Research Topics

Perspectives and opinions in health services

2022, 2nd edition

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Editorial: Perspectives and opinions in health services: 2022

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Editorial on the Research Topic
Perspectives and opinions in health services: 2022

Introduction

Knowing what affects the effectiveness and efficiency of health services is the first necessary step to aim. Firstly, the quality of health services is the result of the *a priori* implementation of interventions considering extrinsic variables that affect their applicability, even in the same territory. But not only that, it is based on a critical review of the internal limits of specific health and academic institutions, in the perspective of the noble objective of protect public health.

Our Research Topic saw the publication of 12 papers all valid points of reflection on the topic.

Proposals to optimize the organization of health systems and to improve the training of health professionals

Zou started from the definition of the world as a “global village”, heterogeneous in ethnicity and sexual orientation, that inevitably results in an increasingly diverse patient population. Language, culture, and gender identity can have a crucial impact on the patient’s health experience. Hence the need to develop a competent and equally diverse workforce in the health sector, able to guarantee fair healthcare.

On a similar wavelength, Balak et al. argue that the management of health systems in accordance with the principles of new public management systems and technological advances risks underestimating the ethical implications underlying any decision in the health field. This could negatively affect the training of resident doctors, scientific research and therefore the real and full efficiency of health care. The authors therefore propose to integrate independent ethics committees in administrative decision-making processes.

Nagele, through an original parallelism between leadership challenges of large academic medical centers (AMC) and large army units, proposed a leadership education program for health professionals drawing on the military model. This responds to the need—recognized by many institutions—to provide training to health professionals who often find themselves in leadership roles without having been properly trained for it.

Proposals to provide health services to disadvantaged populations, vulnerable patients, and health professionals

Marini et al. proposed a model for delivery of volume sweep imaging (VSI) lung teleultrasound. This model, also used during the COVID-19 pandemic in rural Peru, has garnered acclaim from patients and physicians, and attempts to overcome the many limitations of diagnostic imaging in similar territories around the world.

Talarico et al. proposed a methodology for the optimization of patient care pathways in rare and complex diseases (RarERN Path^{TM}). The approach—based on the indispensable involvement of different stakeholders (patients' representatives, healthcare professionals, hospital managers, and experts in a healthcare organisation)—could contribute to delivering concrete health benefits to these patients whose healthcare has been particularly affected by the COVID-19 pandemic.

Gharebaghi et al. highlighted poor health and social protection for health workers in Iraq. During their career, health professionals face a large list of challenges (in the economic, social, and professional spheres) that have been further exacerbated during the COVID-19 period, with inevitable repercussions on mental well-being. These data, together with the numerous suicides recorded in Iraq among the physician residents, make clear the need to provide all healthcare professionals free access to psychiatric counseling for preventive purposes.

Proposals and opinions for the implementation of interventions in health field

Nilsen et al. through the examination of the objectives and characteristics of the four scientific fields (intervention, innovation, implementation, and improvement sciences), have proposed interesting ideas on the optimization of the use and adaptation of artificial intelligence in the healthcare sector. Indeed, the application of artificial intelligence in healthcare should start from the critical evaluation of its usefulness in the various fields of science.

Pérez Jolles et al. argue that the promotion of collaborative approaches is crucial to achieving synergistic goals in the field of implementation science. The authors proposed a guide based on five principles, useful for researchers to structure implementation collaborations with a variety of stakeholders (co-creation). The effective involvement of partners in the implementation of the services they finance, provide, or receive could help bridge the gap between what we know in theory and the actual implementation of health interventions.

Fort et al. proposed the use of the Practical Implementation Sustainability Model (PRISM) for the implementation of health programs. PRISM, for its structural characteristics (such as multi-level assessments of the characteristics of the intervention, the environment, and the target subjects) could be effectively adapted in the healthcare sector with an equity lens to tackle health inequalities at the root, that is, from the planning and implementation of interventions.

Knox and Curran agreed with researchers who promote the adoption of an effectiveness-implementation hybrid design in the health field, especially in those contexts where implementation must focus on *a priori* assessment of possible barriers to effectiveness. In support of their thesis, the authors presented implementation data that could have been collected if vaccine efficacy trials used hybrid designs and that would have allowed to predict the vaccination hesitation.

In a similar vein, Leeman et al. proposed a method to identify how external influences can impact the implementation of new healthcare interventions. The authors formulated 20 propositions from five classic organization theories (Complexity, Contingency, Institutional, Resource Dependence, and Transaction Cost Economics theory) which they used for the implementation of intervention for the prevention of tobacco smoke. The classical theories of the organization can be a useful empirical support to develop implementation strategies and to understand external factors that can influence them.

Kalver et al. proposed a novel consensus group approach—the CORE (Consensus on Relevant Elements) approach—to determine the initial core components of the Department of Veterans Affairs (VA)'s Post-Incarceration Engagement (PIE) program, to date implemented in only two states in the United States but in increasing diffusion. The Core approach is a multi-step process that involves a team of experts and moderators and can be a guide to determine the initial core components, to be understood as the principles and essential elements of evidence-based interventions. The systematic isolation of core components is fundamental to allow the health interventions to be improved and adapted to other application contexts.

Conclusion

Despite the various issues addressed, the common thread between these papers is that improving the effectiveness and efficiency of health services can mean, at the same time, drawing on classic reference models and innovative tools. Both, however, should be balanced and adapted to changing external factors and to ethical implications underlying any intervention in the health field.

Author contributions

AC: Conceptualization, Methodology, Supervision, Validation, Writing – original draft, Writing – review & editing. DŚ: Writing – review & editing. MR: Writing – review & editing. PM: Writing – review & editing. FA: Writing – review & editing. CC: Conceptualization, Data curation, Writing – original draft, Writing – review & editing.

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.

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The CORE (Consensus on Relevant Elements) Approach to Determining Initial Core Components of an Innovation

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Identifying an intervention's core components is indispensable to gauging whether an intervention is implemented with fidelity and/or is modified; it is often a multi-stage process, starting with the first stage of identifying an initial set of core components that are gradually refined. This first stage of identifying initial core components has not been thoroughly examined. Without a clear set of steps to follow, interventions may vary in the rigor and thought applied to identifying their initial core components. We devised the CORE (Consensus on Relevant Elements) approach to synthesize opinions of intervention developers/implementers to identify an intervention's initial core components, particularly applicable to innovative interventions. We applied CORE to a peer-based intervention that aids military veterans with post-incarceration community reintegration. Our CORE application involved four intervention developers/implementers and two moderators to facilitate the seven CORE steps. Our CORE application had two iterations, moving through Steps 1 (individual core component suggestions) through 7 (group discussion for consensus), then repeating Steps 4 (consolidation of component definitions) through 7. This resulted in 18 consensus-reached initial core components of the peer-based intervention, down from the 60 that the developers/implementers individually suggested at Step 1. Removed components were deemed to not threaten the intervention's effectiveness even if absent. CORE contributes to filling a critical gap regarding identifying an intervention's initial core components (so that the identified components can be subsequently refined), by providing concrete steps for synthesizing the knowledge of an intervention's developers/implementers. Future research should examine CORE's utility across various interventions and implementation settings.

Keywords: core components, consensus approach, intervention development, justice-involved veterans, community reintegration, behavioral health, social services, implementation evaluation

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INTRODUCTION

To successfully implement and spread interventions, it is essential to identify their core components for the purposes of fidelity, adaptation, replication, and evaluation. The U.S. Department of Health & Human Services defines core components as "essential functions or principles, and associated elements and intervention activities that are judged necessary to produce desired outcomes (1)." The notion of core components is key to implementation science, which focuses on promoting authentic adoption and replication of evidence-based interventions (2).

Such adoption requires ensuring that the intervention is implemented with fidelity—i.e., offering its identified core components (3). However, exact replication of the components across multiple implementation settings may be challenging (4) given the diverse and dynamic contexts that influence the feasibility of replication. This challenge is reflected in the growing focus on identifying and documenting adaptations (i.e., planned modifications) and unplanned modifications to interventions (5–9), so that resulting implementation and clinical outcomes can be understood in light of any deviations from the intervention's core components. Successfully identifying an intervention's core components is thus indispensable to gauging the extent to which an intervention is adopted and to assessing the modifications that were made for adoption. Identifying the core components of an intervention is not a simple task, however. Reviews of published literature on an intervention, when there is a sufficient body of articles, can shed some light on an intervention's core components (10–12). Without knowing an intervention's core components, it will be unclear during implementation, especially when it occurs across a range of contexts, which aspects of the intervention need to be maintained when making context-appropriate modifications (13, 14).

Identification of an intervention's core components is often a multi-stage process. First, the intervention developers, individuals with expertise regarding the implementation setting/context, implementers, or evaluators (or some combination) determine an initial (i.e., provisional) set of core components (henceforth, "initial core components"). These are then gradually refined as the intervention is implemented in multiple settings and contexts over time. Haynes et al. (15) offer a comprehensive test-and-refine process for identifying the core components of a new intervention. A critical element of the process' first stage is to inductively identify initial core components with input from both intervention designers and implementation evaluators. In this process, the evaluators draft the components then further develop them with the designers. How to conduct the process' first stage—i.e., how to identify initial core components—has not been thoroughly examined. Without a clear set of steps for this initial identification, different interventions may vary in the rigor and thought applied to identifying their initial core components. This may leave some interventions not well-specified, where, for instance, substantial differences may exist in what the intervention developers and implementers consider to be the core components.

To contribute to filling this gap, we devised a consensus group approach—the CORE (Consensus on Relevant Elements) approach—to gather and synthesize expert opinions to identify and refine an intervention's initial core components, particularly applicable to innovative interventions (henceforth, "innovations") with limited empirical evidence. Specifically, guided by Landeta et al. (16)'s Hybrid Delphi methodology, innovation developers and implementers iteratively and systematically determine the initial core components. **Figure 1** depicts where CORE sits in the overall development and refinement of an intervention's core components. We outline below each step of CORE then demonstrate CORE's application to specifying a peer support-based innovation that aids military veterans with community reintegration after their release from incarceration (17).

STEPS OF THE CONSENSUS ON RELEVANT ELEMENTS (CORE) APPROACH

Table 1 shows the CORE steps. CORE utilizes an expert panel and a moderator team. The expert panel consists of individuals knowledgeable about the purpose, context, and details of the innovation—typically the developers and implementers of the innovation. The moderator team typically consists of individuals experienced in facilitating group discussions toward consensus; their prior familiarity with the innovation can be helpful but is not required. The number of panel members and moderators should be large enough to (i) sufficiently represent expert knowledge about key aspects of the innovation and (ii) feasibly moderate the panel through the approach's seven iterative steps outlined in **Table 1**, respectively.

CONTEXT OF THE POST-INCARCERATION ENGAGEMENT (PIE) INNOVATION

We applied CORE to determine the initial core components of the Department of Veterans Affairs (VA)'s Post-Incarceration Engagement (PIE) innovation (17). PIE uses peer specialists ("peers") to enhance reentry support for veterans, extending the reach, duration, and intensity of support provided by the VA's Health Care for Reentry Veterans (HCRV) program. Peers are selected and hired for their "lived experience" that reflects many of the experiences of the reentry veterans, such as criminal justice involvement or recovery from mental illness and substance use disorders (SUDs). HCRV case managers work with veterans on an initial reentry plan and ensure they have housing and health care referrals upon release. There can be a warm handoff to the PIE peers (i.e., veteran is present when their HCRV case manager transfers their case to the PIE peer) who can work over a period of months with reentry veterans to enable their appointment attendance, both for VA health care (primary care, mental health, and/or SUD services) as well as to housing, employment, and other VA or community services as needed. To date, PIE has

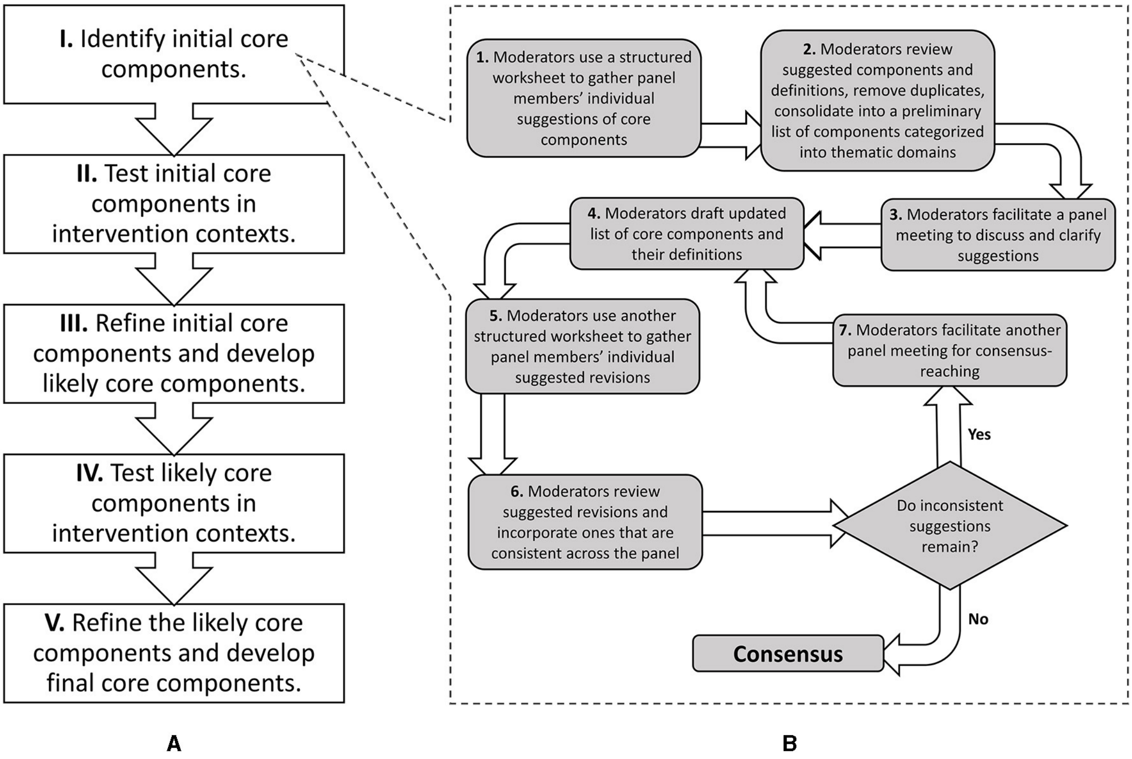

FIGURE 1 | Depiction of where the CORE (Consensus on Relevant Elements) approach sits in the overall development and refinement of an intervention's core components. **(A)** Stages of the process of developing core components, adapted from Haynes et al. (15). **(B)** Flow of CORE steps for identifying initial core components.

been implemented in two northeastern states in the United States, and is embarking on a larger implementation trial at six sites across four additional states through 2025. Hence, there was a pressing need to have consensus among the implementation team as to what the initial core components were, to ensure that at the subsequent sites there would be effective implementation, evaluation, and fidelity monitoring.

Section Application of CORE to Determine PIE's Initial Core Components outlines the detailed steps, and what was accomplished at each step, for our application of CORE to determine PIE's initial core components. The PIE implementation effort, of which this is a part, was submitted to the Institutional Review Board (IRB) at the VA Bedford Healthcare System (Massachusetts, USA), which determined it was a quality improvement project as per VA handbook 1200.05. The need for continued IRB review was waived.

APPLICATION OF "CORE" TO DETERMINE PIE'S INITIAL CORE COMPONENTS

Our application of CORE to determine PIE's initial core components involved a four-person expert panel and a two-person moderator team. Each expert panel member had extensive knowledge of PIE and its current evidence base, through developing, implementing, and/or evaluating the innovation. Both moderators were experienced facilitators of group discussions. One moderator did not have prior familiarity with PIE, while the other had continuously been a part of PIE implementation efforts. This CORE application had two iterations, first consecutively moving through Steps 1 through 7, then iterating back to repeat Steps 4 through 7. The steps are described below.

Step 1

Using Worksheet A (**Appendix 1** in Supplementary Material), the four panel members individually suggested, respectively, 11, 11, 17, and 21 core components (60 in total), along with their definitions, to be considered by the panel. To encourage original descriptions of the components, the worksheet deliberately did not require panel members to adhere to a rigid structure in describing their suggestions. There was considerable overlap among the four lists (see Step 2). Many of the definitions included wordings such as "if possible," "ideally," and "this often involves ...." For example, one suggestion was "If possible, the peer meets with the veteran on the day of the veteran's release from incarceration, to begin providing social and logistical support." These wordings previewed that a main discussion point over the subsequent steps of the approach would be regarding whether a particular suggestion is a core component that is absolutely required for PIE or is a desirable but not essential feature.

TABLE 1 | Steps of the CORE (Consensus on Relevant Elements) approach to determining an innovation's initial core components.

Step 1	Moderators use a structured Worksheet A (**Appendix 1** in Supplementary Material provides an example) to gather panel members' individual suggestions of core components into a table. Worksheet A prompts panel members to: • Suggest core components of the innovation • Define those components within the table
Step 2	Moderators review the suggested components and their definitions, remove duplicates, and consolidate them into a preliminary list of core components categorized into thematic domains—for example, categorized by the actions (e.g., training stakeholders on the innovation), entities (e.g., trainers, stakeholders), or timings (e.g., before/during/after training) indicated by the core components.
Step 3	Moderators facilitate a panel meeting to discuss and clarify overlapping/distinct suggestions of core components and their definitions.
Step 4	Moderators draft an updated list of core components and their definitions, based on the previous step's facilitated discussion. They structure this information into a Worksheet B (see **Appendix 2** in Supplementary Material for an example), for panel members to individually complete as specified under Step 5.
Step 5	Each panel member independently fills out Worksheet B (created under Step 4) with their own suggested revisions to the updated list of core components and their definitions. Worksheet B prompts panel members to: • Revise the core components' definitions • Propose a short "code" (a brief phrase) for each component, to be used to refer to it in subsequent discussions • Suggest whether each component be split into multiple components, merged with another component, or moved under a different thematic domain • Suggest whether the thematic domain titles should be changed • Suggest whether each domain should be split into multiple domains or merged with another domain • Review questions tabled during the previous panel discussion, and suggest whether to address them as a part of determining the initial core components, or to revisit them following further innovation testing and implementation
Step 6	Moderators review the suggested revisions, incorporate ones that are consistent across the panel, and organize others into a list for further consideration (either as a part of determining the initial core components or to be revisited following further testing of the innovation's effectiveness and implementation).
Step 7	If inconsistent suggestions remain for considerations in determining the initial core components, moderators facilitate another panel meeting for consensus-reaching, then return to Step 4. If not, the latest list is considered to reflect the initial core components of the innovation.

Step 2

The moderators reviewed the 60 suggestions gathered under Step 1, and removed clear duplicates. Then, they consolidated the remaining suggestions into a preliminary list of core components that grouped together thematically related or similar (but not entirely overlapping) suggestions. For example, three panel members suggested that training peers to support post-incarceration veterans is a core component of PIE, but there were differences in training content. These suggestions were grouped together in the consolidated list, with each proposed content presented side-by-side. After trying several different options for grouping the suggestions by actions (e.g., training stakeholders on the innovation), entities (e.g., trainers, stakeholders), or timings (e.g., before/during/after training), the moderators settled on grouping by the timings.

Step 3

The moderators asked panel members to individually review the consolidated list from Step 2 before meeting as a panel. During the hour-long meeting, moderators facilitated discussions to identify individual aspects of each suggestion that are both essential to PIE (i.e., would fundamentally alter the nature of PIE if they could not be accomplished) and considered to be feasible for those practicing PIE. As an example, through discussions there was agreement that a core component was that the peer meet the veteran within the first 48 hours of release, without the strict requirement that the first meeting must occur on the day of release. One of the topics that came up most frequently was training of peers, for which four core components were proposed: training on PIE (what it involves and its underlying principles); VA health care system-required trainings; training for using the electronic health record (EHR) system (so peers can document in the EHR their encounters with veterans); and trainings to orient peers to correctional facilities' safety, security, and operations protocols (a requirement of many correctional facilities).

Step 4 (First Iteration)

Based on Step 3, the moderators drafted an updated list of core components and their definitions. This updated list contained 20 core components grouped by three domains:

- (Domain I) Onboarding (hiring, orientation, and training) of peers, including
  - What qualifications are looked for in a peer (e.g., experience with relevant VA services)
  - What supervision of the peer involves (e.g., problem-solving challenges the peer faces)
- (Domain II) Peers' veteran-facing work, including
  - Tasks before a veteran's release from incarceration (e.g., planning to meet post-release)
  - Tasks after the release (e.g., linking the veteran to health care and other resources)
- (Domain III) Ongoing peer supervision, coordination, and networking, including
  - Continued documentation in the EHR of the peer's encounters with the veteran
  - Continued networking between the peer and services/resources relevant to the veteran

Step 5 (First Iteration)

Using Worksheet B (**Appendix 2** in Supplementary Material), the panel members individually suggested revisions to the list generated in the previous step. Suggested revisions included combining peer training on PIE with the training on the EHR system, and also combining the health care system-required/recommended trainings with trainings needed to access correctional facilities. An additional core component was suggested, regarding how the peer is expected to flexibly tailor their veteran-facing tasks based on the unique needs of the veteran.

Step 6 (First Iteration)

Based on the previous step, the moderators updated the list of core components and their definitions. Changes included (i) emphasizing the need for the peer to remain up-to-date on both VA-based and non-VA-based services and resources relevant to the veteran, and (ii) checking that the core components related to ongoing tasks (e.g., continued supervision of the peer, from Domain III) are not redundant with the initiation of those tasks mentioned as core components under Domains I or II (e.g., establishing supervision procedures).

Step 7 (First Iteration)

The moderators facilitated a second hour-long expert panel meeting to discuss additional suggestions of refining, combining, and/or de-duplicating core components. The panel members added the peer's tailoring of veteran-facing tasks to each veteran, and they discussed potential definitions for the component. They also moved the ongoing task of coordinating with the VA's existing justice outreach programs (in Domain III) to Domain I instead, where expectations for coordination are set as a part of onboarding. Component definitions and decisions of which domain each component belonged to were still not finalized at this point, so we iterated back to Step 4.

Step 4 (Second Iteration)

Based on the previous step, the moderators drafted an updated list of core components and their definitions. The moderators added to Domain II the peer's tailoring of veteran-facing tasks to each veteran, with a working definition to be reviewed by the panel in the next step. The moderators clarified within the updated list that "supervision" refers to clinical supervision (separate from, for instance, guidance on the innovation that is provided to peers by individuals implementing PIE). Relatedly, the updated list emphasized that the clinical supervisor should be closely involved in decisions regarding how frequently the peer is to interact with the veteran.

Step 5 (Second Iteration)

Using an updated Worksheet B reflecting the changes made in the previous step, the panel members individually suggested revisions to the updated list. These included specifying the peer's expected caseload of veterans, while keeping in mind the varied needs of veterans and expected differences across (i) geographic areas (e.g., an appropriate caseload for a peer may vary based on factors such as driving distances to correctional facilities and to veterans' housing) and (ii) peers' professional expertise (e.g., more experienced peers may be able to handle more cases simultaneously).

Step 6 (Second Iteration)

Based on the previous step, the moderators updated the list of core components and their definitions. Changes included addressing the peer's expected caseload under Domain I, noting the peer's caseload from the first two states in which PIE was implemented. The previous step did not result in additional thoughts on whether core components related to ongoing tasks (Domain III) are redundant with the initiation of those tasks mentioned under Domains I or II (a topic of discussion under the first iteration's Steps 6 and 7, as noted above), so no changes were made yet to moving additional components away from Domain III.

Step 7 (Second Iteration)

The moderators facilitated a third hour-long expert panel meeting to review the revised core components and their definitions. Two major decisions were made during this meeting. First, returning to the original conceptualization of training, the panel decided that there should be four distinct peer training-related core components, by decoupling peer training on PIE from the training on the EHR system, and also decoupling the health care system trainings from trainings needed to access correctional facilities (**Appendix 3** in Supplementary Material shows the changes in the definitions of the training-related core components through our application of CORE, as an example of how the approach refines core components and their definitions). Second, Domain III was dissolved, following consensus among the expert panel that a separate domain was not necessary to represent the continuation of core components initiated under Domains I or II. Applying CORE resulted in the panel members agreeing that PIE consisted of 18 initial core components under two domains, as shown in **Appendix 4** in Supplementary Material.

DISCUSSION

In this paper, we introduce CORE, an iterative consensus group approach relying on an expert panel and experienced moderators, to determine the initial core components of an innovation. The approach contributes to filling an existing gap in the literature on how to identify an innovation's initial core components, by providing a concrete sequence of steps for synthesizing the knowledge of an innovation's developers and implementers.

Our application of the approach has led to determining and specifying the initial core components of a VA innovation, Post-Incarceration Engagement (PIE), to assist veterans with community integration after incarceration. PIE is being spread to other sites around the United States, providing an important opportunity for the implementation team to record and analyze modifications that are made to adapt to local contexts (18). For innovations such as PIE that are in the midst of expanding their empirical evidence base, careful examination is warranted regarding (i) which of the initial core components need to be maintained as the innovation is modified to meet local needs, (ii) which modifications are enhancements to the core components, and (iii) which modifications are less desirable deviations from the core components, which may represent "program drift" (becoming a wholly different innovation) or "voltage drop" (a weakening of the active ingredients that make the innovation effective) (18).

Frameworks help assess modifications to core components – for instance, Wiltsey-Stirman et al.'s Framework for Reporting Adaptations and Modifications-Enhanced (FRAME) (5). Notably, CORE can be adapted for methodically incorporating expert opinions into assessing modifications. For example, per FRAME, determining the extent to which a modification is consistent with the core components, and/or the reason(s) for the modification, can be pursued through steps analogous to those that are described above. Namely, a moderator team can facilitate an expert panel to iteratively brainstorm, discuss, and reach consensus on both the nature of modifications to the innovation and whether the modifications suggest that core components need updating. Such discussion can also be useful for proactively planning future modifications prior to further implementation.

A potential limitation of CORE is that its utility could depend heavily on the moderators' meeting facilitation skills, and possibly also on their knowledge of the innovation and implementation science. This may increase the number of iterations through the steps, making the approach more time consuming, especially when panel consensus is difficult to reach. Additionally, as a novel approach, CORE has not been tested across various innovations and settings. However, given that the CORE steps are reliant neither on population nor content specifics of PIE, we expect that CORE can be applied to other health care innovations. CORE has also not been directly compared to other approaches that identify an innovation's initial core components. Thus, further work is needed to make such comparisons, and to apply CORE to a variety of innovations and in different health care settings. Accordingly, future enhancements to CORE may include (i) strengthening the validity of the expert panel's consensus through making explicit the panel's consideration of theories and mechanisms that link core components to desired outcomes and (ii) reflecting the field's evolving understanding of the extent to which core components may undergo context-specific modifications.

As rigorous methods are increasingly being applied in health care with guidance from implementation science, it is an opportune time to promote using a systematic approach for identifying core components that deliberately documents decisions made and makes explicit which components of an innovation are core, and which are desirable but would not threaten the innovation's effectiveness if they were absent. The CORE approach provides a systematic roadmap that innovation developers and implementers can follow to determine the initial core components, which can subsequently be tested and refined.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/**Supplementary Material**, and further inquiries can be directed to the corresponding author.

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

EHK and BK led the writing of the manuscript and served as the expert panel moderators. DKM and BK initially conceptualized the project. VY provided consultation to the study team on expert panel procedures. DKM, VY, JH, and BAP served as the expert panel members and provided critical revisions to the manuscript's intellectual content. All authors contributed to the article and approved the submitted version.

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SUPPLEMENTARY MATERIAL

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OPINION
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Serial Deaths of Young Trainee Physicians in Iran During COVID-19 Pandemic; Messages to Policy Makers

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INTRODUCTION

The untimely and serial death of the physician residents in recent months in Iran shocked the public and the profession, and refocused consideration on young physicians.

