach and effectiveness resulting in sustained practice change (RE-AIM), and modifiable factors that explain and enhance implementation outcomes (CFIR). We applied both frameworks to study the implementation planning process for a technology-delivered asthma care intervention called Breathewell within an integrated care organization. The goal of the Breathewell intervention is to increase the efficiency of delivering resource-intensive asthma care services.

Methods: We reviewed historical documents (i.e., meeting agendas; minutes) from 14 months of planning to evaluate alignment of implementation team priorities with RE-AIM domains. Key content was extracted and analyzed on topics, frequency and amount of discussion within each RE-AIM domain. Implementation team members were interviewed using questions adapted from the *CFIR Interview Guide Tool* to focus their reflection on the process and contextual factors considered during pre-implementation planning. Documents and transcripts were initially coded using RE-AIM domain definitions, and recoded using CFIR constructs, with intent to help explain how team decisions and actions can contribute to adoption, implementation and maintenance outcomes.

Results: Qualitative analysis of team documents and interviews demonstrated strong alignment with the RE-AIM domains: Reach, Effectiveness, and Implementation; and with the CFIR constructs: *formal inclusion* of provider and staff stakeholders in implementation planning, *compatibility* of the intervention with workflows and systems, and alignment of the intervention with organizational *culture*. Focus on these factors likely contributed to RE-AIM outcomes of high implementation fidelity. However, team members expressed low confidence that Breathewell would be adopted and maintained post-trial. A potential explanation was weak alignment with several CFIR constructs, including *tension for change, relative priority, and leadership engagement* that contribute to organizational receptivity and motivation to sustain change.

Conclusions: While RE-AIM provides a practical framework for planning and evaluating practice change interventions to assure their external validity, CFIR explains *why* implementation succeeded or failed, and when used proactively, identifies relevant modifiable factors that can promote or undermine adoption, implementation, and maintenance.

Keywords: adoption, implementation, maintenance, sustainability, dissemination, frameworks

INTRODUCTION

Dissemination and implementation (D&I) research has demonstrated that evidence of effectiveness is insufficient to promote adoption of evidence-based interventions if fit and feasibility have not been addressed (1, 2). A growing body of research has also found that even feasible interventions may not be fully adopted or sustained if organizational demands related to market forces (e.g., competitive, consumer, capacity, or regulatory) or other strategic imperatives (e.g., patient wants and needs) are not considered (3, 4).

D&I frameworks, such as RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) (5, 6), can be used during implementation planning (7) to guide selection, adaptation, and evaluation of interventions on key indicators associated with successful implementation of evidence-based interventions. By defining whose health or health behavior will benefit from the intervention (*Reach*), identifying which components of the intervention are considered the "active ingredients" necessary for the desired impact (*Effectiveness*), describing relevant characteristics of the delivery setting, and those involved in delivering the intervention (*Adoption*); evaluating the extent that the active ingredients are delivered with fidelity to the established protocols (*Implementation*), and describing facilitators and barriers that may influence organizational decisions to sustain the intervention after the study is completed (*Maintenance*), RE-AIM provides practical information that can improve translation of evidence-based interventions into practice and their public health impact (8). The framework's emphasis on balancing rigor with relevance is clearly important to adoption, implementation and maintenance (9). Implementation success (i.e., post-trial sustainment of an intervention, with protocols and infrastructure in place to assure continued fidelity) can depend on the extent that an organization has internal capacity (10) and is willing to accommodate the intervention by modifying setting systems, protocols, and/or roles (11); and the extent that researchers are willing to adapt the intervention, so that it fits and is feasible to maintain long-term (3).

However, RE-AIM does not explain the conditions that influence implementation success (12). Other frameworks, such as the Chronic Care Model (CCM) (13) and the Practical, Robust Implementation and Sustainability Model (PRISM) (14), include constructs from improvement science important to intervention design and acceptance, such as external and internal support for the intervention, internal preparedness/readiness, compatibility with internal systems, and observed effectiveness of the intervention. However, they lack clear definitions, guidance or measures to assist planning teams in understanding or improving results (15). Use of qualitative methods, such as asking stakeholders and observing processes to identify barriers to implementation, have been recommended to further our understanding of why implementers got the results they did (12, 16). While anticipating barriers is important, understanding individual, situational and structural influences on outcome expectations, behavior and decision-making can identify specific mechanisms that could be assessed and addressed during implementation planning (4, 15). In addition to improvement science, marketplace principles that include understanding customers (i.e., payors) and competition (i.e., other priorities, programs) for the intervention, can be useful to improving success (or understanding failure) (17). Lessons from marketing science describe how researchers have a tendency to rely on "push," defined as systematic efforts to convince potential adopters of the value of our interventions (i.e., dissemination), vs. "pull," defined as pre-existing preferences, needs, or demands that intrinsically motivate potential adopters to change (i.e., diffusion) (3). Improving receptivity to adopting interventions may require using push techniques to elicit pull, by tailoring dissemination to address the wants, needs, and concerns of decision-makers within the organization (18).

The Consolidated Framework for Implementation Research (CFIR) is a comprehensive framework composed of constructs associated with effective implementation (19). CFIR's 39 constructs are organized into five domains: *Intervention Characteristic*; *Outer Setting*; *Inner Setting*; *Characteristics of Individuals*; and *Process* (20). Like CCM and PRISM, CFIR draws on theories of behavior change, improvement science, and Diffusion Theory, but also provides a taxonomy with definitions, codebook, and interview questions, to facilitate its usefulness as an explanatory model (21). Understanding which constructs, or sets of constructs promote or inhibit adoption, implementation, and maintenance, can inform development during planning of tailored and testable implementation strategies (22) to balance internal and external validity (4), as well as push and pull (3). In other words, examining the presence or absence of CFIR constructs can explain "why" implementation was or was not successful, while RE-AIM describes outcomes in terms of "who, what, where, how, and when" (12) (see **Figure 1**).

Used together, RE-AIM and CFIR could enhance the effectiveness of implementation planning by elucidating relationships between factors emphasized (or missed), which potentially could promote implementation fidelity and adoption, and thus lead to optimal post-trial maintenance outcomes.

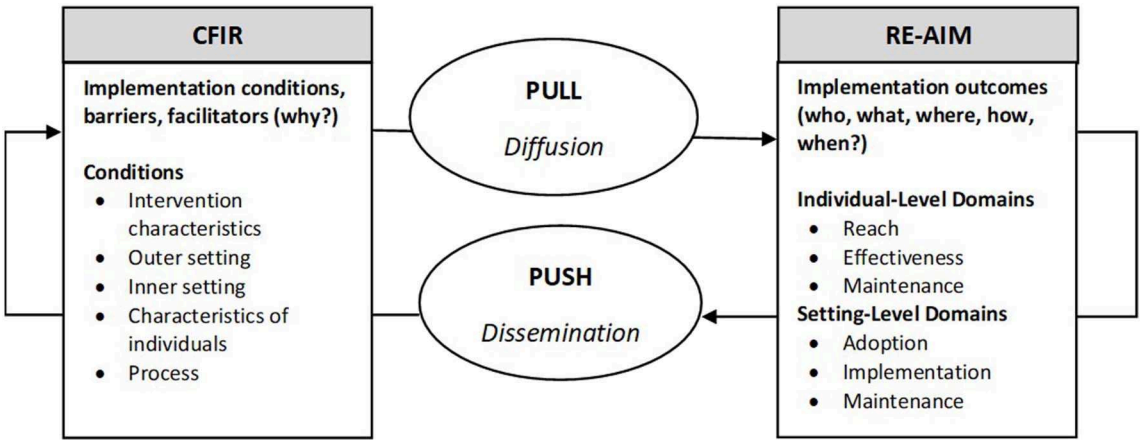

FIGURE 1 | Implementation planning conceptual framework: Using RE-AIM and CFIR to plan for successful implementation.

RE-AIM and CFIR domains, definitions, constructs and the "who, what, where, how, when, and why" questions for planning teams are summarized in **Table 1**.

The objective of this paper is to describe our complementary use of the RE-AIM evaluation framework and the CFIR explanatory framework to go beyond listing barriers; to identify potentially testable mechanisms that influence implementation success, and in turn contribute to the forward progression of Implementation science. Using a recent technology-based asthma intervention, the Breathewell study, as the example, we: (1) identify the presence or absence of variables that contribute to implementation success; (2) develop potential implementation strategies that could improve comprehensiveness of the implementation planning process; and (3) recommend areas for future research.

MATERIALS AND METHODS

Context

Setting Characteristics and Breathewell Study Description

The setting for the Breathewell study was Kaiser Permanente Colorado (KPCO), an integrated healthcare organization serving ∼600,000 members in the Denver-Boulder area. The Breathewell study is a pragmatic randomized controlled trial to experimentally test a technology-enabled outreach intervention targeted to patients diagnosed with asthma who are potentially overusing inhaled beta-agonists (asthma reliever medication). Potential overuse is identified when (1) patients request a refill of their inhaled beta-agonist (asthma reliever) medication more frequently than every 60 days; or (2) request a refill of a beta-agonist without having filled an asthma controller medication (such as an inhaled corticosteroid) within the last 4 months. The technology-based intervention used KPCO's interactive voice response (IVR) system and interfaced between the electronic health record (EHR), patients, and providers (nurses and pharmacists). We conducted our planning for implementing the beta-agonist refill intervention from November 2015 through January 2017, which is the focus of this study. Participants in the trial were Kaiser Permanente Colorado current members, 18 years and older, with a diagnosis of asthma at the time of randomization. Enrollment occurred from February 2017 to February 2018. Participants were randomized to 1 of 3 groups: Text/Phone call intervention, Email, or Usual Care. Participants were followed for 6–18 months, depending on enrollment date. The study was approved by the Institutional Review Boards of National Jewish Health and Kaiser Permanente Colorado. Details of the study design are described elsewhere (23, 24).

Reasons for Implementing the Practice Change-Increase Efficiency of Asthma Care

In usual asthma care at KPCO, a group of nurses known as asthma care managers (ACMs) followed-up with patients identified as having too frequent refills of their asthma reliever medication because frequent refills can be an indicator of poor asthma control. The ACMs followed a standard clinical protocol that included time consuming review of the patient's health record along with phone, EHR email portal, or mail contact to the patient to assess patient symptoms and prevent exacerbation. The ACMs indicated to the Breathewell study team that many patients they contacted regarding what appeared to be asthma reliever medication overuse were in fact not overusing the medication, but rather had situations such as requesting an extra asthma reliever inhaler to keep in their gym bag or refilling the medication early due to travel, etc. As a result, the ACMs believed they spent a great deal of time reviewing records and contacting patients who did not have poor asthma control and did not need the expertise of the ACM. The technology-enabled Breathewell study outreach was designed to determine whether the patient currently had symptoms to guide ACM contact.

Implementation Team Composition

The 13-member multi-disciplinary planning and implementation team consisted primarily (but not exclusively) of

TABLE 1 | RE-AIM and CFIR domains, planning questions, and definitions/constructs.

RE-AIM Framework	
Reach[a]	
Planning questions	**Who (which patient) is intended to benefit from the intervention? Who will be exposed to the intervention?**
Definition	The absolute number, proportion, and representativeness (whether participants have characteristics that reflect the target population's characteristics) of individuals exposed to the intervention; as well as characteristics of those who were eligible but not reached
Effectiveness[a]	
Planning questions	**What are the most important benefits you hope to achieve? How will we know if the intervention achieved these benefits?**
Definition	The impact of an intervention on important outcomes. This includes potential negative effects, quality of life, and economic outcomes
Adoption	
Planning questions	**Where is the intervention being delivered? How do we develop institutional support to deliver it?**
Definition	The absolute number, proportion, and representativeness of settings and staff who are willing to initiate a program or approve a policy
Implementation	
Planning questions	**How do we assure the intervention is delivered properly and consistently? How do we adapt it to make sure it fits and is feasible?**
Definition	To what extent is the intervention delivered as designed; includes how closely and consistently staff members follow established protocols, as well as the time and cost of the program
Maintenance	
Planning questions	**When will the intervention become operational? How do we assure the intervention continues to be effective and delivered as designed, over time?**
Definition	At the setting level, the extent to which a program or policy becomes part of the routine organizational practices and policies
Consolidated framework for implementation research	
Intervention characteristics	
Planning questions	**Is this intervention superior to the status quo? Can we adapt it so that it will work here?**
Constructs	Intervention source; evidence strength; relative advantage; adaptability; trialability; complexity; design quality; and cost
Outer setting[b]	
Planning questions	**Why is it important for our institution to do this intervention now? Does it address a gap in patient care? Are there regulatory or competitive reasons?**
Constructs	Patient needs; organizational networks; peer or competitive pressure; policies, regulations and incentives
Inner setting	
Planning questions	**Will the intervention fit within our system? Is it feasible to do this now?**
Constructs	Structural characteristics; networks and communication; culture; implementation climate (tension for change; compatibility; relative priority; incentives and rewards; goals and feedback; learning climate); readiness for implementation (leadership engagement; available resources; intervention knowledge and access)
Characteristics of individuals	
Planning questions	**Do our providers and staff have the skill and will to deliver it?**
Constructs	Knowledge, attitudes and beliefs about the intervention; self-efficacy to deliver the intervention; individual stage of change; identification with the organization; personal attributes and values
Process	
Planning questions	**Whose work is affected by the intervention? Whose buy-in, input and expertise is needed? Who can commit the resources required to implement and sustain the intervention?**
Constructs	Planning; Engaging (opinion leaders, formally appointed stakeholders, champions, external change agents); Executing; Reflecting

[a] *These RE-AIM domains were not used in our assessment as these domains are at the individual level.*

[b] *These CFIR domains were not used in our assessment as these domains relate to external factors to implementation; our intervention was delivered via technology, so characteristics of individuals were not as significant.*

RE-AIM planning questions were adapted from a recent publication on pragmatic applications of the framework (7); CFIR planning questions were conceived by the authors.

researchers and healthcare professionals from KPCO. The make-up of the implementation team included physician, psychologist, and PharmD co-investigators, an ACM, two biostatisticians, a data manager, a data analyst/informatics specialist, a behavioral scientist, an economist, two project managers, and a research assistant. While patients with asthma did not participate as implementation team members, patients did review and edit the content and wording of the intervention messages prior to their use in study outreach.

Approach

We used a mix of prospective and retrospective data, and qualitatively analyzed documents and individual interview transcripts, to describe and evaluate the priorities, challenges, and decisions made by the implementation team during the 14-month planning period. First, we compiled all meeting agendas and minutes, then analyzed them by coding for RE-AIM domain alignment. Second, we adapted a subset of CFIR interview questions to further our understanding of setting-level

constructs important to planning for implementation of a technology-based intervention designed to improve efficiency of service delivery. Third, we interviewed implementation planning team members individually in a private office or conference room to encourage candor, and coded transcripts by RE-AIM domains and CFIR constructs to help identify what was emphasized (or missed) during planning that likely influenced outcomes for implementation fidelity and potential for post-trial adoption and maintenance. Fourth, we validated these findings with the implementation planning team. Finally, we summarized lessons learned, and formulated a process for developing implementation strategies to improve future implementation planning and implementation success.

Data

Data included (1) implementation team documents consisting of meeting agendas and detailed bi-monthly team meeting minutes recorded by a research assistant and reviewed after each meeting for accuracy by a project manager and one co-principal investigator; and (2) verbatim transcripts from retrospective interviews with members of the implementation team.

Analyses

Document Review

We used historical document review methods (25) to identify and describe components of the RE-AIM framework that were prioritized during implementation planning. To analyze these documents, we first independently coded the meeting minute content using inductive coding to identify topics and themes discussed during the planning phase. Second, the five RE-AIM domains were applied to the meeting minute content. To compare relative application of RE-AIM domains by the team during planning, from 1 to 10 points were assigned to each domain using a weighting method suggested by Glasgow, et al.: 1–4 = low application, 5–6 = medium application, 7–8 = high application, and 9–10 = very high application of the framework (7).

Interviews

After completing the RE-AIM coding of meeting agendas and minutes, we conducted interviews with the planning team, and analyzed them using components of the CFIR framework, organized by the A, I, and M domains of RE-AIM, to explain why planning team priorities impacted implementation success. The interview guide was developed by an external co-investigator removed from day-to-day project operations, and an internal project manager, using the interview guide tool available on the CFIR website (20). Both developers were experienced applying RE-AIM (6, 26) and other implementation frameworks (2, 10). They reviewed the CFIR interview guide tool to identify questions relevant to adopting, implementing and post-trial maintenance of an internally developed, technology-based intervention. Questions were intended to guide reflection about problems and decisions made to maximize intervention fit, feasibility and fidelity at the setting-level, and to describe its potential for sustainability. Because our focus was on the setting-level, we did not include questions that focused on the RE-AIM individual-level domains of Reach or Effectiveness. Also, given that the intervention was developed internally to improve efficiency of service delivery using technology, questions directly related to the CFIR domains of Outer Setting and Characteristics of Individuals were excluded. Twenty-five questions were developed or adapted from the interview guide tool (see **Table 2**). Eleven of 13 implementation team members were interviewed (the two team members who developed the interview tool were not interviewed). Interviews lasted 45-min on average (range 30–75 min) and were digitally recorded and professionally transcribed.

Two team members independently analyzed all interview transcripts, first applying *a priori* codes that included the setting-level RE-AIM domains (Adoption, Implementation and Maintenance), the selected CFIR domains (Intervention Characteristics, Inner Setting, and Process) and the specific CFIR constructs within those domains that were targeted by the specific interview question (8, 20). Transcripts were then coded a second time, adding any relevant CFIR constructs or subconstructs that emerged from participant responses. After coding three interviews, coders compared coding, discussed discrepancies, and reached consensus on code interpretations. After all interviews were analyzed, coders completed an Excel worksheet that listed each interview question, and its respective RE-AIM and CFIR domain codes, CFIR construct codes, emerging themes, and interviewee quotes that exemplified the assigned codes and themes. Coders then compared their worksheets, discussed any discrepancies and reached final consensus on codes and themes.

Based on the final worksheets, one rater created a matrix that grouped the relevant CFIR constructs under the RE-AIM categories of Adoption, Implementation and/or Maintenance. CFIR constructs listed were those deemed as potentially influencing one or more of the "AIM" domains, hence, some constructs were listed more than once (e.g., the construct of organizational *culture* was listed under Adoption and Implementation). Each rater independently extracted representative quotes that confirmed and/or negated alignment of planning team activities with the CFIR constructs. Each rater then assigned a preliminary rating of weak (one point), moderate (two points), or strong (three points) alignment with the CFIR-constructs based on these quotes and summarized the evidence that supported their ratings. Raters then compared quotes and ratings across the two matrices, discussed any differences, and reached consensus on ratings and evidence. During an implementation team meeting, the combined qualitative matrix of results, ratings and quotes were presented, and the full team reached consensus on data interpretation and major themes.

RESULTS

Historical Document Review

Application of the RE-AIM domains during planning varied by domain, with assigned points ranging from 3 to 9, with an average of six, indicating medium overall application of the framework (see **Table 3**). Ratings indicating very high (nine points) and high (eight points) framework application

TABLE 2 | Interview guide and a priori RE-AIM and CFIR codes.

Interview questions organized by RE-AIM domain	CFIR domains	CFIR constructs	CFIR sub-constructs
Adoption: characteristics that influence an organization's motivation or capacity to accept or reject an intervention			
Who was engaged in the decision process to implement an IVR-mediated medication refill service (i.e., BW[a]) at [the organization]? Probe: Was this decision driven by researchers, leadership, or providers?	Intervention characteristics	Intervention source	
What kind of information or evidence did you consider when selecting the BW implementation strategy for your setting?		Evidence strength & quality	
What are the core components of the asthma care intervention (usual care) that contribute to its effectiveness (i.e., need to be present whether human or IVR-delivered)?		Relative advantage	
What costs were considered when deciding to implement BW?		Costs	
To what extent was [the organization's] culture and/or values considered when designing BW. Please describe. In what way is [the organization's] culture different from other settings? In what way is it similar?	Inner setting	Culture	Compatibility
Was there a strong need for this implementation strategy? What was the need driving BW?			Tension for change
To what extent did implementing BW (i.e., IVR-mediated medication refill service) align with organizational goals and priorities?		Implementation climate	Relative priority
Implementation: consistency of delivery as intended			
When designing BW, did you think about the core components of asthma care that must be retained in both arms, to assure BW arm was NOT inferior to usual care? (i.e., consider the core components of the usual care intervention that made it effective)	Intervention characteristics	Adaptability	
What factors were considered to assure acceptance of BW to Asthma clinicians and care managers (i.e., would minimize resistance/disruption and/or maximize its acceptability and feasibility)? What factors in the use of technology for patient outreach were considered to assure acceptance of BW to patients (i.e., would maximize its acceptability and reach)?		Relative advantage	
Which of these factors do you feel were the most critical to address early on (i.e., would threaten success/derail the project if not addressed?)		Complexity	
When designing BW, to what extent did piloting components factor into the ultimate design.		Trialability	
Are there things that you wish you had piloted with patients or asthma care managers?			
Why did you think the BW implementation strategy would be effective here? Any concerns [regarding using technology for outreach] (e.g., past negative experiences or patient resistance)?	Inner setting	Implementation climate	Compatibility
What kind of approvals were needed? Who was involved?		Readiness for implementation	Leadership engagement
What kinds of infrastructure changes were necessary to accommodate the intervention (e.g., scope of practice; formal policies; information systems or electronic records systems)? Can you describe the process used to make these changes?			Available resources
When designing BW, what key stakeholders did you need to get on board (i.e., whose work or workflows could potentially be impacted by this implementation strategy)? What was your communication or education strategy with these stakeholders?	Process	Engaging	Opinion Leaders Champions
How did you decide who to include on the planning/design team? Were all the appropriate voices at the table from the start?			Formally appointed internal implementation leaders
When planning, did you consider how changes to the process or IVR intervention could be made during the intervention, if needed? Were there elements of the design that could not be altered that were discussed during planning?	Process	Planning	
Describe the process for making decisions about what to track (process and outcomes)? How was the information used?		Reflecting and evaluating	
What process measure(s) was/were most important to monitoring implementation fidelity? Provide an example of how this metric was used to identify issues, problem solve, and/or inform adaptation?			
Has BW been implemented according to plan? To what extent has the plan needed to be modified?		Executing	
Maintenance: extent that intervention becomes part of an organization's routine practice			
Whose approval will be needed for maintenance of BW after the study is over (if hypothesized outcomes are demonstrated)? Do these approvers know about the BW study?	Inner setting	Readiness for implementation	Leadership engagement
Do you anticipate any barriers or threats to maintaining BW?			Available resources
Were there factors or costs that weren't considered during implementation, that you wish you had prioritized in hindsight?	Process	Planning	
To what extent will these factors/costs impact BW's adoption or maintenance after the grant?	Intervention characteristics	Relative advantage Cost	

[a] *BW: Breathewell, a technology-enabled intervention to improve efficiency of asthma medication refills and/or care manager follow-up.*

TABLE 3 | Findings from analysis using RE-AIM[a] to describe planning team priorities over time.

Timing	Months 1-4	Months 5-6	Months 7-8	Months 9-11	Months 12-14	Application of RE-AIM domains during planning 1 (low)– 10 (very high)
Themes	**Preferences and barriers to asthma service delivery**	**Intervention characteristics and implementa-tion strategy development**	**Systems integration, logistics and piloting**	**Reach and intervention logistics**	**System barriers, logistics, monitoring**	
		REACH (R)				8
	–	• Define target population (denominator)	• Define patient eligibility and exclusion criteria	• Address barriers to reach; opt out options	– –	
		EFFECTIVENESS (E)				6
	–	• Analyze patient health outcomes, risk factors, and service gaps • Use internal data to select intervention	– –	– –	–	
		ADOPTION (A)				4
	• Provider-level needs assessed	– –	– –	– –	• Get buy-in from ACMs [b]	
		IMPLEMENTATION (I)				9
	• Stakeholder input to describe usual care and potential service- delivery gaps • Data availability and quality • Potential implementa-tion barriers	• Define intervention parameters and analytic plan	• Map logistics, information flow, and workflows • Develop, test, and refine intervention content	• Test and refine logistics, information flow, and workflows • Problem-solve system-level and structural challenges	• Address IT resistance, with help of internal champion • Test intervention and electronic information flow among systems • Fidelity monitoring plans	
		MAINTENANCE (M)				3
	– –	• Cost-benefit measures; replication costs	– –	• RE-AIM review including sustainability indicators	– –	

[a] *RE-AIM: Reach, Effectiveness, Adoption, Implementation, Maintenance.*

[b] *ACMs: Asthma Care Managers.*

Weights ranging from 1–9 were assigned by coders, to illustrate relative application of RE-AIM domains during planning, based on meeting agendas and minutes: 1–4 indicates = low application, 5–6 = medium application, 7–8 = high application, and 9–10 = very high application of the framework (7).

for Reach and Implementation, reflected the team's chief foci during intervention planning. Parameters for designing the intervention included using technology to enhance usual care by addressing asthma risk factors. Meeting minutes reflected a focus on risk factor data outputs from the EHR and stakeholder input from the ACMs to identify processes and potential opportunities for enhancement. Process metrics to monitor fidelity were established during planning to be used during implementation, e.g., percent of identified patients contacted by the ACM, ACM perceptions of changes to how they allocated their time, and ACM perceptions of benefit of the intervention to patients. In addition, multiple conversations about integrating the technology into the system to resolve technology-related challenges took place throughout the planning process.

Moderate framework application for effectiveness (six points), was evidenced by discussions in the early stages of planning that reviewed asthma care performance indicators and patient health data to identify an appropriate intervention. Lastly, adoption and maintenance had low framework application (four points and three points, respectively), evidenced by limited discussion of what it might take for the technological intervention to be sustained beyond the study period as a part of routine care. While adoption discussions that considered Breathewell's acceptability to the ACMs and physicians involved in direct service delivery took place with relative frequency, strategic and fiscal decision-makers were not identified or discussed during planning. For example, the importance of capturing costs, a topic that is acknowledged as highly relevant to adoption and maintenance decisions at the health systems level (12), was discussed intermittently, from the perspective of costs relevant to the design and ongoing maintenance of Breathewell, should another healthcare system want to adopt it. The team also discussed quantifying the value of reallocating ACM time toward patients at higher risk for exacerbations, and reducing time spent reviewing charts and providing outreach to asymptomatic, well-managed patients based solely on their beta-agonist refill request.

It was acknowledged that communicating how Breathewell added value would be necessary for its continuation after the study was completed.

Interviews

The results of our combined RE-AIM and CFIR analyses of interview transcripts follows, organized by strongest to weakest alignment within the setting-level RE-AIM domains of implementation, adoption, and maintenance.

Implementation

Team reflections confirmed moderate to strong alignment with CFIR constructs associated with the Process domain. Where possible, the Breathewell intervention was designed to align with established protocols and minimize changes to existing information flows between departments. As one person confirmed, "there was really nothing within the pharmacy department that changed because where the project was really focusing on was at the junction between the pharmacy and the asthma care managers…" Also, a team member explained that manual daily monitoring of patients was instituted to assure every patient received appropriate care, and that no patient was missed, "The data pull part is essentially automated with the exception of IT issues that come up from time to time. So that part is automated but the manual checking—that takes a few minutes every morning."

Team members agreed that involvement of stakeholders was necessary to promote their buy-in and the fit of the intervention within established workflows. Attention was paid to *engaging opinion leaders,* "[the] asthma doc helped us get any other additional signoff we [needed]..."

Formally appointing key stakeholders as members of the implementation planning team early on, was emphasized by several people as critical, "…it meant that the nurse, who was one of the asthma care managers, met every time we met, and she became the go-between between the [ACMs] and our team, and very much a part of our team."

On the other hand, *engaging champions* was limited to those stakeholders who were formally appointed as members of the planning team (i.e., asthma care physician, clinical pharmacy specialist, and ACM). For example, one person noted that narrow awareness of the study presented a threat to fidelity when a group inadvertently made changes within the EHR that impacted intervention programming, stating that "… no one would have thought that changing a couple of words in a template that they (pharmacists) were using would impact this thing over here that we were doing in the research space." In response the team instituted daily monitoring to identify unexpected problems, but acknowledged this was not a sustainable solution, "we monitor things daily … to make sure that if something does happen [that] we didn't realize was going to happen we catch it." Another explained that settling for a monitoring vs. a programming solution was partly due to the time and budget constraints of research, "figuring out how to not have it be a research person who does so much oversight… it's a real catch-22 of how do you decide when and where to put that effort?"

Team activities and decisions that especially supported implementation fidelity, i.e., taking time for *planning* and *executing* the intervention according to protocol were evident:

> …from my perspective there have been very, very few bumps along the road of big things that needed to be changed ... that those things are being identified in the planning process and not waiting until they get to implementation.

Also, a clear focus of the team when designing the intervention was the need for alignment with the organization's *culture* that emphasizes patient safety and service quality, a construct associated with the Inner Setting domain:

> the perspective of trying to take a more population-based approach to something, to be more all-encompassing, to make sure everyone's getting consistent care to make sure that we're reaching everyone, that it's as timely and innovative and as cost effective as it can be… I think speaks to the culture of …[the] organization. So I see it aligning really well…

CFIR constructs associated with Intervention Characteristics greatly influenced planning, with moderate to strong emphasis. Designing a technology-based intervention that required interface with patient devices, healthcare data systems, and providers was acknowledged to be highly *complex*:

> So there were potential barriers –on how to extract data from the – several databases and how to integrate them and put them together, and how to fuel that or feed that over so the [intervention] would actually run and work, and how to engage patients....

This complexity, in turn, constrained *adaptation* and *trialability*. One person said, "I think adaptations during the intervention would've been kind of difficult because it was already 'this is how it's going to be at the beginning'."

When asked about piloting components (i.e., *trialability*), this individual indicated that conducting a pilot was not feasible given the complex programming involved, "we did a lot …to make it work for that patient population to test it to make sure everything was working but there wasn't an actual pilot where we had like a 100 people start."

Adoption

As described above, there was a strong focus on two Inner Setting domains relevant to adoption: consistency of the intervention with organizational *culture* and assuring that Breathewell was *compatible* with technology-enabled communication tools and systems already in use. One person said, "[we] looked at the goals of innovation, of good care, of using technology to our advantage…" Another commented that "we were already doing outreaches as asthma care managers. So it was part of what we were already doing."

On the other hand, two Inner Setting CFIR constructs that would suggest a "pull" toward adopting the intervention, i.e., that it was driven by a *tension for change*, and that it was a strategic

priority, were not supported by team reflections. As one person stated, "people weren't asking for the intervention necessarily."

The absence of a clear pull was further confirmed when the team was asked about whether the decision to implement Breathewell was driven by research, operations, or organizational leaders, and the amount of *leadership engagement* in implementation planning. Team members agreed that the intervention was primarily based on their identification of an opportunity for improving efficiency of care, "I guess in all honestly we have to say this is our product. The [research institute] is driving the tweak that we're looking at here…"

Intervention Characteristics also were relevant to the potential post-trial adoptability of the intervention, given team-member belief that the intervention would provide a *relative advantage* to usual care by streamlining service delivery and reducing burden on ACMs. However, team members also acknowledged that it would be up to them to "push" the intervention to leadership by demonstrating that it provided a competitive advantage. "it was designed to make a difference on system effectiveness. . . . partially up to us to help others understand what niche we're filling."

Maintenance

From a Process perspective, despite the team's care in designing the intervention so that it would be compatible with existing infrastructure and align with cultural values that the "right patients receive the right care at the right time," there were a few "work arounds" necessitated by constraints to fully integrating the intervention into existing systems. *Planning* for post-trial modification and ongoing maintenance of Breathewell was weak. Members of the team acknowledged the intervention would need investment by the organization to fully integrate it into existing systems but had not yet evaluated the cost. One person stated that "the way it's currently structured, it's not that portable from a technical standpoint and that's probably the biggest concern I have in terms of translating it into – sustaining it in usual care."

From an Inner Setting perspective, as described earlier, providers and staff directly involved in asthma care management were engaged throughout planning, however, higher level organizational leadership were not. Uncertainty was expressed as to which individuals or level of approvals would be needed to continue Breathewell as usual care because there was no prior commitment from operations leadership to allocate *available resources* to sustaining Breathewell after the trial.

From an Intervention Characteristics perspective, given that Breathewell is a technology-based intervention designed to improve efficiency, the team expressed the potential to promote post-trial maintenance by demonstrating its alignment with organizational priorities of optimizing efficiency without sacrificing quality:

> If we can demonstrate it's cost-effective to usual care, we might be able to still have it translated, but if it turns out that there's not really any cost implications, I think in the short-term, … [there won't be interest] in doing it.

Figure 2 summarizes the relative strength of alignment between team responses to the interview questions and the sub-set of CFIR constructs deemed relevant to the setting-level RE-AIM domains of Adoption, Implementation and Maintenance.

DISCUSSION

> "It's kind of like – you go this direction, you run into a wall, you back up, you go that direction, you run into a wall. You just keep going until you find the path."

