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Learning for action in policy implementation

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Learning for action in policy implementation

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Table of contents

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Editorial: Learning for action in policy implementation

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Learning for action in policy implementation

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Introduction

Policy implementation science (IS) is an emerging field that intersects implementation science and public policy studies to support the translation of evidence into policy. As a multidisciplinary field, Policy IS uses methodologies and frameworks from economics, political science, sociology, public administration, knowledge translation, and other fields. Policy IS would benefit from broader consensus on definitions, theories, frameworks, methodologies, and outcomes, so that a wide range of studies could build on a common conceptual foundation and thus build scientific knowledge more rapidly. The objective of this Research Topic is to reach consensus and drive learning for action in policy implementation by strengthening connections among a range of policy IS working partners, including implementation scientists, policy researchers, technical advisers, policymakers, and policy implementation practitioners.

In this special collection, 82 authors contributed to publishing 12 manuscripts on topics relevant to the design, processes, and impacts of policy implementation. The collection includes one theoretical discussion on global context (List and Agamile et al.); reviews on service integration (Tao et al.) and tobacco licensing (Bera et al.); methodological studies on equity-centered hybrid policy implementation studies (Asada et al.), quantitative policy IS measures (Smith et al.) and the integration of legal epidemiology and IS (Lane and Stergachis); one measurement study on acceptability and feasibility of policy implementation strategies (Purtle et al.); one qualitative comparative case study on policy intermediaries (Bullock et al.); and one case study on food assistance policy implementation (Kenney et al.); one quantitative evaluation effective communication related to policy IS (Dodson et al.); one mixed-method study on inter-sector care for the homeless (Martins et al.); one design study on participatory development of a target policy profile (Means et al.). Reviewing the papers included in this Research Topic, we identified several themes salient to the future of policy IS.

Working definitions of policy implementation

Policies include regulatory, promotional, and redistributive decisions and guidelines for implementing programs to achieve societal goals (1). Lane and Stergachis addressed the importance of systematic collection and coding of laws to enable policy implementation analysis. It is notable to observe that a consensus was implicitly reached in the 12 manuscripts regarding the importance of the evidence base for policy and practice (EBPP). The working definition of policy IS in the 12 manuscripts aligns with the National Cancer Institute definition of policy IS (2). However, from a policy perspective, research evidence is not the only input into policy decisions and that is why evidence-informed policies and practices (EIPP) was raised as a critical concept (3). In public administration, policy implementation is defined as a deliberate, sanctioned change to public policy legitimized by a political authority, with an emphasis on changing the status quo and adapting to diverse contexts (4). Scientific evidence is considered as one of multiple resources in implementation. Policy implementation strategies include information campaigns (Kenney et al.), licensing (Bera et al.), as well as others (e.g., contracting, subsidies, accreditation). Through literature review and synthesis, Tao et al. highlighted policy implementation strategies, including training, resource reallocation, and increased insurance coverage.

Theories and conceptual frameworks for policy implementation

Policy IS has distinctive challenges in different settings and contexts (e.g., global vs. domestic). Incorporating contextual contingencies is important to address the factors affecting policy IS. List and Agamile et al. brought the discussion of global policy implementation in decolonizing global health. This includes the application of frameworks and processes through a global perspective that aligns with diverse governance, power, resources, stakeholder relationships and health systems. They highlighted opportunities for reimagining policy implementation science across the policy cycle from agenda setting and policy formulation, to policy implementation and evaluation using real world examples.

In synthesizing scientific evidence, conceptual frameworks are crucial to cluster the findings and aggregate knowledge, with the potential of theorization. Health Triangular Policy Framework by O'Brien et al. was applied in the narrative review by Tao et al., with an emphasis on actor-relevant contexts, contents, and processes (5). Comparatively, Bera et al. applied a framework for contextual analysis, categorizing strength, weaknesses, opportunities, and threats, in tobacco retailer licensing as a crucial policy implementation strategy in regulating tobacco access.

Several papers present examples of using policy IS frameworks to drive implementation evaluation and outcomes. For instance, Means et al., Kenney et al., and Smith et al. directly linked implemented policies to implementation outcomes (e.g., reach, adaptability) and final outcomes relevant to health and equity. Kenney et al. illustrated the utility of a policy IS framework by Bullock et al. through a case study (3). Asada et al., Bullock et al. demonstrated how frameworks from related fields of political science, public policy, and IS can inform policy IS.

Methods for studying policy implementation

This Research Topic represented a wide range of empirical evidence from surveys (e.g., Purtle et al., Dodson et al.), comparative case studies (e.g., Bullock et al., Smith et al.), mixed-method studies (e.g., Martins et al.) and design studies (Means et al.).

In survey-based studies with policymakers and implementers, low response rates are a general challenge. For example, Dodson et al. had a 4.5% response rate in a national survey of local officials. Nonetheless, the results from these studies shed light on policy implementation practice. Dodson et al. studied the strategies to deliver policy briefs to facilitate information dissemination to local policymakers. Their study found that the narrative policy briefs had the lowest score (42%) related to strength in reasoning. In contrast, usual-care and risk-framing brief types had significantly higher scores to reflect strong reasoning (59% and 52%, respectively).

This Research Topic collected diverse studies to learn for action. Bullock et al. elaborated the role of intermediaries in implementing mental health policies through document analysis, site visits, and interviews in three distinctly different high-income countries. Smith et al. discussed four design considerations of policy implementation measures using three case studies. Martins et al. used secondary quantitative data and documents as well as collected first-hand data through interviews and focus groups to study tailored inter-sector care in the COVID-19 pandemic among the homeless. Means et al. showcased the holistic development of a Target Policy Profile as a single document to guide future work.

Looking forward

Challenges in policy IS include the complexity of developing overarching theories that address diverse contexts and evolving implementation partners. Contextual analysis often lacks direct causal links to outcomes, while randomized trials are difficult due to the nature and scale of policy implementation. Other useful policy IS methods include legal epidemiology (Lane and Stergachis) and coincidence analysis (6). Additionally, measuring outcomes across macro, meso, and micro levels, accounting for both intended and unintended effects, remains complex.

A limitation of this Research Topic is that all of the manuscripts are in health and related domains such as food and nutrition (Kenney et al., Smith et al.) and housing instability (Martins et al.). We anticipate that future Research Topics will cover other social policies, such as unemployment, poverty, education, and LGBTQIA+ marriage. We also anticipate future studies on systematic reviews to understand the overarching landscape of policy implementation, modeling studies to predict policy impacts, costing methods for use in policy implementation, and others.

Author contributions

YS: Conceptualization, Funding acquisition, Writing – original draft, Writing – review & editing. HB: Conceptualization, Writing – review & editing. MT: Conceptualization, Writing – review & editing. KE: Conceptualization, Writing – review & editing.

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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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Applying hybrid effectiveness-implementation studies in equity-centered policy implementation science

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Policy implementation science (IS) is complex, dynamic, and fraught with unique study challenges that set it apart from biomedical or clinical research. One important consideration is the ways in which policy interacts with local contexts, such as power and social disadvantage (e.g., based on ability, race, class, sexual identity, geography). The complex nature of policy IS and the need for more intentional integration of equity principles into study approaches calls for creative adaptations to existing implementation science knowledge and guidance. Effectiveness-implementation hybrid studies were developed to enhance translation of clinical research by addressing research questions around the effectiveness of an intervention and its implementation in the same study. The original work on hybrid designs mainly focused on clinical experimental trials; however, over the last decade, researchers have applied it to a wide range of initiatives and contexts, including more widespread application in community-based studies. This perspectives article demonstrates how effectiveness-implementation hybrid studies can be adapted for and applied to equity-centered policy IS research. We draw upon principles of targeted universalism and Equity in Implementation Research frameworks to guide adaptations to hybrid study typologies, and suggest research and engagement activities to enhance equity considerations; for example, in the design and testing of implementing strategies. We also provide examples of equity-centered policy IS studies. As the field of policy IS rapidly evolves, these adapted hybrid type studies are offered to researchers as a starting guide.

KEYWORDS

policy implementation science, hybrid effectiveness-implementation, equity, study design, policy research

1. Introduction

Policy is a cornerstone of public health interventions, as evidenced by the many policies, such as seatbelt and tobacco laws, that were critical to advancing public health (1). The field of policy implementation science (IS) is distinct from policy implementation research, the latter originated from political science and focuses broadly on how governments put policies into effect (2). Both fields consider the recursive cycles, feedback loops, and processes involved in the policy cycle (3). Policy IS is defined as a field that "seeks to understand how the roll out of policies can be optimized to maximize health benefits" (4); broadly, the field aims to ensure policies are developed with high quality evidence, and/or inform successful implementation of policies once they are codified (4, 5).

Implementation science offers important advancements for policy IS research, which traditionally has measured policy impact or effectiveness (did the policy "work" as intended) with a lighter focus on understanding how, why, and in what contexts? (6). In a review of NIH-funded D&I research, 110 studies were identified that included the term "policy" (or a related term, e.g., law); of those, only 16 studies (14.5%) examined factors or mechanisms of implementation, or tested strategies to improve policy implementation (7). A better understanding of implementation outcomes, processes, contexts, and determinants of policy implementation allows us to discern whether the observed organizational, health, or behavioral outcomes are a result of the policy or in fact are artifacts of incomplete or poor implementation.

Policy IS inquiries may draw from effectiveness-implementation hybrid studies, which were developed to address research questions around the effectiveness of an intervention and its implementation in the same study (8). This original work was mainly focused on clinical experimental trials; however, researchers have applied it to a wide range of interventions and contexts, including more widespread application in community-based studies of evidence-based interventions (EBIs) (9). While typologized in nomenclature, the hybrid study types are more of a continuum than distinct categories, with a focal decision point being the level of "evidence" available about the "thing" or intervention of interest (see discussion on the "thing" below) (10, p. 2). Typically, a researcher may consider starting with a Type 1 study when there is less data on intervention effectiveness, to understand its effectiveness while understanding the context for implementation; Type 2 focuses on collecting intervention effectiveness data but also moves simultaneously toward understanding feasibility/utility of an explicit implementation strategy (either alone or comparatively) to support delivery of an intervention; and Type 3 determines utility of (two or more) implementation strategies and also collects intervention effectiveness data but as a secondary outcome category (9). Hybrid studies allow policy IS research to advance an understanding of how policy is a critical public health tool, while gathering important contextual implementation data to inform uptake in other settings.

The field of implementation science has increasingly called for a greater attention to the intersection of health equity and implementation (4, 5, 12–16). Notably, some research may centrally feature equity while others may not; at minimum, researchers are urged to "leave no one behind" by being intentional about the potential to exacerbate inequities (16). This is notable with policy IS research which is dynamic and fraught with unpredictable real-world events, politics, and ideology (5, 17, 18). Adding to the complexity is an important consideration for the ways in which policies interact with local contexts, including power and social disadvantage (e.g., based on ability, race, class, sexual identity, geography and many others; hereafter: historically disadvantaged groups/communities) (5). Historically disadvantaged communities may not have the resources to fully adopt or implement a policy (19–21). For example, the 2006 Massachusetts statewide universal health care law expanded access to health insurance for all state citizens; however, after implementation, 96% of non-Hispanic white citizens were insured, compared to only 79% of Hispanic citizens (22). Although Hispanic groups saw an increase in coverage, those with limited English proficiency faced enrollment barriers; also, communities with poorer access to primary care physicians also faced access barriers. Limited attention to the unique needs of historically disadvantaged groups led to exacerbation of racial disparities in health coverage (22).

In this paper, we discuss how effectiveness-implementation hybrid studies can be applied to equity-centered policy IS research (23). We focus on big "P" policy (hereafter, policy) defined as laws, ordinances, rules, regulations, executive orders and court decisions that are enacted by federal, state, or local governments; we do not include small "p" policies (defined as organizational policies and guidelines that are typically not required by laws/regulations from governments) (24) due to distinct implementation factors. We also focus on the study of policies after they are passed, rather than indirectly informing policy development, awareness or adoption, while recognizing that this is an iterative, non-linear, and often dynamic process (4).

2. Considerations for policy IS hybrid studies in equity-centered research

2.1. Conceptualization of policy as the "intervention" or "thing" of interest

Historically in public health research, policy was more typically conceptualized as a distal "outer setting" determinant and not as the central "intervention" [i.e., as described by Curran using plain language as, "the thing being implemented" (4, 6, 7, 24)]. Policy can be conceptualized as the "thing" of interest, or an "implementation strategy," (i.e., as described by Curran, "the stuff we do to try to help people and/or places to do the thing") (24), or a determinant that influences the implementation of strategies (6). For example, school nutrition standards intend to decrease consumption of sugary, low-nutrient foods and beverages. In this case, the "thing being implemented" or the intervention is the policy that intends to make healthier foods and beverages more accessible to students in the school built environment. In comparison, earmarked taxes, defined as "taxes for which revenue can be spent only on specific activities" are conceptualized as an implementation strategy that facilitates access to evidence-based practices, such as mental health services (25). For the policy of interest, articulating clearly its place as "the thing" or an "implementation strategy" early in study conception is critical to the selection of frameworks, study designs, and associated methods (6). We contend that it matters less how it is conceptualized; rather, the important point is that it is clearly described.

2.2. Centering equity in policy IS research

Two frameworks: (a) Equity in Implementation Research (EquIR); and (b) targeted universalism inform this work. Briefly, EquIR aims to address inequalities during implementation and was selected because it calls for an explicit and intentional focus on equity—particularly on social determinants of health—from the planning and design phases (23). The framework encourages researchers to consider a continuum of participatory approaches that center historically disadvantaged groups' priorities. Such efforts will avoid constructing historically disadvantaged communities as "homogenous groups with static traits and shared beliefs" (26). Targeted universalism is defined as "pursuing targeted strategies that respond to the urgent needs of some people, and wrapping those strategies in a universal goal that holds wide appeal" (22). This framework was selected because it offers an equity-driven focus to policy strategies and aligned with approaches to health; for example, goals may include providing food, housing, and affordable health care, and the "targeting" component involves measuring the impediments to filling gaps, not with reference to each other but to the universal goal (22). The examples described next are designed with the principles of both EquIR (intentionally building equity into study approaches) and targeted universalism (developing equity-driven policy strategies that promote structural change). Finally, an essential component of equity-centered work is the need for researchers' to deeply engage in reflexive practices (27). Reflexivity requires researchers to continuously check their own social positions and deeply examine the ways in which they exercise and are influenced by power, as well as the ways in which these positions influence the particular research subject (27). While this practice should be conducted in all research, policy is fraught with ideology and values; thus, researchers should be mindful and transparent about their own biases and privileges.

2.3. What are policy and equity goals?

Figure 1 illustrates two key considerations. First, at the top of the figure, researchers are reminded to consider equity early in the design phase and across effectiveness and implementation considerations. Second, to address "effectiveness," researchers may consider what the policy intended to do and identify the

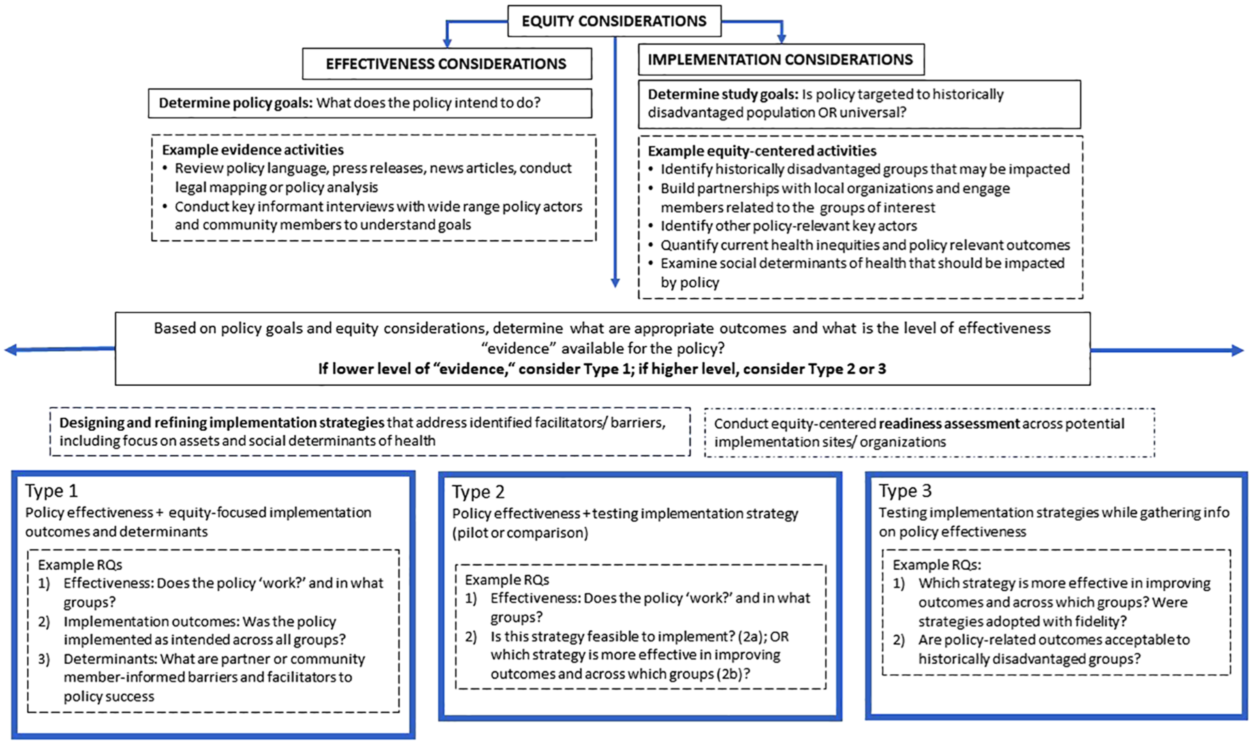

FIGURE 1
Considerations for equity-centered policy implementation science hybrid studies.

appropriate "evidence" (described next) to support success, failure, or other (6). Unlike clinical interventions, policy as an "intervention" can be ambiguous (i.e., unclear policy language or multiple goals); in response, researchers may conduct (pre-study or phased) activities to better understand policy goals, such as policy analysis (28) or qualitative interviews with key policy actors and community groups (6). Policy analysis may be part of a policy surveillance, the latter is defined as "the ongoing, systematic collection, analysis, interpretation and dissemination of information about a given body of public health law and policy" (28).

We offer a few dimensions of "evidence" to inform policy success or failure. Scholars have outlined the problematic nature of applying post-positivist, clinical hierarchies of "evidence" (for example, based on large, randomized samples, and controlled for confounding variables) to the study of public health policy (3, 29). This discussion sits within a broader conversation and advocacy toward transforming the ways that "evidence" on policy effectiveness is generated and disseminated for decision making (3, 30). Policy "evidence" requires broader data that is derived from multiple sources/actor groups, tailored to context, and responds to the interests of those impacted by the policy (3, 30). Parkhurst and Abeysinghe (2016) suggest considering key questions: "(1) what are the policy concerns at hand (and is the evidence selected the most useful to address the multiple policy concerns at hand)?; (2) are the data constructed in ways that best serve policy goals?; and (3) do we have reason to believe that the evidence is applicable to our local policy context?" (29). Finally, and importantly, we highlight the equity dimension: "evidence" generation has historically been the privilege of white, Western, male researchers, with the intentional exclusion of historically disadvantaged groups, including women and people of color (27, 28). Here again, inclusion of a broader range of outcomes as "evidence," such as nonbiomedical outcomes more salient to communities of interest is paramount (27). Researchers may determine implementation considerations with an equity lens by identifying who the policy will impact (i.e., is it targeted to a specific historically disadvantaged group or group with documented disparities?) and whether the current "evidence" points to any existing disparities or differential outcomes across groups (23). We restate here that policy "evidence" without this equity lens can unintentionally lead to exacerbation of inequitable conditions (3, 21).

2.4. What are policy-specific implementation outcomes?

In addition to investigating outcomes to better understand policy effectiveness (e.g., health or behavioral outcomes), hybrid studies examine implementation outcomes, such as acceptability, feasibility, sustainability and costs (31). Previous scholars have adapted these definitions and identified quantitative measures (outcomes and determinants) for policy IS research (23); for example, acceptability may measure perceptions of historically disadvantaged groups to understand if the policy is "agreeable" and why/why not. Implementation cost may measure total costs of implementation for historically disadvantaged and non-disadvantaged groups and calculate a final adjusted cost-effectiveness (23). More work is needed to further test and develop psychometric properties of such tools, as well as ensure rigorous qualitative and mixed methods approaches to measuring outcomes (23).

3. A continuum of hybrid studies for equity-centered policy IS

While not distinguished as a hybrid type, for illustrative purposes, we consider a non-hybrid Type 0 example, which is akin to those typically conducted in health policy studies, and examines effectiveness outcomes after a policy is adopted (e.g., did the smoke-free policy reduce smoking in the jurisdiction?) without measuring implementation outcomes (e.g., did the jurisdiction implement the smoke-free policy as intended?) or contextual factors (e.g., what factors led to policy success or failure?) (32). Type 0 studies do not elucidate whether some groups implemented the policy more effectively and/or benefited disproportionately. We include this example to illustrate the status quo from which these proposed hybrid approaches depart.

3.1. Hybrid type 1

Table 1 provides key characteristics of each hybrid type to align with policy IS research. Again, they are presented as distinct types here, but can be conceptualized more as a continuum. As illustrated in **Figure 1**, Hybrid Type 1 is considered when there is the lowest availability of "evidence" on whether the policy is effective (9), while considering whether outcomes differ in historically disadvantaged groups: if the policy "works," did it "work" across all groups? For example, in the case of sugary beverages taxes, a policy goal may be a decrease in purchasing of sugary beverages, based on prior research that has shown differential rates of exposure to targeted marketing across ethnic groups (33, 34). In addition to behavioral outcomes at the individual level, studies may consider policy-level outcomes, such as revenue generated by the tax (35), and community-level outcomes, such as the number of community organizations offering tax-funded programs. A secondary aim is to understand why (or why not) the policy "worked", including equity-focused implementation outcomes, may examine fidelity to the policy (e.g., were all groups of interest within the jurisdiction able to implement the policy as intended?), as well as perceptions of acceptability of the policy among historically disadvantaged groups. A tertiary aim for the Hybrid Type 1 approach is to understand whether there were unique barriers or facilitators within historically disadvantaged groups that impacted implementation. Addition of contextual and determinant factors allows for a comprehensive understanding: what unique assets facilitated implementation; what were barriers that could inform future implementation strategies? (36).

TABLE 1 Hybrid approaches for policy IS studies with an equity emphasis [adapted from Curran et al. (8)].

	Hybrid type 1 Policy effectiveness and implementation determinants + outcomes	Hybrid type 2 Policy effectiveness + implementation strategy feasibility	Hybrid type 3 Comparing implementation strategies + policy outcomes
Research aims	Primary aim: determine if policy is effective across groups, including historically marginalized groups; Secondary aim: determine policy implementation outcomes, including whether the policy was implemented as intended; Tertiary aim: determine if there are unique facilitators/barriers, including focus on assets and structural factors supporting/impeding implementation for historically marginalized groups	Co-primary aim: determine if policy is effective across groups, including socially minoritized groups; Co-primary aim: 2a. Determine if an equity- focused implementation strategy is feasible *or* 2b. Compare which equity- focused implementation strategy is most effective + implementation outcomes	Primary aim: compare which equity-focused implementation strategy is most effective Secondary aim: gather policy-related outcomes that are community- and/or partner-centered
Sample research questions	Effectiveness: is the policy effective and how do expected outcomes differ across historically marginalized groups? Implementation outcomes: was the policy implemented as intended across all groups/ settings? Determinants: what factors led to success or failure of the policy; and do historically marginalized communities experience unique barriers/facilitators	Effectiveness: is the policy effective and how do expected outcomes differ across historically marginalized groups? 2a. Pilot strategy: is a pilot strategy feasible in historically marginalized groups? What is readiness to implement the implementation strategy? 2b. Comparing (two or more) strategies: which strategies best facilitate implementation of policy, and across which historically disadvantaged groups?	Comparing (two or more) strategies: which strategies best facilitate implementation of policy, and across which historically disadvantaged groups? Policy outcomes: are policy outcomes acceptable to historically marginalized groups?

3.2. Hybrid type 2a—pilot

Type 2a approaches aim to understand policy effectiveness and pilot test a potential implementation strategy. There may be some evidence to support the policy but effectiveness data is still of interest. A co-primary aim is to understand whether the policy showed differential effectiveness across groups, which requires a baseline understanding of the existing historically disadvantaged groups and potential disparate health status. In addition, a co-primary aim for Type 2a is to test the feasibility of an implementation strategy and "preliminary effectiveness" of the strategy on implementation outcomes (e.g., adoption or fidelity); the latter could be part of a readiness assessment to understand whether historically disadvantaged groups and partners are ready to adopt the strategy of interest. Conducting a rigorous readiness assessment—with an explicit equity emphasis—is considered an important strategy for policy IS research.

3.3. Hybrid type 2b—comparison

Type 2b approaches may be considered when there is interest in comparing two (or more, including packages of) implementation strategies in their ability to facilitate implementation, along with implementation outcomes, such as adoption and fidelity. Like Type 2a, a co-primary aim is to measure effectiveness of the policy amongst the historically disadvantaged groups and/or across all groups of interest. Another co-primary aim is to compare effectiveness outcomes between the two (or more) implementation strategies. For example, the same sugary beverage tax study may compare two implementation strategies: (1) a retailer education program to improve knowledge of sugary beverage among retailers; versus (2) a random check monitoring strategy that checks compliance to sugary beverage tax, to determine which of these strategies was more successfully adopted with fidelity. This type of examination may also use a commonly applied framework—such as RE-AIM—to evaluate equity-centered implementation outcomes associated with each implementation strategy, such as how many and what types of retailers received the trainings, to understand if there was differential uptake across retailers and why (37).

3.4. Hybrid type 3

Type 3 studies are recommended when there is substantial "evidence" available supporting the effectiveness of the policy (e.g., a systematic review). Pilot testing of implementation strategies—including readiness assessment—would already be completed via a partner-informed approach. Like Hybrid Type 2b, the primary aim is to understand which of the implementation strategies (or packages) "worked" better in facilitating implementation of the policy (comparison of strategies). A secondary aim is to also gather policy effectiveness outcomes (as described in Type 1) to determine if there was success, including in historically disadvantaged groups.

3.5. Equity-centered implementation strategies

Figure 1 includes the design or refinement of implementation strategies across the continuum of types as an equity-centered activity. This process aligns with a "targeted universalism" process, where targeted strategies—not a "one size fits all"—are designed based on partner-informed data (22). There are several compilations of general (e.g., Expert Recommendations for Implementing Change (ERIC), school [e.g., School Implementation Strategies, Translating ERIC Resources (38)] and policy-specific implementation strategies [e.g., Bullock et al. (17)] available. In addition, once implementation strategies are identified, a partner-engaged readiness assessment is recommended to understand whether the target partners have the capacity and motivations to implement (39). Many of the processes used in designing for dissemination (e.g., stakeholder engagement, participatory codesign, context analysis) will facilitate partner-focused implementation (40).

4. Discussion

To our knowledge, this is the first paper that has described application of hybrid approaches for policy IS research. This paper is intended to be a starting point for discussion, particularly for the ways in which equity can be addressed in examination of policy implementation. Given the potential for policy IS research to advance public health on a population level, we strongly advocate that policy IS studies devoid of an equity approach provide a rationale for the omission.

We offer additional considerations toward this work. First, these typologies do not dictate the research study design; a wide range of designs (e.g., interrupted time series, mixed methods evaluations) may fit and importantly, should be dictated by research questions (9). Although hybrid studies were designed with experimental designs in mind (9), a policy-focused Type 1 hybrid study likely will apply an *observational implementation-effectiveness* hybrid approach since policies do not lend themselves to randomization in experimental trials, particularly studies including social determinants to health (36). Guidance is available for applying hybrid types to observational studies that are particularly salient for policy-focused implementation research; for example, studies may apply quasi-experimental or natural experiment designs that leverage existing or routinely collected (individual or aggregate) program or administrative data (36). Type 2 and 3 studies that test and compare implementation strategies may lend themselves to prospective, experimental studies. In selecting study designs for policy-focused implementation science work, researchers highlight the need to balance the goals of academic rigor with partner- and community-members' capacities and willingness to participate (7).

Second, the examination of policy implementation is necessarily complex and fraught with feedback loops, (un) intended outcomes and consequences due to political, economic, and social inequities (3, 4). **Figure 1** is necessarily simplistic. For example, a policy IS hybrid study that examines implementation of a smoke-free public housing policy requires an understanding of social determinants of health—such as access to safe housing, environmental exposure to toxic chemicals—and the impacts of structural racism on policy implementation. The study may intersect with housing, health, and policy sectors, along with a wide range of policy actors and community groups (e.g., public housing residents). Researchers are required to manage the complexity of these multi-level determinants, intersecting sectors, and potential (un)intended outcomes that will shape the research findings (3).

Lastly, policy IS studies can contribute best to health equity by elucidating which policies have the maximum impact on structural support and social determinants of health (5). To this end, instrument development for policy specific implementation outcomes is needed, currently there are some tools for school settings (41, 42) and more broadly (31); however development and testing—including for qualitative data—remains nascent. In addition, examples of policy-specific implementation strategies are organized by target organizational level (e.g., educational trainings) vs. policy authority level (e.g., appointment of state leaders to garner resources) (17). Not captured in these examples but are important considerations include: small "p" policies as an important space to examine equity; as well as when implementation strategies are best targeted to the policy cycle (e.g., exploration, preparation, initial implementation, full implementation, and sustainment) (17). Further work is needed to build the body of literature examining both policy-related outcomes and implementation strategies (6, 32).

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

YA led the writing and conceptualization of this manuscript. All co-authors contributed to the conceptualization of the paper and provided substantive feedback over several iterations of the manuscript draft. 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.

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Health policy considerations for combining exercise prescription into noncommunicable diseases treatment: a narrative literature review

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Objectives: In this review, we aim to highlight the evidence base for the benefits of exercise in relation to the treatment of noncommunicable diseases (NCDs), draw on the Health Triangular Policy Framework to outline the principal facilitators and barriers for implementing exercise in health policy, and make concrete suggestions for action.

Methods: Literature review and framework analysis were conducted to deal with the research questions.

Results: Exercise prescription is a safe solution for noncommunicable diseases prevention and treatment that enables physicians to provide and instruct patients how to apply exercise as an important aspect of disease treatment and management. Combining exercise prescription within routine care, in inpatient and outpatient settings, will improve patients' life quality and fitness levels.

Conclusion: Inserting exercise prescription into the healthcare system would improve population health status and healthy lifestyles. The suggestions outlined in this study need combined efforts from the medical profession, governments, and policymakers to facilitate practice into reality in the healthcare arena.

KEYWORDS
exercise prescription, health policy, noncommunicable diseases, medical provision, health policy triangle framework

1. Introduction

The 2011 United Nations Declaration on Noncommunicable Diseases (NCDs) recognized the importance of NCDs as a global health issue, particularly for low- and middle-income countries (1). NCDs are highly prevalent, costly, and are responsible for more than 74% of deaths worldwide, totaling 41 million people each year (2). In all but 20 countries, prior to the Covid-19 pandemic individuals were at a greater risk of premature death from NCDs than from all communicable diseases, maternal problems, perinatal issues, and poor nutrition combined (3). An estimated 17 million people die globally from NCDs before the age of 70, and 86% of these recorded premature deaths occur in low- and middle-income countries (4, 5). The four main groups of NCDs are cardiovascular diseases, cancers, chronic respiratory diseases, and diabetes. These diseases are responsible for over 80% of premature NCD deaths. Disease onset has several underlying modifiable risk factors, including using tobacco, the use of excessive alcohol, sedentary behavior, and unhealthy diets (6). The patient suffering and family economic burden resulting from NCDs is associated with profound negative consequences for families, health care systems and countries (7). The United Nations has estimated that the burden of chronic disease cumulative cost to the global economy may reach $47 trillion by 2030 if current trends do not change (8). NCDs have been included in the Sustainable Development Goal (SDG) Target 3.4. This target has been established to reduce premature mortality by one-third by 2030, through improved NCDs treatment and prevention, in addition to promoting mental health and well-being (3, 9).

The beneficial impact of exercise on health has been well documented since the 5th century BC; this relationship has been investigated, defined and reinforced by many years of scientific research. The evidence indicates a strong and consistent positive association between exercise participation and health status (10–14). Many systematic reviews and meta-analyses have revealed the comprehensive benefits that can be obtained from physical exercise (15–19). Exercise as a validated methodology has endured the test of time and can help individuals develop healthy lifestyles (20). Exercise is also a proven applied intervention for addressing illness and improving health and wellness (21). For example, exercise has been used in both the prevention and treatment of many chronic conditions such as pulmonary disease, heart disease, obesity, and diabetes (22, 23). Each year, hundreds of billions of dollars are invested in healthcare provision for NCDs; exercise interventions can often provide similar and/or greater health benefits as those provided by pharmaceutical interventions, without most of the associated expenses or the problematic side-effects (24, 25). In some instances, exercise can complement and influence traditional medicine treatments while enhancing the medicinal positive effect (26). The World Health Organization provides general exercise guidelines and recommendations for different age groups and specific populations. These groups include postpartum and pregnant women, individuals that have chronic conditions, and the disabled. The guidelines outline in brief the quantity of physical activity that is required for health benefits (27). However, the guidance is not targeted for individual NCD patients and cannot be used to prescribe individualized specific exercise programmes.

Exercise prescription (EP), based on the findings of previous studies, can be defined as: written and structured instruction by supervised/medical staff that establishes and uses supported exercise programmes that are clearly defined and contain elements of exercise advice stating exercise type, intensity, duration and frequency. Prescribing exercise should also include the patient's health, exercise ability and cardio-pulmonary function based on medical examination and treatment outcomes (24, 25). Exercise prescription can be implemented by clinical exercise physiologist and qualified exercise professional physicians in a variety of settings (28). However, an interview study completed at the national level in the United States revealed that only 32% of patients received advice about exercise or the benefits of continuing to be physically active during visits with a physician (29). Physician counselling and exercise prescription referrals may be helpful for reducing morbidity and mortality rates from NCDs (30). Unfortunately, most physicians, who are traditionally trained (pharmaceutically or medically) to manage noncommunicable disease have not been extensively trained in exercise prescription at their associated medical schools or healthcare institutions (30).

Enhancing primary health care using exercise prescription is a low-risk, cost-effective approach to maximize health benefits at population levels. For this to be achieved there is a requirement for medical systems to create the necessary infrastructure and environment to ensure that supervised exercise can be prescribed as medicine. Exercise prescription is an additional healthcare provision that enables physicians to support their patients to engage in exercise as part of their disease prevention and treatment (22). Realizing these benefits to health care needs to be facilitated by large-scale investment from governments, non-government organizations, and the private sectors (2). Healthcare systems around the world are highly disparate, and vary according to the level of development in a particular country, and in local and national public health service provision. For example, inequality in health services coverage is common across South Asia, and the service does not achieve the key global target of at least 80% of essential health care service coverage (2). A 2020 World Health Organization survey revealed that the ongoing COVID-19 pandemic was disrupting NCD services in 122 of 159 countries; the combination of COVID-19 and NCDs has had devastating consequences for many patients' access to health systems (5). There needs to be a stronger political commitment, the development of institutional and human capacity, and creative sustainable solutions to finance health systems that offer the widespread provision of exercise prescription within medical services at affordable rates (2).

Most intervention and review studies designed around physical activity and exercise therapy are terminated at the efficacy trial stage, without transfer as best practices for clinical provision systems and public health policy-making processes (16, 18, 31–34). As the available evidence indicates that exercise is effective as a treatment for NCDs, exercise treatment should be sufficiently recognized as a stimulating and beneficial policy change in the healthcare and wellness agenda. In the previous two decades, numerous health policy studies have focused on how to manage and improve treatment performance and outcomes (35). However, public health policy changes can also be implemented to provide a strategy to create better conditions for population health.

Based on the narrative provided above, this article aims to provide evidence, and outline a feasible plan for consideration, to implement exercise as medicine for future NCDs medical treatment provision. This article has been divided into three main sections. First, the article outlines the evidence base underpinning exercise as a medicine for NCDs. Second, the article discusses the health policy-making process, drawing on the Health Triangular Policy Framework. Third, the article presents specific suggestions for exercise prescription in the medical provision system.

2. Methods

2.1. Literature review

A structured comprehensive search strategy was conducted using PubMed, Google Scholar, Embase, Web of Science, Scopus and ProQuest to identify publications in English using search terms in the titles and abstracts (search strategies were adjusted to fit different databased setting): 'exercise prescription', 'exercise treatment', 'health policy', 'medical system', 'clinical provision', 'healthcare', 'inpatient', 'outpatient', 'noncommunicable diseases', 'cardiovascular diseases', 'cancer', 'respiratory diseases', 'diabetes'. The search process was focused on original studies and reviews articles (in peer-reviewed journals) over the last 15 years. Further related articles were identified from reference lists of retrieved articles; and authority data (e.g., WHO) that were also considered. A total of 76 articles were finally included and the literature search was completed on November 16, 2022.

2.2. Framework analysis

Our health policy-making analysis below is based around the Health Triangular Policy Framework (HPF) (36). The HPF was developed in 1994 by Wall and Gilson, and has been used in a retrospective or prospective manner to analyze many health-related policy issues (37). The framework highlights how policy implementation is influenced by the elements of policy *Content*, *Context*, and *Process*, and also emphasizes the influence of *Actors* on these three elements in the policy-making process (38). In the HPF, *Content* includes policy objectives, operational policies, legislation, regulations, and guidelines. *Context* refers to systemic factors: social, economic, political, cultural, and other environmental conditions. *Process* refers to the way in which policies are initiated, developed or formulated, negotiated, communicated, implemented, and evaluated. *Actors* refer to influential individuals (such as senior policy- and decision-makers), groups, and organizations (see Figure 1) (36). Studies have used this framework to analyze health policy issues in contexts as diverse as Kenya (39), Cambodia (40), and the Eastern Mediterranean regions (37).

3. Results

3.1. Exercise as a treatment for NCDs

Physical exercise is increasingly recognized as of importance in the primary medical care of at least 35 chronic diseases. Exercise not only reduces the risk of developing new chronic NCDs, but also decreases the progression of many existing chronic noncommunicable conditions while improving quality of life (41, 42). Specifically, the significance of exercise intervention as the first-line treatment for several chronic NCDs has been investigated extensively during the past two decades (26). Exercise may induce modifications in gene expression, and affect cardiovascular risk, musculoskeletal function, pulmonary function, hyperinsulinemia, sensitivity to insulin, oxygen consumption, fasting plasma/blood glucose intolerance, body fats, cholesterol, blood pressure, dosage of antidiabetic medications, immunity, sleep quality, self-satisfaction, and consequently general health and fitness. Furthermore, exercise can also improve aerobic capacity, and the mental health of patients (7, 17, 33, 34, 43).

Not everything is known, of course, and there remains important work to be done to explore the different types and dosage of exercise that are suitable for exercise prescription following specific diagnoses and conditions for NCD patient populations. A 2008 American College of Sports Medicine (ACSM) report noted, for example, that Moderate to Vigorous Physical Activity (MVPA) reduced breast and colon cancer risk. In 2018, the ACSM report was expanded to include more types of cancers whose risk was reduced by MVPA. These included endometrial, esophageal, kidney, lung, stomach, and bladder cancers (7, 41). Engagement in regular exercise activity is not only feasible and safe for cancer patients but also improves the tolerance for treatment, facilitates recovery, reduces the length of hospital stays, slows progression, and reduces risks associated with recurrence, readmission, and mortality (44).

3.2. Exercise intervention guidelines and education for NCD patients

The 'Health Care Providers Action Guide' was developed by the ACSM. It outlines six basic steps for working with health care providers and patients to facilitate and manage medical referrals, including assessment of the physical activity levels of patients, determination of patients' readiness to change, prescription of exercise for patients, provision of patients' physical activity referrals, and promotion of exercise in clinics (45). Several resources have also been developed, including exercise implementation tools, handouts, and patient reports. Examples such as physical activity algorithms with an initial assessment by a nurse or clinician, link into exercise prescription and patient education, concluding with suggested readings to encourage patients to change behavior from inactive to active (46). Adaptation of the physical activity algorithm into clinical practice allows for an opportunity to increase patients' participation in their own health outcomes using a prescribed exercise routine. Similar forms of guidance have been developed by ACSM and other organizations: examples include ACSM guidelines on using exercise for cancer survivors (47); the Enhanced Recovery After Surgery (ERAS) programme (48); and the Pulmonary rehabilitation exercise prescription in chronic obstructive pulmonary disease guidelines etc. (49).

Exercise education and consultation are further relevant factors for patients with NCDs. The identification of patient intervention capacity and suitability can be achieved by considering the various contraindications and constraints, preferences, barriers and facilitators for exercise, and the potential benefits relevant to them, whether those be physiological, psychosocial or economic (50). Further steps, aims and objectives of exercise need to be prioritized according to the most valuable outcome for the patients (e.g., symptom management, improving mood, minimizing a decline in cardiorespiratory fitness, reversing loss of muscle mass, survival etc.). Therefore, it is essential to provide the patients with information relating to the exercise components that are necessary for achieving specific goals. It is worth noting here that some may prioritize long-term exercise benefits over short-term goals, physiological over psychosocial or functional benefits, and that the goals and priorities for many will likely change over time (50). The flexibility of exercise education and consultation

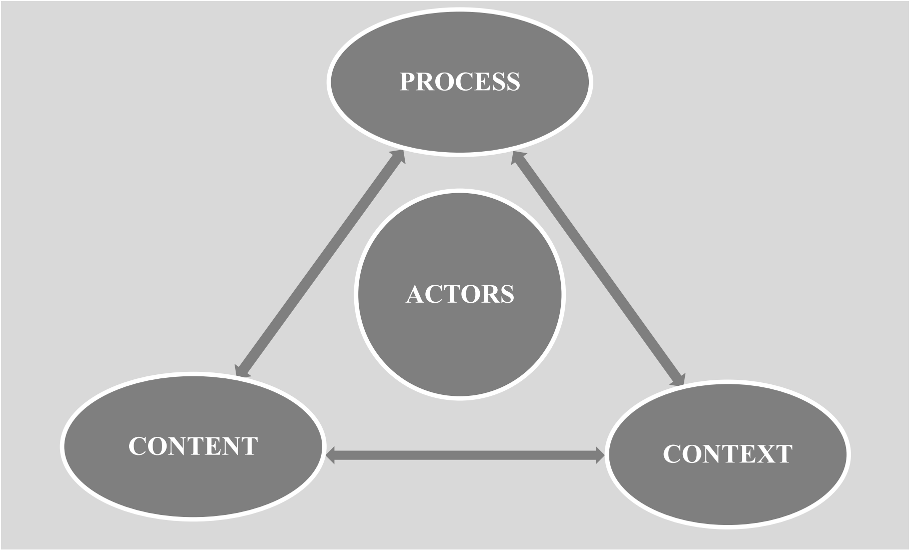

FIGURE 1
Health policy triangle framework (HPF) model.

are particularly important when patient exercise preferences fail to align with achieving their desired goals (50). Physical exercise education and consultation are facilitators for NCDs patients to participate in exercise programmes. The skills and knowledge developed by patient education and exercise guidelines may provide confidence and competence in minimizing adverse reactions to related individual medical situations, such as the fear of hypoglycemia. Additionally, health professional training and improving community engagement is also essential in exercise prescription support following discharge, based on the physician's guidance (51).