Physician residents refers to early career physicians in training immediately after graduation from medical school (1). Although the exact reason for this mortality of physician residents is not yet known, social activists believe that the frustrating long shift hours, sometimes involving working in the hospital for 72 h with no break, the educational conditions, difficult jobs, limited facilities, and negligence of authorities are responsible for this disaster.

This story of extreme work pressure and lack of support, which has been experienced as unbearable, is pure tragedy (2). This paper presents evidences with recommendations to policy makers on this issue.

Break the Silence: Angels Are Dying

There is no official report on physician trainee's death in Iran; however, local reports have shown that the 13th physician trainee in the past year has lost his life (2). Generally, physicians constitute a profession at-risk of suicide. However, the rate of suicide has also been reported to be increasing in trainees (3). Therefore, it is suggested that healthcare workers, including physician trainees, should have access to mental health consultation and early detection and treatment of potential illnesses including anxiety disorders and depression, as well as self-help resources along with the determination of a cause of this pathology.

Immigration and Shortage of Healthcare Workers

The World Health Organization (WHO) estimates that the world may face a global shortage of almost 4.3 million healthcare workers. The crisis in the healthcare human resource has been labeled as one of the most pressing global health challenges (4). To date, 3,000 physicians have lodged emigration applications at the Medical Council of Iran (5) and 300 healthcare workers in Iran have died of COVID-19 within 18 months (6). On the other hand, many subspecialty fields are vacant, with reports showing the collective withdrawal of young physicians from anesthesiology, emergency medicine, internal medicine, and infectious disease departments (7). These unfortunate facts require swift and appropriate intervention. While promises have been made to improve the situation, the lack of policy interventions risks the healthcare human resource crisis to become severe and consequently to limit the availability of health services.

A Big List of Challenges

Table 1 summarized a list of challenges before and after graduation that physician trainees in Iran may have (2, 3, 7). This is a serious situation that demands urgent attention. Medical residents pass a difficult examination and submit an affidavit to practice in disadvantaged regions in order to be admitted to the residency training program. This commitment must be upheld even after the death of the affiant, when his/her family are obligated to pay compensation to the government when the deceased cannot meet their obligation. These young physicians are mostly in the prime of their life, in the range of 25–30 years of age. They are not civil servants, and are paid a trivial amount, around 100 United States Dollar per month, while they are providing a full-time service, which is even less than the pay of a construction worker or even a street sweeper. Such a salary typically does not even cover rental accommodation. They work long shifts, sometimes up to 400–500 h per month, while an unskilled construction worker works about one-third of these hours for almost twice the wage. In Iran, the residency program takes 3–5 years to finish. Residents work for longer hours and receive lower salaries than any other job. Moreover, most of the time, they have no supporting system, such as liability insurance, retirement fund, or social security insurance. At the same time, they are not allowed to practice in the private sector for their free time outside the hospital (**Table 1**).

Fatigue, frustration, heavy responsibility in medical wards, undeserving treatment from higher levels, assignment of increasing numbers of shifts as punishment, and witnessing the untimely death of their colleagues have given this group a sense of abandonment (**Table 1**). They have a sense of being completely neglected and unseen, which in turn could result in unintentional errors and a decrease in the quality of medical services.

The reports show that new physicians are not being recruited; instead, residents are assigned to work in COVID-19 wards. There have also been instances where specialists in unrelated fields, such as ophthalmology, have been used to triage cases in COVID-19 sectors.

Researchers believe that fostering healthcare working conditions that supports intrinsic motivation and improves working hours, as well as rewarding physicians fairly and equitably may preclude burnout and job dissatisfaction (8).

In Iran, medical trainees, who are mostly of marriage or reproductive age, either show no intention to start a family due to high work pressure and stress; or, if they marry, do not have children because of their poor economic conditions and considering that childbirth-related leave is not included in their service period.

Although medical education in Iran is free, those who are transferred from foreign universities to state universities are forced to take a supplementary course and pay a heavy annual tuition fee to the universities. These individuals sometimes do not even receive a small salary. The main challenges of physician trainees are listed as below.

TABLE 1 | List of challenges that trainee physicians may encounter in the health system in Iran.

Challenges prior to graduation	➢ Low salary, bonus, profit-sharing, and no overtime pay ➢ High number of night shifts, particularly for first-year trainees ➢ Lack of full employee benefits ➢ Unsuitable on-call rooms in hospitals ➢ Insufficient personal loans for emergencies ➢ Impossibility of working in the private sector while studying ➢ Lack of medical and dental insurance for residents and their family members ➢ Lack of social security insurance, social support, and communication, leading to maladaptive coping mechanisms ➢ Lack of accommodation facilities after shifts (e.g., university campus) ➢ Concerns about proper personal protective equipment and booster dose of COVID-19 vaccine ➢ Long period of self-isolation away from close relatives during COVID-19 pandemic ➢ No maximum number of shifts and working hours ➢ Insufficient opportunities for study and research ➢ Non-observance of professional ethics by superiors ➢ Inability to take full advantages of leave while studying ➢ No direct channel to report burnout issues or present whistleblower reports ➢ Compelled to publish dissertation outcomes in an indexed journal as a graduate requirement ➢ Lack of supervision system on annual examination appeals and remark request ➢ Lack of clinical mentoring programs ➢ Extra-legal councils and approvals committees (e.g., 7-member council) ➢ Disagreement of education deputy to decisions of Court of Administrative Justice ➢ Lack of complete trust to the annual departmental evaluations ➢ Insistence of Health Ministry to complete examinations even at the peak of the COVID-19 pandemic
Challenges after graduation	➢ Lack of full employee benefits ➢ Low salary, bonus, and profit-sharing ➢ Unjust tax cut in comparison to other jobs ➢ Lack of transport and accommodation facilities ➢ Irregular payment of physician's salary ➢ Distance from the spouse's place of study and work ➢ Long-term commitment to serve the government ➢ Lack of timely counseling services and social and mental support ➢ Low health care services tariffs in Iran ➢ Restriction on private entrepreneurship

Financial Struggle

Heavy debt burdens place financial pressure on residents and this trend might have been accelerated during COVID-19 (9). **Figure 1** shows the average salary overall and the average wage and benefits among medical residents in different countries based on the online calculator and up-to-date exchange rate (10). Regardless of residency year and university tuition fee, this rate may vary based on the location, year, as well as the seniority of physician trainees in different cities. Generally, the medical education in Iran is free of charge however the residents have not been fairly compensated when considering the demands made of them. This condition is considerably different from the salaries paid in neighboring or Asian countries of the same socioeconomic status.

Long Shift Hours

The recent Medscape survey on 1,509 US medical residents showed that more than half of US residents spend 1–5 nights per month on call, while nearly 92% overall spend <10 nights working (9). Reports in Iran indicate around 15 night-shifts per month during the first-year residency program in some departments (7).

Evaluation

Medical residents undergo academic and practical assessment by their education department regularly once a month, and the universities issue permits for their continuation to higher years only after those assessments. However, in 2021, the insistence of the authorities in deputy of education of the Ministry of Health that centralized examinations for medical residents involve in-person examination of the resident collective, even during the fifth peak of the COVID-19 emerging pandemic, requires answers or investigation. In selected countries, nationwide examinations were postponed due to the COVID-19 pandemic (12) and government rushes new doctors into service (13). In 2020, the Iranian government did the same due to the intensive demand for human resources. Yet, in 2021, the deputy of education unexpectedly decided to hold academic assessments for thousands of candidates and physicians that lasted for many hours in a closed space, even though these candidates had already been assessed on a monthly basis by their own universities. The recent decision to reduce the capacity of residency entrance examinations in the current year made a great concern even at the parliament level. In this time, more than 1,200 protesters have requested legal investigation of the performance of the deputy of education in the Ministry of Health. Conflict in management and various internal regulations have caused dissatisfaction (14). For example, annual exams were held for many years at the university level, it became conjoint for a few years, and now it has been centralized at a national level. Implementing this intervention during the pandemic situation calls for investigation and evaluation.

Crippling Sanctions, Flying Without Wings

Under conditions where healthcare personnel are frustrated and suffer from intensive fatigue, the medical equipment is worn out, and the country faced crippling sanctions which may have significantly contributed to the damage to the healthcare system (15). Sanctions imposed on Iran mean the cash-strapped

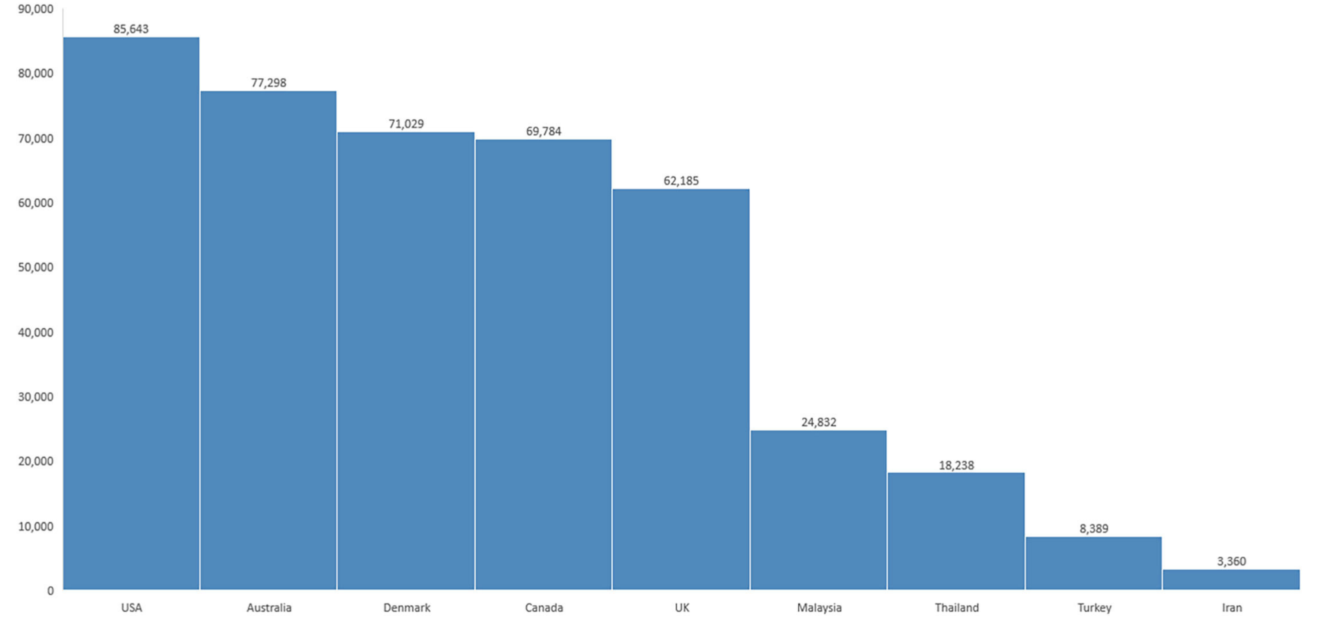

FIGURE 1 | Annual medical resident salaries by country, converted into United States Dollar (10). The mean monthly salary of physician trainees in Iran is 70 million Rials (11). The conversion was made based on the exchange rate to United States Dollar by online currency converter, www.xe.com October 31, 2021 without purchasing power parity.

administration has insufficient reserves to purchase medical equipment and vaccine which may cause the country and global public health into subsequent challenges. However, it is not an unreasonable demand to expect officials to show more responsible attitudes toward healthcare worker in the current fifth and most intense COVID-19 peak, and to anticipate some support for healthcare trainees from the relevant authorities. It is necessary to remain one step ahead of COVID-19, rather than that this pandemic serve as a tool to create dissatisfaction and push healthcare personnel toward protests as the healthcare policymakers should be more realistic. While fighting the pandemic, front line healthcare workers need support and protection instead of frequently working without adequate equipment and remuneration.

COVID-19 and Higher Burnout Rates

COVID-19 pandemic professed an unprecedented major challenge to the international scientific community (16) that transcends public health. Accumulative stressors during the COVID-19 pandemic may have health implications, with high rates of depression, anxiety, insomnia, and distress in frontline healthcare providers, which require particular attention (17). Studies acknowledged the stressors, burdens, and psychological requirements of the healthcare workers, and the importance of transformation efforts to mitigate these issues confronting those working on the frontlines during the pandemic (18). A survey on 1,420 international physician trainees revealed that exposure to cases with COVID-19 is significantly associated with higher burnout rates (1). Similarly, researchers found a high prevalence of burnout among healthcare providers during the COVID-19 pandemic in Iran. Physician trainees were found to be at a higher risk of developing burnout. Additional research is necessary to elucidate the cause of this, but concerns about heavy workload, changes in duty schedules, as well as having less access to personal protective equipment, may have caused the phenomenon (19). Although the physician trainees may face a burnout during COVID-19 pandemic, the surveys have shown large dissatisfaction among general people about the handling of the COVID-19 pandemic by the former Iranian administration. In a survey conducted by the Iranian State Television, 78% of people gave poor scores to the former administration performance in handling the pandemic and in taking preventive and control measures (20) although the current health administration made a hope and success with mass COVID-19 vaccination strategy.

Conflict of Interest, a Serious Scourge in the Iran Health System

Conflict of interest still remains a serious challenge in Iran's health system. The following are considered as the underlying causes of conflict of interest in the healthcare system: the structure of the existing financial system fee for service, lack of transparency in the healthcare system, existence of the problem of having two simultaneous jobs dual practice in governmental and private sector, and lack of an integrated information system and electronic healthcare structure (21). Recently, the conflict of interest challenge has attracted the attention of public and media however there is no clear strategy to resolve the potential conflict of interest in the healthcare management structure.

RECOMMENDATIONS

1. Based on the Accreditation Council for Graduate Medical Education (ACGME) regulations, institutes should supply sleep facilities that are quiet, safe, private, and must be accessible and available for fellows/residents to support safe patient care and education. Moreover, the institution must ensure satisfactory sleep facilities and safe transportation opportunities for fellows/residents who may be too tired to return home safely (22). These recommendations should be applied in Iranian institutes in cooperation with governing bodies.
2. The residency program in the Iranian medical education system is considered to be a student course and therefore the student is given a low salary, bonus, and almost zero profit-sharing. However, it should be noted that physician trainees are medical doctors and Medical Council members who should work 3–5 years in the frontline of hospitals and while at the same time receiving education. By redefining the residency program as a "job" these issues could be resolved (23). In consideration of the protest against the prevailing educational conditions, as well as the mass resignations of physician trainees in some departments, the importance of turning these individual's situation from "student" into "employee" should be considered.
3. The national educational curriculum of the residency program has not been revised for many years (7). Additionally, the ministry's extensive health and medical functions has virtually sidelined education and research that requires a structural reform. To protect the health of the community and that of physician trainees, the curriculum of education should be revised. Furthermore, the extreme authority of the heads of departments has been highlighted as complicating changes in the status of the residency into a safe condition.
4. These policies should be driven from higher authority levels, such as parliament, Medical Council, Ministry of Health, and universities. It is difficult to convey the deprived nature of stakeholders to higher authorities. Whistleblowers and nongovernmental organizations must be able to report directly to law enforcement and regulatory agencies and to competent authorities without risking loss of protection and risk of reprisal.
5. The short term strategies to reduce further challenges are listed below: increasing salaries and wages, amending some post-graduation commitment laws, standardizing the number of night shifts and working hours, coercing the administration to hire medical staff instead of using trainees as low-cost employees, improving and equipping doctor's on-call rooms, providing welfare and livelihood packages with an emphasis on insurance facilities, and eliminating conflicting interests from those who interfere with education policy-making. The list of challenges has been presented in **Table 1**; these require a specific strategy to resolve.

6. The ACGME-accredited program has recommended that institutes encourage fellows/residents to alert their higher authorities when they are concerned that another trainee or lecturer may be displaying signs of burnout, substance abuse, depression, suicidal ideation, or potential for violence (22). The same strategies should be implemented in most countries with a high rate of burnout of physician trainees.
7. In the context of COVID-19, the best way to combat burnout seems to be precise organization within the hospital and practical training sessions. Effective measures must be taken at the institutional and individual levels (24). However, a national policy in response to burnout of physician trainees is also necessary.
8. Despite the significant successes in the field of knowledge and skills transfer in various clinical areas, insufficient attention is paid to personal development and communication skills. Although attention to medical ethics and professional commitment has been emphasized in the latest version of health education reform in Iran (25), it is questionable to what extent this is planned for implementation and adhered to in practice. In a report by Medscape, 84% of medical residents noted a positive relationship with attending physicians (9) however, there is no nationwide report to show this satisfaction rate among physician trainees in Iran.
9. Despite several reforms within the last few decades, the Iran Ministry of Health, as the steward of the healthcare system in Iran, has not been performing efficiently enough to respond clearly to emerging challenges (26). With 67 medical universities across 31 provinces, Iran is currently among the few countries with medical education integrated with healthcare services. Reform on the medical education seems to be mandatory even if the policy makers reach a decision to constrain the medical education as an independent organization.
10. Protecting healthcare providers is a significant component of public health measures during the COVID-19 pandemic (27). Special interventions to promote mental wellbeing in healthcare workers during COVID-19 need to be implemented immediately.
11. The challenge of ensuring educational equity is remarkable. Different types of quotas and exemptions apply to physician trainees administrative process in Iran. By law, the children of faculty members are allowed to change the majors of their studies (for example from veterinary sciences to pharmacy), or change the city in which they study, easily, while these possibilities are not available to other candidates (28). Recognizing disparities in education opportunities may present better prospects to elites and stakeholders. The governmental body had to become directly engaged in health policy implementation over the past years in Iran (29), without the involvement of non-public sectors and non-governmental organizations. Therefore, policies to control governmental monopoly should be placed.

CONCLUSION

With a mixture of success and failure, Iran's healthcare system has undergone several major reforms. Unless this essential transformation takes place within the healthcare system, sustainable development in healthcare may remain a moving goal (29). The performance of healthcare authorities in dealing with physician trainees has not been analyzed. Eliminating potential conflicts of interests in decision-making and administrative process, as well as ensuring sustainable resources, are key elements. Our point is that of unfavorable job description of physician trainees that have been neglected by researchers and decision makers. The lack of health policy in this issue may causes dissatisfaction, outburst, and might affect negatively on the contextual social capital. Healthcare reform will require policy makers to change their attitudes toward young physicians otherwise the country can be expected to have to face a tsunami of migration, brain drain, and lack of human resources in near future.

Healthcare workers are mourning the death of their colleagues and are frustrated and tired, but are still standing tall in the defense of the nation against pandemic. It is imperative that officials make haste in presenting a plan to support healthcare workers, and medical residents in particular. Physician trainees are the foot soldiers and front line of the healthcare system in the battleground for protecting people, and their hardship deserves to be noticed, if the authorities would just take note.

AUTHOR CONTRIBUTIONS

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

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Applying Theory to Explain the Influence of Factors External to an Organization on the Implementation of an Evidence-Based Intervention

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Despite its widely acknowledged influence on implementation, limited research has been done on how the external environment (i.e., outer setting) determines when organizations adopt and implement new interventions. Determinant frameworks identify several outer setting-level factors such as funding streams, inter-organizational relationships, and peer pressure. However, these frameworks do not explain how or why outer-setting factors influence implementation. To advance research in this area, we argue for the importance of deriving theory-based propositions from organization theory to explain how outer setting factors influence organizations. Drawing on the work of the Organization Theory in Implementation Science (OTIS) project, we identified 20 propositions from five classic organization theories—Complexity Theory, Contingency Theory, Institutional Theory, Resource Dependence Theory, and Transaction Cost Economics. We then applied those propositions to hypothesize relationships among outer setting factors, implementation strategies, and implementation outcomes in five case studies of evidenced-based tobacco control interventions. The five case studies address the implementation of smoke-free policies, community health worker-led tobacco education and cessation programs, 5 A's (Ask, Advise, Assess, Assist, and Arrange), point-of-sale tobacco marketing policy interventions, and quitlines. The case studies illustrate how propositions may be used to guide the selection and testing of implementation strategies. Organization theories provide a menu of propositions that offer guidance for selecting and optimizing high-leverage implementation strategies that target factors at the level of outer setting. Furthermore, these propositions suggest testable hypotheses regarding the mechanisms underlying the influence of outer-setting factors on how and why organizations adopt and implement interventions.

Keywords: organizational theory, implementation determinants, evidence-based interventions, cancer prevention and control, implementation strategies

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INTRODUCTION

Implementation scientists continue to study new and better ways to accelerate the implementation of evidence-based interventions (EBIs) into practice by designing strategies to target the multilevel factors (i.e., determinants) that influence implementation (1). Despite these efforts, a recent study of five cancer control EBIs found they took an average of 15 years to achieve wide scale implementation (2). The slow rate of EBI implementation may relate in part to the relatively limited attention implementation scientists have given to how environmental factors influence organizations. To date, implementation scientists have focused on determinants at the level of the individuals who adopt and implement EBIs and the inner setting of the organizations where they work, with less attention to determinants at the level of the external environment or outer setting (3, 4). In this paper, we argue for the value of organization theory as a means of closing this gap.

Within organization theory, organizations are conceptualized as goal-directed, social entities that are influenced by their environments (5). Organization theories include environmental variables and propositions that explain how those variables influence the organization as a unit. As such, these propositions offer a rich resource for implementation scientists to use as a guide to selecting implementation strategies and hypothesizing the causal pathways or mechanisms through which those strategies affect proximal outcomes (e.g., changes to the organization) and more distal outcomes (adoption and implementation of EBIs), as well as barriers and facilitators that may moderate the strategies' impact on those outcomes (6).

In this paper, we build on the work of the organization Theory in Implementation Science (OTIS) project (https://cpcrn.org/projects) to describe how propositions from five classic organization theories might be applied to select implementation strategies and hypothesize relationships among outer-setting determinants, implementation strategies, and implementation outcomes. The focus on classic theories addresses Kislov et al.'s recommendation that implementation scientists draw on grand or classic theories as one starting point for theorizing mechanisms underlying implementation (7).

Organization Theory for Implementation Science (OTIS)

The OTIS project aims to identify organization theories relevant to implementation and extract and summarize their constructs and propositions. OTIS project methods are described elsewhere (8). Briefly, we surveyed scholars with expertise at the intersection of implementation and organization science and through that survey identified nine organization theories relevant to implementation science. Two members of the team then abstracted information about the theories from seminal texts. Two members of the team then summarized information about the theory into a structured template that includes the theory's central constructs and propositions together with guidance on relevant implementation strategies. Summaries of each of the nine theories are available on the Cancer Prevention and Control Research Network's (CPCRN) website (https://cpcrn.org/resources). The purpose of this paper is to illustrate how propositions from these organization theories might be used to hypothesize relationships among outer-setting factors, implementation strategies, and implementation outcomes. Building on co-authors' expertise, we selected a subset of five organization theories and illustrated their use in case studies of the implementation of tobacco control EBIs.

FIVE ORGANIZATION THEORIES AND THEIR PROPOSITIONS

Table 1 presents central propositions from five classic organization theories: Complexity Theory, Contingency Theory, Institutional Theory, Resource Dependence Theory, and Transaction Cost Economics. Below we describe each theory and provide a case study to illustrate the theory's application. In proposing relevant implementation strategies, we named strategies using terminology developed by the Expert Recommendations for Implementing Change (ERIC) project (10).

Complexity Theory

Complexity Theory explains how change occurs within complex systems that are comprised of diverse yet interconnected parts that affect and influence each other in dynamic ways over time (11). As organizations interact with others in their network and develop relationships (i.e., interdependencies), they learn from each other, adapt behaviors, engage in sense-making (in which they assign meaning to their collective experiences), and develop patterns of organization (i.e., self-organization) unique to their system. Outputs of a system process may become inputs within a chain of cause-and-effect that forms a loop (i.e., feedback loops). Feedback loops influence the magnitude of effects and, given the dynamic interactions occurring within the system, can create paradoxical effects; small changes may have large effects on outcomes and large changes may have small effects.

Complexity Theory offers possible mechanisms for developing and fostering interactions and social processes to optimize EBI implementation within a system. Hypothesized mechanisms for facilitating effective sense-making include developing interconnections among those with diverse perspectives to promote trust, innovation, and respect for differences and thereby build support for an EBI (9). Minimum specifications, or flexible rules that allow for innovation, are posited to increase the effectiveness of self-organization and thus improve EBI adaptation and integration to fit the parameters of a complex system (11). Prior studies have called for applying Complexity Theory to EBI scale-up and spread across systems (9) and conducting complexity-informed implementation science (12).

Abbreviations: 5 A's, Ask, Advice, Assess, Assist and Arrange; CHW, Community Health Worker; CPCRN, Cancer Prevention and Control Research Network; DHHS, Department of Health and Human Services; DSME, Diabetes Self Management Education; EBI, Evidence-Based Intervention; ERIC, Expert Recommendations for Implementing Change; FQHCs, Federally Qualified Health Centers; OTIS, Organization Theory for Implementation Science; RDT, Resource Dependency Theory; TCE, Transaction Cost Economics.

TABLE 1 | A partial list of propositions for each of five organizations theories.

Theory	Propositions
Complexity theory	• Interdependencies contribute to sense making. • Interdependencies that are "trusting, attentive to new ideas, and mindful of differences between ideas" are most likely to result in effective sense making [Lanham et al. (9) as cited in Lanham et al. (9)] • Interdependencies and sense making contribute to self-organization. • Change that is guided by minimum specifications allows individuals to self-organize most effectively. • Feedback loops may amplify some effects and reduce others, and therefore small changes may lead to large-scale differences in outcomes (i.e., "the butterfly effect") and vice versa.
Contingency theory	• Optimal work structure is contingent on the degree of uncertainty in both the task and in the task environment. • When there is higher uncertainty in a setting, unprogrammed (more flexible) coordination structures will be more effective. • When there is lower uncertainty in a setting, programmed (less flexible) coordination structures will be more effective. • Higher levels of interdependence (both within and between departments) will require greater investment in coordination. • The greater the differentiation between departments, the more difficult it will be to coordinate.
Institutional theory	• The degree of isomorphism in an organizational field is positively related to the degree of (1) coercive, (2) mimetic, and (3) normative pressures in that field. • Coercive pressures are greater to the extent that: - Organizations in a field transact with agencies of the state (or depend on public financing). - Organizations in a field are dependent upon a single (or several similar) source of support for vital resources. • Mimetic (i.e., peer) pressures are greater when an organizational field has high levels of uncertainty (e.g., evidence for what is effective is limited, technologies are poorly understood, goals are ambiguous, etc.). • Normative processes are greater in organizations with higher levels of professionalization.
Resource dependence theory	• To acquire power, organizations exchange their autonomy for resources from other organizations within their field. • Multiple environmental factors influence an organization's willingness to exchange autonomy for power, including competition, interdependence, and munificence.
Transaction cost economics	• Organizations incur costs when they transact with other organizations for goods and services (transaction costs). • Organizations strive for greater efficiency by implementing governance structures that will minimize transaction costs. • These governance structures range from (a) buying the good or service with no contract, (b) contracting with another organization to provide the good or service, and (c) integrating production within the organization (i.e., producing the good or service themselves). The following characteristics of a transaction determine the optimal type of governance structure: ○ asset specificity (i.e., investment of personnel, materials, and other resources required to establish the transaction) ○ transaction frequency ○ transaction complexity ○ uncertainty about future transactions • Integrating production will be more efficient than transacting with other organizations to produce a good or service to the extent ath asset specificity is high and transactions are infrequent, uncertain, and complex.