In this qualitative evaluation of planning for the implementation of an effective intervention of technology enhanced asthma care management, we found that formally appointing key stakeholders as planning team members, addressing workflow and system complexity, and assuring compatibility with organizational culture were key factors in promoting very high implementation fidelity. We also found that weak alignment of planning activities with Inner Setting CFIR constructs that promote leadership receptivity to interventions, such as identifying a tension for change, aligning the intervention with relative priorities, and engaging leadership in planning, likely limited post-trial adoption and maintenance of the intervention. Furthermore, by excluding CFIR constructs associated with the Outside Setting and Individual Characteristics domains, our analyses of planning overlooked potential facilitators of adoption and maintenance that may have further informed planning activities, such as competitive pressure on the organization, as well as potential barriers such as the knowledge and beliefs about the value of the intervention to the organization.

This is the first study known to us that comprehensively evaluated the planning activities and team reflections using RE-AIM and CFIR frameworks. Combining frameworks judiciously enhanced our ability to develop testable, theory-informed implementation strategies (27). Applying RE-AIM to the objective and prospectively documented meeting agendas and minutes, we observed that throughout planning the team was focused on identifying problems and solutions to ensure maximal reach of the target population, minimize disruption to existing workflows while assuring the intervention delivered patient services effectively, and with high implementation fidelity. Discussions of systems-level barriers related to the complexities of integrating a technology-based intervention into multiple electronic communication systems demonstrated the team's concerns about threats to maintaining the intervention beyond the study. However, missing from the agendas and minutes were discussions about who would ultimately need to approve and allocate organizational resources to maintain Breathewell. The result was an intervention with relatively high reach (i.e., 1080 patients (84.5%) of those potentially overusing a beta agonist, were reached for EHR assessment); and high fidelity (i.e., the Breathewell intervention was completed as designed with few exceptions). The intervention also effectively improved the efficiency of care delivery, as 41% of too-frequent asthma reliever inhaler requests were resolved by the IVR intervention (i.e., did not require ACM outreach) (24). Yet despite success in Reach, Effectiveness (i.e., improved efficiency), and Implementation, the team agreed there was low likelihood that Breathewell

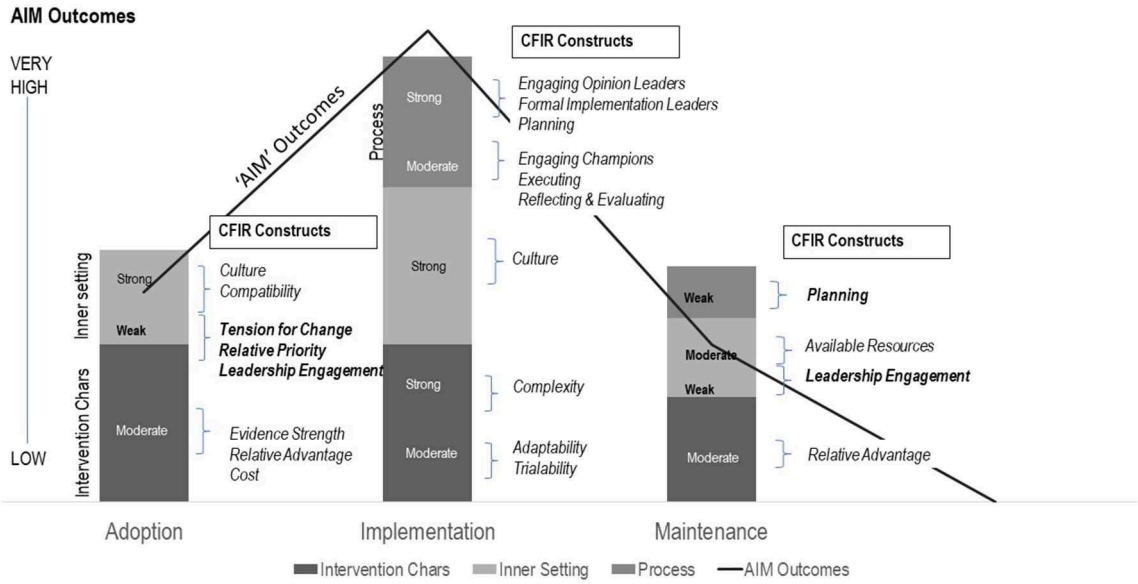

FIGURE 2 | Adoption, implementation, and maintenance outcomes, explained by weak, moderate, or strong alignment with CFIR constructs. CFIR constructs were grouped within "AIM" domains, based on theory and consensus, and were assigned points to indicate their relative emphasis during planning (weak = 1; moderate = 2; strong = 3). An average "score" was then calculated for the CFIR domains of *Intervention Characteristics (Chars)*, *Inner Setting*, and *Process* to create the stacked columns in the figure. The AIM Outcomes line graph was generated based on methods recommended by Glasgow et al. (7) for weighting relative application of RE-AIM domains by scoring them as follows: 1–4 = low application, 5–6 = medium application, 7–8 = high application, and 9–10 = very high application of the framework.

would be adopted and maintained. While partial use of RE-AIM (i.e., use of select domains) has been supported by its authors in recent reviews of the framework (6, 12), attention to all five RE-AIM domains during planning is necessary for implementation success. Discussions of maintenance at the onset and throughout implementation planning is particularly important for multi-year projects, to identify any unanticipated changes in the outer and/or inner setting domains that might impact organizational priorities.

When combining frameworks, it is important to ensure they can yield complementary information and avoid overly complex, conflicting or redundant sets of constructs (27). Recommendations and tools for selecting the most appropriate frameworks for different purposes are under development (28, 29) and in the future can potentially help implementation scientists select the most relevant frameworks for their specific project needs. At minimum, justification for why a framework or combination of frameworks were selected should be provided (30).

In this project, using CFIR constructs to guide team reflection illuminated the presence or absence of motivational and structural factors that, if attended to, could have improved the likelihood of adoption and maintenance. Present were characteristics of the intervention itself that were carefully aligned with organizational *culture* and assured its *compatibility* with existing infrastructure. Absent were several indicators related to *institutional climate* and *readiness*, which, if present, could potentially increase motivation or "pull" to adopt the intervention. The absent factors included lack of a known *tension for change*, *relative priority,* or a pre-existing agreement from leadership to commit *available resources* to fully integrate and maintain Breathewell if it was effective. The team acknowledged that, in hindsight, the lack of *leadership engagement* or *champions* outside of the implementation team and asthma care managers, (e.g., IT, pharmacy, and healthplan and asthma leadership), may have limited its full integration into organizational systems and workflows.

It was illuminating to reflect on our planning processes through a CFIR lens. However, unlike RE-AIM, where consideration of all five domains can improve implementation and dissemination outcomes across diverse interventions (31), the relevance of the CFIR domains and constructs used to explain why implementation succeeded or failed may vary by intervention and setting (32). For example, constructs associated with behavior change, such as *self-efficacy* and *individual stage of change* (33, 34) are accepted as important to human-delivered interventions but are likely less necessary for successful implementation of an automated intervention. On the other hand, post-trial adoption and maintenance of an internally developed intervention can still require demonstration of its relative advantage from a patient, competitor or regulator perspective (17). Thus, while CFIR is designed to be flexible, all five CFIR domains should be reviewed during planning to proactively identify which sets of constructs may influence full integration of the intervention into usual care, as well as receptivity or "pull" to adopt and maintain the intervention post-trial, and any constructs that are not relevant given the project.

TABLE 4 | Key lessons for implementation planners.

Lesson 1	Time spent in planning for implementation, that involves decision-makers and stakeholders as members of the planning team, is critical to implementation success
Lesson 2	Use of D&I frameworks both prospectively, to assess potential threats to implementation and to evaluate process and outcomes, will guide planning for implementation success
Lesson 3	No one D&I framework tells the whole story, so understanding their strengths and limits, and justifying your selection is important
Lesson 4	When using RE-AIM, all five domains enhance planning and should be monitored to assure implementation success
Lesson 5	When using CFIR, all five domains should be reviewed to identify presence or absence of relevant pull, push and infrastructure variables that can inform implementation strategies
Lesson 6	CFIR's Outer Setting domain and constructs identify relevant "pull" variables including industry trends, competitive pressure, leadership wants, and consumer demands
Lesson 7	Identifying and enlisting internal champions at all levels of the organization, who broadly promote and reinforce the value of the intervention, can facilitate implementation success

The practice change literature recommends that organizations take time for pre-implementation planning to assure that the intervention fits within existing systems, structures, and workflows (35, 36), and can be delivered with high fidelity (2). We found that our strong focus on several key determinants of implementation success: *engagement* of key stakeholders to understand their workflow challenges; knowledge of the organization's structural *complexity; compatibility* with its complex systems; and understanding of its *culture* that prioritized patient experiences and quality of care resulted in a technology-based intervention that was executed with high fidelity. However, planning to maximize fit and fidelity was insufficient to assure post-trial adoption and maintenance, given the absence of several determinants that are associated with "pull" in the diffusion literature (3, 37). The absence of these pull factors signals a need to use targeted dissemination or "push" strategies to elicit a "pull" to adopt and maintain the intervention (3, 4). Thus, our Breathewell implementation team could possibly use "push" strategies to create "pull" by promoting its alignment with the organization's *culture*, its *compatibility* with existing systems and services, and evidence of its *relative advantage* over the status quo. A key lesson is that while proactive attention to RE-AIM and CFIR factors throughout planning is ideal, using these frameworks to guide reflection at any time during implementation could help implementation teams increase pull, by (1) communicating how the intervention will specifically fulfill organizational leaders, stakeholders and patient wants and needs; and (2) specifying what investments are necessary to assure there is organizational capacity to sustain it. A summary of our key lesson learned can be found in **Table 4**.

Recommendations to Implementation Planning Teams to Improve the Odds of Implementation Success

When asked whether specific challenges were anticipated during planning, an implementation team member responded,

> I've learned that there's not much rationale to sitting and trying to figure out what's going to go wrong, per se, because it'll never be that...you have to plan a process for how you're going to make a decision when something does go wrong or when you run into a barrier, but not what that specific one is.

The extreme variation in external and internal contexts, structures, and types of interventions may limit the generalizability of our specific findings about factors whose presence or absence likely influenced our adoption, implementation and maintenance outcomes. Also, factors such as the tension for change and organizational priorities may shift over the course of a multi-year study, given the dynamic context in which healthcare operates. We therefore recommend that implementation teams take the time to identify a set of relevant system- and intervention-specific determinants of adoption, implementation and maintenance, tailor their implementation strategies, and build in a process to periodically reflect and re-evaluate factors and strategies for continued relevance. Doing so will create an ongoing method for identifying and resolving problems as they occur. For specific strategies to increase RE-AIM Adoption, Maintenance, and Implementation success (see **Table 5**).

LIMITATIONS

While our use of the two frameworks in combination enabled us to not only evaluate, the *who*, *what*, *where*, *when* and *how* (RE-AIM) but to also explain *why* (CFIR) implementation may have succeeded or failed, particularly with regard to the presence or absence of pull factors (e.g., tension for change or peer pressure), other frameworks, such as PRISM, include contextual variables useful to adapting interventions to improve their fit and feasibility (38). Also, outcome-specific frameworks such as the Program Sustainability Assessment Tool (39), which focuses on setting-level maintenance, can be used to define the sets of conditions that need to be present or absent to sustain practice change (10, 40).

We also made some theory-informed decisions in an attempt to identify which CFIR constructs most likely influenced specific RE-AIM domains. We discovered, however, that while some constructs were well-understood as important determinants to success within a specific domain (e.g., *tension for change* for Adoption; commitment of *available resources* for Maintenance) (41); others may be relevant to performance on multiple RE-AIM domains (e.g., *leadership engagement* for Adoption and Maintenance, and *culture* for Adoption and

TABLE 5 | Examples of implementation strategies recommended to address CFIR constructs and improve RE-AIM outcomes.

Strategies to increase adoption and maintenance	
Why should the organization invest resources in this intervention?	
CFIR constructs	**Implementation strategies**
Tension for change Relative priority	Engage leaders at proposal and funding stages; assess needs; identify/confirm relevant pull factors, current priorities and challenges; Increase demand for the intervention by selecting performance objectives and metrics that include at least one relevant pull factor; Develop a presentation and/or report that specifically ties the intervention to the performance objectives; clearly explains what "problem" the intervention solves; and how it supports priorities; Encourage leaders to champion or mandate the change by communicating its relative advantage and allocating resources
Track	Perceived value of, and satisfaction with, the intervention
Leadership engagement	Identify whose buy-in for implementing the intervention will be needed; Assess their understanding of the problem, and their receptivity to the proposed intervention; Increase demand for the intervention by reinforcing goal and priority alignment; Include leaders in all stages of the research including formative discussions and dissemination of findings
Track	Leadership use of process and fidelity data; reporting of feedback and findings in meetings and distribution of reports
Available resources	Identify the level of approvals that will be needed to allocate resources to modify and maintain the intervention; Determine what information (e.g., cost-benefit) they will require to commit to sustaining the change; Communicate cost-benefit data to all stakeholders
Track	Costs, cost reduction ideas, alternative funding ideas, solutions implemented
Reflecting and evaluating	Anticipate that specific preferences, needs, or demands may change given the amount of time that often elapses between proposal, funding, and study completion; Continue to engage (or re-engage) leaders throughout the study; Continue to review implementation protocols, share feedback; Disseminate progress or new evidence throughout the study, to elicit or maintain pull
Track	Changes that may impact priorities and threaten sustainability; integration of intervention into existing operations including onboarding, performance expectations, documentation, quality reports
Strategies to increase implementation fit and fidelity	
How do we design the intervention so that it could become a part of routine care?	
Complexity	Include internal systems experts and users in the design team; Avoid "work arounds" or have a plan (e.g., blueprint) for fully integrating the intervention into existing workflows and systems; Conduct rapid cycle tests, adapt/ refine with expert and user input
Track	Representativeness of implementation planning team; assigned roles; and extent of participation
Compatibility	Promote adaptability of intervention; Design intervention protocols to fit with existing roles and systems; Draft written protocols that can be piloted; Conduct rapid cycle tests of protocols, adapt and refine with user input; Revise written protocols to reflect user input
Track	Development and/or adaptation of written protocols, training, implementation guides
Culture	Include internal stakeholders who can identify the organizational values and norms that must be preserved by the intervention; Review workflows, training and resources for consistency with organization's values and norms; Develop and test monitoring protocols; Design and test a standard report that can be used to identify problems and address them iteratively
Track	Fidelity to established protocols, including reach and unanticipated positive or negative consequences of the intervention
OTHER	Assess for other CFIR constructs that may be relevant to implementing the proposed intervention at the System-level (e.g., networks and communication; incentives and rewards); Provider and staff-levels (e.g., knowledge and beliefs, self-efficacy); Intervention-type (e.g., adaptability, trialability)

Strategies adapted and incorporated tips and recommendations from CFIR-ERIC Implementation Strategy Matching Tool (20) and RE-AIM key questions and tips for improving AIM performance (8).

Implementation) (1). Formally measuring the CFIR constructs and modeling them quantitatively may be useful to determine the extent specific constructs, moderated or mediated the individual RE-AIM domain outcomes (42). On the other hand, since several of the CFIR constructs overlap (e.g., leaders, stakeholders, or champions may be the same or different people, depending on their role in implementation), what or who to measure would need to be defined for the specific setting and intervention (43). It may be the case that it is not practical to measure organizations on a wide range of hypothesized determinants, and impractical to generalize which CFIR factors are determinants of which RE-AIM domains.

Our study reveals several areas for future research. First, complementary application of RE-AIM and CFIR to other implementation studies is needed to confirm the utility of

using CFIR constructs to explain and improve performance on RE-AIM domains. Second, applying analytic methods, such as qualitative comparative analysis (10), to compare sets of factors or conditions that are sufficient or necessary to implementation success, may help to inform appropriate implementation strategies. Third, using measures to quantitively model the pathways in which CFIR factors moderate (pull) or mediate (push) RE-AIM results may lead to an integrated conceptual model that will improve their complementary use. Last, experimentally testing implementation strategies designed to promote conditions favorable to implementation success, such as those recommended in **Table 5**, will contribute to improving the effectiveness of implementation planning.

CONCLUSIONS

Our study addresses an important gap in implementation science—illustrating how complementary application of evaluation (RE-AIM) and explanatory (CFIR) frameworks can identify the presence or absence of variables necessary for implementation success. This approach demonstrated that attention to factors important to maximizing the fit of an intervention within a healthcare system, and monitoring patient receipt of the most appropriate services, yielded an intervention with high reach and implementation fidelity, but low likelihood of post-trial adoption or maintenance. We identified modifiable CFIR constructs that could improve receptivity to adopt and maintain evidence-based interventions. We recommend early assessment and attention to these constructs to inform tailoring of implementation strategies to maximize implementation success.

DATA AVAILABILITY STATEMENT

The datasets generated for this study are available on request to the corresponding author.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Institutional Review Board at Kaiser Permanente Colorado. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

AUTHOR CONTRIBUTIONS

DK and JS developed the design plan, selection of frameworks, analytic approach, development of interview questions, and a priori codes. JS and CA assisted with compiling and coding of historical documents and conducted the implementation team interviews. DK and JS coded and analyzed intervention transcripts, which were validated by BB, MR, DR, NW, and CA. All authors contributed content, provided feedback on tables and figures, reviewed the manuscript, and contributed to the concept and design of the study.

FUNDING

The development and publication of this article was funded by the National Institute of Allergy and Infectious Diseases (R01HL126125).

REFERENCES

1. Huijg JM, Crone MR, Verheijden MW, van der Zouwe N, Middelkoop BJ, Gebhardt WA. Factors influencing the adoption, implementation, and continuation of physical activity interventions in primary health care: a Delphi study. *BMC Fam Pract*. (2013) 14:142. doi: 10.1186/1471-2296-14-142
2. King DK, Neander LL, Edwards AE, Barnett JD, Zold AL, Hanson BL. Fit and feasibility: adapting a standardized curriculum to prepare future health professionals to address alcohol misuse. *Pedagogy Health Promot*. (2019) 5:107–16. doi: 10.1177/2373379918785924
3. Dearing JW, Kreuter MW. Designing for diffusion: how can we increase uptake of cancer communication innovations? *Patient Educ Couns*. (2010) 81(Suppl):S100–10. doi: 10.1016/j.pec.2010.10.013
4. Brownson RC, Fielding JE, Green LW. Building capacity for evidence-based public health: reconciling the pulls of practice and the push of research. *Annu Rev Public Health*. (2018) 39:27–53. doi: 10.1146/annurev-publhealth-040617-014746
5. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health*. (1999) 89:1322–7. doi: 10.2105/AJPH.89.9.1322
6. Gaglio B, Shoup JA, Glasgow RE. The RE-AIM framework: a systematic review of use over time. *Am J Public Health*. (2013) 103:e38–46. doi: 10.2105/AJPH.2013.301299
7. Glasgow RE, Estabrooks PE. Pragmatic applications of RE-AIM for health care initiatives in community and clinical settings. *Prev Chronic Dis*. (2018) 15:E02. doi: 10.5888/pcd15.170271
8. RE-AIM Website: www.re-aim.org (accessed June 1, 2019).
9. Peek CJ, Glasgow RE, Stange KC, Klesges LM, Purcell EP, Kessler RS. The 5 R's: an emerging bold standard for conducting relevant research in a changing world. *Ann Fam Med*. (2014) 12:447–55. doi: 10.1370/afm.1688
10. King DK, Gonzalez SJ, Hartje JA, Hanson BL, Edney C, Snell H. Examining the sustainability potential of a multisite pilot to integrate alcohol screening and brief intervention within three primary care systems. *Transl Behav Med*. (2018) 8:776–84. doi: 10.1093/tbm/ibx020
11. Weiner BJ. A theory of organizational readiness for change. *Implement Sci*. (2009) 4:67. doi: 10.1186/1748-5908-4-67
12. Glasgow RE, Harden SM, Gaglio B, Rabin B, Smith ML, Porter GC, et al. RE-AIM planning and evaluation framework: adapting to new science and practice with a 20-year review. *Front Public Health*. (2019) 7:64. doi: 10.3389/fpubh.2019.00064
13. Wagner EH, Austin BT, Davis C, Hindmarsh M, Schaefer J, Bonomi A. Improving chronic illness care: translating evidence into action. *Health Aff*. (2001) 20:64–78. doi: 10.1377/hlthaff.20.6.64
14. Feldstein AC, Glasgow RE. A practical, robust implementation and sustainability model. (PRISM) for integrating research findings into practice. *Jt Comm J Qual Patient Saf*. (2008) 34:228–43. doi: 10.1016/S1553-7250(08)34030-6
15. Kaplan HC, Brady PW, Dritz MC, Hooper DK, Linam WM, Froehle CM, et al. The influence of context on quality improvement success in health care: a systematic review of the literature. *Milbank Q*. (2010) 88:500–59. doi: 10.1111/j.1468-0009.2010.00611.x
16. Holtrop JS, Rabin BA, Glasgow RE. Qualitative approaches to use of the RE-AIM framework: rationale and methods. *BMC Health Serv Res*. (2018) 18:177. doi: 10.1186/s12913-018-2938-8

17. Oh A, Gaysynsky A, Knott CL, Nock NL, Erwin DO, Vinson CA. Customer discovery as a tool for moving behavioral interventions into the marketplace: insights from the NCI SPRINT program. *Transl Behav Med*. (2019) 9:1139–50. doi: 10.1093/tbm/ibz103
18. Yano EM. The role of organizational research in implementing evidence-based practice: QUERI Series. *Implement Sci*. (2008) 3:29. doi: 10.1186/1748-5908-3-29
19. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci*. (2009) 4:50. doi: 10.1186/1748-5908-4-50
20. Consolidated framework for implementation research website: www.cfirguide.org (accessed June 1, 2019).
21. Breimaier HE, Heckemann B, Halfens RJ, Lohrmann C. The Consolidated Framework for Implementation Research. (CFIR): a useful theoretical framework for guiding and evaluating a guideline implementation process in a hospital-based nursing practice. *BMC Nurs*. (2015) 14:43. doi: 10.1186/s12912-015-0088-4
22. Powell BJ, Beidas RS, Lewis CC, Aarons GA, McMillen JC, Proctor EK, et al. Methods to improve the selection and tailoring of implementation strategies. *J Behav Health Serv Res*. (2017) 44:177–94. doi: 10.1007/s11414-015-9475-6
23. Raebel MA, Shetterly SM, Goodrich GK, Anderson CB, Shoup JA, Wagner N, et al. Non-response to communication technology outreach for beta-agonist overuse in a pragmatic randomized trial of patients with asthma. *J Gen Intern Med*. (2018) 33:809–11. doi: 10.1007/s11606-018-4395-9
24. Bender BG, Wagner NM, Shoup JA, Goodrich GK, Shetterly SM, Cvietusa PJ, et al. Adults with asthma experience no increase in asthma related exacerbations when technology enabled communication tools are employed to offset clinician workload: a pragmatic randomized trial. *Med Care*. (2019). doi: 10.1097/MLR.0000000000001265. [Epub ahead of print].
25. Bowen GA. Document analysis as a qualitative research method. *Qual Res J*. (2009) 9:27–40. doi: 10.3316/QRJ0902027
26. King DK, Glasgow RE, Leeman-Castillo BA. RE-AIMing RE-AIM: using the model to plan, implement, evaluate, and report the impact of environmental change approaches to enhance population health. *Am J Public Health*. (2010) 100:2076–84. doi: 10.2105/AJPH.2009.190959
27. Birken SA, Powell BJ, Presseau J, Kirk MA, Lorencatto F, Gould NJ, et al. Combined use of the Consolidated Framework for Implementation Research (CFIR) and the Theoretical Domains Framework (TDF): a systematic review. *Implement Sci*. (2017) 12:2. doi: 10.1186/s13012-016-0534-z
28. Birken SA, Powell BJ, Shea CM, Haines ER, Alexis Kirk M, Leeman J, et al. Criteria for selecting implementation science theories and frameworks: results from an international survey. *Implement Sci*. (2017) 12:124. doi: 10.1186/s13012-017-0656-y
29. Birken SA, Rohweder CL, Powell BJ, Shea CM, Scott J, Leeman J, et al. T-CaST: an implementation theory comparison and selection tool. *Implement Sci*. (2018) 13:143. doi: 10.1186/s13012-018-0836-4
30. Nilsen P. Making sense of implementation theories, models and frameworks. *Implement Sci*. (2015) 10:53. doi: 10.1186/s13012-015-0242-0
31. Klesges LM, Estabrooks PA, Dzewaltowski DA, Bull SS, Glasgow RE. Beginning with the application in mind: designing and planning health behavior change interventions to enhance dissemination. *Ann Behav Med*. (2009) 29-S:66–75. doi: 10.1207/s15324796abm2902s_10
32. Keith RE, Crosson JC, O'Malley AS, Cromp D, Taylor EF: Using the Consolidated Framework for Implementation Research (CFIR) to produce actionable findings: a rapid-cycle evaluation approach to improving implementation. *Implement Sci*. (2017) 12:15. doi: 10.1186/s13012-017-0550-7
33. Bandura A. Self-efficacy. In: Ramachaudran VS, editor. *Encyclopedia of Human Behavior*, Vol. 4. New York, NY: Academic Press (1994). p. 71–81.
34. Grol RP, Bosch MC, Hulscher ME, Eccles MP, Wensing M. Planning and studying improvement in patient care: the use of theoretical perspectives. *Milbank Q*. (2007) 85:93–138. doi: 10.1111/j.1468-0009.2007.00478.x
35. Kilbourne AM, Neumann MS, Pincus HA, Bauer MS, Stall R. Implementing evidence-based interventions in health care: application of the replicating effective programs framework. *Implement Sci*. (2007) 2:42. doi: 10.1186/1748-5908-2-42
36. Huynh AK, Hamilton AB, Farmer MM, Bean-Mayberry B, Stirman SW, Moin T, et al. A pragmatic approach to guide implementation evaluation research: strategy mapping for complex interventions. *Front Public Health*. (2018) 6:134. doi: 10.3389/fpubh.2018.00134
37. Green LW, Ottoson JM, Garcia C, Hiatt RA. Diffusion theory and knowledge dissemination, utilization, and integration in public health. *Annu Rev Public Health*. (2009) 30:151–74. doi: 10.1146/annurev.publhealth.031308.100049
38. McCreight MS, Rabin BA, Glasgow RE, Ayele RA, Leonard CA, Gilmartin HM, et al. Using the Practical, Robust Implementation and Sustainability Model. (PRISM) to qualitatively assess multilevel contextual factors to help plan, implement, evaluate, and disseminate health services programs. *Transl Behav Med*. (2019) 9:1002–11. doi: 10.1093/tbm/ibz085
39. Calhoun A, Mainor A, Moreland-Russell S, Maier RC, Brossart L, Luke DA. Using the program sustainability assessment tool to assess and plan for sustainability. *Prev Chronic Dis*. (2014) 11:130185. doi: 10.5888/pcd11.130185
40. Luke DA, Calhoun A, Robichaux CB, Elliott MB, Moreland-Russell S. The program sustainability assessment tool: a new instrument for public health programs. *Prev Chronic Dis*. (2014) 11:130184. doi: 10.5888/pcd11.130184
41. Weiner BJ, Belden CM, Bergmire DM, Johnston M. The meaning and measurement of implementation climate. *Implement Sci*. (2011) 6:78. doi: 10.1186/1748-5908-6-78
42. Fernandez ME, Walker TJ, Weiner BJ, Calo WA, Liang S, Risendal B, et al. Developing measures to assess constructs from the inner setting domain of the consolidated framework for implementation research. *Implement Sci*. (2018) 13:52. doi: 10.1186/s13012-018-0736-7
43. Proctor E, Silmere H, Raghavan R, Hovmand P, Aarons G, Bunger A, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Adm Policy Ment Health*. (2011) 38:65–76. doi: 10.1007/s10488-010-0319-7

Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

frontiers in Public Health

ORIGINAL RESEARCH
published: 20 December 2019
doi: 10.3389/fpubh.2019.00389

Adapting and Operationalizing the RE-AIM Framework for Implementation Science in Environmental Health: Clean Fuel Cooking Programs in Low Resource Countries

Ashlinn K. Quinn[1], Gila Neta[2], Rachel Sturke[1], Christopher O. Olopade[3], Suzanne L. Pollard[4], Kenneth Sherr[5] and Joshua P. Rosenthal[1]*

[1] Fogarty International Center, U.S. National Institutes of Health, Bethesda, MD, United States, [2] National Cancer Institute, U.S. National Institutes of Health, Bethesda, MD, United States, [3] University of Chicago Medicine, University of Chicago, Chicago, IL, United States, [4] Department of Medicine, Johns Hopkins University, Baltimore, MD, United States, [5] Department of Global Health, University of Washington, Seattle, WA, United States

OPEN ACCESS

Edited by:
Russell E. Glasgow, University of Colorado Hospital, United States

Reviewed by:
Sapana R. Patel, Columbia University, United States
Anna Chapman, Deakin University, Australia

***Correspondence:**
Ashlinn K. Quinn
ashlinn.quinn@nih.gov

Specialty section:
This article was submitted to Public Health Education and Promotion, a section of the journal Frontiers in Public Health

Received: *14 June 2019*
Accepted: *02 December 2019*
Published: *20 December 2019*

Citation:
Quinn AK, Neta G, Sturke R, Olopade CO, Pollard SL, Sherr K and Rosenthal JP (2019) Adapting and Operationalizing the RE-AIM Framework for Implementation Science in Environmental Health: Clean Fuel Cooking Programs in Low Resource Countries. Front. Public Health 7:389. doi: 10.3389/fpubh.2019.00389

Introduction: The use of models and frameworks to design and evaluate strategies to improve delivery of evidence-based interventions is a foundational element of implementation science. To date, however, evaluative implementation science frameworks such as *Reach, Effectiveness, Adoption, Implementation, Maintenance* (RE-AIM) have not been widely employed to examine environmental health interventions. We take advantage of a unique opportunity to utilize and iteratively adapt the RE-AIM framework to guide NIH-funded case studies of the implementation of clean cooking fuel programs in eleven low- and middle-income countries.

Methods: We used existing literature and expert consultation to translate and iteratively adapt the RE-AIM framework across several stages of the NIH Clean Cooking Implementation Science case study project. Checklists and templates to guide investigators were developed at each stage.

Results: The RE-AIM framework facilitated identification of important emerging issues across this set of case studies, in particular highlighting the fact that data associated with certain important outcomes related to health and welfare are chronically lacking in clean fuel programs. Monitoring of these outcomes should be prioritized in future implementation efforts. As RE-AIM was not originally designed to evaluate household energy interventions, employing the framework required adaptation. Specific adaptations include the broadening of *Effectiveness* to encompass indicators of success toward any stated programmatic goal, and expansion of *Adoption* to include household-level uptake of technology.

Conclusions: The RE-AIM implementation science framework proved to be a useful organizing schema for 11 case studies of clean fuel cooking programs, in particular highlighting areas requiring emphasis in future research and evaluation efforts. The

iterative approach used here to adapt an implementation science framework to a specific programmatic goal may be of value to other multi-country program efforts, such as those led by international development agencies. The checklists and templates developed for this project are publicly available for others to use and/or further modify.

Keywords: RE-AIM, household air pollution, case studies, clean cooking, implementation science, program evaluation

INTRODUCTION

The Health Potential of Cooking With Clean Fuels

Reducing the morbidity and mortality attributable to cooking with solid fuels (e.g., wood, dung, charcoal, and crop residues) and kerosene is a significant public health priority. Approximately 3 billion people currently cook with these polluting fuels, and exposure to household air pollution (HAP) from burning these materials is estimated to result in 2.6–4.3 million premature deaths a year (1, 2). Shifting to cleaner alternatives [e.g., liquefied petroleum gas (LPG), ethanol, biogas, and electricity] would result in progress toward multiple global goals, from improvement in public health to climate change mitigation (3). As the transition to cleaner cooking technologies has already occurred in higher-income countries, the existing imperative is therefore one of implementation: how do we achieve the extension of what is known (clean fuels reduce air pollution and protect health) to what is practiced (sustained and exclusive use of clean fuels for cooking), in the variety of settings where people rely on polluting solid fuels to meet their cooking needs?

There are numerous examples demonstrating the implementation gap that has impeded the achievement of health goals in the clean cooking sphere. For example, many programs have promoted "improved" stoves that still use relatively unprocessed biomass fuels such as wood and charcoal. While they may reduce fuel use, often can be produced locally, and may provide some reduction in air pollution, these stoves generally do not reduce pollution to the guideline levels established by the World Health Organization (WHO) that are understood to be required to minimize adverse health impacts (2). A shift in focus to stoves powered by "clean" fuels such as gas (biogas/LPG/natural gas), electricity, and in some cases processed biomass pellets (4) would help greatly in at least setting the stage for achieving the HAP reductions that are sought.