3.3. Multidisciplinary team care

The scope of exercise prescription practice is dynamic and can be responsive to the needs of patients and society. The ideal condition is for health services to provide adequate recognition and support for interdisciplinary intervention through proper legislation and policies (52). Unstructured referral from physicians deprives patients of medical services such as diagnosis, health promotion, and complication prevention (53). The most significant considerations for implying multidisciplinary team care are cost and convenience (54). In primary care, physicians, nurses, physiotherapists, and other health professionals working together in a medical services team is an effective strategy to achieve multidisciplinary health service goals. Furthermore, at the primary health care level, organizing people-centered integrated health services that are safe for patients and of assured quality with effective referral networks between basic health care and hospital care is essential (53, 55, 56). Multidisciplinary practice can be aided by standardized procedures, policies, and regulations. Furthermore, the organizational structure of service delivery and clinical responsibilities suggests that it can be responsive to the needs of patients and communities rather than practitioner-led delivery (53).

Health clubs and personal trainers are traditional outlets for the promotion of physical activity and exercise regimens, and physicians are not depending on these partnerships to promote physical activity to their patients in a sufficient manner (54). Not only is inter-hospital collaboration required, collaboration between physicians and community practitioners is an important link for patients with NCDs after they leave the clinic or are discharged from the hospital (54). Fostering multisectoral public and commercial partnerships that bring together government and society to promote health policies is vital to address concerns such as financing, accessibility, efficiency, and the quality of health care (57).

3.4. Barriers to exercise prescription implementation

From a patient perspective, common reasons for non-adherence to exercise prescription include physical and psychosocial factors such as patient missed sessions, dropouts because of wellness problems, hospital readmissions, disease progressions, adverse skeletal events, or a paucity of interest, motivation, knowledge and/or confidence (24, 44, 51, 58). From an institutional and physician perspective, major barriers for service integration are related to limited funding, lack of a detailed implementation plan, limited availability of suitable programmes, and low organizational buy-in (lack of public funding and resources). In addition, the physicians' characteristics of lacking exercise science educational backgrounds, related knowledge, and specific professional qualifications have also been noted as detrimental (24, 32, 44, 51, 58). Furthermore, in real work situations the lack of time for counselling, workload pressures, and extra work concerns, would all disrupt clinic efficiency and have been identified as related issues contributing to barriers for providing exercise prescription to patients (58). Some accessibility barriers related to location, cost and exercise schedules coinciding with treatment days have also been identified. In addition, political and economic context arrangements, such as minimal structured reimbursement policies; and barriers related to collaboration and leadership with stakeholder and other actor groups in social context are also issues that cannot be ignored (58).

3.5. Related examples

Among the documented international examples of effective uses of exercise in the prevention and treatment of NCDs are the following three initiatives:

- Singapore has adapted a systematic approach for integrating exercise as medicine into the disease and management pathway. This resulted in the design of an Exercise as Medicine template, and progressively incorporated the Physical Activity Vital Sign (PAVS) structure into electronic case notes in numerous departments at Changi General Hospital. The mainstay of Exercise is Medicine (funded in 2007 by the American College of Sports Medicine) in the Singapore development is to train physicians in the prescription of exercise (22).
- Another example is the implementation of tailored exercise interventions for women following breast cancer diagnosis in Brisbane, Australia. A supervised exercise intervention led to significant improvements in fitness parameters and significant decreases in breast cancer health care utilization (32) This provided a cost-effective treatment compared to usual care with eight-year follow-up (59).
- A further example comes from the Jewish General Hospital, Montreal, Quebec. During the operation of a Rehabilitation and Exercise Oncology model of care (ActivOnco), patients were encouraged to participate in exercise based on individual goals and preferences in a group environment or individual setting (60). Most of the referrals (71%) came from members of the multidisciplinary team, including nutritionists, nurse coordinators, social workers, and treating oncologists (60). The programme benefited from easy access to medical records, and interaction with medical teams providing constant updates on the treatment and medical status for patients and patients' families (50).

3.6. Health policy analysis

Health policy design comprises a set of decisions, plans and actions taken within a society to achieve a specific healthcare goal, or a set of actions taken by an agency or organization at the national, regional or local levels of government to promote public health (36). Based on the evidence discussed above we can reasonably claim that NCDs patients would be greatly advantaged by a healthcare system shift in conceptualization toward an exercise health promotion initiative, including re-orientation of the general practice environment and collaboration with exercise professionals in inpatient and outpatient provision. At a societal level, healthcare support includes developing practical infrastructure, equipment base and peer networks; and improvements in the confidence of patients for exercise interventions, making them more receptive to exercise prescription. The following table outlines the health policy-making analysis for implementation of exercise prescription in regard to NCDs (See Table 1).

4. Discussion

4.1. Applying a formal exercise prescription curriculum in the physician training system

There is evidence that providing effective exercise guidance for patients can help increase physical activity levels and decrease disease rates, thereby reducing the financial burden on governments (28). However, exercise prescription or physical activity advice for patients with NCDs are not included in the academic curriculum of most medical professionals (30, 61, 62). A previous survey outlined a lack of formal undergraduate medical education knowledge related to the medical benefits of exercise and physical activity in 1975. Subsequent surveys since 1975 have demonstrated little improvement (30). For example, most US medical students do not have the competence, skills, or confidence to counsel patients on exercise prescription following graduation (30). It is essential that newly qualified physicians are aware of the role that exercise as medicine can play in treating and preventing disease. A more recent study reported that exercise guidelines and exercise prescription education programmes provide the tools and knowledge to assess properly patients' activity levels and offer individualized recommendations, while also increasing practitioner confidence to engage in exercise prescription (28).

Physicians may lack knowledge and confidence to prescribe exercise as medicine because of the paucity of detailed instruction in medical schools (63). Training and education for physicians on the benefits of different modes of exercise prescription, and how to structure exercise intervention to each patient's needs, can empower them with confidence and knowledge (28). Conceptualization and implementation of an exercise prescription medical education course is needed to provide health care staff with the ability to assess, counsel, and refer patients for physical activity and exercise. This development is crucial to prevent and treat chronic noncommunicable diseases and is required urgently (22). Exercise prescription training needs to be integrated into most of phases of medical education, and can be facilitated in medical schools, residency programmes, credentialing processes and continuing education requirements (30). The development and implementation of professional standards must include performance and ethics, standards of conduct, and core clinical skills. They need to be established under a standards development framework in which all aspects are evidence-based, benchmarked against international standards such as those of the American College of Sports Medicine, and consistent with the needs of patients and practitioners (61). Assessment of the quality of education and training programmes is also required, to ensure they give clinical exercise physiology graduates the skills and knowledge to practice safely and competently. A university curricula programme accreditation framework should be developed based on current national health service provision models (61). There may also be a need to include specialized mandatory courses and conduct an evaluation of exercise prescription within the physicians' final examination for the degree.

There is also a requirement to develop physicians' communication skills to enable them to guide patients in the behavioral change scenarios of exercise adaptation and maintenance in daily life. Furthermore, physicians need to be encouraged to engage with community physical activity/exercise resources, which is consistent with the evolution of patient-centered care (30). When medical students graduate, they should be able to demonstrate proficiency in the prescription of exercise

TABLE. 1 The health policy-making analysis for implementation of exercise prescription into the noncommunicable diseases medical provision based on the health triangular policy framework.

Items	Details
Actors	• *National and regional governments* that develop the policy and local governments that deliver and implement the policy • *The hospitals* where exercise prescription is specially used • *Medical schools and universities* that provide resources for physicians who are qualified to prescribe exercise • *Business organizations* that provide the resources for exercise tests and exercise practice equipment • *Community healthcare providers* that ensure follow-up to exercise prescription • *Researchers* in the field that provide valid references to guide both healthcare providers and patients • The *patients* with NCDs
Content	• The *provision of medical healthcare* for NCDs is modified to include exercise prescription within routine care for the patient as the main content • A *physician's professional qualification* in exercise prescription is a basic requirement • Evidence-based *exercise guidelines and consulting guidance principles* that can be tailored for the individual patient into scientific professional exercise prescription • *Implementation* of the prescription, including instruction and guidance for individual patients • *Follow-up monitoring* of how patients implement the prescription after they leave the clinic or are discharged from the hospital, and the impact on their health
Context	• The *hospital or clinic setting* – the inpatient or outpatient environment – where patients and medical professionals interact • The *medical training system* where expertise in exercise prescription can be acquired • The *domestic, local, broader societal environments and home-based exercise programme* for all patients receiving exercise prescription • *Political, economic, cultural, social, national, regional, local, and international factors* that can affect or influence policy development, and shape the context for health policy-making
Process	• *Assess* possible exercise intervention options based upon a theoretical foundation from scientific sources of evidence and information • *Analyze* the patients' health level or medical needs, and the alignment of actual activities implemented with the proposed policies • *Break down the boundaries* between traditional health exercise science and exercise as a medicine treatment • *Develop* detailed health policy choices for providing inpatient and outpatient exercise interventions, then choose the most cost-effective options • *Implement* policy in the inpatient and outpatient settings of both primary and secondary healthcare • *Ensure* that relevant legislation and government policies are consistent with and supportive of the implementation of exercise prescription • *Evaluate* the policy effect

and assessment; and should also be knowledgeable about the principles of exercise counselling and behavioral strategies related to patients' personal health (30). Additionally, developing collaborations between medical schools/universities and healthcare institutions not only provides more exercise medicine practical information, but also provides internship opportunities.

There is a programme available in the US called Exercise is Medicine Greenville (EIMG). This is the first partnership engaging a medical school, a health care system, and a community organization combining resources collectively to educate physicians on the clinical benefits of exercise (22). Several universities have now successfully incorporated sports and exercise medicine into their medical curriculum in places as diverse as Colombia, South Carolina, the United Kingdom, and Iran. These curricula have included a focus on exercise medicine and how to successfully prescribe exercise for patients (30, 64–67). This extensive system needs further development, consolidation, expansion, and exploration as a model of best practice.

4.2. Guarantee adequate exercise medicine resources

The installation of an exercise prescription facility within existing NCDs medical care provision settings may require slight infrastructural adjustment to ensure the availability of suitable spaces, and any necessary equipment, to provide instruction in different forms of exercise. There will also be a need for the hiring of experienced exercise science specialists, and medical staff who possess exercise prescription skills. A concerted effort is required to identify and develop the correct implementation strategies to stimulate a cultural shift and debate in the host organization (44).

Exercise testing is necessary when health/fitness and clinical exercise professionals are concerned about individuals' risk, or when they require additional information to design exercise prescription (68). An 18-year cross-sectional study provided data on the safety of clinical Chinese population-based exercise testing, and was expressed as the number of adverse events per 10,000 tests (using 95% confidence intervals). These results suggested that clinical exercise testing was safe and that the low incidence of adverse events recorded might be due to the overall changes in clinical practice over time (69). In real practice, the clinical exercise test would need to meet three important aspects: address patients' needs, be time efficient, and be cost-effective. NCDs patients should be screened using a health risk appraisal questionnaire or a self-reported medical history (including patients and family health history, comorbidities, additional chronic diseases and related treatments, and physical activity and exercise history). An example would be the modified American Heart Association/ACSM Health/

Fitness Facility Preparticipation Screening Questionnaire (41) for the presence of risk factors for various cardiovascular, pulmonary, renal, and metabolic diseases as well as other conditions such as pregnancy and orthopedic injury that require special attention when developing exercise prescription. Further medical evaluation measures, including blood pressure, heart rate and some anthropometric indicators should also be conducted to determine any health issues that contribute to risks of morbidity and/or mortality. Physical activity assessment needs to be incorporated into standard medical examination routines during clinical visiting and as part of the treatment plan (22). This recommendation should be considered not only for patients at high risk of exercise-related complications; regular exercise testing should be recommended for all patients prior to participating in a light- to moderate-intensity exercise programme (68). Evidence-based, specific, and valid measures of physical status would aid physicians in examination and discussion of exercise prescription with patients (70).

Technology-based support, such as mobile-technology, wearable devices, texts, and emails, improves compliance among patients and has been validated previously (31, 71–73). Suggestions to design and develop special software/applications to enhance exercise prescription adherence are gaining momentum. Digital support tools can be used for the purpose of including information such as the patient's medication history, illness, and physical fitness levels; follow-ups using remote monitoring after outpatient's service or discharge should be attractive to many healthcare systems and providers. Using these methodologies, patients can live at home and by using multiple intelligent devices communicate with the physician to access supervision and instructions. This communication helps with follow-up over the next weeks or months to monitor compliance with exercise prescription and provide encouragement. This method can also expand the opportunities for increased accuracy and acceptance of exercise intervention. Remote consultation is also featured by consistency and regularity, low cost and acceptability to the patient's family. In addition to the digital health system mentioned previously, the workflows for exercise prescription will need to be compatible with existing workflows and working procedures to limit burdens and increase efficiency (24).

Community exercise resources are another important component for effective exercise continuation in compliance with physician's instructions following discharge. Health providers and physicians will often wish to refer patients to community resources to integrate exercise into their daily lives. These include the use of self-directed resources, such as public sports facilities, bike-sharing programmes, and the use of local parks (22). Aligning community and healthcare partners to provide a clinic-to-community model may be beneficial for implementing exercise as a core prevention strategy for assisting patients who are at risk for NCDs, to regress, reverse, and minimise the progression of disease (74).

4.3. Effective evaluation for exercise prescription implementation

For general practitioners and fitness related personnel, focusing on the theoretical study and practical operation of exercise interventions for NCDs needs to be re-evaluated. The potential way to ensure the quality of exercise prescription is the development of an exercise prescription credential to recognize qualified and certified fitness professionals who work with patients referred from health care providers (22). This includes medical practice, health care knowledge, NCDs prevention and treatment, exercise rehabilitation, and scientific exercise understanding. Follow-up evaluation after the implementation of the policy should not be ignored, and investigations and surveys should be conducted to further determine the effectiveness of exercise prescription implementation, as well as patients' confidence levels and intervention effects.

4.4. Including exercise prescription into medical insurance programmes

Achieving universal health coverage (UHC) is a sub-target of the Sustainable Development Goals (SDGs) (36). The acceptance and coverage of government universal medical insurance and commercial insurers to include exercise prescription in the claim for reimbursement is the cornerstone of long-term development of exercise prescription. Medical insurance system support is essential for physicians and patients to adhere to exercise prescription. If medical insurance policies generally provide more reimbursement for inpatient care, this incentivizes patients to use hospital resources for even minor health conditions, and therefore inhibits healthcare treatment from primary clinics (75). The government's healthcare policy could support the treatment of most NCDs in outpatient settings. This would provide savings in medical resources and medical expenses and improve the health level of the entire population in the long term. In addition, this provision would increase the treatment capacities of related hospitals and healthcare establishments. For example, outpatient medical body checks/tests related to patient symptoms and physical exercise ability, should be part of every physician's exercise prescription, and follow-up exercise medical assistance should be reimbursed as usual. The implementation of exercise prescription in clinical provision would reduce the expenditure of drugs, intravenous infusion therapy and inpatient care. On the other hand, it also indirectly reduces the expenses of inpatient medical reimbursement and provides a virtuous healthy cycle. Nevertheless, medical insurance policies should set a limited coverage for exercise prescription in primary health care/clinic provision, by means of setting a maximum limit for total reimbursement, to avoid over-use of medical services. Figure 2 provides a general outline of the suggestions of implementation of exercise prescription.

5. Conclusion

Based on the available evidence, exercise is a powerful intervention to prevent and manage NCDs, improve patients' life quality and mitigate the effects of chronic diseases, and lower mortality rates. Exercise prescription is a non-pharmaceutical health intervention and should be promoted in combination with traditional medical support. Individual patients will be at different stages of readiness to participate in exercise, and each will present with different unique health and environmental challenges, so the individual prescription of exercise recommendation is necessary and beneficial. This review summaries the evidence and suggestions for implementing exercise prescription into the NCDs medical healthcare provision. The information provided here also identifies barriers that need to be overcome for success in implementation of the health policy-making process. There is a paucity of studies documenting the process of exercise as medicine in different and varied healthcare settings. This gap creates difficulties for providers, in the selection and choice of appropriate strategies at

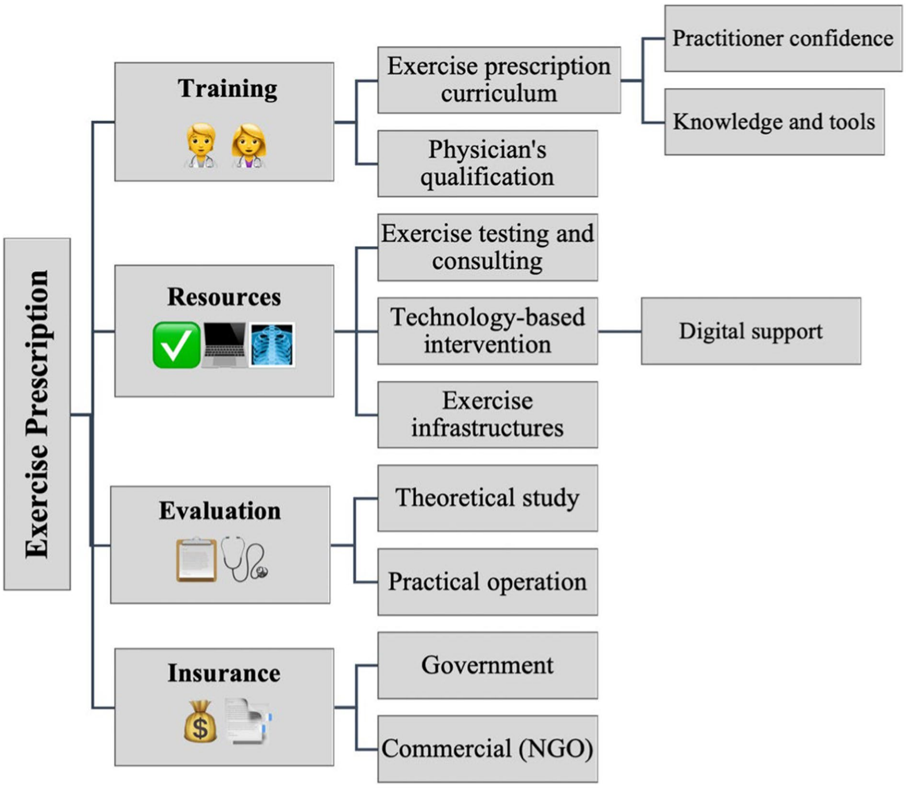

FIGURE. 2
Map of exercise prescription implementation.

organizational levels that recognize the factors enabling the adaption and development of new working methods. Healthcare professionals also need to be aware that prescribing exercise as medicine in one particular setting may not be applicable and beneficial in the same way when implemented elsewhere. Medical practitioners need to select and modify appropriate and useful strategies at each organizational level, recognizing the combination of factors that enable development and adoption of new working practices.

Inserting exercise prescription into the healthcare system would improve population health status and healthy lifestyles. We have attempted to link the literature to the structure of the specific policy-making process, bridging the gap from theory to practical implication suggestions. Following the scientific policy-making process and suggestions, we need to keep the general alignment between policy and practice to ensure long-term success, effective implementation, and delivery. The suggestions outlined in this study need combined efforts from the medical profession, governments, and policymakers to facilitate practice into reality in the healthcare arena.

Author contributions

DT performed writing-original draft, conceptualization, and data interpretation. DT and JSB performed the literature searches and contributed to the screening process and selection of included studies. DT, RA-S, GIA, and JSB performed writing-review and editing, verification. ZP, YDG, YG, AC, RS, YS, and RX provided critical feedback on the protocol. YDG performed project administration. 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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How policy implementation shapes the impact of U.S. food assistance policies: the case study of the Child and Adult Care Food Program

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Much of the chronic disease burden in the U.S. population can be traced to poor diet. There has been a sustained focus on influencing children's diets and encouraging healthier eating habits by changing policies for what foods and beverages can be served to children through large federally-funded nutrition assistance programs. Yet without attention to how nutrition policies are implemented, and the surrounding context for these policies, these policy changes may not have the intended results. In this perspective, we used Bullock et al.'s (2021) Process Model of Implementation from a Policy Perspective to analyze how the complexities of the implementation process of large-scale nutrition policies can dilute potential health outcomes. We examine the Child and Adult Care Food Program (CACFP), a federal program focused on supporting the provision of nutritious meals to over 4 million children attending childcare, as a case study. We examine how the larger societal contexts of food insecurity, attitudes towards the social safety net, and a fragmented childcare system interact with CACFP. We review the "policy package" of CACFP itself, in terms of its regulatory requirements, and the various federal, state, and local implementation agencies that shape CACFP's on-the-ground implementation. We then review the evidence for how each component of the CACFP policy implementation process impacts uptake, costs, feasibility, equity, and effectiveness at improving children's nutrition. Our case study demonstrates how public health researchers and practitioners must consider the complexities of policy implementation processes to ensure effective implementation of nutrition policies intended to improve population health.

KEYWORDS

policy, implementation science, nutrition assistance, childcare, public health

1. Introduction

The United States (U.S.) faces substantial public health challenges related to poor nutrition. Diet-related chronic diseases (1)—including heart disease, stroke, type II diabetes mellitus, and certain types of cancer (2, 3)– are experienced by most U.S. adults, contributing to poor health and early mortality (4, 5). Moreover, inequities in access to affordable, nutritious foods have resulted in socioeconomic and racial/ethnic disparities in diet quality (6–8). Income and race are also closely linked with a higher risk of food insecurity (9), which further increases the risk of both poor diet and cardiometabolic diseases (10, 11). These problems start in childhood (2, 12, 13).

To address these population-wide challenges, policymakers have leveraged federal child nutrition assistance programs, such as the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), the National School Lunch and Breakfast Programs (NSLP/SBP), and the Child and Adult Care Food Program (CACFP), as policy levers for achieving public health nutrition goals (14–17). These programs, which provide financial support to improve food security and access for Americans, especially those with lower incomes, show promise for improving diet quality and reducing health inequities. In recent years, efforts to bring minimum nutrition standards for WIC and NSLP/SBP in line with current dietary science have resulted in substantial improvements in the diet quality and chronic disease risk of program participants (18–24), suggesting that policy changes to these programs can be a promising approach to population health. However, similar updates to CACFP appear to have had less strong effects (25).

In this perspective, we use a conceptual framework of policy implementation, developed by Bullock et al. (26), to outline the challenges in leveraging federal nutrition policies as public health interventions. We specifically examine CACFP, which provides reimbursements to child and adult daycare providers to support serving meals and snacks meeting basic nutritional standards (27), as a case study (we focus here solely on childcare providers and child-level outcomes, given that these are the majority beneficiaries of CACFP). Given that CACFP appears to have less consistently strong impacts on child nutrition compared to other federal nutrition programs, we seek to understand how its policy implementation process may explain why.

2. Conceptual framework for the analysis

Bullock et al.'s Process Model of Policy Implementation (2021) (26) posits that policies are first borne out of a larger context of existing ideas, interests, and other external factors that determine how a problem is defined and whether it is addressed by policy in the first place. This brings about the development of a policy package, a collection of strategies like regulations or statutes, economic incentives, voluntary guidelines, or information campaigns. The implementation process of the policy package then flows through implementing organizations to street-level bureaucrats to recipients. To evaluate policy implementation, outcomes at several levels can be considered, including implementation outcomes (28) (e.g., fidelity, uptake, acceptability, costs, feasibility, sustainability), service outcomes (e.g., effectiveness, equity, efficiency), recipient outcomes (e.g., changes in actual recipient behavior, satisfaction), and policy/system level outcomes (e.g., reductions in food insecurity at a population level).

Figure 1 presents an adaptation of Bullock et al.'s model for this paper's analysis of CACFP. In the following sections, we explore each of the key phases of the implementation process described in the Process Model—context, developing the policy package, processing through implementing organizations, street-level bureaucrats, and recipients, and finally outcomes—for CACFP.

3. CACFP's implementation process and how its attributes determine implementation outcomes

3.1. Outer context: child food insecurity, child development, the childcare industry, and attitudes towards social safety net programs

CACFP exists in a larger context related to child health, and specifically children's nutrition, in the U.S. Food insecurity currently affects 12.5% of households with children in the U.S. (9). Additionally, even for children not experiencing food insecurity, the nutritional quality of foods available to and consumed by children is often poor, with high amounts of inexpensive, highly palatable ultraprocessed foods (29) and inadequate consumption of vegetables, whole grains, and lean protein sources (12, 30). Several decades ago, a key dietary concern was inadequate intake of essential micronutrients; more recently, overconsumption of foods and beverages that can lead to excess weight gain for healthy growth has become a concern for children (31–36).

While social safety net programs have been designed to mitigate these public health nutrition challenges for households with low incomes, there are disagreements on how comprehensive the programs should be (37).CACFP falls within this challenging context.

This struggle can be seen in CACFP's history (38). CACFP's roots lie in a federal pilot program called the Special Food Service Program for Children, started in 1968, at a time in U.S. history when the social safety net was being radically expanded through President Lyndon B. Johnson's "War on Poverty". This program was expanded and formalized into CACFP across the 1970s and 1980s providing childcare providers with resources to serve free rather than including meal costs in tuition or not serving meals at all (38). However, in the Personal Responsibility and Work Opportunity Reconciliation Act of 1996—a law which made several safety net programs more difficult to access—CACFP was modified to cut costs. This law reduced the number of meals for which providers could receive reimbursements and introduced an income-based tiering system for reimbursements that reduced the overall financial support most providers could receive and also introduced additional administrative burden (39) to the program, as it necessitated providers' collection of income information for the families they served (38). Although future legislative actions allowed for relatively small expansions of the program after this, little changed about CACFP until 2017, when the nutrition standards for CACFP meals were updated as part of the Healthy, Hunger Free Kids Act of 2010 (40, 41). A report

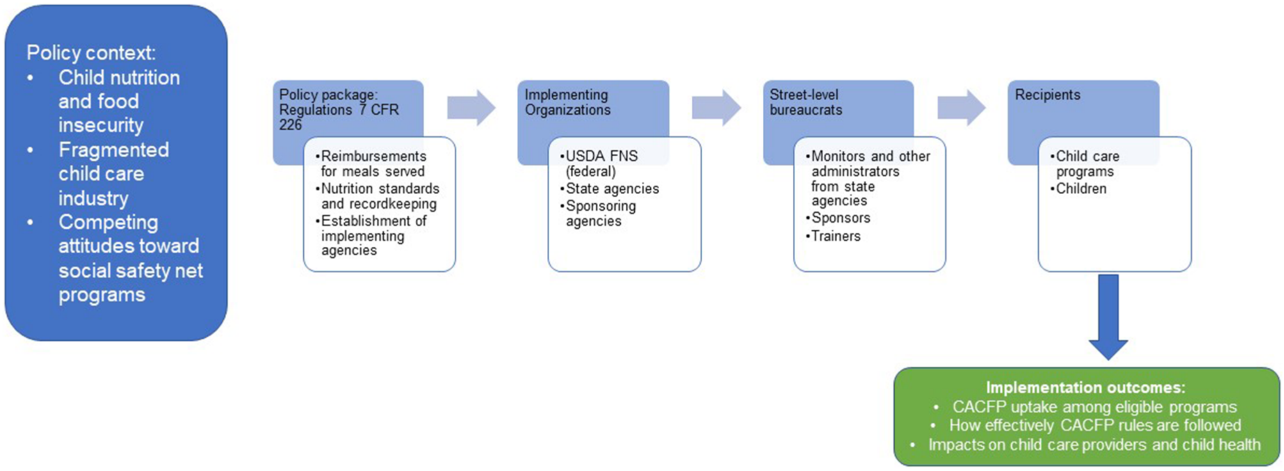

FIGURE 1
Process model of policy implementation applied to the Child and Adult Care Food Program.

by the National Academies of Medicine in 2011 suggested sweeping changes were needed to bring CACFP meal pattern standards in line with dietary science regarding child health and development (38), yet no additional federal funding was appropriated to support these changes (41).

An additional complexity is how fractured and underfunded the childcare system is in the U.S. Unlike most other economically developed countries; the U.S. has no universal public system of childcare (42). The childcare industry mostly relies on tuition payments from families and depressed wages for childcare workers in order to function (43). The industry has been referred to as a "textbook example" of a broken market (44): parents have to pay so much in tuition that it prohibits many from participating in the workforce at all, educators and other staff are underpaid, and owners are often barely able to keep the programs breaking even. Childcare providers and educators, who face substantial physical and mental health challenges personally (45), thus often face multiple intense challenges related to simply maintaining operations and adhering to their state's existing regulatory requirements. In this organizational context, participating in CACFP, or even serving meals in the first place, can add an additional layer of complexity to an already challenging situation.

3.2. Policy package: what are the regulations and unofficial rules that make up CACFP?

The regulations for CACFP (7 CFR Part 226) (46) outline minimum requirements for foods and beverages served for various age groups (see **Table 1**). Participating providers can

TABLE 1 CACFP meal pattern requirements and reimbursements per meal, 2023-2024.

	Required components	Reimbursement for centers	Reimbursement for daycare homes[a]
Breakfast	Fluid milk (4 oz for ages 1–2, 6 oz for ages 3–5, 8 oz for ages 6 and up) Vegetables, fruits, or both (1/4 cup for ages 1–2, ½ cup for ages 3 and up) Grains (1/2 oz for ages 1–5, 1 ounce for ages 6 and up)	Free: $2.28 Reduced price: $1.98 Paid: $0.38	Tier I: $1.65 Tier II: $0.59
Lunch and supper	Fluid milk (4 oz for ages 1–2, 6 oz for ages 3–5, 8 oz for ages 6 and up) Meat/meat alternates (serving sizes vary by type, generally between 1 and 2 oz) Vegetables (1/8 cup for ages 1–2, ¼ cup for ages 3–5, ½ cup for ages 6 and up) Fruits (1/8 cup for ages 1–2, ¼ cup for ages 3 and up) Grains (1/2 oz for ages 1–5, 1 ounce for ages 6 and up)	Free: $4.25 Reduced price: $3.85 Paid: $0.40	Tier I: $3.12 Tier II: $1.88
Snack	Select two of the components listed above for lunch, with larger serving sizes for fruits/vegetables and smaller serving sizes for meat/meat alternates	Free: $1.17 Reduced price: $0.58 Paid: $0.10	Tier I: $0.93 Tier II: $0.25
Other nutrition requirements:	Milk must be unflavored, whole milk for children aged one, unflavored low fat or skim milk for children ages 2–5, and unflavored or flavored low fat milk for ages 6 and up. Yogurt must contain no more than 23 g total sugars per 6 ounces. 100% juice may be used to meet a vegetable or fruit requirement at only one meal each day Vegetables may be used to meet entire fruit + vegetable requirement at lunch At least one serving of whole grains is required each day Breakfast cereals cannot contain >6 g sugar per dry ounce		

Sources: Available at: https://www.fns.usda.gov/cacfp/meals-and-snacks; Available at: https://www.fns.usda.gov/cacfp/reimbursement-rates.
[a] Amounts presented are for contiguous U.S. states; amounts are higher for Alaska, Hawaii, and U.S. territories.

receive reimbursements for up to three meals and/or snacks. The reimbursement amount for centers varies according to the household income status of the recipient child; reimbursements for family childcare providers (who provide care in their home to a smaller group of children compared to childcare centers) vary based on neighborhood-level income metrics (using either Census or local school meals data) (46). To participate in CACFP, providers must prove that they either have a nonprofit status or that they serve at least 25% of children from low income households (47) and must prove financial viability (46). They must submit paperwork on the foods and beverages served for each meal, the amounts served, and child attendance as well as documentation of receipts and compliance with civil rights law. Providers and key staff participate in annual trainings and periodic monitoring visits from state auditors to assess compliance (46).

3.3. Implementing organizations and street-level bureaucrats: who implements CACFP?

CACFP is a federal program that is administered by state agencies. At the federal level, the U.S. Department of Agriculture Food and Nutrition Service (USDA FNS) tracks participation, issues guidance to state agencies on how to comply with regulations, releases technical assistance tools (like recipes and worksheets), and commissions program evaluations. State agencies, however—typically education or public health agencies—are the organizations that are responsible for most administrative activities, including approving and onboarding new participating providers, disbursing reimbursements, monitoring compliance, providing technical assistance, and maintaining participation records (48).

The state agency is also responsible for registering and working with sponsoring agencies or sponsors, which also support implementation. Family childcare providers are required to work with sponsors so that these agencies can complete some of their administrative paperwork and provide technical assistance; depending on the state, some centers can also work with sponsors, or operate independently (49).

The "street-level bureaucrats" involved in implementing CACFP on the ground are state agency staff responsible for auditing participating programs and sponsors, as well as sponsors themselves, who help participating providers comply with program rules.

3.4. Recipients: childcare programs and children

One unusual aspect of CACFP is that childcare providers can be thought of both as the recipients of the program—they receive the reimbursements for the meals they serve—and also a type of "street-level bureaucrat" as they are implementing the program day-to-day: planning menus, obtaining or preparing food, gathering families' income-eligibility information, participating in training, maintaining paperwork, and submitting to monitoring visits. The other recipients of the program are the children receiving the meals and snacks.

3.5. Outcomes: what do we know about CACFP's impact?

3.5.1. Implementation outcomes

These include acceptability, adoption, appropriateness, costs, feasibility, fidelity, uptake (penetration), and sustainability (26, 28). We present evidence for four of these constructs with existing evidence below.

3.5.1.1. Penetration

While the USDA estimates that CACFP served up to 4.6 million children in 2021, it does not track the percentage of eligible programs that participate. A recent analysis of state administrative records, however, estimated that only about a third of licensed childcare centers participate in CACFP nation-wide, with large variability across states (16%–86%) (50).

3.5.1.2. Fidelity

Studies of the degree to which programs adhere to CACFP's regulatory standards generally suggest that programs meet the standards most of the time, but not perfectly (25, 51, 52).

3.5.1.3. Feasibility

Providers have consistently reported that CACFP is difficult to use, citing the burden of paperwork, inadequate staff, insufficient reimbursements, mismatch of the meal pattern standards with child preferences, and inflexibility of the standards for cultural foods as being key barriers to feasibility (53–56).

3.5.1.4. Cost

Although CACFP reimburses providers for each qualifying meal and snack served (as described above), many studies have found that the reimbursement is not adequate. While some studies have found that the reimbursement covers the costs of food (57–59), studies have also found that the reimbursement is not adequate for supporting foods with more variety that can improve diet quality and support children's preferences (60, 61), and that the reimbursement is not adequate to cover labor costs (59).

3.5.2. Service outcomes

Include efficiency, safety, effectiveness, equity, client-centeredness, and timeliness (26, 28). We present analysis for four of these constructs with existing evidence below.

3.5.2.1. Efficiency

As described above, there are substantial monitoring activities involved that make CACFP's efficiency questionable. Daily meal and attendance counts, menu planning, managing food receipts to demonstrate compliance, reviewing food labels to assess whether foods are creditable, and also the work involved in soliciting and organizing income-eligibility paperwork from parents all contribute to substantial administrative burden (39).

3.5.2.2. *Effectiveness*

A recent systematic review of studies of the impact of CACFP on the nutritional quality of meals served in childcare programs found mixed evidence overall for a beneficial impact of CACFP, partly due to a lack of rigorous, large-scale studies. Existing studies either find null associations between CACFP and nutritional quality or typically very small positive associations (62).

3.5.2.3. *Equity*

It is unknown whether CACFP is accessed inequitably. There are concerns, however, in how programs located in food deserts—which often track with both rural locale and with areas subjected to racialized segregation (63, 64)—may have difficulty accessing foods compliant with CACFP meal pattern standards. Additionally, the administrative burden of this program itself may produce inequities. Childcare providers serving higher income families can opt out of CACFP. Such programs can either have parents provide meals themselves, or pay extra in tuition to cover meal service costs. Therefore, the administrative burden is borne by providers serving children from households with lower income.

3.5.3. Recipient outcomes

3.5.3.1. *Providers*

It is unclear the extent to which CACFP benefits providers themselves; most studies evaluate the impacts of CACFP on childcare program practices and policies. For example, it is unclear whether CACFP actually helps providers financially so that they have less business challenges or are able to keep program tuition lower. It is also unclear whether CACFP helps with providers' own health and wellness. Notably, despite the fact that childcare teachers are strongly encouraged to sit and eat with children during mealtimes, meals for teachers are not reimbursable through CACFP currently.

3.5.3.2. *Children*

Similar to what has been found in evaluations of CACFP's impact on childcare program-level food practices and policies, evidence for a beneficial impact of CACFP on child-level outcomes, including diet quality, food security, and healthy weight, are mixed, with studies either finding null or very slightly positive associations (62).

3.5.4. Policy outcomes

Overall, it is unclear whether CACFP has population-level impacts on childcare meal quality or child health.

4. Discussion

Nutrition policies, especially federal nutrition assistance programs, show enormous potential for supporting children's nutrition on a population level. CACFP could be particularly promising given that it focuses on supporting healthy meals for young children, who are at a crucial stage of development. Yet despite its promise, it has not been shown to have strong impacts on child food insecurity, growth, or diet quality (62) While it is often suggested that CACFP participants need more training or technical assistance to support better adoption of CACFP, the analysis above suggests that simply providing training or technical assistance is not enough; rather, we argue that several key misalignments between CACFP's policy implementation process and the current structure of the childcare industry have contributed to weaker impacts. These include:

4.1. Fractured childcare industry and conflict over resources for safety net programs

The daily challenges that childcare providers face in maintaining operations—low wages, high staff turnover, high operating costs, and the need to comply with multiple regulations outside of food-related rules—may make participation in CACFP infeasible for many programs; they just may not have the bandwidth given the current structure of childcare. While increasing operational and financial support given through CACFP could increase its feasibility for programs, as well as providing more support and structure to the childcare industry in general, this would require expansions of the existing social safety net that are controversial in the current political climate.

4.2. Insufficient financial support for providers to effectively implement the program

While existing reimbursements may cover food costs on average, they do not appear to be adequate for covering the cost of the labor needed to complete CACFP's administrative requirements or to plan and prepare meals. They also may not be adequate for supporting a variety of foods that can fit children's preferences or help towards introducing children to new foods, leaving providers with a situation where they are repeating the same few meals and reducing satisfaction with the program. Reimbursements that fairly cover the costs of labor and can support a truly healthful food service—with the provision of a variety of foods that meet CACFP's nutritional standards and children's preferences—are needed.

4.3. Inadequate implementation structure for some programs

An implementation structure more similar to that of the NSLP/SBP—where there are agencies with dedicated staff for overseeing compliance paperwork, planning meals, and preparing and serving meals—could be helpful. For many childcare providers, especially those without a sponsor, participating in CACFP would be akin to asking school principals and teachers to add school meal compliance paperwork and food service to their workloads. Sponsoring agencies help support family childcare providers and some centers in overseeing administrative duties; perhaps a more robust role for these agencies, with support available for more center-based programs and more help with the meal planning and food preparation tasks necessary for participation, could be a solution.

Additionally, increasing communication across levels of implementation (federal, state, sponsor, provider) is needed. The agency involved in setting policy—USDA—is far removed from the day-to-day activities involved in implementation. One implication of this is that some of the policy memorandums that USDA provides to try to support implementation, as well as informational resources designed to help providers comply, may be out of sync with what providers need. For example, one co-author, who is involved in providing food service for CACFP-participating programs, has found that USDA's example recipes often include foods that are too expensive (like nuts or dried fruits) and/or foods that are not creditable for that dish. Communication between state agencies and food vendors could be further developed, rather than relying on childcare centers to navigate those communications. Finally, supporting newly-formed childcare providers in the transition of opening could be a useful investment to ensure the food programs are a support rather than a burden to newly-formed business enterprises.

5. Conclusions

Policymakers and others involved in policy formulation and implementation processes should consider strategies to reshape CACFP's implementation to better fit the existing context of childcare in the U.S.—not only through more robust financial support, but also through perhaps a reconsideration of what administrative paperwork is truly necessary for program participation and a retooling of existing implementation supports, like training, technical assistance, and meal planning, that are available to childcare programs. Meanwhile, as this analysis demonstrates, we suggest that researchers, policymakers, and public health practitioners who want to leverage food policies to promote public health nutrition must go beyond focusing only on requiring the provision of foods and beverages in line with dietary science—we must also carefully consider the context in which these policies operate, and the implementation process that can determine their success.

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

EK: Conceptualization, Data curation, Funding acquisition, Investigation, Project administration, Writing – original draft, Writing – review & editing. MP: Conceptualization, Writing – original draft, Writing – review & editing. NF: Conceptualization, Data curation, Investigation, Writing – review & editing. KK: Data curation, Writing – review & editing. RM: Data curation, Formal Analysis, Project administration, Writing – review & editing. TA: Conceptualization, Writing – review & editing.

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Conflict of interest

NF is employed by Seed 2 Roots LLC.

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

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Combining legal epidemiology and implementation science to improve global access to medicines: challenges and opportunities

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Laws and policies affecting access to medicines have been in the global health spotlight for decades, yet our understanding of their effects remains substantially underdeveloped. The emerging field of legal epidemiology combined with the methods of implementation science presents an opportunity to help address this gap. Legal epidemiology refers to the scientific study and deployment of law as a factor in the cause, distribution, and prevention of disease and injury in a population. Legal epidemiology studies consist of a systematic collection and coding of laws and policies relating to a particular topic. Quasi-experimental or observational research methods can then be applied to take advantage of natural experiments resulting from heterogenous adoption and/or implementation of laws and policies. Often legal epidemiology studies fail to account for heterogenous law implementation processes, presenting a need and opportunity to integrate implementation science methods. Researchers may face challenges in integrating these methods for access to medicines studies, including data access issues and a complex legal and implementation environment. Yet, the opportunities presented by increasingly transparent legal environments, improved monitoring of medicine availability, universal health coverage expansion, and electronic health and insurance records integration may facilitate overcoming these challenges. Improved collaboration and communication between researchers, health authorities, manufacturers, and health providers from public and private sectors will be critical. In spite of the challenges, combining the fields of legal epidemiology and implementation science may present an important strategy toward creating a legal and policy environment that supports global and equitable access to medicines.