Illustration: Complexity Theory Applied to Implementation of Smoke-Free Housing Policies

Mills and colleagues' causal loop diagram of individual, environmental, and root causes influencing disparities in smoking rates (13) visualizes the complexity surrounding tobacco control efforts. Their diagram illuminates pathways to explain how implementing smoke-free policies in multi-unit housing could decrease smoking, and possible unintended effects that could sustain or exacerbate smoking disparities. For example, enforcement of smoke-free policies may lead to evictions and threats of eviction, which may contribute to housing instability, stress, and anxiety, thereby increasing smoking rates (14, 15). Complexity Theory suggests the value of implementation strategies that foster interactions among the multiple other organizations that support the residents of multi-unit housing (e.g., housing advocates, public health departments, housing authorities, and eviction courts). These strategies might include building a coalition to capture and share local knowledge, engage in local consensus discussions, and facilitate sense-making to develop and plan for implementation of smoke-free policies with the goal of maximizing public health outcomes (e.g., decreased smoking, decreased secondhand smoke exposure, stable housing). Such inter-organizational collaborations can also formalize feedback loops for improved decision-making by the system and flexibility in policy implementation (e.g., outdoor designated smoking areas to improve compliance among smokers; provision of nicotine tobacco replacement therapy and Quitline referrals as part of the violation response process).

Contingency Theory

Contingency Theory posits that there is no best way for organizations to operate but rather, the most effective or optimal way for an organization to structure and coordinate tasks is contingent on characteristics, particularly the level of uncertainty, of both the task and the task environment (16–18). Uncertainty in the task refers to gaps between the information needed vs. information available to perform the task. Uncertainty in the task environment (inner and outer setting) refers to the degree that factors in the environment are predictable (e.g., to what extent and how quickly are changes happening in the evidence-base, resource availability, community needs, or guidelines and policies). Depending on the degree of uncertainty, different strategies will be best suited to coordinate a task. Programmed/inflexible approaches to coordination will be optimal when uncertainty is low and less programmed/flexible approaches will be optimal when uncertainty is high (19). Thus, the effectiveness of an organization's actions are contingent upon the organization's dynamic internal and external contexts, which also continuously shape the organization's structure and development.

While still underutilized in implementation science, researchers have begun to identify potential applications of Contingency Theory. For example, some authors have linked Contingency Theory to advancements in adaptation research. Since organizational structure is a critical determinant of implementation success, they suggest regularly revisiting and adapting implementation strategies to fit how organizations are continuously altering their structure in response to dynamic factors in the inner and outer setting (20). In another example, researchers applied Contingency Theory to inform a study of strategies that foster cross-systems collaborations between child welfare and substance use treatment agencies (21).

Illustration: Contingency Theory Applied to Implementation of Community Health Worker led Tobacco Education and Cessation Programs

We use an example of a coalition of community-based health care and social services organizations that aimed to address gaps in local tobacco control implementation and growing inequities in smoking prevalence and smoking-related cancer among immigrant communities. To improve the reach and effectiveness of tobacco education and cessation programs, the coalition shared local knowledge and built collective capacity to implement intervention strategies, including leveraging community health workers (CHWs). Coalition members have varying capacities to adopt, implement, and sustain a tobacco specialist CHW program. Contingency Theory can be used to identify and monitor risks, vulnerabilities, and capacity to inform planning and implementation among coalition members. For example, assessing characteristics of the task and task environment of member organizations (e.g., organization size and budget, staff turnover, prior experience delivering CHW-led programs) may offer coalition leaders insight into potential sources of uncertainty. Some organizations may face higher uncertainty related to the task (e.g., hiring and training CHWs) while others may face higher uncertainty related to the task environment (e.g., stability of funding, shifting community priorities). Concretely assessing and monitoring these uncertainties will inform how the coalition implements the CHWs intervention to align with the capacity of each organization. In cases of low uncertainty, the coalition may establish standardized protocols for the roles of CHWs and their supervisors. Alternatively, in cases of high uncertainty, the focus may shift to promoting adaptability, quality monitoring, and small tests of change with the goal of supporting organizations and CHWs to develop the best local approach to implementation. By acknowledging areas where either more programmed or unprogrammed coordination will be more effective, member organizations will be better positioned to benefit from participation in the coalition and have opportunities to select tailored strategies that best meet their organizational context and ideally lead to stronger and more sustainable collaboration.

Institutional Theory

Institutional Theory hypothesizes that organizations within a field (e.g., regional healthcare market) become increasingly similar (i.e., 'isomorphic') as a result of mimetic, normative, and coercive pressures (22). Mimetic pressures are evident when organizations copy the approaches of others within their field; the greater the uncertainty about which approaches are best, the greater the mimetic pressure. Normative pressure comes from institutions that legitimize a field (e.g., professional societies) and is greatest in highly professionalized fields such as healthcare (20, 23, 24). Jensen et al. and Sherer used Institutional Theory as a lens for understanding how the 'rationalized myth' of electronic health records promoted their adoption and implementation (25, 26). Burnett et al. used Institutional Theory to explain hospitals' responses to often conflicting pressures to improve quality and constrain spending (27). Birken et al. used Institutional Theory to explain how child welfare systems responded to demands from policymakers for evidence-based solutions to child abuse and neglect by adopting SafeCare, a widely vetted intervention (20).

Illustration: Institutional Theory Applied to Implementation of the 5 A's in a Network of Community Health Clinics

The "5 A's" specifies five steps (Ask, Advise, Assess, Assist, and Arrange) to identify tobacco users and either provide or refer them to interventions (28–30). A network of community health clinics seeking to implement the 5 A's could leverage institutional pressures by partnering with accrediting bodies and payers to require clinics to use 5 A's to meet quality standards or funding requirements. Mimetic pressure may be invoked by forming a learning collaborative to increase awareness of 5 A's use among peer organizations. Partnering with professional organizations or highlighting their endorsement of the 5 A's may leverage normative pressures among healthcare providers.

Resource Dependence Theory

Resource Dependency Theory (RDT) describes how procurement of external resources by an organization affects the strategic and tactical management of the organization. Most notably, RDT predicts the conditions under which organizations will compromise autonomy to gain power. An organization's power may include not only its financial standing but also its prestige and reputation (31). RDT identifies multipe environmental factors that influence when an organization will trade autonomy to gain power including competition within the external environment, interdependence with other organizations, and munificence (i.e., richness of resources), among others (32). RDT has been used to understand the relationship between an organization and its external environment including strategies, structure, and/or performance in both healthcare and non-healthcare settings (33–36). For example, Fareed & Mick used RDT to hypothesize that more interdependent hospitals in munificent environments would be more likely to engage in patient safety innovations than hospitals with fewer dependencies and less munificent environments (31).

Illustration: Resource Dependence Theory Applied to Implementation of Point-of-Sale Tobacco Marketing Policy EBIs

RDT aids in understanding the dynamic, interdependent relationships among organizations that compete for resources, such as state health departments and other community organizations interested in changing point-of-sale tobacco marketing policies. Community organizations often must apply for government and foundation funding to finance the implementation of programs. External funding enables organizations to access training, technical assistance, and software needed to collect, manage, visualize, and analyze data on tobacco marketing practices, and the locations of tobacco retailers (e.g., near schools) (37, 38). Tobacco retailer data can be shared with local policy makers, giving community organizations increased power to inspire change to promote public health. At the same time, relying on external funding may limit organizations' autonomy as they comply with funding requirements. They may also need to increase their interdependence with other organizations to garner the expertise and resources needed to collect local data and promote policy change. In exchange for this expertise and resources, organizations may need to adjust the direction of their work, make changes to their timeline, or institute other changes to meet the needs of other organizations upon which they depend for resources, thus further decreasing their autonomy. Community organizations may limit the loss of autonomy and protect their power through the use of implementation strategies such as resource sharing agreements, formal commitments, and shared timelines.

Transaction Cost Economics

Organizations incur costs as a result of planning, implementing, and enforcing transactions with other organizations to exchange goods and services. Transaction Cost Economics (TCE) posits that organizations will transact with other organizations to produce a good or service ("buy" from another organization instead of "make" in-house) when the transactions required to do so are less than the cost of producing the good or service in-house (39, 40). Several authors have argued for the relevance of TCE to healthcare generally and to implementation science more specifically. For example, authors have argued that TCE could be applied to explain why some Accountable Care Organizations vertically integrate a service (e.g., adding rehabilitation services within the Accountable Care Organization) while others opt to purchase the service from an external organization (41). In another case, authors argued that TCE might explain when a health insurer would hire their own case managers to provide Diabetes Self-Management Education (DSME) as opposed to reimbursing community practices to provide DSME services (42).

Illustration: Transaction Cost Economics Applied to Quitline Implementation

Tobacco quitlines are an EBI that has been shown to increase tobacco cessation rates, particularly when quitline counselors proactively call participants to provide multiple counseling sessions (43). To increase referrals to the quitline, a state department of health and human services (DHHS) might explore whether it would be more efficient to work within their own network of health departments (internal integration) or with the state's federally qualified health centers (FQHCs) (external transaction). This decision could be viewed through the lens of TCE. For either health departments or FQHCs, DHHS would need to invest personnel time and other resources in training, technical assistance, and performance monitoring. The value of this investment would depend on the frequency of potential referrals, complexity of transactions, and uncertainty of continuing the transactions over time. FQHCs may have the potential to generate more frequent referrals but have higher levels of complexity and uncertainty. The most efficient choice would depend on how many more referrals FQHCs would generate compared to health departments, and whether the additional referrals merited the higher levels of complexity and uncertainty. TCE also could be used to identify factors that might moderate the impact of efforts to increase referral rates. This might include increased uncertainty about whether transactions will continue due to potential reductions in funding. TCE might inform implementation strategies related to formal commitments between transacting organizations and efforts to increase demand for a service (e.g., by marketing the quitline), which would increase the frequency of transactions.

DISCUSSION

As we have illustrated in this paper, organization theories offer propositions that may be used to better understand how, when, and why outer setting-level determinants influence organizations' adoption and implementation of EBIs. These propositions can also guide the selection of implementation strategies and generate testable hypotheses about the mechanisms through which those strategies affect implementation outcomes. As summarized in **Table 2**, organization theories may inform the selection and testing of a wide range of implementation strategies.

Our presentation of the five organization theories is not intended to be comprehensive but rather to illustrate the potential of organization theory to advance implementation research related to the influence of outer setting-level determining when and how organizations adopt and implement EBIs. We provide only a broad level overview of the five theories, each of which has a long history that includes multiple permutations with varying constructs and propositions. We also recognize that implementation scientists face barriers to studying the impact of outer setting determinants on implementation that extend beyond gaps in knowledge of organization theory. These barriers include,

TABLE 2 | Propositions from organizational theories aligned with implementations strategies.

Theory	Central propositions	Relevant implementation strategies [Powell et al. (1)]
Complexity theory	Systems are complex. Facilitating interdependencies and sense making contributes to self-organization within complex systems.	• Build a coalition • Capture and share local knowledge • Conduct cyclical small tests of change • Conduct local consensus discussions • Create new clinical teams • Facilitate relay of clinical data to providers • Model and simulate change • Develop and organize quality monitoring systems • Organize clinician implementation team meetings • Promote adaptability • Promote network weaving • Purposefully re-examine the implementation
Contingency theory	When task and/or environmental uncertainty are high, unprogrammed coordination will be most effective.	
	When task and/or environmental uncertainty are low, programmed coordination will be most effective.	• Mandate change • Provide clinical supervision
Institutional theory	The degree of isomorphism in an organizational field is positively related the degree of (1) coercive, (2) mimetic, and (3) normative pressures in that field.	• Alter incentive/allowance structure • Change accreditation or membership requirements • Create a learning collaborative • Create or change credentialing and/or licensure standards • Use capitated payments • Visit other sites • Place innovation on fee for service lists/formularies
Resource dependence theory	To acquire power, organizations exchange their autonomy for resources from other organizations within their field.	• Develop resource sharing agreements • Obtain formal commitments • Develop academic partnerships • Fund and contract for the clinical innovation • Increase demand
Transaction cost economics	Integrating production (making the product or service) will be more efficient than transacting with other organizations to produce it to the extent that asset specificity is high and transactions are infrequent, uncertain, and complex.	

but are not limited to, difficulties manipulating outer setting variables, controlling exposure to outer setting variables across study arms, and garnering the sample sizes needed to test hypotheses related to the influence of outer setting variables on organizaitons.

This paper represents one piece of our broader effort to make classic theories more accessible to implementation scientists, propelling the field toward improved success in translating evidence into practice. Without theory, the mechanisms that drive implementation will remain unclear, and strategies for facilitating implementation will remain elusive. This paper also contributes to recent calls for multilevel implementation interventions. By combining organization theories with theories that address factors at the level of individual or inner setting, we can develop high-leverage, multilevel implementation strategies rooted in well-established theories with extensive empirical support (44).

DATA AVAILABILITY STATEMENT

The datasets presented in this study can be found in online repositories. The names of the repository/repositories and accession number(s) can be found at cpcrn.org/resources.

AUTHOR CONTRIBUTIONS

JL, MW, MK, ML, MO'L, LK, and SB wrote case studies and theory overviews. JL wrote the introduction and discussion and combined all sections. MF contributed to the introduction and conclusion and provided feedback on the overall manuscript. All authors read and approved the final manuscript.

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An Opportunity to Harmonise the Approach to Patients' Care Pathways for Rare and Complex Diseases: RarERN Path™

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As a matter of fact, organisation always matters when discussing about healthcare, since it is fundamental in order to ensure the delivery of the most appropriate care to patients in the most appropriate way. Unfortunately, the pandemic brought by the severe acute respiratory syndrome-coronavirus 2 (SARS-CoV-2) imposed a huge reorganisation of the healthcare systems, with several repercussions on the care of several chronic conditions, that were in many cases discontinued. This was the case of rare diseases (RDs), conditions that even under normal circumstances can experience diagnostic delays and difficulties in receiving appropriate care. The context of the European Reference Networks (ERNs) represents one of the most appropriate settings for the creation of organisational reference models for patient care pathways (PCP). As a matter of fact, the main mission of ERNs is to improve the care of patients with RDs in Europe through a patient-centred approach, thanks to real multistakeholder involvement. For this reason, in the last years, an extensive effort has been made towards the creation of a methodological approach aimed at providing organisational reference models for PCP in RDs across the different Member States. In fact, in order to develop the reference model, a structured methodology was created to enable the design of the PCP based on a deep sharing of expertise on high-quality care and characterised by a strong patient-centred approach: RarERN Path^{TM}. Among the different stakeholders that need to be involved in planning strategic actions to ensure care also during an emergency, patients' representatives, healthcare professionals, hospital managers, and experts in healthcare organisations play a crucial role.

Keywords: rare diseases, organisation of care, patients' care pathways, healthcare system, RarERN Path^{TM}

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INTRODUCTION

Rare diseases (RDs) affect more than 30 million people in Europe and many of them still have limited access to timely diagnosis and high-quality treatment. Moreover, improving the scientific evidence in RDs can often represent a challenge due to the low number of patients. In order to address these challenges, the European Commission launched the European Reference Networks

(ERNs), virtual networks involving healthcare providers (HCPs) across the European Union (EU). The mission of the ERNs is to tackle low prevalence and RDs that require highly specialised treatment and a concentration of knowledge and resources and therefore to promote equity of care (1).

It is well known that no health care system model can be considered the most appropriate and extensively accepted from different points of view. Even within the same country, several dissimilarities can be often detected, and they can be related to different aspects, including structures, resources, and other specific characteristics of the health care system itself. However, there is a common aspect that each health system requires, and it is represented by an appropriate level of organisation. As a matter of fact, an organisation always matters when discussing healthcare, since it is fundamental in order to ensure the delivery of the most appropriate care to patients in the most appropriate way (2, 3).

In the last years, the severe acute respiratory syndrome-coronavirus 2 (SARS-CoV-2) pandemic imposed a huge reorganisation of the healthcare systems, due to the care needed for patients with COVID-19 and a consequent concentration of resources in the COVID-19 units[1]. The main repercussion of this necessary reorganisation was represented by the concentration of human resources from different units to be often entirely devoted to COVID-19 units. This resulted in many units being often closed or reduced to the provision of emergency services. Unfortunately, due to these big challenges, the care of several chronic conditions was in many cases discontinued and patients and healthcare professionals treating these conditions had to cope with a new arduous scenario. This was the case with RDs (4). Even under normal circumstances, patients with RDs can experience diagnostic delays, and difficulties in receiving appropriate support and care, and this may have a high impact on prognosis as well as morbidity and mortality. During an emergency, vulnerable patients are even more vulnerable.

Therefore, the relevant impact that COVID-19 had during the different waves and is still having on the provision of services to chronic patients highlights the need to develop specific organisational strategies for healthcare systems. Every single challenge that the health systems are experiencing in these hard times highlights how organisation matters, especially during a health emergency (5). In fact, the only way to ensure appropriate care to chronic disease patients during an emergency is to have detailed strategic plans for health care systems; for this purpose, it is desirable that specific actions may create or optimise existing organisational models for the care of chronic diseases. This is particularly crucial not only in case of future emergencies but also in other situations that might threaten the provision of routine care. These pathways should be based on efficient healthcare planning and referral systems that would help better define the different appropriate tasks of the professionals involved in patient care (6). Emergency plans should be designed or adapted to ensure that the diagnostic, monitoring, and therapeutic pathways of rare disease patients remain accessible for these patients. To do that, detailed organisational procedures need to be defined as soon as possible, identifying the different healthcare services to be maintained and preserved in case of a new pandemic or other health emergencies. Thus, it is desirable that *ad hoc* organisational models are adopted at a worldwide level to guarantee a homogeneous provision of care for chronic disease patients, considering also the geographical and cultural settings.

AN INNOVATIVE APPROACH TO IMPROVE THE FUTURE OF RDs: RarERN PATH™

As reported by the European pathways Association (EPA) "A care pathway is a complex intervention for the mutual decision making and organisation of care processes for a well-defined group of patients during a well-defined period[2]". Therefore, considering that the main purpose of patients' care pathways (PCP) is to enhance the quality of care, their role is particularly crucial in the field of RDs and complex diseases as well. The context of the European Reference Networks (ERNs) might represent one of the most appropriate settings for the creation of organisational reference models for PCP across Europe. As a matter of fact, the main mission of ERNs is to improve the care of patients with RDs in Europe, through a patient-centred approach, thanks to real multistakeholder involvement.

For this reason, in the framework of the collaboration between the ERN on Rare and Complex Connective Tissue and Musculoskeletal Diseases ReCONNET (https://reconnet.ern-net.eu) Coordination Team and the group of Health Economics of the Institute of Management of the Scuola Superiore Sant'Anna, an extensive effort has been made towards the creation of a methodological approach aimed at providing organisational reference models for PCP in RDs across the different Member States. In fact, in order to develop the reference model, a structured methodology was created to enable the design of the PCP based on a deep sharing of expertise on high-quality care and characterised by a strong patient-centred approach: RarERN Path™ (7). RarERN Path™ represents a specific methodology aimed at improving organisation in real life and it was created by implementing the existing approaches already in use for the assessment of PCP with several innovative ways to look at the organisation itself. An organisation is, in fact, the core of the application of clinical practise guidelines (CPGs) or recommendations, and when an organisation fails it is really difficult to apply evidence-based guidelines in a homogeneous way. An *ad hoc* methodology was needed to address the specificity and the innovative asset provided by the ERNs and their unique environment represented by a multi-national and multi-stakeholder collaborative framework. RarERN Path™ brings the expertise of the different excellent centres across

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[1] https://covid19.who.int/

[2] http://e-p-a.org/

Europe at the local level, producing as the main result of its application, a reference organisational model that can be applied and adapted in a flexible way to different disease-specific and geographical contexts and that can be monitored and measured. As a matter of fact, an efficient implementation of existing clinical pathways can only be ensured by means of an efficient organisation of the healthcare systems and of the related services. Without an appropriate organisation, the journey of patients and of their caregivers can become long and exhausting and it can lead to limited and unequal access to care (8).

The RarERN Path$^{\text{TM}}$ approach foresees six consecutive phases, that start with mapping of what is in place in the different excellence centres, mainly focusing on the organisational aspects of the PCP, and collecting the perspectives of patients. This kind of approach provides the possibility to catch the different organisational challenges and best practises already in place and to design an optimised common PCP that reaches a consensus among the different stakeholders. Moreover, the co-design process with the different stakeholders is essential in the definition of disease-specific key performance indicators (KPI) able to monitor the application of the reference model and its advantages in terms of organisation and costs (7).

ORGANISATION AS A JOURNEY TOWARDS EQUITY OF CARE

It is widely accepted that CPGs are defined as "statements that include recommendations intended to optimise patient care that is informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options" (9); however, one of the main barriers in the application of CPGs in daily care can not only be truly represented by local legislative restrictions, time constraints (10) but also by pragmatic difficulties in the organisation of PCP. Therefore, improving the organisational structure of PCP may surely contribute to a more efficient and sustainable application of the CPGs, especially in the case of different health contexts characterised by different expertise and resources.

Taking into account all these considerations, it becomes clear that improving the organisational aspects of PCP is particularly crucial in the field of RCs, where the knowledge is often scattered and access to care and treatment can be heterogeneous. Thus, improving organisation is definitely one of the main successful ways by which equity of care can be guaranteed across the different geographical areas. Improving organization of care means improving care to patients with RDs and it can be implemented in different ways; RarERN Path$^{\text{TM}}$ is definitely one of these ways. Thanks to the availability of appropriate methodologies aimed at improving the organisation of care, ERNs and other institutions can strongly commit to and support an improvement of the access both to treatments and to healthcare services for rare disease patients, thus contributing to increasing also more equity of care in RDs.

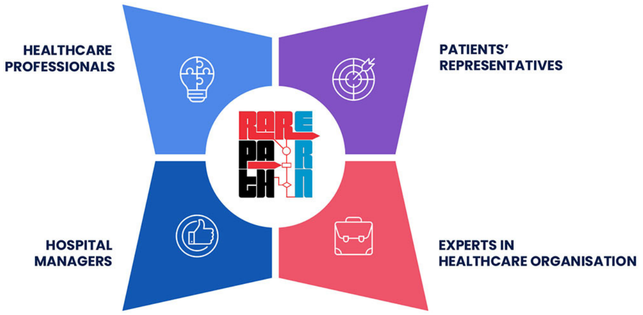

FIGURE 1 | The different stakeholders involved in the application of RarERN Path$^{\text{TM}}$.

THE ADDED VALUE OF MULTI-STAKEHOLDER INVOLVEMENT IN THE ORGANISATION OF CARE

A multi-stakeholder approach ensures the identification and integration of the different needs and priorities in all contexts. Applying this approach in the organisation of care, for example in RarERN Path$^{\text{TM}}$, can be considered a must, as participatory processes ensure, among many factors, to define current challenges more accurately and to co-design strategies that are more tailored to the different needs. A tangible example of the RarERN Path$^{\text{TM}}$ multi-stakeholder involvement is, for example, the establishment of a patients' panel that is fully involved in the process, from the co-designing of the narrative medicine survey to the elaboration of the storeys and in the co-designing of the KPIs. Another example is represented by the consensus meeting (Phase 3 of RarERN Path$^{\text{TM}}$), in which expert clinicians gather with patients' representatives, economists, and hospital managers to discuss the patient's care pathway and the related organisation to be provided in order to deliver appropriate care to patients. Among the different stakeholders that need to be involved in planning strategic actions to ensure care also during an emergency, patients' representatives, healthcare professionals, hospital managers, and experts in a healthcare organisation play crucial roles (**Figure 1**). Their contribution should be encouraged and planned during all phases of the process in order to ensure on one side the applicability of the strategy designed and on the other side, that the needs and the priorities of all stakeholders are carefully addressed.

CONCLUSION

Learning from the current pandemic is a necessary process that should ensure that vulnerable patients, such as patients with chronic and RD, will be able to access care also during health emergencies. A multi-stakeholder and multi-dimensional approach is needed to design health strategies that will enable RD PCP to continue to be active also in challenging conditions. RarERN Path^{TM}, represents, in this vision, a pragmatic approach that could be beneficial to the future of RD communities.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

AUTHOR CONTRIBUTIONS

RT and DM written the paper. All authors discussed and agreed on the content, contributed on the message that the paper should bring to the readers, and approved the submitted version.

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The crucial role of ethical hospital administration in neurosurgery education

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Introduction

Ensuring patient safety is the foremost principle in surgery. Neurosurgery, which is a high-technology dependent, high cost and high-risk surgical specialty, is one of the most demanding branches of medicine (1–9). Professionalism and patient safety cannot be fully ensured by providing only technical skills during neurosurgical residency training (1, 10). Continuous ethical education is also essential for competent medical practice. Therefore, formal ethics curricula for the professional training of residents have been introduced in several countries (10). However, moral practices are required not only from individuals but also from systems and institutions as a whole (10–13).

All decisions and practices within institutions directly affect ethical healthcare. The climate of change within which healthcare is provided, such as population growth, aging, increased demand for addressing chronic conditions, shortage of resources and the rapid growth of technological advancements, which includes diffusion of innovation and digital health revolution, can affect healthcare and its ethics (13). For instance, the rapid growth of technology can bring about challenges for administrators in the areas of finance, staffing and patient demands (13). The crucial effects of administrative decisions came to light very clearly during the COVID-19 pandemic (14–20). The inadequacy of available medical resources, such as the scarcity of intensive care beds, necessitated institutional decisions which may have adversely affected the provision of basic medical needs for neurosurgery patients.

Hospital managers are expected to provide accountable and optimal distribution of resources and to avoid conflict of interests between themselves and the needs of society and of the individual patient (21). Furthermore, the creation of an ethical climate in hospitals is essential for the fostering of an educational environment open to ethical discussions. Unfortunately, resident physicians in a strict hierarchical system where they do only what they are told are at risk of failing to grasp ethical issues. Government policies and hospital management can conflict with patient preferences and/or resource constraints and ultimately undermine traditional medical practice and education (1). To avoid creating global disparities in neurosurgery, trainees must have to understand the ethical dimensions of power imbalances, priority settings, the role of funding mechanisms in driving clinical care and research (22).

Ethical structure in hospital administration

The creation of the ethical climate is necessary for the establishment of a robust resident training. Two main factors underpin ethics in hospital administration. The first of these is the obligation to ensure the autonomy, priority and safety of the patient, and the second is the personal ethics of the healthcare manager as the moral representative and leader of the hospital (3, 11, 13, 23, 24).

Virtually all administrative decisions that arise in managing health services have ethical dimensions (11–13). These ethical issues are qualitatively distinct from those encountered in the business world. In business ethics, profitability is the only goal in the framework of established law (2). Furthermore, the concept of respect for individuals—which emphasizes autonomy, fidelity and confidentiality—is essentially absent in business world. Moreover, the principle of justice is found only at the periphery of business ethics. It has been argued that even guidelines such as "the Hospital Financial Management Association Code of Ethics" and "the Guidelines on Ethical Conduct and Relationships for Health Care Institutions" adopted by the American Hospital Association fail to prevent hospital administrations from giving priority to economic goals, either explicitly or implicitly (25–27).

Contemporary hospital administration

Increasingly, healthcare systems are managed according to the principles of new public management systems (1). However, this approach leads to a perceived loss of professional autonomy for physicians and trainees (1, 3). Physicians are required to be autonomous and make independent decisions. The tension between physicians' demands for the individual patient always to come first, due to their professional ethical obligations, and the requirements of the health institution, which usually forces attention to the needs of the community rather than to a single individual, is an ever-present source of conflict in today's healthcare organizations (28, 29). Furthermore, technological advances such as the digitization of the healthcare industry, the use of big data and deep learning, artificial intelligence applications, robotic skull base surgery, virtual reality application, focused ultrasound, and new application areas of deep brain stimulation have undoubtedly led to the transition to more complex treatments in neurosurgery (3, 5, 8, 30–35). Parallel to this, complexity in hospital administration and imbursement structures have escalated.

Meanwhile, performance management, which is one of the most important tools of current public management methods, carries the risks of causing problems because it requires time consuming and burdensome bureaucracy with measurement parameters which may not always be appropriate. No matter how optimized the measured parameter is, the use of surrogate parameters can be impractical or even destructive in the evaluation of the original object of interest. For example, the length of hospital stay of patients is a common variable (36). With this variant, a short stay is considered favorable. However, if a surgeon's daily mortality is 100 percent, the length of stay will be very short and the surgeon will be found to be paradoxically efficient (1). As another example, using "complications" as a measurement parameter may lead surgeons to select simple, less risky cases to avoid this negative efficacy parameter, and not only may patients with complex problems remain untreated but also resident training may be adversely affect (1). Thus, new public management systems, in which proxy parameters are used to measure efficiency, seem to have increased "efficiency" but negatively affected the focus on education and scientific research (1).