All these fuels require money to purchase, however, so financing for clean stoves and fuels is another area ripe for implementation research. As is true for many other development objectives, the populations most affected by HAP are often those least able to afford the financial investments required to transition to clean fuels (5, 6). Nonetheless, income has been shown to be less strongly associated with use of clean fuels than otherwise might be expected (7). Meanwhile, despite the fact that recent field and modeling studies show that exclusive or near exclusive use of clean fuels is required to achieve the WHO air quality targets (8, 9), adoption of clean fuels for cooking is often incomplete. Households regularly continue to cook with their traditional stoves even as they begin cooking with a new and cleaner stove (10), a practice called "stacking" which subverts the achievement of substantial air pollution reductions. Lastly, to achieve meaningful reductions in household air pollution, attention must also be paid to background ambient air quality that reflects larger, community-scale energy use and structural dynamics, and not just individual and household-level behaviors (11).

The Clean Cooking Implementation Science Network's Case Study Project

The field of implementation science is well-suited to investigate these questions (12). Implementation science makes ample use of theories and frameworks, which have been shown to enhance the effectiveness of evidence-based health interventions (13) by informing development of nd implementation strategies that are adapted to different settings and improve intervention success (14, 15). Employing the tools of implementation science to better understand how to close the clean-fuel cooking implementation gap has been identified as a priority by the U.S. National Institutes of Health (16), which launched the Clean Cooking Implementation Science Network (ISN), https://www.fic.nih.gov/About/Staff/Policy-Planning-Evaluation/Pages/clean-cooking-implementation-science-network.aspx, in 2015 in partnership with the U.S. Agency for International Development (USAID), the Centers for Disease Control and Prevention (CDC), the Environmental Protection Agency (EPA), and the Clean Cooking Alliance (CCA). The network is composed of researchers working on issues related to household air pollution and cooking energy transitions hailing from a number of academic disciplines (e.g., environmental health, medicine, epidemiology, economics, anthropology, and ecology), as well as government officials from relevant agencies and ministries, representatives of clean fuel implementing organizations and NGOs, and experts in implementation science. The guiding aims for the network are to advance the science of uptake and scale-up of clean-fuel cooking technology in low-and middle-income countries and to foster collaborative efforts and understanding among researchers and implementers toward this end.

The Clean Cooking ISN's case study project was initiated after a series of meetings in 2016 with the ISN network and its Steering Committee. In these meetings, participants identified a notable lack of documented literature relating to specific cases of success and/or failure of clean-fuel cooking implementation efforts, despite the fact that clean fuel programs and clean cooking programs are rolling out around the world. The Clean Cooking Alliance, a network of partners invested in expanding

adoption of clean cooking solutions, set an initial goal of fostering the adoption of clean cooking in 100 million homes globally by 2020 (17), a target that is likely to be exceeded. Meanwhile, efforts led by national governments and multinational organizations are promoting clean-fuel cooking solutions at a grand scale: India's Pradhan Mantri Ujjwala Yojana program, for example, reports that it has already expanded access to LPG to 85% of the national population (18). World Bank programs and other bilateral funders have also participated in funding and promoting clean-fuel cooking solutions. Despite all of this investment, however, evaluation of these programs has been minimal to date.

The ISN thus initiated a call for proposals in late 2016 for the development of case studies to evaluate clean fuel cooking programs in low and middle-income countries. Eleven programs were selected for development into case studies and were subsequently published as a Special Issue in *Energy for Sustainable Development*, titled "Scaling up clean fuel cooking programs in low and middle-income countries"(19). Briefly, the case studies comprise: four LPG scale-up initiatives, in Cameroon, Ghana, Indonesia, and Peru; two biogas programs, in Cambodia and East Africa; two compressed biomass projects, in Rwanda and China; two alcohol fuel programs, in Ethiopia and Nigeria; and a case study of energy transitions in Ecuador encompassing both a historical LPG effort and a more recent electric induction program (see **Table 1**).

The RE-AIM Framework

We chose to organize the case study project around the commonly used implementation science framework, *Reach, Effectiveness, Adoption, Implementation, Maintenance* (RE-AIM) (20), in an effort to standardize data collection and reporting. RE-AIM is one of the most frequently applied implementation frameworks (21), and had previously been introduced to the ISN network at its initial network meeting in 2015. RE-AIM is often used to evaluate programs and thus was seen as appropriate to the largely retrospective nature of the case study project. Although RE-AIM has previously been used outside of health care systems [see (21, 22) for some examples], and the developers of RE-AIM have been actively engaged in exploring applications of the framework in a diversity of settings (23), applications of RE-AIM in low- and middle-income countries (LMICs) are still relatively uncommon. To date there are also relatively few examples of the use of RE-AIM in the field of environmental health [see (24)]. The ISN felt that using RE-AIM to guide the case study project was an opportunity not only to learn generalizable lessons about clean cooking programs and compare case studies across countries, but also to provide the field with information that would advance the use of RE-AIM in LMIC settings.

The RE-AIM framework posits that public health impact of an evidence-based intervention will be achieved if an EFFECTIVE intervention REACHes a broad and representative segment of the population by being ADOPTED by willing organizations

TABLE 1 | Clean fuel cooking program case studies.

Case study title	Location	Cooking fuel	DOI
Assessment of the Cambodian national biodigester program	Cambodia	Biogas	https://doi.org/10.1016/j.esd.2018.06.008
The Government-led initiative for LPG scale-up in Cameroon: programme development and initial evaluation	Cameroon	LPG	https://doi.org/10.1016/j.esd.2018.05.010
Development of renewable, densified biomass for household energy in China	China	Biomass pellets and briquettes	https://doi.org/10.1016/j.esd.2018.06.004
Government policy, clean fuel access, and persistent fuel stacking in Ecuador	Ecuador	LPG; electricity	https://doi.org/10.1016/j.esd.2018.05.009
A case study of the ethanol CleanCook stove intervention and potential scale-up in Ethiopia	Ethiopia	Ethanol	https://doi.org/10.1016/j.esd.2018.06.009
Ghana's rural liquefied petroleum gas program scale up: A case study	Ghana	LPG	https://doi.org/10.1016/j.esd.2018.06.010
The Mega conversion program from kerosene to LPG in Indonesia: lessons learned and recommendations for future clean cooking energy expansion	Indonesia	LPG	https://doi.org/10.1016/j.esd.2018.05.011
Africa biogas partnership program: a review of clean cooking implementation through market development in East Africa	Kenya, Tanzania, Uganda	Biogas	https://doi.org/10.1016/j.esd.2018.05.012
Building a consumer market for ethanol-methanol cooking fuel in Lagos, Nigeria	Nigeria	Ethanol/Methanol	https://doi.org/10.1016/j.esd.2018.06.007
An evaluation of the Fondo de Inclusión Social Energético program to promote access to liquefied petroleum gas in Peru	Peru	LPG	https://doi.org/10.1016/j.esd.2018.06.001
Implementation and scale-up of a biomass pellet and improved cookstove enterprise in Rwanda	Rwanda	Biomass pellets	https://doi.org/10.1016/j.esd.2018.06.005

and staff, IMPLEMENTED as intended, and MAINTAINED over time by organizations and individuals. Each of the five elements, thus, is equally important to success as measured by public health impact—and importantly, data associated with all five aspects are essential to understanding the success, or failure of any implementation effort and to generalize from this experience to other settings. Initially used primarily as an evaluation tool for health behavior research, RE-AIM has expanded to cover diverse public health content and multiple research stages, including planning and study design, as well as assessment and evaluation of programs and policies (22, 25). Here, we discuss how we used RE-AIM to develop a generalizable framework for use in the evaluation of clean fuel adoption programs in LMIC settings.

METHODS

RE-AIM was used at each stage of the case study project, namely: during the call for proposals, proposal evaluation and selection, data collection, manuscript writing, and summarization. The framework for clean-fuel cooking was iteratively adapted as the project progressed (see **Figure 1**). The main outputs of this process were two RE-AIM templates: first, a checklist used during the proposal stage (see **Table 2**); and second, a data collection template to guide case study teams in gathering and summarizing data for each RE-AIM dimension (see **Table 3**). The checklist in **Table 2** contained fields for case study developers to indicate the availability of data pertaining to each RE-AIM dimension, indicating whether the data were qualitative or quantitative in nature and a description of plans to collect any data that were not pre-existing.

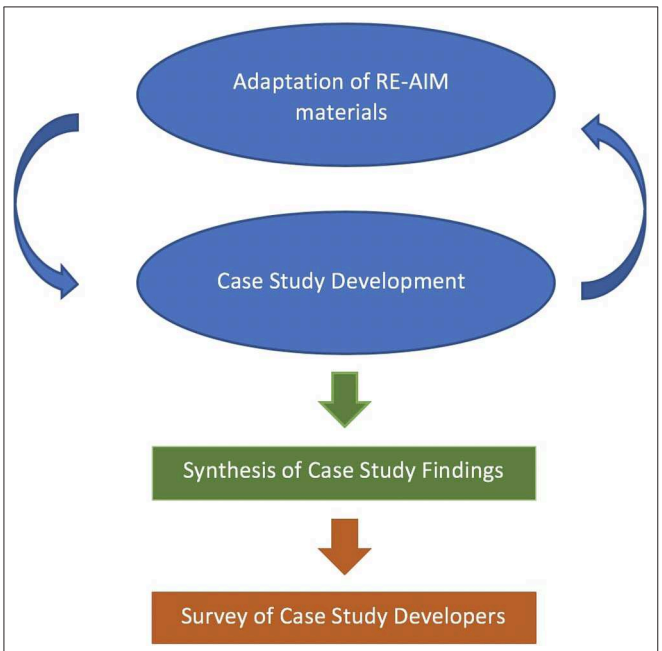

FIGURE 1 | Flow chart of activities.

Development of Templates for Case Study Proposal Selection and Case Study Development

The development of each of the two templates (the RE-AIM checklist and the data collection template) occurred iteratively. A case study working group comprised of ISN leadership and interested ISN members convened in a series of virtual meetings and via email correspondence to develop and refine these templates. The working group members were academics and government officials trained in a variety of specialties spanning the health sciences (epidemiology, environmental health, medicine, global health), social sciences (economics, anthropology, and management), and implementation science. In developing the templates, we consulted existing RE-AIM material (e.g., that available on the website re-aim.org) and prior literature on the use of RE-AIM in environmental health and community-based applications [e.g., (24, 26)]. We used these pre-existing materials alongside our prior knowledge of clean cooking programs to generate indicators that were thought to be relevant to the case study project.

Over time, we iteratively modified the indicators based on feedback and the experiences of the case study teams. For example, each prospective case study team submitted a RE-AIM checklist (**Table 2**) along with their case study proposal. When the working group reviewed these checklists, we noted areas of potential overlap, points of confusion, and categories that were commonly reported as "data not available" across the proposals. We then used these learnings to create the case study development template (**Table 3**). Lastly, we made small modifications to each template prior to presenting them in this manuscript to further refine and clarify any elements that had presented any confusion during the development of the case studies. Elements that contributed to these iterative changes included the availability of data, clarity of indicators (and differentiation from other indicators), and qualitative and quantitative feedback from the case study authors.

Synthesis of Case Study Findings

After the case studies had been developed, ISN leadership consolidated and edited the 11 RE-AIM data tables submitted alongside the narrative case studies into a single summary spreadsheet that was published with the Special Issue in *Energy for Sustainable Development* (19).

Perceptions of Case Study Developers

We gathered the perceptions of the case study developers on the utility of RE-AIM for the case study project using a questionnaire. The questionnaire consisted of 13 questions covering the following general areas: (1) prior experience with RE-AIM; (2) Perceived ease and usefulness of employing RE-AIM for this project; (3) Challenges presented by the particular RE-AIM constructs (reach, effectiveness, adoption, implementation, maintenance); (4) Impact on future work. The questionnaire employed a mixture of question types, including multiple choice, Likert scale, ranking, and open-ended responses and was deployed to the case study developers using an online

TABLE 2 | Initial RE-AIM checklist developed for case study proposals.

Dimensions/Data elements	Available? Quantitative or Qualitative
REACH (scale and coverage of intervention)	
Description of target population (geographic coverage, numbers targeted, demographic characteristics)	
Duration/dates of intervention project/programme	
Setting characteristics (urban vs. rural, seasonal climate, access to roads, and transport infrastructure, etc.)	
Percent individuals/households reached based on target population	
Characteristics of households reached compared to non-participants or to target population (e.g., baseline fuel/s used, socioeconomic characteristics, education etc.)	
Other factors that affect reach of program including policy context, program budget constraints, conflict, fuel availability, and cost.	
EFFECTIVENESS (ability of fuel/technology to achieve desired goals)	
Description of clean cooking intervention fuel/technology (relate to IWA's Tiers and/or ISO standards if possible)	
If available, from literature or measured in the field (please address availability of each item): Measures of stove emissions • Measures of household/personal air pollution exposure before and after intervention • Measures of safety (e.g., burns) before and after intervention • Measures of fuel and/or time savings • Measures of impact of the intervention on desired health outcomes	
ADOPTION—Program and Societal level (factors influencing adoption of the clean cooking intervention)	
Description of financial, tax, and subsidy aspects and how these have affected adoption and use over time (including cost of intervention to end-users and price comparison for other available energy alternatives)	
Description of supply chain (from fuel/stove production to fuel/stove distribution, consistency of supply etc.), and how these have affected adoption and sustained use	
Description of market development (e.g., promotional strategies, aspects influencing business expansion), and how these have affected adoption and sustained use	
Description of regulation and legislation (particularly around fuel supply, distribution and enforcements effectiveness of market rules), and how these have affected adoption and sustained use	
Description of policies, programmatic and policy mechanisms, and how these have affected program implementation and adoption	
Other factors important to adoption at the program and societal level	
ADOPTION – Household and Community level (factors influencing adoption of the clean cooking intervention)	
Measure of household use of technology, including if possible, degree of fuel, or stove stacking	
Perception of affordability, Willingness To Pay measures	
Perceived benefits and/or disadvantages of the intervention, and influence of these perceptions on adoption and sustained use. Important aspects to consider are perceptions of the intervention's effect on: • health • cooking time • opportunity cost • cleanliness • safety • quality of food prepared • other	
Accessibility/reliability of fuel supply, and its effect on adoption and sustained use	
Other factors important to adoption at the household and community level	
IMPLEMENTATION (How the program is rolled out and scaled up)	
Description of implementation strategy including underlying theory, if any, and how it may be integrated with any other interventions (e.g., sanitation, antenatal services)	
Implementing agency / organization / company etc. (or a combination of these)	
Cost of intervention (time or money) from the implementer perspective	
Consistency of implementation across staff/time/settings/subgroups (not about differential outcomes, but process)	
Preparation for reliability of supply chain and price fluctuations	
Community involvement; including women's engagement, and how these factors have affected adoption and sustained use of the intervention	
User and/or provider training	
Adaptations made to intervention during program/project roll out (i.e., was the intervention delivered as intended?)	

(Continued)

TABLE 2 | Continued

Dimensions/Data elements	Available? Quantitative or Qualitative
Other factors important to implementation, including policy and regulatory environment.	
MAINTENANCE—Household and community Level (how well the intervention is sustained at the household/community level)	
Indicate availability of data for each category and the time frame for initial and follow-up data (Ideally at 6 months to a year after initial intervention): • Measure of air pollution exposure (with or w/o comparison to a public health goal) and follow-up after final intervention contact • Measure of stove use (with or w/o comparison to a benchmark) • Measure of fuel use (with or w/o comparison to prior) • Measure of attrition (%) and differential rates by demographic/geographic characteristics or treatment condition • Measure of stove breakdown/repair • Measure of continued financial investment in the intervention by the household or community	
Other factors important to maintenance at the household and community	
MAINTENANCE—Program and societal Level (factors influencing the sustainability of the intervention at the program level)	
Availability/ accessibility of intervention over time, and importance of these factors to adoption and sustained use	
If program is still ongoing at ≥12 months post intervention funding (provide timeframe)	
If and how program was adapted subsequently (which elements retained AFTER program completed)	
Some measure/discussion of alignment to organization mission or sustainability of business model	
Description of long-term repair and maintenance infrastructure, including forms of post-acquisition support, and their effects on adoption and sustained use)	
Description of any long-term subsidies/incentives and plans for continuity or phase-out, and their effects on adoption/sustained use	
Other factors important to maintenance at the program and societal level	

survey platform. The full set of survey questions can be found in the **Supplemental Material**. Eighteen case study developers provided feedback using the online questionnaire, and this feedback was synthesized and analyzed by the authors of this manuscript. Analysis of responses consisted of summary statistics (for quantitative items) and grouping of responses by theme and content (for qualitative items).

The clean cooking fuel case studies that employed the adapted RE-AIM tool were reviewed and approved through the institutional review boards (IRBs) of their respective lead investigators. Feedback from the case study investigators regarding the utility of this tool was treated as exempt, and the use of this data in this manuscript was cleared by the Fogarty International Center at the U.S. National Institutes of Health.

RESULTS

Adapted RE-AIM Templates

Outputs of this project include the RE-AIM checklist (**Table 2**) and data collection template (**Table 3**) created for the case study developers. In the initial checklist (**Table 2**), general RE-AIM indicators were combined with domain-specific information about clean fuel cooking programs and policies. For example, the checklist asked for ratings of the stove and fuels used according to the International Organization for Standardization's Interim Workshop Agreement Guidelines for evaluating cookstove performance (27). We also asked for information about fuel supply policies, stove stacking, and women's engagement in implementation efforts. Some of these indicators were drawn from a framework of Adoption Indicators previously generated by the Clean Cooking Alliance (28).

Table 3 is the RE-AIM data collection template that was provided to case study developers to define case study metrics across the five RE-AIM dimensions as part of case study development. This template was informed by the information collected at the proposal stage (in the submitted **Table 2** checklists). In some cases, alternative metrics were generated for data that were indicated in **Table 2** as unlikely to be available. For example, the submitted **Table 2** checklists indicated that health outcomes data were very seldom available. Due to this lack of data availability, the corresponding metric in **Table 3** became one related to the *potential* health impact of the stove/fuel combination that was utilized in the case (relying, for example, on laboratory, and field emissions testing data conducted elsewhere for the same stove/fuel combinations being deployed; these data are often used to estimate health benefits that would be expected to accrue from reductions in exposure to particulate matter and other compounds). A comprehensive table of the RE-AIM data gathered across the eleven case studies can be found in Quinn et al. (19).

Synthesis of Case Study Findings

Figure 2 presents a summary of the availability of data for each RE-AIM dimension. In general, data were widely available for all five RE-AIM dimensions. Data to address *Adoption* (defined for the purposes of this project) was the most widely available, with no case studies reporting a lack of access to data related to this RE-AIM dimension. Data pertaining to *Reach*, *Implementation*, and *Maintenance* were also widely available. Across the 11 case

TABLE 3 | Simplified RE-AIM data gathering template for clean cooking programs.

RE-AIM dimension	Definition	Case study-specific metrics
Reach	No. of people and percentage of the target population affected. The extent to which the individuals reached are representative and include those most at risk.	1. Absolute numbers and characteristics of the target population 2. Number of people/households and percentage of the target population that have been reached. 3. How do the characteristics of the people reached differ from target population? 4. How do the characteristics of the people reached differ from target population? 5. Duration/dates of the program 6. Sociodemographic trends that affect program (e.g., migration etc.)
Effectiveness	A measure of effects, including positive, negative, and unanticipated consequences.	1. Toward program goals a. Stated goals of the program b. Success achieved toward each of the stated goals c. Unanticipated consequences 2. Toward health improvements a. POTENTIAL of the program for achieving improvements in health (e.g., ISO tier of the technology; exposure reductions; baseline levels of HAP related diseases; etc.) b. Degree to which technology displaced polluting fuels in target populations c. If health data available, were there changes associated with program
Adoption (inclusion and approval)	No. and percentage of settings participating, and the extent to which the settings selected are representative of settings that the target population will access.	1. How were program sites selected? Who was involved in selecting implementation sites and was this an inclusive process? 2. Were the implementation agents viewed positively or negatively by the communities? 3. How much fuel stacking in those homes that did take up new technology 4. Perceptions of affordability, perception of intervention benefits, and/or disadvantages
Implementation	Level of adherence to implementation principles or guidelines, the extent to which all vs. selected elements are implemented, and the cost.	1. Policy context 2. Who financed, and who implemented? 3. Monitoring process and measures 4. Cost of the program, over what time period? (To the program leadership. Could be total cost, cost per capita, or cost projection) 5. Major changes to program targets/goals/drivers/timelines that occurred during implementation, and why did they occur?
Maintenance	Individuals continue to exhibit the desired behavior changes; change is maintained; development of new barriers to use is prevented or mitigated.	1. To what extent has the reach of the program been maintained over time? (e.g., households still using the technology at least 1 year post-adoption vs. abandoning it). 2. Ongoing access to fuels? Supply side and cost to consumer. 3. Indicators of program's sustainability? Risks to sustainability?

studies, data was least available for the *Effectiveness* dimension. This was especially true for data concerning health outcomes—only two of the 11 case studies were able to report data on health impact, and these were on a limited scale. Nine of the case studies were not able to gather any data related to health outcomes. Other aspects of *effectiveness* that related to programmatic goals were sometimes unavailable as well, with three case studies each reporting a lack of data related to "success achieved toward each of the stated goals" and "unanticipated consequences." The prospective nature of several case studies, e.g., Cameroon (29) and Nigeria (30), meant that less data were available across all dimensions to track RE-AIM indicators for these cases in particular.

Perceptions of Case Study Developers

Perceptions of case study developers on using RE-AIM for this project were assessed using an online questionnaire. A total of 18 case study developers, including representatives from all 11 case studies, contributed their feedback on the utility of the tool. Despite the fact that the RE-AIM framework had been introduced to the ISN at a meeting in 2015, a number of case study developers did not attend that initial meeting. Thus, of the 18 respondents, the majority (12, or 67%) had never heard of RE-AIM prior to the case study project. Four respondents had heard of RE-AIM but had never used it, and only two had used it in a previous project. Nonetheless, 9 respondents (50%) found it "easy" to use, while seven found it "neither difficult nor easy," and only two found it "difficult," or "very difficult."

Figure 3 shows how the case study developers ranked the different RE-AIM dimensions according to two factors: (a) level of conceptual challenge to understanding the dimension as it applied to their case; and (b) difficulty in gathering data for their case study. Case Study developers consistently ranked *Reach* as the least challenging dimension both for applicability to the case and for the ease of gathering relevant data. They found *Effectiveness*, *Implementation* and *Maintenance* to be the most challenging both to apply to the case and in terms of difficulty collecting relevant data for each dimension. This was because certain case studies were of programs at a nascent stage (with little implementation, maintenance, or outcome data yet available), and/or because of a perceived lack of fit between RE-AIM's emphasis on "program" implementation and the national-level

RE-AIM DIMENSION	REACH			EFFECTIVENESS					ADOPTION			IMPLEMENTATION			MAINTEN-ANCE	
Indicator	Absolute numbers and characteristics of the target population	Number of people/households and percentage of the target population that have been reached	How the characteristics of the people reached differ from target population	Stated goals of the program	Success achieved toward each of the stated goals	Unanticipated consequences	Degree to which technology displaced polluting fuels in target populations (uptake and stacking)	Health changes, if available	How were program sites selected and who was involved in this process	Were the implementation agents viewed positively or negatively by the communities?	Who financed, and who implemented?	Monitoring process and measures	Cost of the program (total cost, cost per capita, or cost projection)	Major changes that occurred during implementation (to program targets/goals/ drivers/timelines)	To what extent the reach of the program has been maintained over time	Indicators of sustainability/ Risks to sustainability
Cambodia (biogas)	YES	YES	YES	YES	YES	YES	YES	NO	YES	YES	YES	YES	YES	YES	YES	YES
Cameroon (LPG)	YES	YES	NO	YES	NO	NO	NO	NO	YES	YES	YES	YES	YES	YES	NO	YES
China (compressed biomass)	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
East Africa (biogas)	YES	YES	YES	YES	YES	NO	YES	NO	YES	YES	YES	YES	YES	YES	YES	YES
Ecuador (LPG)	YES	YES	YES	NO	NO	YES	YES	NO	YES	YES	YES	YES	YES	YES	YES	YES
Ethiopia (ethanol)	YES	YES	YES	YES	YES	YES	YES	NO	YES	YES	YES	YES	YES	YES	YES	YES
Ghana (LPG)	YES	YES	YES	YES	YES	YES	YES	NO	YES	YES	YES	YES	NO	YES	YES	YES
Indonesia (LPG)	YES	YES	YES	YES	YES	YES	YES	NO	YES	YES	YES	YES	YES	YES	YES	YES
Nigeria (ethanol)	YES	NO	NO	YES	NO	NO	YES	NO	YES	YES	YES	YES	NO	NO	NO	YES
Peru (LPG)	YES	YES	YES	YES	YES	YES	YES	NO	YES	YES	YES	YES	YES	YES	YES	YES
Rwanda (biomass pellets)	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
TOTAL NOT AVAILABLE	0	1	2	1	3	3	1	9	0	0	0	0	2	1	2	0

FIGURE 2 | Summary of RE-AIM data availability across 11 case studies.

policies and regulations that drove some cases. Across both the prospective and retrospective case studies, it was most difficult to gather data for *Effectiveness* (with 10 out of 18 respondents, or 55%, ranking the dimension as among the top two "most difficult" dimensions in terms of gathering data).

Qualitative responses to open-ended questions in the survey enhance understanding of the reported challenges. For example, the reported challenges in understanding how to incorporate the dimensions of *Implementation* and *Maintenance* appear to derive from the fact that the case study project included several evaluations of clean-fuel cooking programs that had not yet been fully implemented, making evaluation of these facets difficult. Comments along these lines included, for example:

- *The work on the ground is still in progress, so we were not yet able to report on many of the metrics.*
- *It seemed challenging to provide responses within the framework for programs that are just getting started and are anticipated to be ongoing and changing, rather than at steady state.*

Difficulty in gathering data related to effectiveness often related to the fact, as discussed above, that these clean-fuel cooking programs were uniformly launched with goals that did not

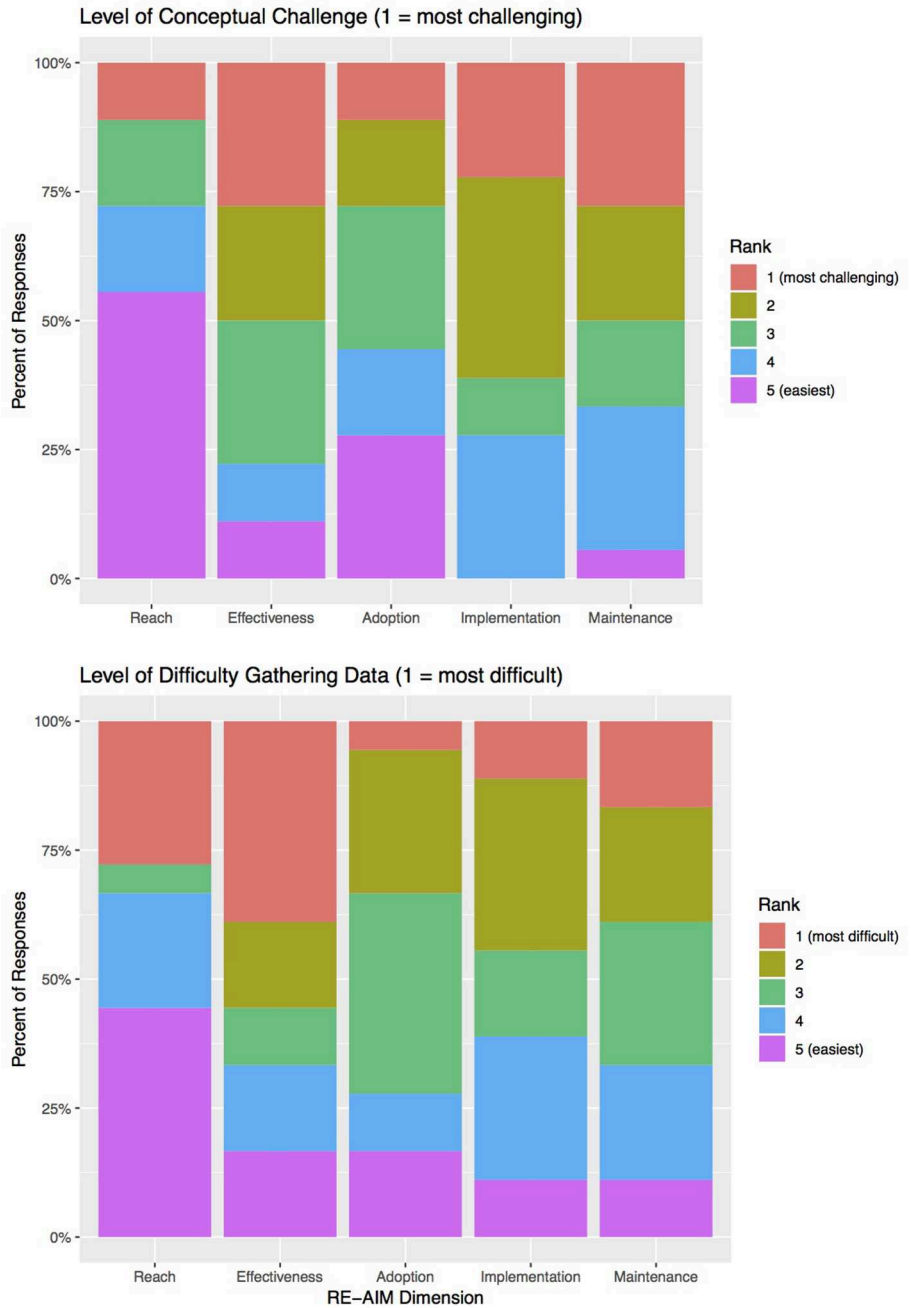

FIGURE 3 | Case Study Developers' surveyed responses to questions about the conceptual challenge of, and difficulty gathering data for, the five RE-AIM dimensions. *N* = 18 responses.

place health improvement at the forefront. They differ, therefore, from more clinically or public-health-oriented programs where effectiveness—in terms of achievement of health improvement—is easier to assess. A number of comments spoke to this, for example:

- *My feeling was the RE-AIM was designed for a more clinical outcome and did not completely fit the context for household energy.*
- *RE-AIM assumes that the program driver is health, but of course often in cookstoves health is a co-benefit rather than the primary outcome.*

Some case study developers additionally felt that it was difficult to fit certain contextual and implementation factors within the RE-AIM framework that were key to the case. Aspects of the case studies that the authors felt were difficult to fit in to RE-AIM included:

- *The political and socio-cultural circumstances that circumscribe the subsidies*
- *The presence of a charismatic, committed leader.*
- *Use of behavior change concepts and techniques.*
- *The strategy for creating the conditions for investment*
- *'Logistical' issues with clean cooking" (supply side of the fuel)*
- *Driving factors for decisions that were made politically*
- *Specific barriers to adoption and factors that can drive a wedge between adoption and health-relevant exposure reduction.*

Despite these challenges and their relative lack of experience with RE-AIM, case study developers reported that the framework was useful to various aspects of the case study development process, as shown in **Table 4**. Using RE-AIM for understanding data availability was the aspect most commonly reported as being "very" or "extremely" useful (reported by 67% of respondents), followed by planning for data collection (56%). In their qualitative comments, however, case study team members also reported that RE-AIM was useful for comparisons across case studies:

- *I do see that having a common framework among the case studies is quite beneficial.*
- *I found the RE-AIM summaries helped greatly in structuring information about quite complex and very different projects—a real asset.*
- *It has been a very useful tool for comparing across case studies.*

Lastly, case study developers were asked to evaluate whether the experience of using RE-AIM for the clean fuel cooking case study project would lead them to approach their work differently in the future. Here, 13 out of 18 respondents (72%) replied "Yes," with some of the specific ways that RE-AIM would influence future work outlined below:

- *REAIM could help us broaden our view a little and possibly adjust some of our study design to be a bit more holistic.*
- *Taking a more holistic approach to data collection.*
- *More emphasis on measures for sustained use.*
- *I appreciated the variables/indicators identified under each heading, and this helped organize my thoughts.*
- *Having a suitable structured framework that covers all aspects of the initiative is very valuable, both for the specific example, but also for making comparisons with others.*

DISCUSSION

Clean-fuel cookstove programs are being rolled out on a massive scale, and a consolidated method for evaluating these initiatives is needed both for individual programs and also to enable cross-initiative comparisons. The NIH clean fuel case study project showed us that the RE-AIM framework has utility for these purposes, particularly with the adaptations that were made here.

The need to adapt RE-AIM for this project was not unlike previous efforts to employ RE-AIM for environmental health interventions. For example, King et al. (24) note that many of the RE-AIM dimensions are difficult to apply to environmental health interventions, such as those meant to affect air quality or improvements to public space. For example, how to calculate the "Reach" of an intervention that improves sidewalks? How to define the settings at which "Adoption" occurs in the context of an intervention targeting outdoor air pollution? Similar challenges—such as defining reach and measuring compliance—have been discussed when it comes to the use of RE-AIM for policy applications, which have some overlap with the case studies here. In the case of policy applications, enforcement is an important aspect of implementation that can directly affect compliance and strongly influence success [see (25) for examples]. In this set of clean fuel case studies, certain initiatives, such as Indonesia's "zero kero" plan, benefited from policy-like structures and robust enforcement measures, while other programs relied more on ground-up marketing and diffusion approaches that did not have the benefit of strong enforcement measures to enhance compliance and implementation.