KEYWORDS
law, policy, legal epidemiology, implementation science, medicines

Introduction

Laws and policies affecting access to medicines (i.e., drugs and vaccines) have been in the global health spotlight for decades, yet our understanding of their effects remains substantially underdeveloped. Inequitable and ineffective distribution of medicines grew on the global agenda in the 1990s and early 2000s in response to lack of universal access to medicines to treat HIV (1). Since then, objections have been raised about inequitable access to a wide range of medicines, including medicines for hepatitis C virus (2), pain management (3), cancer (4), COVID-19 (5), and pediatric pneumonia (6).

Debates around access to medicines laws and policies often focus on the role of intellectual property laws, in particular national patent laws. The widespread adoption of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) in the mid-1990s led to near global adoption of national laws allowing for the patentability of medicines (7). TRIPS contained certain flexibilities that have been applied to improve access to medicines, but implementation of these flexibilities has been mixed (8). The ability of some countries to implement these flexibilities has also been limited by unilateral adoption of stricter patent laws or as a result of bilateral or multilateral trade agreements (7). Patent laws play an important role in the legal environment affecting access to medicines, especially for novel medicines. However, a range of laws and policies outside of patents also play important roles in affecting access to medicines, including those governing health insurance coverage, drug formularies and national essential medicines lists, medical products assessment and registration, import and export, taxes, medical product quality and safety surveillance, and licensing of health establishments and personnel (9).

Despite tremendous advancements in pharmaceutical development in recent decades, global access to medicines remains far from universal. Pharmacy supply chain, pricing, and affordability surveys have been implemented widely in resource limited settings and regularly find substantial stockouts and unaffordability (10). These surveys have used various methodologies, including the methodology developed by Health Action International and the World Health Organization (WHO) (10). A multi-country study of persons with chronic conditions in 2007-10 found that only 35% of respondents in Ghana, 33% of respondents in Kenya, 16% of respondents in Uganda, 49% of respondents in Jordan, and 38% of respondents in Philippines reported they had access to medicines to treat their chronic diseases (11). Attai, Khatib et al. measured the affordability of blood pressure lowering medicines in 20 countries and found the percentage of households unable to afford two blood pressure-lowering medicines was 31% in low-income countries, 9% in middle-income countries, and less than 1% in high-income countries (12). Other surveys have found substantial inequities in access to medicines, even in high income countries. For example, a 2023 survey in the U.S. found that 31% of respondents reported not taking their medicines as prescribed due to cost, with 21% reporting not filling their prescription or taking an over-the-counter medicine instead, and 12% reporting cutting pills in half or skipping a dose (13).

To help address this challenge, the Sustainable Development Goals included a target 3.b to provide access to affordable essential medicines and vaccines (14). Two indicators associated with this target directly call for monitoring the "Proportion of the target population covered by all vaccines included in their national programme" and the "Proportion of health facilities that have a core set of relevant essential medicines available and affordable on a sustainable basis." Monitoring coverage of selected vaccines occurs regularly in most countries (15), but regular monitoring of progress against the indicator for access to non-vaccine medicines has been limited (16).

While we have growing evidence describing the problem of access to medicines globally, there have been relatively few real-world evaluations of the impact of laws and policies on access to medicines (17–19). The emerging field of legal epidemiology combined with the methods of implementation science presents an opportunity to help address this gap.

Legal epidemiology

The field of legal epidemiology refers to the "scientific study and deployment of law as a factor in the cause, distribution, and prevention of disease and injury in a population." (19) Legal epidemiology studies are grounded in a systematic collection and coding of laws relating to a particular topic, resulting in a database of laws that reveals meaningful differences between laws in different jurisdictions. These databases can be cross-sectional or longitudinal to show changes in laws by jurisdiction and over time. For example, the Policy Surveillance Program has published legal epidemiology databases coding laws in the U.S. on a wide range of public health topics, including health worker scopes of practice, health insurance coverage requirements, housing, environmental health, and food safety (20). The U.S. CDC has also developed and published databases mapping U.S. state laws affecting HIV/AIDS programs and services (21). Legal epidemiology studies can also include quasi-experimental or observational research methods that take advantage of natural experiments resulting from heterogenous adoption and/or implementation of laws (19). This natural heterogeneity is especially common in federalized systems that grant substantial lawmaking authority to local governments (e.g., states, provinces, counties, or cities). Under these natural experiments, quasi-experimental statistical analysis methods, such as interrupted time series or difference-in-difference estimation, can be used to explore causal inferences between law adoption, implementation, and public health outcomes (19).

While the emergence of the field of legal epidemiology is relatively new, the study of laws and their relationship to health has occurred for many decades (22). For example, MacKillop studied the effects of seatbelt legislation and reduction of highway speed limits in Ontario, Canada in the late 1970s (23). Rigotti and Pashos systematically mapped and coded anti-smoking laws in public spaces in U.S. cities and states (24), and Faden and Kass mapped U.S. state health insurance regulations for coverage of HIV/AIDS in the late 1980s (25).

Focus on the connection between law and health has grown following the establishment of the U.S. CDC Public Health Law Program in 2000 (26). Burris and colleagues at Temple University have been key leaders in the growth of the legal epidemiology field, including establishing the Public Health Law Research Program in 2009 (27). While the first use of the term legal epidemiology in journals indexed on Medline/PubMed did not occur until 2015 (28), between 2015 and August 2023, 89 articles indexed on Medline/PubMed have used the term legal epidemiology, showing the growing footprint of this field in the traditional public health and medical literature.[1]

Recent applications of legal epidemiology relating to laws affecting access to medicines include Salvant-Valentine, Carnes, et al. analysis of nurse practitioner prescribing laws on HIV pre-exposure prophylaxis prescriptions in the U.S. (29), and Aaltonen's analysis of the effect of austerity measures (which are essentially budget laws) on medication access in Finland (17). The potential application of legal epidemiology methods to the study international law was also recently explored by Poirier, Viens, et al. (30)

Implementation science

Implementation science methods present an important complement to the emerging field of legal epidemiology because implementation science utilizes "methods to promote the adoption and integration of evidence-based practices, interventions, and policies into routine health care and public health settings to improve our impact on population health." (31) The complexity of legal implementation can be especially important in access to medicines policy, because of the complex legal and operational systems that intersect with medicine procurement, distribution, prescribing, and dispensing. Often legal epidemiology studies focus on law adoption or effective dates, which fail to account for the sometimes lengthy and heterogenous process of implementing laws.

Implementation science has developed a range of implementation outcome frameworks well-suited to rigorously evaluate the implementation of laws affecting access to medicines. One example is Procter, Silmere, et al.'s taxonomy of implementation outcomes consisting of acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration, and sustainability (32). These outcomes can be used to measure multiple attributes of law implementation (e.g., adoption vs. fidelity vs. penetration). Glasgow et al.'s Reach, Effectiveness, Adoption, Implementation, Maintenance/sustainment (RE-AIM) framework may also help with integrating implementation science outcomes into legal epidemiology analyses, especially to organize implementation outcomes data over time (33).

Other implementation science frameworks address laws and/or policies as a factor influencing implementation outcomes. A recent review by Crable, Lengnick-Hall, et al. found 26 implementation theories, models, or frameworks that address policy in some way (34). For example, the Aarons, Hulbert, Horwitz Conceptual Model of Evidence-Based Practice Implementation in Public Service Sectors (EPIS) includes a construct on service environment/policies (35). Crable, Lengnick-Hall, et al. recently made six recommendations to advance policy within EPIS and other dissemination and implementation frameworks (34). The Consolidated Framework for Implementation Research (CFIR) also includes a construct within its Outer Setting domain for Policies and Laws. CFIR defines Policies and Laws as "Legislation, regulations, professional group guidelines and recommendations, or accreditation standards support implementation and/or delivery of the innovation." (36) However, as of November 2023, the CFIR website did not contain any guidance on quantitative or qualitative measures for coding policies and laws, illustrating the need to build out the law and policy construct within CFIR (37). While EPIS and CFIR each acknowledge the potential influence of laws and policies on implementation outcomes, legal epidemiology seeks to understand the effect of the laws themselves on public health. Therefore, integrating implementation science and legal epidemiology will require a greater recognition of law not just as a factor influencing intervention outcomes, but law as an intervention itself (34).

Challenges & opportunities

Applying a combination of legal epidemiology and implementation science methods to study laws affecting access to medicines is not without challenges. Some of the most significant barriers involve lack of access to key data on laws, legal reforms, implementation processes, medicine availability, and medicine prices and affordability. Lack of collaboration between researchers, evaluators, implementers, and policymakers also presents barriers to integrating these fields. In spite of the challenges, we see many opportunities to vastly expand this work.

Conducting sound legal epidemiology requires access to the text of laws and regulations adopted in the jurisdictions that will be studied. Many local jurisdictions and even some countries lack a publicly available online version of existing and past legislation. However, governmental websites with current national laws and recently passed legislation are becoming more common (38). As more national and local legislatures and administrative agencies post their current and archived laws and policies online, conducting retrospective law and policy evaluations is becoming easier.

Implementation data relating to access to medicines can also be difficult to obtain at the population-level. In many countries, longitudinal data on medicine availability and stockouts do not exist or are typically not publicly available. As a result, a large percentage of medicine availability and affordability studies must collect primary data at a small number of facilities. However, ministries of health and others around the world have begun to collect and publish more data on medicine availability and distribution as a result of the COVID-19 pandemic response. For example, COVID-19 vaccine distribution dashboards were established in many countries (39). The WHO established a dashboard that aggregated COVID-19 vaccine distribution data globally (40), as did Johns Hopkins University (41). An increasing number of medicine regulatory authorities are also beginning to systematically monitor medicine shortages. Often these authorities publish notices of potential medicine shortages on public websites and databases (42, 43). Some countries, such as South Africa, have established medicine availability surveillance systems within departments of health to monitor medicine stock rates across the

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[1] Searches conducted on August 21, 2023.

health system (44). These public medicine stock datasets and dashboards could be used to conduct legal epidemiology studies measuring the effect of law changes on medicine availability.

In many countries, medicines are dispensed through a mixed market of private and/or public pharmacies, which presents challenges in wholistically evaluating the effect of law reforms on stock and dispensing rates. The ongoing expansion of universal health coverage can help overcome this barrier (45), because insurance claim databases, where available, aggregate claims from public and private sector providers. These payor claims databases can include claims data from a single public insurance plan or can be structured as all payor claims databases that aggregate claims data across multiple public and private insurers (46). Ideally, we would also be able to assess the effects of medicines access-related law reforms on health outcomes, but integrating medicine access data with health outcomes data has been challenging in the absence of integrated record systems. However, health information exchanges and electronic medical record systems are becoming more prevalent in lower resource settings (47), allowing for the potential to integrate medicine prescribing, reimbursement, and dispensing data with health outcomes data.

In many countries, there continues to be a divide between researchers and implementers making it more challenging to access key data. However, formal academic-practice collaborations between departments of health and universities, sometimes referred to as academic health department partnerships, are becoming more common (48). These collaborations support mutually beneficial research and training collaborations between health departments and local universities. More than one hundred formal academic health department partnerships have been established in the U.S. (49), and similar academic-practice collaborations have been established in other countries, including Australia and Canada (50). Expanding the transdisciplinary nature of graduate training programs across medicine, pharmacy, law, public health, and public policy fields can help foster these types of collaborations (19).

Demand and funding for law and policy evaluation from policymakers and implementers can sometimes be lacking. Establishing formal policy research collaborations between policymakers and universities is helping to overcome this divide in some settings. Many legislatures have established formal legislative policy research units to conduct policy research and evaluation in support of legislation, such as the Parliamentary Research Service in Kenya (51) and the Congressional Research Service in the U.S (52). These units can support formative policy research to inform the development of new legislation or conduct retrospective evaluations of previously passed legislation. Policy research units can also be established within administrative agencies, such as a ministry or department of health or medicine regulatory authorities.

Discussion

The emerging field of legal epidemiology may present an opportunity to advance the rigor and timeliness of evaluations of laws and policies affecting access to medicines. To realize this potential, however, we must ensure that the evaluation models address the important role of law and policy implementation. Implementation science outcomes and methods are well-positioned to support this goal. Researchers may face challenges in integrating these approaches, including data access issues and a complex legal and operational environment. Yet, the opportunities presented by increasingly transparent law and policy environments, improved medicine availability monitoring, universal health coverage expansion, and increasingly integrated electronic health and insurance record systems may overcome these challenges. Improved collaboration and communication between researchers, health authorities, pharmaceutical manufacturers, and pharmacies from the public and private sectors will be critical to this endeavor. In spite of the challenges, combining the fields of legal epidemiology and implementation science presents an important strategy in the path toward creating a legal and policy environment that finally achieves global and equitable access to medicines.

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

JL: Conceptualization, Writing – original draft. AS: Writing – review & editing.

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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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Participatory development of a target policy profile to support soil-transmitted helminth elimination

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Introduction: Soil-transmitted helminths (STH) are parasitic worms that infect nearly a quarter of the world's population, particularly those living in communities without access to adequate water, sanitation, and housing. Emerging evidence suggests that it may be possible to interrupt transmission of STH by deworming individuals of all ages via community-wide MDA (cMDA), as opposed to only treating children and other focal populations. Transitioning from a policy of STH control to STH elimination in targeted areas would require a fundamental shift in STH policy and programming. This policy change would require updated guidance to support countries as they adapt their current approaches for STH surveillance, supply chain management, community mobilization, and core programmatic activities in pursuit of STH elimination. There is an opportunity to engage with key stakeholders, such as program implementers and implementation partners, to understand what evidence they need to confidently adopt a new policy guideline and to deliver guideline adherent management at scale.

Methods: We aimed to engage with STH stakeholders to develop a Target Policy Profile (TPoP), a single document that describes optimal characteristics and evidence requirements that STH stakeholders prioritized in future potential STH transmission interruption efforts. Steps in TPoP development included a scoping review and key informant interviews (KIIs), which were used to design a two-stage Delphi technique to identify and verify TPoP components.

Results: The scoping review resulted in 25 articles, and 8 experts participated in KII's. Twenty respondents completed the first Delphi survey and 10 respondents completed the second. This systematic effort resulted in a net of 3 key information domains (background/context, clinical considerations, and implementation considerations) encompassing 24 evidence categories (examples include evidence regarding safety and adverse events, implementation feasibility, or evidence dissemination). For each evidence category, STH stakeholders reviewed, endorsed, or revised a range of options for how the evidence could be presented.

Discussion: This information can be used by guideline committees or global policy makers prior to convening guideline advisory groups. The TPoP tool may also speed the process of stakeholder consensus building around guidelines, accelerating progress towards implementing evidence-based policy at scale.

KEYWORDS

soil-transmitted helminths, neglected tropical diseases, guidelines, Delphi, policy implementation, participatory methods

Introduction

Soil-transmitted helminths (STH) are intestinal parasitic worms that infect nearly a quarter of the world's population, particularly those living in communities without access to adequate water, sanitation, and housing (1). When individuals have heavy-to-moderate intensity infections with STH, they may experience adverse outcomes such as diarrhea, weakness, malnutrition and impaired growth in children, and chronic anemia in women of reproductive age (WRA) (2). The current standard-of-care for controlling STH-associated morbidities in current WHO guidelines includes annual or bi-annual preventive chemotherapy delivered via mass drug administration (MDA), which requires large-scale delivery of deworming medications to all eligible pre-school and school-age children and WRA living in at-risk areas. MDA for STH control is often delivered via school-based delivery platforms (i.e., school-based MDA) that engage both teachers and volunteer community drug distributors (CDDs) as the primary implementers for reaching pre-school and school-age children (3, 4).

Morbidity control programs using school-based MDA have been successful in many settings, however in the absence of continued treatment such programs may need to be continued indefinitely, or at least until major improvements in infrastructure and sanitation can be realized (5). Emerging evidence suggests that it may be possible to interrupt transmission of STH by deworming individuals of all ages via community-wide MDA (cMDA), as opposed to only treating children and other focal populations (6–8). A cMDA approach would reduce the presence of adult reservoirs of infection in the community and the risk of re-infection for individuals post-deworming (9). Field trials and observational studies are currently underway to determine definitively whether transmission interruption via cMDA is feasible (10, 11). While several similar neglected tropical disease (NTD) programs, such as lymphatic filariasis (LF), onchocerciasis, and trachoma programs currently target entire populations with treatment during MDA, transitioning from a policy of STH control to STH elimination in targeted areas would require a fundamental shift in STH programming. This policy change would require updated guidance to support countries as they adapt their current approaches for STH surveillance, supply chain management, community mobilization, impact assessment, and other core programmatic activities in pursuit of STH elimination.

The World Health Organization (WHO) has developed a rigorous process for creating, updating, and approving clinical, public health, and health policy guidelines (12, 13). Briefly, standard guidelines are produced following requests for guidance, often from endemic country governments, and typically following the release of promising new evidence or interventions. Once a guideline development or updating process is initiated, advisory groups develop questions and outcomes for the guidelines to address. These groups also prioritize which questions require systematic reviews of the evidence to inform subsequent recommendations. A guideline development group (GDG) composed of external experts appraises existing evidence summarized and assessed by an evidence review team using systematic review methodology and the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach (14). The guidelines also undergo multiple rounds of review prior to approval from the WHO Guidelines Review Committee (GRC). Many guidelines are also accompanied by operational guides to support country governments in implementing new recommendations. The WHO Handbook for guidelines requests Evidence to Decision (EtD) frameworks, such as the GRADE-EtD, to be used as tools for guideline panels to move from evidence to recommendations by considering and discussing evidence within the context of a list of key criteria, such as the "certainty of the evidence", "balance of effects", "cost", "equity", "feasibility", and "acceptability" (15, 16).

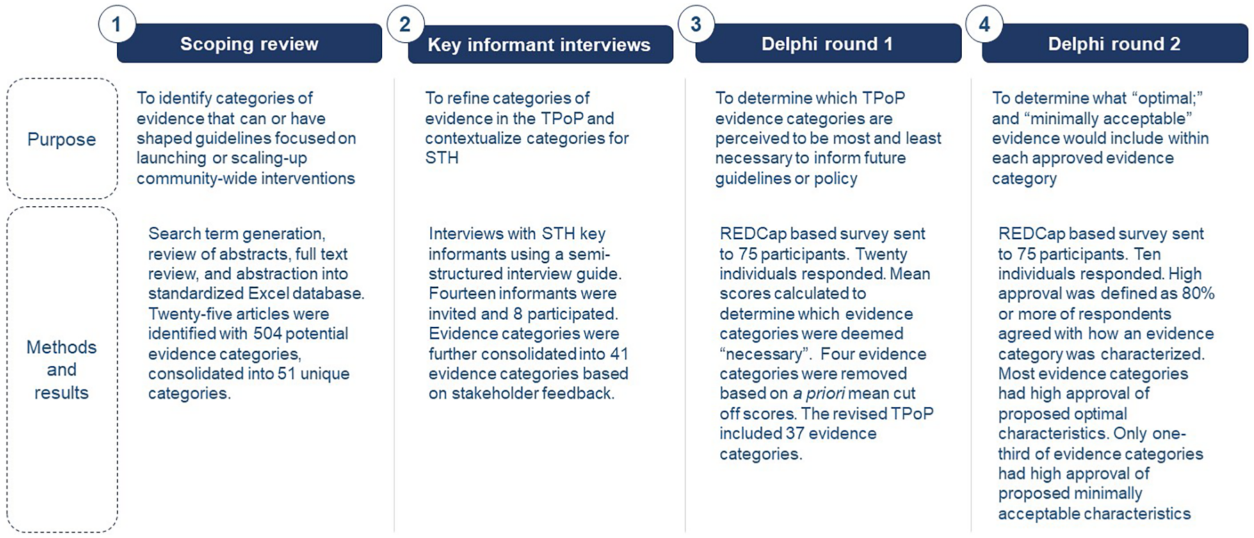
Before initiating a guideline creation or updating process, there is an opportunity to engage with key stakeholders, such as program implementers and implementation partners (ex. non-governmental organizations, NGOs), to understand what evidence they need to confidently adopt a new policy guideline and to deliver guideline adherent management at scale. As increasing evidence is emerging suggesting the possibility of interrupting the transmission of STH and the recognition that a shift in future STH guidelines towards transmission interruption would require updates to future guidelines, we aimed to engage with STH stakeholders to develop a target policy profile (TPoP). The purpose of the TPoP is to systematically describe the optimal characteristics and requirements of evidence to include in clinical and operational guidelines for future potential STH transmission interruption efforts (17). A TPoP would in no way replace established WHO or national-level guideline development processes. Rather, findings from the TPoP could be used by stakeholders, including potentially a WHO steering group and GDG, prior to starting a guideline develop process in order to understand STH stakeholder priorities for guidance, and to consider what types of evidence would be most helpful to include in an updated STH guideline and/or accompanying operational guidance documents.

Methods

The objective of the TPoP development process was to describe optimal and minimally acceptable evidence desired by STH stakeholders in the context of guidance for potential STH transmission interruption efforts. Steps in TPoP development included a scoping review and key informant interviews (KIIs), which were used to design a two-stage Delphi technique to identify and verify TPoP components (Figure 1).

Scoping review and development of first TPoP prototype

Scoping reviews can be conducted to clarify concepts and examine characteristics of a specific concept (18). Here we conducted a scoping review to understand categories of evidence that have been used to shape guidelines focused specifically on launching or scaling-up community-wide interventions, such as MDA for STH elimination. A list of search terms was developed to conduct online searches on PubMed, Google Scholar, Google, Global Health Database, PAIS Index, Scopus, and Web of



	1 Scoping review	2 Key informant interviews	3 Delphi round 1	4 Delphi round 2
Purpose	To identify categories of evidence that can or have shaped guidelines focused on launching or scaling-up community-wide interventions	To refine categories of evidence in the TPoP and contextualize categories for STH	To determine which TPoP evidence categories are perceived to be most and least necessary to inform future guidelines or policy	To determine what "optimal;" and "minimally acceptable" evidence would include within each approved evidence category
Methods and results	Search term generation, review of abstracts, full text review, and abstraction into standardized Excel database. Twenty-five articles were identified with 504 potential evidence categories, consolidated into 51 unique categories.	Interviews with STH key informants using a semi-structured interview guide. Fourteen informants were invited and 8 participated. Evidence categories were further consolidated into 41 evidence categories based on stakeholder feedback.	REDCap based survey sent to 75 participants. Twenty individuals responded. Mean scores calculated to determine which evidence categories were deemed "necessary". Four evidence categories were removed based on *a priori* mean cut off scores. The revised TPoP included 37 evidence categories.	REDCap based survey sent to 75 participants. Ten individuals responded. High approval was defined as 80% or more of respondents agreed with how an evidence category was characterized. Most evidence categories had high approval of proposed optimal characteristics. Only one-third of evidence categories had high approval of proposed minimally acceptable characteristics

FIGURE 1
Overview of steps involved in TPoP development.

Science databases (Supplementary Material S1). Abstracts were reviewed for relevance and full texts downloaded when appropriate. Upon identifying relevant texts, we also employed citation chaining and reviewed works cited for additional resources.

We used an Excel-based abstraction database to track articles included in the review. The spreadsheet included a summary of the article and descriptions of evidence that the article noted could or should inform guideline development. A single reviewer abstracted data and an additional author reviewed abstractions, referring to full text articles when necessary. We determined that we reached review saturation when no new or unique descriptions of evidence needed to inform guidelines emerged.

We sorted the evidence descriptions identified from the review into broad groupings informed by the WHO 2017 guidelines for preventative chemotherapy for STH and a prior TPoP developed for other initiatives (17, 19). These groupings were henceforth referred to as "evidence categories". Categories of evidence that were similar to one another (e.g., overlapping definitions) were then refined into a single evidence category to be included in the TPoP. These evidence categories were then used to design interview guides for subsequent KIIs and develop the template for the first TPoP prototype.

Collation of expert advice and development of second TPoP prototype

To further refine categories of evidence ahead of the Delphi process, we conducted KII with STH stakeholders with expert knowledge on prior STH guideline development including WHO staff, technical experts, and country-level NTD program managers. We used a semi-structured interview guide to solicit information about the guideline updating and development process, TPoP specifications, and proposed categories of evidence. Fourteen individuals were purposively identified and invited to participate in interviews. An interviewer and notetaker were present during all interviews. All interviews took place over Zoom and were recorded following verbal consent. Key insights and highlights from the interviews were summarized using a matrix approach, deductively organized by proposed categories of evidence (20, 21). Newly proposed categories of evidence were inductively added to the matrix, as appropriate, and data summarized accordingly. Following interviews with key stakeholders, we undertook a second iteration of editing to incorporate stakeholder feedback into proposed TPoP categories of evidence.

Overview of Delphi technique and finalization of TPoP tool

Following KIIs, a two-round Delphi method was used to solicit feedback about the TPoP prototype and finalize the TPoP tool. The Delphi method includes iterative "rounds" in which experts are asked their opinion on a particular issue, and questions for each round are based in part on the findings from the previous round (22). We used a series of two REDCap-based surveys that were emailed to individuals who participated in the KIIs and additional STH and NTD policymakers and technical experts ($N = 75$ individuals invited in total). Invitees were sent one email reminder to participate and were not offered incentives to complete the surveys.

During the first Delphi survey, participants were presented with possible TPoP evidence categories (e.g., groupings of types of evidence that may be included in a future guideline) and asked to rate each evidence category on a 1–3 scale (23), with 1 being "not necessary" evidence for inclusion in a future guideline or policy, 2 being "desirable but not necessary" evidence for inclusion in a future guideline or policy, and 3 being "necessary" evidence for inclusion in a future guideline or policy. We calculated the mean score and the proportion of respondents indicating an evidence category was "necessary" for inclusion. Evidence categories with a mean score above 2.5 and proportion of "necessary" responses greater than or equal to 60% were deemed potentially important for inclusion in future STH guidelines and were included in the revised TPoP (third iteration). Participants were not asked to rate 15 of the proposed evidence categories, as these categories were deemed *a priori* as mandatory for inclusion because they are criteria within the EtD framework.

The purpose of the second survey was to incorporate feedback from the first survey regarding the evidence categories that should be addressed in future guidelines and define what "optimal" or "minimally acceptable" evidence would include within each category. Survey respondents were provided a brief overview of findings from the first Delphi survey, and then were asked to review minimally acceptable and optimal characteristics of potential evidence categories to include in a future STH guideline. "Optimal" characteristics represented ideal attributes of evidence while "minimally acceptable" characteristics described the necessary basic level of evidence to be included in future guidelines. For example, evidence regarding "surveillance" could range from minimally acceptable levels of "*provides surveillance guidance that includes clear criteria (thresholds) for starting and stopping community-wide MDA*" to optimal levels of "*provides surveillance guidance that includes clear criteria (thresholds) for starting and stopping community-wide MDA, monitoring for recrudescence, and verifying transmission interruption. Additionally includes guidance for use of existing and new diagnostics, including drug resistance surveillance*."

Participants were asked if they agree or disagree with the proposed approaches to defining optimal and minimally acceptable characteristics of each evidence category. Participants were also provided space for qualitative reactions to each description of optimal and minimally acceptable evidence, if they chose to provide one. We identified "optimal" and "minimally acceptable" characteristics with particularly high approval and low approval. High approval was defined as 80% or more of respondents agreed with how an evidence category was characterized. Low approval was defined as 50% or fewer respondents disagree with how a category was characterized.

Ethical review

The study was approved by The Human Subjects Division at the University of Washington (STUDY00000180).

Results

This project systematically engaged stakeholders to learn about the type and depth of information that they seek in future STH guidelines that might target the interruption of transmission of STH. The results of this analysis provide a range of approved "optimal" and "minimally acceptable" categories of evidence that may support implementers of future STH elimination guidelines or operational documents.

Scoping review and development of the first TPoP prototype

The scoping review search yielded 75 potential articles, 25 of which included relevant information about evidence needed to guide scale-up of community-wide interventions. These articles included 504 potential evidence categories. We grouped similar evidence categories and removed any duplicates. We further organized evidence categories into nine broad domains: background, evidence of effectiveness, intervention costs and benefits, contextual considerations, partnerships, implementation considerations, intervention/product details, existing use of the intervention, and dissemination. After this process, a total of 51 unique evidence categories were identified and included in the first iteration of the TPoP.

Collation of expert advice and development of second TPoP prototype

Fourteen individuals were invited to participate in KIIs and eight individuals ultimately participated (response rate of 57%). This included two individuals based at the WHO, four individuals who had been involved in previous relevant GDGs, and two individuals who had led national STH programs. Many key informants noted that evidence included in existing STH guidelines has been perceived as minimal and incomplete. KIIs noted that guidelines have included limited or no evidence related to program duration, outcome certification, feasibility, acceptability, and other aspects of implementation. They noted that this may be, in part, because the methods used to collect this evidence are not from randomized trials and therefore traditionally receive lower assessments of rigor using GRADE domains. There are also evidence gaps, such as the inclusion of cost of implementation data, that need to be addressed in future guidelines. Should there be a future policy shift, adding specific milestones for when a country might be eligible for cMDA will help motivate countries to move from control to elimination.

In addition to providing feedback about proposed evidence categories, key informants also provided feedback that coalesced into two additional main themes. First, many interviewees noted that guidelines will be most impactful if there are updates to how evidence is presented. For example, current STH guidance from the WHO is scattered across guidelines, technical manuals, and M&E plans, which poses challenges for implementers. Consolidating guidance and implementation information would make it easier for implementers to apply recommendations in their setting. Several respondents noted that guidelines should be simple but with sufficient detail needed to guide countries with STH programs of varying levels of maturity.

KIIs also noted that there may be opportunities to speed the evidence-to-recommendation process, even before guideline committees are convened. For example, trials can sign memoranda of understanding that allow their results to be pooled in systematic reviews as soon as they are available, parallel to the publishing of primary outcomes. The evidence-to-recommendation process would also be improved by engaging a more heterogenous mix of experts and linking STH evidence to evidence from other NTDs or even universal health coverage (UHC) endeavors.

Information from the KIIs helped refine the draft TPoP by reducing the number of proposed evidence categories from 51 to 41, across six refined domains and sub-domains, including: background and context, clinical considerations, and implementation considerations (including sub-domains of community considerations, distribution considerations, health system considerations, and partnership considerations.

Overview of Delphi technique and finalization of TPoP tool

Twenty individuals responded to the first Delphi survey (27% response rate). Four evidence categories were deemed unnecessary and removed from the TPoP based on *a priori* criteria described above: incentive systems, regulatory/legal context, public-private partnerships, and civil-society partnerships. The revised TPoP incorporated stakeholder feedback and included 37 evidence categories.

Ten individuals responded to the second Delphi survey (13% response rate). We identified higher agreement for “optimal” descriptions of evidence, as compared to the “minimally acceptable” descriptions of evidence. Thirty (81%) of the evidence categories had high approval of their proposed optimal characteristics. Meanwhile, only 13 (35%) of the evidence categories had high approval of their proposed minimally acceptable characteristics (Table 1, with category-levels of evidence presented in Supplementary Table S2).

Many respondents qualitatively responded that the “minimally acceptable” descriptions of evidence were too basic and, in many cases, the “optimal” levels of evidence should be considered the only option (e.g., that only the presented optimal characteristics of evidence would be acceptable in future guidelines). Other qualitative responses include that narrative reviews may be just as helpful as systematic reviews for certain evidence categories and could in fact speed the evidence-to-recommendations process, that the

TABLE 1 Summary of Delphi round 2 survey responses, by domain.

Domain	Domain defintion	Optimal characteristics of evidence[a]	Minimally acceptable characteristics of evidence[a]
Domain 1: Background & context	This domain includes evidence categories that describe and compare the differences between the current standard-of-care for STH (school-based MDA and deworming of WRA) and the new potential recommendation (cMDA), as it relates to key stakeholders involved and the potential effect on STH burden in communities	• 5 of 6 evidence categories had high approval (≥80% approval) • One evidence category received low approval (≤50% approval): *Burden of associated morbidity & mortality*	• 2 of 6 evidence categories had high approval • Two evidence categories received low approval: *Burden of associated morbidity & mortality* and *research priorities*
Domain 2: Clinical considerations	This domain includes evidence categories that describe and compare clinical evidence supporting current standard-of-care and a new policy recommendation.	• 4 of 6 evidence categories had high approval • Lowest approval (70% approval) was for *desirable effects* and *undesirable effects: drug resistance*	• 3 of 6 evidence categories had high approval • Lowest approval (60%) was for *desirable effects* and *undesirable effects: safety and adverse events*
Domain 3: Implementation considerations	This domain includes evidence categories that compare the multi-level characteristics of implementation for both the standard-of-care and a potential new recommendation, including implementation factors influencing policy formation such as characteristics of global coordination, intervention delivery, and community perceptions.		
Sub-domain 1: Community considerations	Criteria that describe and compare community-level implementation for the standard-of-care and a potential new recommendation.	• 3 of 4 evidence categories had high approval • Lowest approval (60% approval) was for the evidence category of *access*	• No evidence categories had high approval. 2 of 4 evidence categories had 70% approval • Lowest approval (60% approval) was the evidence category of *access* and *acceptability*
Sub-domain 2: Distribution considerations	Evidence categories that describe and compare characteristics of intervention delivery for the standard-of-care and a potential new recommendation.	• 7 of 8 evidence categories had high approval • Lowest approval (70% approval) was for the evidence category of *time to impact*	• 2 of 8 evidence categories had high approval • Low approval (≤50% approval) was for the evidence category *administration and distribution*
Sub-domain 3: Health system considerations	Evidence categories that describe and compare health systems-level considerations for the standard-of-care and a potential new recommendation, including implementation context and organizational preparedness.	• 11 of 13 criteria had high approval • Lowest approval (60% approval) was for the evidence categories *sustainability* and *feasibility*	• 6 of 13 evidence categories had high approval • Low approval (≤50% approval) was for the evidence category of *feasibility*

[a] High approval is defined as 80% or more of respondents agree with how an evidence category has been characterized. Low approval is defined as 50% or fewer respondents agree with how an evidence category has been characterized. .

presentation of systematic reviews can be confusing content in guidelines and presentation should be simplified, and that stakeholders value very clear and concise recommendations/guidance. Lastly, several respondents noted that the guidelines should focus on endemic countries as the target users and recommendations should be accompanied with detailed information on best practices for operationalizing the recommendations.

Based upon these responses, we updated 30 optimal and/or minimally acceptable characteristics of evidence across 24 evidence categories (65% of all evidence categories), most of which were minor adaptations to include respondent clarifications and preferences (Table 2).

Discussion

With new evidence regarding the feasibility of achieving STH transmission through cMDA emerging in the near future, there may be opportunity to revisit guideline content and scope in future updates. This study included a participatory approach to soliciting and incorporating feedback from key STH stakeholders in planning for such possible updates. Following multiple rounds of stakeholder engagement, we created a final TPoP that includes categories of evidence and characteristics of evidence that may be useful in introducing and implementing future STH policies.

STH stakeholders generally endorse more detailed information in future guidelines

During the second of a two-cycle Delphi survey, participants were asked not only to provide a final endorsement of evidence categories to include in future guidelines and/or associated operational materials, but also to provide feedback on the range of evidence characteristics that could be included. We found that most of the proposed “optimal characteristics” of evidence were approved by survey respondents (Table 1). In contrast, only about one-third of “minimally acceptable characteristics” of evidence were approved by survey respondents and respondents often thought the minimal levels of proposed evidence would be insufficient for future guidelines. This highlights that stakeholders generally sought more detailed guidance. The evidence categories that consistently had lowest approval reflect topics of ongoing controversy within STH literature. For example, the evidence categories of *burden of associated morbidity and mortality* had low approval of both optimal and minimally acceptable proposed levels of evidence. This may reflect ongoing controversies around the burden of STH-associated morbidities and methods used to detect STH-associated outcomes (24). We also observed lower approval of evidence regarding desirable effects and undesirable effects related to drug resistance and adverse events, for optimal and minimally acceptable characteristics of evidence. This may reflect mixed perceptions of the risks of clinically relevant resistance to deworming medications in humans or adverse events, and simultaneous recognition that cMDA would increase drug pressure and the number of adverse events as more people are treated (25, 26).

An STH TPoP can be used prior to initiating a guideline update, in order to identify categories of evidence of highest priority to implementers

A TPoP would be useful for guideline committees or global policy makers prior to convening guideline advisory groups. Because the TPoP incorporates stakeholder priorities, global policy makers can use it to assess where existing evidence falls within identified minimally acceptable and optimal ranges, where there are gaps in evidence that need to be addressed prior to guideline updating, what questions should be answered within a guideline update, and if there are other criteria that could be added to EtD frameworks used during the evidence-to-recommendation process. In particular, the “implementation considerations” such as *program delivery platform* and *time till impact* that were proposed in the TPoP may be valuable additions to the EtD. The implementation considerations domain, including sub-domains of community, distribution, and health systems considerations, was highly endorsed during KIIs and the first Delphi round. In the second Delphi survey only two of 25 evidence categories in this domain received low approval endorsements (both for proposed minimally acceptable levels of evidence). This highlights that evidence about implementation is highly valued by guideline stakeholders, including both guidance for how to operationalize guidelines but also rigorous evidence regarding best practices for implementers.

Target product profiles (TPPs) have long been used as planning tools to guide the development of new technologies to ensure that they meet necessary design specifications (27). A TPoP could similarly be used during early policy development as a collaborative approach to understanding stakeholder priorities. A similar initiative was undertaken to identify vaccine-related evidence anticipated to facilitate global policy recommendations (28). The Evidence Considerations for Vaccine Policy (ECVP) initiative, based on a tool developed by the Bill & Melinda Gates Foundation called the Target Policy Profile, developed a tool to identify the anticipated clinical trial and observational data or evidence that could support WHO and/or policy decision making for new vaccines (17). Like the ECVP, the STH TPoP does not preclude or supersede independent guideline convenings or GRADE-based recommendations.

Strengths and limitations

While this study used a series of participatory approaches to generate robust information about evidence that could inform policy and guidelines, there are a number of limitations to using participatory approaches like a Delphi technique. For example, this approach does not include live conversations, which may limit generation of new and creative ideas. We also did not have a third round of Delphi surveys for participants to verify final amendments to TPoP category descriptions. In addition, the study had a relatively low sample of engaged experts and participation rates were not optimal. The degree to which these findings are generalizable is influenced by the perspectives and positionality of the included

TABLE 2 Target policy profile, including optimal and minimally acceptable characteristics of evidence.

Background information		
Current policy	STH control (reduce worm burden in pre-school and school-age children [PSAC and SAC], adolescent girls, women of reproductive age [WRA], and pregnant women).	
Potential policy update	STH transmission interruption (defined as <2% prevalence of infection amongst all eligible age groups).	
Proposed intervention for consideration in a future guideline update		
Population	All populations vulnerable to STH infection in endemic areas.	
Intervention	Expand STH MDA target populations to include all individuals over one-year of age. Community-wide MDA (cMDA)with albendazole or mebendazole would be delivered annually or biannually as a standalone strategy, or in conjunction with school-based MDA.	
Comparator:	School-based MDA and targeted MDA of adolescent girls, women of reproductive health, and pregnant women.	
Outcomes:	STH transmission interruption.	
Domains, Evidence categories, & Definitions	**Characteristics of potential new guidelines**	
	Optimal guideline characteristics	**Minimally acceptable guideline characteristics**
Domain 1		
This domain includes evidence categories that describe and compare the differences between the current standard-of-care for STH (school-based MDA and deworming of WRA) and the new potential recommendation (cMDA), as it relates to key stakeholders involved and the potential effect on STH burden in communities.		
Key stakeholders affected Groups or individuals who can affect or are affected by a public health policy. They provide critical perspectives and new insights on the complex determinants of health.	In addition to the stakeholders outlined in existing guidelines, includes recommendations for improving stakeholder engagement (e.g., establishing a community advisory board).	Includes list of people and organizations involved in funding, planning, managing, implementing, evaluating, or participating in NTD or STH programs globally and nationally, but does not include guidance for how to improve engagement.
Alignment with existing priorities Compatibility between policies and existing guidelines, global norms, and priorities for a disease.	Guideline aligns with new (hypothetical) WHO-endorsed priority of STH transmission interruption.	Same as optimal characteristics.
Population vulnerable to infection and transmission[a] Individuals who are at risk of becoming infected by a disease.	Includes specific age range of populations vulnerable to infection and transmission, and population-specific contributions to transmission by species of STH.	Includes specific age range of all populations vulnerable to infection and who contribute to transmission. Each target population is explicitly included in any guidance related to treatment, who is treating them, and surveillance.
Target treatment population[a] The population that has been included in a guideline as to the target group for the intervention.	Target population aligns with the population vulnerable to infection and who contribute to transmission of STH.	Same as optimal characteristics.
Burden of associated morbidity & mortality Morbidity: A measure of the frequency of illness, or a departure from a state of physiological or psychological well-being. Mortality: A measure of the frequency of death in a defined population during a specified interval of time.	Includes updated systematic review and meta-analysis of key morbidity (with clear definitions of morbidity) and mortality outcomes as well as prospectively collected data confirming there is low morbidity in areas where transmission interruption was achieved. The measurement approach, level of evaluation (e.g. district), and the age groups assessed for morbidity should be clearly stated.	Includes updated systematic review, meta-analysis, or narrative review of key morbidity and mortality outcomes (with clear definitions of morbidity).
Research priorities[a] Uncertainties that can be resolved through research, including problems to be understood or solutions to be developed or tested.	Includes updated list of clinical, operational, and implementation science research gaps related to preventive chemotherapy, or other associated interventions, for both STH transmission interruption and morbidity reduction.	Same as optimal characteristics.
Domain 2		
This domain includes evidence categories that describe and compare clinical evidence supporting current standard-of-care and a new policy recommendation.		
Desirable effects[a] Benefits of an intervention, including beneficial health outcomes and reduced morbidity burden in the affected population.	Describes the benefits of deworming with updated evidence related to morbidity reduction, including both short- and long-term health outcomes related to transmission interruption. Additionally include evidence about non-health benefits, including school absences.	Describes the benefits of deworming with updated evidence related to health outcomes related to transmission interruption.
Undesirable effects[a] Harms of an intervention, including adverse events, drug resistance, and increased disease burden.	Describes updated evidence regarding all documented direct harms (e.g., safety and adverse events, and drug resistance) and indirect harms (e.g., increased asthma, erosion of hygiene education programs in schools, longer term health impacts of de-implementation if rebound occurs, etc.) of deworming.	Describes updated evidence regarding all documented direct harms and burden of deworming on health.
Undesirable effects (A): Safety & adverse events Safety reflects the risk of unnecessary harm. An adverse event is an unexpected harm that happens during treatment with a drug or other therapy.	Includes an updated systematic review (quantitative and qualitative studies) and meta-analysis from albendazole and mebendazole drug safety trials. Includes recommendations for surveillance of adverse events within a standardized STH pharmacovigilance program.	Includes an updated systematic review (quantitative and qualitative studies) and meta-analysis from albendazole and mebendazole drug safety trials.