Qualities of administrators: morality, power, and leadership

Administrators tasked with keeping costs under control in order to organize and sustain the provision of health services will seek to reduce costs and maximize efficiency (3). Given these challenges, pragmatism may make the application of ethics seem less important. For example, it might be expedient to ignore the mission, vision and values of an organization when using the argument that costs are the most important factor for survival of the healthcare system.

Although healthcare administrators may need to take additional issues into consideration, they must nevertheless provide an environment where patients receive both appropriate and compassionate care. They must respond to the business needs of healthcare while respecting the patient, staff members, organization and society. Administrators also represent the political owners of power. Unfortunately, there is evidence that power has the potential to corrupt (37–39). Power may often lead people to place their own interests above the needs and goals of others. Power liberates individuals to focus inward, leading them to place greater weight on their own aims and interests. Power also appears to cause individuals to "objectify" others, to see them as tools and to see relationships as peripheral in nature. This may lead to administrators making self-interested decisions when faced with ethical dilemmas.

The regrettable reality is that leadership power is frequently abused. According to research, administrators are accountable for 60% of workplace misconduct (40). In workplace settings there are common ethical concerns including immoral leadership, a toxic workplace culture, unachievable and conflicting goals, the misuse of tools and technology and employee discrimination and harassment based on certain parameters such as color, ethnicity, gender, handicap, or age (40–42).

It will be very difficult to attract the best and brightest medical students for residency training in a teaching hospital without an ethical climate. Educational environments where gender, ethnicity, religion, culture, sexual orientation or identity, socioeconomic strata or any other individual identifying characteristics are the cause of mobbing will harm the future of our profession (43). The underrepresentation of neurosurgery in undergraduate teaching and training further increases the importance of creating an ethical climate (44). In particular, the fact that female physicians are not attracted to neurosurgical residency training at a rate similar to their entrance to medical faculties may worsen this situation (45, 46).

The moral framework of managers is their personal ethics, which impact their communications with patients, healthcare personnel, healthcare institutions, insurance companies, governments, and society in general (3). However, it would be wrong to explain the behavior of managers only by their personalities, because the power of social influence cannot be underestimated. So much so that even small changes in the social environment can overcome differences in people's personalities. In other words, how managers perceive, comprehend and interpret the world around them is also important (1).

Ethical behaviors and practices

From an ethics standpoint, the first step to the application of ethics in decision-making is to understand its definitions, theories and principles (24). The general terms of ethics are relatively well-known. Unfortunately, the problem is that the details are not known. Healthcare administrators must not only have a basic knowledge in ethics—which consists of autonomy, beneficence, non-maleficence, justice, dignity, and honesty—but also be able to apply ethics at a more profound level through appropriate behaviors that maintain both personal and organizational integrity.

Martin Buber was a major theorist who helped to lay the groundwork for health-care ethics (13). Buber centered on the idea of relationships. The least effective human relationship is the "I-I" relationship. In this relationship, the needs of others do not exist, nor does the accountability of moral conduct toward them. The next level is the "I-IT" relationship. Because a person is seen as an "it", they can be used as a tool for personal benefit or the benefit of one's organization. An example of an the "I-IT" relationship occurs when administrators use such terms as "my people" or "my workers". Another example is reference to a patient as "room number" or "diagnosis" instead of by her or his name. The third category of relationships is the "US-THEM" relationship. In this category, people are grouped as "us" and "not us". People who are in the "us" group believe themselves to be superior and avoid dialogue with those in the "not us" group. It is therefore easier to attribute negative events or actions to those who are "not us". The fourth category of relationships is the "I-YOU" relationship. Only in this category are individuals recognized as having value, unique abilities, gifts, and thoughts. These distinctions are not only acknowledged, but they are also accepted and valued. Unfortunately, administrators may rely on the directing function of management rather than engaging in dialogue with their staff regarding the adaptation process for responding to change.

Hospital managers begin their careers as adults who have an implicit personal ethic. In developing that ethic, managers are affected by numerous influences beyond their own introspection, including family and friends, religious principles and teachings, secular education and the law. While one's basic worldview is tending to remain rather constant, one's personal morals can be enhanced by experience, maturation, and technological advances and education. Administrators can develop ethical decisions through a foundation in ethics theories and principles that can be applied to situations in hospital. They can also engage in dialogue with clinical staff for insight into the practice of ethics.

Hospital administrators should bring together all stakeholders with the ultimate goal of continuously improving healthcare delivery, training, and scientific research (47). This includes a broader scope for public engagement in allocation of research funding and approval of research projects. Hospital administrators, who already play a relevant decisional role, should pay a renewed attention to the issues of equality and diversity in neurosurgery. Thus, they could positively address the unmet needs of unbalanced academic systems where the rank achieved can still differ by gender despite identical performance metrics (48, 49).

Administrators must realize that universal truth in moral human societies does not differ, and it does not depend on the moral norms of the society in which it is practiced (24). A proposition is either right or wrong, but it cannot be both right and wrong. Snap decisions may lead to poor choices. Instead of "right now" decisions, "right way" decisions must be pursued. Few substantial ethical changes come easily without time and devotion. Healthcare administrators should be encouraged to speak up about the ethics concerns related to policies or practices. Concerns can be voiced through attending meetings and asking questions. Patience, courage and persistence are also a part of the formula for addressing ethics in an era of great change.

Robbins suggested that ethics committees be included in the decision-making process for addressing change in healthcare organizations (50). Having ethics resources—such as ethics committees, a well-articulated vision statement and support for practicing ethics—enhances the ability to make changes while respecting ethics practice.

Conclusion

Moral practices are required not only from individuals, but also from healthcare institutions as a whole and continuing ethical education of trainees is necessary for adequate medical practice.

Professional experience, values-based ethics and trust underpin improved healthcare management. Greater improvements and changes can be made if independent ethics committees are included in administrative decision-making processes.

Author contributions

NB: creation and design of the study, literature search, data collection and analysis, writing of the manuscript, and revision of the manuscript and final approval. PS and KA: literature search, data collection and analysis, writing of the manuscript, and revision of the manuscript and final approval.

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Merging lanes for science

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Introduction

In a recent editorial published in Science (1), Proctor and Geng argue that COVID-19 has made evident that we need to more formally prioritize implementation research, the study of the uptake of evidence-based interventions, to ensure that our nation's health discoveries are fully realized. Relatedly, Dr. Francis Collins, head of the National Institutes of Health, recently acknowledged that we have underinvested in research on human behavior, as evidenced by the 60 million eligible Americans who have not been vaccinated against COVID-19 despite the widespread availability of safe and effective vaccines. While Proctor and Geng propose a new lane for science, made possible through significant changes to NIH-funding priorities, we argue that methodological approaches within implementation research also need prioritization. To build on their metaphor, in addition to building a new lane for science, we could also merge lanes to improve science.

Examples

One example of this would be greater use of hybrid effectiveness-implementation designs (2), which blend elements of clinical effectiveness and implementation research to foster more rapid translational science gains. Had COVID-19 vaccine efficacy trials used hybrid designs to assess implementation challenges and efficacy, we could have anticipated some of the implementation barriers that emerged sooner. For example, the trials could have assessed the potential reach of the COVID-19 vaccines, surveying those who refused to participate in the trials, which would have shown that a sizable proportion of Americans would be vaccine-hesitant. We also could have captured covid-specific vaccine hesitancy concerns and created vaccine hesitancy mitigation strategies more specifically and rapidly. Table 1 provides a more detailed description of the implementation data that could have been collected had COVID-19 vaccine efficacy trials used hybrid designs. While we lament this missed opportunity, we note that we could correct this moving forward. For example, we could use hybrid effectiveness-implementation designs more frequently in future vaccines and other clinical trials.

TABLE 1 Examples of data that could be collected as part of a hybrid effectiveness-implementation study on COVID-19 vaccination.

Effectiveness*	Ratio of those assigned to the COVID-19 vaccine arm compared to the placebo arm of who experience:
	• COVID-19 infection
	• COVID-19-related hospitalization
	• COVID-19-related death
Acceptability	• Reasons for refusal (among those who refused)
	• Patient satisfaction questionnaires regarding the delivery of the COVID-vaccine (among those enrolled)
Feasibility	• Ratio of individuals screened eligible to those enrolled in the trial
	• Time required to recruit participants
Fidelity	• COVID-19 vaccine delivered as intended, including timing of the second dose (if applicable)
Implementation factors	• Cost of delivering the COVID-19 vaccine (e.g., staffing, training, storage).
	• Patient need/demand for COVID-19 vaccine
	• Incentives for providing the COVID-19 vaccine
	• Compatibility of COVID-19 vaccine with existing workflows and systems
	• Readiness for implementation of COVID-19 vaccine
	• Patient knowledge and beliefs about the COVID-19 vaccine
	• Provider self-efficacy to offer patients COVID-19 vaccine

*Data collected as part of the standard COVID-19 vaccine efficacy trials.
Data could be collected as part of routine study implementation, as well as enhanced by additional primary data collection (e.g., semi-structured interviews with healthcare providers at COVID-19 vaccine trial implementation sites).

Discussion

Further application of innovative approaches like hybrid effectiveness-implementation designs could supplement the actions called for by Proctor and Geng.

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Conceptualization and writing—original draft: JK. Writing—review and editing: JK and GC. All authors contributed to the article and approved the submitted version.

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Realizing the potential of artificial intelligence in healthcare: Learning from intervention, innovation, implementation and improvement sciences

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Introduction: Artificial intelligence (AI) is widely seen as critical for tackling fundamental challenges faced by health systems. However, research is scant on the factors that influence the implementation and routine use of AI in healthcare, how AI may interact with the context in which it is implemented, and how it can contribute to wider health system goals. We propose that AI development can benefit from knowledge generated in four scientific fields: intervention, innovation, implementation and improvement sciences.

Aim: The aim of this paper is to briefly describe the four fields and to identify potentially relevant knowledge from these fields that can be utilized for understanding and/or facilitating the use of AI in healthcare. The paper is based on the authors' experience and expertise in intervention, innovation, implementation, and improvement sciences, and a selective literature review.

Utilizing knowledge from the four fields: The four fields have generated a wealth of often-overlapping knowledge, some of which we propose has considerable relevance for understanding and/or facilitating the use of AI in healthcare.

Conclusion: Knowledge derived from intervention, innovation, implementation, and improvement sciences provides a head start for research on the use of AI in healthcare, yet the extent to which this knowledge can be repurposed in AI studies cannot be taken for granted. Thus, when taking advantage of insights in the four fields, it is important to also be explorative and use inductive research approaches to generate knowledge that can contribute toward realizing the potential of AI in healthcare.

KEYWORDS

artificial intelligence, intervention, innovation, implementation, improvement

Introduction

Artificial intelligence (AI) is widely seen as critical for tackling fundamental challenges faced by health systems, including increasing demand and higher costs, workforce pressures and limited resources, and the need to deliver high-quality patient outcomes and experiences (1–3). AI is an umbrella term that refers to the application of machine learning and other cognitive technologies to perform tasks or reasoning processes that are usually associated with human intelligence (4). In recent years, there have been promising advances in AI-based applications in healthcare, drawing on enhanced computing power and vast amounts of digital data becoming available for analysis (5).

AI includes techniques to improve the ability to detect and predict various conditions, with implications for screening, assessment and clinical decision-making (6). AI can be used to improve health by identifying individual treatments or treatment elements most likely to provide benefit for a particular person, thus promoting personalized healthcare (7). AI can also be incorporated into digital tools, such as smartphone apps and health wearables, to create novel interventions, thus reducing reliance on care processes and actions taken by healthcare professionals (8). Nevertheless, healthcare has been slow to make use of AI compared with other societal sectors (9–11).

AI has predominantly been viewed through a rather narrow technology-centric lens, with research focusing on the design of the technology and its interaction with the immediate users (12–14). However, some of the major challenges in AI are faced in the "last mile" of the AI research and development (R&D) process, i.e., the implementation and routine use of AI-based applications in clinical settings (15, 16). Research is scant on the factors that influence the implementation and routine use of AI in healthcare, how AI may interact with the context in which it is implemented, and how it can contribute to wider health system goals (17).

Deploying and using AI in healthcare could benefit from the extensive knowledge about health technologies and new practices that has been generated in four established fields of science: intervention, innovation, implementation, and improvement sciences. First, AI-based applications, e.g., AI incorporated into digital tools, can function as an intervention with the aim of improving patient health outcomes by means of better detection, prevention, treatment, and monitoring of health and ill-health. Second, AI-based applications in healthcare represent an innovation when adopted and used in clinical practice because they introduce novel processes and practices. Third, implementation of innovations and new interventions in healthcare typically require supportive strategies because there are often barriers to their use in the form of healthcare professionals' existing habits, routines, work processes and professional cultures that tend to be difficult to change. Fourth, how AI-based applications will contribute to the improvement goals of the broader health system and fit with overall care delivery practices and processes need to be considered.

We propose that AI development can benefit from knowledge generated in these four scientific fields to realize the potential of AI and accelerate its use in healthcare. Thus, the aim of this paper is to briefly describe intervention, innovation, implementation, and improvement sciences, and to identify potentially relevant knowledge from the four fields that can be utilized for understanding and/or facilitating the use of AI in healthcare. The paper is based on the authors' experience and expertise in the four fields and a selective literature review.

Utilizing knowledge from the four fields

Intervention science

Intervention science is the study of purposive efforts (i.e., interventions) to change the natural order of things or a foreseeable sequence of events. Intervene literally means "to come between," from Latin *inter* ("between") and *venire* ("to come") (18). Health intervention science starts with the premise that each intervention, such as an AI-based application, is seeking to address a specific health issue. The aim is to establish the extent to which or whether a desirable outcome is achieved. The development of evidence for various treatments, therapies, procedures, and actions to improve health-related outcomes is an important goal for intervention studies in healthcare contexts (19). It is also important to assess the appropriateness, acceptability, and feasibility of interventions because these characteristics influence the degree to which it is possible to use these interventions in routine practice (20–22).

An important goal of health intervention research is to contribute to a more evidence-based healthcare practice, which is relevant to the study of AI-based applications in healthcare, i.e., evidence for their effectiveness in having an impact on various health-related problems. However, interventions also need to account for risks and other aspects beyond the intended health-related goals, thus balancing the need for evidence with other meaningful and value-creating outcomes (19), e.g., person-centered care and shared decision-making.

Interventions need to address health issues in a way that makes it possible to put them into routine healthcare use if proven effective (19). Intervention science involves both efficacy studies (can it work?) conducted under ideal controlled conditions to establish internal validity, and effectiveness studies (does it work in practice?) conducted under more realistic real-world conditions, with more emphasis on external validity (while still retaining internal validity) (22). External validity is threatened if interventions are delivered in resource-intensive pilot studies that are difficult to scale up (23, 24) or if the interventions are provided by unrepresentative healthcare professionals (e.g., perhaps having very experienced staff or receiving extensive training in delivering the intervention) and if the patients are atypical of routine practice (e.g., due to restrictive exclusion criteria) (25). Like other interventions, AI-supported interventions should be investigated in effectiveness research after efficacy has been established.

Innovation science

Innovation science is the study of how problem-solving ideas, processes, products, and services are developed, diffused, and adopted by various stakeholders, ranging from individuals through organizations to whole systems. The aim is to understand how innovations can contribute to increased value, productivity, profitability, competitiveness and other desirable goals (26). Innovation can be conceptualized in several dimensions: stages of the innovation process (e.g., R&D, efficacy and market validation, regulatory approval, adoption, diffusion), level of analysis (e.g., individuals, organizations, and systems), and type (e.g., product versus process innovations and incremental versus radical innovations). Innovation is new knowledge incorporated into ideas, processes, products and services. However, an innovation does not need to be objectively new; it is sufficient that it is perceived as new in a specific context by individual adopters (e.g., healthcare professionals) or adopting units (e.g., a hospital) (27).

An important strand of innovation research focuses on adoption and diffusion, exploring the factors that influence the way in which innovations are brought into use. Factors may be related to the attributes of innovations themselves or to the wider context for adoption (27). Typically, the innovation literature argues that innovations are more likely to be adopted if they are perceived to have low complexity but high compatibility with existing values, beliefs, past experiences, and needs of potential users (28). Adoption has also been linked with the relative advantage of the innovation over existing processes or practices (e.g., the innovation is more economical), trialability (the degree to which an innovation may be experimented with on a limited basis), and observability (the degree to which the results of an innovation are visible) (27).

Adoption of certain innovations may often be more challenging than the R&D process (29). This is particularly the case in healthcare, as shown in an increasing body of innovation research accounting for the specificities of the healthcare sector (30). This research emphasizes the importance of a thorough understanding of contextual conditions, such as the way key stakeholders, including healthcare professionals, patients, and managers, influence adoption decisions (31, 32). This is relevant to the use of AI in healthcare because the system within which AI innovations are being introduced is complex and highly regulated.

Other areas within innovation science center on service innovations (33) and business model innovations (34). AI systems built into physical products, such as health wearables or which enhance the processes involved in providing a healthcare service, have the potential to alter or disrupt existing service and business models. A strand of innovation research addresses issues such as user involvement and how leadership, strategy, and management influence success (35), and how organizations innovate in their value propositions and their underlying operating models (36).

Implementation science

Implementation science as a field emerged in response to the challenges of putting evidence-based interventions and innovations into routine practice. The focus is on studying barriers and facilitators to implementing evidence-based practices (e.g., interventions, programs, and services) and evaluating the effectiveness of strategies to support implementation of such practices. The aim is to reduce the knowing-doing gap in healthcare and other sectors of society, thus improving patient and population outcomes (37). The word "implementation" is derived from the Latin *implere,* meaning to fulfill or carry into effect, which provides a basis for a broad definition of implementation science as the study of the uptake of innovations and interventions into everyday use in healthcare and other settings (38).

Implementation science has established the importance of considering implementation from the outset and planning to create conditions conducive for implementation (39). Process models have been developed in the field to describe important activities, including various supportive strategies (i.e., interventions directed at healthcare professionals and/or the organization), to be undertaken during the implementation process (40). Preparing for implementation is likely to be just as important when various AI-based applications are considered for use in healthcare settings.

Implementation science has largely focused on implementation of various evidence-based practices, typically different forms of health interventions with support for their efficacy and effectiveness established in empirical research (41). However, a key lesson in implementation science is that evidence is not sufficient to ascertain real-world use. Rather, there is a need for implementation strategies to support implementation. Taxonomies of strategies and their effectiveness to influence implementation outcomes have been assembled in the field, but the results tend to be highly context-dependent (42).

Frameworks have been developed in the field to identify and structure determinants (i.e., barriers and facilitators) of implementation success. The field has borrowed the concept of innovation attributes from innovation science (40), but has added healthcare-specific attributes such as perceptions of evidence strength and quality and source of the intervention (e.g., developed externally or internally) (43). Knowledge about the determinants provides input for selecting the most appropriate strategies to overcome barriers and/or harness facilitators (44).

Outcomes in implementation science include adoption (i.e., decision or action to use an intervention), fidelity (degree to which an intervention was implemented as intended), sustainability, and cost. There is some overlap with intervention science because the acceptability, appropriateness, and feasibility of an intervention are considered proximal outcomes that predict adoption and other more distal outcomes such as sustainability (20).

Improvement science

Improvement science refers to the study and practice of achieving improvements in complex systems, such as healthcare. The field has a similar aim to implementation science, understanding the gap between ideal and actual care and bridging this gap by improving healthcare quality within local practices, processes, and culture. However, improvement science extends beyond implementation of evidence-based practices to consider the quality of wider system performance (e.g., safety, timeliness, effectiveness, efficiency, equality, patient-centeredness) (45). The field has grown out of the wider quality improvement movement, which entered healthcare in the late 1980s (46, 47).

Improvement science provides a holistic approach to health system improvement, of which an AI system or application may be just one complex intervention within a wider multifaceted attempt to improve a system. Improvement approaches advocate a process that begins with exploring the problems and opportunities within a specific setting, which could inform what AI-based applications might be relevant and what features would be required to make them useful and effective. The next step involves identifying and testing potential interventions (e.g., AI-based applications) alongside other interventions that may be required to improve quality using a process of informed iterative development until an improvement goal is achieved. This is followed by embedding a process of continual improvement to sustain initial improvements and respond to emerging problems and opportunities (48).

The importance of understanding local context and its influence on outcomes is a cornerstone of improvement science (49). Understanding, influencing, and adapting to local context, e.g., practices, processes and cultures, is critical to improvement. Thus, the people within each local system, e.g., healthcare professionals, managers, and patients, are seen as important stakeholders to achieve improvement. Improvement approaches aim to enable them to take a structured, systematic approach to navigating the change process (48).

Improvement science offers both a way of thinking and a methodological toolkit that might be useful to understand, adapt, and apply AI-based applications in various healthcare contexts. A range of approaches and tools are used to understand problems and to inform and evaluate solution designs and efforts to facilitate their application in practice, e.g., Plan-Do-Study-Act cycles, Six-Sigma, Root Cause Analysis, Process Mapping, and simulation (50–53). These approaches and tools can be used to enable people to understand their local contexts and define important outcomes (e.g., improved patient safety, patient outcomes, reduced costs) and to intervene in the health system to improve overall performance (54).

Discussion

The four fields of intervention, innovation, implementation, and improvement sciences have generated a wealth of often-overlapping knowledge, some of which we propose have considerable relevance for understanding and/or facilitating the use of AI in healthcare (Table 1). Thus far, AI research has largely focused on engineering, computer science and programming (12–14). However, this research does not ascertain the adoption and subsequent use of AI in everyday healthcare. Implementation and use of new interventions and innovations in healthcare often face considerable organizational inertia and skepticism or even resistance from leaders, physicians and nurses (38, 39, 43). Thus, the four fields have an important role in the future of AI in healthcare because they generate knowledge based on studying interventions and innovations in the real-world context in which they are introduced and used. Research is needed to investigate the effectiveness of AI-based applications when efficacy studies have established that they work. Real-world evidence of AI-based applications is important because it provides a more comprehensive understanding of how new practices will work under realistic healthcare conditions and makes it possible to establish whether they contribute to the intended improvements in care quality and other desirable outcomes.

Knowledge from the four fields is primarily relevant to the latter stages of the innovation process, which is often described in terms of three overarching stages, from invention to development and realization. The development stage typically encompasses various forms of prototyping, testing and efficacy studies conducted under more controlled conditions (55, 56). Knowledge generated in intervention and innovation sciences is important for this stage. The realization stage can be distinguished into introduction, operation and refinement (55, 56). Implementation science knowledge is particularly useful when introducing AI, while improvement science knowledge is useful for improving operation and refining AI systems and AI-based applications. However, the stages are interdependent and knowledge from the four fields largely overlaps. For

TABLE 1 The four scientific fields' aims, research characteristics, and relevance for AI in healthcare.

Scientific field	Aims of the research	Characteristics of the research	Relevance in the AI invention, planning and realization stages	Examples of research question of relevance for the understanding and/or facilitation of AI use in healthcare
Intervention science	To establish the extent to which or whether a desirable clinical, health-related, cost-effectiveness or other outcomes is achieved by an intervention	Studies to evaluate the efficacy and effectiveness of interventions	Applicable both to the planning stage (e.g., efficacy studies) and the realization stage (e.g., effectiveness studies)	• What is the efficacy of AI-based applications under more ideal conditions? • What is the effectiveness of AI-based applications under routine healthcare conditions? • To what extent do AI-based applications contribute to other outcomes such as a person-centered care and shared decision-making?
Innovation science	To understand how innovation can contribute to increased value, productivity, profitability, competitiveness and other desirable goals	Studies to investigate how problem-solving ideas, processes, products and services are developed, diffused, and adopted by various stakeholders	Applicable both to the planning stage (e.g. studies of factors influencing adoption decisions) and the realization stage (e.g. studies of the influence of contextual conditions and stakeholders)	• What AI-related factors influence adoption decisions concerning AI in healthcare? • What contextual conditions and stakeholders influence adoption decisions concerning AI in healthcare? • How can AI change existing healthcare service and business models?
Implementation science	To understand the knowing-doing gap and facilitate the reduction of the gap	Studies to identify barriers and facilitators to implement evidence-based practices and to evaluate the effectiveness of strategies to support implementation of such practices	Primarily applicable in the realization stage	• How can it be ascertained that AI in healthcare is planned from the outset to create conditions conducive to implementation? • What are the barriers and facilitators to implementing AI in healthcare? • What strategies can be used to support the implementation of AI in healthcare and how effective are these strategies?
Improvement science	To understand the gap between ideal and actual care and bridge this gap by improving healthcare quality within local practices, processes, and culture	Studies to investigate the quality of complex systems, e.g. in terms of safety, timeliness, effectiveness, efficiency, equality and patient-centeredness and other goals	Primarily applicable in the realization stage	• What are the problems and opportunities to achieving a process of continual improvement with regard to AI in healthcare? • How does AI contribute to system improvement in terms of safety, timeliness, effectiveness, efficiency, equality, patient-centeredness and other goals? • How can the context and stakeholders in the local system in which AI is used contribute to healthcare system improvement?

example, implementation science involves studies of various implementability characteristics (e.g., feasibility), which has more to do with planning than with realization. Conversely, intervention science involves studies of effectiveness conducted under real-world conditions, which is more relevant in the realization stage than the planning stage.

Intervention science underscores the relevance of taking a broad perspective on intervention goals. Hence, the effectiveness of AI-based applications should not be in conflict with other important goals, such as patient involvement in their care or trusting communication between the healthcare professional and patient. Implementation science points to the importance of understanding the use of interventions in routine practice, e.g., how AI-derived information is interpreted and used by healthcare professionals. Similarly, improvement science emphasizes the relevance of studying AI-based applications in a larger context of how they can contribute to wider health system goals. Intervention and implementation sciences highlight the importance of the acceptability, appropriateness, and feasibility of interventions to enable their routine use in healthcare. These outcomes and others described in implementation science such as fidelity, sustainability, and costs are important to investigate with regard to AI-based applications.

The four fields address the influence of context on interventions and innovations to varying degrees. The use of AI in healthcare represents a sociotechnical system that requires contextual understanding of the interrelations of social and technical aspects of the organization as a whole (57). Applications of AI in healthcare can circumvent traditional workflow and care delivery pathways (58). Improvement science is particularly concerned with how practices are integrated within the local context and how they might interact with and/or disrupt existing work practices and processes.

Innovation, implementation, and improvement sciences further emphasize the role of stakeholders and other contextual influences, which is relevant because the decisions involved in the introduction and use of some AI-based applications in healthcare may involve many stakeholders and have widespread or disruptive impact across the health system. On the other hand, there may also be AI-based applications that are simple, uncontroversial, involve few stakeholders, and have limited impact outside the immediate processes in which the applications are used. Implementation determinants tend to be multi-factorial and multi-level (43), which suggests the relevance of using strategies to support AI implementation that address multiple determinants at different levels of the health system.

The development and deployment of AI represents a complex sociotechnical process that spans work associated with data acquisition, algorithm selection and development, organizational design, professional education, and associated governance and regulatory activities (59). This sociotechnical complexity complicates the study and practice of AI in healthcare. New studies drawing on empirical and theoretical knowledge from the four fields will need to consider whether and how to distinguish between the general requirements of any AI system and the specific requirements for any particular type of AI-based application. AI is not one single type of technology but rather encompasses many technologies covering a range of practical applications (10, 60). For example, AI-based applications may, or may not, be perceived as complex and/or compatible (i.e., two key innovation attributes), depending on what the application is and what context it is used in; e.g., breast cancer or cataract screening vs. algorithms to help decision-making about mental health therapies. This may limit the usefulness of generalizable findings, and it is likely to also be important to investigate determinants in relation to specific AI-based applications.