Notable dimensions of the RE-AIM framework that required adaptation for use in the clean fuel case study project included *Effectiveness* and *Adoption*. First, translating *Effectiveness* for this project required acknowledgment that clean fuel scale-up initiatives have largely been driven by goals outside the health domain, e.g., pertaining to the environment and economic concerns. For example, Indonesia's "Zero Kero" program was designed to phase out highly-subsidized kerosene and thus provide savings to the national budget (31), while the aims of Ghana's rural LPG program included reducing deforestation, reducing drudgery, and creating jobs, as well as reducing the health impacts of cooking with wood and charcoal (32). We therefore proposed case study metrics for this dimension that covered effectiveness in two areas: not only effectiveness related to the reduction of household air pollution and associated health improvement, but also effectiveness in relation to the goals as put forth by the specific clean-fuel cooking program (however those may have been stated).

Adoption, in the context of clean-fuel cooking, presents a different problem since the term "adoption" is widely used in this field to refer to individual-level initial uptake of a new cooking technology, e.g., (2, 16, 33–35). This conflicts with the RE-AIM definition of adoption situated at the organizational and setting level. Defining the "setting" of a clean-fuel cooking program presented its own challenges as many programs are not managed by a clear intermediary organization (as would be the case, for example, in an intervention operating through a hospital or clinic to meet patient needs). Rather, many clean-fuel cooking programs are defined by geography or demographics (e.g., income). For the *Adoption* dimension of RE-AIM we therefore chose to focus on "inclusion and approval," as suggested in King et al. (24). We developed metrics here that focused on how the program rollout was determined, who was involved in these decisions, and how the implementing agents were viewed by the community.

To minimize confusion for the clean cooking community who use adoption to mean household-level uptake of technology, we also included metrics within *Adoption* that pertained to cooking technology usage at the household level. An important aspect

TABLE 4 | Reported usefulness of RE-AIM for different aspects of the case study project.

		Not at all *n* (%)	Somewhat/ Moderately *n* (%)	Very/ Extremely *n* (%)
How useful did you find RE-AIM for:	Understanding data availability	1 (6)	5 (28)	12 (67)
	Planning for data collection	1 (6)	7 (39)	10 (56)
	Understanding factors that led to the success or failure of the case	2 (11)	9 (50)	7 (39)
	Drawing generalizable conclusions that extend beyond the case	1 (6)	9 (50)	8 (44)
	Structuring the manuscript	2 (11)	10 (56)	6 (33)

of clean fuel adoption in terms of achieving health gains is the distinction between uptake (adding a stove) and displacement (replacing a stove). This has important implications: without discontinuation of the use of polluting fuels for cooking, exposure to health-damaging emissions may not be sufficiently reduced to improve health outcomes [e.g., see (8)]. In the clean cooking research community the practice of using multiple types of stoves within a household (adding new stove technology to an existing mix, rather than replacing the older cooking technology with the newer one) is termed "stacking." In the RE-AIM framework, the practice of stacking fuels could theoretically fit either into adoption (where it pertains to initial decisions upon adoption of a new technology) or implementation (where it pertains to patterns of use over time). The decision to include these activities in "adoption" in this project are justified by the fact that we considered fuel choice and fuel usage—including decisions to stack fuels—as intrinsic to the potential adoption process and not merely as patterns that emerge over time. Initial adoption is often only partial adoption. We also asked about household-level perceptions of the new cooking technology as part of *Adoption*, since these perceptions are important determinants of uptake and use of new cooking technology (36).

The remaining RE-AIM dimensions were less in need of adaptation for this purpose, although we included a metric in *Maintenance* focused on fuel supply (covering ongoing access to fuels and the cost to the consumer over time).

Despite its comprehensiveness, case study developers identified a number of aspects crucial to understanding their cases that were difficult to fit in to the RE-AIM framework, even after adaptations of data collection tools and templates to fit the household energy context. Some of these missing factors had to do with the larger sociopolitical context in which the cases were embedded. Notable missing elements included: "The political and socio-cultural circumstances that circumscribe the subsidies," "driving factors for decisions that were made politically," and the impact of "the presence of a charismatic, committed leader." "Logistical" issues (e.g., all the steps involved in distributing clean fuels to customers and ensuring steady supply) were also mentioned as hard to fit into the RE-AIM framework, along with specific barriers impeding the transition to clean fuels for cooking, and the potential role of behavior change interventions in overcoming these barriers.

The fact that aspects of the contextual setting that are essential to implementation success were difficult to capture in RE-AIM has been noted by other researchers, and in fact RE-AIM extensions such as PRISM (37) combine RE-AIM outcome measures with other dimensions crucial to success, including "external environment" and "implementation and sustainability infrastructure." In future applications of RE-AIM to complex community-based programs, we might suggest that researchers and program evaluators consider using PRISM or another RE-AIM extension to more comprehensively evaluate those aspects of the contextual environment that are difficult to describe using RE-AIM alone.

Using RE-AIM for the case study project also highlighted the fact that some key outcome data—in this case particularly pertaining to long-term program maintenance and health outcomes—was not routinely monitored and thus unavailable. This data gap highlights the need for engaging the health sector in longitudinal monitoring and evaluation of clean-fuel cooking initiatives. Current programmatic evaluation might focus, for example, on the number of stoves distributed. Such simplistic metrics, however, do not come close to covering the complexity of the processes related to adoption and sustained use of clean fuel cooking technologies. For example, in addition to tabulating the initial distribution of a clean-fuel cooking solution, it is imperative to also investigate whether households use the stoves, whether they continue to use them over time, and whether the use of the stoves is exclusive or in conjunction with other, polluting stoves and fuels. Employing systematic approaches, ideally with common metrics, will greatly enhance the ability of the international development community to evaluate projects taking place around the world against national, bilateral and global targets, for example targets associated with the Sustainable Development Goals (38).

The overall approach of this case study project was to engage interdisciplinary teams of researchers who employed RE-AIM in a complementary fashion with additional tools to enhance the value of the project by providing data on these additional dimensions of context and climate. This approach could certainly be extended to additional domains beyond clean fuels for cooking. Meanwhile, the specific adaptations and templates developed for this project could be useful starting points to guide future researchers in the household energy domain who are interested in program planning and/or evaluation.

CONCLUSIONS

Implementation science frameworks such as *Reach, Effectiveness, Adoption, Implementation, Maintenance* (RE-AIM) have been shown to enhance the effectiveness of interventions and can be used to evaluate factors associated with implementation success. This is the first known example using RE-AIM to evaluate clean fuel cooking programs in low- and middle-income countries.

Utilizing RE-AIM for the clean cooking community required adapting and operationalizing the framework. Specific adaptations included: specifying the metrics that would be able to inform each of the RE-AIM dimensions, taking account of the pre-existing meaning of some terms (e.g., adoption) in the clean cooking community, and broadening certain dimensions (e.g., effectiveness) to capture program-relevant outcomes. Case study developers found RE-AIM to be useful and relatively easy to use for gathering data and evaluating the clean fuel initiatives. The case study teams reported particular value from the RE-AIM framework when it came to comparing common elements of disparate programs. In the future, RE-AIM extensions such as PRISM might be useful to consider when evaluating community-based interventions to capture aspects of the contextual environment that were difficult to describe using RE-AIM alone.

Key findings from the case study project suggest that long-term monitoring and evaluation of clean-fuel cooking scale-up programs is often lacking, particularly regarding indicators relevant to sustained use of new cooking technology. Health outcome measures and measures of air pollution reduction are also insufficiently tracked. A recommendation to future implementers and evaluators of clean fuel cooking programs is to build infrastructure into their programs that will ensure middle- and long-term monitoring of these key indicators of implementation success.

Finally, this effort demonstrates how a commonly used implementation science framework can be adapted for use in low-and middle-income settings and in contexts where programs are not specifically driven by health objectives. Employing frameworks like these can yield robust program evaluations that can be used to assess program performance in light of national and international goals.

DATA AVAILABILITY STATEMENT

All datasets generated for this study are included in the article/**Supplementary Material**.

AUTHOR CONTRIBUTIONS

AQ and JR managed the project. AQ, JR, GN, and RS contributed to the design of the RE-AIM templates. AQ and GN compiled the data. AQ drafted the manuscript. CO, SP, and KS contributed sections of the manuscript. All authors contributed to manuscript revision, read and approved the submitted version.

FUNDING

The Clean Cooking ISN is hosted by the Center for Global Health Studies at NIH's Fogarty International Center (FIC) and was supported by the NIH Common Fund.

SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2019.00389/full#supplementary-material

REFERENCES

1. GBD 2016 Risk Factors Collaborators. Global, regional, and national comparative risk assessment of 84 behavioural, environmental and occupational, and metabolic risks or clusters of risks, 1990–2016: a systematic analysis for the global burden of disease study 2016 - the lancet. *Lancet.* (2017) 390:1345–422. doi: 10.1016/S0140-6736(17)32366-8
2. World Health Organization. *Who Indoor Air Quality Guidelines: Household Fuel Combustion.* (2014). Available online at: http://www.who.int/indoorair/guidelines/hhfc/HHFC_guidelines.pdf
3. Rosenthal J, Quinn A, Grieshop AP, Pillarisetti A, Glass RI. Clean cooking and the sdgs: Integrated analytical approaches to guide energy interventions for health and environment goals. *Energy Sust Dev.* (2018) 42:152–9. doi: 10.1016/j.esd.2017.11.003
4. Champion WM, Grieshop AP. Pellet-fed gasifier stoves approach gas-stove like performance during in-home use in Rwanda. *Environ Sci Technol.* (2019) 53:6570–79. doi: 10.1021/acs.est.9b00009
5. Malla S, Timilsina GR. Household cooking fuel choice and adoption of improved cookstoves in developing countries: a review. In: *Policy Research Working Paper Series 6903.* The World Bank (2014). doi: 10.1596/1813-9450-6903
6. Mobarak AM, Dwivedi P, Bailis R, Hildemann L, Miller G. Low demand for nontraditional cookstove technologies. *Proc Natl Acad Sci USA.* (2012) 109:10815–20. doi: 10.1073/pnas.1115571109
7. van der Kroon B, Brouwer R, van Beukering PJH. The energy ladder: Theoretical myth or empirical truth? Results from a meta-analysis. *Renew Sust Energy Rev.* (2013) 20:504–13. doi: 10.1016/j.rser.2012.11.045
8. Johnson MA, Chiang RA. Quantitative guidance for stove usage and performance to achieve health and environmental targets. *Environ Health Perspect.* (2015) 128:820–6. doi: 10.1289/ehp.1408681
9. Snider G, Carter E, Clark S, Tseng JTW, Yang X, Ezzati M, et al. Impacts of stove use patterns and outdoor air quality on household air pollution and cardiovascular mortality in southwestern china. *Environ Int.* (2018) 117:116–24. doi: 10.1016/j.envint.2018.04.048
10. Ruiz-Mercado I, Masera O. Patterns of stove use in the context of fuel-device stacking: rationale and implications. *Ecohealth.* (2015) 12:42–56. doi: 10.1007/s10393-015-1009-4
11. Smith KR. Changing paradigms in clean cooking. *Ecohealth.* (2015) 12:196–9. doi: 10.1007/s10393-015-1020-9
12. Eccles MP, Mittman BS. Welcome to implementation science. *Implement Sci.* (2006) 1:1. doi: 10.1186/1748-5908-1-1
13. Tabak RG, Khoong EC, Chambers DA, Brownson RC. Bridging research and practice: Models for dissemination and implementation research. *Am J Prev Med.* (2012) 43:337–50. doi: 10.1016/j.amepre.2012.05.024
14. Galea S. An argument for a consequentialist epidemiology. *Am J Epidemiol.* (2017) 178:1185–91. doi: 10.1093/aje/kwt172

15. Neta G, Brownson RC, Chambers DA. Opportunities for epidemiologists in implementation science: a primer. *Am J Epidemiol.* (2017) 187:899–910. doi: 10.1093/aje/kwx323
16. Rosenthal J, Balakrishnan K, Bruce N, Chambers D, Graham J, Jack D, et al. Implementation science to accelerate clean cooking for public health. *Environ Health Perspect.* (2017) 125:A3–7. doi: 10.1289/EHP1018
17. Clean Cooking Alliance. *100 Million by 2020: the Global Alliance for Clean Cookstoves Is Expected to Reach Its Phase I Goal Ahead of Schedule.* (2014). Available online at: https://www.cleancookingalliance.org/about/news/09-30-2014-100-million-by-2020-the-global-alliance-for-clean-cookstoves-is-expected-to-reach-its-phase-i-goal-ahead-of-schedule.html (accessed November 4, 2019).
18. Kar A, Zerriffi H. *Pradhan Mantri Ujjwala Yojana: Smokeless Kitchens Are Becoming a Reality*. New Delhi: Financial Express (2018).
19. Quinn AK, Bruce N, Puzzolo E, Dickinson K, Sturke R, Jack DW, et al. An analysis of efforts to scale up clean household energy for cooking around the world. *Energy Sust Dev.* (2018) 46:1–10. doi: 10.1016/j.esd.2018.06.011
20. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the re-aim framework. *Am J Public Health.* (1999) 89:1322–7. doi: 10.2105/AJPH.89.9.1322
21. Glasgow RE, Harden SM, Gaglio B, Rabin B, Smith ML, Porter GC, et al. Re-aim planning and evaluation framework: adapting to new science and practice with a 20-year review. *Front Public Health.* (2019) 7:64. doi: 10.3389/fpubh,0.2019.00064
22. Gaglio B, Shoup JA, Glasgow RE. The re-aim framework: a systematic review of use over time. *Am J Public Health.* (2013) 103:e38–46. doi: 10.2105/AJPH.2013.301299
23. Glasgow RE, Estabrooks PE. Pragmatic applications of re-aim for health care initiatives in community and clinical settings. *Prev Chronic Dis.* (2018) 15:E02. doi: 10.5888/pcd15.170271
24. King DK, Glasgow RE, Leeman-Castillo B. Reaiming re-aim: using the model to plan, implement, and evaluate the effects of environmental change approaches to enhancing population health. *Am J Public Health.* (2010) 100:2076–84. doi: 10.2105/AJPH.2009.190959
25. Jilcott S. Applying the re-aim framework to assess the public health impact of policy change. *Ann Behav Med.* (2007) 34:105–14. doi: 10.1007/BF02872666
26. Sweet SN, Ginis KAM, Estabrooks PA, Latimer-Cheung AE. Operationalizing the re-aim framework to evaluate the impact of multi-sector partnerships. *Implement Sci.* (2014) 9:74. doi: 10.1186/1748-5908-9-74
27. ISO/IWA. *Guidelines for Evaluating Cookstove Performance.* (2012). Available online at: https://www.iso.org/obp/ui/#iso:std:iso:iwa:11:ed-1:v1:en (accessed February 25, 2018).
28. Clean Cooking Alliance. How do we define and measure adoption (2016)? Available online at: http://cleancookingalliance.org/about/news/02-18-2016-how-do-we-define-and-measure-adoption.html (accessed March 6, 2019).
29. Bruce N, de Cuevas RA, Cooper J, Enonchong B, Ronzi S, Puzzolo E, et al. The government-led initiative for lpg scale-up in Cameroon: programme development and initial evaluation. *Energy Sust Dev.* (2018) 46:103–10. doi: 10.1016/j.esd.2018.05.010
30. Ozier A, Charron D, Chung S, Sarma V, Dutta A, Jagoe K, et al. Building a consumer market for ethanol-methanol cooking fuel in Lagos, Nigeria. *Energy Sust Dev.* (2018) 46:65–70. doi: 10.1016/j.esd.2018.06.007
31. Thoday K, Benjamin P, Gan M, Puzzolo E. The mega conversion program from kerosene to LPG in Indonesia: lessons learned and recommendations for future clean cooking energy expansion. *Energy Sust Dev.* (2018) 78:274–6. doi: 10.1016/j.esd,0.2018.05.011
32. Asante KP, Afari-Asiedu S, Abdulai MA, Dalaba MA, Carrión D, Dickinson KL, et al. Ghana's rural liquefied petroleum gas program scale up: a case study. *Energy Sust Dev.* (2018) 46:94–102. doi: 10.1016/j.esd.2018.06.010
33. Kumar P, Dhand A, Tabak RG, Brownson RC, Yadama GN. Adoption and sustained use of cleaner cooking fuels in rural India: a case control study protocol to understand household, network, and organizational drivers. *Arch Public Health.* (2017) 75:70. doi: 10.1186/s13690-017-0244-2
34. Puzzolo E, Pope D, Stanistreet D, Rehfuess EA, Bruce NG. Clean fuels for resource-poor settings: a systematic review of barriers and enablers to adoption and sustained use. *Environ Res.* (2016) 146:218–34. doi: 10.1016/j.envres.2016.01.002
35. Ruiz-Mercado I, Masera O, Zamora H, Smith KR. Adoption and sustained use of improved cookstoves. *Energy Policy.* (2011) 39:7557–66. doi: 10.1016/j.enpol.2011.03.028
36. Rehfuess EA, Puzzolo E, Stanistreet D, Pope D, Bruce NG. Enablers and barriers to large-scale uptake of improved solid fuel stoves: a systematic review. *Environ Health Perspect.* (2014) 122:120–30. doi: 10.1289/ehp.1306639
37. Feldstein AC, Glasgow RE. A practical, robust implementation and sustainability model (prism) for integrating research findings into practice. *Jt Comm J Qual Patient Saf.* (2008) 34:228–43. doi: 10.1016/S1553-7250(08)34030-6
38. UN General Assembly. *Transforming Our World: The 2030 Agenda for Sustainable Development*. UN General Assembly (2015). Available online at: https://www.refworld.org/docid/57b6e3e44.html (accessed December 10, 2019).

Disclaimer: The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the U.S. National Institutes of Health or Department of Health and Human Services.

Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

frontiers in Public Health

GENERAL COMMENTARY
published: 09 June 2020
doi: 10.3389/fpubh.2020.00218

Commentary: Adapting and Operationalizing the RE-AIM Framework for Implementation Science in Environmental Health: Clean Fuel Cooking Programs in Low Resource Countries

*Ana A. Baumann**

Brown School of Social Work, Washington University in St. Louis, St. Louis, MO, United States

Keywords: adaptation, implementation, low-middle income countries, framework, RE-AIM (reach, effectiveness, adoption, implementation and maintenance)

A Commentary on

Adapting and Operationalizing the RE-AIM Framework for Implementation Science in Environmental Health: Clean Fuel Cooking Programs in Low Resource Countries
by Quinn, A. K., Neta, G., Sturke, R., Olopade, C. O., Pollard, S. L., Sherr, K., et al. (2019). Front. Public Health 7:389. doi: 10.3389/fpubh.2019.00389

OPEN ACCESS

Edited by:
Matthew Lee Smith,
Texas A&M University, United States

Reviewed by:
Caroline Diane Bergeron,
Bexar County Community Health Collaborative, United States

***Correspondence:**
Ana A. Baumann
abaumann@gwbmail.wustl.edu

Specialty section:
This article was submitted to Public Health Education and Promotion, a section of the journal Frontiers in Public Health

Received: *06 May 2020*
Accepted: *12 May 2020*
Published: *09 June 2020*

Citation:
Baumann AA (2020) Commentary: Adapting and Operationalizing the RE-AIM Framework for Implementation Science in Environmental Health: Clean Fuel Cooking Programs in Low Resource Countries. Front. Public Health 8:218. doi: 10.3389/fpubh.2020.00218

The field of implementation science has seen an accumulation of theories, models and frameworks in the past years. However, few empirical studies are informed by them (1), and when informed, few clearly describe how they applied the frameworks in the study (2). The study by Quinn et al. (3) provides an exception to this rule and gives us an example of how to use the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) (4) framework in their study of a consortium of 11 sites in low middle income countries (LMIC). Instead of focusing on one study at a time, a consortium can advance the field by having common metrics across different settings, providing an unique opportunity for theory testing [e.g., (5, 6)].

TESTING THE BOUNDARIES OF CONSTRUCT DEFINITIONS

Quinn et al.' study (3) developed a checklist and case studies to evaluate household energy interventions. The results showed that the constructs *effectiveness* and *adoption* needed more adaptation in their definitions compared to the other constructs of the framework. *Effectiveness*, defined as "the impact of an intervention on important outcomes" (7), was hard to gather in their context because health is considered a co-benefit of the programs, and therefore health outcomes and measures of air pollutions are not usually readily available. To address this challenge, the authors adapted the definition to capture "potential" health impact of the stove/fuel, relying on estimated data accrued from stove emissions. We need more empirical studies in different contexts to continue to refine the definition of effectiveness.

Adoption, a construct used to capture the proportion and representativeness of organizations willing to adopt a program (7), was challenging because usually clean fuel cooking programs do not involve an intermediary organization. To address this issue, the authors re-defined the construct to encompass factors at society level (e.g., description of supply chain) as well as

household/community factors (e.g., household use of technology). The *adoption* construct in this case was also difficult because it should refer not only to the uptake of something (i.e., adding a stove) but also to the discontinuation of older stoves who are health-damaging. This discussion is timely as the field starts to understand the unique aspects of de-implementation and how to define them. Accordingly, Prusaczyk et al. (8) suggest expanding the adoption concept to include *de-adoption,* defined as the intention or initial decision to stop a practice.

The results from Quinn et al. (3) showed that, while *Reach* was the easier construct to gather data across sites, the definition of reach is challenging in the context of public health programs. As Quinn et al. (3) comment: it is difficult to evaluate "Reach" of an intervention that improves sidewalks. Gaglio et al. (9) recognize the challenges in the definition, which has also been adapted to refer to awareness of a program (10). Finally, *Maintenance* was hard to capture because the sites were at the beginning of implementation the program. It will be interesting to see how this consortia captures maintenance later on.

CONTEXT AND LMIC

When stakeholders were asked about their perceived ease and usefulness of employing RE-AIM on their project, they mentioned the challenges in capturing context using RE-AIM, particularly the political and social aspects of the studies. In fact, as May et al. (11) state: "context is a problem in implementation science." Let me explain.

Quinn et al. (3) mention that a solution to capture contextual outcomes could be using the Practical, Robust Implementation, and Sustainability Model (PRISM) framework, which is an expansion of RE-AIM. In fact, PRISM's constructs of *External Environment, Intervention, Implementation* and *Sustainability, Infrastructure,* and the *Recipients* align well with the RE-AIM constructs (12) and could be a great fit for Quinn et al.'s project.

However, as is shown by Quinn et al.'s data (3), we need to be careful about our assumptions that frameworks and constructs developed in high income countries (HIC) would fit in LMIC without any adaptation. This is because often contextual factors, such as health system structures, resource availability, cultural, and political norms and values are different in HIC compared to LMIC (13). In fact, the issues with fitting definitions of the implementation science constructs in LMICs are not unique to RE-AIM. In a systematic review of papers and authors survey, Means et al. (14) also identified challenges with some of the Consolidated Framework for Implementation Research (CFIR) (15) constructs. For example, similar to Quinn et al., their stakeholders also asked for more system level constructs, as they had difficulties applying the construct *patient needs* with interventions that took place at district or national levels. The examples of Quinn et al. and of Means et al. highlight the necessity of being humble with our frameworks, and to examine carefully our definitions to avoid the ethnocentric bias of implementation studies (16).

Several of us have written about the challenges of working in LMIC including issues with: (a) defining the evidence of the intervention (e.g., the fact that one intervention is proven efficacious in HIC, does not mean that it is efficacious in a LMIC), (b) measurement (i.e., issues of validity, availability of data), and (c) mechanisms of action (which may differ depending on context) (17, 18). As we continue to define our implementation constructs and outcomes, and better understand the theories and conceptual approaches, we should incorporate the testing of the boundaries of our implementation science frameworks in LMICs, as the majority of the frameworks and measures were developed in HICs. Perhaps now it is time for us to consider *how is implementation being conceptualized* (19). That is, in addition to adapting the definitions of the constructs of our frameworks, we should also have an explicit conversation about what is context and how context defines the boundaries of these definitions, our evidence, and who judges the usefulness of the frameworks and theories in which context. I look forward to more empirical studies so that we can continue to "theorize" (2) and contribute to the advancement of the field of implementation science.

AUTHOR CONTRIBUTIONS

The author confirms being the sole contributor of this work and has approved it for publication.

FUNDING

AB was funded by P50 CA-19-006, 3U01HL13399403S1, UL1TR002345, NCT 03380351, and 5U24HL136790.

REFERENCES

1. Damschroder LJ. Clarity out of chaos: use of theory in implementation research. *Psychiatry Res.* (2020) 283:112461. doi: 10.1016/j.psychres.2019.06.036
2. Kislov R, Pope C, Martin GP, Wilson PM. Harnessing the power of theorising in implementation science. *Implement Sci.* (2019) 14:103. doi: 10.1186/s13012-019-0957-4
3. Quinn AK, Neta G, Sturke R, Olopade CO, Pollard SL, Sherr K, et al. Adapting and operationalizing the RE-AIM framework for implementation science in environmental health: clean fuel cooking programs in low resource countries. *Front Public Health*. (2019) 7:389. doi: 10.3389/fpubh.2019.00389
4. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health*. (1999) 89:1322–7. doi: 10.2105/AJPH.89.9.1322
5. Knight DK, Belenko S, Wiley T, Robertson AA, Arrigona N, Dennis M, et al. Juvenile Justice—Translational Research on Interventions for Adolescents in the Legal System (JJ-TRIALS): a cluster randomized trial targeting system-wide improvement in substance use services. *Implement Sci.* (2016) 11:57. doi: 10.1186/s13012-016-0423-5
6. DiMartino LD, Baumann AA, Hsu LL, Kanter J, Gordeuk VR, Glassberg J, et al. The sickle cell disease implementation consortium: translating evidence-based guidelines into practice for sickle cell disease. *Am J Hematol.* (2018) 93:E391–5. doi: 10.1002/ajh.25282

7. Glasgow RE, Harden SM, Gaglio B, Rabin B, Smith ML, Porter GC, et al. RE-AIM planning and evaluation framework: adapting to new science and practice with a 20-year review. *Front Public Health*. (2019) 7:54. doi: 10.3389/fpubh.2019.00064
8. Prusaczyk B, Swindle T, Curran G. Defining and conceptualizing outcomes for de-implementation: key distinctions from implementation outcomes. *Implement Sci Commun*. (2020) 1:43. doi: 10.1186/s43058-020-00035-3
9. Gaglio B, Shoup JA, Glasgow RE. The RE-AIM framework: a systematic review of use over time. *Am J Public Health*. (2013) 103:e38–46. doi: 10.2105/AJPH.2013.301299
10. Jones A, Thow AM, Mhurchu CN, Sacks G, Neal B. The performance and potential of the Australasian Health Star Rating system: a four-year review using the RE-AIM framework. *Aust N Z J Public Health*. (2019) 43:355–65. doi: 10.1111/1753-6405.12908
11. May CR, Johnson M, Finch T. Implementation, context and complexity. *Implement Sci*. (2016) 11:141. doi: 10.1186/s13012-016-0506-3
12. McCreight MS, Rabin BA, Glasgow RE, Ayele RA, Leonard CA, Gilmartin HM, et al. Using the Practical, Robust Implementation and Sustainability Model (PRISM) to qualitatively assess multilevel contextual factors to help plan, implement, evaluate, and disseminate health services programs. *Transl Behav Med*. (2019) 9:1002–11. doi: 10.1093/tbm/ibz085
13. Bergström A, Skeen S, Duc DM, Blandon EZ, Estabrooks C, Gustavsson P, et al. Health system context and implementation of evidence-based practices—development and validation of the Context Assessment for Community Health (COACH) tool for low- and middle-income settings. *Implement Sci*. (2015) 10:120. doi: 10.1186/s13012-015-0305-2
14. Means AR, Kemp CG, Gwayi-Chore M-C, Gimbel S, Soi C, Sherr K, et al. Evaluating and optimizing the consolidated framework for implementation research (CFIR) for use in low- and middle-income countries: a systematic review. *Implement Sci*. (2020) 15:17. doi: 10.1186/s13012-020-0977-0
15. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci*. (2009) 4:50. doi: 10.1186/1748-5908-4-50
16. Ridde V, Pérez D, Robert E. Using implementation science theories and frameworks in global health. *BMJ Glob Health*. (2020) 5:e002269. doi: 10.1136/bmjgh-2019-002269
17. Baumann AA, Cabassa LJ. Reframing implementation science to address inequities in healthcare delivery. *BMC Health Serv Res*. (2020) 20:190. doi: 10.1186/s12913-020-4975-3
18. Baumann AA, Mejia A, Lachman JM, Parra-Cardona R, López-Zerón G, Amador Buenabad NG, et al. Parenting programs for underserved populations in low- and middle-income countries: issues of scientific integrity and social justice. *Glob Soc Welfare*. (2018). doi: 10.1007/s40609-018-0121-0
19. Boulton R, Sandall J, Sevdalis N. The cultural politics of 'implementation science.' *J. Med. Humanit*. (2020). doi: 10.1007/s10912-020-09607-9. [Epub ahead of print].

Disclaimer: The content is solely the responsibility of the author and does not necessarily represent the official view of the NIH.

Conflict of Interest: The author declares that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

frontiers in Public Health

ORIGINAL RESEARCH
published: 25 February 2020
doi: 10.3389/fpubh.2020.00043

Adaptation for Regulatory Application: A Content Analysis of FDA Risk Evaluation and Mitigation Strategies Assessment Plans (2014–2018) Using RE-AIM

Gita A. Toyserkani[1]*, *Linda Huynh*[1,2] *and Elaine H. Morrato*[1,3]

[1] Food and Drug Administration, Silver Spring, MD, United States, [2] Oak Ridge Institute for Science and Education (ORISE) Program, Silver Spring, MD, United States, [3] Colorado School of Public Health, University of Colorado Anschutz Medical, Aurora, CO, United States

OPEN ACCESS

Edited by:
Bridget Gaglio, Patient Centered Outcomes Research Institute, United States

Reviewed by:
Patricia Silveira Martins, Independent Researcher, Belo Horizonte, Brazil
Jo Ann Shoup, Kaiser Permanente Colorado Institute for Health Research (IHR), United States
Michelle Henton, Patient Centered Outcomes Research Institute, United States

***Correspondence:**
Gita A. Toyserkani
gita.toyserkani@fda.hhs.gov

Specialty section:
This article was submitted to Public Health Education and Promotion, a section of the journal Frontiers in Public Health

Received: *21 September 2019*
Accepted: *07 February 2020*
Published: *25 February 2020*

Citation:
Toyserkani GA, Huynh L and Morrato EH (2020) Adaptation for Regulatory Application: A Content Analysis of FDA Risk Evaluation and Mitigation Strategies Assessment Plans (2014–2018) Using RE-AIM. Front. Public Health 8:43. doi: 10.3389/fpubh.2020.00043

Background: Risk Evaluation and Mitigation Strategies (REMS) are safety programs that U.S. Food and Drug Administration can require to ensure a drug's benefits outweigh its risks and can be considered public health interventions. FDA's 2019 *draft Guidance for Industry on REMS Assessments* encourages the development of "novel methods for assessing REMS [to] help advance the science of post-market assessment of effectiveness of risk mitigation strategies."

Objective: To characterize REMS assessment plans using RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) framework and identify areas for advancing methods for evaluating REMS programs. RE-AIM was selected for its wide application evaluating the translation of scientific advances into practice for public health impact.

Methods: A content analysis of REMS assessment plans (N = 18) and measures(n = 540) was conducted for REMS programs approved by FDA between 1/1/2014–12/31/2018. Eligibility criteria were: a new drug application or biologic license application, included FDA-mandated mitigation strategies called elements to assure safe use (ETASU), and represented a single product REMS program. Assessment plans were collected from publicly available regulatory approval letters from REMS@FDA website. Blinded reviewers categorized each REMS assessment measure to a RE-AIM dimension, adjudicated their application (average IRR 75%), and refined the adapted dimensions' definitions. Dimensions were also mapped to *REMS Assessment guidance* categories.

Results: The median number of assessment measures per REMS assessment plan was 31 (IQR: 21–36). Frequency of measures per RE-AIM criteria per REMS program was: Reach (median = 2; IQR: 2–4); Effectiveness (median = 2.5; IQR:1–4); Adoption (median = 3.5; IQR: 2–5); Implementation (median = 18; IQR: 15–24); Maintenance (median = 0; IQR: 0–1). Adoption (among prescriber, health system agents of implementation) was more commonly assessed than Reach (population-attributable number of patients affected). Assessment of heterogeneity of Adoption and Reach was generally absent.

Implementation assessment measures were most common among drugs requiring evidence of safe-use conditions before dispensing or administering the drug. Patient-level Effectiveness and Maintenance assessments were most common among drugs requiring patient monitoring.

Discussion: Implementation science frameworks, such as RE-AIM, can be applied to characterize REMS assessment measures and identify opportunities for standardizing and strengthening their evaluation. Methods to measure Maintenance are needed to provide real-world evidence of REMS integration into the healthcare system.