(*Continued*)

TABLE 2 Continued

Domains, Evidence categories, & Definitions	Characteristics of potential new guidelines	
	Optimal guideline characteristics	Minimally acceptable guideline characteristics
Undesirable effects (B): Drug resistance The risk of reduced efficacy of a drug in a treated population.	Includes updated systematic review and meta-analysis of drug efficacy data in front line treatments, with data from several randomized controlled trials. Includes recommendations on the use of drug combinations to increase drug efficacy and limit the development of resistance. Also includes guidance on routine assessment of drug resistance in programs (e.g. sentinel based surveillance).	Includes updated systematic review of drug efficacy data in front line treatments, with data from at least one randomized controlled trial.
Balance of effects[a] The balance between desirable and undesirable effects associated with a policy, informed by the magnitude of the difference between the benefits and harms, the certainty about or variability in values and preferences, and other factors.	Describes the balance between benefits of transmission interruption and harms of expanded deworming using cited literature. Compares the balance of effects in morbidity control and transmission interruption programs.	Describes the balance between benefits of transmission interruption and harms of expanded deworming using cited literature.
Certainty of evidence[a] Describes the level of confidence or certainty in the estimates of the effect of an intervention on a specific outcome in a given target population	Provides an updated evaluation of desirable and undesirable health effect evidence quality using GRADE. An ideal GRADE rating for all evidence presented would be moderate to high-quality evidence.	Provides an updated evaluation of desirable and undesirable health effect evidence quality using GRADE.
Domain 3		
This domain includes evidence categories that compare the multi-level characteristics of implementation for both the standard-of-care and a potential new recommendation, including implementation factors influencing policy formation such as characteristics of global coordination, intervention delivery, and community perceptions.		
Sub-domain 1: Community considerations Criteria that describe and compare community-level implementation for the standard-of-care and a potential new recommendation.		
Access The degree to which a target population is reached with services or can access services in terms of location, time, and approach.	Outlines optimal drug delivery platforms (including integrated platforms), the number of health workers needed for each platform, and the number of days of delivery needed per population size and for each population subgroup.	List options of delivery platforms. Does not provide recommendations about evidence-based strategies for increasing access.
Adaptability The degree to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs and context.	Details specific guidance for planning and implementation activities that can be contextually adapted by implementation unit (e.g., sensitization), and specific core activities that should not be adapted (e.g., surveillance).	Same as optimal characteristics.
Equity[a] Equity is the absence of systematic or potentially remediable differences in health status, access, and treatment across populations or population groups. Equity may drive policy or be a consequence of policies that distribute well-being fairly.	Provides evidence-based equity guidance for deworming of all eligible populations and subpopulations, including hard to reach or marginalized populations. Includes simple tools for monitoring equity.	Provides updated equity considerations for deworming target populations.
Acceptability[a] The perception among stakeholders (e.g., consumers, providers, implementers policymakers) that an intervention is agreeable.	Includes qualitative and quantitative systematic reviews of studies assessing acceptability as well as community values and preferences of community-wide MDA among key stakeholders, including policymakers, implementers, and community members. Includes recommendations for improving acceptability.	Includes qualitative and quantitative systematic reviews of studies assessing acceptability as well as community values and preferences of community-wide MDA among key stakeholders, including policymakers, implementers, and community members.
Sub-domain 2: Distribution considerations Evidence categories that describe and compare characteristics of intervention delivery for the standard-of-care and a potential new recommendation.		
Drug procurement Process of acquiring high-quality medical/intervention products with reliable supplier services and the lowest possible prices.	Includes guidance for how to procure drugs from the WHO drug donation program or other local manufacturers for community-wide MDA.	Refers to generic companion WHO materials (e.g., procurement guidance) highlighting best practices for drug procurement.
Supply chain The processes needed to deliver goods or services to a consumer and/or the regulation of the flow of medical goods and services from manufacturer to consumer.	Provides recommendations and best practices for supply chain management from national to local levels. Provides link to further, more detail supply chain management guidance specifically for STH.	Provides recommendations and best practices for supply chain management at national level. Provides link to existing generic WHO supply chain information for further guidance.
Product, dose, & storage Characteristics of the medical product, product dosing, and product storage, including conditions and mechanisms that enable the preservation, stock management, and distribution of essential products.	Provides specific recommendations for the drug product and dose as well as recommendations for storage at national, regional, and local levels.	Same as optimal characteristics.

(*Continued*)

TABLE 2 Continued

Domains, Evidence categories, & Definitions	Characteristics of potential new guidelines	
	Optimal guideline characteristics	Minimally acceptable guideline characteristics
Administration & distribution The process by which products are proportioned and timed for consumers. Includes explanation to consumers, documentation of delivery, and record-keeping by designated staff responsible for product delivery.	Includes detailed algorithm (e.g., prevalence cut-offs) for selecting community-wide or school-based MDA with campaign frequency based on STH prevalence.	Same as optimal characteristics.
Program delivery platform The platform used to reach a target population and deliver a product.	Includes evidence-based guidance for selecting optimal delivery platforms for community-wide MDA based upon local characteristics (e.g., percent urban or baseline prevalence).	Provides index of potential treatment delivery platforms to select from, including continued school-based MDA combined with community-wide MDA.
Time to impact An estimate of the time needed to fully implement an intervention for it to achieve targeted impact.	Provides estimated time to impact for transmission interruption based on baseline prevalence (using combinations of target groups and dominant species) and coverage levels, to assist with budgeting and forecasting. Includes modeled impact over the same time horizon for ongoing morbidity control programs, for comparison.	Provides estimated time for transmission interruption based on baseline prevalence and coverage levels, to assist with budgeting and forecasting.
Implementation timeline A list of chronological activities estimating the time necessary to implement a public health intervention, including necessary time intervals between activities.	Details example timelines for critical planning, implementation, and evaluation activities, including: prevalence mapping, drug and materials procurement and distribution, training of distributors, community sensitization, intervention delivery, coverage assessments, and other monitoring and evaluation activities.	Details critical planning, implementation, and evaluation activities without providing specific timeline intervals between activities.
Resources required[a] Financial (e.g., cost) and non-financial (e.g., drug donations, materials, volunteers) costs needed for the implementation of guidelines with fidelity	Provides guidance related to the comparative financial and material resources and opportunity costs (e.g., time cost for health workers) necessary for delivering school-based and community-wide MDA.	Provides a list of resourced needed for delivery of community-wide MDA.
Sub-domain 3: Health system considerations Evidence categories that describe and compare health systems-level considerations for the standard-of-care and a potential new recommendation, including implementation context and organizational preparedness.		
Implementation infrastructure Ideal infrastructure needed to implement a program including training, management/supervision, and data collection systems necessary for operationalizing a policy.	Includes specific evidence-based recommendations for leveraging existing health system infrastructure (e.g., health information management systems for data monitoring or supply chain for drug procurement).	Includes general best practices for leveraging existing delivery infrastructure of ongoing community-based programs.
Workforce involved Cadre, qualifications, recruitment, and distribution of people by gender within the workforce, and attributes of workers engaged to implement a public health intervention.	Provides recommendations for recruitment and number of health workforce and drug distributors needed per capita at regional and local levels.	Provides recommendations for recruitment and number of drug distributors needed per capita at a local level.
Feedback mechanisms for intervention Recursive process of collecting and integrating feedback from key stakeholders about the intervention and using feedback to iteratively improve an intervention.	Provides guidance for embedding feedback systems for program managers to communicate and update coverage activities throughout intervention planning (e.g., implementer training or drug distribution) and delivery (e.g., coverage monitoring).	Provides best practices for program managers to communicate and update coverage activities throughout intervention planning and delivery.
Scalability The likelihood that an efficacious health intervention will be expanded under real-world conditions to reach a greater proportion of the eligible population while retaining effectiveness.	Provides treatment coverage targets and equity based coverage targets during the rollout of community-wide MDA at scale (e.g., sTPoPs for a phased scale-up, with embedded quality improvement processes).	Provides treatment coverage targets during the rollout of community-wide MDA at scale (e.g., sTPoPs for a phased scale-up, with embedded quality improvement processes).
Sustainability The continued use of a product and delivery platform to achieve health outcomes in a target population.	Includes specific recommendations for program financing and budgeting. Includes recommendations for measuring and addressing population treatment fatigue. Includes links to sustainability prognosis tools (e.g. Dahlberg tool).	Includes specific recommendations for ensuring programs are fully resourced.[b]
Dissemination strategies The distribution method and frequency for sharing policy changes with target audiences and decision-makers, including populations with high burdens of disease or those at risk of infection.	Provides specific recommendations for disseminating guidelines at global, national, and local levels, including tools for adapting dissemination strategies to optimize coverage, suggested dissemination channels, messaging, and frequency.	Provides specific recommendations for disseminating guidelines at global and national levels, including suggested dissemination channels, messaging, and frequency.[b]
Surveillance data Processes for ongoing systematic collection, analysis, and interpretation of data that are essential to the planning, implementation, and evaluation of public health interventions.	Provides surveillance guidance that includes clear criteria (thresholds) for starting and stopping community-wide MDA, monitoring for recrudescence, and verifying transmission interruption. Additionally includes guidance for use of existing and new diagnostics, including drug resistance surveillance.	Provides surveillance guidance that includes clear criteria (thresholds) for starting and stopping community-wide MDA, monitoring for recrudescence, and verifying transmission interruption.

(*Continued*)

TABLE 2 Continued

Domains, Evidence categories, & Definitions	Characteristics of potential new guidelines	
	Optimal guideline characteristics	Minimally acceptable guideline characteristics
Feasibility[a] The extent to which an intervention can be carried out in a particular setting or organization.	Provides quantitative and qualitative evidence that community-wide MDA (or a combination of school-based and community-wide MDA) is feasible to implement, or challenges in feasibility where present. Includes recommendations for increasing feasibility.	Provides qualitative evidence that community-wide MDA is feasible to implement, or challenges in feasibility where present.
Feasibility (A): Existing policies/directives Existing policies currently guiding decision-making or resource allocation for a specific public health goal or social group.	Aligns with existing WHO and national-level policies for STH transmission interruption.	Aligns with WHO policies for STH transmission interruption.
Cost effectiveness[a] Comparison of both the costs and health outcomes of one or more interventions by estimating costs to gain a unit of a health outcome.	Provides an updated systematic review to compare the costs and cost effectiveness of different delivery models, including community-wide MDA compared to school-based MDA over a variety of time horizons. Includes assumptions about when elimination occurs due to infrastructure development alone.	Provides an updated systematic review to compare the costs and cost effectiveness of different delivery models, including community-wide MDA compared to school-based MDA.
Monitoring[a] The continuous oversight of an activity to determine if it is delivered according to plan.	Recommends process monitoring activities throughout intervention planning and delivery with specific monitoring quality indicators, performance measures, and performance indicators and timelines for data collection.	Recommends process monitoring activities throughout intervention planning and delivery with specific monitoring quality indicators, performance measures, and performance indicators only (no timelines for data collection).
Evaluation[a] The effectiveness of a program in achieving its predetermined goal through empirical measurement of various indicators over extended periods. Evaluations produce information on both positive and negative outcomes.	Recommends key evaluation activities with specific coverage and impact indicators, and timelines for data collection for each delivery platform.	Recommends key evaluation activities with coverage and impact indicators only (no timelines for data collection).
Cross-ministerial partnerships Two or more government ministries or departments work together to initiate, plan, and implement programs intended to achieve health outcomes that necessitate the involvement of varying sectors.	Recommends multi-sectoral collaboration and provides best practices for multi-sectoral collaboration.	Recommends multi-sectoral collaboration, with concrete examples and case studies.

[a]These evidence categories were not assessed during the first round of the Delphi survey and were automatically included in the final Target Policy Profile because they align with criteria included in the GRADE Evidence to Decision (EtD) framework that is used by the WHO to guide the process of translating evidence to recommendations.
[b]Some key stakeholders noted these criteria would be "nice to have" but should not be considered minimally acceptable.

experts. However, because the STH community is relatively small, we feel confident that a small sample size of key experts can have a deep understanding of STH implementer experiences and important insights into the challenges at hand. Finally, the formative scoping review in this study was used to map a body of literature and was therefore not systematic; a systematic approach to synthesizing evidence about factors influencing evidence uptake for community-based interventions may also be useful in the future to ensure that new guidelines are successfully implemented. Despite these limitations, the systematic approach undertaken in this study provided the opportunity to garner feedback and ideas from a heterogenous mix of STH stakeholders to co-envision next steps for STH guidance.

Conclusion

We developed a TPoP using participatory methods to guide decision makers as they consider updating STH guidelines, including for guidelines to support a potential transition from STH control to STH transmission interruption. The TPoP reflects areas of evidence, ranging from clinical to pragmatic implementation evidence, that are important to a wide array of STH stakeholders and can be used to craft guidelines and operational materials that are appropriate and useful for guiding future implementation at scale.

Data availability statement

The datasets presented in this article are not readily available because the raw datasets may contain identifiable information such as the participants place of work or past experiences. Redacted datasets are available upon request. Requests to access the datasets should be directed to deworm3@uw.edu.

Ethics statement

The studies involving humans were approved by The Human Subjects Division at the University of Washington. The studies were conducted in accordance with the local legislation and institutional requirements. The ethics committee/institutional review board waived the requirement of written informed consent for participation from the participants or the participants' legal guardians/next of kin because this research was determined to be minimal risk, and verbal consent was obtained from key informants as a result.

Author contributions

AM: Conceptualization, Methodology, Supervision, Writing – original draft. KL: Data curation, Investigation, Writing – review & editing. AR: Conceptualization, Data curation, Investigation, Writing – review & editing. MG: Data curation, Investigation, Methodology, Writing – review & editing. SD: Conceptualization, Writing – review & editing. HS: Conceptualization, Supervision, Writing – review & editing. TN: Conceptualization, Writing – review & editing. JW: Conceptualization, Methodology, Supervision, Writing – review & editing.

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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

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frhs.2023.1310694/full#supplementary-material

SUPPLEMENTARY TABLE S1
TPoP scoping review search terms.

SUPPLEMENTARY TABLE S2
Category-level findings from second round of Delphi technique.

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Access to health and social protection policies by homeless people during the COVID-19 pandemic: a mixed-methods case study on tailored inter-sector care during a health emergency

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Introduction: The article analyzed homeless people's (HP) access to health and social protection policies and tailored inter-sector care, including emergency measures, during the COVID-19 pandemic in Belo Horizonte (BH), capital of Minas Gerais state, Brazil. It intended to provide data on HP and evaluate existing public policies focused on vulnerable populations during this health emergency.

Methods: The study adopted a mixed-methods design with triangulation of quantitative and qualitative data.

Results: Social cartography showed that in the early months of the pandemic, the health administration had difficulty reordering the health system, which experienced constant updates in the protocols but was nevertheless consolidated over the months. The evidence collected in the study showed that important emergency interventions in the municipality of BH involved activities that facilitated access by HP to the supply of services.

Discussion: The existence of national guidelines for inter-sector care for HP cannot be ruled out as a positive influence, although the municipalities are responsible for their implementation. Significantly, a health emergency was necessary to intensify the relationship between health and social protection services. Roving services were among those with the greatest positive evidence, with the least need for infrastructure to be replicated at the local level. In addition, the temporary supply of various inter-sector services, simultaneously with the provision of day shelters by organized civil society, was considered a key factor for expanding and intensifying networks of care for HP during the emergency phase. A plan exists to continue and expand this model in the future. The study concluded that understanding the inter-sector variables that impact HP contributes to better targeting of investments in interventions that work at the root causes of these issues or that increase the effectiveness of health and social protection systems.

KEYWORDS

homeless, inter-sector collaboration, health services access, social assistance services, social protection, triangulation of methods, COVID-19

Introduction

Brazil experienced wide variations between state capitals in their responses to the COVID-19 health emergency. Such variations were associated with geographic inequalities and different health care capacities, highlighting the positive response by the municipality of Belo Horizonte (BH) (1), whose Greater Metropolitan Area is home to five million inhabitants, the third largest in Brazil (2). The city is known historically for strong investments in public policies, including the structuring of health systems (under Brazil's Unified Health System, known in Portuguese as *Sistema Único de Saúde*—SUS) and social protection systems (under Brazil's Unified Social Assistance System, known in Portuguese as *Sistema Único de Assistência Social*—SUAS) (3, 4). During the pandemic, public policy action in BH was known in the country for good performance in tackling COVID-19 based on strong crisis management and multidimensional responses to the emerging challenges (4). A study by Imperial College London reported that BH showed the lowest COVID-19 mortality rate among 14 Brazilian state capitals and estimated that half of the deaths in the other Brazilian cities could have been averted if they had followed the same trend as BH (1). One of the city's little-known achievements involved multiple efforts to supply care for homeless people (HP) during the pandemic, which is the object of the study reported in this article.

Homelessness puts individuals in a situation of significant social vulnerability, marked by prior living and health conditions, exposure to risk factors and violence due to limited access to financial resources, leaving them subject to constant violations of their human and social rights, and exposure to discrimination in access to health services and health care goods (5, 6). We propose that multidisciplinary approaches involving health and social protection have the potential to increase access to multiple inter-sector and specific services for HP (7, 8).

There is currently an important gap in the literature on policies for HP and responses targeted to them during health emergencies. Since HP are marked by extreme vulnerability (7, 8), this gap currently poses a clear challenge for "reaching those left behind," a principle enshrined in the multilateral agreement on the Sustainable Development Goals (SDGs) under the 2030 Agenda for prioritization of policies targeted to more vulnerable groups (9, 10). In the early phase of the pandemic, there was a concern over the possibility of HP's increased vulnerability to COVID-19 due to their precarious status and the intersection between various chronic health conditions (11, 12). However, difficulties in obtaining public data on HP prevent the identification of the scope of this impact, while the lack of evaluation of targeted policies hinders the development of knowledge on effective responses to their specific needs. The case of BH, with its attempt to prioritize care for HP during the pandemic, thus represents an important potential contribution to the literature.

The city's positive performance is known to have benefited from Brazil's national guidelines on care for HP as a social right, by recommending targeted services and actions with continued care for this social group (rather than merely temporary interventions). Public health and social protection are Constitutional rights in Brazil, ensured as part of social welfare policy since 1988 (13, 14). The National Policy for Homeless People (known in Portuguese as *Política Nacional para a População em Situação de Rua*—PNPSR) was approved in 2009, drafted in dialogue with social movements and civil society for the national structuring of inter-sector policies for this population. In the operationalization of targeted policies, the PNPSR functions as a legal framework that seeks to guarantee rights and promote inter-sector assistance and comprehensive care for HP throughout the country (15).

The definition of HP in this article is the same as recommended by the PNPSR, namely, "a heterogeneous population group with the common characteristics of extreme poverty, broken or weak family ties, lack of regular conventional housing, and that uses public byways and degraded areas as spaces for temporary or permanent housing and subsistence, as well as overnight or temporary shelters as provisional housing" (15). This definition excludes people that sleep on the streets some days of the week due to pendular movement (commuting) between cities to work but who return to their homes periodically.

This article's objective was to analyze access by HP to emergency measures related to health and social protection policies and their inter-sector relations during the COVID-19 pandemic in BH until late 2021, using a mixed-methods convergent study design. The quantitative data also included 2019 as the cutoff year prior to the start of the pandemic for purposes of comparing information. The study further intends to help mitigate the gap in data on HP and in the evaluation of public policies targeted to vulnerable populations in the health emergency.

Methods

Study design

The article is based on a mixed-methods study with triangulation of quantitative and qualitative methods through a convergent design, also known as a parallel study or concurrent design. Considering the complexity of variables that affect HP and the difficulties in obtaining data on this population, the convergent design was adopted due to its capacity for dialogue among data of various types and complementary data on the same theme. The study's underlying paradigm is pragmatism, which features pluralist characteristics centered on the research problem and oriented by real-world practices, consequences, and limitations, as a philosophical premise that fosters openness to the aggregation of different data collection methods for studying the problem (16).

Quantitative secondary data from government databases on health and social protection, qualitative secondary data from administrative documents, qualitative primary data from interviews and focus groups with representatives of HP, administrators, staff, and others were collected simultaneously and triangulated. Each method will be discussed separately. Figure 1 provides a flowchart with the mixed data collection stages that led to the triangulation of methods.

Added to the triangulation of methods was the creation of a Follow-Up Committee, active during the research, consisting of: (i) health and social protection administrators and staff from various areas and with various roles; (ii) representatives from the National Pastoral of the Street People (known in Portuguese as *Pastoral Nacional do Povo de Rua*), a civil society organization with a historical influence on policies for HP; and (iii) representatives of the National Homeless People's Movement. The inclusion of this heterogeneous committee aimed to correlate the literature with the contextual reality in the field, map the various activities in the territories, mitigate biases, language barriers, and administrative processes, discuss, qualify, and contrast the interpretations of contexts and analyses, and produce an understanding of the results in dialogue with the field of practice in care for HP in the municipality.

The convergent design recognizes the strengths and weaknesses of the quantitative and qualitative methods when assessed separately to expand the theme's complexity and strengthen the results' methodological backing (16), as discussed in detail at the end of the discussion. The breadth and density of the quantitative secondary data from the respective government databases allowed an objective and broad direct visualization of the longitudinal evolution in the target population's profile and the care provided during the pandemic and its trends. Meanwhile, the qualitative sample allowed greater contextualization of the processes, practices of care, and various subjectivities experienced during the same period, while adding qualitative depth to the crosscutting relations between the variables found in the results.

Data collection

The data that comprised the quantitative and qualitative analyses were collected with different timeframes, according to the study's analytical objectives in its quantitative and qualitative stages.

Quantitative

For the quantitative methodology, there were time differences between the health services data and the social protection data. For health, we adopted the timeframe from 1 year prior to 1 year after the start of the pandemic (2019–2021) to allow an evaluation of the municipal health service's resilience in the face of the health emergency. For social protection, we selected the month with the last update to the social protection database called the Federal Government's Single Registry for Social Programs (known in Portuguese as CadÚnico) in the study's target timeframe (September 2021).

The information used in the quantitative stage referred to the following services: (i) for health services: Health Centers, including data from the Street Outreach Clinic teams (a roving primary care service), Mental Health based on information from the Mental Health Referral Centers (known in Portuguese as *Centro de Referência em Saúde Mental*—CERSAM) and Referral Centers for Mental Health Related to Alcohol and Other Drugs (known in Portuguese as *Centro de Referência em Saúde Mental Álcool e Drogas*—CERSAM-AD), and Urgent Services and (ii) for social protection services: the CadÚnico, the unified enrollment system for social benefits.

The scarcity of specific secondary data on the homeless population posed a significant barrier to robust quantitative analyses. One initial obstacle involved the use of tags to categorize homeless individuals in health databases. The first database that was analyzed revealed an unusually high contingent of HP under 5 years of age. Given this scenario, meetings were held with the study's Follow-up Committee, leading to the decision to approach health care professionals on the correct application of the homeless tag. A new dataset was later received for analysis, with the corrections to the previously detected inconsistencies (this dataset was used in the study).

The CadÚnico registry showed a predominance of records with outdated data. The evidence indicated that given the homeless population's mobile nature, part of this dataset was no longer representative of the group. In the process of linking various databases, for example, only 5.6% of the individuals whose records had been updated more than 48 months before were found in the other databases, in contrast with a proportion of 55.0% of the records updated within the previous 18 months. We thus opted to limit the performance of statistical tests to individuals with data updated within the previous 18 months, which coincided with the pandemic, since this database is from September 2021.

Qualitative

For the qualitative methodology, we adopted two timeframes for the data collection. The document collection included public documents produced by the municipal government with a focus on the health and social protection departments, where the timeframe covered from March 2020, the month in which the municipality declared the pandemic, to December 2021, the period with the largest accumulation of documents on management of the pandemic in the city. The collected documents included national and local laws and guidelines, technical notes, annual management reports, patient flows, clinical protocols, patient follow-up, and other relevant public documents published on the website of the Belo Horizonte Municipal Government. The qualitative primary data collection, through interviews and focus groups, took place from June 2021 to June 2022 due to the restrictions imposed by the pandemic on in-person activities. Key informants were selected for the interviews and focus groups through the snowball sampling method until the researchers identified data saturation (17). The snowball method was chosen for its capacity to reach hard-to-reach groups (18) such as HP. Primary data were collected with 48 semi-structured interviews and four focus groups, totaling 86

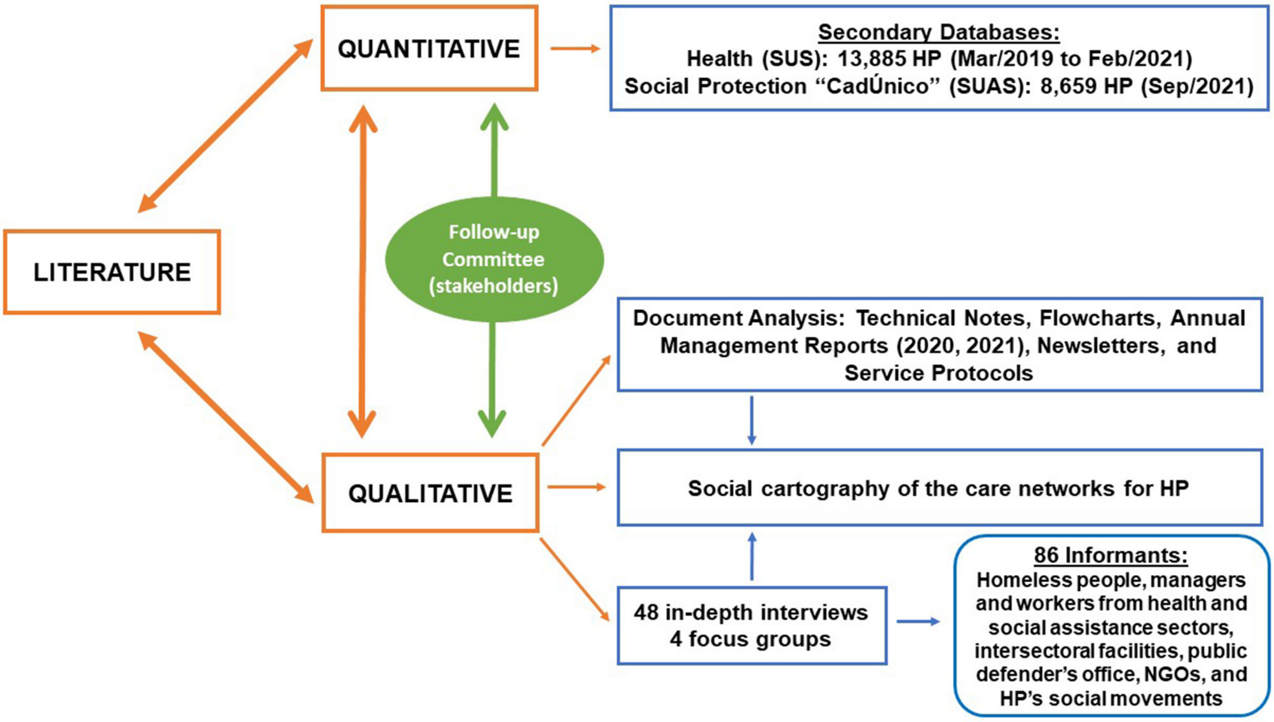

FIGURE 1
Methodological triangulation. Source: authors.

interlocutors during the above-mentioned period. The interviews were conducted with HP, persons with experience living in the streets, staff and administrators from health and special social protection services, a representative from the office of the public defender, and members of organized civil society with initiatives acknowledged by the municipal government in care for the homeless population. The four focus groups were conducted with HP at different locations with the aim of identifying their experiences with access to public services and actions in the response to the pandemic, besides their survival strategies. At the start of the qualitative stage, we conducted preliminary fieldwork to understand the territory's dynamics and the services attended by the HP, which included visiting 17 services, either formally planned as such and/or those viewed as references by the HP. The scripts for the semi-structured interviews and focus groups were developed by the researchers and validated by the study's Follow-up Committee.

Data analysis

Quantitative

In the quantitative stage, epidemiological statistical methods were applied to assess the profile of HP in the municipality, as well as the profile of care supplied to them in health and social protection, using the R software. Given the lack of a unified municipal or national information system on HP, the data were assessed individually and jointly based on probabilistic database linkage. The sizes and time windows assessed in the databases were: (i) health database: 13,885 unique HP from March 2019 to February 2021; (ii) the social protection database, called the "CadÚnico:" 8,659 HP registered in September 2021.

The study variables for the analyses were: (i) health: consultations performed 1 year before and 1 year after the start of the pandemic, evaluated according to the number of consultations and classified according to the International Classification of Diseases (ICD-10) and characterization of the HP treated by the health services according to sex at birth, race/skin color, and age; (ii) social protection: identification of the HP registered in the CadÚnico and their characterization according to sex at birth, age, schooling, duration of homelessness, and per capita family income.

The descriptive analysis used contingency tables, which allowed comparing the distribution of the analytical variables according to groups of individuals. Considering only persons with up-to-date enrollment in the CadÚnico database, i.e., within the previous year and half, that is, up to date during the pandemic, we evaluated the differences in their profile according to duration of their homelessness (1 year or less vs. more than 1 year) using the chi-square test with 5% significance.

The pandemic's impact on the number of health consultations for HP was evaluated through interrupted time series analysis (19). Since the data on the number of patient consultations displayed overdispersion, identified by the Cameron and Trivedi test (20), a quasi-Poisson regression model was adjusted with the covariables time in months, occurrence of the pandemic (yes, no), and interaction between them. The model's fit was assessed by the deviance residuals' normality and the residuals' autocorrelation and partial autocorrelation functions. Based on the results, graphs were produced with the time series of the total monthly consultations predicted by the model considering the pandemic's effect, and the

TABLE 1 **Profile of homeless people seen at health care units in Belo Horizonte.**

Variables	Health care units *n* (%)				Total *n* (%)**
	Health centers		Mental health	Urgent care*	
	Outreach clinics	Other teams			
Consultations					
Before the pandemic	597 (73.0)	6,865 (68.3)	360 (66.8)	4,110 (72.5)	9,999 (72.0)
During the pandemic	372 (45.5)	5,960 (59.3)	311 (57.7)	2,393 (42.2)	7,707 (55.5)
For respiratory symptoms					
Before the pandemic	0 (0.0)	426 (4.2)	1 (0.2)	12 (0.2)	438 (3.2)
During the pandemic	0 (0.0)	612 (6.1)	3 (0.6)	5 (0.1)	619 (4.5)
COVID-19					
Tested	0 (0.0)	173 (1.7)	2 (0.4)	0 (0.0)	175 (1.3)
Confirmed cases	0 (0.0)	30 (0.3)	1 (0.2)	0 (0.0)	31 (0.2)
Sex					
Female	260 (31.8)	4,136 (41.2)	147 (27.3)	2,264 (40.0)	5,714 (41.2)
Male	558 (68.2)	5,909 (58.8)	392 (72.7)	3,403 (60.0)	8,172 (58.9)
Race/skin color					
Brown	532 (65.0)	5,434 (54.1)	340 (63.1)	4,197 (74.1)	8,415 (60.6)
White	104 (12.7)	3,489 (34.7)	89 (16.5)	1,003 (17.7)	4,098 (29.5)
Black	182 (22.2)	975 (9.7)	104 (19.3)	407 (7.2)	1,199 (8.6)
Asian descendant	7 (0.9)	143 (1.4)	8 (1.5)	73 (1.3)	187 (1.3)
Not recorded	0 (0.0)	35 (0.3)	0 (0.0)	0 (0.0)	35 (0.3)
Age (years)					
0–15	7 (0.9)	2,535 (25.2)	4 (0.7)	888 (15.7)	3,079 (22.2)
16–40	469 (57.3)	4,093 (40.8)	324 (60.1)	2,774 (49.0)	6,035 (43.5)
41–60	338 (41.3)	2,746 (27.3)	211 (39.1)	1,522 (26.9)	3,770 (27.2)
61 or more	26 (3.2)	854 (8.5)	13 (2.4)	544 (9.6)	1,255 (9.0)
ICD-10					
I10—Hypertension	0 (0.0)	504 (5.0)	5 (0.9)	7 (0.1)	515 (3.7)
F19—Psychoactive substance use disorders	28 (3.4)	61 (0.6)	186 (34.5)	0 (0.0)	244 (1.8)
F10—Alcohol use disorders	15 (1.8)	78 (0.8)	173 (32.1)	0 (0.0)	235 (1.7)
F20—Schizophrenia	4 (0.5)	72 (0.7)	93 (17.3)	1 (0.0)	140 (1.0)
Other	809 (98.9)	5,616 (55.9)	420 (77.9)	684 (12.1)	6,589 (47.5)
Not recorded	4 (0.5)	4,394 (43.7)	16 (3.0)	4,978 (87.8)	7,234 (52.1)
Consultations					
Before the pandemic	3,844 (51.7)	31,674 (55.5)	4,354 (48.5)	8,099 (65.2)	47,971 (55.9)
During the pandemic	3,593 (48.3)	25,373 (44.5)	4,622 (51.5)	4,324 (34.8)	37,912 (44.1)
Total	7,437 (100.0)	57,047 (100.0)	8,976 (100.0)	12,423 (100.0)	85,883 (100.0)

Source: authors. *Patients treated in emergency may also have been treated in Health Centers and Mental Health and vice versa. **Total of unique patients (does not refer to the sum of the previous columns).

TABLE 2 **Descriptive data related to homeless people enrolled in the Brazilian Federal Government's Single Registry for Social Programs (CadÚnico; *N* = 8,659).**

CadÚnico variables	*n* (%)
Mean age	42.4 years
Biological sex	
Female	904 (10.4)
Male	7,755 (89.6)
Race/skin color	
Indigenous	0 (0.1)
Asian descendant	38 (0.4)
Brown	5,189 (59.9)
White	1,366 (15.8)
Black	2,044 (23.6)
No information in the database	12 (0.1)
Time in homelessness in relation to last update in the registry	
Up to 6 months	2,518 (29.1)
Six months to 1 year	1,136 (13.1)
One to 2 years	1,014 (11.7)
Two to 5 years	1,664 (19.2)
Five to 10 years	1,112 (12.8)
More than 10 years	1,215 (14.0)
Contact with family members off the streets	
No contact	3,832 (44.2)
Frequent family contact	2,876 (33.2)
Annual contact	448 (5.2)
Monthly contact	1,269 (14.6)
Weekly contact	812 (9.4)
Daily contact	347 (4.0)
Schooling	
None	649 (7.5)
Incomplete primary	4,482 (51.8)
Complete primary	1,246 (14.4)
Incomplete secondary	888 (10.4)
Complete secondary	1,282 (14.8)
Incomplete university	102 (1.2)
No information in the database	10 (0.1)
Per capita family income	
Up to BRL 89.00	8,005 (92.4)
More than BRL 89.00	654 (7.6)

Source: authors.

counterfactual, equal to the predicted number of consultations in case they had maintained the same profile as prior to the pandemic.

Qualitative

Meanwhile, the analysis of the qualitative data was divided into two lines. The first line was the content analysis through use of the qualitative analytical software ATLAS.ti. The principal theoretical and methodological reference for the content analysis was Bardin (21), who proposes his method as controlled hermeneutic. This analysis has two main functions, one of which is heuristic, enriching the content's exploration and increasing the propensity to discovery, and the other, "proof administration," which uses the systematic analysis method to verify provisional questions or affirmations. The discursive content is treated by inference or logical deduction of the evident indices, in this case the transcriptions of the interviews and focus groups (21). The transcribed interviews and focus groups were read carefully by eight independent researchers, with no prior definition of categories, oriented by the study's lines: health actions, social protection actions, actions by civil society, and strategies by HP for dealing with the pandemic. The categories that emerged from this reading were consolidated and validated in meetings with the entire research team, and the contents were later reviewed according to the defined concepts.

The second line was the document analysis, based on the principles of contemporary historiography, seeking to explore the documents as representations of realities and narratives. From this perspective, documents are viewed as institutions and thus also as social constructions from a critical and intellectual context that constitute local and temporal demands in their production (22, 23).

Results

Profile of homeless people

The quantitative analysis showed that the profile of HP in BH corresponded to the profile identified in the population censuses conducted in the city in 2009 and 2013, as a mostly adult, male, Black population with incomplete primary education (Tables 1, 2). However, although this profile predominated, we identified a trend toward change during the pandemic, with an increase in the number of homeless women and individuals with more schooling. Data from the CadÚnico pointed to a higher proportion of persons with a year or less of homelessness, incomplete secondary schooling (44.8%) or with complete secondary schooling or more (47.2%), white skin color (39.9%), age from 0 to 29 years (54.9%), and female gender (44.8%) (Table 3).

Meanwhile, the qualitative analysis showed that the pandemic raised new concerns for those working with HP, one of which involved the intersectional vulnerabilities attributed to this population's sociodemographic profile, leaving them more susceptible to COVID-19, besides a consensus among the interviewees that there had been an increase in the number of HP since the start of the health emergency. The main reasons cited in the interviews for this increase were loss of jobs, inability to pay rent due to the country's economic crisis, migration from the interior to the state capitals in search of work, and family conflicts resulting from the increase in shared time indoors.

Health care

Two days after official confirmation of the first case of COVID-19 in BH, the municipal government published Decree no. 17.304 on March 18, 2020, locking the city down through temporary suspension of activities with the potential for gathering, including commerce and public services. Starting on this date, essential services were defined, and the health and social protection services were reordered according to the new emergency circumstances. All health services were considered essential and continued to function throughout the pandemic.

To contextualize the quantitative results, we begin by highlighting the mapping conducted by social cartography of the network of health care for HP. Primary health care (PHC) services are the preferred portal of entry for users, besides coordinating the care and organizing the flow of care in network format. The principles are universality, comprehensiveness, and equity, and the guidelines are regionalization, territorialization, and person-centered care, among others. Other important portals of entry for HP into the health care system are mental health services, referred to in Brazil as psychosocial care, including the Centers for Psychosocial Care (CAPS, acronym in Portuguese) that comprise the Network of Psychosocial Care (RAPS, acronym in Portuguese) and the Rapid Care Units (UPA, acronym in Portuguese) in urgent and emergency care that comprise the Network of Urgent and Emergency Care (RUE, acronym in Portuguese).

The health care system in BH features a broad primary care network that includes 152 Health Centers and various modalities and health teams with 595 family health teams, 310 oral health teams, and 152 mental health teams distributed across the city's nine regional health divisions. The Network of Urgent and Emergency Care consists of nine Rapid Care Units. As for the Network of Psychosocial Care, the city has nine Mental Health Referral Centers, five Referral Centers for Mental Health Related to Alcohol and Other Drugs, and one Urgent Psychiatric Care service.

Besides the health services at fixed locations, BH has roving PHC services in the Street Outreach Clinics and the program called "BH Joining Hands Against AIDS," which features mobility to reach users on the streets in sensitive locations, such as public drug use scenes and hard-to-reach areas such as under street overpasses and other unconventional gathering places. The documents on reordering of the services during the pandemic and the interviews point to these services as portals of entry into the health care systems for persons that experienced homelessness recently during the pandemic.

The quantitative analysis of the health database pointed to an overall decrease in care, totaling 85,883 consultations for HP, 47,971 of which before the start of the pandemic (representing 9,999 individuals) and 37,912 after the start of the pandemic (representing 7,707 individuals). The downward total numbers of care reflect the decrease in individuals seen mainly in PHC (Health Centers and Street Outreach Clinics). In the urgent services, before the pandemic, 4,110 HP were seen in 8,099 consultations, while during the pandemic 2,393 HP were seen in 4,324 consultations, that is, a decrease of 41.77% in persons seen and 46.61% in consultations (Table 1).

The most prevalent diagnosis was hypertension, despite a 1.13% decrease during the pandemic. However, the evaluation stratified by type of service revealed different profiles of care according to the services' respective expertise. The highest prevalence rates in the Street Outreach Clinics and Mental Health Referral Centers and Referral Centers for Mental Health Related to Alcohol and Other Drugs were for mental and behavioral disorders involving multiple psychoactive substance use, alcohol-related disorders, and schizophrenia (Table 1).

Despite difficulties with health care since the start of the pandemic, the health care network succeeded in increasing the number of treatments for HP with respiratory symptoms, with a resumption of the number of treatments for other complaints during the pandemic (Figures 2, 3).

The qualitative data helped contextualize the decrease in the number of consultations. The documents showed that the principal orientation for the general population was to avoid using the health system for mild symptoms or medical conditions other than COVID-19, to avoid causing agglomeration that would increase the risk of SARS-CoV-2 transmission. The interviews indicated that this orientation also tended to keep HP away from the health services, even for treatment of chronic conditions that should not have been interrupted.

The social cartography also indicated that in the early months of the pandemic, the health administration experienced difficulties in reordering the health system, with constant updates to the protocols, but the system's reorganization was gradually consolidated over the months. The health services' eventual readaptation, including stabilization of new flows and guidelines for individuals with respiratory symptoms, correlated directly with the period identified in the quantitative analysis with an increase in care for HP with respiratory symptoms and with the resumption of consultations for other health complaints.

Reordering of the health care system during peak transmission

Quantitative data showed that health services in general had their activities affected by the peak waves in COVID-19 transmission, testing the limits of the network's capacity. The number of treatments for respiratory symptoms in HP increased by 43.7% after the start of the pandemic (Table 1). The peak treatments for respiratory symptoms occurred in July and December 2020 (Figure 3). We also identified an increase in confirmed COVID-19 cases in December 2020. Importantly, the curve of COVID-19 cases in BH resembles that in other municipalities and countries around the world.

Social cartography emphasized that one of the most important measures in reordering the health care network was influenced by periods with the highest peak transmission of the disease, when the administration determined that each regional health division would have a Health Center temporarily converted into a 24-Hour Non-COVID-19 Health Care Unit, aimed at absorbing the excess volume from the Rapid Care Units. During this period, users enrolled in the urgent care units were referred to other Health Centers.

TABLE 3 Profile of persons enrolled in the CadÚnico registry for less than a year and a half according to the last update (September 2021).