There might be a need to develop new theoretical approaches or augment and re-contextualize existing ones from the four fields. Frameworks have been developed for implementation of healthcare technologies, e.g., the Non-adoption, Abandonment, Scale-up, Spread, Sustainability (NASSS) framework (61), but it has been shown that existing frameworks do not consider all of the specific issues relevant to AI systems and AI-based applications (17). Development of bespoke AI frameworks would benefit from interdisciplinary work by researchers in the four fields and collaboration with healthcare professionals, AI developers, patients, policymakers, and other stakeholders.

This paper has addressed knowledge from intervention, innovation, implementation and improvement sciences of potential importance for understanding and/or facilitating AI use in healthcare. However, the scope of the paper has obvious limitations and it does not address everything that might have relevance when introducing and using AI in healthcare, e.g., issues related to data integrity, transparency, governance and reimbursement. AI has a wide range of applications beyond healthcare and health, including in domains such as agriculture, engineering, commerce, marketing, finance, gaming, education, navigation, and transportation (62). The broad use of AI in many different sectors and areas of life requires multidisciplinary knowledge from many fields other than those covered in this paper to address issues such as ethics, fairness, equity, accountability, protection of privacy and respect, transparency, trustworthiness and auditing (63–65).

In conclusion, the four fields of intervention, innovation, implementation, and improvement sciences have generated many insights of potential relevance for understanding and/or facilitating the use of AI in healthcare. Knowledge derived from these fields provides a head start for research on the use of AI in healthcare, but the extent to which this knowledge can be repurposed in AI studies cannot be taken for granted. Thus, when taking advantage of insights in the four fields, it is important to also be explorative and use inductive research approaches to generate knowledge that can contribute toward realizing the potential of AI in healthcare.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author/s.

Author contributions

PN conceptualized the study, but all aspects were discussed with the other authors and he drafted the first version of the manuscript with input from all authors. All authors discussed further drafts, revised the manuscript, and approved the final manuscript.

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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.

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Understanding implementation research collaborations from a co-creation lens: Recommendations for a path forward

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Increasing calls within the field of implementation science (IS) research seek to promote active engagement of diverse and often disenfranchised stakeholder voices to increase buy-in, fidelity, outcome relevance, and sustainment of evidence-based practices (EBPs). Including such voices requires cultural humility and the integration of multiple perspectives and values among organizations, groups, and individuals. However, the IS field lacks guidance for researchers on structuring collaborative approaches to promote a co-created process (i.e., synergistic approach to goal attainment). We contend that improved operationalization of co-created implementation collaborations is critical to sparking synergy and addressing differentials based on power, privilege, knowledge, and access to resources among stakeholders. These differentials can undermine future implementation and sustainment efforts if not addressed early in the research effort. An insufficient understanding of the guiding principles of co-created implementation collaborations may limit the scientific value of evaluation processes, and researchers' ability to replicate outcomes. We propose a perspective foregrounded in the concept of co-creation to guide the structuring of implementation collaboratives through five principles. We offer three case examples informed by the Exploration, Preparation, Implementation, Sustainment (EPIS) Framework to illustrate the application of these co-creation principles. Lastly, we offer recommendations for promoting co-creation in IS research moving forward.

KEYWORDS

co-creation, principles, implementation, collaborations, CBPR

Introduction

Implementation strategies describe actions for promoting the uptake of evidence-based practices (EBPs), programs and policies (1). Implementation strategies often rely on multi-stakeholder collaborations to foster buy-in, inform implementation, and increase sustainment of EBPs (2). The Implementation Science (IS) field is re-assessing and broadening its approach to stakeholder engagement to incorporate the perspectives of a range of contributors, including patients, consumers, health professionals, and policy makers (hereafter called "stakeholders") to tailor strategies to local contexts. Explicit concerns for involving individuals who experience health disparities, health injustices, and inequitable representation in the planning and implementation of EBPs and policies are increasingly central to such efforts.

Advancing health and social equity is critical to meeting IS goals of promoting action-based pragmatic research and closing the evidence-to-practice gap (3). Equity-centered IS entails naming researchers' assumptions, identifying our differences and systematic accountings of power relationships influencing study designs and decision-making (4). Equity-centered IS requires interaction with broader groups of stakeholders to identify, measure implementation strategies and outcomes, and to have an accurate understanding of how local contexts impact implementation (5–8).

We propose a perspective foregrounded in the concept of co-creation (i.e., synergistic approach to goal attainment) (9, 10), offering five principles to guide structuring implementation collaborations in research. Co-creation emerged in early late 1990s and early 2000s from business management (11) and has gained traction in healthcare and implementation research (12) as it has been heralded as a novel solution to the research to practice gap (13–15). We present three federally-funded implementation research studies as case examples to illustrate the application of these co-creation principles that are informed by the Exploration, Preparation, Implementation, Sustainment (EPIS) Framework (6). EPIS is a framework that guides the examination of determinants of implementation at the inner, outer and bridging levels and through four iterative phases as included in this name (16). Lastly, we offer recommendations for promoting co-creation in IS research.

State of the literature on stakeholder collaboration during implementation

Successful design and deployment of implementation strategies typically require coordinated action among organizations, groups, and individuals. Participatory approaches used by IS researchers include implementation mapping (17–19), user-centered design (19), group prioritization processes (20), community advisory boards and expert panels (21–23). IS researchers have also adopted engagement approaches from community-based participatory research (CBPR) to enhance the active inclusion of all relevant stakeholders in IS work. CBPR necessitates shared leadership and co-learning relationships among researchers and community partners (24). CBPR elucidates the benefits of involving end-users in research planning and implementation of EBPs and other innovations, reducing stakeholder power differentials, and illuminating key factors to address health equity efforts (24).

Current collaborative approaches in IS lack concrete guidance on synergistically integrating all stakeholders' expertise, values, and priorities for the joint, integrated creation of knowledge. IS researchers would benefit from such guidance given variations in stakeholder backgrounds and lived experience, professional roles, access to resources (e.g., fiscal and material capital), and thus privilege and power represented at the table (3). We must better understand collaboration processes in IS that often unfold within complex contexts with stakeholders who may not share the same priorities. We must enhance our knowledge of how implementation collaborations operate in these contexts and ways to optimize them to benefit diverse stakeholders, including end-users who are often not included or meaningfully involved in collaborative processes.

Consequences of "collaborations" lacking co-creation

Stakeholder engagement, governance arrangements, and building capacity for productive and successful co-creation can be challenging (14). Improved understanding of successful approaches for developing researcher and community stakeholder collaborations into co-creation partnerships is critical to achieving meaningful implementation and sustainment outcomes. Guidance on nurturing such collaborations should address power imbalances and support communication and trust among stakeholders (3). In co-creation relationships, all stakeholders ideally participate in and share control throughout all phases of research. This approach contrasts with traditional research dynamics that position researchers as external experts and gatekeepers of information. Such dynamics can perpetuate power differentials and information asymmetries between researchers and community stakeholders (25). Power imbalances may be heightened in research conducted with socially and economically marginalized communities (26). Power imbalances contribute to low acceptability, appropriateness and adoption of new practices, or abandonment of new practices soon after a study concludes (27, 28). Stakeholders lacking meaningful engagement in decision-making and implementation may be left without a clear understanding of how their participation contributes to results (29). Sustainment is challenged when stakeholders identify little value in or from their engagement in an implementation collaborative. Conversely, partnerships built on power-sharing and democratic principles can promote multilevel buy-in, capacity for change, and encourage adoption of new practices (30).

The absence of clear co-creation principles in IS fosters insufficient knowledge about individual actions and responsibilities for achieving implementation goals (31). Role ambiguity engenders confusion about what researchers or community partners are expected to do, curtailing their ability to improve or sustain EBP use (32). When researcher-provided resources recede at the end of the implementation phase, community stakeholders may struggle to organize necessary supports and sustain EBPs (32). Green et al. contend that "without significant changes, the adoption of co-production on its own will not lead to significant changes," meaning we must become more intentional in overcoming challenges and applying knowledge from stakeholders (33).

These challenges may result in selecting EBPs that fit poorly with community needs, resources and priorities. Fit—*the perceived appropriateness of the intervention/implementation strategy and setting*—is central to implementation success (16). Researchers and community stakeholders must meaningfully consider their context when selecting an EBP, and be prepared to adapt interventions and strategies to accommodate for changing contextual influences (30, 34). Collaborations that support highly generalizable approaches to intervention design and testing may not fit well with local conditions, and thwart uptake (35).

Proposed solution: Specifying practical and research applications of co-creation

Although IS underscores collaboration's value in implementation research, it lacks guidance for nurturing collaborative efforts, and ensuring they reflect contributions and meaningful participation from all stakeholders. Despite growing awareness that IS must proactively engage with health equity (4), IS researchers struggle with structuring equitable, collaborative processes to support transformative impacts through successful implementation. We draw from organizational research, community-engaged studies, and patient-centered care to argue that the concept of co-creation in implementation collaborations can catalyze contextually relevant insights and approaches to help reach expected outcomes. We next describe co-creation and the application of five co-creation principles through case examples.

Concept of co-creation

Co-creation is the process of convening a diversity of stakeholders who are willing to share their knowledge, skillsets and resources to spark synergy and persevere to an end-result surpassing the sum of its parts (5, 6, 36). The goal is for these partners to contribute to the planning, design, testing, and implementation of the services they fund, deliver, or receive (37, 38). Although there is limited outcomes research on co-creation, current evidence suggest that co-creation leads to stakeholder trust, equitable contributions, and a sense of ownership (39), and in turn to quality research as well as meaningful research which meets individual and community expressed needs and goals (21). This concept is referred to as "co-design" or "co-production," terms often used inter-changeably in the literature as they focus on jointly producing, designing or creating (e.g., knowledge to be applied, such as an intervention prototype or research design) (38, 40–44). We present co-creation as a multi-dimensional concept for "all things co" that necessitates meaningful engagement among stakeholders (45). This type of engagement requires co-creators (particularly researchers) to grapple with what it means "to open up their processes" to forge effective partnerships with different stakeholders (46). Members of 'all things co' processes are often specified as stakeholders with relevant and unique expertise and experience to contribute. Graham et al. assert that participatory co-production processes are critical to advancing the science of evaluating stakeholder engagement (47, 48).

Much like CBPR, co-creation research is driven by power-sharing governance arrangements (e.g., partnership agreements) between stakeholders. It is guided by end-users who are *experts by experience* (49), meaning partners whose lived realities enable them to share knowledge, values, and needs that are often not known or fully appreciated by program developers or researchers. This type of exchange is often characterized as *local end user-driven* collaboration (50). Stakeholder voices and contributions are engaged at the behavioral, cognitive and/or emotional levels and shaped by the group's motivation(s) for collaborating (51).

Pearce et al. clarify that the co-creation of new knowledge for health interventions must address conceptual ambiguity and the pragmatics of participation by proposing core principles (rigorous research methods and embeddedness) (41). In a special issue of Evidence & Policy on co-creation, Metz [(32), p. 333] assert that the "legitimacy of co-creation approaches is underpinned by explicit core values and assumptions about how affected parties will be involved in the work." To follow on this recommendation, we draw from a growing body of work (9, 25, 37–39, 52) to assert the following five principles of a co-created collaborative process to enhance implementation efforts:

1. **Equity:** This principle calls for greater equity in relationship-building among stakeholders, with end-user knowledge and

experience being valued equally with that of professionals. By evoking equality, we do not naively assume each stakeholder holds equal power in collaboration. Rather all stakeholders in an implementation pursuit deserve *equitable access* to shared responsibility, decision-making power, and the resources required for participation. Equitable access recognizes that participation needs may differ across stakeholders based on individual (e.g., culture, preferences, and values), organizational (e.g., professional roles) and contextual characteristics of the implementation environment (e.g., resource-rich vs. underserved). Facilitators of co-creation group processes are tasked with promoting a more active role among implementers and end users in research (50). Equity is supported through access to information, networks and resources, transparency, and value alignment (9). Equity in relationships during co-creation engagement promotes trust and lead to meaningful engagement among non-academic partners and to higher engagement in the research process (53, 54).

Application in IS: This principle is applied by convening collaborations with multi-disciplinary academic researchers, implementers (e.g., service providers), end-users (e.g., patients, clients), and other relevant stakeholders (e.g., community leaders, policy makers) based on the nature of the effort (25). It is also reflected in re-designed governance structures before, during and after the implementation process and in stakeholders, especially researchers, striving to become more self-aware of implicit bias possibly affecting attitudes, interactions, and fundamentals (55).

2. **Reflexivity:** This principle acknowledges that researchers (and other co-creation partners) strive to be aware of and analyze how their positions within collaborative research processes may influence its dynamics, including how stakeholders interact with one another and engage in implementation (5, 56). Reflexivity is seen as critical to situating positionality and power within the collaborative, likely reducing stigma and promoting respect for all perspectives and values (57). This principle also supports sustainability and long-term goal setting as well as growth of partners' networks over time (57, 58).

Application in IS: Reflexivity requires making time and space for ongoing group reflections to identify and redress power imbalances and processes for sharing information and making decisions, and to recognize limitations of using dominant frameworks, including unintended consequences of well-intended research for diverse implementers and end-users, and social dynamics shaping our collaborations (57, 59, 60).

3. **Reciprocity & Mutuality:** This principle concerns the degree to which stakeholders are open and interested in learning from each other, referred as the "knowledge appetite" (50). Relationships are perceived and experienced as mutually beneficial through the combined and generative knowledge and the deepened connections and networks developed among all partners (50). This reciprocity leads to perceived stakeholder ownership of the collaboration process. This value can foster accountability, co-learning and learning transfer in a bi-directional fashion between researchers and other partners (32, 53).

Application in IS collaborations: Reciprocity and mutuality is promoted through the inclusion of stakeholders in power-sharing governance arrangements (36), and by researchers communicating the evidence base for potential implementation strategies to inform decision-making (25). Reciprocity can be achieved when co-creation stakeholders collectively create products useful to all partners including community-facing materials (e.g., toolkits, brochures) beyond research manuscripts.

4. **Transformative & Personalized:** This principle refers to a collaborative process that benefits the study while also offering an individual experience that is enriching, given the emphasis on end-user orientation through use-value and empathy (9). Research is perceived as having room for new possibilities because of the collaborative process. When this principle is met, it is easier to obtain buy-in and support from implementers (50). This principle can foster activation and self-advocacy among patients, families, and community members as a result of their works side-by-side with researchers (59). In addition, promoting an understanding of each partner's motivations for joining a collaborative, and opening the space for them to take on or lead roles that align with those motivations can become a transformative and meaningful participation for individuals (61).

Application in IS collaborations: This principle necessitates increasing knowledge and skills among non-academic stakeholders to relevant theory and research methods (25), and by organizing knowledge and skill-building activities during the Preparation phase, such as IS training boot camps. Training may also need to focus on increasing contextual knowledge and engagement skills for co-creation initiatives among researchers. Stakeholders are empowered to develop their own solutions (53) by participation in identifying and selecting interventions/implementation strategies and desired outcomes. These efforts create not only research value but also individual and community value.

5. **Relationships Facilitated:** Relationship structures (e.g., partnerships) or procedures (e.g., agreements on roles/responsibilities) are developed collectively to support a co-creation implementation collaborative. Participation is encouraged and facilitated through organizations and social networks and by creating explicit spaces and time for partners to network, invite their own networks to contribute to the implementation process at key phases of the project,

and by formalizing roles and responsibilities in writing such as through Memorandum of Understanding or MOUs (50). Relationships are joint, reciprocal and fostered through iterative group processes, active communication, and/or engagement. Facilitated relationships promote trust, shared power, and problem-solving orientations necessary to sustain implementation efforts (61).

Application in IS: This principle is applied by structuring collaborations with diverse and inclusive implementation networks (which requires periodically reflecting on which stakeholders are not at the table and need to be (re)invited to participate), facilitating interdependence by engaging and using mutual resources across all stakeholders, and by building cooperative inter-organizational relationships through participation agreements (9).

Application of principles through EPIS

A key recommendation for using IS frameworks is to establish and maintain community stakeholder partnerships (62). The co-creation concept fits well with existing frameworks. One prime example is EPIS, which encourages stakeholder engagement across the implementation ecosystem to facilitate efforts longitudinally and contextually (16, 63). For EPIS, co-creation is a bridging factor necessitating collaboration among stakeholders in the ecosystem's outer and inner contexts to shape an innovation's adoption and scale-up (64). Bridging factors are the relational ties, arrangements, and processes serving as the connective tissue across and between contexts (64).

Co-creation principles can inform feedback-driven collaborations throughout EPIS phases to increase synergy and equity (Figure 1). Although the three case studies below all used the EPIS to guide the collaborative process, co-creation principles are transferable to other frameworks. An engagement process driven by co-creation principles compels us to critically look at power among partners and how it manifests across each of the EPIS phases. One example is the work of Stanton et al. (3) who offer critical questions to pose across the implementation phases as a way to more intentionally address power in implementation collaborations, and we would add co-creation principles.

A description of three federally-funded implementation studies are presented in the next section as case examples.

Example # 1: Participatory implementation approaches to advance health equity for gender diverse and sexual minority (GSM) students.

"Reducing LGBTQ+ Adolescent Suicide (RLAS)," or RLAS for short, is a cluster-randomized study that uses a multisectoral community-academic partnership (CAP) involving stakeholders from schools, intermediary organizations, state government, and research institutions. The trial operationalized EPIS using the Dynamic Adaptation Process (DAP) (66), a data-driven implementation planning methodology that was used to facilitate uptake of interventions to enhance school climates and reduce suicidal behaviors for GSM high school students in New Mexico. This inclusive planning methodology made it possible for the CAP to convene implementation resource teams of educators, health professionals, and youth in 19 high schools. As described below, the CAP-provided feedback and technical assistance. The teams engaged in iterative assessment and planning processes to build school capacity, and select and implement interventions/implementation strategies, working closely with researchers to co-create and deploy locally responsive educational materials, tools, and action plans to introduce inclusive practices in socially-conservative school communities.

Levels of partner engagement in RLAS spanned the modes of "involve," "collaborate," and "empower" on the Spectrum of Public Participation continuum (67). The process of context-driven adaptation and site-specific tailoring placed IRTs in the highest level of involvement ("empower") because members were charged with all final decisions regarding implementation. While they were engaged throughout the study, the participation of CAP members ranged from the "involve" to the "collaborate" modes. National organizations were consulted on training materials and data collection, and provided critical information about outer-context efforts concerning school health and GSM advocacy. State agencies were similarly engaged, yet more directly involved in shaping study objectives, providing resources to school sites, and responding to and applying study findings.

They benefited directly from engagement with implementation sites, as RLAS allowed for increased access to school settings that were otherwise difficult to reach. National- and state-level members were more closely aligned with the "involve" mode in that their guidance influenced RLAS, as the core study team maintained continued dialogue with them throughout the course of their work. The members with a more intermediary function were closely aligned with the "collaborate" mode, in that they partnered closely with study coaches, IRTs, and schools to shape implementation on a local level.

Two primary, yet not unsurmountable, challenges affected participation in RLAS. First was staff turnover at all levels. For example, turnover in schools (e.g., constantly changing administration and IRT membership) could undermine progress in implementing GSM supportive practices. Although turnover in the IRTs exerted the greatest direct impact on implementation, personnel at intermediary organizations and state agencies also changed over this 5-year study. Time emerged as a second factor affecting IRTs specifically. As school staff were already stretched thin, time for IRT members to meet, plan, and carry out action items to support implementation came to represent a scarce, highly valuable resource.

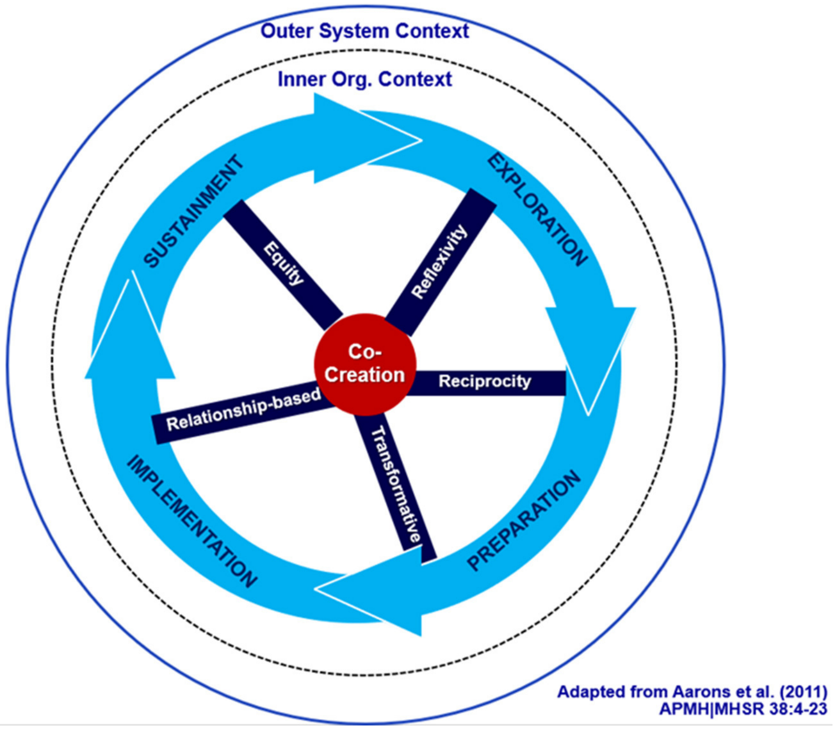

FIGURE 1
Co-creation EPIS model (65).

Three main facilitating factors balanced the above challenges. First, coaches were key to establishing and maintaining connections among schools, study staff, and intermediary organizations, providing guidance to IRTs, recruiting new IRT members, obtaining administrative buy-in, and ushering resources from outer to inner contexts. Second, the team structure of IRTs and their ability to evolve according to the needs of schools was a boon to sustaining implementation progress despite changes in membership. Third, the personal and institutional relationships fostered through the CAP, coaches, and schools allowed for problem-solving, mutually beneficial leveraging of resources, and tailoring supports to school-based needs, including addressing challenges of time constraints and changes in staff.

Example # 2: Implementation mapping to co-create protocols for supporting state-mandated screening of children for Adverse Childhood Experiences (ACEs).

ACEs are potentially traumatic events occurring before age 18, such as maltreatment or exposure to violence (68, 69). ACEs screening identifies these events and their associated health and wellbeing outcomes. In 2020, California issued an "ACEs Aware" policy that reimburses primary care clinics for annual patient screenings. In partnership with a health system serving over 6,000 children annually, this randomized trial is testing the impact of ACEs screenings on child service access and outcomes as well as the role of a multi-faceted implementation strategy in supporting such screenings for children ages 0–5 years. The co-creation process involved: (a) the clinical partner bringing their identified service gap to academic partner (i.e., need to address patient trauma) to co-develop a plan of action, (b) establishing a Trauma-Informed Care (TIC). Workgroup comprised of clinical staff, providers and managers to address this gap during the Exploration phase; (c) bridging this gap by adopting the state's ACEs Aware policy; and (d) undertaking participatory implementation mapping (70) (i.e., six step iterative and systemic collaborative approach to develop, select and/or tailor multi-level implementation strategies) to co-create implementation strategies for screenings and protocols for delivering trauma-informed care for future pilot-testing. The type of engagement for this project, based on the Spectrum of Public Participation continuum, falls within the collaboration and empowerment levels. The researchers partnered with healthcare administrators, service providers, program managers, members of the Information Technology and Quality Improvement departments, and caregivers of child patients to make decisions on every phase of the research process. That is, partners were collaborators of researchers in 2019 during the exploration implementation phase when the healthcare system was considering and ultimately adopted the ACEs Aware program, in 2020 during grant proposal writing and in 2021–2022 once the project received federal funding, during the planning process and pilot testing of the implementation strategy.

In addition, partners were empowered to make final decisions on which challenges and aligned implementation strategies to focus on, how to structure the activities for implementation of the ACEs screenings, how to organize the planning groups in terms of structure and process, and to have the power to request changes to data collection timeline, as possible by the funding agency, to accommodate significant changes within their system (e.g., high turnover) as well as changes to the ACEs policy requirements or other external events (i.e., inner or outer contexts). During the engagement process, the identification of challenges was complemented with acknowledgment of facilitators or assets within the partner healthcare system. Main challenges faced by partners were the high turnover and the financial and personal impact of the COVID-19 pandemic (i.e., 2020–2022) for implementers, leadership and caregivers of child patients.

Departure from key partners significantly impact engagement and the co-creation process as their expertise, gained knowledge and experiences and support is lost during a period of time or permanently if the position is not filled as it happened often with our healthcare partners. Nonetheless, facilitators that were leveraged to inform strategies included the use of implementation mapping (70) that allowed partners to work within smaller workgroups during the planning phase. This engagement early on during exploration and preparation phases (16) facilitated partners' ability to fill in relatively quickly for colleagues no longer at the organization. In addition, having two co-leads (aka champions) who were internal healthcare personnel co-lead the project along with the research team starting during grant proposal writing facilitated troubleshooting, decision-making, and coordination.

Example # 3: CO-CREATE: co-creating a COVID-19 testing program to promote health equity in a U.S./Mexico border region.

CO-CREATE is a rapid response, mixed methods implementation research study funded by the National Institutes of Health Rapid Acceleration of Diagnostics for Underserved Populations (RADx-UP) initiative to co-design and implement a culturally responsive and competent COVID-19 testing program for San Diego communities near the U.S./Mexico border (71). Co-creation drives this community engagement project through several methods: (a) a Community Advisory Board of community health workers, healthcare providers and administrators, and public health researchers who developed a project-driving theory of change and engaged in Appreciative Inquiry, to evaluate selection and implementation of co-created COVID-19 public health strategies (71); (b) qualitative brainwriting data collection sessions with patients and providers to identify and address implementation barriers; (c) partnership and co-leadership of all project activities with a federally-qualified health center to promote successful implementation and refinement of the testing program. For this project, the level of partner engagement fell between the collaborate and empower modes on the Spectrum of Public Participation continuum. Specifically, through the Theory of Change process (71), the Community and Scientific Advisory Board members were invited to collaborate with community and academic organizing team to identify root causes of inequitable COVID-19 testing and to develop community-vetted solutions to mitigate these inequities. After completion of the Theory of Change, the Community and Scientific Advisory Board has been engaged in an Appreciative Inquiry process to guide the implementation and evaluation of the identified solutions from the Theory of Change (71).

A primary facilitator was the community partner leaders of the project, the Global Action Research Center, who are an intermediary non-profit organization with strong and enduring relationships with community-based and ethnically-based community organizations in the region. The Global Action Research Center identified and invited the community leaders and health workers who were members on the Community and Scientific Advisory Board. They also primarily led each meeting, which fostered trust among the Board members and with the academic research team that organized the project. Another facilitator was the ongoing and multi-method evaluation of engagement that the project team undertook. This included ethnography and survey measurement of partner engagement after each meeting that allowed for near real-time assessment to inform changes needed within Board meetings to promote equitable and meaningful engagement.

Balanced with these facilitators were two primary and naturally-occurring challenges. First, to ensure equitable participation of Board members who represented the Latino, Spanish-speaking communities that were prioritized for the project, the Community and Scientific Advisory Board was structured to host live Spanish language interpretation and translation at each meeting. While this incurred more costs and reserved time for interpretation and translation, this was critical for important community perspectives to be shared. Second, because the levels of engagement were within the collaborate and empower modes, this required significant resources in terms of person-hours and fiscal costs. An analysis of the community engagement resource needs and costs are reported elsewhere (71).

Table 1 provides an overview of how each of the EPIS phases can be approach through a co-creation lens. For each phase(s), we also provide an overview of the activities used by the case examples to meet each of the co-creation principles.