Keywords: RE-AIM, REMS, FDA, risk management, regulatory science, drug safety, program evaluation, implementation science

INTRODUCTION

The U.S. Food and Drug Administration (FDA) is responsible for protecting the public health of Americans by assuring the safety and efficacy of human drugs and biological products (1). Over the past two decades, modernization of post marketing drug safety and risk management has received increasing attention (2, 3). Post marketing safety issues include serious adverse events, product quality issues, and medication errors (4). Given the U.S. population's large and increasing magnitude of medication exposure, the potential for harms from adverse drug events constitutes a critical patient safety and public health challenge. An estimated one-third of all hospital adverse events and over 3.5 million physician office visits each year are attributable to adverse drug events (5).

The Food and Drug Administration Amendments Act (FDAAA) of 2007 granted FDA authority to require risk evaluation and mitigation strategies (REMS) to ensure that the benefits of a drug outweigh its risks (6). REMS are required risk management plans that use risk minimization strategies beyond the professional product labeling (7). REMS can be required for existing drugs on the market, new drug applications (NDAs), abbreviated NDAs (ANDAs) for generic drugs, and biologics license applications (BLAs) (6). Between enactment of FDAAA and September 2019, 284 REMS programs have been approved by FDA for a wide-range of therapeutic areas affecting the treatment of obesity and diabetes, depression, and pain management (8). Please see **Table 1** for definitions of common FDA and REMS terms.

Early in the implementation of REMS, the majority of programs included strategies focused on dissemination of risk information. REMS programs may require that drug manufacturers develop materials for patients, such as a Medication Guide, which contain FDA-approved information in patient-friendly language that can help inform patients about how to use a medication and avoid serious adverse events. After guidance issuance in 2012, FDA no longer required every Medication Guide to be part of a REMS, however, they still remain part of the FDA-approved labeling (9). In most cases, FDA includes a Medication Guide as part of a REMS only when the REMS includes other clinical interventions such as patient counseling (10). Other dissemination strategies include targeting healthcare providers; these are known as Communication Plans. REMS may require drug manufacturers to communicate directly to healthcare providers involved in the delivery of health care or medications or develop certain packaging and safe disposal technologies (11, 12). Most of the REMS that included only a Medication Guide or Communication Plan have now been released under the mandate of REMS.

Today, the majority of active REMS programs (84%, 51 out of 61programs) involve complex multi-level interventions (8). In these situations, FDA requires healthcare providers to conduct clinical interventions known as elements to assure safe use (ETASU) that support the safe use of the medication. ETASU may include: training or certification of prescribers, training or certification of dispensers, dispensing/administering the drug in certain settings, requiring evidence or documentation of safe use conditions, monitoring of patients, and/or enrolling patients in a registry (13).

REMS programs, although developed by drug manufactures, are essentially one form of public health intervention programs that need to be implemented within the US healthcare system and adopted by healthcare providers. For example, the Opioid Analgesics REMS program is one strategy among multiple national and state efforts to reduce the risk of abuse, misuse, addiction, overdose, and deaths due to prescription opioid analgesics. It requires that training be made available to all healthcare providers who are involved in the management of patients with pain, including nurses and pharmacists (14). In 2009, the Zyprexa Relprevv REMS was approved to reduce the risk of post-injection delirium sedation syndrome. The REMS was developed to make sure all patients receive special monitoring during the period just following drug administration when post-injection delirium sedation syndrome is most likely to occur, so it can be detected and treated (15).

Drug manufacturers are also required to assess the effectiveness of their REMS program and submit assessment reports to FDA at specified frequency. Manufacturers generally develop a REMS assessment plan prior to approval. The REMS assessment plan is a specific plan for how the drug manufacturer intends to assess the performance of the REMS in meeting its risk mitigation goals and objectives (10). Each assessment plan includes a number of assessment measures to evaluate processes and outcomes. Depending on the complexity of the program,

TABLE 1 | Common terms and acronyms for US Food and Drug Administration (FDA) and Risk Evaluation and Mitigation Strategies (REMS).

Terms, acronyms, abbreviations	Definition
Relevant Legislation	
Food and Drug Administration Amendments Act (FDAAA)*	Law enacted in 2007 reauthorizing and expanding PDUFA, among others, to provide FDA with new authorities to require postmarket studies, safety labeling changes, and REMS
Prescription Drug User Fee Act (PDUFA)†	Created by Congress in 1992 to authorize FDA to collect fees from companies producing certain human drugs and biological process to expedite the drug approval process
Application Types and Submissions‡	
Abbreviated New Drug Application (ANDA)	Vehicle through which drug sponsors formally propose that FDA approve a generic drug product for sale and marketing in the U.S.
Biologics License Application (BLA)	Vehicle through which drug sponsors formally propose that FDA approve a biologic product for sale and marketing in the U.S.
New Drug Application (NDA)	Vehicle through which drug sponsors formally propose that FDA approve a new drug product for sale and marketing in the U.S.
Periodic Safety Update Reports (PSUR)**	Documents intended to provide a safety evaluation of the drug product for submission by manufacturers at defined time points during the post marketing phase
REMS Programs¶ and Components#	
REMS	A drug safety program that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks
Active REMS	Products whose REMS program and requirements are in effect
Released REMS	Products whose REMS program is no longer required by the FDA
Shared System REMS‖	REMS programs developed for multiple prescription drug products and implemented jointly by two or more manufacturers
Communication Plan (CP)	Letters, websites, and fact sheets directly to healthcare providers informing of specific safety risks identified in the REMS and steps to take to reduce the risk
Medication Guide (MG)	Handouts for patients distributed with prescription medications that contain FDA-approved information to help inform about how to use a medication and avoid serious adverse events in patient-friendly language
Elements to Assure Safe Use (ETASU)	Required activities such as healthcare provider training, patient counseling and monitoring that support the safe use of the medication

*FDA. FDAAA Implementation—Highlights One Year After Enactment. Available online at: https://www.fda.gov/regulatory-information/food-and-drug-administration-amendments-act-fdaaa-2007/fdaaa-implementation-highlights-one-year-after-enactment [cited 2020 January 28].

**21 CFR 314.80(c)(2) and 600.80(c)(2).

†FDA. Prescription Drug User Fee Amendments. [cited 2020 January 17]. Available online at: https://www.fda.gov/industry/fda-user-fee-programs/prescription-drug-user-fee-amendments.

‡FDA. Types of Applications. Available online at: https://www.fda.gov/drugs/how-drugs-are-developed-and-approved/types-applications [cited 2020 January 17].

¶FDA. Approved Risk Evaluation and Mitigation Strategies (REMS). Available online at: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm [cited 2020 January 17].

‖FDA. Development of a Shared System REMS: Guidance for Industry. Draft Guidance In: DHHS, editor. (2018).

#FDA. What's in a REMS? Available online at: https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/whats-rems [cited 2020 January 17].

the number of assessment measures may vary. An example of a measure assessing processes may include the number of prescribers, health care settings, and pharmacies that have undergone training in the REMS program. An example of a measure assessing outcomes may include numbers and rates of a specific adverse event of interest such as rates of serious bleeds or severe neutropenia (16). The REMS assessment plan is outlined in the original REMS approval letters for all NDAs and BLAs and is made publicly available through the FDA website, REMS@FDA (also available at DRUGS@FDA).

Assessing the effectiveness of REMS programs is challenging. For example, drug manufacturers and healthcare providers have expressed concerns associated with the challenges of collecting data and lack of standardized format for assessment plans (17). Early following the implementation of REMS, the Office of the Inspector General report raised concerns about the effectiveness of the REMS programs and recommended that FDA should develop and implement a plan to identify, develop, validate, and assess REMS components (2). The report also recommended that FDA should identify and implement reliable methods to assess the effectiveness of REMS.

In response and to modernize post-marketing drug safety, the FDA committed as part of the fifth authorization of the prescription drug user fee program to develop evidence-based methodologies for assessing the effectiveness of REMS (3). The Prescription Drug User Fee Act (PDUFA) gives FDA authority to collect fees from companies that produce drugs when they submit NDA and BLA applications in exchange for ensuring timely review; PDUFA is reauthorized by Congress every 5 years, providing new windows of opportunity for advancing public policy by allowing manufacturers and the FDA to discuss and negotiate commitments to facilitate "timely access to safe, effective, and innovated new medicines for patients."

In 2019, FDA issued a draft guidance entitled "REMS Assessments: Reporting and Planning" (*henceforth referred to as the Assessment Guidance*) in which it encouraged "applicants and the research community to develop novel methods for assessing REMS" (10). The draft Assessment Guidance outlines five categories for evaluation, including: Outreach and Communications, Implementation and Operations, Knowledge, Safe-Use Behaviors, and Health Outcomes; see **Table 2**.

Using the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) framework may be suitable for evaluating REMS programs. RE-AIM is a framework to enhance the translation of research into practice through the adoption and implementation of evidence-based interventions. The framework was initially used to evaluate prevention and health behavior change programs, and more recently, has been used to help plan programs and improve their chances of working in "real-world" settings. The overall goal of the RE-AIM framework is to encourage program planners, evaluators, researchers, funders, and policymakers to consider essential program elements including external validity. Its five dimensions are designed to enhance the quality, speed, and impact of public health efforts and involve the following: reach of intended target population, effectiveness on important outcomes, adoption by target staff or settings, implementation consistency, and

TABLE 2 | Adaptation of RE-AIM dimensions as applied to REMS assessment measures and Assessment Guidance categories.

RE-AIM dimension	General description*	Description as applied to REMS assessments**	Assessment guidance category	Definitions of assessment guidance category
Reach	Reach refers to the absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative, intervention, or program	**Patient (individual level)** • Number of patients treated or enrolled (numerator) • Proportion of eligible patients ("valid denominator" given the drug's indicated use) treated or enrolled • Characteristics of patients treated or enrolled compared with nonparticipants—representativeness	Outreach and Communications	Measures of the extent to which the REMS materials reached the intended stakeholders
Effectiveness	Effectiveness refers to the impact of an intervention on important outcomes, including potential negative effects, quality of life, and economic outcomes	**Patient (individual level)** • Knowledge-Attitudes; Process-Behavior; Health Outcomes and/or Surrogates • Positive and negative (unintended) impacts; observed vs. expected rates of effectiveness • Heterogeneity (variability) of effect across different subpopulations	Safe Use Behaviors and Knowledge Health Outcomes	Measures of the extent to which safe use conditions are being adopted or followed, or of stakeholders' knowledge about the REMS-related risk or knowledge of any safe use conditions Measures of the safety-related health outcome of interest or a surrogate of a health outcome
Adoption	Adoption refers to the absolute number, proportion, and representativeness of settings and intervention agents (people who deliver the program) who are willing to initiate the program	**Health Care System (setting level)** • Number of practices, clinics, hospitals or pharmacies certified or enrolled (numerator) • Proportion of eligible practices, clinics, hospitals or pharmacies ("valid denominator" given the drug's indicated use) certified or enrolled • Characteristics of practices, clinics, hospitals or pharmacies certified or enrolled compared with non-adopters—representativeness **Health Care Provider (agent level)** • Number of prescribers and/or pharmacists certified or enrolled (numerator) • Proportion of eligible prescribers and/or pharmacists ("valid denominator" given the drug's indicated use) certified or enrolled • Characteristics of prescribers and/or pharmacists certified or enrolled compared with non-adopters—representativeness	Outreach and Communications	Measures of the extent to which the REMS materials reached the intended stakeholders
Implementation	At the setting level, implementation refers to the intervention agents' fidelity to the various elements of an intervention's protocol, including consistency of delivery as intended and the time and cost of the intervention Implementation elements include: implementation fidelity, adaptation, and cost of intervention At the agent level, implementation refers to the clients' use of the intervention strategies	**Health Care System (setting level)** • Percent of targeted groups who were sent, received REMS information and/or training (by mode and frequency of distribution) • Curriculum consistency—fidelity and adaptation over time (by training modality) • Extent of completed, successful training and/or certification in the program • Incremental costs and resources required (fixed and variable) for REMS participation • Heterogeneity (variability) of implementation across different settings	Implementation and Operations	Measures of the extent to which the intended stakeholders are participating in the program, how effectively the REMS program is being implemented and any unintended consequences such as patient access or burden to the healthcare system
		Health Care Provider (agent level) • Educational effectiveness measured by: knowledge-attitudes, behavioral intention for safe use processes and procedures, observed behavior-compliance • Heterogeneity (variability) of implementation across different settings and/or provider characteristics	Safe Use Behaviors and Knowledge	Measures of the extent to which safe use conditions are being adopted or followed, or of stakeholders' knowledge about the REMS-related risk or knowledge of any safe use conditions
Maintenance	At the setting level, maintenance reflects the extent to which the program or processes become institutionalized or sustained as part of routine practice over time	**Health Care System (setting level)** • Cumulative real-world evidence of the integration of REMS processes and procedures into state and institutional policies, treatment guidelines, insurance requirements	Not included	Not applicable
	At the agent or individual level, maintenance reflects the extent to which practices become a stable part of the behavioral repertoire of the individual	**Health Care Provider (agent level) and Patient (individual level)** • Cumulative evidence over time to include: durability of knowledge; compliance with REMS processes and procedures; attrition rate (from the program); heterogeneity (variability) of attrition by subgroups, unintended outcomes, e.g., access or burden issues	Not included	Not applicable

**Defined in Gaglio et al. (18).*

***Informed by the National Cancer Institute (19).*

maintenance of intervention effects over time in individuals and settings (20).

RE-AIM addresses all components of REMS programs, including compliance processes, program participation, and overall outcomes, as suggested by the Assessment Guidance (10). Moreover, RE-AIM is an evaluation framework from implementation science that has been widely applied to evaluate health interventions similar to REMS programs (18). For example, RE-AIM has been used by the Centers for Disease Control and Prevention (CDC) for the evaluation of the implementation of the Diabetes Prevention Group (21). Another example includes the application of RE-AM to evaluation of implementing physical activity as a standard of care in healthcare settings (22). Its application has been proposed as an extension to assess the public health impact of policy change (23). The objective of this study was to characterize REMS assessment plans using RE-AIM and to identify areas for advancing methods for evaluating REMS programs.

METHODS

A content analysis of REMS assessment plans ($N = 18$) and measures($n = 540$) was conducted for REMS programs approved by the FDA between January 1, 2014 and December 31, 2018. Given that the first REMS was approved in 2008, we limited our study sample to REMS programs approved in the past 5 years as these would be more aligned with current policy. Programs were excluded if they had been released during this timeframe and were no longer required by the FDA to be implemented. We also excluded REMS containing Medication Guides and Communication Plans as the sole elements because we wanted to study complex multi-level, multi-system interventions, leaving active REMS with ETASU for analysis. Finally, shared system REMS were excluded because we wanted to focus on new programs, and shared system REMS programs reflect sustaining programs that have been adapted for generic products. **Figure 1** shows the selection process.

Source Data

The assessment plan for each REMS program was obtained from the publicly-available regulatory approval letters downloaded from the FDA's website REMS@FDA on January 15, 2019. Assessment plans include a listing of measures that drug manufacturers need to address in their scheduled assessment reports, often at 6-, 12-month, and annually. Each assessment plan is tailored to each REMS program which results in variability in number and type of measures assessed per program. The original approval letters represent measures pre-specified at the time of approval.

Adaptation of the RE-AIM Dimensions

Using the established RE-AIM framework (20, 21), the authors Toyserkani (GT), Huynh (LH), and Morrato (EM) created construct definitions applicable to REMS assessments by adapting from those defined by the framework as shown in **Table 2**.

The adaptation for applying RE-AIM to assessment of REMS was informed by the Scoring Instrument developed for assessing NCI Research-Tested Intervention (RTIPs) programs (19). RTIPs is a searchable database of evidence-based cancer control interventions and program materials and is designed to provide program planners and public health practitioners easy and immediate access to research-tested materials. The

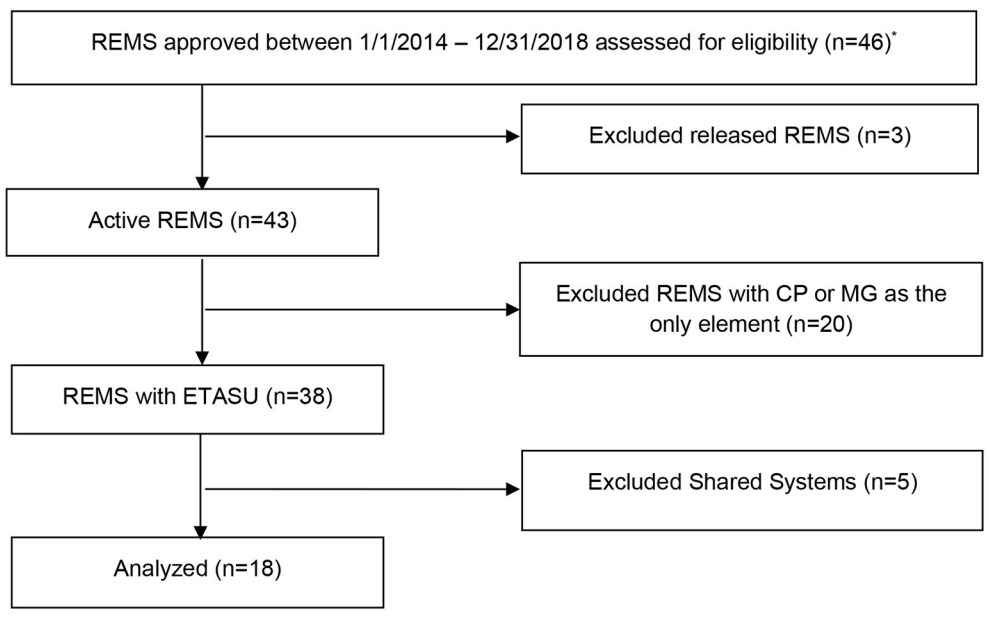

FIGURE 1 | Flow diagram of 2014–2018 active, single product REMS with ETASU program selection for content analysis of assessment plans using the RE-AIM framework. ANDA, Abbreviated New Drug Application; CP, Communication Plan; MG, Medication Guide; *REMS programs were accessed for eligibility January 2019.

adaptation was also informed by the RE-AIM checklist for "RE-AIM Dimensions When Evaluating Health Promotion Programs and Policies" found at RE-AIM.org (24).

The goal was to be as consistent with the constitutive definitions of the RE-AIM dimensions as possible. For example, Adoption was defined as the number and proportion of healthcare settings and providers that agree to initiate program or policy change and how representative they are of the intended audience in terms of the setting and the staff. As REMS programs are multi-level interventions, dimensions were further delineated based on the healthcare setting (system level), healthcare provider (agent level), and patient (individual level).

The dimensions were then mapped to categories outlined in the Assessment Guidance to discern the ease of mapping RE-AIM to the Guidance and determine where opportunities in the assessment process may exist.

Coding

Three blinded reviewers (GT, LH, EM) adjudicated the application of RE-AIM dimensions by coding each REMS assessment measure for three randomly selected REMS assessment plans (average IRR = 75%). They discussed coding discrepancies and refined the dimensions' definitions accordingly. Two blinded reviewers (GT, LH) then categorized each assessment measure(n = 540) for the remaining 15 assessment plans with a third reviewer (EM) serving as an adjudicator.

Analysis

Sensitivity analyses were performed to examine qualitative differences over time, by type of application (NDA vs. BLA), and by type of ETASU required. Descriptive statistics were calculated to determine the proportions of RE-AIM dimensions per REMS assessment program. The median number of assessment measures were then independently analyzed by the variables: year approved, application type, and ETASU to identify any correlations.

Using the alignment between RE-AIM dimensions and Assessment Guidance categories, each assessment measure was then assessed for its inclusion of the categories. This was done by noting how many assessment measures were reflective of each category and then measuring these individual values against the total number of assessment measures for each program. Aggregate summary statistics were reported for the number of measures per category and frequency distribution across all programs.

RESULTS

A total of 18 REMS programs involving nine NDAs and nine BLAs met evaluation eligibility criteria. **Table 3** shows the characteristics of the REMS programs meeting criteria at the time of their original REMS approval. Programs by year approved ranged from two in 2016 to five in 2018. The drug products carried a variety of risks intended to be mitigated by the REMS, ranging from cancers such as lymphoma and osteosarcoma, immune system disorders such as autoimmune conditions and cytokine release syndrome, and psychiatric disorders such as suicidal ideation and behavior. The number of assessment measures per program ranged from 10 to 57.

Frequency Distribution Analysis of RE-AIM Dimensions

Table 4 shows the distribution of REMS programs (N = 18) and assessments measures (n = 540) across the RE-AIM dimensions. The 18 programs yielded a total of 540 assessment measures; of these, only three measures (0.6%) could not be mapped to a single RE-AIM dimension. These included measures where the intent was unclear or there were multiple intents of the assessment measure that it could have been categorized into more than one dimension.

Of 18 REMS programs, the median number of assessment measures assessing Reach per assessment plan was 2 (IQR: 2–4). Prototypical examples of REMS assessment measures categorized as assessing reach included "age and gender of enrolled patients" and "total number of orders shipped to pharmacies."

Similarly, the median number of assessment measures assessing Effectiveness per REMS assessment plan was 2.5 (IQR: 1–4). Prototypical examples of REMS assessment measures categorized as assessing effectiveness included "adverse event assessments" and "an evaluation of knowledge of patients of the increased risks."

Regarding Adoption, the median number of assessment measures assessing this dimension per REMS assessment plan was 3.5 (IQR: 2–5). Prototypical examples of REMS assessment measures categorized as assessing adoption included the "number of newly enrolled and active pharmacies stratified by type of pharmacy and geographic location" and "number and location of REMS training programs."

The median number of assessment measures assessing Implementation per REMS assessment plan was 18 (IQR: 15–24). Prototypical examples of REMS assessment measures categorized as assessing implementation included: "date when the REMS website went live," "summary report of program problems reported and corrective actions resulting from issues identified," and "number of prescriptions written by non-certified prescribers and detailed root-cause analysis."

Finally, the median number of assessment measures assessing Maintenance per REMS assessment plan was 0 (IQR: 0–1). Prototypical examples of REMS assessment measures categorized as assessing maintenance included: "number of discontinued patients" and "number of healthcare settings re-enrollments and the expected number of re-enrollments."

Figure 2 shows a lack of time trends in RE-AIM dimensions by year of REMS approval. No trends in the number or distribution of RE-AIM dimensions were observed by drug application type or specific ETASU element required.

Alignment With FDA Assessment Guidance

Consistent with the adaptation of RE-AIM to REMS, the application of RE-AIM dimensions to the Assessment Guidance demonstrated heavy focus on Implementation and Operations. Because assessment measures categorized into the Implementation dimension could be measuring either

TABLE 3 | Characteristics of selected active, single product REMS with ETASU programs at time of original approval (2014–2018) included for content analysis of assessment plans using the RE-AIM framework.

Year	Drug** (active ingredient)	Type	ETASU***	Indication (benefit)	Risk(s) requiring risk mitigation	Number of assessment measures
2014	Myalept (*metreleptin*)	BLA	A, B, D	Treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy	Lymphoma and anti-metreleptin antibodies that neutralize endogenous leptin and/or Myalept	26
	Aveed (*testosterone undecanoate*)	NDA	A, B, C	Testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone	Anaphylaxis and pulmonary oil microembolism	22
	Lemtrada (*alemtuzumab*)	BLA	A, B, C, D (CP)	Treatment of patients with relapsing forms of multiple sclerosis	Autoimmune conditions, infusion reactions, and malignancies	36
2015	Natpara (*parathyroid hormone*)	BLA	A, B, D	An adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism	Osteosarcoma	21
	Xyrem (*Sodium oxybate*)	NDA	A, B, D (MG)	Treatment of cataplexy or excessive daytime sleepiness in patients 7 years of age and older with narcolepsy	Serious adverse outcomes resulting from inappropriate prescribing, misuse, abuse, and diversion	57
	Ionsys (*fentanyl iontophoretic) transdermal system*)	NDA	B, C	Short-term management of acute postoperative pain severe enough to require an opioid analgesic in the hospital and for which alternative treatments are inadequate	Respiratory depression resulting from accidental exposure	29
	Addyi (*flibanserin*)	NDA	A, B	Treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder, as characterized by low sexual desire that causes marked distress or interpersonal difficulty	Hypotension and syncope due to interaction with alcohol	32
2016	Probuphine (*buprenorphine hydrochloride*)	NDA	A, B, C, E (MG)	Maintenance treatment of opioid dependence in patients who have achieved and sustained prolonged clinical stability on low-to-moderate doses of a transmucosal buprenorphine-containing product	Migration, protrusion, expulsion and nerve damage associated with insertion and removal and accidental overdose, misuse and abuse	22
	Zinbryta (*daclizumab*)	BLA	A, B, D, E, F (CP)	Treatment of adult patients with relapsing forms of multiple sclerosis	Hepatic injury and immune mediated disorders	27
2017	Siliq (*brodalumab*)	BLA	A, B, D	Treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies	Suicidal ideation and behavior, including completed suicides	31
	Kymriah (*tisagenlecleucel*)	BLA	B, C	Treatment of: Pediatric and Young Adult Relapsed or Refractory (r/r) B-cell Acute Lymphoblastic Leukemia and Adult Relapsed or Refractory (r/r) Diffuse Large B-Cell Lymphoma	Cytokine release syndrome and neurological toxicities	21
	Yescarta (*axicabtagene ciloleucel*)	BLA	B, C	Treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy	Cytokine release syndrome and neurological toxicities	21
	Sublocade (*buprenorphine extended-release*)	NDA	B	Treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a transmucosal buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days	Intravenous self-administration	20

(Continued)

TABLE 3 | Continued

Year	Drug** (active ingredient)	Type	ETASU***	Indication (benefit)	Risk(s) requiring risk mitigation	Number of assessment measures
2018	Jynarque (*tolvaptan*)	NDA	A, B, D, E, F (CP)	Slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease	Liver injury	42
	Palynziq (*pegvaliase-pqpz*)	BLA	A, B, D	Reduce blood phenylalanine concentrations in adult patients with phenylketonuria who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management	Anaphylaxis	31
	Tegsedi (*Inotersen*)	NDA	A, B, D, E, F	Treatment of polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults	Bleeding with thrombocytopenia and glomerulonephritis	57
	Dsuvia (*sufentanil*)	NDA	B, C	Use in adults in certified medically supervised healthcare settings for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate	Respiratory depression from accidental exposure	35
	Ultomiris (*ravulizumab-cwvz*)	BLA	A	Treatment of adult patients with paroxysmal nocturnal hemoglobinuria	Meningococcal infections	10

BLA, Biologic License Application; NDA, New Drug Application; ETASU, Elements to Assure Safe Use; CP, Communication Plan; MG, Medication Guide.
***REMS programs were selected January 2019.*
****ETASU A, training or certification of prescribers; ETASU B, training or certification of dispensers; ETASU C,dispensing/administering the drug in certain settings; ETASU D, requiring evidence or documentation of safe use conditions; ETASU E, monitoring of patients; ETASU F, enrolling patients in a registry.*

TABLE 4 | Distribution of REMS programs and assessment measures across RE-AIM dimensions.

	Programs Addressing the RE-AIM Dimension (*N*, percentage of total)	Assessment measures per REMS program (median, range)	Assessment Measures (*n*, percentage of total)
Total Sample	18 programs	31 (range 10–57)	537 assessment measures*
RE-AIM Dimension			
Reach	15 (83.3%)	2 (range 0–7)	48 (8.9%)
Effectiveness	16 (88.9%)	2.5 (range 0–8)	49 (9.1%)
Adoption	18 (100%)	3.5 (range 0–7)	61 (11.4%)
Implementation	18 (100%)	18 (range 4–41)	371 (69.6%)
Maintenance	8 (44.4%)	0 (range 0–1)	(1.5%)

**3 measures (0.6%) could not be mapped to a single RE-AIM dimension.*

the healthcare provider's knowledge or processes, these were categorized as either Implementation and Operations (n = 315, 58%) or Safe Use Behaviors and Knowledge (n = 52, 10%) according to the Assessment Guidance. Likewise, measures categorized into the Effectiveness dimension were categorized as Safe Use Behaviors and Knowledge (n = 20, 4%) if they assessed knowledge, and Health Outcomes (n = 30, 5%) if they measured patient understanding. Outreach and Communications (n = 112, 22%) were akin to Reach or Adoption depending on the target audience. Measures of maintenance (n = 8, 1%) were lacking in REMS assessments.

DISCUSSION

To our knowledge, this is the first systematic content analysis examining the feasibility and utility of applying an implementation science framework across a range of REMS programs. The application of social science theories and frameworks to pharmaceutical risk minimization design, implementation and evaluation has been discussed by Smith and Morrato (25). Others have proposed a variety of implementation measures for health services research and pharmaceutical risk minimization evaluation (26–28). Theories and frameworks can provide a social science mechanism of action to understand the relationship between measures and the causal pathway affecting the success of REMS programs in much the same way that a biological mechanism of action guides the clinical development of new medicines. Even risk minimization programs that address only a subset of constructs with a theoretical model can be framed conceptually, so that regulators and the public perceive the larger context and body of literature guiding these programs (29). Ultimately, the use of theories and frameworks helps enable cross-program comparisons and foster generalizable knowledge to advance the science of risk mitigation dissemination and implementation.

Our pragmatic application of RE-AIM to REMS assessment plans were feasible and relatively intuitive to perform. The primary challenge was defining who is the program recipient and who is the program agent, given the complex and multi-faceted nature of REMS programs and their systems-, provider- and patient-level involvement. As Glasgow et al. have defined the product of Reach and Effectiveness to be the individual level, we interpreted this to refer to patients—the recipient of the

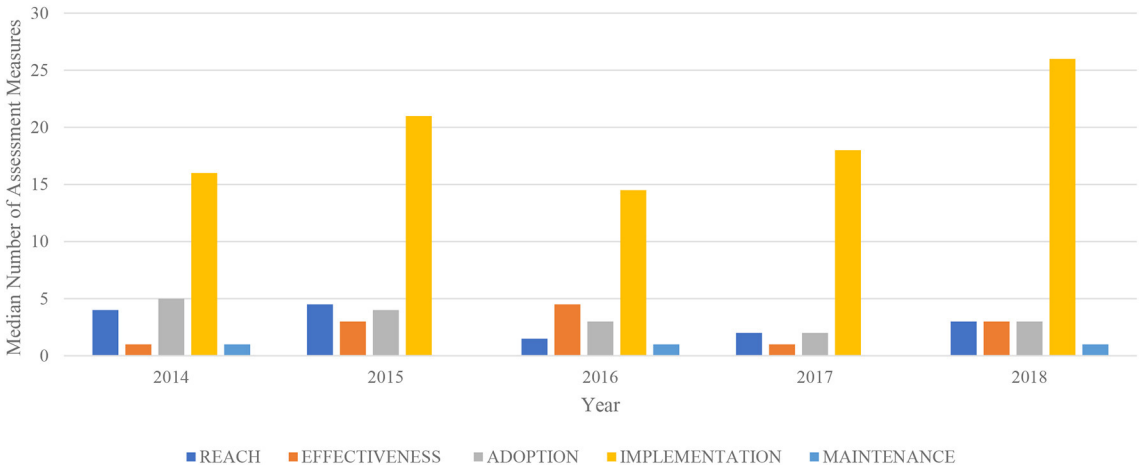

FIGURE 2 | Median number of REMS assessment measures per RE-AIM dimension by year (2014–2018).

program or "groups receiving" the intervention (21). Adoption and Implementation then corresponded to the agents of the program, or "staff members" and "program-level" participants who facilitate the delivery of the program to the patients. Glasgow identified the product of these two dimensions to be at the organization level, which we construed to apply to the healthcare providers and healthcare settings. Once we established this distinction of program recipient vs. agent, determining the RE-AIM dimension of each REMS assessment measure was intuitive.

Our findings demonstrate strong congruence between the RE-AIM framework and REMS assessment measures. Consistent with the Assessment Guidance statement that "REMS can be assessed using both process indicators and the intended outcomes," application of RE-AIM to REMS assessment plans found heavy emphasis on Implementation and Operations measures (10). However, this research also detected lighter emphasis on Health Outcomes measures in REMS assessment plans. Health outcomes in general are difficult to assess especially given rare adverse drug events. For the majority of drugs, FDA relies on routine pharmacovigilance and spontaneous adverse event reporting(passive surveillance) received through post-market periodic safety update reports (PSURs) (30). However, under-reporting is a major drawback and may underestimate the number of adverse drug events (30, 31). In certain REMS programs, FDA does require patient registries, such as pregnancy registry for drugs with risk of birth defects, that collect case data on safety events (active surveillance) (32). Given that health outcomes are generally challenging to assess, assessment of REMS program effectiveness typically relies on process measures such as knowledge attainment and safe use behaviors.

This research also observed very low inclusion of Maintenance measures in REMS assessment plans. Adding measures of Maintenance to REMS assessment plans can strengthen the quality of REMS programs. Maintenance measures represent an area for real-world evidence of REMS integration into the healthcare system and its sustainability. For example, these metrics would measure the durability of knowledge of healthcare providers or cumulative enrollment of healthcare providers in a program over time or evaluate for the evidence of the integration of REMS processes and procedures into state and institutional policies, treatment guidelines, insurance requirements. Our findings are very similar to conclusions reached by previous studies citing that maintenance and representativeness were reported much less often in other health intervention evaluations (33).