Variable	Time in homelessness in relation to last update in registry—*n* (%)		Total—*n* (%)	*p**
	Up to 1 year	More than 1 year		
Age (years)				**<0.001**
0–29	293 (54.9%)	241 (45.1%)	534 (100.0%)	
30–39	343 (38.5%)	548 (61.5%)	891 (100.0%)	
40–49	279 (29.7%)	660 (70.3%)	939 (100.0%)	
50–59	146 (25.5%)	427 (74.5%)	573 (100.0%)	
60–89	57 (24.4%)	177 (75.6%)	234 (100.0%)	
Total	1,118 (35.3%)	2,053 (64.7%)	3,171 (100.0%)	
Biological sex				**<0.001**
Female	163 (44.8%)	201 (55.2%)	364 (100.0%)	
Male	955 (34.0%)	1,852 (66.0%)	2,807 (100.0%)	
Total	1,118 (35.3%)	2,053 (64.7%)	3,171 (100.0%)	
Race/skin color				**0.018**
White	203 (39.9%)	306 (60.1%)	509 (100.0%)	
Non-white	911 (34.3%)	1,747 (65.7%)	2,658 (100.0%)	
Total	1,114 (35.2%)	2,053 (64.8%)	3,167 (100.0%)	
Contact with family off the streets				**<0.001**
Never	457 (34.7%)	859 (65.3%)	1,316 (100.0%)	
Almost never	245 (33.3%)	490 (66.7%)	735 (100.0%)	
Every year or month	199 (32.0%)	423 (68.0%)	622 (100.0%)	
At least every week	217 (43.6%)	281 (56.4%)	498 (100.0%)	
Total	1,118 (35.3%)	2,053 (64.7%)	3,171 (100.0%)	
Schooling				**<0.001**
None	75 (29.3%)	181 (70.7%)	256 (100.0%)	
Incomplete primary	483 (30.3%)	1,113 (69.7%)	1,596 (100.0%)	
Complete primary	156 (34.4%)	297 (65.6%)	453 (100.0%)	
Incomplete secondary	143 (44.8%)	176 (55.2%)	319 (100.0%)	
Complete secondary or more	256 (47.2%)	286 (52.8%)	542 (100.0%)	
Total	1,113 (35.2%)	2,053 (64.8%)	3,166 (100.0%)	

*p-value, chi-square test.

Source: authors. Significant values considering a significance level of 5%.

The restructuring deeply affected HP, as it involved the Carlos Chagas Health Center, historically the principal care provider for this group due to its strategic location and established role as a referral hub for HP care, transitioning temporarily to emergency services in Central-South BH. The teams at this unit reported that the temporary change in patient flows hindered care, since it interrupted the ties with frequent users and the effects were still felt after the resumption of regular care.

> *We experienced a period at the Rapid Care Units when our patients were divided between three Health Centers, and this interfered with care, understand? This confused our patients, who came here to the Rapid Care Units saying, "I want to speak with Dr. so-and-so, who treated me before." This created confusion and harmed the patients. The patient would say, "I've been treated here for 20 years!" They had to go elsewhere [for care] which they could do on a day-to-day basis, but when they were forced to go, it got complicated. It was a break in the bond, like, "Oh, right, they're cutting me loose now, when I've been seeing the same doctor for 20 years."*
>
> Health care worker, Health Center (EGT 011)

Mental health

The quantitative data also showed an increase in care at the Mental Health Referral Centers for psychosocial care during the pandemic (before, $n = 4{,}354$, during, $n = 4{,}622$), with peaks in care in May 2020 (Table 1). Meanwhile, the qualitative data showed that this increase in care related to mental distress was interpreted by health care workers as a consequence of the pandemic, with a

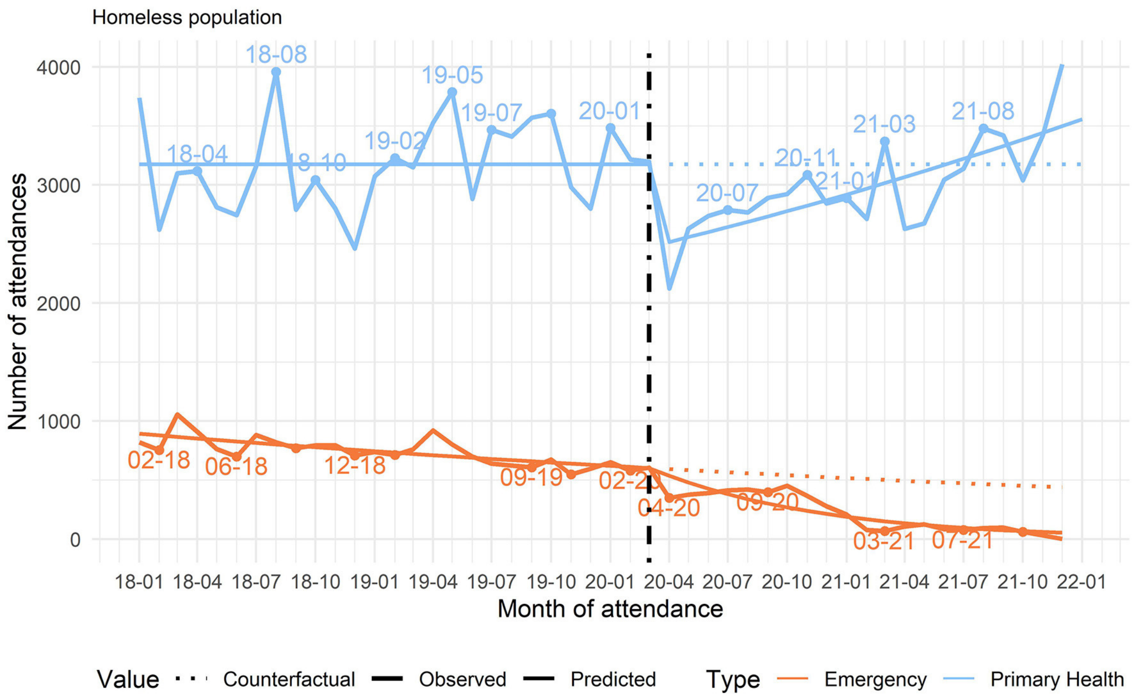

FIGURE 2
Changes in the monthly number of patient consultations in primary care (Health Centers, Street Outreach Clinics, and Mental Health Referral Centers) and in Urgent Care, Belo Horizonte, Minas Gerais, Brazil, 2018–2022. Source: authors.

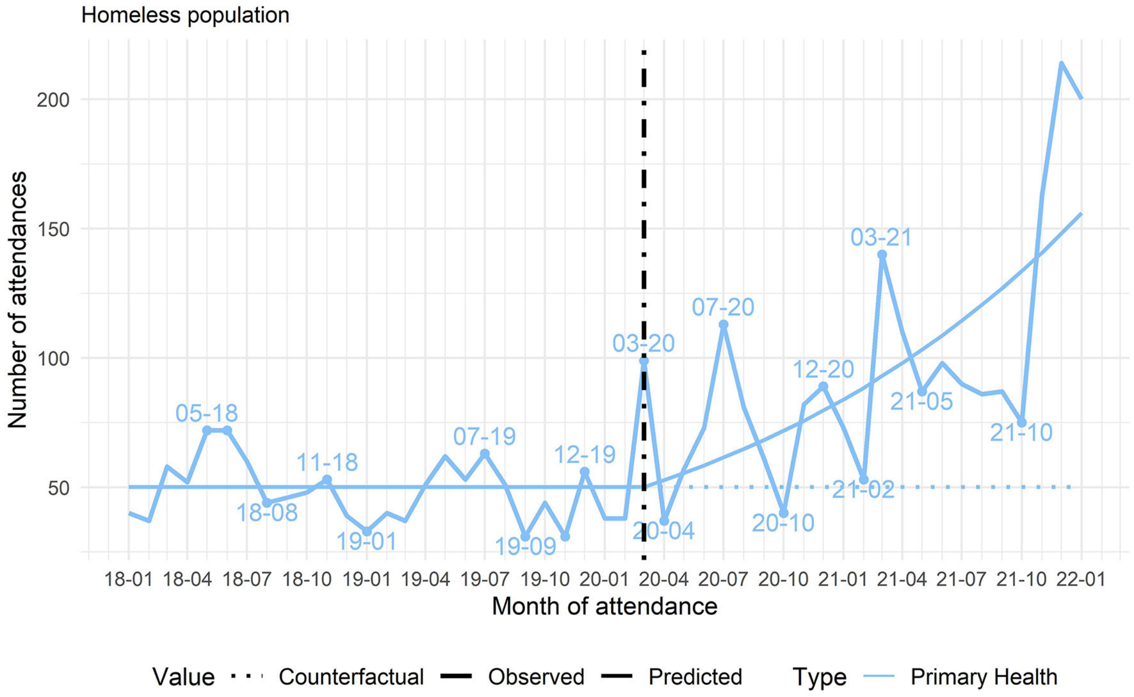

FIGURE 3
Changes in the mean number of consultations for respiratory symptoms in primary care (Health Centers, Street Outreach Clinics, and Mental Health), Belo Horizonte, Minas Gerais, Brazil, 2018–2022. Source: authors.

resulting economic crisis that in turn led to increased exacerbation of psychosocial crises, as illustrated in the following quote.

> *It was very evident that this crisis thing is really a psychosocial crisis, right, an economic crisis. A poverty crisis, not only in the amount of people that began to circulate in the Health Center, which is also real. Our feeling is that there was an increase in the amount of people circulating and experiencing situations of destabilization, it's... psychiatric, you know... psychiatric on the streets. It's not just the amount [of people], I think it's their precarious situation, which became very clear. The patients were increasingly precarious from this social point of view.*
>
> Administrator of a Mental Health Referral Center (EGT 012)

A major difficulty related to mental health, emphasized by patients and health care professionals, was the use of psychiatric medication with its side effects, affecting the patients' treatment. There was a perception of risk among HP that left the users apprehensive toward the use of medicines that might make them drowsy and leave them more vulnerable to violent circumstances on the streets. The supply of medication to reduce abusive drug use and deal with withdrawal syndrome appeared as an important type of care for this population. Health care workers also highlighted the juxtaposition of harmful use of alcohol and other drugs and underlying mental health conditions in some patients.

Social protection

Social cartography of the social protection network for HP highlighted Brazil's national policy guidelines for social protection, defined as part of social protection, which determines that users in situations of social risk or vulnerability such as HP should be served by the Special Social Protection modality. This is divided into high and medium complexity, but only medium complexity will be included, since high complexity includes sheltering as a condition and has different qualities from the other social care services mentioned.

Medium-complexity social protection adopts as its territorial reference the Specialized Social Work Reference Centers (CREAS, acronym in Portuguese), a regional unit that manages modalities of specialized care for various vulnerable groups, including the Specialized Social Approach Service (SEAS, acronym in Portuguese), a roving service known popularly as Street Approach Outreach. BH has nine Specialized Social Assistance Reference Centers and 102 roving staff in Street Approach Outreach (BRASIL, 2004; PBH, 2022). Another modality features a day shelter service and exclusive care for HP, called the Specialized Reference Center for Homeless People (Centro POP, acronym in Portuguese). In addition to psychosocial care and referrals, the day shelter at the Specialized Reference Center for Homeless People provides facilities for storing personal belongings, restrooms and showers, material for bathing and personal hygiene, laundry, meals, and socialization activities. Before the pandemic, the municipality only had two Specialized Reference Center for Homeless People for adults, with daily capacities to serve 450 and 300 people, respectively.

As for social protection activities, the documents indicated that only some services were considered essential for continuous functioning during the pandemic, but even so their supply of services was restricted by health protocols. The following services continued to function for homeless people: Street Approach Outreach and the Specialized Reference Center for Homeless People. However, the documents and interviews indicated that these services suffered cutbacks in their capacity and vacancies and that the time allowed for people to stay on their premises was reduced due to the COVID-19 protocols.

The cartography of the social protection network identified a major barrier to access by HP, namely the suspension of Specialized Social Assistance Reference Centers in the first 2 months. These are regional referral centers that conduct territorial coordination of a large share of the special social protection network. They later operated exclusively on a remote basis until the 7th month into the city's lockdown. Changes in the supply of social benefits during the pandemic impacted homeless people significantly, especially given this population's new profile. *Bolsa Família*, the principal income transfer program in Brazil, had its entry registry suspended for 4 months by the federal government. Later, the updates to enrollment in the CadÚnico, a prerequisite for the *Bolsa Família* program, were only performed remotely in BH. Despite the implementation of greater bureaucratic flexibility in access to the benefits, the lack of in-person care and the need to use technology for access became a barrier for HP, as reported below:

> *We were closed for ∼7 months [at the Specialized Social Assistance Reference Centers]. Which was a huge, huge mistake in my opinion! And we're still suffering the effects of this mistake. There were people that didn't have access to anything, to information, nothing. They didn't even know that emergency aid existed. Users were ignored if they didn't have a telephone, with no access to technology, with no access to information. There was an absurd increase in homeless people during this period. Why are we still suffering the effects of this? Because there were people that I saw in the spontaneous demand in these last months who had just become homeless, in the first 7 months of the pandemic, a lot of people.*
>
> Social worker, Specialized Social Assistance Reference Centers (EGT028)

The period from November 2020 to January 2021 saw a gradual return to in-person activities in the services. However, due to the new wave of COVID-19 cases in the city, the in-person activities in social protection services established harsher restrictions from January to July 2021. The complete resumption of in-person activities and regular functioning of social protection services only happened in December 2021.

There is a shared recognition among administrators and staff in various services that the social protection services that maintained the in-person format in the Street Approach Outreach and Specialized Reference Center for Homeless People had difficulty meeting the growing needs of HP given the partial lockdown of other social protection services and other services and civil society initiatives. The following quotes express these difficulties:

> *You know that situation when you go somewhere and see all those people crowding around? We didn't even know what we were doing, and everybody was begging for help. Because the food donations dried up, everybody disappeared, and they were left out on the streets, with no place to stay, because they had none, so they would go to the Specialized Social Assistance Reference Centers. The Specialized Social Assistance Reference Centers only had us [Street Approach Outreach] (...), the team couldn't go out into the territory, it couldn't, because we were already treating them all there, non-stop. So, I said to the team, what are we going to do? We treated people to the limits of our possibilities, and later, since the demand never stopped inside the Specialized Social Assistance Reference Centers, we had to take the [Street Approach Outreach] team out of the Specialized Social Assistance Reference Centers and allocate them elsewhere to be able to go out on the streets.*
>
> Administrator, Street Approach Outreach (EGT033)

> *There were all kinds of difficulties! We had to work without the network. The only network was the health network, and even so it was extremely saturated. And the services soon devised ways to conduct things online! But how are homeless people supposed to do things online? We had to make calls from our cellphones.*
>
> Staff worker, Specialized Reference Center for Homeless People (EGT018)

Meanwhile, given the increase in demand, the social protection administration expanded its medium-complexity services. A third Specialized Reference Center for Homeless People was created in 2020, plus the expansion of another Specialized Reference Center for Homeless People to serve 600 people per day in 2021. The administrators emphasized that although these expansion plans for the services had been considered before, the pandemic accelerated their funding and deployment.

Facilitators of inter-sector integration

According to the conjunctural analysis from the cartography of the networks of care, despite the initial difficulties in the networks' reorganization, the existence of a greater shared concern over the increased vulnerability of HP during the pandemic allowed executing inter-sector actions with greater collaboration between social protection and health administrators and staff, such as active searches for users with positive COVID-19 tests, the vaccination campaign, or even the inter-sector district meetings that were held online with increased participation.

> *So, to talk about the network is always sensitive, right? [laughter]. We managed closer cooperation during the pandemic, right? We managed to establish better dialogue, right? With the pandemic, I mean, things were messed up, really messed up, and we managed to establish closer collaboration and linkage, because my feeling is that [normally] each person wants to focus on their own responsibilities, understand?*
>
> Administrator, Specialized Reference Center for Homeless People (EGT 032)

A key source of care for HP involved the roving health and social protection services, aimed at reaching the target public more effectively. These services managed to maintain the bonds with HP in their territories (often hard to reach), even during the periods with the harshest health restrictions and the city's lockdown. There was a consensus among interviewees that the city's emergency lockdown created barriers for HP to access their minimum necessities, since their survival hinged on actions related to movement in the city, such as donations, work, permission to use private installations and resources, etc. The roving teams' work was thus particularly important because of the distribution of supplies to meet this population's basic health and food needs, especially in the initial months, during the standstill in the city's services to support HP and the reduction in donations from civil society.

> *I think the first vulnerability we saw in the field work was food, food security. People starting voicing complaints and demands that hadn't existed before. Like, "I'm hungry, really starving." So, I think [serving this food need] was positive, among so many other vulnerabilities, and I think we're going to maintain it in the program. Selfcare, the use of personal hygiene supplies, is going to remain in the program regardless of the pandemic. These supplies to the population are going to continue. Due to the complexity of cases, the linkages in the territories improved considerably.*
>
> Administrator, BH Joining Hands Against AIDS (EGT009)

In addition, the mobility of the services and inter-sector coordination in the distribution of the territories' coverage allowed reaching a share of the homeless population that does not normally use public services The roving services thus served as important public channels for communicating guidelines for dealing with the pandemic and distributing supplies for selfcare and to prevent COVID-19. The administrators of both the health and social protections services also acknowledged that the emergency needs during the pandemic allowed speedier approval of budget resources and various processes for subsequent expansion of the services.

Barriers to inter-sector integration

The results from the cartography of networks of care showed that despite the initial quick reaction by the municipal government, various administrative difficulties emerged during the pandemic. The constant announcement of different guidelines and recommendations with new technical bulletins or updates to the old ones led to disorganization of the work flows due to the difficulty in adapting the services. Staff members reported difficulty in communicating with administrators and insecurity in relation to the protocols, while the administrators reported that this resulted from the speed of the pandemic's spread and the initial lack of knowledge concerning the disease.

In addition, the Municipal Health Department was designated in the 1st week as responsible for helping with the protocols and health training for workers in the Social Protection Department, while there was a 3-month delay in extending the same training to the workers dealing with HP. This delay led the social protection services to make their own health decisions to deal with pandemic, besides jeopardizing health-related communication with homeless people themselves, due to discrepancies in the recommendations. Even so, there was a shared perception between the health and social protection sectors concerning close collaboration as the pandemic unfolded, resulting in more constant recommendations and intensity in the inter-sector actions, including shared management of the Emergency Sheltering service.

On the other hand, a major barrier to integration of the services supply was the lack of a shared information system among public services, especially between health and social protection, which provide care according to the objectives of the National Policy for Homeless People (according to which they are supposed to be integrated). There was also major difficulty in sharing data between various social protection services, which in turn affected the network's integration since the civil society organizations mainly administered the services using their own information systems.

The difficulties and barriers for health care included such aspects as ignorance of inter-sector flows, red tape, users' lack of understanding of protocols, lack of transportation to health services, high turnover of personnel, occasional absences of physicians, perception of health care workers' prejudice or disrespect toward HP, and users' impatience with waiting time for care. Issues involving lack of ID papers also appeared as a barrier to accessing health services, although there is a specific ruling exempting homeless people from presenting any kind of documentation to be treated. The pandemic also created difficulty in accessing medicines. Health professionals reported that the repurposing of Health Centers as Rapid Care Units caused problems with the distribution of medications, since users were unable to receive medicines in some centers that they had used normally as their references and had to turn to other centers.

Inter-sector innovation: COVID-19 emergency sheltering

The social cartography on the networks of care showed that the health emergency created space not only for reordering public services, but also for innovation. The public concern over COVID-19 transmission among homeless people included public debates (and other discussions inside the services' administration) on their treatment and their inability to social distance on the streets. A new inter-sector service was thus launched on April 7, 2020, administered jointly by the Health and Social Protection Departments, called "Temporary and Emergency Sheltering Service for Homeless and Other Socially Vulnerable People." Flows were established for screening and referral of people with respiratory symptoms and suspicion of COVID-19, but without clinical indication for hospitalization. Access to Emergency Sheltering was exclusively via referrals by the health services, after evaluation of symptoms, without allowing direct access by users and/or referrals by social protection services. The services that referred users were Rapid Care Units, Health Centers, Street Outreach Clinics, and the municipal program Belo Horizonte Joining Hands Against AIDS. In 2021, about 70% of the referrals came from the Central-South Rapid Care Units, which implemented the Specialized Center for Patients with Suspected Coronavirus Infection (CECOVID, acronym in Portuguese), concentrating care for individuals with respiratory symptoms, besides other specialized COVID-19 services at the beginning of the pandemic.

Emergency Sheltering initially offered 260 vacancies in a hotel building (SESC) for 14 days of social distancing. The service operated at this location until August 28, 2020, and was transferred that September to a smaller hotel with just 22 places. In both cases the service was located outside the city's central areas (which have the largest concentration of homeless people), so they had to travel long distances to reach it (they saw this as a barrier). Meanwhile, the staff reported overuse of the Specialized Center for Patients with Suspected Coronavirus Infection and emergency sheltering by users who wanted to spend a night in the shelter with hotel-style facilities. This overuse occurred particularly at the beginning of the pandemic, when the criteria for referral were exclusively clinical, since rapid tests were still not available and the turnaround time for COVID-19 Reverse transcription polymerase chain reaction (RT-PCR) results was more than a week, given the heavy demand in the municipality.

> ***R1:** (...) on the one hand it was bad, since the place [a hotel unit belonging to SESC] was cool, so people started showing up too often . . .*
>
> ***R2:** Misusing the service.*
>
> ***R1:** Pretending to be ill.*
>
> ***R2:** Especially on weekends, couples. . .*
>
> ***I:** Didn't they do the [COVID] test here?*
>
> ***R1:** They did, but it took a long time to get the result back.*
>
> R1 and R2: Social workers, Specialized Center for Patients with Suspected Coronavirus Infection (EGT004)
>
> I: Interviewer

Even so, administrators reported that the decision to change the location and reduce the number of vacancies was based on the lack of demand, since there were fewer COVID-19 cases in homeless people than initially predicted and the pandemic's follow-up indicators had improved. In fact, the health care staff reported that there were few cases in proportion to the general population. The purported reasons were isolation of HP from close contacts with the general population due to stigma and the fact that they circulated in the open air. The emergency service was transferred in July 2021, this time to a health unit, UAPI Barreiro, with a supply of 30 vacancies. This move from hotel installations to a hospital unit was identified by the unit's staff as an important reason for the decrease in the spontaneous demand by symptomatic homeless people at health services and the greater evasion from the unit during lockdown. In addition, during the period of the move from the first location, a more efficient testing flow had already been organized, allowing a more rapid response for individuals with symptoms and thus shorter waiting time for cases with negative results.

> ***R2:*** *Barreiro is more like a hospital, an isolation unit today. Not like the SESC [hotel]. At the SESC, there was a cable TV, refrigerator bar, and cold drinking water, so it was like a party. Some people even went there as many as 12 times.*
>
> ***R1:*** *They would be discharged and return immediately to the Rapid Care Units. And they would go to the Rapid Care Units to ask to come back [to the hotel].*
>
> ***R2:*** *We had a lot of cases like that, but at Barreiro, now, we only get people who really are sick.*
>
> ***R1:*** *And when we linked with the health [department], the results started coming back fast. [The patient would say]:"But I've only been staying here for 2 days!" They thought it was odd, because at the SESC it took longer for them to be discharged.*
>
> R1 and R2: Administrator and worker, Emergency Sheltering (EGT013)

The evasion of homeless people during lockdown was a source of conflict between health and social protection during administration of the emergency service. Users had difficulty adhering to the 14 days in isolation, considering the service's rules, such as abstinence from alcohol and other drugs and the ban on pets. Evasion was a major issue in both individual care (because of interruption of treatment) and collectively, because of COVID-19 transmission (users were prohibited from accessing other public services until returning from treatment). The following quote from a mental health administrator explains that part of the conflict between the health and social protection sectors resulted from differing views on the practice of necessary care for HP pertaining to their mental health and substance abuse vulnerabilities.

> *The person would come and ask [to stay] as a mental health [patient] or even as a homeless person, and if they got a little rowdier, mental health wouldn't let them stay. And they had a flu syndrome, and was I supposed to leave them in the Mental Health Referral Center? The person was in a [psychiatric] crisis, understand? Where was I going to send this person? It they were unable to stay, this stimulated evasion. Especially these people.*
>
> Administrator, Mental health (EGT003)

Evasion was particularly high in homeless people with mental distress. There were also barriers to the use of medication due to difficulties in managing mental health crises during isolation. A flow was later created for health units to dispense prescriptions and medications to patients in Emergency Sheltering.

Inter-sector innovation: inter-sector care at the day shelter

Finally, there was important agreement among users, staff, and administrators in the health and social protection sectors on the significantly positive impact of initiatives by the civil society organization Pastoral of the Street People, which conducted systematic activities in care and referrals, promoting integration between the health and social protection networks, mobilizing other organizations and government agencies to care for HP during the pandemic. Two main activities stood out: the installation of a day shelter and inter-sector services in the city center called the "Emergency Street Corner" and housing facilities for temporary shelter and psychosocial support for HP.

Participants in the Emergency Street Corner had access to nursing and social protection services, which provided orientation and referrals to the various networks, besides in-person participation by the roving health services and Offices of the Public Defender and Public Prosecutor. The initiative also provided a series of inter-sector activities such as registration for accessing services and benefits, distribution of food and donations, shelter and care for pets, workshops and work orientation, classes, artistic activities, and socialization, besides showers, toilets, running water, and a laundry. Health and social protection users, staff, and administrators all identified this service as an important reference and source of support in care for health and social protection for HP during the pandemic, as seen in the following quotes:

> *Thank God this emergency street corner came, but now they're trying to take it away from us. It's a big necessity, you know, because the street corner meets a lot of our needs. They help us with everything. You can come any day of the week and there's a social worker there with everything, see? There's nothing like it elsewhere. The city government doesn't work right. They reduced the staff, they reduced the hours, they cut back on a lot of things. And now there's talk about closing this down, too, and we're all asking each other, what are we going to do?*
>
> Homeless person (EPSR03)

> *You can see how much support we're getting, right? People are taking showers, people are doing their laundry, people are eating, people are making handicrafts at the workshop. All this keeps people busy, keeps their minds occupied. I think that more of the Street Corner and activities like it are needed, regardless of whether it's the Pastoral of the Street People or the government. They shouldn't even think of shutting down a place like this.*
>
> Homeless person (EPSR04)
>
> *The Street Corner was set up there, which, my God, was a huge relief, because homeless people had somewhere to go, a space to stay, because they didn't have a place. This helped us a lot, because [HP] concentrated there, and [the staff at Emergency Street Corner] contacted me regularly. Whatever they needed, we would work out an exchange. So, that space benefited all of us. We were unable to cover all the locations, so the Street Corner was a space that truly worked. And the Street Corner is run by the Pastoral of the Street People, which does work in the territory, like we do, too, we as a public policy agency and they as an institution.*
>
> Administrator, Street Approach Outreach (EGT033)

The Emergency Street Corner operated from September 2020 to August 2021 and was the initiative most frequently cited by the various interviewees due to its innovation in integrating services and activities, the need for it to continue, or as an inspiration for the supply of analogous inter-sector services.

Table 4 summarizes a compilation of the study's main results.

TABLE 4 Main results of the study.

Profile of HP in the pandemic
Population mostly male, adult, Black, with incomplete primary schooling. However, although this profile was still predominant, a trend toward change was seen during the pandemic, with an increase in homeless women and people with more schooling.
Health
There was an overall decrease in patient consultations for homeless people during the pandemic, except for an increase in mental health services. Interviewees attributed the overall decrease to public orientation to avoid crowding in services. Hypertension was the most frequent diagnosis in homeless people. Reordering of the health system was influenced by periods of peak COVID-19 transmission. During this period, users linked to support units for urgent care were referred to other Health Centers, which particularly affected HP, since this broke the bond with frequent users (and the effects were observed even after the resumption of care at the unit).
Social protection
A major barrier for access to social protection services by HP was the suspension of Specialized Social Assistance Reference Centers, referral centers that organize regional services (later they only operated online). Changes in the supply of social benefits during the pandemic significantly impacted HP, especially considering this population's new profile. The principal income transfer program (*Bolsa Família*) had its entry registry suspended for 4 months by the federal government. The updates to the CadÚnico registry, a prerequisite for the *Bolsa Família* program, were done exclusively by remote access from this time on in Belo Horizonte. The increase in demand for medium-complexity services due to the health emergency accelerated the plans for permanent expansion of the supply of day shelter services (Specialized Reference Center for Homeless People).
Facilitators and barriers for inter-sector integration
Increased shared concern between health and social protection over the increased vulnerability of HP during the pandemic triggered an increase in the volume and intensity of inter-sector actions and greater dialogue between the sectors. The roving health and social protection services stood out for their territorial coordination, guaranteeing maintenance of access and bonds with services for HP, considering their locations and mobility and distribution of supplies for standard necessities and COVID-19 prevention. A major barrier for integration of supply was the lack of a shared information system between public services, especially between health and social protection. Other barriers to care for HP remain as before the pandemic, including the following: lack of knowledge of many of the inter-sector flows; excess red tape in the services, such as denial of access to services for undocumented homeless people; lack of transportation to health services; high staff turnover and occasional lack of physicians; and perceived staff prejudice or disrespect toward HP, among others.
Emergency inter-sector innovations
Emergency care for suspected COVID-19 cases showed positive results. However, no organization of a service was identified that aimed to manage mental health crises during the lockdown. Major evasion from lockdown was identified due to harm reduction care for people with alcohol and other drug use. The inter-sector day shelter services at the Emergency Street Corner were extremely important in care for HP: supply of nursing and social protection services; orientation and referrals to the service networks; registration of HP for access to services and benefits; distribution of food and donations; workshops and work orientation; art activities and socialization; showers, toilets, running water, and laundry tanks, among others.

Source: authors.

Discussion

Contrary to international evidence pointing to neglect for homeless people in situations of disaster and emergency preparedness and response (24), key factors were found in BH that facilitated more equitable access to care during the COVID-19 pandemic. The study's results provided greater evidence for increased access to services by HP in the face of existing barriers, considering real-time adaptations in the reorganization of health and social protection services, increased inter-sector care, expansion of existing services, and the creation of new inter-sector services targeted to HP, such as Emergency Sheltering and the day shelter at the Emergency Street Corner. However, a reading of the literature suggests that many interdependent variables directly affect the situation of HP and their access to health and social protection services.

Homelessness and its underlying causes

Epidemics and pandemics are predicted to affect the health of marginalized groups more intensely due to the social determinants of health, which include structural determinants such as poverty and discrimination, which in turn influence intermediate determinants such as health, housing, and employment (25). No global study exists on the pandemic's effects on HP, but the 2022 Human Development Index (HDI) (a comprehensive metric that includes health, education, and living standard) reports a significant setback for countries and an increase in inequalities, reverting to the same level as in 2016 (26).

According to the health and social protection databases, the profile of homeless people in BH mirrors the same historical trend found in Brazil's national and municipal censuses for this population group (27–29), and in government registries (30). However, the qualitative data point to agreement among the various stakeholders in terms of a perceived increase in the number of HP since the beginning of the pandemic. According to an estimate by Brazil's Institute for Applied Economic Research (IPEA), there were 281,472 homeless people in Brazil in 2022, or an increase of 211% from 2012 to 2022, with the largest concentration of homeless people in Southeast Brazil, including BH (31). That same year, nationwide data from the CadÚnico database pointed to 236,400 individuals registered as homeless, only 4% of immigrants, i.e., ∼1 out of 1,000 Brazilians were homeless that year (30). Economic crises, lack of affordable housing, poverty, unemployment, and family breakdown are considered determinant in the increase in HP in large cities, according to the Brazilian and international literature (32, 33).

The increase in Brazilians living in the streets during COVID-19, including women and people with more schooling, also reflects the country's rising unemployment, political instability, and government disorganization during the pandemic, which affected economic classes that were previously more protected (34). Despite local specificities, homelessness is known to be a global phenomenon that affects an estimated 2% of the world population (32). Not coincidentally, the internationally shared reasons are linked intrinsically to capitalist modernity which, through the drivers of economic progress and globalization, creates "growing masses of 'wasted humans'" that it is incapable of reassimilating or annihilating (35).

In Brazil, there is a relationship between the phenomenon of homelessness and the country's socio-historical formation. In this context, it is important to consider the extensive period of slavery and its transition at the end of the nineteenth century. Under the myth of the free African, the freed black population were "thrown onto the streets to fend for themselves like undesirable human waste" (36) in precarious living conditions without concrete possibilities for social and economic inclusion. Added to this, they were targets of a criminalization process that affected those who were jobless and considered idle, with black and poor people being the main targets (37). On these foundations, an unequal society was established (38) sustained by structural racism (39). The combination of these elements is reflected in the fact that the HP is composed of ∼78% (30) black individuals, while in the general population this number is about 55% (2). Furthermore, it is observed that health indicators in the general population are worse among the black individuals when compared to white individuals, as is the case with morbidity and mortality rates (40). Additionally, among people in homelessness, there is a considerable statistical difference between white and black individuals in terms of illiteracy, education, and time spent living on the streets, with black individuals presenting the worst rates (41).

Challenges in accessing care during the pandemic

Many studies have identified adequate permanent housing (absent for HP) as an important social determinant of health (42), while illness and lack of care related to unhealthy behaviors have also been identified as factors for loss of housing (43). The homelessness phenomenon is thus often associated with worse health, higher rates of acute and chronic diseases, and higher mortality rates (44).

In BH, the break in continuity of care, as reflected by the decrease in the number of treatments for HP immediately after the start of the pandemic, was a factor in this group's acute-on-chronic vulnerability, with difficulty reestablishing ties to return to care, also observed in Brazil's general population (45, 46). Although there is an overall national trend, the status of homeless people is known to deserve special attention, as a population naturally susceptible to symptomatic infections due to their increased risk of environmental exposure, greater risk of hospitalization, exacerbation, and death, accelerated physical decline, and mental health problems sometimes associated with alcohol and drug use. Homeless people also suffer great social vulnerability and face huge barriers to access the health and social protection systems, a situation exacerbated by the pandemic. Thus, with or without COVID-19 or another future pandemic, the decrease in care by the health system for these individuals is worrisome, with major implications for their health conditions (47–50).

An emergency intervention that directly harmed HP was the city's general lockdown (even with the counter-response through the distribution of supplies by the roving services and maintenance of health services) since it raised barriers to meeting basic needs. Consequently, the lockdown may have affected the prioritization of HP even more and negatively impacted selfcare in health. This is based on evidence in the literature that homeless people may have different healthcare-seeking behaviors than the general population, emphasizing: (i) their prioritization of basic needs such as food, clothing, and shelter rather than health; (ii) postponing the search for services until serious aggravation of their health condition; and (iii) mistrust of health services due to stigmatization, physiological difficulties, and emotional stressors (6).

The literature also corroborates the findings that barriers (both systemic and those related to the pandemic) to accessing health and social protection services can lead HP to feel stigmatized. These barriers add to those considered "contextual," such as staff attitudes and perception of access, documentation, lack of knowledge, transportation to health services and long waiting time, causing evasion or dropout from care and follow-up (6, 51–53). This was further aggravated by the structural barrier involved in homeless people's difficult access to digital services (due to the pandemic's circumstances, access to many social benefits was only regularized online). This exacerbation of homeless people's exclusion was also seen in other cases with the online transition of health and social services previously provided in person (25, 26, 54).

Inter-sector responses, resilience, and innovations

Even so, the health system showed its resilience and capacity for inter-sector rearticulation with the special social protection system during the pandemic, even after the initial decrease in care. There was an increase in care for homeless people with respiratory symptoms, a priority at moments of peak COVID-19 incidence, with a resumption in the number of treatments for other factors even during the prevailing pandemic (Figures 2, 3). The continuity of care in mental health, the inter-sector links that emerged during the pandemic, and the reorganization of services to comply with the health safety rules also showed their capacity for resilience. Another study in BH corroborated the importance of inter-sector linkage between health and social protection for increasing the flows of respiratory patients and access by HP to social distancing (3). The health systems' resilience was an important factor for continuity of care and the guarantee of rights (55).

The major increase in mental health care during the pandemic (including alcohol and drug treatment centers) differed from the other results and signaled the capacity of these services to absorb the increased demand. One can infer that the increase in care may have resulted from the increase in the number of homeless people during the pandemic and the fact that this population was more exposed to exacerbated vulnerability and decreasing care in other services, with a direct impact on these people's psychological distress. According to an integrative review on access by HP to the Network of Psychological care in Brazil (56), studies have identified limitations in public policies for mental health targeted to this group. The increase in mental health care is even more atypical if one considers the evidence that health services restrict the access, fail to provide adequate support, and fail to meet the specific needs of homeless individuals with mental disorders, a situation observed in other studies in BH (57). Other studies confirm the hypothesis raised by health care staff that the increase in the amount and severity of mental distress during the pandemic is related to the pandemic's context (58–60). In addition, homeless people were identified as one of the population groups most vulnerable to exacerbation of mental health conditions during the pandemic (61), possibly explaining the increase in their care.

The study also showed increased capillarity of the networks of care through greater constancy and intensity of inter-sector action between health and social protection during the pandemic, which included more frequent inter-sector communication, referral, and user follow-up. Strengthening inter-sector care has emerged as a possibility for solving complex problems affecting populations. Based on an integrated view of users and social problems, systems should attempt to overcome policy fragmentation in response to demands that extrapolate single social policies (62). However, in the current case, there was no proper regulation or systematization of this inter-sector collaboration, built on an emergency basis during the pandemic.

The importance of inter-sector care adds to the challenges of treating various vulnerabilities in this specific group. The increase in homeless people can be understood as a complex social phenomenon that requires a high degree of linkage between policies, sectors, and social actors, where isolated specific programs are insufficient, considering the interdependent social, housing, health, safety, and other challenges (25, 43). In Brazil, the literature on social policy management based on inter-sector care emphasizes the need for operationalization of the concepts of equity, decentralization, territory, networks, and social rights (62).

The Emergency Street Corner initiative, as a temporary inter-sector service, showed the capacity to deal simultaneously with interdependent challenges for homeless people. It also became a positive example based on its capacity for rapid linkage with the health and social protection networks, even though it was not a service planned in typical public services. Its concentration of inter-sector services and users in the same location intensified the communication and flows with other services, thereby improving the inter-sector follow-up of users and increasing the intensity of inter-sector referrals during the pandemic.

The territorial reach and equity of access to public services underscore the essential work of roving health and social protection services and their inter-sector territorial mapping to guarantee greater access by the population to the itinerant services, even in locations with more restricted access. In addition, the services were important public channels for health promotion and orientation to deal with the pandemic. Health promotion advocacy is a successful alternative for psychosocial issues, with the potential to alter the pattern in the search for help by HP and reduce the burden of work for primary care teams (63).

The creation of new inter-sector services during the pandemic, such as Emergency Sheltering and the Emergency Street Corner, further indicated the capacity for innovation in the face of the health emergency, but consistent with preexisting needs in vulnerable populations (64). The innovation in public efforts driven by the pandemic and the provision of new facilities for HP was also observed elsewhere in the world in various cities with different configurations and coverages, while noting a trend toward sudden and unusual funding for this public (12, 65, 66). These initiatives should not be lost. An opportunity thus emerges to take advantage of the recently created structures to expand the coverage for other transmissible and epidemic diseases, because the lack of housing for homeless people makes them proportionally more vulnerable to a series of diseases, as exemplified by recent outbreaks of typhus, hepatitis A, tuberculosis, trench fever, and *Shigella* among HP in the United States (11).

The current study proved the hypothesis in the literature that chronic physical and mental health conditions and substance abuse by some homeless people are obstacles to social distancing and treatment for COVID-19 (11). The difficulties with evasion and dropout from Emergency Sheltering provided an opportunity to rethink the prevailing model, especially considering the initial difficulty in dealing with individuals with abusive or chronic drug use, who normally have greater difficulty accessing services due to negative and stigmatizing experiences with staff (51). Alcohol and drug abuse is also a permanent issue that requires expanding the supply of services for HP, since the literature identifies such abuse as both a potential contributing factor and consequence of homelessness (32).

On the other hand, the expectation that HP would be a specific risk group for COVID-19 (11, 67) was not proven in BH. There were fewer cases among homeless people than in the rest of the population, attributed to isolation from close contacts with most of the population due to stigma and the fact that they spent most of the time in open spaces. Studies corroborated the hypothesis that these conditions favor less contagion, noting that SARS-CoV-2 is transmitted predominantly by the airborne route in close quarters (68, 69), with shared rooms as the main cause of superspreading (69) and much lower risk of infection in outdoor environments (70).

Even so, the investment in (and acceleration of) municipal plans for expansion of social protection and health services showed that the pandemic acted as a factor reorienting the priority and deployment of more funding for such services. In 2020, the Brazilian federal government allocated some BRL 635.5 billion (US$ 121 billion) in budget funds to fight the COVID-19 pandemic, with BRL 113.5 billion (US$ 20.6 billion) transferred to states and municipalities (71). In addition, preliminary data from the WHO (72) on public expenditures in health show that the pandemic induced a new world record. In 2020, global health expenditures reached US$ 9 trillion, the equivalent of 10.8% of global GDP. Yet the investments were highly unequal in international terms, with high-income countries accounting for some 80% of total spending. A large increase was also seen in per capita health and social protection expenditures in upper middle-income countries. However, the limitation of available data still prevents a conjunctural analysis of expenditures in most countries during the 3 years of the pandemic (72).

Study limitations and strengths

The study presented some limitations. We were unable to access all the databases in the same timeframes, since the CadÚnico database adopts different logistics for updating, which prevents a longitudinal reading of the data (as done with the health database). Thus, the data may have been outdated in some datasets, both recording the presence of homeless people that were no longer living on the streets and failing to track others whose homelessness was recent. In addition, Brazil's social protection services do not require enrollment in the CadÚnico for care, but only for receiving social benefits, so it was not possible to quantify access to the services. All the information for characterizing HP in services was based on self-declaration of homelessness. This means that the study based on this database had high sensitivity and low specificity. The last limitation involves data on urgent care provided by the BH Municipal Health Department. We did not have access to the data from the main Rapid Care Unit in BH, the Central-South Rapid Care Unit, which prevents us from generalizing the results for urgent care for HP.

The study's strengths featured the database linkage method, which allowed minimizing the data collection challenges for identifying HP (who may be undocumented or choose not to show their ID papers during care at health services or social organizations). In Brazil, the lack of completion of the taxpayer identification number (CPF in Portuguese) or its non-existence in some databases (although it is currently used by the federal government as the standard personal identification document) means that the probabilistic method is extremely important for linking databases produced by different institutions (73). Other strengths were: the unprecedented scope, for Brazil, of methods and data from the same city; the partnership with the municipality of BH, with the availability of large identified databases, which allowed evaluation of data from specific services for HP; the possibility of conducting a longitudinal study based on health data; the study's Follow-up Committee, which allowed identifying biases, qualified the data analysis, and contributed to a productive dialogue on practices of care for HP in the municipality and thus led to subsequent spinoffs in the field. The interviews and focus groups sought to encompass the variations in subjectivities with actors from different locations, roles, and social positions, both administrators, staff, and homeless people as well as representatives of social movements. Finally, the triangulation of methods contributed to a convergent dialogue among different types of data for a more comprehensive understanding of homeless people and the effects of adaptations of policies targeted to this population, aimed at expanding the data on this vulnerable group and learning from the specific case to encourage the debate on practices and policies for them.