EPIS sustainment phase

From a co-creation lens, the focus should be on supporting partners to lead their own engagement process locally to maintain goals achieved and to continue the implementation

TABLE 1 Implementation research collaboration summary case analysis from a co-creation lens and guided by the EPIS framework.

Co-Creation principle*	Example 1: Health equity for gender diverse and sexual minority (GSM) students	Example 2: ACEs policy implementation in an FQHC system	Example 3: COVID-19 testing program at the US/Mexico border
EPIS exploration and preparation phases: From a co-creation lens, focus on understanding diversity, and power differentials in local contexts, examining who needs to be at the table, and agreeing on governance, roles, and responsibilities. Prioritize opportunities for interaction (in-person or virtual) to convene and work collaboratively with partners			
Equity in relationship building: End-user knowledge and experience being valued equally with that of professionals	• Convened a multidisciplinary and multisectoral CAB, workgroups, and IRTs • Subawards and monetary incentives for members and organizations to formalize roles and responsibilities	• Trauma Informed Care (TIC) workgroup members and study champions (FTE % covered) self-organized the healthcare system (clinics and central personnel) into implementation mapping workgroups • Bilingual community health advisors and Latinx mothers joined the planning process, honorarium for caregiver time	• Community partners and CAB members were identified via existing relationships • Compensation was provided to all co-creators *via* sub-awards or honoraria
Reflexivity: Researchers (and other partners) strive to be aware of and analyze how their positions may influence the collaborative's dynamics	• Partners negotiated research design issues while sharing ideas informed by their unique but complementary positionalities to troubleshoot challenges and facilitators to implement GSM-centered school interventions	• Partners negotiated clinical efficiency of the screening process while accessing available resources • Planned composition of group meetings and separate follow-up meetings ensured that partners with traditional less power in clinics (e.g., staff, community health advisors, and caregivers) had additional spaces to share and fully participate	• After each CAB session, CAB members, community partners leading CAB sessions, and research team members completed a validated survey to assess partner engagement
Reciprocity & mutuality: Partners are interested in learning from each other. Relationships are perceived and experienced as mutually beneficial through the combined knowledge and the deepened networks developed	• Partners recognized and reinforced their shared commitment to reducing health disparities for GSM youth through consistent participation and by celebrating successes both large and small, particularly the co-design and sharing of training materials	• Power-sharing governance was structured by funding a percentage of clinical staff salaries and including them in weekly research meetings • Discussions of benefits and unintended consequences resulted in several concrete actions such as adding a strength-based section, focused on family resiliency, to the REDCap screening system	• Benefit was assessed through willingness to collaborate on projects, products, proposals beyond the current project and through ethnographic and survey assessment of CAB member engagement satisfaction and benefit to their personal and professional work
Transformative & personalized: The collaborative process benefits the study while also offering an enriching individual experience through use-value and empathy	• Qualitative interviews with partners, young people with lived experience, and technical assistance providers pointed to the value of the engagement experience, with one partner coming out of retirement to promote GSM student health, another changing their academic career path to focus on GSM student health, and a third securing employment at a large school district to implement programs to improve school climate and culture for GSM students	• Members of the healthcare system identified the need for TIC training for their clinic staff to address burnout and self-care and to focus on a culturally relevant approach to screenings • National coaches (one coach was bicultural and bilingual Spanish) provided this training to clinics based on their identified need	• Primarily assessed through CAB evaluation methods that include both ethnographic assessment in CAB sessions and a self-report survey completed by CAB members using the Goodman et al. (72) engagement survey

(Continued)

TABLE 1 (Continued)

Co-Creation principle*	Example 1: Health equity for gender diverse and sexual minority (GSM) students	Example 2: ACEs policy implementation in an FQHC system	Example 3: COVID-19 testing program at the US/Mexico border
Relationships facilitated: Relationship structures and procedures are developed collectively to support the implementation collaborative	• Dialogue among school nurses, school health advocates, and academic partners set the foundation for the CAB • The structure of the collaboration shifted to address needs (e.g., workgroups to develop professional education competencies)	• A multilevel network structure was developed: (a) TIC workgroup meeting monthly/quarterly, (b) bi-monthly meetings with top executives, (c) planning sub-groups in five areas of development, and (d) caregiver group as advisors during the planning process	• The CAB intentionally includes a mix of community health workers, clinical providers and staff, and researchers
EPIS implementation phase: From a co-creation lens, focus on deepening partner relationships, and monitoring the collaborative's activities to make sure they are meeting relevant co-creation principles or goals; focus on addressing each partner needs to maintain collaborative capacity			
Equity in relationship building: End-user knowledge and experience being valued equally with that of professionals	• Partners expanded to include new youth liaisons, intermediary organizations, school, and state agency personnel with situated knowledge and expertise, and were resourced as needed to contribute to project activities	• Use of coaching and feedback with community health advisors once or twice a month to troubleshoot and listen to their suggestions for adaptations	• Simultaneous Spanish translation promoted equitable access, and information sharing during CAB meetings
Reflexivity: Researchers (and other partners) strive to be aware of and analyze how their positions may influence the collaborative's dynamics	• Formal periodic reflections with study coaches and community-based technical assistance experts enhanced partner understanding of challenges and potential solutions • The contributions of partners were tracked, including for the co-design and delivery of local, state, and national presentations • These contributions were formally acknowledged for their influence on engagement and implementation efforts	• The composition of implementation mapping sub-groups was revised to add members or move members to a different group based on their role/expertise and preference • The TIC workgroup served as a space in which to discuss potential care team members' burnout and emotional stress due to ongoing ACEs conversations with caregivers	• Community members suggested that Spanish-speaking members be invited to speak first or in more explicit ways to encourage more equitable participation • Partner engagement surveys included items on shared power in decision-making, and open-ended questions to solicit critiques of and recommendations for engagement
Reciprocity & mutuality: Partners are interested in learning from each other. Relationships are perceived and experienced as mutually beneficial through the combined knowledge and the deepened networks developed	• Non-academic partners forged or further cultivated mutually beneficial connections in the broader collaboration, resulting in new and stronger initiatives to address GSM student health • Non-academic partners advocated and raised awareness of key outer-context determinants (e.g., legislation) to leverage to enhance health equity for GSM students in schools and statewide	• The project's clinical co-lead received introductory training in Implementation Science provided nationally (i.e., Implementation 101) • Academic partners learned about potential unintended consequences of ACEs screenings and the impact of COVID-19 on the capacity to innovate within the partnered clinical system	• New opportunities for collaboration among academic and non-academic partners were shared, resulting in several new proposals and dissemination products
Transformative & personalized: The collaborative process benefits the study while also offering an enriching individual experience through use-value and empathy	• Regular check-ins with partners (including IRT members) ensured the timely identification of needs and facilitated involvement in project activities through equitable engagement • Partners agreed on the collective value that GSM student health is a major societal health issue that can no longer be neglected, and that collaboration is the way to prioritize and address this issue	• Partners regularly implemented an adapted co-creation survey (9) to assess how partners perceived the individual value of their participation in the ACEs implementation collaborative • Partners strove to build implementation capacity through ongoing training and coaching	• The review of survey results after every CAB session informed ways to modify group processes to promote equitable engagement, such as encouraging non-academic partners to share their perspectives first • Continuous assessment of values alignment across within multilevel partnerships

(Continued)

TABLE 1 (Continued)

Co-Creation principle*	Example 1: Health equity for gender diverse and sexual minority (GSM) students	Example 2: ACEs policy implementation in an FQHC system	Example 3: COVID-19 testing program at the US/Mexico border
Relationships facilitated: Relationship structures and procedures are developed collectively to support the implementation collaborative	• An annual training institute was co-created to develop skills and intentionally nurture mutually supportive relationships among the IRTs and other partners, affording time and space to individually and collectively reflect on lessons learned and encourage each other's implementation efforts • Resources (e.g., coordination and communication support) were key to maintaining structures for co-creation	• A multilevel group structure (i.e., management, quality department, IT, providers, health advisors, and patients) derived from the implementation mapping workgroups facilitated the continuation of partner engagement during extreme turnover due to the COVID-19 pandemic • Iterative communication flowed upwards to clinic executives and other leaders and downwards to staff and caregivers	• Monthly CAB meetings provided a socially safe space that, over time, led to increased comfort in sharing personal experiences and trust among the partners

*Abbreviated definitions due to space limitations. ACEs, Adverse childhood experiences; CAB, Community advisory board; GSM, Gender and sexual minority; IRT, Implementation resource teams; IT, Information technology; TIC, Trauma-Informed care.

collaborative, if relevant. This work entails the exploration of alternative funding opportunities and new partnerships based on the shared commitment to addressing emergent and dynamic needs. Some of the case example projects described here are further along in the Sustainment Phase than others. All projects are currently seeking to maintain funding and developing new or complementary projects with partners. Connections developed in previous EPIS phases have allowed for continued resource provision after the withdrawal of study support. These connections also serve as a springboard for co-designing new initiatives. During this phase, attention to dissemination practices that adhere to each co-creation principles as a guide (e.g., sharing with equity, reciprocity, and mutuality) may involve concrete activities, including efforts to gradually shift control and decision-making to local champions through implementation coaching and feedback, co-presentations at academic and community forums, and new training opportunities for partners grounded in emerging needs and priorities from the co-created implementation process.

Discussion

In this commentary, we argue for co-creation in IS collaborations using five principles and by linking IS activities linked to each principle. These principles are transferable to any research area to enable a synergistic collaborative process. They can also foster longer-term relationships that can support resource intensive implementation efforts and sustainment of new practices. Thus, it is critical for researchers, implementers, and community partners to engage in co-creation to identify the need for change, the research-practice gap to address, prepare for and implement new practices, and sustain efforts long-term. The rich and inter-dependent knowledge that a co-created process promotes across diverse stakeholders is critical for ensuring fit and relevance to local contexts.

We recognize the challenges to co-creation in IS, with available infrastructure and time varying dramatically among academics, funders, and community-based stakeholders. Co-creation should not be expected to be a tidy process—it requires time, compromise and means IS researchers might need to step outside their comfort zones. We need to embrace rather than eschew the tensions possibly arising through co-creation (38), as they likely comprise a source of creativity and new ideas to plan for successful implementation. Furthermore, there is also a need for researchers to be clear on what exactly needs to be co-created and to balance a co-created process with the expectations of rigorous scientific endeavors (73). Co-creation in IS will require re-evaluating prioritization of academic knowledge and frameworks that do not align with or are irrelevant for community partners, especially given cultural, language, and social differences. Last, promoting implementation co-created implementation collaborations require specific knowledge and skills need to be incorporated into existing IS training.

In this paper, we make a case for further developing the concept of co-creation in IS with the goal of answering an ultimate question:

> *Does a co-created implementation collaboration provide stakeholders, especially end-users and community partners, with a deepened capacity to advocate for quality services, and as defined by local communities?*

IS researchers may be familiar with system-level challenges to collaboration, but less aware of dynamics specific to local contexts. This blind spot can compromise their understanding of barriers, facilitators, mechanisms of change associated with implementation. Co-creation will enable such insights, enhancing the scientific value of our evaluations, our ability to replicate outcomes, and increasing the potential for achieving health equity and social justice through successful implementation of needed interventions.

In this paper, we present co-creation as a multidimensional concept and identified five concrete principle that were illustrated through three case examples. These principles have pragmatic values as they can be transferable across groups, topics and systems. Implementation collaboratives can use a prioritization approach to selecting all or the relevant co-creation principles, and as standard goals for the group. Then, partners can identify concrete activities that will allow them to achieve each of those goals and that align with the EPIS phases as presented in Table 1. This mapping of standard goals and tailored activities can facilitate ongoing monitoring and evaluation of the co-creation process through rapid iterative cycles (74). We also recommend complementing this approach by raising Stanton et al. (3) power-based questions for each of the EPIS implementation phases and as a way to translate co-creation from a high face validity value in engagement research to a formal and more standard practice in implementation research.

Prior research have used qualitative interviewing and ethnographic approaches to describe how co-creation builds co-creative relationships that support ongoing collaboration and problem-solving to sustain and scale out implementation efforts (53, 58, 61). However, there is still a dearth of outcomes research on co-creation (32). Mixed methods research is needed to simultaneously measure and explain the impact of co-creation on implementation proximal and distant outcomes such as partner experience, adoption, appropriateness, feasibility and sustainment. Last, future research should explore the alignment of co-creation with spectrums of engagement such as the IAP2 model (67). From that model, if collaboration and empowerment are seen as suitable levels of engagement to be achieved by a group, co-creation could be the vehicle to reach that goal.

An IS approach foregrounded in co-creation will help us better elucidate aspects of collaborations that adhere to co-creation principles, and whether outcomes are achieved through synergistic and equitable approaches among diverse stakeholders. It is our aspirational goal that the co-creation principles we described will inform current efforts to assess the quality of co-produced research (71), and that they will become a more normative and explicit application in IS research.

Author's note

There is growing interest for the field of implementation science research to promote the active engagement of diverse and often disenfranchised stakeholder voices. Including multiple perspectives can increase project buy-in, promote adherence to implementation protocols, improve the selection of meaningful outcomes, and overall sustainment of evidence-based practices. Currently, there is no clear guidance to help implementation science (IS) researchers identify and build collaborative approaches guided by co-creation principles for working with the community. This manuscript provides background on IS collaborations and identify the following co-creation principles relevant to the field and informed by organization, community-engaged and patient-centered literatures: (1) equity, (2) reflexivity, (3) reciprocity and mutuality, (4) transformative and personalized collaborative processes, and (5) relationships facilitated through inclusive networks, iterative processes, and active communication. Applications of these principles are further described using three IS research case examples. Principles for structuring co-creation collaborations will help researchers and community members engaged in implementation science research to spark synergy, address imbalances in power, privilege, knowledge, and access to resources. These principles will help researchers and community members collaborate in meaningful, equitable ways. Additionally, these principles provide the field with guidance that can be tested for its impact on producing meaningful, co-creation collaborations.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

Author contributions

MP conceptualized the original idea for this manuscript and led the manuscript drafting and revision process. All authors drafted text, contributed original ideas across different sections of the manuscript, revised, and approved of the final manuscript text.

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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.

Publisher's note

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Colonels and generals, chairs and deans: How the military educates its leaders and what we can learn in academic medicine

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Introduction

While the professions may be profoundly different, successful physician leaders and military officers will rise to lead organizational units with increasing complexity and size over the course of their careers. Military officers are required to participate in professional military education and its successful completion is a mandatory requirement for promotion. Professional military education spans the whole career, is robust, extremely well designed and continually reviewed and updated. The goal of this article is to inform how the US military has successfully structured professional military education and to discuss how we may apply a similar approach to the leadership development and education of academic physician leaders. The focus of this article is on physician leadership in academic medical centers due to the complexity of managing a healthcare business and an academic enterprise, but the concepts are broadly applicable to all leaders in healthcare in academic and non-academic settings.

Using the US Army as an example, I will briefly review the organizational structure of modern armies, review requisite skill sets and expectations for US Army officers at different echelons (organizational levels), and review how the US Army has designed professional military education and training for officers over the course of their careers. The basic concepts are very similar in other branches of the US military (e.g., Navy, Air Force) and armed forces of other Western nations.

Military echelons—from platoon to field army

For simplicity, we will use infantry as example to illustrate the military organizational hierarchy ("levels of command" or echelons) (1) and use a typical career path of an US Army infantry officer, starting at the junior officer level (**Table 1**).

Infantry is the original form of military force and conducts ground combat. The smallest infantry unit is a squad, which is typically lead by a non-commissioned officer (typically a sergeant). The first infantry unit a new officer graduate (second lieutenant) will command is an infantry platoon. An infantry platoon consists of approximately 40 soldiers (typically split into 3–4 squads) with little if any formal command and control or logistical support elements. The requisite skill set is small unit tactics, and the expectation is that the platoon be ready and capable of completing any mission assigned. Leadership at the platoon level is immediate, personal, and direct with a focus on "doing" and achieving mastery of the unit's weapon systems and performance in combat. The next echelon is an infantry company (150–200 soldiers), commanded by a captain, and typically comprised of 3 infantry platoons and one heavy weapons platoon. For an army officer, this is the first time they have a formal

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TABLE 1 Military levels of command/echelons (in increasing size and complexity) with typical leader rank—using infantry as an example.

Military element	Number of soldiers (range)	Leader rank
Squad	7–10	Sergeant
Platoon	35–45	Lieutenant
Company	150–250	Captain
Battalion	800–1,200	Major/ Lieutenant Colonel
Brigade	3,500–5,000	Colonel/Brigadier General
Division	15,000–20,000	Major General
Corps	50,000+	Lieutenant General
(Field) Army	150,000+	General

headquarters unit and a logistical support element. The requisite skills include being able to direct and lead platoons, use the headquarters as an asset to generate the best plans and provide the highest level of support (supply, intelligence) to the platoons. Leadership at the company level remains immediate and personal (Table 2).

Leading at the next level of combat, the infantry battalion (500–1,000 soldiers), is much more complex. A battalion, comprised of 3–5 companies and commanded by a lieutenant colonel, is the smallest army unit that has a formal headquarters staff organization with staff officers responsible for human resources (S-1), intelligence (S-2), operations (S-3), logistics (S-4), communications (S-6), a supply/logistics (headquarters) company and several other support elements for which the battalion commander no longer is a formally trained expert. The headquarters staff also includes an executive officer (typically a major) and a senior non-commissioned officer (NCO). The coordination of support elements, such as mortar/artillery, scouts, snipers, air-defense, combat engineers, a medical platoon, with the main fighting force in combat is complex and requires a high level of expertise and training. At the battalion level, leadership transitions from direct to more indirect leadership *via* staff officers and company commanders.

An infantry brigade, the next military echelon, has 3,000–5,000 soldiers and consists of 3–5 infantry battalions and has even more disparate support elements than an infantry battalion. An infantry brigade, typically commanded by a colonel (sometimes by a brigadier/1-star general) is the central combat maneuver unit of the US Army. The slightly larger infantry brigade combat team (IBCT) is composed of 7 battalions, including three infantry, cavalry, artillery, engineering, and support battalions. The ability to plan and support combat operations at the battalion level are requisite skills for a brigade commander, who must also understand how to allocate artillery and engineering assets to best support the brigade's mission. The brigade commander is also tasked with coordinating operations with forces from other branches of the army (e.g., armored & mechanized infantry units) and aviation support (from the army or the air force). A brigade commander straddles the boundary between tactical and operational levels of warfare (Table 2).

An infantry division (10,000–20,000 soldiers), commanded by a two-star general, consists of three infantry brigades and similarly a significant amount of command, control, communications, planning, intelligence, and other support elements, and is an operational command. Divisions conduct large-scale operations that can span 50–100 miles and involve highly complex combined warfare operations (Table 2).

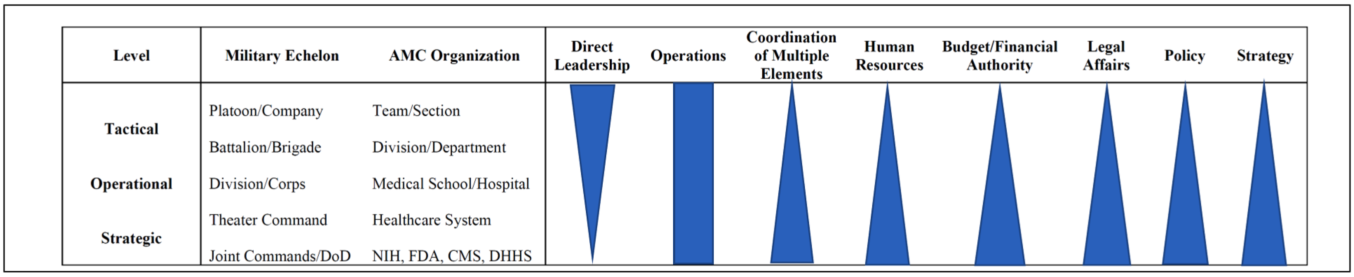
The final organizational unit that the United States Army deploys as a maneuver unit is the field corps (commanded by a 3-star general). A field corps (size: >50,000 soldiers) executes theater-level operations, and its leadership requires a deep understanding of joint military operations involving multiple military services (e.g., Army, Navy, Air Force), military strategy and policy, and interfaces closely with central military planners in US combatant commands and the Department of Defense (Table 2). The U.S. military has higher echelons in its formal organization, such as field army, unified combatant commands, the Joint Chief of Staffs, and ultimately the Department of Defense. These organizational units do not deploy as maneuver units in a theater of war and provide command and control and administrative coordination.

Thus, over the span of a 25-year career, an infantry officer may lead units as small as 40 soldiers and as large as several tens of thousands of troops. How does the military train and educate its leaders to be effective and successful at each echelon when the demands and qualifications are so different? The answer is that the US military invests substantial resources towards professional military education with multiple rounds of mandatory formal education interspersed with what could be referred to as training on the job (2). The next section will take a detailed look at professional military education for U.S. infantry officers.

Professional military education

A typical career as active-duty infantry officer begins after graduating from college and being commissioned as second lieutenant in the Army. Successful active-duty Army officers stay in

TABLE 2 Comparison of military and AMC leadership.



Level	Military Echelon	AMC Organization	Direct Leadership	Operations	Coordination of Multiple Elements	Human Resources	Budget/Financial Authority	Legal Affairs	Policy	Strategy
Tactical	Platoon/Company	Team/Section								
	Battalion/Brigade	Division/Department								
Operational	Division/Corps	Medical School/Hospital								
	Theater Command	Healthcare System								
Strategic	Joint Commands/DoD	NIH, FDA, CMS, DHHS								

the military for 20 years at which point they will have attained the rank of lieutenant colonel and be eligible for retirement (3). A select few officers are selected to continue their active-duty career and are promoted to the rank of colonel (and subsequently to a general officer rank), which allows them to remain in the army until the mandatory retirement age at 62 (a 40-year career) and continue their career as general officers (brigadier general (one-star), major general (two-star), lieutenant general (three-star), and general (four-star). Four-star general is the highest rank in the peacetime United States military.

After graduating from United States Military Academy, active-duty US Army officers receive more than 30 months of mandatory formal military leadership education during their typical 25-year career. These 30 months do not include continuing training in and with their units or specialized training courses such as intelligence school, airborne school, or the Ranger course.

The first formal leadership training is the Basic Officer Leaders Course (previously known as Officer Basic Course), a 19-week course that teaches young officers small unit tactics and how to effectively lead a platoon in combat. Around year 5 of service, the next formal training step is the Captain's Career Course (CCC). The Captain's Career Course is a 22-week course that prepares officers to lead a company-sized element and effectively serve as a staff officer at the battalion level. At the 10-year mark, officers must complete the 10-month Intermediate Level Education course, formerly known as the Command & General Staff College (CGSC) in Ft. Leavenworth, Kansas, an accredited graduate-level program where students receive a Master of Military Arts and Sciences degree upon completion. The Intermediate Level Education course prepares rising officers to lead battalion-sized elements and task forces and serve as staff officers at the brigade and division level. It is at this level when infantry officers take a deep dive into the operational art of warfare and are expected to master battalion- and brigade-level tactics. The capstone of U.S. military education is the U.S. Army War College (known as Senior Service College/ SSC), taken by lieutenant colonels or colonels between year 16–25 of service. Over 10 months, select lieutenant colonels and colonels study strategic level content including unified operations, theater-level campaign planning, and national military and security strategy (4).

In a typical 25-year career (300 months), a U.S. Army officer receives thus a minimum of 30 months of formal military education to prepare themselves for effective and successful assignments at higher levels of command. This does not include all the additional training within the officer's specialty that can add several months to the total. For example, a tank officer will undergo the same formal training outlined above plus specialized training how to conduct combat operations as commander of a tank company, armored battalion, or armored brigade combat team. Thus, the U.S. military invests and reserves at least 10% (!) of the total time spent in a military career to formally train its leaders.

Leadership levels in academic medical centers

Compared to the military, academic medical centers (AMC) and healthcare systems have far fewer organizational levels or echelons (Table 2 contrasts military and AMC echelons). The first leadership opportunities for physicians arise as leads of small teams or programs that often match the core clinical expertise of the faculty member. The leadership challenges for physician team leaders are not dissimilar to that of an infantry platoon leader and often focus on immediate people management, clinical operations, quality and safety and to some degree education and teaching.

The next, and first formal, organizational unit in an academic medical center is typically that of a section or division. Section heads or division chiefs are mostly senior faculty (associate professor or higher) and often have more than a decade of experience in the specialty. At the level of section or division, new leadership challenges arise: management of a large and often more diverse group of physicians and other healthcare professionals, oversight of and responsibility for the section/division budget and tripartite mission (clinical, education, and research), recruitment, human resources, and to some degree, faculty development. Unlike the military, physician leaders can and often chose to remain at the level of section/division chief and not pursue higher leadership roles, such as department chair or dean, so that they can continue to work predominantly within their clinical subspecialty.

At the department level, chairs are responsible for planning and implementing departmental strategy; fiduciary oversight of departmental finances; the complete spectrum of the tripartite mission, including clinical operations, undergraduate, graduate and post-graduate medical education, and research; human resources including management of diverse groups of employees (faculty, staff, trainees, healthcare professionals, researchers, etc.), to name a few core responsibilities. Chairs are expected to understand and align their departmental strategy with the overall strategy of the medical center and the university. They thus function at the interface between the operational and strategic level and have to navigate the often conflicting priorities from the hospital and university. Clinical departments often have a formal "headquarters" unit that may include an executive committee, business administration and support staff—in this regard the leadership structure of a clinical department is somewhat similar to that of an infantry battalion or brigade.

Leadership of an academic medical center—as dean, CEO, or in similar role—has been described as leading the most complex business organization mankind has invented. AMCs integrate the full spectrum of healthcare business operations with managing a medical school, often the largest academic unit in a university. Historically, academic medical centers operated a single or only a small number of interconnected hospitals on a single campus. However, over the last 20–30 years, AMCs have evolved into large healthcare systems that may comprise of a large number of diverse healthcare facilities over a wide geographic range, sometimes in multiple states and even international (e.g., Cleveland Clinic, UPMC). Thus, the leadership challenges of large AMCs are not dissimilar from leading a large Army unit such as a division or corps (Table 2).

Physician leadership training

Academic physicians are not required to obtain formal leadership training before assuming a leadership role. This is true for team leaders all the way to deans. Nevertheless, many aspiring leaders do so on a voluntary basis. Many academic medical centers have begun to offer leadership training for promising or recently appointed section/division chiefs and vice chairs. In my own experience, Barnes-Jewish Hospital/BJC and Washington University school of Medicine offered a one semester long course, Friday and Saturday once a month, that covered the basics of healthcare finance, supply chain logistics, leadership and management essentials (5). This course was targeted mostly for mid-level leaders, and was open to academic physicians, nurse leadership and hospital management. It was co-taught by faculty from the business school. The University of Chicago Medical Center offers a somewhat similar program that is restricted to physician leaders (6). The Harvard T.H. Chan School of Public Health offers a 2-week immersive program for new clinical chairs (7). Other institutions, the Association of American Medical Colleges (AAMC), and many subspecialty organizations, have established similar programs and have recognized the need for focused physician leadership training and education (8–12). It is beyond the scope of this perspective to discuss the details of each program.

The challenges of many of these programs are two-fold: first, the participants have often markedly different management and leadership experience, and wildly different foundations in content knowledge (from total novice to highly experienced). This is unavoidable when one single course is intended cover the whole range of health care leadership, from section/division to dean-level management. Second, these bi-weekly/monthly semester-long courses often can only scratch the surface of the content. There is insufficient time to go deeply into any topic. This is especially a problem with healthcare finance and business operations, two domains in which most physician leaders have little knowledge or experience.

On the other hand, a substantial number of physicians enroll in a formal MBA or executive MBA program, which are rigorous but often require a serious 1-to-2-year time commitment. While MBA programs "go deep", they are difficult to get the timing right. Too early in one's career and it's difficult to apply the knowledge in practice; too late in a career and it may be extremely hard to find the time to devote to an MBA program.