The RE-AIM framework offers a number of strengths, including the fact that it considers representativeness and characteristics of the participants to assess heterogeneity of impact. By assessing heterogeneity of impact, RE-AIM permits evaluations of patient access, healthcare system, and patient burden, a potential unintended consequence of risk mitigation requirements that is of public stakeholder interest. RE-AIM also addresses the often-neglected goal of long-term maintenance at both the individual and organization levels. Finally, RE-AIM considers both process and outcome measures, covering the scope of many domains of interest for REMS.

Another important strength is using frameworks like RE-AIM can help REMS assessments be more transparent and better understood across all stakeholders, as it was originally intended. Having a framework for evaluating REMS can facilitate standardization, consistency, and completeness in assessing REMS to enable comparisons across programs (33). By using the commonly recognized constructs and terminology of RE-AIM, data collected by the REMS program can be more meaningful.

Our application of RE-AIM demonstrated some challenges of the framework. The first challenge is one of definition. It has been acknowledged that RE-AIM application has "frequent issues with confusing different dimensions" (33). For example, as aforementioned, defining the agent and recipient of the program is open to interpretation. Others suggest defining Reach at the healthcare provider-level, not the patient-level as we did (34). Effectiveness has been applied to non-patient stakeholders, such as the healthcare provider and pharmacists, at times "requir[ing] multiple creative and innovative combinations of metrics" (34,

35). This contrasts our interpretation of Effectiveness to apply only at the patient-level, which, as aforementioned, was to be as consistent with the constitutive definition of RE-AIM as possible (24).

The second challenge is one of longitudinal assessment. It is not readily apparent how best to apply the framework in a longitudinal and time-dependent manner, although RE-AIM has been proposed for evaluating adaptation over time (33). Pharmaceutical risk management consists of the iterative process of assessing a product's risk-benefit balance, developing and implementing tools, evaluating the tools, and making adjustments to maintain or improve the benefit-risk balance (36). A single REMS program may be implemented for decades as long as the drug product remains on the market. Moreover, the FDAAA requires that assessments be conducted at 18 months, 3 years, and 7 years post-market, at a minimum (13). FDA has required more frequent assessments for REMS with ETASU. Further research is needed to elucidate the pragmatic use of the framework during the REMS life cycle by aligning and differentiating specific RE-AIM measures at different time points of adoption. For example, what are early markers of Effectiveness vs. later markers? What are early markers of Maintenance vs. later markers?

The third challenge is one of utility for decision making. Regulators need to use assessment data to determine whether to sustain, modify or eliminate a REMS program. Should a REMS regulatory determination require a collective gestalt of all RE-AIM dimensions or rely on a single dimension, and if so, how might that best be accomplished in a standardized manner? Our research, similar to previous applications of RE-AIM, found that not all dimensions were assessed equally (18). This observation raises the question of whether all five dimensions are of equal importance, or are there dimensions that are more important, when determining whether a REMS program is meeting its public health drug safety goals.

The limitations of our study include examining only the RE-AIM framework to characterize REMS assessment plans. Future work should evaluate the application of other established frameworks such as PRECEDE-PROCEED, Consolidated Framework for Implementation Research (CFIR), and Practical, Robust Implementation Sustainability Model (PRISM) (33, 37–39). Secondly, this study looked at REMS assessment plans from 2014 to 2018 and does not consider the potential impact or evolution of REMS assessment plans since the publication of the Assessment Guidance issued in 2019. Furthermore, assessment measures from Shared Systems REMS (multiple products of the same class or molecular moiety under two or more sponsors) can offer additional insights into the strengths and opportunities for REMS assessments.

Of note, our study examined the type and quantity of REMS assessment measures from the original approval; however, it did not assess the rigor of proposed study designs nor the quality of their reports. Reporting standards for risk minimization communication and program evaluation have been described by members of the International Society for Pharmacoepidemiology (40). A systematic review of the published literature on pharmaceutical risk minimization evaluation found limited use of conceptual frameworks guiding process and outcome measurement selection and program design and implementation (41).

FDA considers public comments and stakeholder feedback as it finalizes guidance to industry. Therefore, learning from the current analysis is one source of input that FDA is considering as it works on the final version of the REMS Assessment Guidance affecting all future REMS programs. The guidance aims to ultimately improve how REMS assessment plans are developed, specifically how the REMS program goals, objectives and REMS design may impact the selection of metrics and data sources, which will be used to assess whether the program is meeting its risk mitigation goals (16).

In addition, findings are also relevant to FDA's efforts on structured benefit-risk assessment process and commitments established in the sixth authorization of the PDUFA VI in 2017. FDA has made several commitments in PDUFA VI for continued implementation of structured benefit-risk assessment, including publishing a draft guidance on benefit-risk assessment. "Risk and Risk Management" is one explicit dimension in the benefit-risk assessment framework (42). How information, including evidence and uncertainties, can be effectively communicated to the public is one area of interest. To meet requirements established in the 21st Century Cures Act, the benefit-risk assessment guidance will also discuss how relevant patient experience data may be used to inform benefit-risk assessments (43). RE-AIM provides a natural structured analytic approach for synthesizing risk management effectiveness evidence and integrating patient data into the assessment.

CONCLUSION

Dissemination and implementation science frameworks can provide a systematic approach for REMS program assessments. They provide a structured and evidence-based approach to guide what should be evaluated and to what extent, and to identify which aspects of the programs will be considered when judging REMS program performance, including *a priori* expectations for program success. Frameworks like RE-AIM, can be readily applied to REMS assessments to strengthen their evaluation and have the potential to advance science, quality of practice, and population health through all participants affected by REMS.

DATA AVAILABILITY STATEMENT

The datasets generated for this study are available on request to the corresponding author.

AUTHOR CONTRIBUTIONS

All authors listed have made a substantial, direct and intellectual contribution to the work, and approved it for publication.

FUNDING

GT was employed by the U.S. Food and Drug Administration. LH was supported by an appointment to the Research Participation Program at the U.S. Food and Drug Administration administered by the Oak Ridge Institute for Science and Education through an interagency agreement between the U.S. Department of Energy. EM was supported by an Intergovernmental Personnel Act appointment to the U.S. Food and Drug Administration, Office of Surveillance and Epidemiology administered through the University of Colorado.

ACKNOWLEDGMENTS

Results were presented in part at the 35thInternational Conference of Pharmacoepidemiology and Therapeutic Risk Management, August 28, 2019. Philadelphia, USA (44).

REFERENCES

1. *About FDA*. Available online at: https://www.fda.gov/about-fda (accessed August 30, 2019).
2. IOM. *To Err Is Human*. Washington, DC: The National Academies Press (2000).
3. *PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022*. Available online at: https://www.fda.gov/media/99140/download (accessed August 30, 2019).
4. FDA. *Classifying Significant Postmarketing Drug Safety Issues*. (2012). Available online at: https://www.fda.gov/media/83087/download
5. *National Action Plan for Adverse Drug Event Promotion*. Washington, DC (2014). Available online at: https://health.gov/hcq/pdfs/ADE-Action-Plan-508c.pdf (accessed August 30, 2019).
6. *Food and Drug Administration Amendments Act of 2007*. *HR, 110th Congress Session*. House Committee on Energy and Commerce (2007).
7. FDA. *FDA's Application of Statutory Factors in Determining When a REMS Is Necessary*. Drug Safety (2019). Available online at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fdas-application-statutory-factors-determining-when-rems-necessary
8. FDA. *Approved Risk Evaluation and Mitigation Strategies (REMS)*. Available online at: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm (accessed September 3, 2019).
9. FDA. *Medication Guides — Distribution Requirements and Inclusion in Risk Evaluation and Mitigation Strategies (REMS)*. Drug Safety (2011). Available online at: https://www.fda.gov/media/79776/download
10. FDA. *REMS Assessment: Planning and Reporting*. (2019). Available online at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/rems-assessment-planning-and-reporting
11. CRS. *The SUPPORT for Patients and Communities Act (P.L. 115-271): Food and Drug Administration and Controlled Substance Provisions* (2018).
12. FDA. *Fixed-Quantity Unit-of-Use Blister Packaging for Certain Immediate Release Opioid Analgesics for Treatment of Acute Pain*; *Establishment of a Public Docket*; *Request for Comments*. (2019). Available online at: https://www.govinfo.gov/content/pkg/FR-2019-05-31/pdf/2019-11283.pdf
13. U.S. Congress. *United States Code: Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ßß301–392 (Suppl. 5. 1934)*. Periodical. Available online at: https://www.loc.gov/item/uscode1934-006021009/
14. FDA. *Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)*. Information by Drug Class. Available online at: https://www.fda.gov/drugs/information-drug-class/opioid-analgesic-risk-evaluation-and-mitigation-strategy-rems (accessed September 27, 2018).
15. FDA. *Zyprexa Relprevv (olanzapine)*. *Approved Risk Evaluation and Mitigation Strategies (REMS)*. Available online at: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=74 (accessed April 11, 2019).
16. FDA. *Risk Evaluation and Mitigation Strategies Assessment: Planning and Reporting; Draft Guidance for Industry*; *Availability*. (2019). Available online at: https://www.govinfo.gov/content/pkg/FR-2019-02-01/pdf/2019-00676.pdf
17. Frame JN, Jacobson JO, Vogel WH, Griffith N, Wariabharaj D, Garg R. Assessment of risk evaluation and mitigation strategies in oncology: summary of the oncology risk evaluation and mitigation strategies workshop. *J Oncol Pract*. (2012) 9:24–39. doi: 10.1200/JOP.2012.000620
18. Gaglio B, Shoup JA, Glasgow RE. The RE-AIM framework: a systematic review of use over time. *Am. J. Public Health*. (2013) 103:38–46. doi: 10.2105/AJPH.2013.301299
19. NCI. *RE-AIM Scoring Intsrument*. Available online at: https://rtips.cancer.gov/rtips/reAim.do (accessed September 04, 2013).
20. Workgroup R-A. *What is RE-AIM? The Basics*. Available online at: http://www.re-aim.org/about/frequently-asked-questions/
21. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am. J. Public Health*. (1999) 89:1322–7.
22. Stoutenberg M, Galaviz KI, Lobelo F, Joy E, Heath GW, Hutber A, et al. A pragmatic application of the RE-AIM framework for evaluating the implementation of physical activity as a standard of care in health systems. *Prev Chronic Dis*. (2018) 15:E54. doi: 10.5888/pcd15.170344
23. Jilcott S, Ammerman A, Sommers J, Glasgow RE. Applying the RE-AIM framework to assess the public health impact of policy change. *Ann Behav Med*. (2007) 34:105–14. doi: 10.1007/bf02872666
24. Workgroup R. *Measures and Checklists*. (2019). Available online at: http://www.re-aim.org/resources-and-tools/measures-and-checklists/
25. Smith MY, Morrato E. Advancing the field of pharmaceutical risk minimization through application of implementation science best practices. *Drug Safety*. (2014) 37:569–80. doi: 10.1007/s40264-014-0197-0
26. Rabin BA, Purcell P, Naveed S, Moser RP, Henton MD, Proctor EK, et al. Advancing the application, quality and harmonization of implementation science measures. *Implement Sci*. (2012) 7:119. doi: 10.1186/1748-5908-7-119
27. Prieto L, Spooner A, Hidalgo-Simon A, Rubino A, Kurz X, Arlett P. Evaluation of the effectiveness of risk minimization measures. *Pharmacoepidemiol Drug Saf*. (2012) 21:896–9. doi: 10.1002/pds.3305
28. Proctor E, Silmere H, Raghavan R, Hovmand P, Aarons G, Bunger A, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Adm Policy Ment Health*. (2011) 38:65–76. doi: 10.1007/s10488-010-0319-7
29. Proctor EK, Powell BJ, Baumann AA, Hamilton AA, Santens RL. Writing implementation research grant proposals: ten key ingredients. *Implement Sci*. (2012) 7:96. doi: 10.1186/1748-5908-7-96
30. FDA. *Providing Postmarketing Periodic Safety Reports in the ICH E2C(R2) Format (Periodic Benefit-Risk Evaluation Report)*. Drug Safety (2016). Available online at: https://www.fda.gov/media/85520/download
31. Alvarez-Requejo A, Carvajal A, Bégaud B, Moride Y, Vega T, Martin Arias LH. Under-reporting of adverse drug reactions *Eur J Clin Pharmacol*. (1998) 54:483–8.
32. FDA. *Risk Evaluation and Mitigation Strategies (REMS): The iPLEDGE Program*. (2018). Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/rems/Isotretinoin_2018_04_23_REMS_Document.pdf
33. Glasgow RE, Harden SM, Gaglio B, Rabin B, Smith ML, Porter GC, et al. RE-AIM planning and evaluation framework: adapting to new science and practice with a 20-year review. *Front Public Health*. (2019) 7:64. doi: 10.3389/fpubh.2019.00064
34. Chan-Liston M, Bourke J, Sheehan P, Niemcryk S, Peng M, Bwire R, et al. 17th ISoP Annual Meeting "Pharmacovigilance in the 21st century" Liverpool, UK 15–18 October, 2017 *Drug Safety*. (2017) 40:937–1045. doi: 10.1007/s40264-017-0580-8
35. CDER. Standardizing and evaluating risk evaluation and mitigation strategies (REMS). In: *FDA Public Meeting*. Silver Spring, MD (2013).

36. Radawski C, Morrato E, Hornbuckle K, Bahri P, Smith M, Juhaeri J, et al. Benefit–Risk Assessment, Communication, and Evaluation (BRACE) throughout the life cycle of therapeutic products: overall perspective and role of the pharmacoepidemiologist. *J Pharmacoepidemiol Drug Safety*. (2015) 24:1233–40. doi: 10.1002/pds.3859
37. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci.* (2009) 4:50. doi: 10.1186/1748-5908-4-50
38. Glanz K, Rimer BK, Viswanath K, editors. Using the PRECEDE-PROCEED model to apply to health behavior theories. In: *Health Behav Health Education: Theory, Research and Practice*, 4 ed. San Francisco, CA: Jossey-Bass (2008). p. 407–33.
39. Birken SA, Powell BJ, Presseau J, Kirk MA, Lorencatto F, Gould NJ, et al. Combined use of the Consolidated Framework for Implementation Research (CFIR) and the Theoretical Domains Framework (TDF): a systematic review. *Implement Sci.* (2017) 12:2. doi: 10.1186/s13012-016-0534-z
40. Smith MY, Russell A, Bahri P, Mol PGM, Frise S, Freeman E, et al. The RIMES statement: a checklist to assess the quality of studies evaluating risk minimization programs for medicinal products. *Drug Saf.* (2018) 41:389–401. doi: 10.1007/s40264-017-0619-x
41. Russell AM, Mullen RJ, Morrato EH, Smith MY. Quality of reporting on the evaluation of risk minimization programs: a systematic review. *Drug Saf.* (2020). doi: 10.1007/s40264-020-00905-8. [Epub ahead of print].
42. FDA. *Benefit-Risk Assessment in Drug Regulatory Decision-Making*. (2018). Available online at: https://www.fda.gov/files/about%20fda/published/Benefit-Risk-Assessment-in-Drug-Regulatory-Decision-Making.pdf
43. Congress. *21st Century Cures Act*. Available online at: https://www.congress.gov/bill/114th-congress/house-bill/34
44. Toyserkani GA, Huynh L, Morrato EH. Characteristics of risk evaluation and mitigation strategies (REMS) assessment plans: a review of REMS with ETASU (2014-2018) using RE-AIM. *35th International Conference on Pharmacoepidemiology & Therapeutic Risk Management*; August 20, 2019. Philadelphia, PA: Pennsylvania Convention Center (2019). p. 466.

Disclaimer: This article reflects the views of the authors and should not be construed to represent FDA's views or policies.

Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

frontiers in Public Health

ORIGINAL RESEARCH
published: 02 September 2020
doi: 10.3389/fpubh.2020.00430

Comparing, Contrasting, and Integrating Dissemination and Implementation Outcomes Included in the RE-AIM and Implementation Outcomes Frameworks

Kathryn Louise Reilly[1], Sarah Kennedy[2], Gwenndolyn Porter[3] and Paul Estabrooks[3]*

[1] School of Medicine and Public Health, University of Newcastle, Callaghan, NSW, Australia, [2] The Priority Research Centre for Physical Activity and Nutrition, School of Education, University of Newcastle, Callaghan, NSW, Australia, [3] University of Nebraska Medical Center, Omaha, NE, United States

OPEN ACCESS

Edited by:
William Edson Aaronson, Temple University, United States

Reviewed by:
Jo Ann Shoup, Kaiser Permanente Colorado Institute for Health Research (IHR), United States
Paul R. Brandon, University of Hawaii at Manoa, United States

****Correspondence:***
Kathryn Louise Reilly
kathryn.reilly@health.nsw.gov.au

Specialty section:
This article was submitted to Public Health Education and Promotion, a section of the journal Frontiers in Public Health

Received: *26 March 2020*
Accepted: *14 July 2020*
Published: *02 September 2020*

Citation:
Reilly KL, Kennedy S, Porter G and Estabrooks P (2020) Comparing, Contrasting, and Integrating Dissemination and Implementation Outcomes Included in the RE-AIM and Implementation Outcomes Frameworks. Front. Public Health 8:430. doi: 10.3389/fpubh.2020.00430

As the field of dissemination and implementation science matures, there are a myriad of outcomes, identified in numerous frameworks, that can be considered across individual, organizational, and population levels. This can lead to difficulty in summarizing literature, comparing across studies, and advancing translational science. This manuscript sought to (1) compare, contrast, and integrate the outcomes included in the RE-AIM and Implementation Outcomes Frameworks (IOF) and (2) expand RE-AIM indicators to include relevant IOF dissemination and implementation outcomes. Cross tabular comparisons were made between the constitutive definitions of each construct, across frameworks, to reconcile apparent discrepancies between approaches and to distinguish between implementation outcomes and implementation antecedents. A great deal of consistency was identified across approaches, including adoption (the intention, initial decision, or action to employ an evidence-based intervention), fidelity/implementation (the degree to which an intervention was delivered as intended), organizational maintenance/sustainability (extent to which a newly implemented treatment is maintained or institutionalized), and cost. The IOF construct of penetration was defined as a higher-order construct that may encompass the reach, adoption, and organizational maintenance outcomes within RE-AIM. Within the IOF approach acceptability, appropriateness, and feasibility did not match constitutive definitions of dissemination or implementation but rather reflected theoretical antecedents of implementation outcomes. Integration of the IOF approach across RE-AIM indicators was successfully achieved by expanding the operational definitions of RE-AIM to include antecedents to reach, adoption, implementation, and organizational maintenance. Additional combined metrics were also introduced including penetration, individual level utility, service provider utility, organizational utility, and systemic utility. The expanded RE-AIM indicators move beyond the current approaches described within both the RE-AIM framework and IOF and provides additional planning and evaluation targets that can contribute to the scientific field and increase the translation of evidence into practice.

Keywords: translational reseach, Implementation Outcomes Framework, scale-up, implementation outcomes, RE-AIM (Reach, Effectiveness, Adoption, Implementation and Maintenance)

INTRODUCTION

As the field of dissemination and implementation science matures, there are a myriad of outcomes that can be considered across individual, organizational, and population levels (1–4). The RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) Framework was one of the first outcomes-focused approaches to address individual and organizational factors that would, if assessed and optimized, improve the generalizability of efficacy trials, and speed the translation of evidence-based interventions into sustained practice (5, 6). More recently, Proctoret al. introduced the Implementation Outcomes Framework (IOF)—specific to dissemination and implementation trials (4). Across these two approaches, 12 dissemination and implementation outcomes are proposed—some are distinct, some overlap, and some are duplicated—which can lead to difficulty in summarizing literature, comparing across studies, and advancing translational science.

The RE-AIM Framework includes 6 dimensions that focus planning and evaluation on balancing internal and external validity to develop intervention approaches that can achieve a public health impact (see **Table 1**). The framework includes dissemination outcomes at the individual (i.e., patient; reach) and organizational (i.e., adoption) levels. It also includes implementation outcomes that are operationalized at the organizational level (i.e., implementation and organizational maintenance). Finally, clinical outcomes are operationalized at the patient/participant level (i.e., effectiveness, maintenance). The overarching planning and evaluation goals of RE-AIM could be described as developing and testing interventions that (1) have the potential to reach a large and representative proportion of the intended audience, (2) effectively improve and sustain positive health outcomes, (3) have high adoptability across a large and representative proportion of the population of staff and settings intended to enact the intervention, (4) can be consistently implemented with a high degree of fidelity to underlying evidence-based principles at a reasonable cost, and (5) can be sustained in typical clinical or community settings (8).

Conceptualization of the RE-AIM framework has evolved over the past 20 years (6) to include a focus on qualitative research (1), cost across dimensions (9), and use in hybrid effectiveness-implementation research (10, 11). RE-AIM also provides composite metrics that address different aspects of intervention impact (**Table 1**) (12). Specifically, individual level impact can be determined using a composite measure of reach and effectiveness/maintenance using participation rate weighted by representativeness and standardized effect size weighted by differential effects across population subgroups. Attributable individual level impact can be determined by including population prevalence in the equation. Efficiency of individual level impacts was also proposed using the cost per unit of reach by effectiveness. Setting level impact measures can be calculated combining adoption rates and implementation fidelity—again with an option to include cost differentials. Finally, an overall summary index can be calculated by including composite equations for reach, effectiveness (or individual level maintenance), adoption, and implementation (12).

The IOF presents eight implementation outcomes, including: acceptability, adoption, appropriateness, costs, feasibility, fidelity, penetration, and sustainability (**Table 1**) (4). The IOF outcomes were conceptualized to improve the quality of dissemination and implementation trials, through the inclusion of measurable outcomes to enhance understanding of implementation success and processes. The IOF was also developed to distinguish between implementation, service, and client outcomes, develop a taxonomy of implementation outcomes, and highlight relationships across implementation outcomes at various stages in implementation research. For example, when considering the phases proposed in the Exploration, Preparation, Implementation, and Sustainment Model (EPIS) (13) differential levels of salience are proposed for each outcome. Acceptability, appropriateness, feasibility, and cost were considered most salient during the exploration phase, though each were also considered to have a lower degree of salience during preparation (i.e., appropriateness, feasibility), implementation (i.e., acceptability, cost), and sustainment (i.e., acceptability, cost) (7). Adoption was the only outcome considered to be most salient during preparation and was not considered salient at any other phase of implementation research. The outcomes that were considered to have primary salience for the implementation phase included fidelity and penetration while fidelity and sustainability were considered the most salient factors for the sustainment phase (7).

Similar to the RE-AIM framework, the conceptualization of IOF outcomes has also evolved over the 9 years since its first publication (4, 7). Of note, the concept of feasibility at the organizational level was extended to include feasibility at the service recipient level (7). Similarly, penetration was described as conceptually similar to reach and some researchers have extended the definition to include service recipients in addition to the service setting and its subsystems (7). Finally, similar to the RE-AIM framework the definition of cost has been refined to include cost of implementation (4), incremental costs (7), and overall financial impact of implementation efforts (14).

Both the RE-AIM framework and the IOF have had a significant impact on the field of implementation and dissemination science. RE-AIM provides a systematic planning and evaluation model that is based on individual and organizational outcomes, while the IOF provides conceptual clarity to distinguish between implementation, service, and client outcomes. Yet, there is considerable overlap between the frameworks and, based on the initial goals of the frameworks, key distinctions. This manuscript sought to compare, contrast and integrate dissemination, and implementation science outcomes included in these frameworks and provide working definitions that could extend the current RE-AIM indicators and outcome measurement approach.

METHODS

Operationalization of RE-AIM and IOF Outcomes

Cross tabular comparisons were made between the constitutive definitions of the IOF and RE-AIM framework variables

TABLE 1 | Definitions of IOF and RE-AIM outcomes.

Implementation Outcome	Definition
a. Acceptability	IOF: The perception among implementation stakeholders that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory RE-AIM: N/A
b. Adoption	IOF: The intention, initial decision, or action to try or employ an innovation or evidence-based practice RE-AIM: The number, proportion, and representativeness of organizations or settings that agree to deliver the intervention, as well as the number, proportion, representativeness, and expertise of individuals in those settings that would ultimately deliver the intervention
c. Appropriateness	IOF: The perceived fit, relevance, or compatibility of the innovation or evidence-based practice for a given practice setting, provider, or consumer; and/or perceived fit of the innovation to address a particular issue or problem RE-AIM: N/A
d. Attributable individual level impact	IOF: N/A RE-AIM: Population Prevalence X Individual Level Impact (see Row l. below for definition)
e. Attributable organizational level impact	IOF: N/A RE-AIM: Population Prevalence X Organizational Level Impact (see Row o. below for definition)
f. Composite individual and organizational level impact	IOF: N/A RE-AIM: Reach + Effectiveness (or individual level Maintenance) + Adoption + Implementation/4 Maintenance (see below for detailed equations)
g. Costs	IOF: The cost impact of an implementation effort and of implementation strategies RE-AIM: Costs related to implementation and cost-effectiveness assessment
h. Effectiveness	IOF: N/A RE-AIM: A measurement of the degree to which the intervention is producing its intended effects while assessing potential unintended consequences and changes in quality of life
i. Feasibility	IOF: The extent to which a new treatment, or an innovation, can be successfully used or carried out within a given agency or setting RE-AIM: N/A
j. Fidelity	IOF: The degree to which an intervention was implemented as it was prescribed in the original protocol or as it was intended by the program developers RE-AIM: A component of implementation
k. Implementation	IOF: Aligns with Fidelity RE-AIM: Measures of cost and the degree to which the intervention is implemented with fidelity
l. Individual level impact (RE1)	IOF: N/A RE-AIM: Reach X composite Effectiveness = (participation rate - median $ES_{differential\ characteristics}$) X (median $ES_{key\ outcomes}$ - median $ES_{negative\ outcomes}$ - median $ES_{differential\ impact}$)
m. Individual level impact efficiency	IOF: N/A RE-AIM: (Incremental cost of treatment - control)/(incremental RE1 of treatment - control)
n. Maintenance	IOF: Included as sustainability RE-AIM: Considered at both the individual (maintenance of health outcomes $\geq$6 months post-intervention) and the setting (the degree to which the intervention has been institutionalized or sustainably adopted) levels
o. Organizational level impact AI1	IOF: N/A RE-AIM: (Organizational adoption rate - median $ES_{differential\ setting\ characteristics}$) X (staff adoption rate X median $ES_{differential\ staff\ characteristics}$) X (median component implementation rate across staff and Tx components - median $ES_{differential\ implementation}$)
p. Penetration	IOF: The integration of a practice within a service setting and its subsystems. Later definitions included integration within service recipients (i.e., reach) (7) RE-AIM: A component of adoption and, if service recipients included, reach
q. Reach	IOF: Included if service recipients included in penetration RE-AIM: The absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative, intervention, or program, and reasons why or why not
r. Sustainability	IOF: The extent to which a newly implemented treatment is maintained or institutionalized within a service setting's ongoing, stable operations RE-AIM: Included as organizational maintenance of intervention implementation or institutionalization

(see **Table 1**). Framework definitions were sourced from both the source papers as well as updated conceptualizations and models to increase the likelihood that definitions included advancements since initial publication (4, 6, 15). Using a content validity approach, all co-authors independently coded IOF constructs across the RE-AIM dimensions as either; (i) consistent between frameworks, (C); (ii) potential combined metrics (CM) (i.e., IOF construct aggregated across RE-AIM dimensions), or (iii) predictors (P) (or antecedents) of dissemination or implementation (**Table 2**). The study team met monthly between

July and December 2019 to discuss and agree on coding for content analyses, to compare individual coding and resolve any discrepancies between team members through consensus. Coding of the framework definitions was completed by a senior scientist, post-doctoral fellow, and two doctoral candidates all specializing in dissemination and implementation science.

For the purpose of this comparison, we defined "predictors" as constructs that act as precursors to implementation and dissemination of evidence-based interventions. For example, an intervention would need to be perceived as acceptable in order for it to be adopted. Characterization as a predictor was based on the degree to which the construct definition aligned with constitutive definitions of dissemination (i.e., an active approach to spreading evidence-based interventions to a target audience) and implementation (i.e., the process of delivering or enacting evidence-based interventions according to protocol or principles) (15). The level of analysis operationalized as individual (reflecting service recipients, patients, participants) or organizational (reflecting staff, settings, and organizations) was also identified. Gaps identified across the RE-AIM framework and the IOF were also considered and addressed through a proposed expansion of the operational definitions of RE-AIM indicators. Specifically, while cost and adaptation have both been discussed and examined in the context of both frameworks—methods to operationalize both have been limited (4, 7, 16–19). Framework operational definitions based on the cross tabular comparisons are shown in **Table 2**.

RESULTS

Operationalisation of RE-AIM and Implementation Outcomes

A great deal of consistency was identified across approaches, including adoption (i.e., the intention, initial decision, or action to try or employ an evidence-based intervention), fidelity/implementation (i.e., the degree to which an intervention was delivered as intended), organizational maintenance/sustainability (i.e., extent to which a newly implemented treatment is maintained or institutionalized), and cost. However, cost was more explicitly defined in the IOF as cost of an implementation effort and of any strategies that targeted improvements in implementation whereas the RE-AIM conceptualization of cost focused on implementation and cost-effectiveness. The IOF construct of penetration was defined as a higher-order construct that may encompass the reach, adoption, and sustainability outcomes within RE-AIM. Within the IOF approach there were also a number of constructs that reflect theoretical antecedents of implementation outcomes including acceptability, appropriateness, and feasibility—rather than reflecting the constitutive definitions of dissemination or implementation. **Table 2** outlines the cross tabulation of the constructs of the IOF and RE-AIM frameworks.

Expanded Operationalization of RE-AIM Dimensions

Integration of the IOF constructs with the RE-AIM framework was successfully achieved by extending the operational definitions of each RE-AIM dimension using IOF outcomes and antecedents. In addition, adaptation and cost considerations by RE-AIM dimension—both highlighted, but not explicitly included across dissemination and implementation outcomes were included in the expanded indicators; see **Table 3**. The dimensions of effectiveness and individual-level maintenance were the only RE-AIM components that were not expanded through this process. In addition, the IOF concepts of adoption and sustainability were identified as duplicates with the RE-AIM domains of adoption (staff/service provider- and organizational-level) and organizational-level maintenance, respectively, and were operationalized as such.

The IOF constructs of acceptability, appropriateness, and feasibility were included as multi-leveled variables across reach, adoption, implementation, and organizational maintenance. However, the level of application is hypothesized to differ by dimension and temporality of assessment of the construct relative to the initial implementation (e.g., before, during, and after). Specifically, initial perceptions of intervention acceptability, appropriateness, and feasibility were operationalized as unique antecedents of reach (i.e., individual-level; participants/patients)

TABLE 2 | Cross-tabular comparison of RE-AIM and IOF outcomes.

Implementation outcome framework	RE-AIM					Level of analysis
	Reach	Effectiveness	Adoption	Implementation	Maintenance	
Acceptability			P	P	P	O
Adoption			C			O
Appropriateness			P	P	P	O
Costs				C		O
Feasibility			P	P	P	O
Fidelity		P		C		O
Penetration	CM		CM		CM	O
Sustainability					C	O
Level of analysis	I	I	O	O	I / O	

C, Consistent between frameworks; CM, Potential combined metric; P, Predictor of implementation/dissemination; I, Individual; O, Organizational.

TABLE 3 | Expanded operationalization of RE-AIM.