Conclusion

Even considering the difficulties in obtaining precise quantitative data on homeless people and the care for them to provide an exact metric on their access during the pandemic, the quantitative and qualitative evidence collected in this study points to more emergency interventions that involved actions or services that facilitated access, more than barriers. However, when considering the application of these lessons to other contexts, whether in emergency situations or in future daily practice, it is important to recall one of the foundations that sustained their relative success, namely the fact that BH already had robust health and social protection services designed specifically for serving HP. These services sustained the new emergency measures such as an increase in inter-sector meetings and greater ongoing follow-up between the existing services, besides using this structure to increase access, as in the expansion of vacancies in the Specialized Reference Center for Homeless People and Specialized Center for Patients with Suspected Coronavirus Infection for testing, diagnosis, and treatment of COVID-19 in the Rapid Care Units.

The existence of national guidelines for inter-sector care for HP cannot be ruled out as a positive influence, although the municipalities are responsible for implementing these guidelines. It was noteworthy that a health emergency was needed to intensify the relationship between health and social protection services. However, there is a critical need for further development and enhancement in inter-sector protection strategies for this population. This progress should be informed by the coordination challenges encountered at the onset of the pandemic, leading to the creation of robust preparedness and response plans for future emergencies. Such plans must prioritize the systematization of inter-sector collaboration, moving beyond *ad hoc* responses to establish a consistent and integrated approach across different sectors. This systematic approach is essential for ensuring that services are not only effectively coordinated during crises but also become a routine part of the care provided to the homeless population. Sustaining and building upon the inter-sector services developed during the pandemic is crucial. These services have demonstrated their value in addressing the complex needs of the homeless population and should be maintained as part of the standard care framework. The continuity of these services ensures that the gains made during emergency responses are not lost but rather integrated into the normal functioning of social and health care systems. In addition, significant advancement is required in the development of shared information systems. Such systems are vital for facilitating efficient data exchange between health and social protection sectors. By improving communication and information sharing, these systems can lead to more informed decision-making, better resource allocation, and more targeted and effective interventions for the homeless population.

The services with the most positive evidence and least need for infrastructure to be replicated locally feature the roving services in both sectors and their inter-sector care. They foster greater reach due to their mobile territorial coverage, which became the portal of entry for access to networks of care, given the mobility of homeless people and the locations with limited presence of other services, in addition to the distribution of supplies, which help attenuate the exacerbation of vulnerabilities in emergency situations. In addition, the temporary provision of various inter-sector services simultaneously with the day shelter at the Emergency Street Corner was considered a key factor in expanding and intensifying the networks of care for HP in BH during the emergency phase (with plans for the model to be continued and further expanded in the future).

As for the Emergency Sheltering initiative, it is necessary to continue this service's model, including other possibilities of care related to chronic and communicable diseases. It is also necessary to expand the debate on practices of care for homeless people to include a better understanding of their vulnerabilities, especially related to mental health and/or abstinence from alcohol and drugs, which were complicating factors for COVID-19 quarantine and treatment. We thus echo the proponents of equity-oriented health care (EOHC), which aims to acknowledge patients' vulnerabilities and orient their care according to their circumstances and difficulties.

It is also necessary to learn from the challenges and barriers that emerged from the emergency measures. It is necessary to create interventions that mitigate the negative effects of the city's lockdown, during which homeless people lacked access to standard necessities, besides difficulties in access to digital online services. The lack of data and more in-depth studies on homeless people also hinders targeting actions and care for this group. Considering the study's evidence and the literature, according to which homelessness can be influenced by economic crises, unemployment, lack of adequate home loan conditions, family breakdown, and others, further investigation of these possible correlations is important. The understanding of inter-sector variables affecting HP would contribute to better targeting of investments in interventions that work at the root causes of these issues or that increase the effectiveness of health and social protection services to mitigate or deal with such circumstances.

Data availability statement

The datasets presented in this article are not readily available because, access to the databases complied with the guidelines of the Brazilian General Act on Protection of Personal Data, Law no. 13.709 of August 14, 2018. The researchers are not authorized to share the databases, since these are public health data. Any such authorization should be requested to Belo Horizonte's Municipal Government. Requests to access the datasets should be directed to Health Secretariat of Belo Horizonte.

Ethics statement

The studies involving humans were approved by Institutional Review Board of the René Rachou Institute, Oswaldo Cruz Foundation (FIOCRUZ), and Institutional Review Board of the Health Secretariat of Belo Horizonte-MG. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study. Written informed consent was obtained from the individual(s) for the publication of any potentially identifiable images or data included in this article.

Author contributions

AM: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Visualization, Writing – original draft, Writing – review & editing. AS: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing. GS: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Software, Writing – original draft, Writing – review & editing. AD: Data curation, Formal analysis, Investigation, Writing – review & editing. RM: Data curation, Formal analysis, Investigation, Writing – review & editing. LF: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Validation, Writing – review & editing. AO: Data curation, Formal analysis, Investigation, Writing – review & editing. HM: Conceptualization, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Supervision, Validation, Visualization, Writing – review & editing. RP-S: Conceptualization, Funding acquisition, Project administration, Supervision, Validation, Visualization, Writing – review & editing.

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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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Effectively communicating with local policymakers: a randomized trial of policy brief dissemination to address obesity

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Introduction: Evidence-based policies are a powerful tool for impacting health and addressing obesity. Effectively communicating evidence to policymakers is critical to ensure evidence is incorporated into policies. While all public health is local, limited knowledge exists regarding effective approaches for improving local policymakers' uptake of evidence-based policies.

Methods: Local policymakers were randomized to view one of four versions of a policy brief (usual care, narrative, risk-framing, and narrative/risk-framing combination). They then answered a brief survey including questions about their impressions of the brief, their likelihood of using it, and how they determine legislative priorities.

Results: Responses from 331 participants indicated that a majority rated local data (92%), constituent needs/opinions (92%), and cost-effectiveness data (89%) as important or very important in determining what issues they work on. The majority of respondents agreed or strongly agreed that briefs were understandable (87%), believable (77%), and held their attention (74%) with no brief version rated significantly higher than the others. Across the four types of briefs, 42% indicated they were likely to use the brief. Logistic regression models showed that those indicating that local data were important in determining what they work on were over seven times more likely to use the policy brief than those indicating that local data were less important in determining what they work on (aOR = 7.39, 95% CI = 1.86,52.57).

Discussion: Among local policymakers in this study there was no dominant format or type of policy brief; all brief types were rated similarly highly. This highlights the importance of carefully crafting clear, succinct, credible, and understandable policy briefs, using different formats depending on communication objectives. Participants indicated a strong preference for receiving materials incorporating local data. To ensure maximum effect, every effort should be made to include data relevant to a policymaker's local area in policy communications.

KEYWORDS

communication, dissemination, evidence-based policy, local policy, obesity policy

Introduction

Obesity affects over one in three U.S. adults and one in five children with estimated annual medical costs reaching nearly $173 billion (1). Evidence-based policies (EBPs) to address obesity prevention exist, but are not systematically applied (2, 3). EBPs have historically had significant influences on public health (e.g., use of seat belts, protection of employees in the workplace) (4). Thus, policy is a powerful tool for improving population health, and policymakers are in positions to enact policies with potential to significantly impact health and reduce obesity (5). Therefore, effectively communicating evidence to policymakers is critical for improving the likelihood that it will be incorporated into policies (5, 6).

There are myriad barriers to effectively communicating evidence-based public health data to policymakers (7, 8). Policymakers and researchers often have conflicting decision-making processes, different timelines, and varying levels of uncertainty in information (2). Further, policymakers function in a world of information overload, receiving hundreds of pieces of information from varied sources every day. In one study, policymakers reported only reading for detail 27% of what they receive and never getting to 35% (9). Finally, policymakers may struggle with finding the data they need when they need it (10). Previous research addresses how policymakers prefer to receive information and what types they seek. These preferences commonly include local data showing economic costs presented in a brief format that is timely and easy to understand (10, 11). Up to 61% of state legislators report that they prioritize unbiased and understandable research (12). Other studies have concluded that there is no “one size fits all” approach to policymaker communication; rather, messages should be tailored to the type of policymaker or utilize audience segmentation (3, 12, 13).

While previous studies present policymaker preferences at the federal and state level, limited knowledge exists regarding effective approaches for the uptake of research-tested, policy interventions among local policymakers (14). All public health is local and tremendous potential exists for addressing obesity through local policies that encourage healthy eating and physical activity (15–18). For example, initiatives to improve access to safe places for physical activity may be accomplished through local zoning and land use ordinances (19, 20). Further, local policymakers are commonly attuned to constituent opinions and data about their local jurisdictions (21). Thus, ensuring that local policymakers have access to information about EBPs presented in relevant and easily-digestible ways is crucial to improving the uptake of EBPs in local policy and ultimately to addressing the burden of obesity.

Accordingly, to effectively translate relevant research to local policy, the purpose of this study was to test a set of approaches for the translation of research to local policymakers.

Materials and methods

This trial was part of a larger study designed to develop and disseminate approaches to increase the implementation of EBPs to reduce obesity disparities and promote health equity, focusing on the uptake of effective local-level policies. One aim of this study was to test a set of approaches for translation of research about obesity EBPs among local policymakers. To this end, we conducted a randomized trial of four types of policy briefs with local policymakers. This allowed for the comparison of different policy brief formats, the examination of various factors influencing issues local policymakers choose to work on, and the contribution of these factors to the likelihood that local policymakers would use the policy briefs.

Policy brief development and content

Four versions of a policy brief were created: usual care, risk framing, narrative, and risk framing plus narrative (mixed). These types were selected based on previous research indicating that narrative forms of communication (compared to a traditional data-oriented presentation of information) can improve understanding of complex information (10, 22, 23). Further, risk framing, which communicates risks using more easily-understandable means (e.g., frequencies, percentages, graphs) is often used in medical decision-making, and may be a promising approach for clarifying policy options, such as the risks and benefits of various interventions, in a local policy context (24, 25). The topic of each brief, zoning and development regulations, was the same for each type. This topic was chosen based on its relevance at the local government level as well as findings from prior research conducted as part of the more extensive study. This research included qualitative interviews with municipal officials and sought, in part, to understand policymaking influences at the local level. Most of the health-related policy action examples mentioned in these interviews are impacted by zoning and development regulations (e.g., food and physical activity environments, housing affordability); thus, the topic was selected for the policy brief randomized trial.

With support from health communication and decision science experts, the four types of policy briefs were developed and refined. The usual care briefs included traditional content for health experts; however, the text was condensed and revised to include plain language and recommended design principles for summarizing scientific language (e.g., use of white space, use of pictures/icons to convey meaning, etc.). The narrative brief included stories presenting protagonists with similar situations but in contrasting settings (one in an area zoned for single-family residences and one zoned for mixed uses) and the impact on daily life. The risk-framing briefs used principles from decision sciences to frame data in meaningful and accessible ways. These briefs were designed to relate specific risk data to local policymakers using social math and meaningful visuals. The risk framing plus narrative briefs combined both narrative and risk framing communication elements. There were two consistent sections across brief versions (for content and look/design): “What can local governments do” (i.e., succinct policy actions), and “Impact” (i.e., briefly stated benefits to the community). All four brief types are available here: https://prcstl.wustl.edu/items/prc-core-research-project/.

Formative testing of the brief versions was conducted with a Community Advisory Board, which is comprised of local policymakers, public health practitioners at the local and state levels, and representatives of public health advocacy organizations.

This testing was designed to ensure distinction in policy brief versions. All board members who tested the briefs correctly identified the versions based on a short description.

Survey measures

The research team developed, edited, and tested a brief survey to accompany the policy briefs. The survey design was pilot tested to assess respondent completion and address concerns about the cognitive load of reading a policy brief and responding to survey items. Two survey designs were tested; both performed similarly well for response of survey items, including open-ended text items, and completion rates. The research team determined to administer the original design, including the four policy briefs described above. Measures were based on previous research (3, 26). The survey, created with Qualtrics (27), included 18 items, three of which were open-ended, and was designed to be completed in 10 min or less.

Covariates

Policymakers were first asked how important a list of factors is in determining issues they work on, using a five-point Likert scale ranging from unimportant to very important. These factors included personal interest, data on the impact in their local area or community, constituent needs or opinions, recommendations of local organizations, evidence of scientific effectiveness, and availability of cost-effectiveness or economic analysis. In addition, participants were asked to rate the level of importance of issues that affect their community, including crime and violence, economy, education, environment, mental health, and physical health.

Next, through simple random allocation (programmed within the Qualtrics survey), participants were presented one policy brief version and asked a series of questions representing various domains. Each question included response options on a five-point Likert scale ranging from strongly disagree to strongly agree. To assess understanding, participants were asked if the information in the policy brief was easy to understand, held their attention, and affected them emotionally. To assess credibility, participants were asked if the information in the policy brief was believable, accurate, and whether it provided a strong reason for local governments to implement zoning and development regulations to address obesity and promote health. Participants were also asked whether they were likely to use the information in the policy brief.

Participants were asked about their political ideology on social and fiscal issues, with response options ranging from extremely conservative to extremely liberal on a seven-point scale. The survey also asked demographic questions (e.g., age, gender, political party). Finally, participants were asked if they have any educational background or experience in land use, planning, or physical design of public spaces, with response options including: a great deal, a fair amount, a little bit, or none. The full survey instrument is available at the link above.

Sample selection and recruitment

The research sample was randomly drawn from a population of elected policymakers representing local U.S. governments with over 1,000 residents, including those at the county (county executives and commissioners), municipal (mayors and councilmembers), and township levels. To select the sample and administer the survey, the research team collaborated with CivicPulse, a non-profit organization focused on producing knowledge of and for local governments through national surveys of local officials. The sample was drawn from their national panel of local government leaders (28). The Institutional Review Board of Washington University in St. Louis approved this study as exempt research (#202110030).

Data collection

CivicPulse conducted data collection between January and March 2022. Respondents were invited via email to take the survey. Three email attempts were made. Consent to participate in the survey was implied when participants followed the survey link.

When participants clicked on the link to complete the survey, they found the policy brief embedded as a graphic within the online survey. This was done for simplicity and to minimize attrition. Incentives were not offered to participants; however, as a benefit to their panel of local government officials, CivicPulse provides a summary of research findings via posts on their website and emailed newsletters, within a few months of survey completion.

Data analysis

Frequencies were run for all categorical variables to examine differences across the study group (policy brief shown), and differences in outcomes were assessed using Pearson's Chi-squared test and ANOVA models, as appropriate. Political ideology responses were collapsed to form three groups: conservative/slightly conservative, moderate, and liberal/slightly liberal. The variables describing the importance of various factors in determining what issues a policymaker works on were stratified by political party. Response options for these questions were collapsed to create the following categories: very important/important, moderately important, and slightly important/not important.

Response options for each variable used to describe policymakers' ratings of the briefs, in terms of understandability and credibility, were combined to create two categories: Agree (mostly agree/strongly agree) and Else (undecided, mostly disagree, strongly disagree). We conducted a factor analysis of six policy brief ratings (understandable, attention held, emotion evoked, believable, accurate, strong reasoning). Factor analysis was used as a dimension reduction method to identify similar dimensions of complex sets of variables and aid in the interpretability of relationships to our dependent variable without a significant loss of degrees of freedom and overfitting models (29). A one-factor solution was reached using orthogonal (varimax) rotation and Thompson's estimator for regression score calculations. The proportion of variance explained with the one-factor solution was

0.47. The resulting variable (understandability/credibility factor score) was used in logistic regression models described below.

Logistic regression models were used to analyze the effects of various factors on the likelihood of brief use, the primary dependent variable (strongly agree/agree = yes, and undecided/disagree/strongly disagree = no). The first or null model included a randomization group (type of brief shown) with the usual care brief as the reference. The second model added two items found to significantly improve model deviance from factors policymakers indicated were important/very important in determining what issues to work on (data on impact in local area/community and evidence of scientific effectiveness). The third model included the understandability/credibility factor score, the one-factor representative of the six variables in which participants reflected on the briefs (i.e., understandable, held my attention, affected me emotionally, believable, accurate, and whether the brief provided a strong reason for governments to implement zoning regulations). All models applied probability weighting based on a post-stratification raking procedure using Census and presidential vote share variables (30). Odds ratios and 95% confidence estimates were calculated for each model. All data cleaning and analysis were performed in R version 4.1.2 (31).

Results

The total number of policymakers invited to participate was 7,950, of whom 331 finished the survey, resulting in a completion rate of 4.5%. This response rate is similar to that of other nationally representative surveys of local public officials (32–34). The median time spent viewing the brief and answering survey questions was 8.4 min. A majority of respondents was non-Hispanic white (84%) men (68%) who hold college or graduate degrees (72%). One-third of the sample was between 52–66 years old, while nearly 48% were over age 67. The average time spent in participants' current positions was 9 years. The sample was relatively evenly distributed in terms of political party, experience with land use, and social ideology. Sixty-three percent worked at the municipal level, 20% at the township level, and 16% at the county level (Table 1).

When asked to rate the importance of various factors in determining what issues they worked on, 92.1% of participants rated data on impact in their local area or community as important or very important, as well as constituent needs or opinions (92.1%) and data on cost-effectiveness (88.9%) (Table 2). Further, evidence of scientific effectiveness was rated as important/very important by 81.3% of participants. By contrast, only 43.6% of participants reported that personal interest was important or very important in determining what issues they worked on.

When participants were asked to rate the policy briefs on a range of factors, the majority agreed or strongly agreed that the briefs were easy to understand (86.9%), believable (76.5%), accurate (52.7%), and held their attention (74.4%). About one-third of participants reported that the briefs affected them emotionally (32.2%). When asked if they were likely to use the information in the policy briefs, 41.6% agreed or strongly agreed that they were. These responses were primarily consistent across the various policy brief types (Table 3). Finally, 46% of respondents agreed or strongly agreed that the brief provided a strong reason for local governments to implement zoning and development regulations to address obesity and promote health. Responses to this item varied across types of policy brief. Those receiving the usual care brief were significantly more likely to agree or strongly agree with this item (58.5%), and those receiving the narrative brief were significantly less likely to agree or strongly agree with the item (31.7%; p = 0.004), as shown in Table 3.

Overall, policymakers were similarly likely to use the policy briefs, regardless of the brief type they were shown (Table 4). While the importance of evidence of scientific effectiveness in determining what issues to work on was significantly associated with increased odds of using the policy brief in model 2 (OR = 2.61, 95% CI: 1.40, 5.08), this association was no longer statistically significant after adjusting for the factor created to represent understanding/credibility (aOR = 1.84, 95% CI: 0.89, 3.91). In model 3, policymakers were much more likely to use the briefs if the presence of data on impact in local area or community was important or very important in determining what issues to work on (aOR = 7.39, 95% CI: 1.86, 52.57). Finally, the policy brief understandability/credibility factor score was associated with increased odds of using the policy brief. Specifically, with each change in one standard deviation of the factor, the odds of using the policy brief increased 4.5 times (aOR = 4.72, 95% CI: 3.16, 7.40).

Discussion

Factors influencing what policymakers work on

This study offers several insights into the factors influencing local policymakers' decisions about what issues to work on, their opinions about various formats of policy briefs, and the likelihood that they might use the information provided in the briefs they were shown. Previous work has shown that policymakers at the state level may make decisions about what issues to work on based on constituent needs and opinions and evidence of scientific effectiveness (35). In the current study, local policymakers also indicated that these factors are important in determining their legislative priorities. This should prompt public health practitioners and researchers to help inform constituents about public health issues and potential policy solutions. Further, these findings support the proactive inclusion of scientific evidence in communications with local policymakers.

Most local policymakers in this study also reported that data on the impact of issues in their local area were important or very important in determining what issues they work on. This confirms similar findings suggesting that many legislators prefer local data, and policymaking may be more successful when local data are utilized (3, 36). Fortunately, including or highlighting local data is a strategy researchers, practitioners, and advocates can increasingly implement into communication efforts with relative ease. The availability of local data has improved in recent years and many online resources now exist where these data can be found. Notable examples include the County Health Rankings & Roadmaps (37), PLACES: Local Data for Better Health (38), City Health Dashboard (39), and PolicyMap (40). Also, local data

TABLE 1 Demographic characteristics of local policymaker study participants, $N = 331$.

	Usual ($N = 82$)	Framing ($N = 82$)	Narrative ($N = 83$)	Mixed ($N = 84$)	Total ($N = 331$)	*p*-value
Age category						0.587[a]
22–51	11 (13.8%)	15 (19.7%)	20 (24.4%)	18 (21.7%)	64 (19.9%)	
52–66	26 (32.5%)	29 (38.2%)	24 (29.3%)	26 (31.3%)	105 (32.7%)	
67+	43 (53.8%)	32 (42.1%)	38 (46.3%)	39 (47.0%)	152 (47.4%)	
Gender						0.710[b]
Female	29 (35.4%)	26 (32.5%)	24 (29.6%)	25 (30.1%)	104 (31.9%)	
Male	53 (64.6%)	54 (67.5%)	56 (69.1%)	58 (69.9%)	221 (67.8%)	
Prefer to self-describe	0 (0.0%)	0 (0.0%)	1 (1.2%)	0 (0.0%)	1 (0.3%)	
Highest education attained						0.577[a]
Graduate degree	31 (37.8%)	26 (32.1%)	24 (28.9%)	32 (38.1%)	113 (34.2%)	
College graduate or some graduate school	32 (39.0%)	25 (30.9%)	33 (39.8%)	34 (40.5%)	124 (37.6%)	
Some college or technical/trade school	14 (17.1%)	23 (28.4%)	20 (24.1%)	13 (15.5%)	70 (21.2%)	
High school or less	5 (6.1%)	7 (8.6%)	6 (7.2%)	5 (6.0%)	23 (7.0%)	
Race and ethnicity						0.519[a]
Non-hispanic white	71 (86.6%)	70 (86.4%)	64 (79.0%)	69 (84.1%)	274 (84.0%)	
Non-white or hispanic	11 (13.4%)	11 (13.6%)	17 (21.0%)	13 (15.9%)	52 (16.0%)	
Years in current position						0.500[b]
Mean (CI)	8.34 (6.77, 9.91)	10.05 (8.20, 11.90)	8.45 (6.69, 10.21)	9.00 (7.19, 10.81)	8.95 (8.09, 9.81)	
Land use experience						0.688[a]
A fair amount/a great deal	27 (32.9%)	27 (34.2%)	25 (30.1%)	33 (39.8%)	112 (34.3%)	
A little bit	23 (28.0%)	19 (24.1%)	27 (32.5%)	25 (30.1%)	94 (28.7%)	
None	32 (39.0%)	33 (41.8%)	31 (37.3%)	25 (30.1%)	121 (37.0%)	
Political party						0.386[a]
Democrat	25 (31.2%)	24 (30.4%)	20 (24.7%)	26 (31.0%)	95 (29.3%)	
Republican	29 (36.2%)	38 (48.1%)	35 (43.2%)	32 (38.1%)	134 (41.4%)	
Independent	24 (30.0%)	16 (20.3%)	22 (27.2%)	26 (31.0%)	88 (27.2%)	
Other party	2 (2.5%)	1 (1.3%)	4 (4.9%)	0 (0.0%)	7 (2.2%)	
Social position						0.122[a]
Conservative/slightly conservative	24 (29.3%)	38 (47.5%)	37 (45.1%)	37 (44.0%)	136 (41.5%)	
Moderate	33 (40.2%)	20 (25.0%)	26 (31.7%)	20 (23.8%)	99 (30.2%)	
Liberal/slightly liberal	25 (30.5%)	22 (27.5%)	19 (23.2%)	27 (32.1%)	93 (28.4%)	
Fiscal position						0.832[a]
Conservative/slightly conservative	51 (62.2%)	49 (61.2%)	50 (61.0%)	58 (69.0%)	208 (63.4%)	
Moderate	25 (30.5%)	25 (31.2%)	25 (30.5%)	18 (21.4%)	93 (28.4%)	
Liberal/slightly liberal	6 (7.3%)	6 (7.5%)	7 (8.5%)	8 (9.5%)	27 (8.2%)	
Government level of respondent						0.007[a]
County	14 (17.1%)	6 (7.3%)	18 (21.7%)	16 (19.0%)	54 (16.3%)	
Municipality	60 (73.2%)	59 (72.0%)	47 (56.6%)	44 (52.4%)	210 (63.4%)	
Township	8 (9.8%)	17 (20.7%)	18 (21.7%)	24 (28.6%)	67 (20.2%)	

[a] Pearson's Chi-squared test.

[b] Linear Model ANOVA.

TABLE 2 Relative importance of various factors in determining what issues local policymakers work on.

	Democrat (*N* = 95)	Republican (*N* = 134)	Independent (*N* = 88)	Total (*N* = 317)	*p*-value
Personal interest					0.400[a]
Important/very important	41 (43.6%)	53 (39.8%)	43 (49.4%)	137 (43.6%)	
Moderately important	30 (31.9%)	36 (27.1%)	24 (27.6%)	90 (28.7%)	
Not/slightly important	23 (24.5%)	44 (33.1%)	20 (23.0%)	87 (27.7%)	
Data on impact in local area/community					0.559[a]
Important/very important	89 (94.7%)	121 (91.0%)	80 (90.9%)	290 (92.1%)	
Moderately important	4 (4.3%)	10 (7.5%)	8 (9.1%)	22 (7.0%)	
Not/slightly important	1 (1.1%)	2 (1.5%)	0 (0.0%)	3 (1.0%)	
Constituent needs or opinions					0.187[a]
Important/very important	84 (89.4%)	123 (91.8%)	84 (95.5%)	291 (92.1%)	
Moderately important	8 (8.5%)	11 (8.2%)	4 (4.5%)	23 (7.3%)	
Not/slightly important	2 (2.1%)	0 (0.0%)	0 (0.0%)	2 (0.6%)	
Recommendations of local organizations					0.466[a]
Important/very important	64 (68.1%)	94 (70.1%)	52 (59.1%)	210 (66.5%)	
Moderately important	26 (27.7%)	32 (23.9%)	30 (34.1%)	88 (27.8%)	
Not/slightly important	4 (4.3%)	8 (6.0%)	6 (6.8%)	18 (5.7%)	
Evidence of scientific effectiveness					0.184[a]
Important/very important	82 (87.2%)	105 (78.4%)	70 (79.5%)	257 (81.3%)	
Moderately important	11 (11.7%)	21 (15.7%)	16 (18.2%)	48 (15.2%)	
Not/slightly important	1 (1.1%)	8 (6.0%)	2 (2.3%)	11 (3.5%)	
Cost effectiveness or economic analysis					0.035[a]
Important/very important	79 (84.0%)	124 (92.5%)	78 (88.6%)	281 (88.9%)	
Moderately important	15 (16.0%)	9 (6.7%)	7 (8.0%)	31 (9.8%)	
Not/slightly important	0 (0.0%)	1 (0.7%)	3 (3.4%)	(1.3%)	

[a] Pearson's Chi-squared test.

need not necessarily be health-focused. Policy communications materials can also incorporate local data from other sectors relevant to health and effective at engaging policy audiences (e.g., transportation, housing, zoning data, etc.).

A majority of local policymakers in this study also indicated that cost-effectiveness data or economic analysis was important or very important in determining what issues they work on. Legislators face myriad needs and requests to address with a limited budget. Providing them with data showing economic evidence of the burden of health issues or the cost savings of evidence-based interventions may persuade them to work on those issues or encourage their support for an EBP. In a recent study conducted with state legislators, Purtle and colleagues found that including local, economic evidence increased legislator interaction with evidence-based dissemination materials, albeit only among Democratic legislators (41).

These findings support the use of local data, cost or economic analysis, and evidence of scientific effectiveness when communicating with local policymakers. However, the importance of knowing one's target audience and tailoring materials to their interests, political persuasions, and priorities is also crucial, as a "one-size-fits-all" approach may be less effective (3). Previous studies of dissemination to policymakers affirm the importance of considering audience characteristics when crafting messages and determining the format of communication (e.g., policy briefs, social media, video, etc.) (9, 42). Further, in a recent study of state legislators, Smith and colleagues used latent class analysis to identify four groups of policymakers based on their prioritization of various research characteristics and then determined group preferences for receiving information (12). For example, they found that "pragmatic consumers" prefer concise communication, including cost data, while "constituent-oriented decision makers" seek information relevant to constituents and delivered by a trusted source. Their findings highlight the importance of considering the unique values, priorities, and preferences in the development of dissemination materials for policymakers (12).

TABLE 3 Local policymakers' ratings of characteristics of policy briefs, by type of brief shown.

	Usual (*N* = 82)	Framing (*N* = 82)	Narrative (*N* = 83)	Mixed (*N* = 84)	Total (*N* = 331)	*p*-value
Understandability						
Easy to understand						0.202[a]
Agree	75 (91.5%)	70 (86.4%)	73 (89.0%)	67 (80.7%)	285 (86.9%)	
Else	7 (8.5%)	11 (13.6%)	9 (11.0%)	16 (19.3%)	43 (13.1%)	
Held attention						0.578[a]
Agree	60 (73.2%)	65 (80.2%)	59 (72.0%)	60 (72.3%)	244 (74.4%)	
Else	22 (26.8%)	16 (19.8%)	23 (28.0%)	23 (27.7%)	84 (25.6%)	
Affected emotionally						0.228[a]
Agree	21 (25.6%)	23 (28.4%)	31 (38.8%)	30 (36.1%)	105 (32.2%)	
Else	61 (74.4%)	58 (71.6%)	49 (61.2%)	53 (63.9%)	221 (67.8%)	
Credibility						
Believable						0.782[a]
Agree	66 (80.5%)	62 (76.5%)	61 (74.4%)	62 (74.7%)	251 (76.5%)	
Else	16 (19.5%)	19 (23.5%)	21 (25.6%)	21 (25.3%)	77 (23.5%)	
Accurate						0.254[a]
Agree	51 (62.2%)	39 (48.1%)	42 (51.2%)	41 (49.4%)	173 (52.7%)	
Else	31 (37.8%)	42 (51.9%)	40 (48.8%)	42 (50.6%)	155 (47.3%)	
Strong reasoning						0.004[a]
Agree	48 (58.5%)	42 (51.9%)	26 (31.7%)	35 (42.2%)	151 (46.0%)	
Else	34 (41.5%)	39 (48.1%)	56 (68.3%)	48 (57.8%)	177 (54.0%)	
Likelihood of use						
Likelihood of use						0.595[a]
Agree	35 (42.7%)	38 (46.9%)	30 (36.6%)	33 (40.2%)	136 (41.6%)	
Else	47 (57.3%)	43 (53.1%)	52 (63.4%)	49 (59.8%)	(58.4%)	

[a] Pearson's Chi-squared test.

Comparison of policy brief types

Overall, local policymakers in the current study found the policy briefs to be believable, accurate, able to hold their attention, and easy to understand, regardless of the version of the brief they received. This could indicate that the type or structure of policy briefs is less important than authors ensuring the information is presented in understandable, accurate, and engaging ways. Ample previous research supports these qualities in materials designed for policymakers (10–12). The lack of significant differences in how local policymakers in this study reacted to the different versions of policy briefs shown may also support the importance of tailoring communications. Narrative-focused, risk-framing-focused, and mixed briefs serve different, valuable purposes depending on the intended audience and communication objective. For example, in the current study, local policymakers reported that narrative communication affected them emotionally more than the other types; thus, in early work on an issue, if one's goal is to raise awareness about a topic, incorporating stories into communication materials may be most effective.

Another explanation of the similarities in responses to each policy brief version may be that, due to careful planning, writing, and collaboration with communication experts, each brief type was similarly well-constructed and thus, similarly received by local policymakers. This is not necessarily true among all communications designed for policymakers, as illustrated by a review of obesity-themed policy briefs. In this review, the authors assessed 100 policy briefs that were readily available online. Of those reviewed, the mean length was five pages, 73% included no tables, and the mean Flesch-Kincaid reading level was 13, which is very high (43). Thus, the consistent quality of the various versions of policy briefs used in the current study may have affected the variability in how local policymakers rated them on the variables of interest.

TABLE 4 Logistic regression models predicting likelihood of policy brief use by local policymakers, $N = 331$.

Predictors	Model 1: study design, weighted			Model 2: study design + policymaker characteristics, weighted			Model 3: study design + policymaker characteristics + brief understandability/credibility factor score, weighted		
	OR	95% CI	*p*-value	OR	95% CI	*p*-value	OR	95% CI	*p*-value
Brief shown (Framing)	1.19	0.63–2.26	0.595	1.37	0.71–2.67	0.354	1.73	0.82–3.71	0.155
Brief shown (Narrative)	0.64	0.33–1.24	0.189	0.67	0.34–1.33	0.251	0.72	0.32–1.61	0.420
Brief shown (Mixed)	0.90	0.48–1.70	0.755	1.17	0.61–2.27	0.638	1.44	0.67–3.12	0.354
Data on impact in local area/community important in determining policymaker agenda				8.82	2.43–59.81	0.005	7.39	1.86–52.57	0.014
Evidence of scientific effectiveness important in determining policymaker agenda				2.61	1.40–5.08	0.003	1.84	0.89–3.91	0.105
Policymaker rating of brief understandability/credibility factor score							4.72	3.16–7.40	<0.001
Observations	327			325			323		
R^2 Tjur	0.008			0.071			0.306		

Likelihood of using the briefs

Logistic regression analyses showed that the type of brief received was not paramount in determining the likelihood of participants indicating they would use the policy briefs. Policymakers placing a high importance on local data as they determine what issues to work on were over seven times more likely to use the policy brief they were shown than those for whom local data were less important in determining legislative priorities. This finding is significant and actionable, strongly supporting the guidance to those communicating with local policy audiences that local data be an important component in communication materials.

It is important to acknowledge the challenges that may exist in smaller, local organizations seeking to incorporate these suggestions into communications efforts. Many may lack capacity and adequate staff to locate, understand, or utilize local data, even when it is available (44). However, efforts to make materials understandable and credible create opportunities for participatory partner engagement. Identifying other organizations, local college or university staff, local health departments, or even community members who can assist with data location and interpretation can support efforts to create effective policy communications.

Logistic regression analyses also showed an association between the likelihood of using the policy brief shown and finding the policy briefs to be understandable, credible, etc. The higher participants rated the briefs, the greater their chance of indicating they would use them. This finding has high face validity and highlights the value of creating communication materials for local policymakers that are understandable, credible, believable, accurate, and engaging. Doing this requires a study of the target audience as well as utilization of best practices for creating concise, clear messages and including local data (regarding both how an issue influences a local community and the local impacts of policy actions), visual aids (images, icons), and evidence of scientific effectiveness.

Some study limitations warrant mention. While the response rate was typical of other studies with similar populations, it limited the study's statistical power (32, 33). However, the non-response was evenly distributed across demographic variables, likely neutralizing the effect of any bias. Also, respondents' answers to some questions may have been influenced by the social desirability of specific responses. Respondents who value research may be more likely to participate in research, which could introduce bias. Generalizability may be limited by the homogeneity of the sample. It is not possible to determine with certainty what influences policymakers' decisions about what to work on when personal interest, interest groups, constituent opinions, etc., compete for top priority. The issue of timing may also be important, especially in its effect on policymakers' likelihood of using the policy briefs shown. If local policymakers were working on issues related to zoning, housing, or obesity at the time they received the policy brief, they may have indicated an increased likelihood of using the briefs than others who may not have been working on such issues. Finally, as noted, all four brief types were well constructed. This may have diminished the potential effects of the differences among brief types and how they were rated for understandability, believability, etc.

Evidence-based policies can improve public health and help reduce the disproportionate burden of obesity in the United States (45, 46). Getting evidence into the hands of local policymakers can be challenging; further, communicating evidence in ways that make it understandable, credible, and likely to be used requires applying existing knowledge of best practices for sharing information with policy audiences. While various communication objectives may call for different elements in materials designed for policymakers, every effort should be made to incorporate data specific to a policymaker's local area to ensure maximum impact. If researchers, practitioners, and advocates can create policy briefs likely to be used, research is more likely to influence policy.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

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

Author contributions

RJ performed the statistical analysis. ED wrote the manuscript and all authors contributed to manuscript revisions. All authors contributed to conception and design of the study. All authors contributed to the article and approved the submitted version.

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Conflict of interest

NL was employed by CivicPulse.

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.

The reviewer CW declared a past collaboration with the author RB to the handling editor.

Publisher's note

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Acceptability and feasibility of policy implementation strategies for taxes earmarked for behavioral health services

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Background: This study's aims are to: (1) Compare the acceptability and feasibility of five types of implementation strategies that could be deployed to increase the reach of evidence-based practices (EBPs) with revenue from policies that earmark taxes for behavioral health services, and (2) Illustrate how definitions of implementation strategies and measures of acceptability and feasibility can be used in policy-focused implementation science research.
Methods: Web-based surveys of public agency and community organization professionals involved with earmarked tax policy implementation were completed in 2022–2023 ($N = 211$, response rate = 24.9%). Respondents rated the acceptability and feasibility of five types of implementation strategies (dissemination, implementation process, integration, capacity-building, and scale-up). Aggregate acceptability and feasibility scores were calculated for each type of strategy (scoring range 4–20). Analyses of variance compared scores across strategies and between organizational actor types.
Findings: For acceptability, capacity-building strategies had the highest rating (M = 16.3, SD = 3.0), significantly higher than each of the four other strategies, $p \leq .004$), and scale-up strategies had the lowest rating (M = 15.6). For feasibility, dissemination strategies had the highest rating (M = 15.3, significantly higher than three of the other strategies, $p \leq .002$) and scale-up strategies had the lowest rating (M = 14.4).
Conclusions: Capacity-building and dissemination strategies may be well-received and readily deployed by policy implementers to support EBPs implementation with revenue from taxes earmarked for behavioral health services. Adapting definitions of implementation strategies for policy-focused topics, and applying established measures of acceptability and feasibility to these strategies, demonstrates utility as an approach to advance research on policy-focused implementation strategies.

KEYWORDS
policy, implementation science, acceptability, feasibility, behavioral health

Introduction

Although public policy has historically been understudied in the contemporary field of implementation science in health (1, 2), it has received increased attention in recent years (3–15). Conceptual frameworks for policy-focused work in the field have been developed (16, 17) and reviews (18–20) have identified measures to characterize policy implementation processes and describe how policy functions as an outer-setting determinant of the delivery of clinical interventions. Despite these advances, research and scholarship on strategies to support policy implementation remains underdeveloped.

While several implementation strategies in the Expert Recommendations for Implementing Change (ERIC) compendium involve policies (e.g., "provide access to new funding," "mandate change") (21), these strategies emphasize the implementation of clinical evidence-based interventions—not the policy itself. Some qualitative work has used ERIC constructs to code strategies used to support policy implementation (22, 23), but the implementation science literature provides little guidance about how to generate evidence to inform decisions about the types of strategies perceived to be most relevant to a particular policy implementation context.

It is well-established that clinically-focused implementation strategies should be perceived as acceptable and feasible to the professionals who would use them (24–26). However, virtually no prior work has quantitatively assessed the acceptability or feasibility of strategies to support policy implementation. This Brief Research Report presents results of an exploratory study of the perceived acceptability and feasibility of potential strategies to support policy implementation. The Report also provides a methodological case example of how acceptability and feasibility can be assessed in a policy implementation study.

Policies that earmarked taxes for behavioral health services

The current study focuses on the implementation of state and local governmental policies that earmark tax revenue for behavioral health (i.e., mental health and substance use disorder) services in the United States (27). Detailed descriptions of these tax policies and the larger policy implementation study from which data are drawn are provided elsewhere (27–31). In short, an earmarked tax is one placed on a specific base (e.g., goods, property, income) for which revenue is dedicated to a specific purpose (32–34). As of 2022, a legal mapping study found that there were at least 207 policies in the United States that earmark tax revenue for behavioral health services and that the number of jurisdictions adopting these policies has increased drastically over the past two decades (30). These taxes generate a substantial amount of revenue, about $3.57 billion annually, and approximately 30% of the U.S. population lives in a jurisdiction with such a tax (30).

Through the creation of a new sustainable and dedicated source of funding, these earmarked tax policies have potential to enhance the reach (i.e., number of people served) of EBPs and the fidelity with which they are implemented (27–31, 35, 36). Professionals involved with earmarked tax policy implementation report many benefits to the financing approach (31), yet these taxes do not necessarily increase the reach of EBPs. For example, a survey of 155 professionals involved with earmarked tax policy implementation in California and Washington found that only about two-thirds strongly agreed that the tax policies increased the number of people served by behavioral health EBPs (31). Although supporting EBP implementation is just one possible goal of earmarked taxes, policy implementation strategies have potential to help achieve this goal. Assessing the acceptability and feasibility of implementation strategies in this policy context is a first step towards candidate strategies that could be deployed at scale, and evaluated in future research.

Study aims

To develop an evidence base related to implementation strategies for policies that earmark tax revenue for behavioral health, and to advance work on policy implementation strategies more broadly, the aims of this study are to:

1. Compare perceptions of the acceptability and feasibility of five types of strategies that could be deployed to support EBP implementation with revenue from policies that earmark taxes for behavioral health services; and
2. Illustrate how definitions of types of implementation strategies were adapted for survey questions focused on policy implementation and demonstrated how measures of acceptability and feasibility were used to assess perceptions of these strategies in a policy implementation context.

Method

Sample and data collection

The methods for the larger policy implementation study are detailed in the published study protocol (27). The study was approved by the MASKED Institutional Review Board (27). The data presented here come from web-based surveys of government and community organization professionals involved with oversight, decision making, and implementation policies which earmark taxes for behavioral health services. These professionals were in positions such as, but not limited to, tax coordinators, leaders of state and county behavioral health agencies, and members of county tax advisory boards. Jurisdictions with policies that earmarked taxes for behavioral health were identified through the aforementioned legal mapping study (30). The survey sample frame was created of professionals involved with earmarked tax policy implementation in seven states: California, Washington, Ohio, Illinois, Missouri, Colorado, and Kansas. The sample frame was created from contact databases maintained by practice partners (e.g., state and county behavioral health professional associations), internet searches, and databases of behavioral health officials compiled by the research team for prior studies (37–39).

Web-based surveys were e-mailed to professionals involved with earmarked tax policy implementation between September 2022 and May 2023. Up to eight personalized e-mails were sent with a unique survey link, and telephone follow-up was conducted. To capture the perspectives of professionals involved with earmarked tax policy implementation who were not included in the original sample frame, we also created an open (i.e., not unique) survey link that was circulated by our aforementioned practice partners. A $20 gift card for survey completion was offered. All four questions about the acceptability or feasibility of at least one implementation strategy (detailed below) were completed by 211 respondents. The response rate for the unique link surveys was 24.9%, consistent with recent state-wide surveys of behavioral health officials (37–39), and 81.1% of responses were from unique survey links (as opposed to the open survey link). The distribution of respondents across states was: California = 35.4%, Washington = 25.0%, Ohio = 21.7%, Illinois = 7.5%, Colorado = 5.2%, Missouri = 4.7%, Kansas = 0.5%. This distribution reflects the number of counties in each state involved with implementing an earmarked tax.