It would, thus, make more sense to establish a ladder-like professional academic leadership education program that starts at the team lead and ends at the dean or health-system level. A concept is provided in **Table 3**. The first program is for team leaders, for example a physician leading a heart failure program, a critical care unit, or a robotic surgery program. The goal of this program is how to become an effective team leader and the curriculum may include team management; clinical operations; achieving excellence in clinical care; QI/QA; fundamentals of healthcare finance. The next level would be a program for section/division chiefs and the curriculum may include managing people; fundamentals of HR; fundamentals of faculty affairs and development; section/division finance and business operations; graduate medical education; clinical operations; research management. The third level is for department chairs or vice chairs and the curriculum may include HR; faculty development and affairs; department finances and business operations; budgeting; controlling; contracting; department operations; strategy and implementation; GME; clinical operations; fundamentals of fundraising and philanthropy; QI/QA; healthcare law and regulations (local, state, federal); research management. The goal of this program is to serve effectively at the department level.

The fourth level is for Deans and leaders at the AMC-level and the curriculum may include management of complex organizations; people management; strategy; operations; healthcare law and regulations (local, state, federal); AMC-level healthcare finance; UME, GME, CME; research management; higher education; marketing; philanthropy. For large healthcare systems, a fifth level may be necessary that will provide education how to effectively manage large healthcare systems (**Table 3**).

One could envision such program being offered through national organizations, such as AAMC, AMA or others. Academic medical centers would send their future leaders to these courses prior to taking leadership roles, which would establish a common standard of

TABLE 3 Concept for professional physician leadership education.

	Leader	Duration of Course	Core Curriculum	Goals
Team	Team Lead	7–10 days	Management of small teams; clinical operations; achieving excellence in clinical care; QI/QA; fundamentals of healthcare finance;	Becoming an effective team leader
Section/Division	Chief/ Head	2–3 weeks	People management; fundamentals of HR; fundamentals of faculty affairs and development; section/division finance; GME; clinical operations; research management;	Enabling the participant to effectively serve as section chief
Department	Chair	4 weeks	HR; faculty development and affairs; dept finances; budgeting; controlling; contracting; dept operations; dept strategy and implementation; GME; clinical operations; fundamentals of fundraising and philanthropy; QI/QA; healthcare law and regulations (local, state, federal); research management	Enabling the participant to effectively serve as department chair or assoc/vice chair.
Academic Medical Center/School of Medicine/ Hospital	Dean/ CEO	4 weeks	Management of complex organizations; people management; strategy; operations; healthcare law and regulations (local, state, federal); AMC-level healthcare finance; UME, GME, CME; research management; higher education; marketing;	Enabling the participant to effectively serve as Dean, hospital CEO or senior officer in the Dean's office/hospital C-suite
Healthcare System	CEO	4 weeks	Same as AMC but focus on system-level	Enabling the participant to effectively serve as system CEO or in the system C-suite

knowledge among leaders from different disciplines, backgrounds, and institutions. Each institution may then elect to supplement the general education with institution-specific education that can now focus exclusively on the nuances of the individual AMC while the general basics have already been covered. Such approach would tie in with established leadership competency models for healthcare managers, such as the National Center for Healthcare Leadership (NCHL) model (13, 14), and Healthcare Leadership Alliance (HLA) model (15).

Using the stepwise approach, the US military takes to train its leaders over a career—from small to large, from rather simple to highly complex—we may be able to offer academic physicians a strong foundation for success as leaders in academic medicine.

Author contributions

The author was the sole contributor to the article and approved the submitted version.

The author is former chair of the Department of Anesthesia and Critical Care at the University of Chicago and military officer in the Austrian Army (Reserves): former executive officer, tank company; battalion surgeon, 2nd mechanized reconnaissance battalion; brigade surgeon, 6th mountain infantry brigade; currently senior staff officer, military medicine division, Federal Ministry of Defense, Austria.

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.

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Sustainable volume sweep imaging lung teleultrasound in Peru: Public health perspectives from a new frontier in expanding access to imaging

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Background: Pulmonary disease is a common cause of morbidity and mortality, but the majority of the people in the world lack access to diagnostic imaging for its assessment. We conducted an implementation assessment of a potentially sustainable and cost-effective model for delivery of volume sweep imaging (VSI) lung teleultrasound in Peru. This model allows image acquisition by individuals without prior ultrasound experience after only a few hours of training.
Methods: Lung teleultrasound was implemented at 5 sites in rural Peru after a few hours of installation and staff training. Patients were offered free lung VSI teleultrasound examination for concerns of respiratory illness or research purposes. After ultrasound examination, patients were surveyed regarding their experience. Health staff and members of the implementation team also participated in separate interviews detailing their views of the teleultrasound system which were systematically analyzed for key themes.
Results: Patients and staff rated their experience with lung teleultrasound as overwhelmingly positive. The lung teleultrasound system was viewed as a potential way to improve access to imaging and the health of rural communities. Detailed interviews with the implementation team revealed obstacles to implementation important for consideration such as gaps in lung ultrasound understanding.
Conclusions: Lung VSI teleultrasound was successfully deployed to 5 health centers in rural Peru. Implementation assessment revealed enthusiasm for the system among members of the community along with important areas of consideration for future teleultrasound deployment. This system offers a potential means to increase access to imaging for pulmonary illness and improve the health of the global community.

KEYWORDS

global health, lung ultrasound, pneumonia, pulmonary disease, telemedicine, ultrasound

Introduction

Respiratory disease, acute and chronic, is a major cause of morbidity and mortality around the world (1–3). In children under 5 years of age, pneumonia remains the leading cause of mortality (4, 5). Diagnostic imaging is critical to diagnosing many respiratory illnesses including pneumonia, as symptoms of respiratory disease such as fever and cough are non-specific (6, 7). However, the majority of the world lacks access to diagnostic imaging (8–11). To bridge this gap, low-cost lung ultrasound imaging could be employed. Lung ultrasound is highly sensitive and specific for the detection of many respiratory diseases including pneumonia, pleural effusion, and pulmonary edema (12–20).

Even with low-cost hand-held ultrasound, deployment of lung ultrasound is limited by the availability of trained staff to perform and interpret examinations particularly in low- and middle-income countries. Teleultrasound offers one means to overcome these issues but remains constrained by availability of specialists, system ease of use, and limited healthcare infrastructure among other obstacles (21, 22). To overcome obstacles to deploy teleultrasound and increase its use, a new user-friendly teleultrasound system that requires neither high-speed internet nor an ultrasound specialist has been successfully piloted utilizing volume sweep imaging (VSI) (23). This approach has already demonstrated excellent performance in controlled clinical trials for obstetric, right upper quadrant, and thyroid scanning indications (23–26). Testing of lung and breast VSI has also shown excellent clinical efficacy (27–29).

Building on this success, lung VSI teleultrasound was deployed at several sites in rural Peru during the COVID-19 pandemic (**Figure 1**) (29). While there is established clinical efficacy of lung ultrasound VSI and clearly great theoretical clinical benefit to the use of lung VSI teleultrasound in practice, there are many questions that remain to be elucidated in regards to integration of lung VSI teleultrasound into clinical practice. We undertook an implementation assessment to inform how such a teleultrasound program could be integrated into the larger healthcare milieu. Specifically, we aimed to analyze the benefits, drawbacks, considerations, and challenges for implementation of this lung teleultrasound system. We speculated that there would be perceived excellent benefits to implementation complicated by logistical challenges such as lack of education regarding lung ultrasound. The goal of this work was to inspire further public health investigation into the potential of this approach to improve global health.

Deployment of teleultrasound in rural Peru

Teleultrasound system

The teleultrasound system used in study activities has been previously described in detail, and a diagram demonstrating its application for lung ultrasound is shown in **Figure 1** (23). Briefly, a user-friendly telemedicine application is installed on a tablet which connects to an ultrasound machine. This application guides the user to enter patient information as well as perform each step of the VSI ultrasound protocol. The tablet screen captures the ultrasound machine screen and saves the data from each sweep of the ultrasound probe over the target anatomy. This system is completely asynchronous meaning it can acquire images in the absence of a radiologist or specialist. Images can also be acquired in environments without internet and stored locally until an internet connection is available. The report from the radiologist is sent back to the tablet to be shared with the patient and health workers.

Imaging is acquired with the lung VSI ultrasound protocol (**Supplementary Figure S1**). VSI is an imaging technique in which an individual with minimal prior ultrasound training performs a specialized scan protocol based on external body landmarks requiring neither significant technical skill or anatomical knowledge (30, 31). The imaging protocol consists of a series of blind sweeps of the ultrasound probe over the thorax. The video of each sweep is saved for expert interpretation and sent via the telemedicine platform. The operator performing the scan does not interpret the imaging. Lung VSI has also been previously shown to be easily taught at a rural Peruvian health center over the course of a few hours (31). A clinical trial of lung ultrasound VSI previously showed 100% sensitivity and 93% specificity for pneumonia (27).

Teleultrasound deployment

The activities conducted in this study were approved by the institutional review board at the Hospital Cayetano Heredia in Peru and began in November 2020. Along with opportunity to evaluate pulmonary pathology, the COVID-19 pandemic posed logistical study challenges that were overcome as effectively as possible. The study was funded by the mining company Nexa Resources as a service to the communities they operate within. The 5 sites for the study were chosen by the mining company based on their sites of corporate operation, not the prevalence of pneumonia or scientific considerations (**Supplementary Figure S2**).

The communities where the teleultrasound system was deployed were in the Peruvian departments of Ancash, Ica, and Pasco. The communities in Ancash were located in Conchucos and Pampas. The community in Ica was Chavín. The communities in Pasco were San Juan de Milpo and Ticlacayán. Elevation in these areas is greater than 3,000 m. According to the Peruvian Ministry of Health, population in each of these areas is on the scale of a few thousand people with the number using each health center even smaller. Imaging was not readily available to these communities prior to the installation of the teleultrasound program. To obtain an imaging exam, transportation would need to be acquired to the closest metropolitan center.

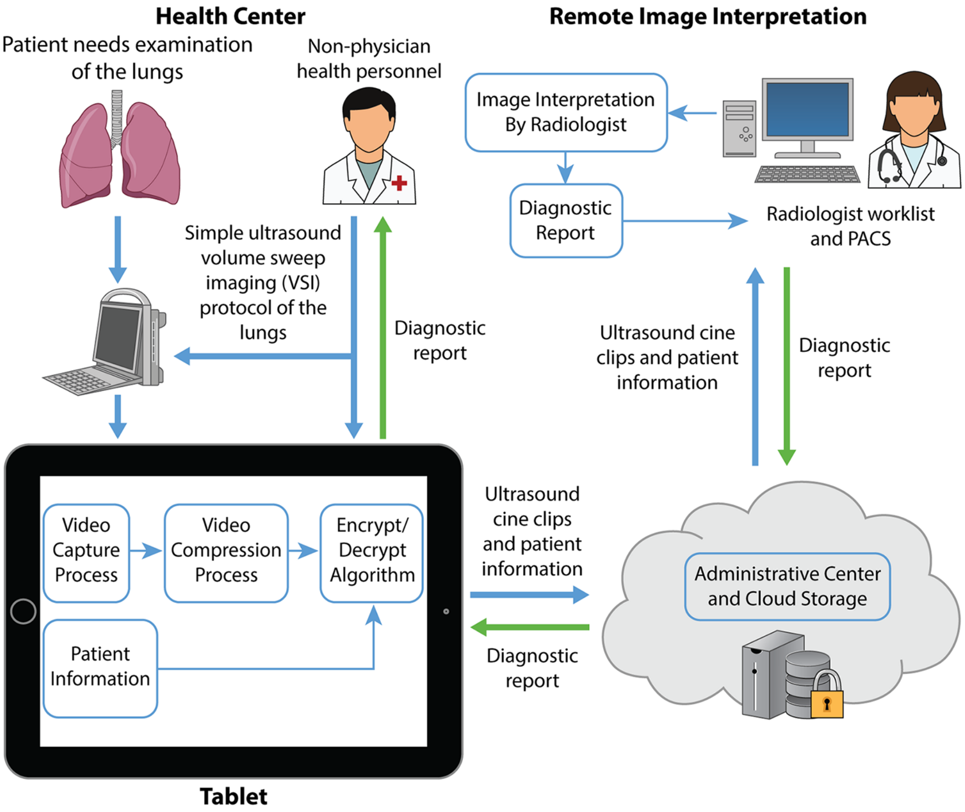

FIGURE 1
Asynchronous VSI lung teleultrasound. Schematic diagramming the components of the lung teleultrasound system utilized in this study. In practice, patients presenting to clinic with an indication for lung imaging would receive a lung VSI exam performed by an individual at the health center. The operator performing the scan may be an individual without prior ultrasound or medical experience. The tablet guides the user to perform the VSI protocol and input relevant patient history which is uploaded to a secure cloud for download by a specialist remotely. The specialist uses the history and images to produce a diagnostic report which is sent back to the health center to be shared with the clinic team.

At all sites, the telemedicine system was set up at a small health post offering basic health services by a team from the Peruvian company Medical Innovation and Technology. The set-up of the teleultrasound unit used at the Ticlacayán site is shown in Figure 2. A photograph of the exterior at Ticlacayán is shown in Supplementary Material S1. In Pasco, the teleultrasound services were also advertised by radio. Trainers traveled to each of the 5 sites and installed the telemedicine system and educated staff. Staff training typically occurred in the span of approximately 8 h over the course of 3 days and involved didactic and hands-on training sessions. Individuals have previously demonstrated basic competence with the lung VSI protocol over the course of a few hours (31). At the end of training, every operator was certified to perform the protocol correctly. Those trained included clinic technicians and nurses.

Patients attending each site were offered a free lung VSI teleultrasound exam for general research purposes or concern of respiratory illness. Upon enrollment, the operator performed the VSI protocol described above, entering the patient's clinical history into the tablet and obtaining the images. The images were transmitted for radiologist reading and the results returned to the health center (to be shared with the patient and healthcare provider). During the initial phase of the study for analysis in this paper, 213 patients were scanned with the lung teleultrasound system (147 female and 66 male). Their average age was 42.8 years (standard deviation 18.2 years, range 0–92 years). The average turnaround time for results was 18.8 h (standard deviation 29.3 h, range: 2–279 h). Of those scanned, 43.2% ($n = 92$) were symptomatic and 56% ($n = 121$) were asymptomatic. Exams were performed on symptomatic patients for many reasons including cough, shortness of breath, and fever/chills.

The clinical results of these examinations have been previously published and thoroughly described elsewhere (29). Cardiothoracic radiologists rated 202 out of the 213 examinations as diagnostic in image quality with only a single truly non-diagnostic exam secondary to a technical error. Among a random subset of these exams, the radiologists had 91% agreement on lung ultrasound interpretation with all discrepancies in agreement related to borderline examinations straddling the line between normal and abnormal. Clinical analysis showed the lung teleultrasound system was able to diagnose sequalae of COVID-19 infection. There were $n = 15$ patients with abnormal ultrasound examinations and $n = 29$ patients with borderline examinations straddling the continuum between normal and abnormal requiring clinical correlation and appropriate follow-up.

FIGURE 2
Example teleultrasound station. Labeled photo from the teleultrasound station at Ticlacayán demonstrating the required setup. The tablet connects to the ultrasound machine and guides the user to input the clinical history and perform the VSI protocol. Posters on the wall remind the operator how to perform the protocol.

Implementation assessment

Concurrent to the study clinical activities, an assessment of the implementation was undertaken. Data were systematically collected from enrolled patients through a structured patient survey administered by the clinic staff in the local language. The survey included open-ended items about patient characteristics, such as the reason for coming to the clinic, whether they were aware of the new service, how they heard about it, and their experience with it.

In addition, clinic staff completed a brief survey after their training on the protocol. The survey queried their perceptions about the teleultrasound system and its potential impact using open-ended questions. Their experience with the training was assessed using 4 items and analyzed using univariate statistics. Responses to the open-ended questions were aggregated and common themes identified.

In addition, more detailed interviews, (conducted via video) were completed with a staff member in Pasco and from those involved with implementation and training, teleultrasound system development, and reading the submitted images. Interviews were conducted in a free-format with open-ended questions regarding the teleultrasound system and implementation. Questions were tailored to the role of the person being interviewed. These interviews were analyzed similarly to the above open-ended questions.

Results

Using the patient survey, 67 patients who had participated in the lung ultrasound scan were interviewed. The results are summarized in **Supplementary Table S1**. Slightly more than half (55%; $n = 37$) were aware of the teleultrasound service before arrival to the health center. Reasons for coming to the center included obtaining teleultrasound (48%; $n = 32$) and “COVID” (22%; $n = 15$). The majority of those who knew about the service learned about it from health personnel. At one site that used radio promotions, a few patients noted that they heard it about it via the radio. Patients uniformly rated their experience as good or very good (100%).

Among the 7 clinic staff who completed a survey, they universally viewed the teleultrasound as important and beneficial to the community/clinic. Example quotations include: “…it is important because we have limited accessibility to this service that we need in our community.”; “…it is going to be very helpful and very useful for… all rural areas.” Respondents also mentioned reducing the need for referral to a higher level of care, more timely diagnosis, and for those who provide pharmacotherapy, initiation of antibiotic treatment as possible benefits. Training was viewed positively with the majority giving the highest rating to each of the 4 questions (**Supplementary Table S2**). Their recommendations for promoting the availability of the service was to disseminate information through multiple means including social media (including radio), word of mouth, and through staff at the health center.

The more in-depth interviews included key members of Medical Innovation and Technology including their CEO, project administrator, and an employee with experience traveling to the health centers and training workers on lung VSI. Additionally, a Peruvian radiologist who read lung VSI scans as well as a member of the rural health post in Pasco were interviewed. Their comments fell into 4 key areas: program planning and site selection, staff training, advertising and outreach, and program implementation.

Program planning

This process involved not only the health clinic but required pre-approval from the Regional Director of Health. Before training, signed contractual agreements had to be in place with the mining company; at some sites there were delays with changes in agreement wording and obtaining required signatures. Originally the process from site selection to implementation was expected to take 2–3 months. One person stated, “We were optimistic that we will go, and people will quickly sign and move and say they love it.” However, the reality was that the process took up to 6 months. The COVID-19 pandemic contributed to some of this delay as health centers had competing priorities, and planning in some cases had to shift to online as transportation to the selected remote sites was sometimes prohibited.

Staff training

Interviews confirmed the above description of the few hours of training that includes demonstrations and practicing with the ultrasound device and the tablet. Depending on the site size, up to 5 individuals were trained. It typically took 3–4 attempts with the protocol to result in an error free set of images consistent with prior study (31). Doing the training online was viewed as inadequate (leading to errors in arcs and speed). Follow-up post-training was offered via video. Generally, if the first use of the teleultrasound is more than 2 weeks after the training an online refresher session was needed.

Advertising and outreach

Within the health center, posters with simple to understand graphics were posted to advertise and explain the service (**Supplementary Materials S2 and S3**). While the local health center is closest (and less expensive), some community members prefer to go to the nearest urban area (which can be hours by car). Someone feeling very sick may skip the health center as the available services are limited and, in some cases, they would be referred elsewhere anyway. Having teleultrasound was thought to be a potential factor in helping to overcome this.

Program implementation

While the potential benefits of this approach were met with general enthusiasm by clinic staff, some brought up concerns regarding implementation challenges including its integration into workflow. In general, there was an inverse relationship between staff viewing this service as extra work and its potential benefit to the community. One person stated, “[Some] health center staff looked at this as a compulsory activity of the health center. They looked at this as extra work, and they are not considering this as a help for the community.” Some staff asked for additional compensation for taking on this new responsibility.

The radiologist reading the scans had no direct contact with the sites but provides feedback about quality or other issues to the respective site. The radiologist reviews the images and generates a report which takes approximately 10 min per patient and is done remotely from a computer. This individual also needs to be specifically trained in the use of ultrasound for diagnosing lung disease which is not always a part of traditional radiology training.

Discussion

Lung VSI teleultrasound performed by individuals without prior ultrasound training was feasible to implement in rural Peru. As respiratory disease remains a major cause of morbidity and mortality worldwide, this model for lung teleultrasound has a potentially vital role in expanding access to high-quality diagnostic imaging globally to underserved areas. The use of VSI and telemedicine circumvents issues relating to lack of specialists, prohibitive costs, and high-speed internet access. In this study, lung teleultrasound was successfully deployed within 8 h of training and produced turnaround times on average less than 24 h. These metrics suggest the approach is sustainable and scalable as a viable solution to improve access to imaging in remote sites. The primary clinical use of this system would be to detect or rule out respiratory disease including pneumonia, pleural effusion, and pulmonary edema. Lung ultrasound has been shown to be diagnostically superior to chest x-ray for many pulmonary conditions including pneumonia (21).

Our implementation assessment provided vital insight in regards to incorporating teleultrasound into remote clinics. There was general enthusiasm for VSI lung teleultrasound and universal acknowledgement of this approach as a means to improve health of local communities. Potential benefits of decreased delay to diagnosis and decreased transportation cost-savings to more urban clinics were frequently noted. Transportation to better equipped health centers can take up to days in Peru and is associated with worse health outcomes (32, 33). Staff training was accomplished through in-person didactic and hands-on sessions that were well-received and required limited follow-up beyond feedback after the first few post-training scans. Patients were motivated to come into the center to get a scan, and their perceptions were positive.

This study occurred during the COVID-19 pandemic. While this was an opportunity to test the system for detection of pulmonary disease, it also posed numerous logistical challenges. Despite these challenges, even in the midst of a global pandemic, the teleultrasound system was implemented successfully producing turnaround times of less than 24 h in rural Peru.

Given the successful implementation in this context, lung VSI teleultrasound should be considered deployable in most situations.

Some interviewed reported patients with severe illness often "leapfrog" basic health centers to go to centers with more treatment capacity. This owes partly because in some of these locations, concern for pneumonia simply results in referral to a larger health center since the lower-resource health centers do not always have the capacity to treat pneumonia adequately. In this context, a negative teleultrasound could preempt a referral in sites which do not offer treatment, but from our interviews, it seems patients often would likely seek a higher level of care even if lung teleultrasound is available if they believe they are sick enough to require treatment. The incidence of respiratory disease, a health center's capacity to treat pneumonia, distance to alternative treatment facilities, and local attitudes all should be considered when identifying sites for deployment. It is also possible that mobile teleultrasound units or screening campaigns could be a useful means to deploy teleultrasound to communities.

Another theme that emerged in our study was the vital role of government and public health policy in deployment. Partnership is needed with local governments and health centers to make lung teleultrasound financially feasible (**Supplementary Material S4**). While the cost of lung teleultrasound using our system is relatively low, teleultrasound will only be sustainable in the context that it is reimbursed. Reimbursements likely will need to come from government funding, but often the government may not reimburse for teleultrasound services adequately. In addition, health centers need to be adequately staffed and provided the appropriate resources to perform VSI teleultrasound. Some staff requested additional pay for taking on the responsibility of teleultrasound which is ultimately a public policy issue to address.

Lung VSI teleultrasound has the ability to improve the value of healthcare by increasing availability of ultrasound which is a relatively cheap imaging modality (34). This increased availability could lead to decreased morbidity and mortality by decreasing delays to diagnosis and allowing more accurate diagnosis further lowering costs of healthcare. To deliver lung VSI teleultrasound requires a tablet, brief training, and a portable ultrasound machine. Traditional ultrasound services also require an experienced operator to obtain images which is another dimension by which lung VSI teleultrasound can potentially decrease the cost of vital health services. In addition, as previously mentioned, there could be substantial cost savings to patients by decreasing the transportation costs associated with seeking care. Further dedicated economic analysis and modeling will be needed to fully assess the economic implications of VSI teleultrasound deployment.

In general, we found no insurmountable obstacles to implementation. Poor internet connectivity can limit efficiency of image transmission. However, as the teleultrasound system is asynchronous, images can be locally saved for transmission when a stable connection becomes available. Importantly, the teleultrasound system can send images at low internet bandwidths also mitigating the impact of poor connections (23). Although patients in this study were also scanned for general research purposes, we noted clinic staff sometimes seemed confused as to the appropriate indications for lung ultrasound scanning. Although these ultrasound scans are of low-cost and otherwise cause no harm to the patient, future efforts should be undertaken to develop educational material on lung ultrasound to increase general knowledge of the appropriate indications for lung ultrasound with clinic staff.

While this study demonstrated feasibility of implementation, there are additional knowledge gaps which remain in relation to implementation of lung teleultrasound. Future studies should examine the effect of such a program on health outcomes including morbidity and mortality. Economic analysis would again be helpful to identify potential cost-savings. There are also additional ancillary benefits to the deployment of lung ultrasound which may result from implementation such as increasing vaccination rates through increased clinic attendance. Ideally future studies will occur on a larger scale in areas with high rates of pathology as well as incorporate artificial intelligence (35, 36).

Conclusion

This pilot of a potentially cost-effective and sustainable model for lung teleultrasound performed by individuals without prior ultrasound training demonstrated the feasibility of the approach and provided vital information regarding its implementation. A system offering diagnostic VSI lung teleultrasound scans and interpretations within 24 h was able to be implemented at 5 sites in rural Peru after minimal time investment and cost. Further public health study is needed to better delineate its impact on health outcomes in terms of morbidity and mortality, analyze economic benefit, and understand the best ways to integrate VSI teleultrasound into regular clinical practice. This user-friendly teleultrasound system's ability to effectively image the lungs in the absence of a specialist or internet circumvents major obstacles that have limited the deployment of teleultrasound in the past. Its proper use could improve diagnosis and treatment of pulmonary disease to the benefit of global health.

Data availability statement

The original contributions presented in the study are included in the article/**Supplemental Material**. Further inquiries can be directed to the corresponding author.

Ethics statement

This study involving human participants was reviewed and approved by Hospital Cayetano Heredia. Written informed consent to participate in this study was provided by the participants or their legal guardian.

Author contributions

TM was involved in study design, study management, data collection, data analysis, and manuscript writing. BC was involved in study design and manuscript writing. MS was involved in data collection, data analysis, and manuscript writing. YZ was involved in the data analysis and manuscript writing. CR was involved in data collection. WS was involved in data collection. TB was involved in statistical analysis of survey results. KK was involved in the data analysis. RA was involved in the data analysis. GR was involved in data collection. AD was involved in the study design, study management, data collection, data analysis, and manuscript writing. All authors contributed to the article and approved the submitted version.

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Conflict of interest

WS, CR, and GR are or were employed by Medical Innovation and Technology. BC has financial stake in Medical Innovation and Technology. 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.

Publisher's note

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frhs.2023.1002208/full#supplementary-material.

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Applying an equity lens to assess context and implementation in public health and health services research and practice using the PRISM framework

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Dissemination and implementation science seeks to enhance the uptake, successful implementation, and sustainment of evidence-based programs and policies. While a focus on health equity is implicit in many efforts to increase access to and coverage of evidence-based programs and policies, most implementation frameworks and models do not explicitly address it. Disparities may in fact be increased by emphasizing high intensity interventions or ease of delivery over meeting need within the population, addressing deep-rooted structural inequities, and adapting to local context and priorities. PRISM (Practical, Robust Implementation and Sustainability Model), the contextual expansion of the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) framework has several elements that address health equity, but these have not been explicated, integrated, or illustrated in one place. We present guidance for applying PRISM with an equity lens across its four context domains (external environment; multi-level perspectives on the intervention; characteristics of implementers and intended audience; and the implementation and sustainability infrastructure—as well as the five RE-AIM outcome dimensions. We then present an example with health equity considerations and discuss issues of representation and participation, representativeness and the importance of ongoing, iterative assessment of dynamic context and structural drivers of inequity. We also elaborate on the importance of a continuous process that requires addressing community priorities and responding to capacity and infrastructure needs and changes. We conclude with research and practice recommendations for applying PRISM with an increased emphasis on equity.