Dimension	Expanded operational definition
Reach	• Number of participants or individuals that participate in or are exposed to a clinical or public health intervention • Proportion of the intended audience that participate in or are exposed to a clinical or public health intervention • The representativeness of participants relative to the intended population that participate in or are exposed to a clinical or public health intervention • *Antecedent assessments—service recipient perceptions of:* ◦ *Appropriateness (IOF definition—consumer level)* ◦ *Acceptability (The perception among service recipients that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory)* ◦ *Feasibility (The extent to which a new treatment, or an innovation, can be successfully used or carried out by a service recipient)* • *Cost of dissemination strategies intended to increase participation of those whose health would benefit from the intervention**
Effectiveness	• The degree to which the intervention is producing its intended effects while assessing potential unintended consequences and changes in quality of life • Cost-benefit based on total intervention costs by magnitude of effectiveness • *No expansion proposed for this dimension*
Adoption	• Number of settings that participate in or are exposed to the public health intervention • Proportion of the intended settings and staff that deliver or are exposed to the public health intervention • Representativeness of settings relative to the intended population that participate in or are exposed to the public health intervention • *Antecedent assessments—organizational staff and stakeholder perceptions of:* ◦ *Acceptability (organizational satisfaction with various aspects of the public health intervention and intervention congruence with organizational mission)* ◦ *Appropriateness (IOF definition—organization or setting level)* ◦ *Feasibility (IOF definition– The extent to which a new treatment, or an innovation, can be successfully used or carried out within a given agency or setting)* • *Start-up cost assessment* • *Costs of dissemination strategies intended to increase participation of staff and settings in implementation of the EBI*
Implementation	• Consistency of delivery as intended and in the time required across staff and organizations • *Adaptation* ◦ *Assessing indicators of adaptation prior to, during, and following implementation of the intervention* ◦ *Document who, what, when, where, and why adaptations were made (18, 20)* ◦ *Document how the adaptation was consistent with the underlying evidence-based principles of the intervention as previously tested (20)* • *Antecedent assessments:* ◦ *Organizational experience of acceptability (organizational satisfaction with various aspects of the public health intervention and intervention congruence with organizational mission)* ◦ *Organizational experience of appropriateness (IOF definition—organization or setting level)* ◦ *Organizational experience of feasibility (IOF definition– The extent to which a new treatment, or an innovation, can be successfully used or carried out within a given agency or setting)* • *Cost of implementation* • *Cost of strategies targeting quality of implementation* • *Budget impact assessment*
Maintenance—individual level	• The extent to which the intervention's primary outcome is sustained ≥6 months after intervention completion • *No expansion recommended for this dimension*
Maintenance—organizational level	The public health intervention becomes institutionalized or part of the routine organizational practices and policies • *Antecedent assessments* ◦ *Experienced acceptability (Organizational satisfaction with various aspects of the public health intervention and intervention congruence with organizational mission)* ◦ *Experienced appropriateness (IOF definition—organization or setting level)* ◦ *Experienced feasibility of EBI to the intended staff and setting intended to implement.* • *Cost of sustained implementation* • *Cost of strategies targeting sustained implementation*
Combined metrics	• Individual-level impact: reach X effectiveness • Individual-level impact efficiency: incremental cost increases by unit of reach X effectiveness • Organizational level impact: adoption X implementation (or organizational maintenance) • Attributable individual-level impact: population prevalence X individual level impact • Attributable organizational-level impact: population prevalence X organizational level impact • Comprehensive individual/organizational impact: reach + effectiveness (or individual level maintenance) + adoption + implementation/4 maintenance • *Penetration: reach X adoption X organizational maintenance* • *Individual level utility: participant ratings of acceptability X appropriateness X feasibility* • *Service provider utility: implementation staff ratings of acceptability X appropriateness X feasibility* • *Organizational utility: organizational decision maker ratings of acceptability X appropriateness X feasibility* • *Systemic Utility: individual utility + service provider utility + organizational utility*

**Text in Italics represents new components of each RE-AIM dimension.*

and adoption (i.e., staff, setting, organization-level; service providers/organizational decision makers). In each of these cases the temporal assessment of these constructs and the potential for predictive validity is hypothesized to be dependent on the initial perceptions of the intervention prior to individual (reach) or organizational (adoption) decisions on engagement or uptake. In contrast, organizational experience—indicating a later temporal assessment following the initial actions of implementation—of acceptability, appropriateness, and feasibility were hypothesized to be antecedents of implementation fidelity (i.e., staff, setting, organizational-level) and organizational-level maintenance.

Cost specification was also expanded across reach, adoption, implementation, and organizational maintenance outcomes. An overarching consideration included that for most outcomes at least two categories of costs could be assessed—the cost of a dissemination or implementation strategy used to enhance a specific RE-AIM dimension and the cost of completing the activities associated with each dimension. For example, an implementation strategy could include the cost of training staff on the intervention delivery and the cost of implementing the intervention itself. The training costs are distinct from the ongoing operational costs for intervention implementation. In addition to these two costs, specific budget impact assessments (16) are included to provide practical information for implementation sites.

Of note, adaptation was not included in the original operational definitions provided by the IOF and RE-AIM framework. Recently, however, there have been suggestions to advance the consideration of adaptation within the context of implementation (17). To address this need we expanded the implementation dimension to include assessing indicators of adaptation prior to, during, and following implementation of the intervention. Initial indicators were based on suggestions from Stirman-Wiltsey et al. to document who, what, when, where, and why adaptations were made (18, 20). In addition, we included documentation on how the adaptation was consistent with the underlying evidence-based principles of the intervention as previously tested (20).

The final area of expansion of RE-AIM indicators was in the realm of combined metrics. Penetration was operationalized to include the product of reach, adoption, and organizational maintenance to provide an overarching system-based outcome. Other expanded combined metrics focused on determining the utility of an intervention at the participant, service provider, and organizational decision-maker level. In each case, utility was defined as the product of ratings of acceptability, appropriateness, and feasibility. Each of these metrics were further combined as an aggregate rating to produce a measure of systemic utility.

DISCUSSION

This manuscript described the process used to compare, contrast and integrate dissemination and implementation science outcomes included in the RE-AIM framework and the IOF. We used a cross-tabular content analysis to compare between the frameworks which highlighted similarities and key differences. In addition, we integrated IOF within the context of the RE-AIM dimensions which generated an increased depth for a number of constructs and provided additional guidance on the possibility to examine combined metrics-particularly during later stages of scale-up activities. Based on this work we hypothesize that assessment of the expanded RE-AIM outcomes will improve the ability of dissemination and implementation scientists to document key outcomes that reflect the achievement of translating evidence-based interventions that promote public health.

The primary distinction between the two frameworks was an inclusion of individual level factors (RE-AIM) and predictors or antecedents of dissemination and implementation outcomes (IOF). The distinctions between these two models is not surprising when considering the rationale for the development of each (4, 5). The IOF was developed to better clarify dissemination and implementation outcomes for the specific field of dissemination and implementation research (4). In contrast, the RE-AIM framework was developed to be used across the translational spectrum of research and encourage some assessment of external validity in efficacy trials while also encouraging some assessment of internal validity in dissemination and implementation trials (21). The comparison between the frameworks allowed the consideration of variables that can be assessed at the individual, service-recipient level and those that can be assessed at an organizational and service provider level.

As **Table 2** demonstrated, the primary overlap between the frameworks was within the organizational components of the RE-AIM framework. This highlighted a limitation of the IOF in the area of understanding a key dissemination outcome—reach. Reach, which can be considered an operationalization of consumer-demand for an evidence-based intervention, has been proposed as a key factor in organizational uptake and sustainability (22). While the explicit focus on reach may have been a limitation of the IOF, the focus on acceptability, appropriateness, and feasibility—albeit at the level of the service provider, organization, and organizational sub-systems—was a strength. We proposed that acceptability, appropriateness, and feasibility could be considered at multiple levels and at different temporal points across the translation research spectrum. First, these constructs would enhance the understanding of acceptability, appropriateness, and feasibility of service recipients. When applied to service recipients, the population that would have health benefits from the evidence-based intervention, understanding these variables can provide valuable information relative to the potential for an evidence-based approach to achieve high reach (23). By integrating these ideas within an expanded operationalization of RE-AIM indicators, it also provides additional planning and evaluation metrics that can heighten the likelihood of achieving broach reach when an intervention is taken to scale. Second, operationalizing these constructs temporally would entail the use of future and present tense language that could easily be applied to existing validated tools. For example, Weiner et al. (24) measures of intervention appropriateness and feasibility include temporal language appropriate for reach and adoption

(e.g., this intervention seems doable) that could be adapted for prediction of ongoing implementation and organizational maintenance (e.g., this intervention is/was doable) reflecting experience in participation and delivery.

The newly expanded RE-AIM indicators has the potential to perform well due to its expanded definitions, in regards to assessment within staged research models such as the Pathways to Scale-Up Model (Pathways) (25), used primarily in Australia, to determine intervention readiness for broad application. "Pathways" describes four stages of scaling up evidence-based interventions: development, efficacy, effectiveness, and dissemination (25). As the RE-AIM framework was developed to be applicable across the translational research spectrum (21, 26), it has greater utility than the IOF for investigators using models such as "Pathways" —which can be applied to both evidence-based interventions as well as novel intervention approaches based on sound theory—and requires the assessment of service recipient outcomes (25). Similarly, the expanded RE-AIM metrics also may be ideal for hybrid effectiveness-implementation trials (27) that necessitate assessing effectiveness at the service recipient level and implementation at the service provider or organizational level. Contextual assessment is also a key component for hybrid type 1 trials that have a primary outcome of effectiveness. The assessment of context can include examining barriers and facilitators to future implementation efforts, potential for adoption and sustainability, and likelihood of high reach. The expanded RE-AIM metrics provide further contextual information related to acceptability, appropriateness, and feasibility that could advance understanding of how best to design implementation fit for the intended audience or service provider.

The assessment of cost was increased to move beyond cost of implementation and implementation strategies, cost effectiveness, and budget impact analysis to a more comprehensive assessment across RE-AIM dimensions. This aligns with the importance of a wide range of cost considerations used by policy makers and organizational leaders (16). The area of cost assessment and analysis in dissemination and implementation science is emerging (16, 19) and the expanded cost metrics provide a methodology for assessing costs related to reach, adoption, implementation, and organizational maintenance—with a focus on both the strategies used to enhance each outcome and the operational costs associated with each dimension. This will allow for the development of cost simulation models (28) that could vary dissemination and implementation strategy use and provide variable budget impact scenarios for systems considering the uptake of a new evidence-based intervention. For example, a new evidence-based diabetes prevention intervention, being introduced for community YMCAs could use dissemination and implementation strategies that include marketing strategies to increase adoption, participant incentives to increase reach, auditing and feedback processes to improve implementation, and a budget matrixing activity to improve likelihood of organizational maintenance. With the appropriate data on responsiveness of each RE-AIM outcome to the respective dissemination and implementation strategy, would allow a determination of the cost and impact with and without each strategy.

Adaptation was not explicitly defined in either the RE-AIM Framework or IOF, but is necessary to consider during the implementation of an intervention (6). Adaptations (i.e., changes to the intervention components, and delivery method) may elicit changes in the effectiveness of interventions (both positive and negative), and as such it is vital that these are noted and assessed when possible, serving as a useful insight into intervention components across the stages. Despite the potential for adaptations to alter effectiveness of interventions, there are several benefits that arise—such as addressing barriers to program adoption, implementation, and sustainment at the individual, service and organizational level (29). As noted by several authors, the key to determining the impact of adaptations is careful tracking and reporting of how, why, and by whom the adaptations were made and the resulting changes in individual and organizational outcomes (20, 30). It is of note that recent conceptual descriptions of adaptations related to the RE-AIM framework (31) highlighted the likelihood that adaptations are iterative and may be addressed across adoption, implementation, and sustainability—additional research in this area will help to determine at which points meaningful adaptation occurs.

The combined metrics proposed for the RE-AIM framework have not been broadly used across the extant public health or dissemination and implementation science literature. It is unclear whether this uptake is based on the lack of applicability of these metrics and/or the difficulty in gathering all the necessary data. Still, the original combined metrics provided an opportunity to consider a single number to assess individual and organizational impact (12). We proposed these metrics to allow for the scientific comparison of differential impact of various dissemination and implementation science strategies. Broader evaluation efforts that include attributable individual-level impact, penetration, and individual-level utility may help researchers and public health professionals better understand intervention reach and, if needed, adapt recruitment and retention efforts to improve individual-level engagement and sustained participation. This is also applicable to adoption at the service provider and system level. These combined metrics may provide additional, and potentially more practical, ways to assess utility at multiple levels and across time with relatively simple measures that can be proactively collected (24). Further, using the expanded RE-AIM outcomes may not only speed up the translation of evidence into practice, in an attempt to alleviate the stark difference that exists between research and policy timelines (32), but may also help researchers and policy makers to determine cost-impacts of interventions. For an intervention to be novel to policy makers, it needs to provide favorable outcomes at the individual and organizational level, aligned with their specific policy goals, as well as having cost benefit (33). The expanded RE-AIM indicators presented here moves beyond current approaches and provided additional planning and evaluations targets that can contribute to dissemination and implementation science and increase the translation of evidence into practice.

A potential limitation of our expanded RE-AIM approach is that, by including antecedents to dissemination and

implementation outcomes we are initiating a shift from an outcome framework to a blended outcome framework and explanatory model (34). As such, the expanded outcomes we propose limit other factors that could provide explanation for specific reach, adoption, implementation, and organizational maintenance outcomes. For example, the Practical, Robust Implementation, and Sustainability Model (PRISM) evaluates the impact of a public health intervention on various domains of RE-AIM as they translate to real-world practice (35). The model considers organizational and patient perspectives of the intervention characteristics, drawing similarities to intervention beneficiary and organizational evaluations of acceptability, appropriateness, and feasibility—though they do not explicitly list these as potential constructs (35, 36). The expanded RE-AIM indicators presented here may simply set the stage to consider theoretically-compelling constructs that could be dissemination and implementation strategy targets to improve RE-AIM outcomes through theoretically derived mediators (37). Additionally, conducting concurrent validity testing on data collected on the indicators that are consistent between the RE-AIM and IOF frameworks would be valuable in a future study.

The expansion to RE-AIM indictors is intended to improve the planning and outcomes related to health-enhancing interventions. However, a potential unintended consequence of this paper is that it is counter to the intuitive nature of the RE-AIM framework (38). That is, by adding complexity to the breadth of RE-AIM indicators it could be a barrier to applying the framework. This paper highlights the similarities between RE-AIM and the IOF, pushes the boundaries of how best to consider dissemination and implementation outcomes, and provides opportunities for confirmation or rejection of the expanded RE-AIM indicators. It is hypothesized that the use of the expanded RE-AIM indicators across the dissemination and implementation research continuum may assist in speeding up the translation of evidence into practice—and advance the science surrounding that translation. Each of the proposed expansions should be examined, from a scientific and pragmatic perspective, to determine the salience of the indicators and metrics across research and practice stakeholder groups. Understanding the practicality, reliability, and validity of our approach will help to advance the planning and evaluation of future translational research studies focused on developing and testing evidence-based interventions.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

AUTHOR CONTRIBUTIONS

KR, SK, GP, and PE equally contributed to the conceptualization of this report, analyzing definitions, compiling cross-tabular comparisons, and manuscript writing. All authors contributed to the article and approved the submitted version.

FUNDING

PE time was supported in part by the National Institutes of Health (Great Plains IDeA CTR U54GM115458). GP time was supported in part by the American Heart Association (18PRE34060136).

REFERENCES

1. Kessler RS, Purcell EP, Glasgow RE, Klesges LM, Benkeser RM, Peek CJ. What does it mean to "employ" the RE-AIM model? *Eval Health Prof.* (2013) 36:44–66. doi: 10.1177/0163278712446066
2. Glasgow RE, Riley WT. Pragmatic measures: what they are and why we need them. *Am J Prev Med.* (2013) 45:237–43. doi: 10.1016/j.amepre.2013.03.010
3. Moullin JC, Dickson KS, Stadnick NA, Rabin B, Aarons GA. Systematic review of the exploration, preparation, implementation, sustainment (EPIS) framework. *Implement Sci.* (2019) 14:1. doi: 10.1186/s13012-018-0842-6
4. Proctor E, Silmere H, Raghavan R, Hovmand P, Aarons G, Bunger A, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Adm Policy Ment Health.* (2011) 38:65–76. doi: 10.1007/s10488-010-0319-7
5. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health.* (1999) 89:1322–7. doi: 10.2105/AJPH.89.9.1322
6. Glasgow RE, Harden SM, Gaglio B, Rabin B, Lee Smith M, Porter GC, et al. RE-AIM planning and evaluation framework: adapting to new science and practice with a 20-year review. *Front Public Health.* (2019) 7:64. doi: 10.3389/fpubh.2019.00064
7. Lewis CC, Proctor EK, Brownson RC. Measurement issues in dissemination and implementation research. In: Brownson RC, Colditz GA, Proctor EK, editors. *Dissemination and Implementation Research in Health: Translating Science to Practice.* 2nd ed. New York, NY: Oxford University Press (2018). p. 15.
8. Glasgow RE, Emmons KM. How can we increase translation of research into practice? Types of evidence needed. *Annu Rev Public Health.* (2007) 28:413–33. doi: 10.1146/annurev.publhealth.28.021406.144145
9. Estabrooks PA, Allen KC. Updating, employing, and adapting: a commentary on what does it mean to "employ" the RE-AIM model. *Eval Health Prof.* (2013) 36:67–72. doi: 10.1177/0163278712460546
10. Almeida FA, Michaud TL, Wilson KE, Schwab RJ, Goessl C, Porter GC, et al. Preventing diabetes with digital health and coaching for translation and scalability (PREDICTS): a type 1 hybrid effectiveness-implementation trial protocol. *Contemp Clin Trials.* (2020) 88:105877. doi: 10.1016/j.cct.2019.105877
11. Zoellner JM, Hedrick VE, You W, Chen Y, Davy BM, Porter KJ, et al. Effects of a behavioral and health literacy intervention to reduce sugar-sweetened beverages: a randomized-controlled trial. *Int J Behav Nutr Phys Act.* (2016) 13:38. doi: 10.1186/s12966-016-0362-1
12. Glasgow RE, Klesges LM, Dzewaltowski DA, Estabrooks PA, Vogt TM. Evaluating the impact of health promotion programs: using the RE-AIM framework to form summary measures for decision making involving complex issues. *Health Educ Res.* (2006) 21:688–94. doi: 10.1093/her/cyl081
13. Aarons GA, Hurlburt M, Horwitz SM. Advancing a conceptual model of evidence-based practice implementation in public service sectors. *Adm Policy Ment Health.* (2011) 38:4–23. doi: 10.1007/s10488-010-0327-7
14. Lewis CC, Fischer S, Weiner BJ, Stanick C, Kim M, Martinez RG. Outcomes for implementation science: an enhanced systematic review of

instruments using evidence-based rating criteria. *Implement Sci.* (2015) 10:155. doi: 10.1186/s13012-015-0342-x
15. Rabin BA, Brownson RC. Terminology in dissemination and implementation science. In: Brownson RC, Colditz GA, Proctor EK, editors. *Dissemination and Implementation Research in Health: Translating Science to Practice*. 2nd ed. New York, NY: Oxford University Press (2018). p. 19–45.
16. Eisman AB, Kilbourne AM, Dopp AR, Saldana L, Eisenberg D. Economic evaluation in implementation science: making the business case for implementation strategies. *Psychiatry Res.* (2020) 283:112433. doi: 10.1016/j.psychres.2019.06.008
17. Rabin BA, McCreight M, Battaglia C, Ayele R, Burke RE, Hess PL, et al. Systematic, multimethod assessment of adaptations across four diverse health systems interventions. *Front Public Health.* (2018) 6:102. doi: 10.3389/fpubh.2018.00102
18. Glasgow RE, Estabrooks PE. Pragmatic applications of RE-AIM for health care initiatives in community and clinical settings. *Prev Chronic Dis.* (2018) 15:E02. doi: 10.5888/pcd15.170271
19. Ward CE, Hall SV, Barnett PG, Jordan N, Duffy SA. Cost-effectiveness of a nurse-delivered, inpatient smoking cessation intervention. *Transl Behav Med.* (2019). doi: 10.1093/tbm/ibz101. [Epub ahead of print].
20. Wiltsey Stirman S, Baumann AA, Miller CJ. The FRAME: an expanded framework for reporting adaptations and modifications to evidence-based interventions. *Implement Sci.* (2019) 14:58. doi: 10.1186/s13012-019-0898-y
21. Estabrooks PA, Gyurcsik NC. Evaluating the impact of behavioral interventions that target physical activity: issues of generalizability and public health. *Psychol Sport Exerc.* (2003) 4:41–55. doi: 10.1016/S1469-0292(02)00016-X
22. Leeman J, Baquero B, Bender M, Choy-Brown M, Ko LK, Nilsen P, et al. Advancing the use of organization theory in implementation science. *Prev Med.* (2019) 129S:105832. doi: 10.1016/j.ypmed.2019.105832
23. Lyon AR, Munson SA, Renn BN, Atkins DC, Pullmann MD, Friedman E, et al. Use of human-centered design to improve implementation of evidence-based psychotherapies in low-resource communities: protocol for studies applying a framework to assess usability. *JMIR Res Protoc.* (2019) 8:e14990. doi: 10.2196/14990
24. Weiner BJ, Lewis CC, Stanick C, Powell BJ, Dorsey CN, Clary AS, et al. Psychometric assessment of three newly developed implementation outcome measures. *Implement Sci.* (2017) 12:1–12. doi: 10.1186/s13012-017-0635-3
25. Indig D, Lee K, Grunseit A, Milat A, Bauman A. Pathways for scaling up public health interventions. *BMC Public Health.* (2017) 18:68. doi: 10.1186/s12889-017-4572-5
26. Dzewaltowski DA, Estabrooks PA, Glasgow RE. The future of physical activity behavior change research: what is needed to improve translation of research into health promotion practice? *Exerc Sport Sci Rev.* (2004) 32:57–63. doi: 10.1097/00003677-200404000-00004
27. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Med Care.* (2012) 50:217–26. doi: 10.1097/MLR.0b013e3182408812
28. Dopp AR, Mundey P, Beasley LO, Silovsky JF, Eisenberg D. Mixed-method approaches to strengthen economic evaluations in implementation research. *Implement Sci.* (2019) 14:2. doi: 10.1186/s13012-018-0850-6
29. McHugh RK, Murray HW, Barlow DH. Balancing fidelity and adaptation in the dissemination of empirically-supported treatments: the promise of transdiagnostic interventions. *Behav Res Ther.* (2009) 47:946–53. doi: 10.1016/j.brat.2009.07.005
30. Chambers DA, Norton WE. The adaptome: advancing the science of intervention adaptation. *Am J Prev Med.* (2016) 51(4 Suppl. 2):S124–31. doi: 10.1016/j.amepre.2016.05.011
31. Shelton RC, Chambers DA, Glasgow RE. An extension of RE-AIM to enhance sustainability: addressing dynamic context and promoting health equity over time. *Front Public Health.* (2020) 8:134. doi: 10.3389/fpubh.2020.00134
32. Glasgow RE, Brownson RC, Kessler RS. Thinking about health-related outcomes: what do we need evidence about? *Clin Transl Sci.* (2013) 6:286–91. doi: 10.1111/cts.12080
33. Jones Rhodes WC, Ritzwoller DP, Glasgow RE. Stakeholder perspectives on costs and resource expenditures: tools for addressing economic issues most relevant to patients, providers, and clinics. *Transl Behav Med.* (2018) 8:675–82. doi: 10.1093/tbm/ibx003
34. Nilsen P. Making sense of implementation theories, models and frameworks. *Implement Sci.* (2015) 10:53. doi: 10.1186/s13012-015-0242-0
35. Feldstein AC, Glasgow RE. A practical, robust implementation and sustainability model (PRISM) for integrating research findings into practice. *Jt Comm J Qual Patient Saf.* (2008) 34:228–43. doi: 10.1016/S1553-7250(08)34030-6
36. McCreight MS, Rabin BA, Glasgow RE, Ayele RA, Leonard CA, Gilmartin HM, et al. Using the practical, robust implementation and sustainability model (PRISM) to qualitatively assess multilevel contextual factors to help plan, implement, evaluate, and disseminate health services programs. *Transl Behav Med.* (2019) 9:1002–11. doi: 10.1093/tbm/ibz085
37. Powell BJ, Fernandez ME, Williams NJ, Aarons GA, Beidas RS, Lewis CC, et al. Enhancing the impact of implementation strategies in healthcare: a research agenda. *Front Public Health.* (2019) 7:3. doi: 10.3389/fpubh.2019.00003
38. Kwan BM, McGinnes HL, Ory MG, Estabrooks PA, Waxmonsky JA, Glasgow RE. RE-AIM in the real world: use of the RE-AIM framework for program planning and evaluation in clinical and community settings. *Front Public Health.* (2019) 7:345. doi: 10.3389/fpubh.2019.00345

Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

frontiers in Public Health

PERSPECTIVE
published: 12 May 2020
doi: 10.3389/fpubh.2020.00134

An Extension of RE-AIM to Enhance Sustainability: Addressing Dynamic Context and Promoting Health Equity Over Time

Rachel C. Shelton[1]*, *David A. Chambers*[2] and *Russell E. Glasgow*[3,4]

[1] Department of Sociomedical Sciences, Mailman School of Public Health, Columbia University, New York, NY, United States, [2] Division of Cancer Control and Population Sciences, National Cancer Institute, National Institutes of Health, Bethesda, MD, United States, [3] School of Medicine, University of Colorado Denver, Aurora, CO, United States, [4] VA Eastern Colorado Health Care System, Aurora, CO, United States

OPEN ACCESS

Edited by:
Shane Andrew Thomas, Australian National University, Australia

Reviewed by:
Miodraga Stefanovska-Petkovska, University of Lisbon, Portugal
Jennifer Leeman, University of North Carolina at Chapel Hill, United States

***Correspondence:**
Rachel C. Shelton
rs3108@cumc.columbia.edu

Specialty section:
This article was submitted to Public Health Education and Promotion, a section of the journal Frontiers in Public Health

Received: 27 September 2019
Accepted: 02 April 2020
Published: 12 May 2020

Citation:
Shelton RC, Chambers DA and Glasgow RE (2020) An Extension of RE-AIM to Enhance Sustainability: Addressing Dynamic Context and Promoting Health Equity Over Time. Front. Public Health 8:134. doi: 10.3389/fpubh.2020.00134

RE-AIM is a widely adopted, robust implementation science (IS) framework used to inform intervention and implementation design, planning, and evaluation, as well as to address short-term maintenance. In recent years, there has been growing focus on the longer-term sustainability of evidence-based programs, policies and practices (EBIs). In particular, investigators have conceptualized sustainability as the continued health impact and delivery of EBIs over a longer period of time (e.g., years after initial implementation) and incorporated the complex and evolving nature of context. We propose a reconsideration of RE-AIM to integrate recent conceptualizations of sustainability with a focus on addressing dynamic context and promoting health equity. In this Perspective, we present an extension of the RE-AIM framework to guide planning, measurement/evaluation, and adaptations focused on enhancing sustainability. We recommend consideration of: (1) extension of "maintenance" within RE-AIM to include recent conceptualizations of dynamic, longer-term intervention sustainability and "evolvability" across the life cycle of EBIs, including adaptation and potential de-implementation in light of changing and evolving evidence, contexts, and population needs; (2) iterative application of RE-AIM assessments to guide adaptations and enhance long-term sustainability; (3) explicit consideration of equity and cost as fundamental, driving forces that need to be addressed across RE-AIM dimensions to enhance sustainability; and (4) use or integration of RE-AIM with other existing frameworks that address key contextual factors and examine multi-level determinants of sustainability. Finally, we provide testable hypotheses and detailed research questions to inform future research in these areas.

Keywords: RE-AIM, sustainability, sustainment, frameworks, health equity, implementation science, evaluation, adaptation

INTRODUCTION

RE-AIM is a robust framework that has been widely applied over the past 20 years across a range of public health, clinical, community, and behavioral settings (1–4). RE-AIM was created to help address the well-documented research-to-practice gap that hinders the reduction of health inequities and widespread population health impact. It is one of the most commonly applied frameworks in public health, health behavior, and implementation science (IS) (2–5). RE-AIM can facilitate transparent reporting (1) and enhance planning for successful dissemination and implementation of evidence-based interventions, programs, practices, and policies ("EBIs"). Recent years have seen expansion of RE-AIM to address contextual factors (e.g., RE-AIM/PRISM); (4, 6) and integrate qualitative methods (7, 8).

As a framework, RE-AIM has both individual-level and staff/setting-level dimensions, including Reach and Effectiveness (individual-level), Adoption and Implementation (staff and setting levels), and Maintenance (both individual and staff/setting levels). Recognizing sustained delivery and impact of EBIs as central challenges across settings, RE-AIM has historically been one of the few IS frameworks that explicitly built in measurement and consideration of "maintenance." "Maintenance" in RE-AIM has been operationalized at the individual level (e.g., long-term effectiveness or impact of EBI) and the setting level (e.g., sustainability of EBI program components after original implementation). The "maintenance" dimension of RE-AIM has typically been assessed at relatively short-term intervals (e.g., 6 months after EBI delivered or initially implemented) and its evaluation has focused on the extent to which a program/policy becomes *institutionalized* (e.g., made part of routine organizational practices and policies) (4).

Within IS, there is growing recognition of the importance of understanding and addressing longer-term sustainability of EBIs (9–12). Achieving sustained impact and delivery of EBIs over time has been identified as one of the most important yet understudied challenges across settings, populations, and health issues (9, 10, 13, 14). There is growing consensus on conceptualizations and definitions of sustainability; e.g., Moore et al. (15) described sustainability as "after a defined period of time, the program, clinical intervention, and/or implementation strategies continue to be delivered and/or individual behavior change (i.e., clinician, patient) is maintained; the program and individual behavior change may evolve or adapt while continuing to produce benefits for individuals/systems." Of note, we recognize that the terms sustainment and sustainability are both used in reference to the outcome of an intervention being delivered over time, as well as the characteristics of the intervention that make it more likely to be delivered over time. For this paper, we used the term "sustainability" to refer to both the desired outcome and the characteristics or processes by which it is more likely maintained.

There has been an important shift away from "static" conceptualizations of sustainability, with awareness that this may impede adoption of more effective practices as the environment changes or new evidence emerges. Investigators also increasingly recognize the need for a dynamic conceptualization of sustainability, in light of complex "real-world" contexts in which EBIs are delivered that require responsiveness, capacity building, and adaptation of EBIs (10, 11, 16). This is consistent with the Dynamic Sustainability Framework (DSF) (17), which focuses on continued learning and evaluation, problem-solving, improvement and ongoing adaptation of EBIs to enhance fit with contexts and populations. Just as a balance between fidelity and adaptation is needed to achieve "fit" in the context of pre-implementation and implementation efforts (18, 19), there is a similar balance between sustainability of original EBIs and ongoing "evolvability" to achieve ongoing fit and sustained population health impact within broader communities or health systems. Evolvability (20) relates to the adaptation of EBIs and implementation strategies in response to changing contexts and resources over time, as well as emerging needs and evidence across the life cycle of an EBI. This includes both the systematic, planned adaptation of EBIs and strategies, as well as ongoing refinement of EBIs and strategies organically within specific community or clinical settings. Over an EBI's life cycle, this evolution within a changing system or organization may ultimately involve "de-implementation," or the removal or replacement of EBIs that no longer fit or are ineffective (21, 22).

As explicated below, equity and costs are foundational driving forces across RE-AIM dimensions that shape sustained impact, and warrant the need for initial and ongoing adaptation. EBIs can only succeed at the population health level if they are affordable across most settings and are delivered routinely and equitably over time across diverse settings and populations. As we consider the life cycle of an intervention (18), it may be less useful to think about "sustainability" of the original EBIs as an "end goal" (17), and instead consider "evolvability" across the dynamic life cycle of the EBI within a broader context or system, with the goal of sustainable and equitable health impact.

Important gaps persist in existing frameworks' ability to provide guidance in concretely conceptualizing, measuring/operationalizing, and planning for longer-term sustainability within a dynamic context. For example, RE-AIM does not capture such dynamic conceptualizations of sustainability, and has often been applied as a "one-time" evaluation and planning tool. Given the numerous conceptual frameworks and models in IS (2, 23, 24), we did not seek to create a new framework. Instead, we propose an expansion of RE-AIM to enhance sustainability by focusing on key issues across RE-AIM dimensions, with the goal of increasing health impact and health equity over time.

The purposes of this article are to: (1) discuss the extension of RE-AIM to address dynamic conceptualization of sustainability over time, including iterative application of RE-AIM to guide adaptation and evolvability of EBIs and implementation strategies; (2) provide concrete guidance on issues pertinent to understanding, measuring, and planning for sustainability in changing context, including explicit consideration of costs and equity; and (3) propose testable hypotheses and detailed research questions to guide future research that applies RE-AIM for sustainability.

Applying Re-Aim to Enhance Sustainability

The following sections discuss and provide recommendations to guide planning, adaptation, and measurement when applying RE-AIM to facilitate sustainability, reflecting dynamic sustainability with a focus on context and equity. Each section concludes with example hypotheses to guide research. Five key issues are discussed below, and summarized in **Table 1** and **Figure 1**.

1. Extending and Reframing "Maintenance" Within RE-AIM to Include Recent Conceptualizations of Sustainability as an Outcome

Given growing consensus of sustainability as dynamic in nature, it is important that indicators of sustainability reflect this longer-term conceptualization. While 6 months, as originally proposed in RE-AIM (1), is useful in providing an indicator of early maintenance, a more comprehensive approach to also capturing sustainability over time includes measurement at least 1 year post initial implementation and over time (e.g., quarterly to annually) (9, 10).

Consistent with recent conceptualizations (10–12), we recommend that operational indicators of maintenance/sustainability include (see **Table 1** for details): (1) extent to which the core components/functions of EBIs and implementation strategies continue to be delivered over time with fidelity (e.g., continuation of active ingredients and essential functions/related activities) (25, 26), and the "evolvability" of the EBI and implementation strategies (27) needed to support continued EBI delivery over time, including adaptations (planned and organic) and why they occur; (2) extent to which the EBI has continued impact on health behaviors/outcomes, when feasible, including patterns in health inequities over time (e.g., who continues to experience health benefits and who does not); and (3) extent to which community and organizational capacity and infrastructure to deliver the EBI are maintained, including partnerships, networks, and coalitions. It is critical to actively engage with stakeholders (e.g., community members, implementers, organizational leaders) to prioritize which maintenance/sustainability outcomes will be measured and when (e.g., which are meaningful and pragmatic to assess and how often). We also recognize the challenges of including ongoing measurement of the effectiveness of EBIs; while in some cases, existing resources may provide data to monitor frequent and continued impact on health behaviors/outcomes, we realize this may not feasible across all settings.