Measures

The survey questions and format are included as a Supplementary. In the survey, respondents were separately presented with adapted definitions of Leeman et al.'s five types of implementation strategies: dissemination, implementation process, integration, capacity-building, and scale-up (40). The Leeman et al.' typology of strategies was derived from Powell et al.'s ERIC compendium (21). Definitions in the survey were adapted for the earmarked tax policy implementation context using Proctor et al.'s recommendations for specifying implementation strategies (41). The strategy *actor*, *action*, and *action target* (i.e., who or what was the intended target) were all anchored to the broad *implementation outcome* of earmarked tax policy revenue supporting the implementation of EBPs. Table 1 shows the definitions of each strategy and actor type that were provided in the survey.

With the definition of each strategy separately displayed on a single web-based survey screen, respondents rated the acceptability and feasibility of each type of implementation strategy in terms of it being used by their organization to support the implementation of EBPs with earmarked tax revenue. Acceptability is defined as the perception a category of implementation strategy is agreeable, palatable, or satisfactory; whereas feasibility is defined as the extent to which a category of implementation strategy can be successfully used or carried out within a given agency or setting (25). These constructs were assessed using Weiner et al.'s measures of acceptability (four items, $\alpha = .85$) and feasibility (four items, $\alpha = .89$) (25). Reponses were summed to calculate aggregate acceptability and feasibility scores for each type of policy implementation strategy (possible scoring range 4–20 for each measure).

Next, respondents separately indicated all of the "actor types"—derived from Leeman et al.'s typology of organizations that can use implementation strategies—that accurately characterized all of their organization's role in earmarked tax policy implementation. Definitions of each of the actor types (i.e., delivery system actors, support system actors, synthesis and translation system actors) was provided, with wording adapted to be focused on their organization's role in earmarked tax policy implementation. Respondents were instructed to select all of the actor types that applied. The proportion of respondents endorsing each actor type was: delivery system actors 52.1%, support system actors 74.2%, and synthesis and translation system actors 40.7%.

TABLE 1 Definitions of leeman et al.'s of types of implementation strategies and actor types, adapted to focus on policies that earmark taxes for behavioral health services achieving the outcome of increasing the reach of evidence-based practices.

Construct	Wording of definition in survey[a]
Policy implementation strategy type	
Dissemination strategies	These strategies entail your organization **communicating information** to behavioral health service organizations to increase leaders' and providers' knowledge and improve their attitudes about evidence-based practices that can be funded with earmarked behavioral health tax revenue.
Implementation process strategies	These strategies entail your organization **helping behavioral health service organizations' select** evidence-based practices funded by earmarked behavioral health tax revenue, plan for their integration, and **evaluate** their impacts.
Integration strategies	These strategies entail your organization **changing the organizational context** within behavioral health service organizations to ensure the delivery of evidence-based practices funded by earmarked behavioral health tax revenue (e.g., by using clinical reminder systems, quality monitoring activities, and changing professional roles with organizations).
Capacity-building strategies	These strategies entail your organization **increasing the capacity** of behavioral health service organizations to select and integrate evidence-based practices funded by earmarked behavioral health tax revenue and evaluate their impacts (e.g., by enhancing the motivation and self-efficacy of leadership and direct service providers).
Scale-up strategies	These strategies entail your organization **increasing the ability** of behavioral health service organizations to ensure that evidence-based practices funded by earmarked behavioral health tax revenue achieve desired outcomes (e.g., by providing training on evidence-based practice to direct service providers).
Policy implementation actor type	
Delivery system actors	Providing direct behavioral health and social services with tax revenue
Support system actors	Supporting system and capacity building efforts for organizations that provide direct behavioral health and social services with tax revenue
Synthesis and translation system actors	Reviewing evidence about promising approaches to using earmarked tax revenue and communicating this information to organizations that provide direct behavioral health and social services

[a] Bolded emphasis included in survey.

Analysis

Cronbach's alpha was calculated for the acceptability and feasibility ratings of each policy implementation strategy. Descriptive statistics (i.e., means, standard deviations, skewness) were calculated for all acceptability and feasibility ratings. Bivariate correlations between the acceptability and feasibility ratings of each strategy were assessed. Two-tailed, paired sample *t*-tests assessed the statistical significance of differences in acceptability and feasibility ratings, respectively, across the implementation strategies. Separate ANOVAs compared differences in acceptability and feasibility ratings between

TABLE 2 Descriptive statistics of ratings of acceptability and feasibility of implementation strategies intended to increase the reach of evidence-based practices with revenue from policies that earmark taxes for behavioral health services.

Strategy	Acceptability					Feasibility				
	n	Mean	SD	Skew	α	*n*	Mean	SD	Skew	α
Dissemination strategies	195	15.9	3.0	−0.1	0.86	197	15.3	3.2	−0.1	0.94
Implementation process strategies	190	15.9	3.2	−0.5	0.91	190	15.1	3.6	−0.3	0.96
Integration strategies	181	15.7	3.3	−0.4	0.91	184	14.5	3.7	−0.2	0.97
Capacity-building strategies	200	16.3	3.0	−0.5	0.87	199	14.7	3.6	−0.2	0.94
Scale-up strategies	191	15.6	3.4	−0.5	0.91	192	14.4	3.7	−0.2	0.96

Possible scoring range 4–20.

respondents who characterized their organization according to different actor types.

Results

Table 2 shows descriptive statistics for the acceptability and feasibility each policy implementation strategy. For each of the five strategies, measures of acceptability (α range = 86–.91) and feasibility (α range = .94–.97) demonstrated strong internal consistency. The mean policy implementation strategy acceptability rating was highest for capacity building strategies (mean = 16.3, SD = 3.0) and lowest for scale-up strategies (mean = 15.6, SD = 3.4). The mean policy implementation strategy feasibility rating was highest for dissemination strategies (mean = 15.3, SD = 3.2) and lowest for scale-up strategies (mean = 14.4, SD = 3.7).

Figure 1 plots the mean acceptability and feasibility ratings for each strategy. As shown, scale-up and integration strategies were rated as least acceptable and least feasible. For each strategy, there was a statistically significant ($p < .001$) positive correlation between ratings of acceptability and feasibility. The mean Pearson correlation coefficient for the five strategies was 0.72 and the magnitude of correlations ranged from 0.81 for dissemination strategies to 0.50 for capacity building strategies.

Table 3 shows the effect sizes and statistical significance of pairwise comparisons between mean ratings of each type of policy implementation strategy. For acceptability, capacity building strategies were rated as significantly ($p \leq .008$) more acceptable than all four other strategies (e.g., $p < .001$ Cohen's D = −0.26 for capacity building strategies vs. integration strategies). For feasibility, dissemination strategies were rated as significantly ($p \leq .001$) more feasible than integration, capacity building, and scale-up strategies. (e.g., $p < .001$ Cohen's D = 0.33 for dissemination strategies vs. scale-up strategies). There were no significant differences in acceptability or feasibility ratings when compared between respondent who classified their organization according to different actor types.

Discussion

This study presents a quantitative assessment of the acceptability and feasibility of policy implementation strategies.

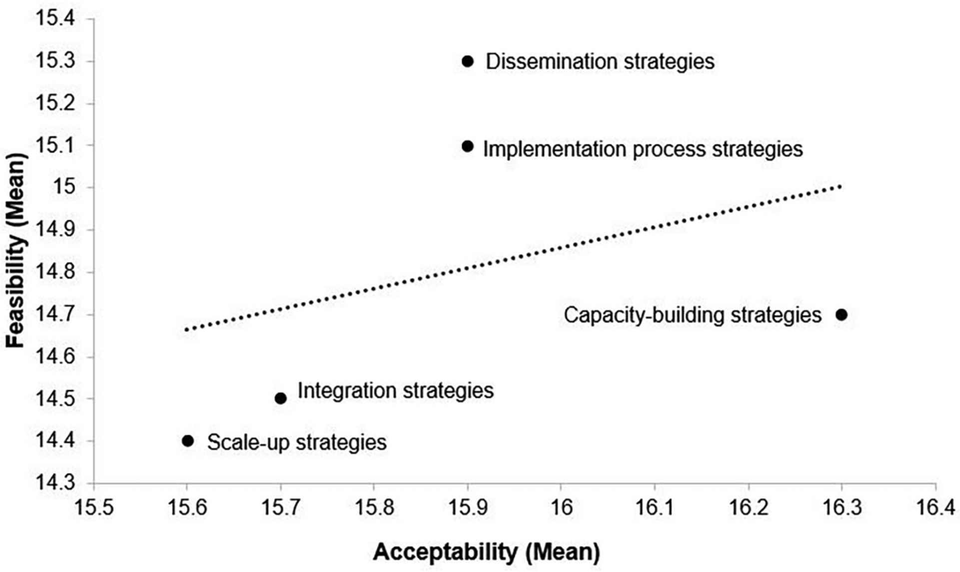

FIGURE 1
Plot of mean ratings of acceptability and feasibility of implementation strategies intended to increase the reach of evidence-based practices with revenue from policies that earmark taxes for behavioral health services. Possible scoring range 4–20.

TABLE 3 Significance of pairwise comparisons of the acceptability and feasibility of implementation strategies intended to increase the reach of evidence-based practices with revenue from policies that earmark taxes for behavioral health services.

Implementation strategies compared	*P*-value	Cohen's d
Acceptability		
Dissemination vs. implementation process	.74	−0.02
Dissemination vs. integration	.13	0.11
Dissemination vs. capacity-building	.007	−0.20
Dissemination vs. scale-up	.39	0.06
Implementation process vs. integration	.09	0.13
Implementation process vs. capacity-building	.008	−0.20
Implementation process vs. scale-up	.22	0.09
Integration vs. capacity-building	<.001	−0.26
Integration vs. scale-up	1.000	0.00
Capacity-building vs. scale-up	<.001	0.37
Feasibility		
Dissemination vs. implementation process	.05	0.14
Dissemination vs. integration	<.001	0.37
Dissemination vs. capacity-building	.001	0.24
Dissemination vs. scale-up	<.001	0.33
Implementation process vs. integration	<.001	0.29
Implementation process vs. capacity-building	0.12	0.12
Implementation process vs. scale-up	0.002	0.24
Integration vs. capacity-building	0.20	−0.10
Integration vs. scale-up	0.52	0.05
Capacity-building vs. scale-up	0.03	0.16

Results shed light on the types of strategies that policy actors judged to be feasible and acceptable to deploy to support the implementation of EBPs with revenue from policies that earmark taxes for behavioral health services. Capacity-building strategies were perceived as the most acceptable strategy to support the implementation of EBPs through these policies, whereas scale-up strategies were identified as least acceptable (as well as least feasible). Although capacity building and scale-up strategies both target the skills and motivation of service providers and organizational leaders, capacity building strategies—as defined in the survey—afford more autonomy to service organizations in terms of selecting EBPs. Scale-up strategies, in contrast, focus on "ensuring" that EBPs funded by tax revenue "achieve desired outcomes." It is possible that this prescriptive language was not well-received by respondents and contributed to lower ratings of acceptability (42).

The finding that dissemination strategies were perceived as most feasible is not surprising given that asynchronous communication of information is typically not resource intensive or politically contentious (43). It is promising that organizations involved with the implementation of earmarked tax policies find dissemination strategies feasible, as well as acceptable, because responsibilities for dissemination are often unspecified in research translation pipelines (44, 45). Dissemination strategies are understudied in implementation science (46, 47), however, and research is needed to inform how organizations might develop messages that are effective at promoting the use of earmarked tax revenue to support EBP delivery.

The methods describe in this Research Brief Report illustrate how definitions of implementation strategies can be adapted for a survey focused on policy implementation. Furthermore, the Report demonstrates how widely used and pragmatic measures of acceptability and feasibility can used in policy implementation research. Weiner et al.'s measures of acceptability and feasible demonstrated strong internal consistency when used to assess policy implementation strategies. However, minimal variance between ratings of these strategies raises questions about their suitability. More in-depth psychometric testing of these measures' applicability to policy implementation strategies is warranted in future research.

Limitations

Findings should be considered within the context of the study's limitations. First, although we observed statistically significant differences in ratings of the acceptability and feasibility of policy implementation strategies, the practical significance of these differences are unclear. Mean ratings of acceptability and feasibility across all strategies were consistently high (i.e., mean ≥14.4 on 20-point scale), suggesting that none of these strategies were perceived as unacceptable or infeasible. The average effect size (Cohen's D) of staticsally significant differences between pairwise ratings of strategies was only 0.13. Relatedly, while acceptability and feasibility are considered conceptually distinct constructs in the field of implementation science research, the extent to which they were perceived as distinct by respondents is uncertain. The fact that there was a statistically significant correlation between the rating of acceptability and feasibility for each strategy suggests that respondents may not have perceived the two constructs of conceptually distinct.

Second, although the response rate of 24.9% is consistent with recent state-wide surveys of behavioral health officials (37–39), respondents may not fully reflect the perspectives of all professionals involved with behavioral health earmarked tax policy implementation. Third, definitions of all strategies were anchored to the broad policy implementation outcome of earmarked tax revenue supporting the implementation of EBPs. As noted, supporting the implementation of EBPs is just one possible goal of policies that earmark taxes for behavioral health. Interviews conducted as part of the larger policy implementation study (27) have revealed that other outcomes—such as reducing inequities in access to behavioral health services and enhancing service infrastructure—are often primary goals of the taxes. Ratings of implementation strategy acceptability and feasibility may have varied if definitions were anchored to a different policy implementation outcome. Fourth, it should be emphasized that the study focused on perceptions of the acceptability and feasibility of implementation strategies and does not shed light on the extent to which these strategies may be effective at supporting EBP implementation. Finally, the survey did not assess if, or the extent to which, respondents had actually used the implementation strategies they rated. Experiences using the strategies would likely affect rating of acceptability and feasibility.

Conclusions

Within the context of the implementation of policies that earmark taxes for behavioral health services, capacity building strategies and dissemination strategies may be well-received and deployed by organizations involved with tax policy implementation to support the implementation of EBPs. Adapting definitions of implementation strategies for policy-focused topics, and using established measures of acceptability and feasibility to elicit feedback about these strategies, demonstrates utility as an approach to advance research of policy-focused implementation strategies.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by New York University Institutional Review Board. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

JP: Conceptualization, Data curation, Formal Analysis, Funding acquisition, Investigation, Methodology, Project administration, Supervision, Writing – original draft, Writing – review & editing. NS: Conceptualization, Methodology, Project administration, Writing – review & editing. MW: Data curation, Methodology, Writing – review & editing. SW: Conceptualization, Writing – review & editing. EB: Conceptualization, Writing – review & editing. GA: Conceptualization, Writing – review & editing.

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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

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frhs.2024.1304049/full#supplementary-material

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Design considerations for developing measures of policy implementation in quantitative evaluations of public health policy

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Typical quantitative evaluations of public policies treat policies as a binary condition, without further attention to how policies are implemented. However, policy implementation plays an important role in how the policy impacts behavioral and health outcomes. The field of policy-focused implementation science is beginning to consider how policy implementation may be conceptualized in quantitative analyses (e.g., as a mediator or moderator), but less work has considered how to measure policy implementation for inclusion in quantitative work. To help address this gap, we discuss four design considerations for researchers interested in developing or identifying measures of policy implementation using three independent NIH-funded research projects studying e-cigarette, food, and mental health policies. Mini case studies of these considerations were developed via group discussions; we used the implementation research logic model to structure our discussions. Design considerations include (1) clearly specifying the implementation logic of the policy under study, (2) developing an interdisciplinary team consisting of policy practitioners and researchers with expertise in quantitative methods, public policy and law, implementation science, and subject matter knowledge, (3) using mixed methods to identify, measure, and analyze relevant policy implementation determinants and processes, and (4) building flexibility into project timelines to manage delays and challenges due to the real-world nature of policy. By applying these considerations in their own work, researchers can better identify or develop measures of policy implementation that fit their needs. The experiences of the three projects highlighted in this paper reinforce the need for high-quality and transferrable measures of policy implementation, an area where collaboration between implementation scientists and policy experts could be particularly fruitful. These measurement practices provide a foundation for the field to build on as attention to incorporating measures of policy implementation into quantitative evaluations grows and will help ensure that researchers are developing a more complete understanding of how policies impact health outcomes.

KEYWORDS

health policy, implementation science, policy research, policy implementation science, policy evaluation

1 Introduction

Public policy plays a major role in improving public health, and most of the greatest public health achievements have resulted from policy action (1, 2). Disciplines such as economics, public administration, political science, and health services research have a long history of evaluating policies and quantifying their effects on health and related outcomes. Methodologically, this is typically operationalized by comparing outcomes in jurisdictions with and without a policy, treating the presence/absence of policies as binary conditions, and using difference-in-differences analyses or related quasi-experimental causal inference methods (3).

However, this approach masks potentially important variability in components of policy implementation, which in turn can affect outcomes and researchers' ability to draw clear conclusions about a policy's effects (3–6). For example, similar policies can have different provisions that affect implementation. One state with retail restrictions on electronic cigarettes may empower state public health officials to enforce the restrictions, while others may rely on local public health or law enforcement officials to ensure compliance. Likewise, variation in funding for policy enforcement and government capacity for monitoring compliance can result in heterogeneity in implementation and subsequent outcomes. In addition, even when jurisdictions (e.g., states) have the exact same provisions in their policy, how the policy is interpreted and implemented may vary based on the entity responsible for implementation. In one published example, McGinty et al. found that state opioid prescribing laws did not significantly change opioid prescriptions or nonopioid pain treatments (7). Their team's parallel qualitative work describing suboptimal implementation and limited penalties for nonadherence among these laws helped to put the quantitative findings into greater context and provided explanation as to why their findings did not change clinical practice (7, 8).

These qualitative studies demonstrate the importance of conducting research to understand policy implementation, but no measures of policy implementation were included in the quantitative components. Inclusion of quantitative measures of policy implementation, combined with qualitative findings, can generate a more holistic understanding of the mechanisms or processes that contribute to policy impact (3, 6, 9). Recent work has discussed that policy implementation can be conceptualized as an effect modifier or a mediator (6); such analyses are promising analytic approaches that are compatible with standard regression modeling methods.

Using such analytic approaches ultimately depends on being able to measure policy implementation in a rigorous way, and there is a major lack of valid and reliable measures of health policy implementation determinants, processes, and outcomes (10–15). As a starting point to address the policy implementation measurement gap, provide guidance for researchers designing studies, and ultimately improve how policy implementation is analytically incorporated into quantitative policy evaluation research, we discuss four considerations for developing or identifying existing measures of policy implementation.

2 Methods

We identified our considerations by drawing on three currently funded NIH research grants that focus on policy implementation across areas of health at the state or local levels, as well as our team's expertise and subject matter knowledge. While these three grants all focus on studying policy implementation and include a quantitative component, their designs are diverse and offer potentially informative comparisons. A key thread linking all of these studies is that all focus on better understanding the "black box" of implementation after a policy has been adopted (16).

Our team met periodically to discuss the development of our considerations and design decisions. Each project lead first completed an implementation research logic model [IRLM, (17)] for their research grant. Group meetings were structured around discussing different components of the IRLM (e.g., determinants, implementation strategies, or implementation outcomes). We additionally used existing implementation science theories, models, or frameworks to guide these discussions. Specifically, we relied on the Consolidated Framework for Implementation Research (18, 19), the Expert Recommendations for Implementing Change compilation of implementation strategies (20), the Bullock et al. policy determinants and process model (21), and the Proctor Implementation Outcomes Framework (22, 23). These helped guide our group discussions and allowed the team to extract key information related to each study in a consistent format. Through group discussions, we iteratively developed a list of key considerations for developing or identifying measures based on commonalities across the three funded studies as well as our combined expertise in quantitative policy evaluation, public policy, and dissemination and implementation science.

2.1 Descriptions of included studies

The VAping POlicy Research (VAPOR) study seeks to (1) characterize the implementation of e-cigarette policies, (2) estimate the impact of these policies – accounting for strength of implementation – on e-cigarette, combustible cigarette, and cannabis use, and (3) project the future impact of alternate policy configurations using simulation modeling.

The Berkeley Choices and Health Environments at CheckKOUT (CHECKOUT) study focuses on the world's first healthy checkout policy, which prohibits the placement of high-added-sugar and high-sodium products and encourages healthy foods and beverages at store checkout areas. This work aims to (1) assess how the policy impacts store food environments, (2) how the policy impacts food purchasing, and (3) examine implementation factors that influence the effectiveness of the policy.

The 988 Lifeline financing study is focused on how states are supporting the implementation of a new three-digit dialing code for the national 988 Suicide & Crisis Lifeline, which was created by a federal law. The study aims to (1) characterize how states are financing 988 implementation, (2) explore perceptions of the financing determinants of 988 implementation success and understand the acceptability and feasibility of different financing strategies, and (3) examine how financing strategies affect policy implementation, mental health crisis, and suicide outcomes.

3 Results

We show key information from each study's design and IRLM in Table 1 and each completed IRLM is included in the Supplementary Appendix. Through our discussions of the IRLMs, we identified four key considerations to developing and identifying measures that researchers may consider as they plan and execute quantitative policy implementation studies. For each consideration discussed below, we provide illustrative examples from each study and provide a summary of the considerations in Table 2.

3.1 Clearly specify the implementation logic of the policy under study

Differences between the three projects underscored that policy implementation cannot be measured with a one-size-fits-all approach. Each policy area is unique, with different policy actors, contexts, and goals - the who, what, how, and why - similar to recommendations for specifying implementation strategies (24). To appropriately identify or develop measures of policy implementation, it is important to clearly define the policy under study, its hypothesized mechanisms of action, and which implementation determinants and outcomes are relevant. Therefore, a key consideration we identified was for investigators to clearly specify the implementation logic of their policy, using existing tools and frameworks from implementation science (including the IRLM) and related fields (e.g., public administration research, political science). Having this implementation logic specified can help ensure that there is conceptual alignment between the policy exposure, implementation outcomes, and behavioral or health outcomes (25). Beyond conceptual alignment, clear specification can also help define the statistical role different elements of the study may play (e.g., mediator, moderator, confounder). Specifying these elements is essential to understand what variables are needed to sufficiently specify statistical models and identify what needs to be measured to statistically identify an effect of interest with a reasonable degree of precision. This in turn enables researchers to identify what type of measurement tools or approaches are needed, identify existing measures in the literature, and understand if new measures are needed. Measures can be derived from routinely collected administrative data or primary data collection.

3.1.1 VAPOR

The VAPOR study is specifically interested in understanding the variety of implementation strategies for different e-cigarette policies

TABLE 1 Key policy implementation study components.

Study component	VAPOR	CHECKOUT	988
Policy(ies)	Six state e-cigarette policies: minimum legal sales age, flavor restrictions, taxes, clean indoor air laws, sales restrictions, licensure requirements	Healthy checkout policy that sets nutrition standards for foods and beverages displayed in store checkout lanes	Federal law that created three-digit dialing code for crisis line, expanded scope of crisis line, and delegated implementation financing responsibility to states
Level	State policies, state implementation	Local policy, local implementation (Berkeley, California)	Federal policy, state implementation
Main focus of study	Identifying implementation strategies for state e-cigarette policies and incorporating strength of policy implementation into quantitative models	Assessing impact of a local policy on food environments and consumer behaviors and understanding the policy implementation process	Determining effects of state implementation financing strategies and understanding policy implementation processes
Key implementation outcomes	Tax revenue collected, enforcement actions taken, inspection and sting operations, total budget for implementation (not measured in this study)	Degree of retailer compliance with healthy checkout policy	988 call volume and answering rates
Key service outcomes	n/a	Healthfulness of food environments	Timely receipt of quality crisis and mental health services
Key effectiveness outcomes (behavior and health)	Youth and adult e-cigarette use, youth and adult use of combustible tobacco products (e.g., cigarettes) and cannabis	Consumer purchases and dietary intake	Suicide attempts, suicide deaths, and emergency department visits for mental health crises and self harm
Data sources/collection methods	Qualitative interviews with state agencies, short implementation survey, CDC and state Behavioral Risk Factor Surveillance System data	Qualitative interviews and short survey with city staff and officials, community organizations, and store owners and managers; primary data collection of retailer compliance	Qualitative interviews with policy implementers, call volume and routing data from Vibrant Emotional Health, CDC mortality data, National Survey on Drug Use and Health, Agency for Healthcare Research and Quality's State Emergency Department database
Primary analytic methods	Thematic analysis of qualitative interviews; Difference-in-differences modeling; Microsimulation modeling	Descriptive analysis of qualitative interviews; Difference-in-differences and synthetic control modeling	Descriptive analysis of qualitative interviews and quantitative survey data; Difference-in-differences analyses
Practice partners	Public Health Law Center, the Truth Initiative, and the Tobacco Control Network (TCN) of the Association of State and Territorial Health Officials	Public health advocate and community leader who helped design the policy	Vibrant Emotional Health, which coordinates the 988 Lifeline, American Foundation for Suicide Prevention, Association of State and Territorial Health Officials

TABLE 2 Design considerations for measuring policy implementation.

Consideration	Rationale
1. Clearly specify the implementation logic of the policy under study	Clear implementation logic is required to fully understand the policy being studied (e.g., conceptualization, mechanisms) and develop or identify appropriate measures.
2. Develop an interdisciplinary team consisting of policy practitioners and researchers with expertise in quantitative methods, public policy and law, implementation science, and subject matter knowledge.	The complexity of policy implementation measurement necessitates an interdisciplinary team to ensure that measures are theoretically and practically sound.
3. Use mixed methods to identify, measure, and analyze relevant policy implementation determinants and processes.	Mixed methods are critical to appropriate measurement development because they support a purposeful integration of policy implementation determinants and processes into quantitative analyses.
4. Build flexibility into project timelines to manage delays and challenges due to the real-world nature of policy.	Measuring policy implementation and including it in quantitative analyses will typically require researchers to be account for delays and challenges encountered during policy implementation.

and identifying simple ways to measure the strength of policy implementation. Studying the simultaneous implementation of more than one policy means that the measurement of policy implementation cannot be policy specific. For that reason, the team developed two short questions that will be fielded to the relevant individuals within state governments: (a) the degree to which policies are implemented as written, and (b) whether they have adequate resources to implement the policies. The team has also had to make choices about classifying policies for the purposes of analyses. There is much heterogeneity between policy details, separate from implementation heterogeneity (e.g., some states with flavor restrictions prohibit sales of all flavored e-cigarettes while others allow sales of mint or menthol products). In studies with large sample sizes, this could be managed by including a variety of analytic variables capturing such heterogeneity, but in evaluations of state policies, sample sizes are limited. Thus, the VAPOR team has had to wrestle with how to collapse similar policies across states into meaningful categories while maintaining sample sizes that are needed for analyses.

As an example of how clearly specifying implementation logic can assist with conceptual clarity and model specification, the VAPOR team used the IRLM process to interrogate what mechanisms (a specific component of the IRLM) would operate as mediators or moderators. Through this process, consensus emerged that moderators are typically contextual elements (inner/outer setting) that affect the relationship between the policy and outcomes, while mediators are typically factors that lie along the causal pathway between the policy and outcomes (generally institutional changes that are directly caused by the policy and its implementation strategy). Specificity is crucial to determine what is conceptually a mediator vs. a moderator (6). We provide a general illustration of this conceptualization as well as a specific example from VAPOR in Figure 1.

3.1.2 CHECKOUT

In comparison to VAPOR, the CHECKOUT study focuses on the implementation of a single policy (a healthy checkout ordinance), implemented in a single jurisdiction (the city of Berkeley), and the first implementation study of this type of policy. As such, their study delves much deeper into the specifics of how the healthy checkout policy is being implemented. In-depth interviews with key stakeholders, combined with a brief quantitative survey, will generate rich data that can be used to develop and refine a broader set of quantitative measures to examine implementation heterogeneity across jurisdictions once healthy checkout policies are more widely adopted.

Although this is the first implementation study of a municipal healthy checkout policy, there are parallels between this policy and others (e.g., SSB excise taxes and restrictions on tobacco placement) that are helpful in developing an intuitive logic model. First, there is evidence from field experiments and voluntary policies that improving the healthfulness of checkouts also improves the healthfulness of consumer purchases (26). Second, prior evaluations of policy implementation have identified the importance of the following for improving health behaviors and outcomes: effective communications with retailers (e.g., definitions and lists of compliant and non-compliant products) (27), retailer compliance (e.g., the extent to which they stock only compliant products at checkout) (28), and enforcement and fines (29). Although this study is assessing implementation in a single city, the researchers expect to observe variability in how store managers and owners understand, interpret, and buy into the policy, and hence their store's compliance. Variability in compliance may also be observed over time based on the timing and robustness of the city's inspections, communications, and fines. The researchers' annual in-store assessments of products at checkout will provide objective quantitative measures of compliance, while the store interviews will indicate reasons for variability in compliance across stores and time. These data will not only inform constructs to assess in future quantitative measures of healthy retail policy implementations, but may also inform how to improve the next healthy checkout ordinance and its implementation.

3.1.3 988 Lifeline

The 988 study focuses specifically on one state financing strategy to support the implementation of the 988 Suicide & Crisis Lifeline: 988 telecom fees. Telecom fees, which are adopted by state legislatures, were identified in the federal law that created 988 as the recommended financing strategy that states should use (though there is no requirement for them to use it). These telecom fees–which are flat monthly fees on cell phone bills (e.g., 30 cents a month)–are consistent with how the 911 system in the United States is in part financed. As of March 2024, eight states had adopted 988 telecom fees. The study

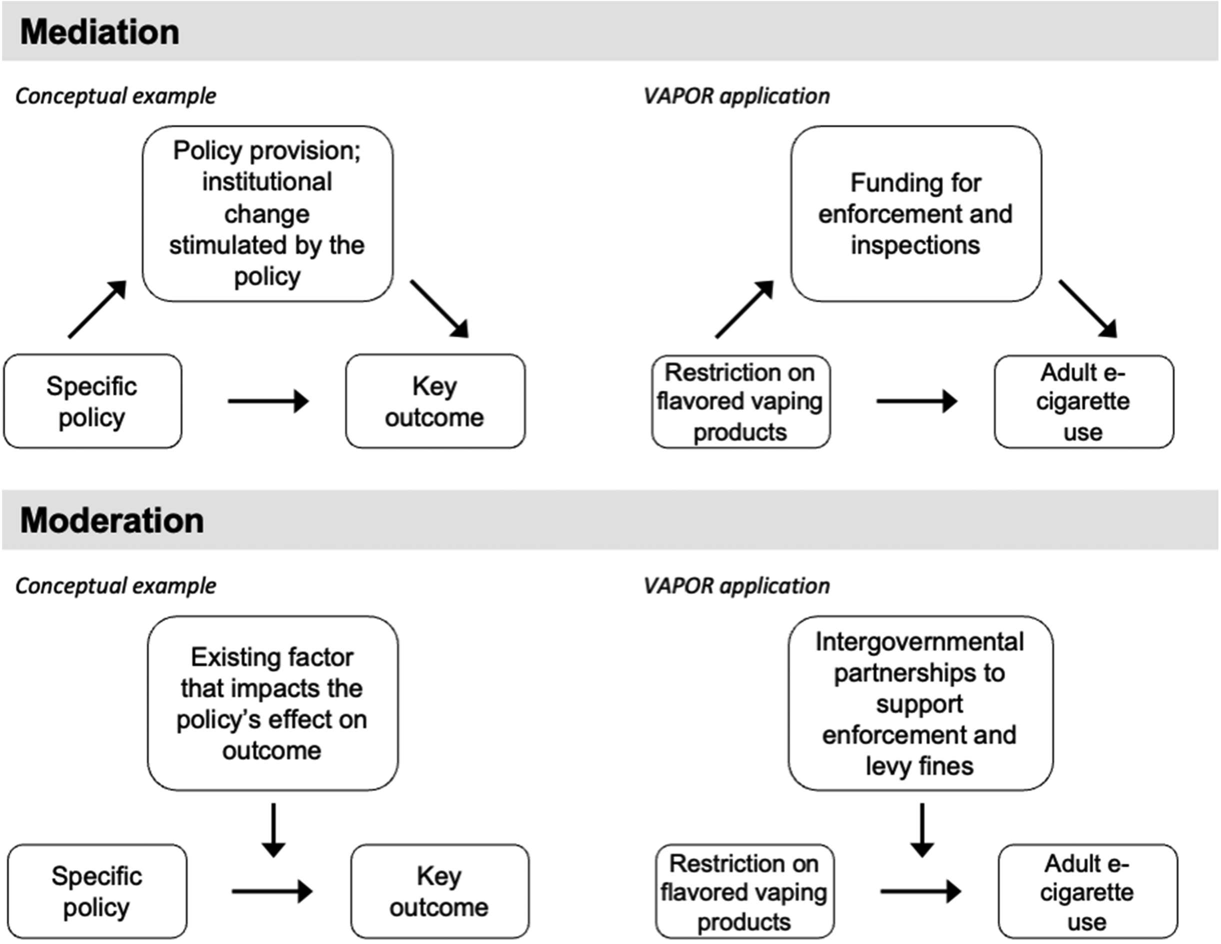

FIGURE 1
Example of policy implementation conceptualized as a mediator or moderator.

conceptualizes the state laws that create the fees as implementation strategies to support federal policy implementation and increase the reach of services provided by the 988 Suicide & Crisis Lifeline. The policies are operationalized as a dichotomous variable (988 telecom fee passed in the state, yes/no) as well as a continuous variable (dollar amount of revenue the 988 telecom fee generated annually per state resident).

3.2 Develop an interdisciplinary team consisting of policy practitioners and researchers with expertise in quantitative methods, public policy and law, implementation science, and subject matter knowledge

The projects illustrate the importance of involving an interdisciplinary team when measuring policy implementation. All study teams included researchers with expertise in methods and models used to evaluate health policies (e.g., difference-in-differences analyses, epidemiological and econometric methods), legal and policy expertise, implementation science, and health subject matter expertise. Implementation science expertise is critical to the clear conceptualization of different components of policy implementation, including the distinction between determinants, implementation strategies, mechanisms, processes, and outcomes – something that the team found difficult throughout our group discussions for this paper. The importance of mixed methods to policy implementation measurement (see next section "Use mixed methods…") also necessitates team expertise with qualitative, quantitative, and mixed methods approaches. Practice partners can help guide the recruitment of individuals who are best able to provide information on policy implementation components, and support other aspects of data collection or access. Including practice partners also ensures that there is a built-in feedback loop to communicate findings to other policy practitioners who may be considering or implementing similar policies.

3.2.1 VAPOR

The VAPOR team is led by a health policy and health services researcher with expertise in tobacco control and implementation science. Additional investigators and consultants bring expertise in tobacco and e-cigarette policy, addiction medicine, youth vaping, qualitative methods, implementation science, statistics (difference-in-differences methods), and simulation modeling. The team's tobacco and e-cigarette control experts come not just from the study's research center, but from major national organizations, including the Public Health Law Center, the Truth Initiative, and the Tobacco Control Network (TCN) of the Association of State and Territorial Health Officials. These team members help guide the execution of the research, including the recruitment of key implementation actors in different states. Representatives from these organizations constitute an important advisory board that is also called on to help guide analyses - for example, using their practice-based knowledge to help identify what policy synergies are useful to probe for in analyses, both independent and dependent on implementation.

3.2.2 CHECKOUT

The CHECKOUT study is led by a nutritional epidemiologist with experience evaluating food policies and their implementation processes using mixed methods. Other investigators include health economists (difference-in-differences and synthetic control methods) and behavioral scientists, and investigators are working with the director of a food policy NGO and with a community leader and public health advocate who has deep community ties and on-the-ground experience developing, advocating for, and implementing public health policies. These practitioners are particularly helpful in understanding mechanisms of policy action and important contextual factors as well as in advising on the recruitment of participants most knowledgeable about policy implementation.

3.2.3 988 Lifeline

The project team is led by an experienced implementation scientist who focuses on policy and mental health. A statistician with substantive expertise in health policy impact analysis is integral to the team and brings deep expertise in methods related to causal inference and quasi-experimental policy impact evaluations. Given the project's focus on understanding variation across state 988 financing approaches–many of which are codified in statutes–a public health lawyer is a key member of the project team and integral to accurately specifying the different implementation financing approaches used by states. Heterogeneity in the effects of 988 financing strategies across demographic groups and equity considerations are core to the project, so a team member has expertise in racial and ethnic disparities in suicide and mental health crises. The team is also working with a public finance/accounting expert in a school of public administration to help measure and quantify financing. Finally, practice partners have been critical in helping the team stay abreast of the rapidly changing 988 financing and policy implementation environment.

3.3 Use mixed methods to identify, measure, and analyze relevant policy implementation determinants and processes

All three studies use mixed methods, though applied in different ways. Often, qualitative methods are used to understand implementation determinants, strategies, and variability across jurisdictions and implementing actors (30, 31). In all three projects discussed here, qualitative findings drive how policy implementation is measured and incorporated into quantitative policy evaluations and provide important context for quantitative findings.

3.3.1 VAPOR

The VAPOR team is conducting interviews with staff in state agencies to understand how they are taking e-cigarette laws and translating them into action on the ground. The team's interview guides are based on Bullock's policy implementation framework, with significant focus on specific questions about determinants of implementation, for example, the clarity of policy language, the degree of vertical integration within state agencies, and the existence of communication and collaboration between state agencies and outside stakeholders (e.g., businesses). Along with the interviews, the team is asking each state to evaluate (a) the degree to which policies are implemented as written, and (b) whether they have adequate resources to implement the policies. The question is asked with respect to the initial implementation period and the current period, with responses taking values from 1 to 5. These numerical assessments will form the basis for the quantitative policy evaluation, allowing the team to move beyond "0/1" policy coding and determine whether policy impacts on study outcomes are different for states reporting "well-implemented" policies vs. "poorly implemented" policies. Interview data will provide further context on why policies do/do not show evidence of effectiveness, and will help the team decide how to approach the question of additive/multiplicative policies.

3.3.2 CHECKOUT

The CHECKOUT investigators are conducting interviews, accompanied by brief quantitative surveys, with city staff, leaders, and community organizations involved in implementing the healthy checkout policy and with managers and owners of stores that are subject to the policy. The measures will characterize the implementation process and strategies, such as the overall implementation framework and timeline, the teams involved and their degree of coordination, training of inspectors, and communication of policy requirements to stores. Measures will also assess implementation outcomes, such as perceived acceptability of the policy, fidelity of enforcement, and costs of implementation, as well as other determinants of implementation, such as the complexity of policy requirements, presence of champions, prioritization of the policy, resources, and other barriers and facilitators (10, 18). A key implementation outcome–the extent to which stores comply with the policy–is being assessed quantitatively using repeated observations of products at store checkouts in Berkeley and comparison cities (32) and analyzed using difference-in-differences models. These observations of checkouts will be used to identify variability in compliance across stores and over time. Although at the time the evaluation was planned, there was only one city with a healthy checkout policy, another city, Perris, CA has since enacted a similar policy, and there are other jurisdictions also considering such policies. The quantitative measures used in this single-city study have the potential to be used in evaluations of subsequent healthy checkout policies, and the qualitative data will inform the expansion and refinement of quantitative measures.

3.3.3 988 Lifeline

Because the 988 study is largely focused on one specific policy implementation financing strategy (i.e., state telecom fee legislation), the quantitative component uses difference-in-differences analyses to understand the impact of telecom user fee legislation on key implementation outcomes (i.e., measures of 988 implementation fidelity and reach–using call volume and routing data from Vibrant Emotional Health) and effectiveness outcomes (suicide death, using Centers for Disease Control and Prevention mortality data; suicide attempts, using self-report data from the National Survey on Drug Use and Health; and emergency department use for mental health crises and self-harm, using data from the Agency for Healthcare Research and Quality's State Emergency Department Databases). Moderation analyses will assess whether the state per capita amount of telecom fee revenue affects the relationship between user fee legislation and outcomes. Prior to the difference-in-difference analyses, surveys and interviews with "policy implementers" (e.g., 988 Lifeline call center leaders, state suicide prevention coordinators) will be conducted to unpack implementation processes and mechanisms of financing strategies. The information gained from these surveys and interviews may inform decisions in the difference-in-difference analyses (e.g., inform the selection and integration of new covariates) and will aid the interpretation of results. The surveys and interviews will draw from psychometrically validated instruments and assess stakeholders' perceptions of the financing determinants of 988 implementation and the acceptability and feasibility of state legislative financing strategies to improve implementation.

3.4 Build flexibility into project timelines to manage delays and challenges due to the real-world nature of policy

These projects' operationalization of implementation measurement also illustrates that policy implementation studies must wrestle with the real-world nature of policy implementation, which is constantly changing. This consideration is especially important when projects are evaluating policies as they are being implemented. The real-world dynamics of policy implementation work mean that investigators may need to consider backup plans in case data are delayed, unavailable, or change over time. Delays in policy implementation can run up against grant timelines, requiring no-cost extensions and even additional funding to sustain repeated measures longer than the initially anticipated need - though the three studies discussed herein are in early stages and have not yet faced these challenges.

3.4.1 VAPOR

Policies affecting e-cigarettes differ across the US. VAPOR evaluations are happening over a five year grant period, and depending on the state, a policy might be recently enacted or amended, or long-standing. Repeated measures are thus critically important to fully understand implementation processes. One anticipated challenge that VAPOR has addressed is data acquisition. Some data on e-cigarette use is held by state departments of public health. Acquiring these data often requires obtaining state-specific data use agreements, which can be time-consuming to complete, file, and execute.

3.4.2 CHECKOUT

Due to staffing shortages and strains on local governments caused by the COVID-19 pandemic, there has been a delay in some key aspects of the healthy checkout policy implementation, including the rollout of inspections and subsequent technical assistance to stores and fines. Such delays are not uncommon with municipal policy, and as such, policy implementation researchers need to be flexible and prepared to shift timelines for data collection and measurement (e.g., conducting interviews and surveys). Additionally, if government staff become too busy to participate in research, it may become necessary to rely on alternative data sources, such as public records and meeting minutes, to complement interview data. Potential delays in policy implementation also highlight the importance of collecting repeated measures of implementation outcomes. The researchers' multi-year assessments of products at checkout have the potential to detect increases in in-store compliance that may be expected immediately following policy communication, inspections, and fines (33).

3.4.3 988 Lifeline

There has been more federal funding for 988 implementation than originally anticipated, and more states have been substantively supporting implementation through budget appropriations than projected. The research team has needed to modify their data collection approach to ensure that these funds are being adequately tracked and measured - including how much is being distributed to each state and how those dollars are being allocated. The 988 Lifeline has also expanded texting capacity, and thus, the team has had to revisit their initial analytic planning to make sure their variables and data appropriately capture text volume in addition to call volume. There is also a major upcoming change in how calls and texts are routed to local Lifeline centers and thus counted at the state level (34). Routing has been based on area code (high potential for measurement error or misclassification bias), and soon it will be based on geolocation (much lower potential for measurement error or misclassification bias). This is a great advancement for the real-world implementation and impact of the policy (i.e., callers will be routed based on their actual location, rather than their area code which does not necessarily reflect their current location) but poses a significant measurement challenge for the study because pre- and post-policy measures reflect different routing methods.