KEYWORDS
re-aim, implementation, context, practice, PRISM, representation, reach, health equity

Introduction

There is an urgent need to address health inequities and translation of evidence-based programs into practice and policy. Both goals can be achieved through implementation research and practice efforts—if designed to prioritize health equity and to track

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Abbreviations
RE-AIM, Reach, Effectiveness, Adoption, Implementation, Maintenance; PRISM, Practical, Robust Implementation and Sustainability Model.

and reduce inequities during implementation. However, current approaches may unintentionally increase health disparities. If the underlying multi-level contextual health disparity landscape (historical, political, cultural, economic and social drivers of inequity) and inequitable delivery are not considered in intervention design, adaptation, and uptake, implementation may well perpetuate inequities (1).

RE-AIM is one of the most widely used frameworks for implementation and evaluation research (2). It has been applied with an equity lens in several instances, but usually with limited emphasis on context. Its contextual expansion to PRISM (Practical, Robust Implementation and Sustainability Model) can enhance health equity efforts. The purposes of this paper are to: (1) describe ways that PRISM can be used to support health equity; (2) provide a detailed example of such use; and (3) offer guidance and recommendations for applying an equity lens in future implementation research and practice using the PRISM framework.

Expansion of RE-AIM to understand external validity and population health impact of programs in context

The purpose of RE-AIM has always been to enhance external validity across diverse settings, including those with limited resources, and public health impact (3). A key enhancement of RE-AIM has been its expansion to the PRISM (4, 5). PRISM adds explicit attention to multi-level contextual factors that impact RE-AIM outcomes. There are four contextual PRISM domains, each of which is multi-level. These are: (1) recipient characteristics (e.g., at citizen, delivery staff, organizational decision makers and community levels); (2) recipient perspectives on the intervention (e.g., history with similar programs, relationships, mental models); (3) external environment (e.g., policies, distribution of resources, health and social system structure and coverage); and (4) implementation and sustainability infrastructure (e.g., resources, and capacity; staff roles and responsibilities; monitoring and evaluation systems).

Figure 1 illustrates key features of PRISM as well as examples of actions to enhance health equity. The center column depicts the key PRISM domains and how they interact with the intervention and implementation strategies to deliver the intervention. The combination and alignment of context, the intervention and the implementation strategies produce the RE-AIM outcomes in the lower part of the figure. The example actions summarized on the left- and right-hand side of the figure illustrate how PRISM can be used to enhance equity. Some key opportunities include: (a) attention to representation in planning, implementation and evaluation stages of an intervention; (b) engagement of participants to co-create and/or adapt the intervention and implementation strategies to fit local context and enhance equity; (c) assessment of structural drivers of inequity, and capacity and infrastructure needs and resources; and (d) iterative assessment of RE-AIM outcomes to identify equity-enhancing approaches and address unintended consequences.

Perhaps the most unique contextual factor in PRISM is the implementation and sustainability infrastructure. This component is critical to institutionalizing the assessment of equitable implementation and outcomes. Relevant questions for gauging whether there is adequate infrastructure to assess and promote equity include: Is there staff responsible for tracking equity? Are there reportable equity indicators? This type of equity assessment often defaults to motivated staff or community partners without being not tracked routinely or linked to performance evaluation.

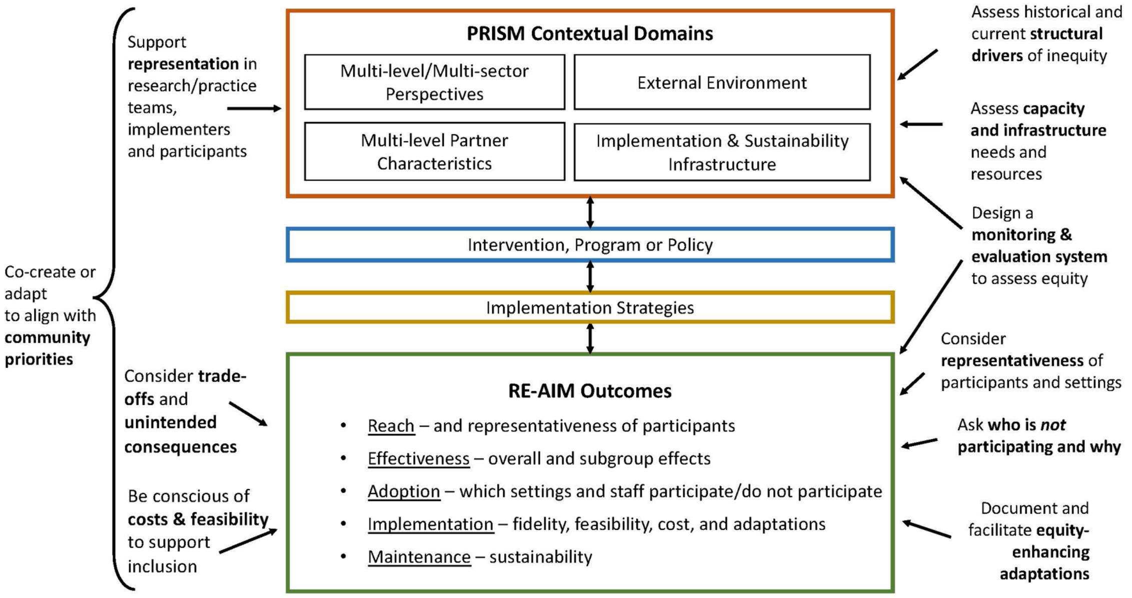

FIGURE 1
PRISM Contextual Domains and RE-AIM Outcomes with an Equity Lens.

Working toward equity

In applying an equity lens to implementation research and practice, it is important to consider what aspect of equity a program aims to address (e.g., redistribution of resources to those with the greatest need; equitable participation in the design, implementation and evaluation processes; extension of health care or a social service to a traditionally underrepresented or excluded group, etc.). Programs, policies, or interventions often are stronger in some of these aspects than others. In many cases, equity is not the central focus but rather is considered an outcome to be assessed only after priority assessment of effectiveness—as measured by a clinical health outcome.

Braveman defines health equity as: "the principle underlying a commitment to reduce—and, ultimately, eliminate—disparities in health and in its determinants, including social determinants" (6). Marmot et al. call attention to structural determinants of health that reside outside the health sector (7). This focus reinforces the commitment in the Alma-Ata Declaration to the multisectoral nature of health described as "a world-wide social goal whose realization requires the action of many other social and economic sectors in addition to the health sector" (8) and which is subsequently recognized in the Ottawa Charter for Health Promotion. More recently the Pan American Health Organization has provided guidance for working toward just societies (9). Jones points to the systems of injustice and inequity—racism, sexism, income inequality, and other forms of oppression—that assign value and structure opportunity benefiting some groups more than others (10). Public health and health service fields can improve efforts to address inequities by drawing on the extensive work from other disciplines (e.g., social sciences; political science; public policy and social work).

Within this background, we re-examine PRISM: how it addresses these issues, and present recommendations for how researchers and practitioners can apply the model with an equity lens.

Context: understanding deep-rooted inequities

Prior to defining the appropriate intervention and adaptations that are needed, it is important to assess the unequal contextual landscape and set goals for health improvement/disparity reduction. In many cases, persistent morbidity and mortality disparities are well-documented and are well-known by communities. However, in implementation research projects, it is common for health and related social and economic disparities to be described almost as a characteristic of the landscape—such as insufficient staffing or lack of access to clean drinking water in a community—rather than the defined problem to be addressed (11).

Underlying drivers of inequity such as colonialism, racism, inequitable access to land, and income inequality are all-too-often viewed as background characteristics and not the focus of change efforts. In some cases, these deep-rooted drivers of inequity are acknowledged, but efforts to address them are targeted at individual-level social needs rather than deeper structural transformation. In PRISM such factors are considered under External Environment or Perspectives of different multi-level participants.

Assessing capacity and implementation and sustainability infrastructure needs in community and health care settings can offer a longer-term road map that links to broader and more sustainable community development and policy change efforts. Inequity in the policy landscape, including the design and structure of health and social service coverage, will influence whether a specific program is offered to different members of the population.

In **Table 1**, we present definitions of PRISM's contextual factors and RE-AIM outcomes along with a case example applying an equity lens. This project sought to improve hypertension control in Guatemala in intervention districts in rural and indigenous communities in 5 provinces (12, 13). A needs assessment conducted at the outset showed that the health care system, part of the *external environment*, is like many in low- and middle-income countries: the public sub-system requires additional funding and system strengthening to ensure sufficient human resources and medications to adequately meet need across the country (14). Within Guatemala's Ministry of Health, actors at *multiple levels* take part in delivery of the intervention (national-level actors based in the capital, provincial-level Health Areas, and district-level providers), and patients, families, and community members are beneficiaries with important insight about implementation and access. An assessment of explanatory models helped to understand their different perspectives on hypertension (15). *Representativeness* was assessed with census (individual-level) and health administration (setting-level) data. Several districts carried out *equity-enhancing adaptations* during the COVID pandemic to increase patient access to medications by making them available at rural health posts instead of requiring patients to travel to health centers in semi-urban areas; family members were also allowed to pick up medications (16). While some districts had resisted making medications available at rural health posts prior to the pandemic, it was recognized as acceptable during the pandemic. There is an opportunity to build equity assessment into the *implementation and sustainability infrastructure.*

Participation and representation: elevating underrepresented voices

Community-based participatory research defines priorities based on the community's expression of primary concerns and emphasizes representation of those most affected by the focal issue throughout the cycle of problem definition, assessment, interpretation, and dissemination (17). The research or practice problem to be addressed is often structural in nature and requires more than a singular evidence-based program.

In applying PRISM to increase equity, it is important to be aware of and document who has a place at the table and which

TABLE 1 PRISM contextual factors and RE-AIM outcomes: definitions, equity implications, and an applied example.

PRISM Factors and RE-AIM Outcomes	Details and Examples	Equity implications: illustrative ways to support equitable implementation and to assess factor/outcome with an equity lens	Example from Hypertension Control Project in Guatemala's Ministry of Health System
Multi-Level Partner Characteristics (citizens, delivery staff, decision makers, community leaders)	Socio-demographic and other project relevant characteristics at multiple levels and extent of participation by different partners in the design, implementation and analysis	• Consider and co-create ways to achieve equitable participation, especially of traditionally marginalized sectors in the community, in the design, implementation and evaluation • Ensure representation of the beneficiaries' socio-demographic characteristics among implementers and organizational decision makers • Support establishment and sustainment of multi-sectoral linkages	Implementation research project led by the Institute of Nutrition of Central America and Panama and the Ministry of Health; a cluster-randomized trial with external research funding and collaborating research institutions. **Organizational:** – Experience was focused within the health sector with participation at central, regional, and local levels – Limited representation of Mayan people in decision-making roles within public institutions and among MDs **Beneficiaries/Participants:** – Conducted a pre-implementation engagement process involving patients, family members, providers, and national-level health system stakeholders

Multi-level Perspectives on the intervention (citizens, delivery staff, decision makers, community leaders)	History with similar programs, relationships required to deliver the intervention, trust among parties, mental models of intervention effects	• Work over time to build trust, especially among marginalized or socially excluded communities
		• Create governance structures that allow for different perspectives to be shared in an ongoing way
		• Elicit and review experiences with similar programs in the past
			Organizational:
			– Differing ideas about fit of the intervention/implementation strategies and amount of additional work that is required
			– Recognition of the importance of primary prevention to curb the tide on surge in non-communicable diseases
			Beneficiaries/Participants:
			– Conducted an explanatory models of disease analysis capturing perspectives of patients, family members, health care providers and administrators, and national-level health system stakeholders which pointed to:
			  – Use of alternative medicines, beyond biomedical HTN treatment
			  – Challenges of unreliable access to medicines, concerns about cost when HTN medications are not available in the public system

External Environment	Policies, guidelines, coverage, level and distribution of resources, current and historical community priorities	• Understand history, legacy and ongoing colonialism, structural racism, and discrimination in policies and norms and work to address them • Influence policy-level and upstream challenges • Support equitable protections/regulations (e.g., environmental protections across communities, restrict advertising that inequitably targets minoritized or low-resource communities, etc.)	– Inequitable society in which rural, Indigenous people experience more social exclusion; history of massacres in rural communities during 36-year internal conflict – Limited public sector budget for health and other social services – Changing food environment; excess availability of low quality, ultra-processed foods and transition away from traditional diets – Dynamic context (e.g., COVID-19 during the implementation period of the trial) that resulted in reduced access to transportation, social distancing rules, and less emphasis on chronic disease programs

Implementation and Sustainability Infrastructure	Organizational commitment, resources, and capacity; staff roles and responsibilities; monitoring, evaluation and supervision systems; existence of audit and feedback procedures	• Enable/strengthen data capacity and supervision/evaluation infrastructure to assess equity
		• Create alignment with organizational mission and priorities
		• Ensure ongoing program evaluation and assessment of equity impacts is an explicit part of someone's job and performance metrics
		• Support capacity building/advocate for additional resources in low-resource settings
			– Conducted needs assessment applying the WHO's health system building blocks framework—identified capacity building needs and infrastructure gaps including:
			  – Medication availability—need to institute an approach to ensure availability of all three classes of medications for hypertension control in all MOH districts
			  – Need to increase resources for staffing to be able to offer intramural and extramural services in all MOH districts and resources to support supervision of the program (e.g., fuel and transport for site visits, phone minutes for routine check-ins)
			  – Opportunity to develop an equity-focused monitoring and evaluation system with priority indicators for ongoing equity assessment

(*continued*)

TABLE 1 Continued

PRISM Factors and RE-AIM Outcomes	Details and Examples	Equity implications: illustrative ways to support equitable implementation and to assess factor/outcome with an equity lens	Example from Hypertension Control Project in Guatemala's Ministry of Health System
RE-AIM Outcomes			
Reach (Individual participant level)	The number, percent and representativeness of individuals who participate vs. those invited/eligible	• Assess characteristics of participants, nonparticipants and those not eligible—capture/measure census-level data for representativeness; apply health equity impact assessment tool • Work with multi-level partners on recruitment strategies, messaging/ interpretation, and locations • Implement strategies to meet underserved/excluded segments of the populations where they are	Assessment of participant representativeness: – Approximately 70% women and 30% men – Work status (most participants do not have formal employment; underrepresentation of employed, especially in agriculture) – Participant identification as Mayan or ladino/a – Literacy/education level – Distance to the health post/center
Effectiveness (Individual participant level)	Short-term results on (a) primary outcome; (b) heterogeneity of effects; (c) generalization effects (e.g., quality of life); and (d) unintended consequences	• Assess differences in health outcomes at the outset to determine existing gap • Analyze subgroup effects on outcomes and unintended consequences • Tailor intervention and implementation to individuals; adapt implementation as needed • Include multi-cultural definitions of health outcomes (e.g., wellness; mental + physical + family health)	– Primary effectiveness outcome: BP control – Assessed differences in BP control by patient characteristics – One of the first large-scale efforts to capture and assess data on BP control within the public health system; opportunity to understand and track differences by subgroups to develop strategies for reducing disparities in the future – Important to consider other priority unmet health needs; project focused on HTN control whereas diabetes is more urgent/relevant to many (emphasized in needs assessment)
Adoption (Multi-level setting and staff levels)	Number, percent and representativeness of (a) settings (e.g., clinics, communities; organizations) and (b) staff (multiple levels/ types of staff)	• Co-create or refine intervention, recruitment and implementation strategies with staff, implementing organization to assure relevance and fit to local context • Promote short- and long-term strategies to increase alignment of setting and staff representativeness with population served • Support capacity building/advocate for additional resources in low-resource settings to enable adoption • Analyze characteristics of participating sites and staff vs. those a) not invited and b) who decline • Assess factors that contribute to limited or slow adoption of the intervention and support the removal of barriers/obstacles and the enhancement of facilitators.	– Representativeness of **staff** (bilingual/ Mayan nurses, primarily Spanish-speaking doctors) – Challenge to fully adopt program and add it to existing workflow, especially with added COVID responsibilities – **Representativeness** of **sites** (selected to have two aux. nurses—most posts have less staff time available; HTN meds were made available for the duration of the study whereas routine availability of medications is not the case in most health posts/centers across the country); conducted assessment of setting-level representativeness using administrative data
Implementation (Setting and staff levels)	Fidelity of delivery; adaptions made; and costs of implementation	• Assessment of fidelity and adaptation to guide iterative implementation to increase equity • Recognize the need for differential implementation: offer more to those who need it most; offer less to those who need it least • Understand implementation costs from different perspectives; assess cost to community members, consider investment that could have alternatively been made elsewhere to address underlying causes of inequity	– Identification of **equity-enhancing adaptations** implemented during COVID pandemic (certain flexibilities were supported: 2-month medication supply, allowing family members to pick up meds, offering medications at health post—closer to patients) – Important to assess extent of implementation to those residing in most rural vs. those in more semi-urban communities – Consider family/community support: patients with additional support from family enabled to implement home BP monitoring. – Recognition of the cost to patients (travel, time) to participate (although medications and services are free) – Cost to providers (time, balancing with other responsibilities).
Maintenance (Individual and Setting levels)	Longer terms effects of (a) individual outcomes and (b) program delivery at 1–2 or more years	• Analyze % and characteristics of individuals and settings that maintain or adapt program and implementation strategies • Adapt intervention resources required (e.g., task sharing) for sustained implementation • Recognize need for ongoing structural change and improved implementation	– Consider ability for patients to maintain BP control and setting-level sustainability – Medication availability may decline after the project period concludes – Supplies (BP monitors purchased by the project—require maintenance)

groups, perspectives, and priorities are included. Equally important is to ask who is *not* at the table and understand why not. It is not sufficient to only engage community members and implementers who are most eager to be involved, have the most time or resources to participate, speak the same language, or share similar backgrounds with the research team. Limited representation in the governance of implementation efforts is likely to perpetuate societal inequities (18). It is especially important to ensure the most marginalized voices are heard rather than default to community leaders or others who may have higher status or access to resources.

Equity of participation across the design, implementation, analysis, and dissemination phases should not be assumed or defined by researchers. Community partners may use tools such as the spidergram developed for assessing community participation (19). Memoranda of understanding and other transparent accountability mechanisms can support communities and partners who come to the table with less power.

Ideally in applying PRISM, community context experts will be involved throughout all phases of a program to improve relevance and prioritization. Community context experts should serve as co-PIs, co-investigators, or in other roles such as community advisory boards. They may identify adaptations of interventions or implementation strategies to render them relevant for their community as well as changes to context to sustain implementation and enhance equity. The next five sections describe equity implications for each RE-AIM outcome.

Reach: representativeness, generalizability, and structural drivers

RE-AIM focuses attention on who is excluded, who participates or is impacted, who declines or is unable to participate, and the underlying reasons. While RE-AIM has always emphasized representativeness across its five dimensions, under Reach most reports only present data on differences of individual participant characteristics such as age, gender, race, and ethnicity. Typically, individual-level participant characteristics are captured in a "Table 1" with columns that compare those participating in a project and those in a comparison or control group. Comparisons between those who participate and the broader population are rarely reported.

One way to increase equity in Reach, especially in the pre-implementation phase of a project, is to use tools such as the Health Equity Impact Assessment (20). This pre-implementation assessment can identify people from historically-excluded groups, elucidate ways to address barriers to reach, and consider intersectionality, or the multiple, interacting dimensions of inequity at the micro-level that reflect interlocking systems of privilege and oppression at the macro-level (21, 22). Recognizing potential inequities in participation prior to offering a program contrasts with a standard "first come, first served" approach that assumes all individuals have equal ability to participate. Rather than frame low participation as a person-centric issue, implementers should consider it a problem of delivery or design. Programs may need to be delivered in a non-dominant language by staff or peers who share lived experiences with those in the community; over-represented groups may need to be waitlisted to ensure implementation is inclusive and reaches those who have the greatest potential to benefit.

Today there are many efforts to capture social determinants of health and social needs. While important to describe individual-level need, assessments also need to include structural drivers of inequity (23). Focusing data capture on structural drivers forces us to consider additional levels of influence.

As discussed below, representativeness should be assessed across all RE-AIM dimensions. Tools such as the Expanded CONSORT figure can assist with reporting (24) and present an opportunity to understand and document reasons for exclusion and nonparticipation and also recognize capacity building and policy-level needs.

Effectiveness: expanding assessment beyond individual-level behavioral and clinical primary outcomes

In defining effectiveness outcomes for an intervention, it is important to recognize the assumptions that underlie how health is defined and who determines health improvement metrics. Local knowledge (25) is seldom considered in defining effectiveness outcomes; health benefit is typically operationalized in biomedical terms to address funder or researcher priorities. We should broaden assessments to include measures such as well-being and quality of life and consider different explanatory models of health (26). Western-centric conceptualizations of health often dominate, emphasizing individual-level change, whereas many other cultures view health in broader socio-centric terms of family or community.

We should also capture the heterogeneity of effects and consider whose health improves, whose does not, and why. It is important to assess changes in health outcomes of traditionally marginalized or socially excluded groups. Effectiveness should be evaluated on more than one dimension; for example, an average increase in blood pressure control or daily fruit and vegetable consumption in one dimension, and a reduction in gaps in the same health outcome measures between groups or neighborhoods at the population level.

Adoption: setting and staff-level representativeness and capacity building

Sites and communities are often excluded from participating because they lack resources and capacity to meaningfully engage in the process. This may happen explicitly—they are not invited because they do not meet certain criteria—or implicitly—they self-select out in the face of demands of a new evidence-based program. For sites and delivery staff afforded the opportunity to adopt a new program or policy, investing in capacity (human and/or financial resources or physical infrastructure) may be necessary to facilitate adoption. Research and practice may not be able to address long-term capacity needs within their respective lifecycles; however, they may still contribute to equity by identifying the capacity required. A needs assessment conducted prior to implementation can clarify strengths and weaknesses in capacity. Public health and health care system frameworks (27, 28) that examine different system components and capacity domains with a systems strengthening perspective offer ways to identify and prioritize needs.

Implementation: addressing inequities in delivery; iterative assessment; and prioritizing adaptations that support equity

Programs should design, implement, and adapt evidence-based interventions to local circumstances, recognizing how the inverse care law (29) operates within their context. Fifty years ago, Hart wrote that: "The availability of good medical care tends to vary inversely with the need for it in the population served." Risk stratification—implementing more care or offering more services or programs for those who have greater health and social care needs—can offset the inverse care law. In some health systems, risk stratification at the family or household level is built within the delivery approach. Such approaches contrast with frequently offering the same intervention to all participants and sites (e.g., the same number of sessions of an evidence-based prevention class) despite differing levels of resources, capacity and need. The targeted or proportionate universalism approach also calls for actions to be implemented with an intensity and a scale proportional to the level of disadvantage (30, 31).

During implementation, PRISM focuses on adaptations to fit local setting resources and changing context. Adapting evidence-based programs or implementation strategies to enhance their delivery in different settings is almost always necessary to fit local culture, history, and resources. Fundamental co-creation and co-design of interventions tailored to community realities is critical and we support the recommendations offered by other colleagues (32). Adaptations during implementation are often needed to improve equity; these equity-enhancing adaptations should be documented and supported (33). Incorporating knowledge from the community experiencing inequities into the program or practice should occur on an ongoing basis and should ideally be built into the implementation and evaluation process. We need to be mindful of potential implementation-generated inequalities, which are more common in some technology-based interventions (34). Monitoring and acting on emerging data through iterative assessment can increase program success and identify equity-enhancing adaptations (35).

Maintenance and sustainability: enabling long-term implementation and equity assessment

Capacity for sustainability should be assessed to understand the extent to which a setting supports the structures and processes that promote sustained evidence-based programs (36). Too often, low resource settings fund services through undependable grant cycles that compromise sustaining positions and programs (37). Frequently, settings lack the level of staffing or resources to continue a program after conclusion of the active intervention. Thus, it can be helpful to conduct a sustainment or replication cost analysis of the financial impact of different sustainment strategies to help with decision making (38).

Discussion: research and practice recommendations

Researchers and practitioners can assist efforts to improve equity by documenting context prior to, during, and post-implementation—in each cycle of a program (e.g., including planning, implementation, and evaluation). Ideally, researchers and practitioners should apply an equity lens that simultaneously considers: (1) equity in the implementation process and outcomes (RE-AIM) for a given cycle and (2) the PRISM contextual factors, recognizing that efforts to promote equity on both will be mutually reinforcing. Ongoing contextual insight will identify needed structural change; program implementers can inform and advocate for infrastructure improvement, resource distribution, and policy change to address persistent gaps and societal inequities.

RE-AIM has often been characterized as the product of its dimensions (Reach X Effectiveness X Adoption X Implementation X Maintenance). An important consideration for applying RE-AIM is its implications for equity of trade-offs among different outcomes and potential unintended consequences. Maximizing impact on one dimension may produce adverse impacts on other dimensions. For example, focusing on enhancing intensity of a program may result in reduced adoption by settings and staff. Similarly, it is challenging to capture and equally weight the various PRISM contextual factors. Unanticipated consequences could also be compensatory effects elsewhere (e.g., harm to the environment or future generations) or inadvertent exacerbation of health disparities. Using systems thinking tools and methods such as behavior over time graphs or dynamic modeling to consider different scenarios prior to implementation is one way to build in consideration of unanticipated consequences (39).

An increased emphasis on multi-sectoral interventions and Health in All Policies approaches promise to increase health equity by working to influence social determinants of health. Using PRISM in combination with equity-focused theories, models and frameworks has great potential for advancing health equity.

Conclusions

This paper adds to the existing literature on health equity and PRISM by: (1) describing equity implications for each PRISM contextual factor and RE-AIM outcome, (2) providing a concrete example to illustrate these issues, and (3) making recommendations for future research and practice. We have not sought to be comprehensive, but rather pragmatic and provide guidance for increasing an equity lens in applying PRISM. We emphasize aspects of equity such as representation, recognizing the potential for unintended consequences that contribute to increasing inequity. It is also important to consider and document changes to the intervention context such as through capacity building and systems level efforts. Finally, we highlight the centrality of the implementation and sustainability infrastructure to enable sustained assessment of equity.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary Material, further inquiries can be directed to the corresponding author.

Ethics statement

The study that is referred to as an example in this article received approval from ethics committees of the implementing institutions in Guatemala and collaborating research partners.

Author contributions

MPF and REG conceptualized the paper and led the analysis and the writing of the manuscript. SMM participated in the analysis and contributed to drafting the manuscript. All authors contributed to the article and approved the submitted version.

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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.

Publisher’s note

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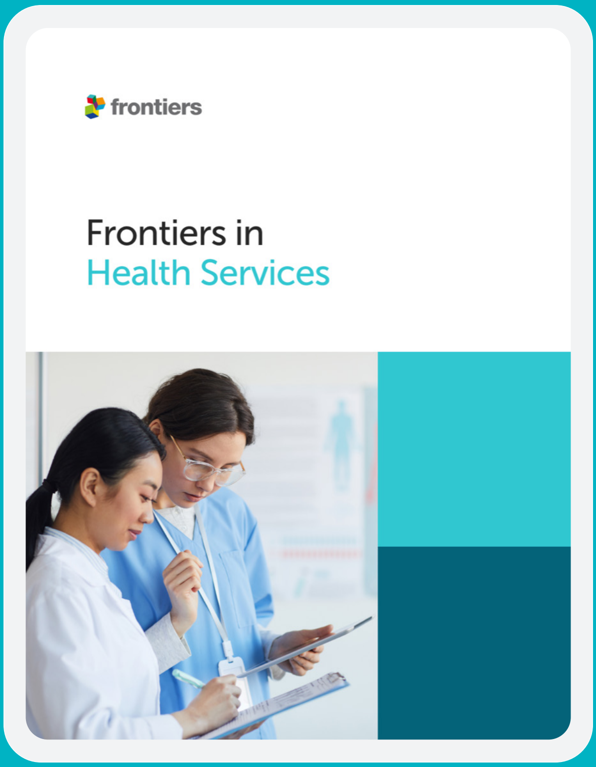
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