Example Hypothesis: Informed by a broadened, longer-term conceptualization of sustainability, the dose and nature of implementation strategies needed to initially implement an EBI will differ from the strategies needed to sustain an EBI over time (e.g. implementation strategies focused on sustainability may relate to providing proactive planning and ongoing evaluation/monitoring to manage likely changes in the implementation setting, including turnover, EHR upgrades, treatment guideline updates, changes in patient population).

2. To Facilitate Sustainability, Planned Adaptations, and Evolutions Must Be Made Across the Life Cycle of EBIs to Respond to Changing Context

In many cases it is neither feasible nor optimal to continue to deliver the same EBI "protocol" with high fidelity, as context changes over time and across settings. There is often a need in early program stages to make planned "fidelity-consistent" adaptations that reflect diverse settings, cultures, and populations in which they are delivered (16, 18, 28). Failing to make planned cultural or contextual adaptations may have adverse impact on effectiveness, and ultimately, perpetuate health inequities (28, 29). EBIs and implementation strategies that are not aligned with and do not reflect changing community needs, culture, and context are unlikely to be sustained or have sustained impact over time.

It is also likely that there will be evolving evidence (e.g., guidelines change, new populations are exposed to EBI with varied results), setting changes (e.g., staff turnover/attrition; resources change), and shifting population health needs over time that require ongoing adaptations or refinements over time. We recommend proactively planning for adaptations, and documenting why adaptations are needed, and the extent to which EBIs and implementation strategies evolve over the life cycle of a program (16). Iterative application and measurement of RE-AIM dimensions over time enables documentation of effective adaptations to retain fit with ever evolving context. De-implementation (e.g., the removal or replacement of low-value, harmful, costly or non-evidence-based care/EBIs (21, 22), including the need to make a program and its delivery less expensive), may also be necessary and should be tracked to inform changes in implementation.

Example Hypothesis: Settings that maintain core functions of EBIs but include proactive, planned, iterative adaptations to intervention components and implementation strategies in response to changing context and needs will be sustained longer than those that do not, and will have greater impact on reducing health inequities.

3. Assessment and Feedback on RE-AIM Indicators as an Iterative Method to Guide Adaptations

Assessment of RE-AIM dimensions can help guide settings on how to proactively monitor or adapt and may identify early indicators of sustainability challenges, including the need to "change course" to promote the sustainability of EBIs over time. Results on RE-AIM dimensions should not be assumed to be static. Thus, as explicated in **Table 1**, RE-AIM indicators (e.g., Reach, Effectiveness) should be measured repeatedly and iteratively when possible to provide insight into how to achieve sustained health impacts (4, 30), monitor progress, and shed light on where and when both equity and sustainability issues arise (e.g., over time, which populations and settings is the intervention reaching, and why or why not?).

These findings may impact the nature and timing of actionable solutions across RE-AIM dimensions and program life cycle —e.g., adapt the recruitment or implementation strategies. RE-AIM qualitative probes (8) can also be used

TABLE 1 | Iterative application and operationalization of RE-AIM for Sustainability, with a focus on health equity and dynamic context over time.

Reach
Indicators: Number, proportion, representativeness of individuals who participate in EBI. *Key Questions:* Who was the intended audience and who actually participated? Why or why not? How can we better reach them and engage with them? *Health Equity Considerations:* Are all populations equitably reached by the EBI? Who is not reached by the EBI (in terms of a range of social dimensions and social determinants of health) and why? How can we better reach those who are not receiving the EBI and ensure we are reaching those who experience inequities related to social dimensions and social/structural determinants of health? *Sustainability Considerations:* Who is/isn't reached by the EBI at various time points over time? (e.g., iterative measurement of Reach). Why or why not?
Effectiveness
Indicators: The impact of an intervention on important health behaviors or outcomes, including quality of life (QOL) and unintended negative consequences; consider heterogeneity of effects. *Key Questions:* Is the EBI effective? For whom? Are there any negative and/or unintended effects? *Health Equity Considerations:* Are the health impacts experienced equitable across all groups on the basis of various social dimensions and social/structural determinants of health- why or why not? Do certain groups experience higher levels of negative effects or burdens? *Sustainability Considerations:* Does the EBI continue to be effective at various time points over time? Among whom?
Adoption
Indicators: The number, proportion, and representativeness of: (a) settings; and (b) staff/interventionists who deliver the program, including reasons for adoption or non-adoption across settings and interventionists. *Key Questions:* Where was the EBI applied and by who? Which sites/staff were invited and which excluded? Which participated and not? Why? How can the setting/context/staff be better supported to deliver the EBI? *Health Equity Considerations:* Did all settings equitably adopt the EBI? Which settings and staff adopted and applied the EBI? Which did not and why? Were low-resource settings able to adopt the EBI to the same extent as higher-resource settings? What adaptations might be needed to facilitate adoption? *Sustainability Considerations:* Which settings/staff continue to deliver the EBI over time? Which do not and why?
Implementation
Indicators: At multiple setting and staff levels, continued and consistent delivery of the EBI (and implementation strategies) as intended (fidelity), as well as adaptions made and costs of implementation. *Key Questions:* Was the EBI and/or implementation strategies delivered consistently- why or why not? How was it be adapted and why? How much did it cost? How can we ensure the key functions of the EBI are delivered? Informed by existing implementation frameworks (e.g., PRISM, CFIR), what multi-level contextual determinants matter for implementation? *Health Equity Considerations:* Were the EBI and implementation strategies equitably delivered across settings/staff? Which settings/staff successfully delivered the EBI and implementation strategies and which did not and why? Do all settings/staff have the capacity and resources to deliver the EBI on an ongoing basis? What adaptations might be needed to promote equity and address social determinants of health? *Sustainability Considerations:* How do we ensure that the EBI continues to be delivered consistently over time, especially in the context of reduced funding? Are certain implementation strategies more likely to sustain EBIs and have sustained impact than others?
Maintenance/Sustainability
Indicators: Extent to which (*a*) health impact/benefits, outcomes, behaviors continue for patients/consumers at the individual level, including patterns in health inequities over time; (*b*) program activities or core components/functions of the original EBI (and strategies) continue to be delivered at setting/staff level with fidelity (e.g., continuation of active ingredients and essential functions/related activities), as well as the "evolvability" of the EBI and implementation strategies needed to support EBI delivery over time, including adaptations (planned and organic) and why they occur; (*c*) community and organizational capacity and infrastructure to deliver the EBI are maintained, including partnerships, networks, and coalitions; and when applicable (d) institutionalization, or extent to which EBI becomes part of routine organizational practices/policies (when considered dynamically over time) (all above measured initially 6 months after initial implementation and at least 1 year post EBI implementation and on ongoing basis, e.g., quarterly to annually). For the above, includes proportion and representativeness of settings that continue EBI and reasons why/not. *Key Questions:* What sustainability strategies can be used to sustain the program long-term beyond 1 year after implementation and longer? What are the costs and return on value of sustainability of an EBI? How can we support and incorporate the EBI so it is delivered past initial implementation or after the funding is over? Informed by existing sustainability frameworks (e.g., PSAT, ISF), what multi-level contextual determinants matter for sustainability? *Health Equity Considerations:* Is the EBI being equitably sustained? What settings and populations continue to be reached long-term by the EBI and continue to receive benefits over time- why or why not? Do adaptations to EBIs reduce or exacerbate health inequities over time? Do all settings have continued capacity and partnerships to maintain delivery of EBIs? Are the determinants of sustainability the same across low-resource and high-resource settings? How do social determinants of health shape inequitable implementation and sustainability of EBIs over time? *Sustainability Considerations:* As the program continues and the context and evidence changes, what adaptations (to the program, strategies, and setting) are needed to continue delivering the EBI long-term? Are there opportunities to build capacity at sites with low maintenance to promote longer-term sustainability? What would it take for sites to sustain the EBI over the long term? What are key multi-level barriers to continued program sustainability over time among a range of stakeholders? What are factors or strategies that might support continuation of the program? Over time as evidence changes, is de-implementation of some program elements a more appropriate outcome than continued delivery of the program? Are there sustainability strategies that are effective at maintaining impact and delivery over time?

to (a) help ensure that the perspectives of key stakeholders and community members are being assessed regularly; and that (b) stakeholders are being actively engaged in planning for sustainability in ways consistent with their values (e.g., "What would it take for you/your organization/your community to sustain the EBI over the long term?") (12). Aligned

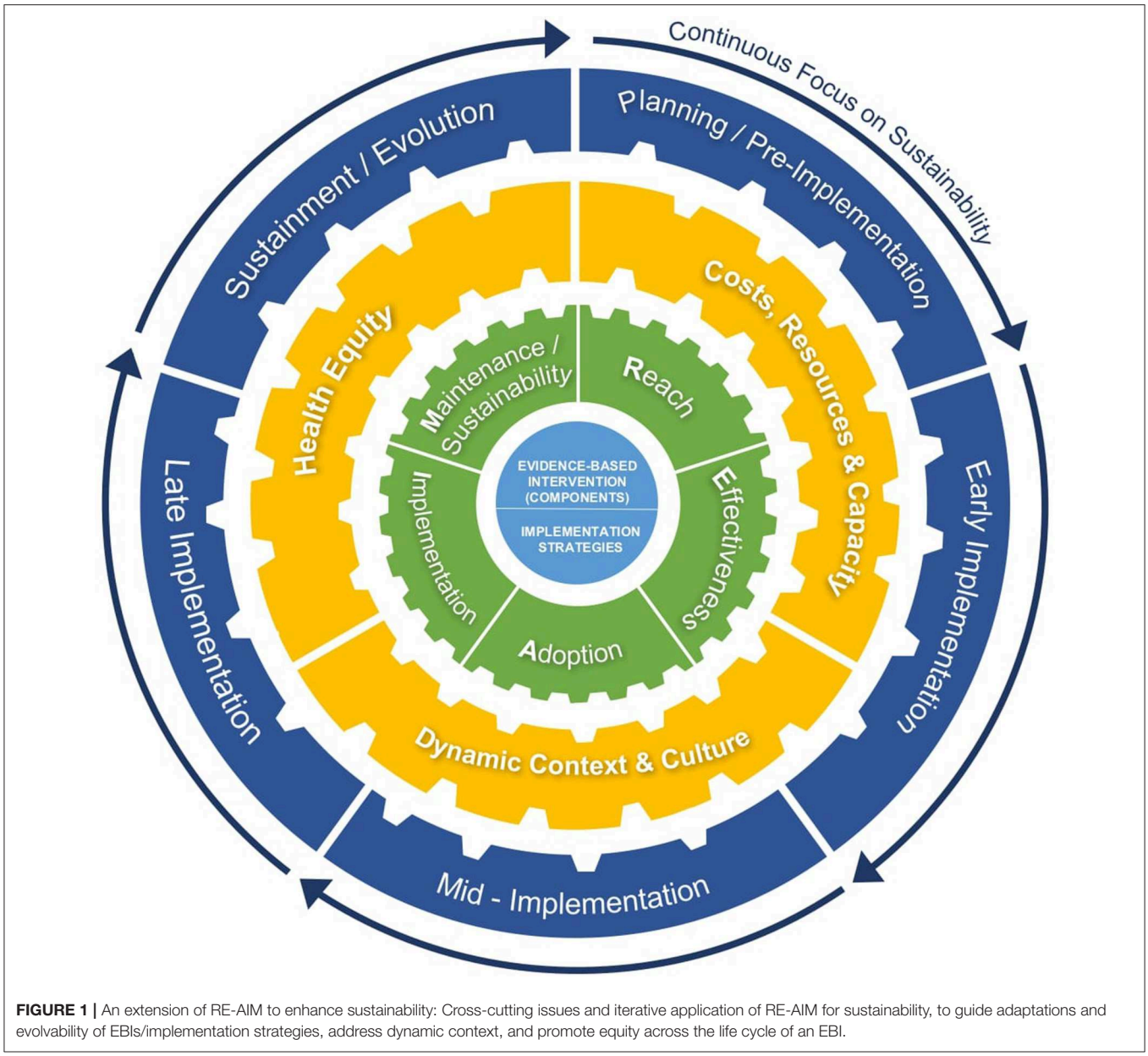

FIGURE 1 | An extension of RE-AIM to enhance sustainability: Cross-cutting issues and iterative application of RE-AIM for sustainability, to guide adaptations and evolvability of EBIs/implementation strategies, address dynamic context, and promote equity across the life cycle of an EBI.

with existing taxonomies of implementation strategies (e.g., evaluation/iterative strategies) (27, 31), RE-AIM can be used as a tool to complement existing quality improvement (QI) and performance management resources (e.g., PDSA cycles) (32, 33). As such, iterative application of RE-AIM can provide guidance and a conceptually-based, standardized evaluation approach to understand what is working or not; this information can be used to inform QI activities (e.g., who participates and why; where in the system is implementation of highest/lowest quality), with implications for long-term sustainability and impact.

Example Hypothesis: Programs that iteratively assess and address RE-AIM dimensions over time to guide their sustainability planning and adaptations will have stronger sustainability outcomes (e.g. higher levels of continued delivery of EBI; higher levels of sustained behavior change across population groups) than those that do not.

4. Other Sustainability Frameworks Can Be Integrated With RE-AIM to Understand Key Sustainability Determinants

While several frameworks provide consideration of multi-level contextual factors that influence sustainability, many have been most explicitly applied in the context of implementation (34) e.g., PRISM (6, 35); and Consolidated Framework for Implementation Research [CFIR; (36)]. There may be value in also considering frameworks that have focused specifically on sustainability, including the Program Sustainability Assessment Tool [PSAT;

(37)] and the Integrated Sustainability Framework [ISF; (11)], which provide a strong foundation for understanding multi-level contextual determinants of sustainability, but less guidance in measuring sustainability outcomes, or thinking explicitly about dynamic sustainability. These multi-level determinant frameworks may call attention to constructs that are particularly important to sustainability (e.g., sustainability planning, funding stability, staff retention over time), and can be integrated with RE-AIM to inform questions, measurements and actions related to contextual determinants of sustainability. For example, the ISF could be used to understand and assess multi-level aspects that may influence sustainability- e.g., "How have program champions played a role in sustaining the EBI?" Data from such qualitative assessments would preferably be integrated with quantitative measures of sustainability determinants (e.g., informed by the ISF or PSAT). It is important to recognize that sustainability determinants themselves are likely not static, and may change over time.

Example Hypotheses: 1) Programs that explicitly address multi-level contextual determinants of sustainability will produce higher levels of sustainability and equity than those that do not; 2) Programs that address changing multi-level context and determinants of sustainability will be sustained longer than those addressing only one level.

5. Focus on Costs and Equity as Key Drivers of Sustainability Can Inform and Guide Dynamic Sustainability

Promoting health equity[1] (39, 40) is a central part of our conceptualization and measurement of sustainability, and RE-AIM indicators should be tracked over time to identify and address inequities when they arise (further explicated in **Table 1**). All RE-AIM dimensions include representativeness (heterogeneity, generalization), which should be assessed across different types of patient/population subgroups of focus (e.g., by race/ethnicity, age, disability, insurance status, literacy level, social determinants of health), and settings (e.g., urban/rural, lower vs. higher resource settings). Consistent with notions of "equitable implementation" (40), it is critical to document and address inequities as they emerge across all RE-AIM dimensions. Not doing so risks maintaining or even exacerbating health inequities, and ultimately inequitable use of EBIs over time.

Issues of cost and resources required are strongly tied to health equity. For example, if an EBI is not feasible for delivery in certain settings (e.g., community health centers) due to constrained resources or insufficient staff, inequities may result. This is because these settings often reach populations that experience disproportionate social stressors and greater structural barriers to care. At the individual level, if participation requires considerable costs or burden such as travel or time off work, unintentional health inequities may result. To prevent such consequences, initial cost estimates and resource requirements should be discussed with stakeholders at the planning stage, and costs can be periodically assessed, discussed and necessary adaptations made over time (41, 42).

We consider "costs" very broadly, including understanding, planning for, and tracking economic costs, time, resources, burdens, and unintended political and social consequences (e.g., social stigma) of an EBI, especially from the perspectives of different stakeholders (e.g., implementers, administrators, community members, and patients). Recent IS research (42–44) provides suggestions for cost assessment to understand the impact on sustainability. We also encourage consideration of economic factors more broadly, including the "value" and return on investment of sustaining the EBI, and the priorities of, and value to, different stakeholders (42), including community partners.

Example Hypotheses: 1) Programs that explicitly and repeatedly assess health equity and equitable implementation, and make iterative adjustments guided by RE-AIM will produce higher levels of sustainability than those only considering equity at the planning stage. 2) Programs that consider and monitor costs (and RE-AIM outcomes), 'return on investment' over time, and discuss and act on these assessments in partnership with stakeholders will produce stronger sustainable outcomes than those that do not.

Summary

The discussion above illustrates key issues involved in extending RE-AIM to enhance sustainability. In **Table 1**, we outline key indicators, guiding questions, and equity and sustainability considerations in applying this extension and iterative application of RE-AIM. Consistent with complex adaptive systems (45, 46), it is more complex than the discussion makes it appear, as the various factors above and the RE-AIM dimensions are interrelated. Thus, we need to consider interactions among the issues above and across RE-AIM dimensions over time. **Figure 1** highlights this complexity and considerations for cross-cutting, intersecting issues and indicators that shift (like gears) over time in different combinations to guide RE-AIM for sustainability in dynamic context across the life cycle of an EBI. This summary figure illustrates the impact of EBIs and implementation strategies on the RE-AIM dimensions, and how factors such as health equity and costs influence the likelihood of sustainability across the phases of a program.

DISCUSSION

This paper encourages iterative application of RE-AIM with early guidance on understanding, evaluating, and planning for sustainability, with a focus on changing context and health equity. While RE-AIM has previously been applied to promote health equity, this paper reinforces the importance of this focus within the context of sustainability. It advances the IS field beyond existing models and prior RE-AIM publications by providing: (1) consideration of planning for sustainability

[1]"Health equity means that everyone has a fair and just opportunity to be as healthy as possible. This requires removing obstacles to health such as poverty, discrimination, and their consequences, including powerlessness and lack of access to good jobs with fair pay, quality education and housing, safe environments, and health care…For the purposes of measurement, health equity means reducing and ultimately eliminating disparities in health and its determinants that adversely effect excluded or marginalized groups" (38).

throughout the life cycle of an EBI and across multiple RE-AIM dimensions; (2) concrete guidance for operationalizing the dynamic and complex nature of sustainability, including the "evolvability" of an EBI and where adaptations and de-implementation may fit within this conceptualization; (3) attention to iterative measurement of RE-AIM indicators to inform and enhance sustainability, and (4) explicit consideration of health equity and costs/value as critical components of sustainability. In summary:

1. Measuring "maintenance" as a RE-AIM dimension is important, but needs to be expanded to address longer-term conceptualizations of sustainability. The conceptualization of dynamic sustainability includes consideration of "evolvability" across the life cycle of an EBI, including continued delivery of the original EBI functions and implementation strategies, adaptations, and potential de-implementation across the EBI life cycle to produce sustained and equitable health outcomes.
2. Multi-level context changes and so must EBIs and implementation strategies to meet emerging needs, resources and challenges over time. Iterative (or at least periodic) use of actionable RE-AIM assessments can guide adaptations to enhance sustainability and respond to changing context.
3. Equity (both equitable implementation across RE-AIM dimensions and health equity) and costs/value are important and understudied cross-cutting issues across all RE-AIM dimensions that impact sustainability. Researchers should assess and address these factors in planning for and facilitating long-term sustainability.

This article has both strengths and limitations. Strengths include its focus on costs and value, from the perspective of multiple stakeholders, and health equity and representativeness across all RE-AIM dimensions as key drivers of sustainability. Additionally, instead of proposing another IS model, we provide an extension of, and guidance from, a widely adopted IS framework. This paper and our recommendations address sustainability processes and planning, as well as sustainability outcomes. Finally, we make recommendations and testable hypotheses that should lead to incremental validation, revision or rejection as we refine this extension of RE-AIM. Limitations include that this proposed expansion of RE-AIM needs further empirical support. We call for future application across diverse health issues and settings, and mixed-methods research to investigate and refine this extension of RE-AIM for sustainability. There is still much to learn about sustainability, and we believe this application will provide a useful guide and addition to the IS literature.

AUTHOR CONTRIBUTIONS

RS and RG initially conceptualized the paper. RS took the lead in writing an initial draft. All authors contributed to reviewing, revising, and rewriting sections for this Perspective piece.

FUNDING

RS was funded by a Research Scholar Grant from American Cancer Society (RSG 17-156-01-CPPB). RG's contributions were supported by NHLBI grant 5K12 HL137862 and NCI grant 1P50CA244688-01.

ACKNOWLEDGMENTS

We'd like to thank Laura Brotzman for design of the figure and assistance reviewing and preparing this manuscript, and Matthew Lee and Bryan Ford for their assistance in reviewing and preparing this manuscript.

REFERENCES

1. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health.* (1999) 89:1322–7. doi: 10.2105/AJPH.89.9.1322
2. Tabak RG, Khoong EC, Chambers DA, Brownson RC. Bridging research and practice: models for dissemination and implementation research. *Am J Prev Med.* (2012) 43:337–50. doi: 10.1016/j.amepre.2012.05.024
3. Harden SM, Smith ML, Ory MG, Smith-Ray RL, Estabrooks PA, Glasgow RE. RE-AIM in clinical, community, and corporate settings: perspectives, strategies, and recommendations to enhance public health impact. *Front Public Health.* (2018) 6:71. doi: 10.3389/fpubh.2018.00071
4. Glasgow RE, Harden SM, Gaglio B, Rabin BA, Smith ML, Porter GC, et al. RE-AIM planning and evaluation framework: adapting to new science and practice with a twenty-year review. *Front Public Health.* (2019) 7:64. doi: 10.3389/fpubh.2019.00064
5. Vinson CA, Stamatakis K, Kerner J. Dissemination and implementation research in community and public health settings. In: Brownson Rc CG, editor. *Dissemination and Implementation Research in Health: Translating Research to Practice*. Proctor Ea Oxford University Press (2018). p. 355–70. doi: 10.1093/oso/9780190683214.003.0021
6. Mccreight MS, Rabin BA, Glasgow RE, Ayele RA, Leonard CA, Gilmartin HM, et al. Using the Practical, Robust Implementation and Sustainability Model (PRISM) to qualitatively assess multilevel contextual factors to help plan, implement, evaluate, and disseminate health services programs. *Transl Behav Med.* (2019) 9:1002–11. doi: 10.1093/tbm/ibz085
7. Glasgow RE, Estabrooks PE. Pragmatic applications of RE-AIM for health care initiatives in community and clinical settings. *Prev Chronic Dis.* (2018) 15:E02. doi: 10.5888/pcd15.170271
8. Holtrop JS, Rabin BA, Glasgow RE. Qualitative approaches to use of the RE-AIM framework: rationale and methods. *BMC Health Services Res.* (2018) 18:177. doi: 10.1186/s12913-018-2938-8
9. Scheirer M, Dearing J. An agenda for research on the sustainability of public health programs. *Am J Public Health.* (2011) 101:e300193. doi: 10.2105/AJPH.2011.300193
10. Stirman SW, Kimberly J, Cook N, Calloway A, Castro F, Charns M. The sustainability of new programs and innovations: a review of the empirical literature and recommendations for future research. *Implement Sci.* (2012) 7:17. doi: 10.1186/1748-5908-7-17
11. Shelton RC, Cooper BR, Stirman SW. The sustainability of evidence-based interventions and practices in public health and health care. *Ann Rev Public Health.* (2018) 39:55–76. doi: 10.1146/annurev-publhealth-040617-014731
12. Shelton RC, Lee M. Prioritizing sustainability research: innovations and future directions in implementation science. *Am J Public Health.* (2019) 109:S132–4. doi: 10.2105/AJPH.2018.304913
13. Proctor EK, Luke DA, Calhoun A, Mcmillen C, Brownson RC, Mccrary S, et al. Sustainability of evidence-based healthcare: research agenda,

methodological advances, and infrastructure support. *Implement Sci.* (2015) 10:88. doi: 10.1186/s13012-015-0274-5
14. Johnson AM, Moore JE, Chambers DA, Rup J, Dinyarian C, Straus SE. How do researchers conceptualize and plan for the sustainability of their NIH R01 implementation projects? *Implement Sci.* (2019) 14:50. doi: 10.1186/s13012-019-0895-1
15. Moore JE, Mascarenhas A, Bain J, Straus SE. Developing a comprehensive definition of sustainability. *Implementation Sci.* (2017) 12:110. doi: 10.1186/s13012-017-0637-1
16. Stirman SW, Baumann AA, Miller CJ. The FRAME: an expanded framework for reporting adaptations and modifications to evidence-based interventions. *Implement Sci.* (2019) 14:58. doi: 10.1186/s13012-019-0898-y
17. Chambers DA, Glasgow RE, Stange KC. The dynamic sustainability framework: addressing the paradox of sustainment amid ongoing change. *Implement Sci.* (2013) 8:117. doi: 10.1186/1748-5908-8-117
18. Bopp M, Saunders RP, Lattimore D. The tug-of-war: fidelity versus adaptation throughout the health promotion program life cycle. *J Primary Prev.* (2013) 34:193–207. doi: 10.1007/s10935-013-0299-y
19. Allen JD, Shelton RC, Emmons KM, Linnan L. Fidelity and its relationship to implementation effectiveness, adaptation, and dissemination. 2 ed. In: Brownson RC, Colditz GA, Proctor EK, editors. *Dissemination and Implementation Research in Health: Translating Science to Practice*. New York, NY: Oxford University Press (2018). p. 267–84. doi: 10.1093/oso/9780190683214.003.0016
20. Stange KC. Refocusing knowledge generation, application, and education: raising our gaze to promote health across boundaries. *Am J Prev Med.* (2011) 41:S164–9. doi: 10.1016/j.amepre.2011.06.022
21. Niven DJ, Mrklas KJ, Holodinsky JK, Straus SE, Hemmelgarn BR, Jeffs LP, et al. Towards understanding the de-adoption of low-value clinical practices: a scoping review. *BMC Med.* (2015) 13:255. doi: 10.1186/s12916-015-0488-z
22. Norton WE, Chambers DA, Kramer BS. Conceptualizing de-implementation in cancer care delivery. *J Clin Oncol.* (2019) 37:93–6. doi: 10.1200/JCO.18.00589
23. Strifler L, Cardoso R, Mcgowan J, Cogo E, Nincic V, Khan PA, et al. Scoping review identifies significant number of knowledge translation theories, models, and frameworks with limited use. *J Clin Epidemiol.* (2018) 100:92–102. doi: 10.1016/j.jclinepi.2018.04.008
24. Damschroder LJ. Clarity out of chaos: use of theory in implementation research. *Psychiatr Res.* (2019) 283:11246. doi: 10.1016/j.psychres.2019.06.036
25. Blase K, Fixsen D. *Core Intervention Components: Identifying and Operationalizing What Makes Programs Work. ASPE Research Brief*. Washington, DC: US Department of Health and Human Services (2013).
26. Jolles MP, Lengnick-Hall R, Mittman BS. Core functions and forms of complex health interventions: a patient-centered medical home illustration. *J General Internal Med.* (2019) 34:1032–8. doi: 10.1007/s11606-018-4818-7
27. Powell BJ, Waltz TJ, Chinman MJ, Damschroder LJ, Smith JL, Matthieu MM, et al. A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. *Implement Sci.* (2015) 10:21. doi: 10.1186/s13012-015-0209-1
28. Baumann A, Cabassa LJ, Stirman SW. Adaptation in dissemination and implementation science. *Dissemin Implement Res Health.* (2017) 2:286–300. doi: 10.1093/oso/9780190683214.003.0017
29. Castro FG, Barrera M, Martinez CR. The cultural adaptation of prevention interventions: resolving tensions between fidelity and fit. *Prev Sci.* (2004) 5:41–5. doi: 10.1023/B:PREV.0000013980.12412.cd
30. Glasgow RE, Battaglia C, McCreight M, Ayele RA, Rabin BA. Making implementation science more rapid: Use of the RE-AIM framework for mid-course adaptations across five health services research projects in the Veterans Health Administration. *Front Public Health*. (2020).
31. Waltz TJ, Powell BJ, Matthieu MM, Damschroder LJ, Chinman MJ, Smith JL, et al. Use of concept mapping to characterize relationships among implementation strategies and assess their feasibility and importance: results from the Expert Recommendations for Implementing Change (ERIC) study. *Implement Sci.* (2015) 10:109. doi: 10.1186/s13012-015-0295-0
32. Balasubramanian BA, Cohen DJ, Davis MM, Gunn R, Dickinson LM, Miller WL, et al. Learning evaluation: blending quality improvement and implementation research methods to study healthcare innovations. *Implement Sci.* (2015) 10:31. doi: 10.1186/s13012-015-0219-z
33. Coury, J., Schneider, J. L., Rivelli, J. S., Petrik, A. F., Seibel, E., D'agostini, B., et al. (2017). Applying the Plan-Do-Study-Act (PDSA) approach to a large pragmatic study involving safety net clinics. *BMC Health Services Res.* 17:411. doi: 10.1186/s12913-017-2364-3
34. Nilsen P. Making sense of implementation theories, models and frameworks. *Implementat Sci.* (2015) 10:53. doi: 10.1186/s13012-015-0242-0
35. Feldstein AC, Glasgow RE. A practical, robust implementation and sustainability model (PRISM) for integrating research findings into practice. *Joint Commission J Qual Patient Safety.* (2008) 34:228–43. doi: 10.1016/S1553-7250(08)34030-6
36. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci.* (2009) 4:50–50. doi: 10.1186/1748-5908-4-50
37. Luke DA, Calhoun A, Robichaux CB, Elliott MB, Moreland-Russell S. The Program Sustainability Assessment Tool: a new instrument for public health programs. *Prevent Chronic Dis.* (2014) 11:130184. doi: 10.5888/pcd11.130184
38. Braveman P. A new definition of health equity to guide future efforts and measure progress. *Health Affairs Blog.* (2017) 22:1–4.
39. Chinman M, Woodward EN, Curran GM, Hausmann LR. Harnessing implementation science to increase the impact of health disparity research. *Medical Care.* (2017) 55:S16. doi: 10.1097/MLR.0000000000000769
40. Dumont K, Metz A, Woo B. *Five Recommendations for How Implementation Science Can Better Advance Equity*(2019). Available from: www.academyhealth.org/blog/2019-04/five-recommendations-how-implementation-science-can-better-advance-equity (accessed September 26, 2019).
41. Ritzwoller DP, Sukhanova AS, Glasgow RE, Strycker LA, King DK, Gaglio B, et al. Intervention costs and cost-effectiveness for a multiple-risk-factor diabetes self-management trial for Latinas: economic analysis of ¡Viva Bien! *Transl Behav Med.* (2011) 1:427–35. doi: 10.1007/s13142-011-0037-z
42. Jones Rhodes WC, Ritzwoller DP, Glasgow RE. Stakeholder perspectives on costs and resource expenditures: tools for addressing economic issues most relevant to patients, providers, and clinics. *Transl Behav Med.* (2018) 8:675–82. doi: 10.1093/tbm/ibx003
43. Saldana L, Chamberlain P, Bradford WD, Campbell M, Landsverk J. The Cost of Implementing New Strategies (COINS): a method for mapping implementation resources using the stages of implementation completion. *Children Youth Services Rev.* (2014) 39:177–82. doi: 10.1016/j.childyouth.2013.10.006
44. Dopp AR, Mundey P, Beasley LO, Silovsky JF, Eisenberg D. Mixed-method approaches to strengthen economic evaluations in implementation research. *Implement Sci.* (2019) 14:2. doi: 10.1186/s13012-018-0850-6
45. May CR, Johnson M, Finch T. Implementation, context and complexity. *Implement Sci.* (2016) 11:141. doi: 10.1186/s13012-016-0506-3
46. Braithwaite J, Churruca K, Long JC, Ellis LA, Herkes J. When complexity science meets implementation science: a theoretical and empirical analysis of systems change. *BMC Med.* (2018) 16:63. doi: 10.1186/s12916-018-1057-z

Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Advantages of publishing in Frontiers

OPEN ACCESS
Articles are free to read for greatest visibility and readership

FAST PUBLICATION
Around 90 days from submission to decision

HIGH QUALITY PEER-REVIEW
Rigorous, collaborative, and constructive peer-review

TRANSPARENT PEER-REVIEW
Editors and reviewers acknowledged by name on published articles

Frontiers
Avenue du Tribunal-Fédéral 34
1005 Lausanne | Switzerland

Visit us: www.frontiersin.org
Contact us: frontiersin.org/about/contact

REPRODUCIBILITY OF RESEARCH
Support open data and methods to enhance research reproducibility

DIGITAL PUBLISHING
Articles designed for optimal readership across devices

FOLLOW US
@frontiersin

IMPACT METRICS
Advanced article metrics track visibility across digital media

EXTENSIVE PROMOTION
Marketing and promotion of impactful research

LOOP RESEARCH NETWORK
Our network increases your article's readership