4 Discussion

It is critical that we incorporate policy implementation into quantitative evaluations of health policies. However, measuring policy implementation is a key gap in the literature. Indeed, while recent work has discussed how policy implementation is conceptualized in evaluations, less work has discussed how to operationalize and measure policy implementation, a prerequisite for including it in any analyses. The subfield of policy (or policy-focused) implementation science is well-poised to address this methodological gap in the literature (3, 16). Through group discussion and comparing the approaches and methods of three NIH-funded research projects, we identified four key design considerations for researchers to use to develop or identify measures of policy implementation for inclusion in quantitative analyses: (1) clearly specify the implementation logic of the policy under study, (2) develop an interdisciplinary team consisting of policy practitioners and researchers with expertise in quantitative methods, public policy and law, implementation science, and subject matter knowledge, (3) use mixed methods to identify, measure, and analyze relevant policy implementation determinants and processes, and (4) build flexibility into project timelines to manage delays and challenges due to the real-world nature of policy.

Our study reinforces the need for more work developing and validating transferrable measures of policy implementation determinants and outcomes (10). This represents a key area where implementation scientists with expertise in measure development and evaluation could greatly enhance policy-focused implementation science. Ideally, determinant and outcome measures would be transferrable across levels of policy (e.g., local, state, national), consistent within content areas, and include a focus on health equity (13–15, 35). Transferrable measurements will greatly enhance our ability to derive broadly generalizable knowledge from policy studies like those discussed here. Measures that are too study-specific will have limited generalizability (though potentially higher internal validity) and limit the ability of broader learning for the field of policy-focused implementation science. Including attention to health equity in measure development will help provide comprehensive understanding of how marginalized populations are impacted by policies (15). As measures are developed, improving the coordination and use of common measures through publicly available measure repositories is crucial to improving the efficiency, reproducibility, and learning potential of policy-focused implementation science research (15). Existing repository and field-building efforts can provide guidance for how to build and disseminate such repositories (36–38).

Prior systematic reviews have focused primarily on measures of policy implementation determinants and outcomes (10, 13, 14). Another area of research that needs to be expanded is understanding the process by which policy implementation occurs and how it unfolds over time. As one example, a number of studies have examined the process of implementing sugar-sweetened beverage taxes across multiple jurisdictions in the US. The collective impact has been to illustrate how the implementation of these tax policies varies by jurisdiction, including what implementation strategies were deployed across contexts (27, 39, 40). Another example investigated how three states chose to implement new substance use disorder care services under a Medicaid waiver policy and identified key implementation strategies deployed (31). As more work in the field studies policy implementation processes and identifies policy implementation strategies, ensuring that implementation strategies are clearly reported (24) and understanding the mechanisms by which implementation strategies affect implementation outcomes will be a critical next step, similar to work being undertaken in the broader field of implementation science (41).

Beyond reporting on successful implementation processes in the scientific literature, the timely and accessible sharing of this learning with policy- makers, writers, practitioners, implementers, and consumer protection organizations is key for disseminating best practices and informing future policy implementation efforts. Engaging policy practitioners as part of the research team is one avenue for timely dissemination. Also, in the process of recruiting policy implementers to participate in surveys and interviews, researchers can establish a preferred mechanism and format for the timely sharing of findings. This is crucial, as prior research has established that a "one-size-fits-all" approach to dissemination will likely not be successful (42–47). Another feedback loop through which the research can strengthen future policy implementations is by presenting to coalitions of public health policy practitioners. For instance, there is a national coalition of healthy retail policy practitioners that invites researchers to present findings that could inform their future policy work.

We urge researchers to be specific about the role that policy plays in their study, particularly when outlining the implementation logic that will drive project decisions. Policy can be conceptualized in many ways in implementation science, including considering policy as the "thing" of interest, policy as an implementation strategy to put an intervention into place, and policy as a "vessel" for interventions (3, 16, 21, 48, 49). Here, all three projects have a common goal of understanding strategies or processes by which policies were (or are being) put into place; the VAPOR and CHECKOUT studies conceptualized policies as the "thing" of interest, while the 988 Lifeline study conceptualized state policies as the implementation financing strategy deployed to support implementation of the federal 988 policy and increase the reach of Lifeline services. All are crucial lines of research that are needed to improve population health, but advancements in the field and collective learning will be impeded without conceptual clarity of the role of policy in individual studies.

A limitation of this work is that due to project constraints, we were limited to three case studies, all of which were in early stages during the development of this manuscript. Our intent was to provide illustrative considerations to measuring policy implementation but are not intended to be inclusive of all possible considerations for measurement, and we do not have evidence on the success of these considerations. However, we also note that our considerations overlap with related work in the policy and implementation science fields (6, 10, 13, 48, 50). For example, Crable et al. discuss the importance of clearly specifying a policy's form and function (48), similar to our suggested practice of clearly specifying the implementation logic of the policy under study using tools such as the IRLM. Second, our practice of considering mixed methods is consistent with considerations outlined in protocol papers from other teams involved in this area (51, 52), and reflections from authors in the field of public administration (53). Third, each of the studies is currently working to handle challenges in measurement because of the real-world nature of policy, consistent with findings from a report on other funded policy implementation studies (54).

5 Conclusions

Quantitative policy evaluations provide critical knowledge of how policies impact behavioral and health outcomes, building the evidence base for further adoption elsewhere. To appropriately evaluate policy impacts on health, we must adequately measure how the policy is implemented, rather than assuming a policy is implemented just because it is "on the books" (3). In turn, this can help researchers better understand the full picture of why policies do or do not affect health outcomes, and their impact on health disparities (3, 10, 15). Policy-focused implementation science research focuses on understanding just this, but the measurement of policy implementation is lacking. Here, we describe four design considerations for policy implementation measurement, particularly when researchers are seeking to include policy implementation quantitative evaluations of health policies. These considerations provide a foundation for the field to build on as attention to measuring policy implementation grows.

Author's note

The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

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

NS: Conceptualization, Writing – original draft, Writing – review & editing. DL: Conceptualization, Supervision, Writing – original draft, Writing – review & editing. JF: Conceptualization, Supervision, Writing – original draft, Writing – review & editing. JP: Conceptualization, Supervision, Writing – original draft, Writing – review & editing. JC: Conceptualization, Supervision, Writing – original draft, Writing – review & editing.

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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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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frhs.2024.1322702/full#supplementary-material

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An examination of mental health policy implementation efforts and the intermediaries that support them in New Zealand, Canada and Sweden: a comparative case study

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Introduction: The implementation of evidence-informed policies and practices across systems is a complex, multifaceted endeavor, often requiring the mobilization of multiple organizations from a range of contexts. In order to facilitate this process, policy makers, innovation developers and service deliverers are increasingly calling upon intermediaries to support implementation, yet relatively little is known about precisely how they contribute to implementation. This study examines the role of intermediaries supporting the implementation of evidence-informed policies and practices in the mental health and addictions systems of New Zealand, Ontario, Canada and Sweden.

Methods: Using a comparative case study methodology and taking an integrated knowledge translation approach, we drew from established explanatory frameworks and implementation theory to address three questions: (1) Why were the intermediaries established? (2) How are intermediaries structured and what strategies do they use in systems to support the implementation of policy directions? and (3) What explains the lack of use of particular strategies? Data collection included three site visits, 49 key informant interviews and document analysis.

Results: In each jurisdiction, a unique set of problems (e.g., negative events involving people with mental illness), policies (e.g., feedback on effectiveness of existing policies) and political events (e.g., changes in government) were coupled by a policy entrepreneur to bring intermediaries onto the decision agenda. While intermediaries varied greatly in their structure and characteristics, both the strategies they used and the strategies they didn't use were surprisingly similar. Specifically it was notable that none of the intermediaries used strategies that directly targeted the public, nor used audit and feedback. This emerged as the principle policy puzzle. Our analysis identified five reasons for these strategies not being employed: (1) their need

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Abbreviations
EIPPs, evidence-informed policies and practices; IIMHL, International Initiative for Mental Health Leadership; IKT, integrated knowledge translation; ISF, interactive systems framework for dissemination and implementation; OCoECYMH, Ontario Centre of Excellence for Child and Youth Mental Health; MOHLTC, Ministry of Health and Long-Term Care; PSSP, Provincial System Support Program; SMH ASSIST, School Mental Health ASSIST; SALAR, Swedish Association of Local Authorities and Regions; MCYS, Ministry of Children & Youth Services; CAMH, Centre for Addiction and Mental Health.

to build/maintain healthy relationships with policy actors; (2) their need to build/maintain healthy relationships with service delivery system actors; (3) role differentiation with other system actors; (4) perceived lack of "fit" with the role of policy intermediaries; and (5) resource limitations that preclude intensive distributed (program-level) work.

Conclusion: Policy makers and implementers must consider capacity to support implementation, and our study identifies how intermediaries can be developed and harnessed to support the implementation process.

KEYWORDS

evidence-informed policy, implementation science, mental health, addiction, intermediary, case study, technical assistance, policy implementation

Introduction

The implementation of evidence-informed policies and practices (EIPPs) at scale across whole systems is a complex, multifaceted endeavor. Yet an effective implementation process is critical in bridging the gap between the promise of EIPPs and positive outcomes for citizens and society. This is particularly true when the EIPP is psycho-social in nature requiring the mobilization of multiple organizations, often multiple roles within organizations, a need to respond to the diversity of individuals or families receiving the EIPP, and a need to take into account a range of contexts. It is this complexity that may account for the continued lack of access to psycho-social EIPPs for both adults and children. For example, in the US, researchers found that the overall penetration rates for six behavioural evidence-based treatments was only 1%–3% and adoption rates were static or declining across the states who had invested in them (1). This is despite an increased understanding of the burden of mental illness and addictions (2) and increased momentum by policy makers around the globe to address the issue (3).

In response to these challenges, policy makers, innovation developers and service deliverers are increasingly looking toward organizations or programs that can facilitate the implementation process. These organizations are often referred to as intermediaries. Intermediaries act as "translators" for EIPPs and provide technical assistance to organizations and providers that deliver services for citizens, while informing policy and systems (4–7). In general, intermediaries fall under the broader implementation construct of facilitation (8, 9) or change agency (10) with the recognition that complex change processes, such as implementing a new EIPP, do not on their own reach a high enough rate of penetration and fidelity in systems to produce their intended benefits. In order for this to happen, external supports are typically required and intermediaries are one way through which facilitation can take place.

Limited research exists on this type of intermediary and there is not yet a consensus on what precisely defines them and how they contribute to implementation. One reason for this is that the scholarship that exists comes from different fields (e.g., public management, social sciences or implementation science), which naturally draw from different theories, methods and ways of reporting. Added to this is a great deal of heterogeneity in terms of topics such as: child, youth and family services (5, 11), education (12, 13), environment (14), mental health and addictions (15, 16), occupational health and safety (17) and technology (18), where the contexts surrounding the intermediaries vary, limiting the comparability across them. Finally, there are a diversity of terms in use, with some of the more common including: intermediary (organization), purveyor, technical assistance center, knowledge brokering organization, centre of excellence, implementation team and backbone organization (19–26). This lack of precision means that different terms may be used to describe similar constructs and the same term may also be used to describe two quite different constructs, leading to further conceptual fuzziness.

The strategies employed by intermediaries vary but the existing literature does point to some common strategies and approaches. A survey of 68 intermediaries found support for seven core functions of intermediaries, including: consultation activities; best practice model development; purveyor of evidence-based practices; quality assurance and continuous quality improvement; outcome evaluation; training, public awareness and education; and policy and systems development (27). More recently, a web scan and survey of child behavioral health intermediaries found that they used an average of 32 distinct strategies to implement evidence-based interventions, with common strategies including educational, planning and quality improvement strategies (15). They found little consensus, however, on which strategies intermediaries perceived as the most effective.

Some authors frame the strategies of intermediaries in different terms. For example, they describe the approaches of intermediaries and other "support system infrastructure" as including both general capacity-building approaches as well as those that are innovation-specific (28), while others identify strategies targeting different levels in the system (e.g., federal, province/state, local) (7). Still others have described intermediaries in economic terms, suggesting intermediaries can address research supply-side issues (supporting the production, translation and consumption of research) as well as the demand-side issues (such as improving service delivery readiness for a particular EIPP, support for implementation, etc.) (13). To our knowledge, the literature has not distinguished intermediaries based on their public vs. private sector placement.

We identified three sub-types of intermediaries in the literature that specifically address the knowledge production-to-implementation continuum: (1) those whose focus is mainly on translation and dissemination of research evidence to inform policy and practice (knowledge translation-focused, or "KT intermediaries") (11, 12, 14, 29, 30); (2) those whose focus is mainly on the implementation of pre-packaged research evidence to service providers in the form of evidence-based practices (practice-focused, or "practice intermediaries") (15, 16, 31); and (3) those whose focus is mainly on assisting policy makers or other system leaders in getting EIPPs embedded at scale in systems (policy-focused, or "policy intermediaries") (13, 32–34). Of course, many intermediaries will engage in activities across all three types, but this characterization may help to clarify the starting point, goals and theories of change related to each.

Given the focus here on policy and supporting implementation at scale in mental health and addictions systems, our study targets the policy intermediary sub-type. We adopted a definition that we first forwarded by Bullock & Lavis (2019): Intermediaries are organizations or programs that have an explicit and recognized role to support the implementation of government mental health and addictions policy goals and employ specific methods of implementation support. In order to achieve these goals, other actors in the system must understand and accept this role, including those in government, service delivering organizations and other stakeholders.

This study examines the role of policy intermediaries supporting the implementation of evidence-informed policies and practices in the mental health and addictions systems of high-income countries. Guided by implementation theory and drawing from established explanatory frameworks, we address three questions: (1) Why were the intermediaries established? (2) How are intermediaries structured and what strategies do they use in systems to support the implementation of policy directions? and (3) What explains their lack of use of particular strategies?

Methods

Integrated KT approach

This study was designed and conducted in collaboration with the International Initiative for Mental Health Leadership (IIMHL)—an international collaborative that focuses on improving mental health and addictions services in eight countries: Australia, Canada, England, Ireland, New Zealand, Scotland, Sweden, and USA (a ninth country, the Netherlands, joined after data collection began). Prior to initiating the study, one of the authors (HB) had been participating with a sub-group of individuals from IIMHL countries who were either working in intermediaries or interested in harnessing the capacity of intermediaries to support systems change. With those relationships in mind, we asked the IIMHL if they would like to partner on this research in an integrated knowledge translation capacity. Integrated knowledge translation (IKT) is an approach to research where those who produce research and those who may use it, partner on a study with the goal on enhancing relevance and facilitating use (35). In this case, our IIMHL partners have thus far participated in three study phases: (1) providing input into the conceptualization and planning of the study, (2) assisting with recruitment and data collection by offering to host the research team during site visits and identifying potential key informants to be interviewed, and (3) assisting with the interpretation of findings and identifying next steps.

Study design

We used the holistic multiple case study approach outlined by Yin (36). A multiple case study approach is often considered more compelling and robust than single case designs because of the replicative nature and the ability to make predictions from theory that can be tested across cases leading to higher explanatory power. It is a suitable methodology for our questions as it allows for an examination of intermediaries in their context. We brought a realist-postpositivist philosophical approach to this research, considering it a form of empirical inquiry and focusing on maintaining objectivity through the use of techniques like triangulation to minimize errors and get as close as possible to the "truth" (37).

Ethics approval for this study was granted by McMaster University through the Hamilton Integrated Research Ethics Board and informed consent was sought and provided by all participants. The study was conducted in two phases: (1) case selection, and (2) comparative case study. For brevity, we refer to mental health and addictions as "mental health".

Phase 1—case selection

Qualitative description was selected as the analytic approach for this phase, which has, as its goal, a comprehensive summary of events in everyday terms (38). The "case" or unit of analysis in this study is defined as: a political jurisdiction with a governing authority that has the ability to develop, implement and evaluate mental health policy and the organizations or programs within them that support policy implementation. This definition means the units may be at different policy levels in systems (e.g., national, provincial/state or municipal). The "population" of potential jurisdictions included countries that are members of the IIMHL. These countries all have well-established health systems and their participation in the IIMHL reflects a commitment to mental health systems improvement and advancement. They provide adequate variation in terms of health service structures, including how mental health services are designed, managed and delivered. They also vary in the factors that may impact successful implementation but have enough similarity to ensure the case study is sensitive to the variables of interest.

The research team worked with IIMHL partners to generate a purposive sample of potential interviewees from each jurisdiction. The list included a mix of leaders in government, agencies of government, non-governmental organizations and service providers who played a leadership role in implementation and could speak to the macro-context of their mental health system. From this list, the research team (HB) contacted one or two leaders from each jurisdiction requesting a brief semi-structured phone interview by telephone or Skype. The questions were targeted toward understanding the policy priorities currently being implemented and the structures in place supporting their implementation. A number of potential interviewees were known to HB through their mutual involvement in the IIMHL.

Interviews were recorded and reviewed by the study team. Using qualitative content analysis and following the qualitative description approach, analysis remained "close" to the data with minimal interpretation. Structured summary sheets of each interview outlining important characteristics and infrastructure were generated and a table was created to facilitate case selection.

Phase 2—comparative case study

Cases for the comparative case study were purposively sampled based on findings from Phase 1 using an approach that approximates the Most Different Systems design or Mill's Method of Similarity (39). Using this method, cases are selected based on a similar outcome or dependent variable but are diverse in other ways. In this study, cases were selected based on the presence of at least one organization or program that has an explicit role supporting mental health policy implementation (policy intermediary). Cases were also sampled for diversity in other domains such as the policy level (state/province vs. national); mental health system factors (e.g., a range of governance, financial and service delivery arrangements); and, political system characteristics (e.g., diversity in the institutional arrangements, interests and ideas at play) (Table 1). Using this approach, the cases selected include: New Zealand, the province of Ontario in Canada, and Sweden. Ontario included three embedded cases. The cases are bounded in two ways. First, by the political areas specified above that have policy authority over mental health and addictions. Second, they are bounded temporally, that is, this research only considers active implementation efforts and the current structures in place to support them and does not look explicitly at past policy efforts.

The methods used for this phase included an analysis of key documents, site visits and follow-up interviews. Field notes were also recorded throughout the site visit by the study team.

Review of key documents

We analyzed key documents collected as part of case selection and additional documents retrieved through web searches of government and stakeholder websites and a search of PubMed, Google Scholar and LexisNexis in October 2016 and again in June 2018 for relevant research articles and media accounts related to the intermediaries or implementation efforts. The types of documents analyzed include: annual reports, government reports, news articles, KT products produced by intermediaries and peer reviewed research. Documents were reviewed and data

TABLE 1 Case selection criteria by jurisdiction.

Jurisdiction	Sub-jurisdiction	Jurisdiction type and population (2015)	Welfare state regime type[b]	Identified structure(s) for policy implementation	Used explicit implementation methods	Receptivity of local stakeholders[c] (1–3)	Similarity of system structure to Ontario	Notes
Australia		Country 23.13 million	Liberal	✓[a]	✗	2	High	Most activity not at national level
	New South Wales	Province/State 7.54 million	Liberal	✓[a]	✗	2	High	Did not participate in interviews
Canada	Ontario	Province/State 13.6 million	Conservative	✓	✓	3	High	Have connections to stakeholders
	Saskatchewan	Province/State 1.13 million	Conservative	Mandate not renewed	✓	3	High	Mandate not renewed for I-Team
England		Country 53.01 million	Liberal Subgroup	✗	✗	2	Med	No current structures with this focus
Ireland		Country 4.60 million	Liberal Subgroup		✗	2	Med	Informal structures contracted for some work
New Zealand		Country 4.47 million	Liberal Subgroup	✓	✓	3	Med	Clearly defined structure
Scotland		Country 5.30 million	Liberal Subgroup	✓	✓	1	Med	No contact with system leaders
Sweden		Country 9.59 million	Social Democratic	✓	✓	3	Med/Low	Clearly defined entity but re-structuring
USA		Country 318.9 million	Liberal	✓	✓	2	Low	Mix of structures across system
	New York City	City 8.55 million	Liberal	✓	✓	3	Low	New structures in place

[a] Structures to support system oversight in form of mental health commissions, but not identified in interview.

[b] Bambra (2005) compares countries based on health care services and decommodification.

[c] Receptivity Scale: 1 = no contact or low receptivity; 2 = some contact and some either some receptivity OR have not asked directly OR consent form indicates interest in being approached; 3 = frequent contact or have asked directly and received positive response.

were extracted based on the following domains: health system and political system characteristics; intermediaries and other structures supporting implementation of mental health and addictions priorities; and implementation strategies being utilized.

We reviewed and analyzed a total of 73 sources: 24 policy documents, 13 reports or other documents generated by or on behalf of the intermediary, 22 websites and 14 scholarly publications. We also reviewed some grey literature on implementation infrastructure that referenced at least one of the cases ($n = 3$) and used news media articles as a source of triangulation to verify events that were mentioned by stakeholders during the interview (Appendix 1). We used each intermediary's website to review reports and publications, so many of those are not counted in the tally above.

Site visits

Our team created a matrix outlining the types of stakeholders we wanted to interview and shared it with the IIMHL IKT partners in each jurisdiction. Partners were instructed to identify at least two individuals for each category and provide contact details. Types of stakeholders included: (1) intermediary, (2) policy makers/government, (3) funder(s) of implementation/intermediary, (4) oversight of implementation/intermediary, (5) researchers familiar with the intermediary, (6) knowledge synthesizers & translators, (7) recipients of implementation supports, (8) partners of intermediary, and (9) others. One to two people from each category were then invited to participate. The consent form was translated into Swedish for the Swedish case, and while the interviews were conducted in English, an informal English/Swedish interpreter (someone who was familiar with the subject) was offered to potential participants.

Interview questions were tailored to the type of stakeholder but were focused on constructing a full picture of how policy implementation is structured and delivered in the system, including: (1) what policy priorities are currently being implemented; (2) who (organizations and individuals) are supporting their implementation; (3) what implementation strategies they use (e.g., training, audit and feedback, etc); (4) how the implementation supports are valued and meeting the identified goals; and (5) what factors were important in the creation of the intermediary (Appendix 1). The interview guide was revised as the analysis of earlier rounds of data proceeded and theoretically or substantively important insights were identified for exploration in later rounds. With consent, interviews were recorded for later transcription and lasted approximately 90 min each. Interviews were conducted until saturation was reached and no key perspectives were deemed missing. Throughout the site visit, the study team took field notes including descriptive (e.g., who, what, where, etc.) and interpretive information (e.g., personal reflections and questions arising from activities). Additional documents, such as presentations or reports, were requested from participants and reviewed. All site visits took place in 2017: New Zealand (February), Sweden (May) and Ontario (July–September). When appropriate based on the rules of the jurisdiction, ethics waivers were sought and acquired prior to the site visit.

Follow-up interviews

A final stage of data collection included interviews with key informants who were unable to participate during the site visits or agreed to a follow-up interview as analysis proceeded. These additional interviews took place in 2017 and 2018. This was done to ensure each case was as complete and as comparable as possible across jurisdictions.

A total of 49 initial interviews were conducted during the site visits or shortly thereafter (13 NZ, 23 ON, 13 SE). More interviews were conducted in Ontario because the three embedded cases meant that a larger sample of stakeholders were required to reach saturation. Three of the interviews in Sweden were supported by an interpreter. Stakeholders from all of the categories identified in the stakeholder matrix were interviewed for each case, providing us with a well-rounded perspective. Four follow-up interviews were also conducted to confirm details or fill small gaps in the analysis.

NVivo12 Qualitative Software was used to manage data, thereby serving to establish a comprehensive and easily accessible case study database.

Analysis

Transcripts and/or audio recordings were reviewed at least twice. Supporting documents were also reviewed and coded. Directed content analysis (40) was employed, which begins the coding process by drawing from existing research and theory as a guide. Within each case, sources were compared with one another to identify themes that emerge across them. The lead researcher (HB) led all stages of the analysis and JNL, GM and MW were involved in reviewing codes, themes and interpretation.

Analytic goals and frameworks

Goal 1

To explain why the intermediaries were originally established and endorsed by governments to support policy implementation, we used Kingdon's multiple streams agenda-setting framework (41). Kingdon's theory identifies activities in independent "streams" that have to come together during a brief "window of opportunity". These include: heightened attention to a problem (problem stream), an available and feasible solution (policy stream), and the motive to select it (politics stream). The three streams must come together in order for a change to be made, and this usually happens through the work of a policy entrepreneur.

Using this framework, we identified the timelines of the relevant events and activities leading up to the establishment of the intermediary(ies) based on stakeholder accounts of what was relevant as well as our document review. Next, we developed a comparative table that highlighted: (1) aspects of the problems in each system that each intermediary was created to address, (2) policy proposals and ideas that were supportive of the need for implementation infrastructure in the form of an intermediary,

(3) the political environment that made the intermediary(ies) as a policy solution feasible, and (4) the relevant actors, including policy entrepreneurs that were important for bringing the intermediary to the decision agenda.

Goal 2

To describe and compare the structures of the intermediaries, their organizational characteristics and the implementation strategies they use, we drew on a modified version of the Interactive Systems Framework for Dissemination and Implementation (ISF) as a descriptive framework. The ISF was originally developed by Wanderman and colleagues (28, 42) and is a heuristic that captures how new knowledge moves from research development to widespread use and the systems and processes supporting this movement. The ISF specifies the three systems needed to carry out dissemination and implementation functions: (i) Synthesis and Translation System; (ii) Delivery System; and (iii) Support System. In an effort to capture the important role of policy in implementation, we modified the ISF by adding a Policy System (links with the three other Systems and provides a variety of policy-related supports for dissemination and implementation) (Bullock. 2019).

We used the modified ISF to sort and classify the strategies used by intermediaries according to the "target" System. We then added some categories that we felt were important to highlight and did not necessarily fit well within one particular System: strategies targeting the public; strategies targeting individuals with lived experience & family members; and strategies focused on performance assessment and/or system-monitoring. Finally, we cross-referenced our strategies with the implementation strategies identified by Powell and colleagues (43) who used the sub-categories of "Plan", "Educate", "Finance", "Re-structure" "Quality Management" and "Attend to Policy Context". Next, we extracted examples of the strategies for each case from the interview data, and cross-referenced/supplemented these with the document and website data sources.

Goal 3

To explain the choice of implementation strategies we first drew on the 3I + E framework (44, 45). The 3I + E framework is used to explain how Institutions (e.g., government decision-making structures and processes), Interests (i.e., groups with a vested interest), Ideas (i.e., values and research-based knowledge) and External factors (i.e., events outside of the policy area of interest) affect the actions of those making decisions or implementing them.

Our original intent was to use this framework for a complete analysis, however, once we had results from the second question, we found we had a far more interesting policy puzzle related to the lack of use of particular strategies that warranted a slightly different analytic approach including a thematic analysis of salient features that fell under two elements of the 3I + E framework.

Context: intermediary case descriptions

Figure 1 depicts the intermediary infrastructure in each case as well as the case boundaries.

New Zealand

The Ministry of Health, through Workforce New Zealand, funds a national infrastructure to support development of the mental health and addictions workforce, including 5 centres with different foci. Over time, Te Pou o te Whakaaru Nui (Te Pou, adult mental health and disability focus) and Matua Raki (addictions focus, housed at Te Pou), have developed into an intermediary that aligns with our definition and is the focus of the NZ case. Two other organizations that are increasingly contributing to the implementation infrastructure include the Werry Workforce Whāraurau (child and youth focus) and the Health Quality & Safety Commission New Zealand.

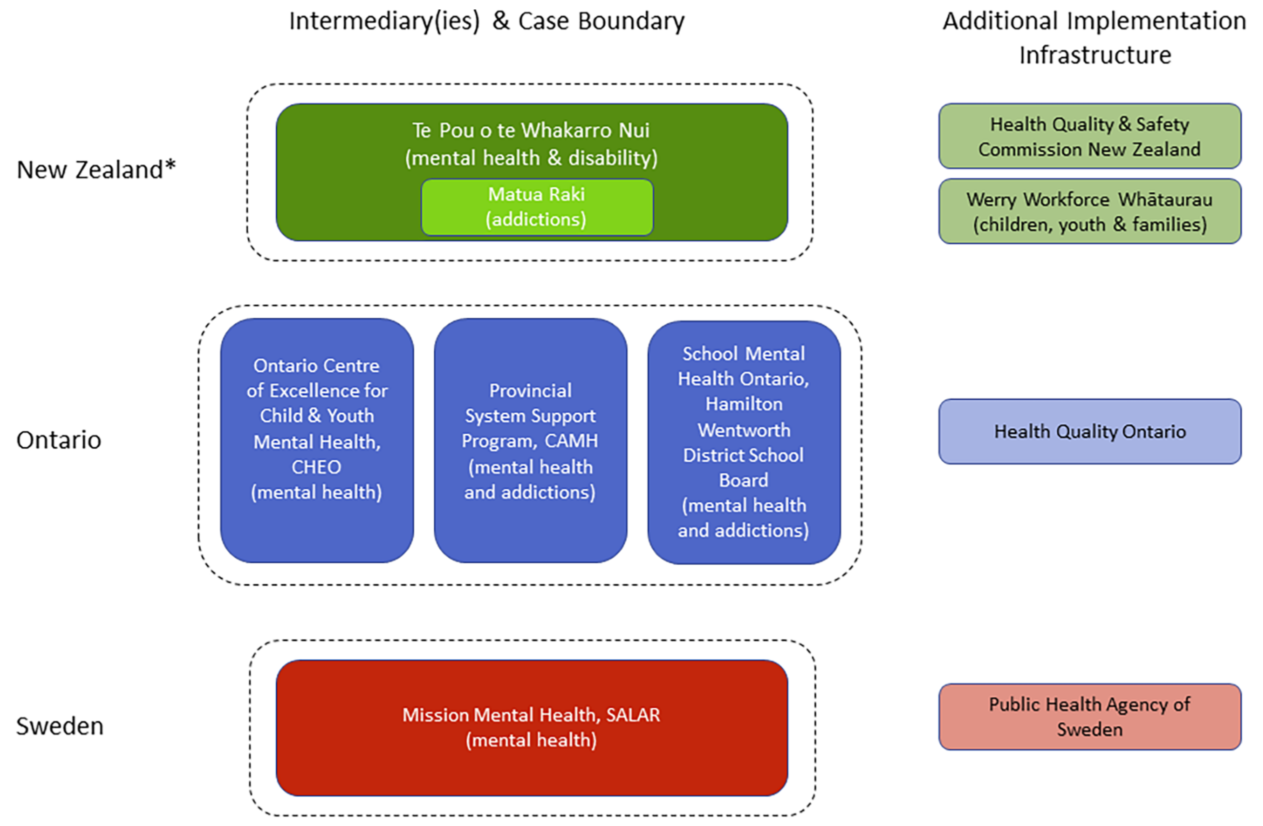
Ontario, Canada

In Ontario, we identified three intermediaries that fit our definition: (1) Ontario Centre of Excellence for Child and Youth Mental Health (OCoECYMH) located at the Children's Hospital of Eastern Ontario and funded by the Ministry of Children and Youth Services (note: post-data collection, funding authority was transferred to the Ministry of Health and Long-Term Care, MOHLTC); (2) Provincial System Support Program (PSSP) located at the Centre for Addiction and Mental Health and funded by MOHLTC; and (3) School Mental Health ASSIST (SMH ASSIST) located at the Hamilton-Wentworth District School Board and funded by the Ministry of Education. These three intermediaries collectively comprise the Ontario case, however, other organizations, such as Health Quality Ontario, were also highlighted as increasingly playing an intermediary function in mental health.

Sweden

Uppdrag Psykisk Hälsa (Mission Mental Health) is the intermediary in Sweden that met our definition and is the focus of this case. Mission Mental Health is located at the Swedish Association of Local Authorities and Regions (SALAR), which is a peak body that acts as both an employers' organization as well as one that represents the interest of the municipalities and regions to the national government. Mission Mental Health is funded through an agreement between SALAR and the Ministry of Health and Social Affairs. The Public Health Agency of Sweden was also highlighted as an organization beginning to take on more of an intermediary function.

It should be noted that the lead researcher (HB) previously worked with PSSP and has pre-existing relationships with all three intermediaries in Ontario.



*There are two other workforce development centres, Te Ra Matatini (Māori health) and Le Va (Pacifika), that are part of the workforce support infrastructure in New Zealand but do not meet our definition of intermediary

FIGURE 1
Graphic depiction of implementation support infrastructure by case.

Results

Why were the intermediaries established?

Table 2 identifies the timelines of the relevant events and activities leading up to the establishment of the intermediary(ies) based on stakeholder accounts and our document review. The results of the analysis of factors influencing the decision to establish the intermediaries is presented in Table 3.

In all three cases, the intermediary infrastructure came on the heels of a monumental shift in how mental health and addictions care was delivered—moving from a system of institutional-based care to one based largely in community. While the timelines and trajectories for deinstitutionalization varied across cases (46–51) the process was completed around the turn of the century—and it is in the decade that followed that these intermediaries were established.

The deinstitutionalization process left policies legacies that differed in each case due to the unique political terrain and health policy features of each jurisdiction. However, this shift in the model of care was largely cited by key informants as a factor that was influential in driving the need for new and different capacities in the system as a result of it becoming more complex and multi-faceted and spanning a new array of community and hospital environments. The type of new capacity required was framed differently across cases and is outlined as part of the analysis below.

New Zealand

During the years following deinstitutionalization, mental health became a much more visible policy issue due to several “dreadful events” involving people with mental illness and feedback about the scale and scope of the issue from the first national epidemiological study on mental health issues (problem stream). This increased visibility of the problem led to a flurry of a policy activity, including a government inquiry, at least seven policy documents and a major change in the law (policy stream). Also during this time was the formation of a Mental Health Commission and a government that was willing to invest heavily in mental health (politics stream). Over time, some of the challenges identified in the system were framed as a need to expand the workforce to include other roles that were not required in an institutionally-based care model and to simultaneously equip the existing workforce to function differently than they had been expected to in the past.

TABLE 2 Timelines of events leading up to the establishment of the intermediaries for each case.

Events and activities by case				
New Zealand Te Pou (est. 2006)	Ontario, Canada			Sweden Mission Mental Health (est. 2008)
	OCoECYMH (est. 2004)	PSSP (est. 2011)	SMH Assist (est. 2011)	
1990s. A number of "dreadful events" involving people with mental illness	**1999.** Mental Health Implementation Task Forces initiated			**1994.** Government Bill 1993/94:218—*Mentally Ill People's Conditions* identifies separation of care for mental health between counties & municipalities
1993. Dr Janice Wilson becomes Director of Mental Health in Ministry of Health	**1999.** *Making It Happen: Implementation plan for mental health reform* published by government			**Early 2000s**. Shift in technology and thinking fostered demand for new ways of thinking and doing things
1995. Judge Kenneth Mason leads national inquiry and publishes findings	**1999.** 2 provincial standard outcome measures announced for children & youth mental health services			**2003.** Murder of Anna Lindh, Swedish Foreign Minister and several other acts of violence involving people with mental illness
1996. Government passes Mental Health Act (1992) replacing Lunatics Act (1882)	**2000.** Ontario Health Services Restructuring Commission recommends reforms to mental health services (*Looking Back, Looking Forward, 2000*)			**2003.** National review of mental health led by Dr Ing-Marie Wieselgren and Anders Milton (2003–2006)
1997. Establishment of Mental Health Commission	**2002.** New premier looking to retain office			**2006.** Commission presents its final inquiry report to government, becoming an important knowledge base for future government activities
1998. Mental Health Commission publishes Blueprint 1	**2002.** *The Time is Now: Themes and recommendations for mental health reform in Ontario* Final Report of the Provincial Forum of Mental Health Implementation Task Force Chairs			**2006.** New government with focus on performance-based reimbursements Lyons/Alliance government, including appointment of Goran Hägglund as Minister of Health and Social Affairs
1999—early 2000s. Government (through Treasury) willing to invest heavily in mental health	**2002.** 1st comprehensive epidemiological reports published on child & youth mental health in Canada *(Waddell, 2002; Health Canada 2002)*			**2007.** Swedish Association of Local Authorities & Regions (Sveriges Kommuner och Landsting) was created as a coordination body between national and regional/municipal levels of government
2001. Ministry of Health announces funding for 2 workforce development initiatives	**2003.** ON Auditor General's report identifies major concerns in children & youth mental health			**2007.** National government institutes new way of supporting mental health by contracting directly with local authorities and regions
2002. Ministry of Health publishes *Mental Health (Alcohol and Other Drugs) Workforce Development Framework*, acknowledging a more systemic approach to workforce development is required	**2003.** Government announces intention to create a centre of excellence for children's mental health at Children's Hospital of Eastern Ontario			**2008.** Government communication document 2008/09:185—*A policy for people with mental illness or mental disability*
2002. Health Research Council begins to run adult mental health workforce programs	**2003.** Election & change in government			**2008. Mission Mental Health (Uppdrag Psykisk Hälsa) at SALAR is established**
***2003**. Werry Centre for Child and Adolescent Mental Health launched by Minister of Health (Annette King) at University of Auckland*	**2004. The Provincial Centre of Excellence for Child and Youth Mental Health at CHEO established**			
2003–2004. First national epidemiological survey/report on mental health and addictions *Te Rau Hinengaro—The New Zealand Mental Health Survey*	**2006.** Ministry of Children and Youth Services publishes *A shared responsibility: Ontario 's policy framework for child and youth mental health.*			
2005. Ministry of Health publishes the second mental health and addiction plan: *Te Tāhuhu: Looking forward, moving forward Improving mental health 2005–2010*	**2006.** Canadian senate committee publishes *Out of the Shadows at Last: Transforming mental health, mental illness and addiction services in Canada,* Kirby & Keon			
2005. Health Workforce Advisory Committee publishes *Strategic Principles for Workforce Development in New Zealand*	**2007.** Mental Health Commission of Canada is established			
2005. *Tauawhitia te Wero Embracing the Challenge* National mental health and addiction workforce development plan 2006–2009 is published by Ministry of Health	**2009.** Minister's Advisory Group publishes *Every Door is the Right Door* discussion paper and 5 theme group papers			
2006. Ministry of Health publishes implementation plan for Te Tāhuhu: *Te Kōkiri—The mental health and addiction action plan 2006–2015*	**2009.** OCoECYMH contracts a policy-oriented paper on school-based mental health: **2009.** *Taking Mental Health to School: A policy oriented paper on school-based mental health for Ontario* (authors include Kathy Short)			
2006. Te Pou o te Whakarro Nui is established	**2010.** Minister's Advisory Group publishes *Respect, Recovery, Resilience: Recommendations for Ontario's Mental Health and Addictions Strategy* final report			
	2010. All-party committee submits final report *Navigating the Journey to Wellness: The Comprehensive Mental Health and Addictions Action Plan for Ontarians*			
	2010. Ministry of Education requests proposal from Kathy Short (for what later becomes SMH ASSIST)			

(*Continued*)

TABLE 2 Continued

Events and activities by case				
New Zealand Te Pou (est. 2006)	Ontario, Canada			Sweden Mission Mental Health (est. 2008)
	OCoECYMH (est. 2004)	PSSP (est. 2011)	SMH Assist (est. 2011)	
	2011. Government publishes *Open Minds, Healthy Minds, Ontario's 10-year mental health and addictions strategy*			
	2011. Provincial System Support Program at CAMH is established			
	2011. School Mental Health ASSIST at Hamilton-Wentworth District School Board is established			

Bolded text highlights when each intermediary was established.

The policy entrepreneur (Janice Wilson) was recognized by almost all key informants as playing a pivotal role in getting the workforce infrastructure established. However, workforce centres in and of themselves, did not meet our definition of an intermediary. Since their establishment, TePou, Matua Raki and more recently, the Werry Centre, have evolved into the role of an intermediary. This broader role may have been bolstered by the government's decision in 2012 to eliminate the New Zealand Mental Health Commission and transfer only limited functions to the Office of the Health and Disability Commissioner, leaving additional gaps in the system now filled by these intermediaries.

Ontario, Canada

In Ontario, the first intermediary to be established was the Ontario Centre of Excellence for Child & Youth Mental Health (OCoECYMH)—almost seven years before the Provincial System Support Program (PSSP) and School Mental Health Assist (SMH ASSIST). Prior to OCoECYMH's creation, there was an increasing visibility of children and youth mental health as an issue that needed to be addressed at the national and provincial levels. For example, a Federal Senator, Michael Kirby, called children's mental health the "orphan of the orphan of health care". In addition, feedback about the problem in the form of research identifying the true scope of the problem in Canada was developed (problem stream). On the political front, the sitting provincial government was not doing well in the polls and was seeking to gain some positive political momentum in an election year by announcing some investments after several years of cuts (politics stream). Children and youth mental health was identified by the provincial auditor general as an area in need of transformation and after a recent round of hospital amalgamations, mental health interest groups were seeking investment to bolster the community sector. From a policy perspective, certain government insiders had been advancing the concept of "centres of excellence" to address a wide variety of policy areas and a new ministry, Ministry of Child and Youth Services had just been created in 2003 (policy stream). The government then reached out to Simon Davidson and colleagues, inviting them to develop a proposal for a centre of excellence for children and youth mental health. Our analysis suggests that two people, Dr Davidson, a prominent child psychiatrist who had developed close relationships with government officials by participating in the hospital amalgamation decisions, and Peggy Taillon, who was an Advisor to the Premier at the time and was very involved in Ontario's Mental Health Implementation Task Force, acted as policy entrepreneurs.

Interestingly, OCoECYMH is also the sub-case that fits most clearly with the Kingdon framework. It is possible that once one intermediary is established in a system for a particular policy area, the concept of additional intermediary capacity is easier for policy makers to buy into based on the policy legacy established by the first. This may mean that the decisions to create PSSP and SMH ASSIST were less "visible" and political in nature and became more "technical" and bureaucratic. In the case of both PSSP and SMH ASSIST, their function was first proposed by those outside of government (CAMH for PSSP and Kathy Short and the OCoECYMH for SMH ASSIST) as a policy solution that could support the implementation of key policy decisions. These policy "solutions" were proposed at a time when the government was developing a new 10-year strategy for mental health and addictions. Bureaucrats in MOHLTC and MEd took advantage of these policy ideas as part of their ministerial commitment and actions related to the new strategy. In general, our analysis suggests for these later intermediaries, most of the activity leading to the decision was in the policies stream (the government was developing a new policy and needed resources that could be mobilized quickly and with a good likelihood of success) and that the decision to invest in this implementation infrastructure was facilitated by the policy legacy created by the establishment of the first.

Sweden

Prior to the establishment of Mission Mental Health, the mental health system in Sweden was in some turmoil due to a highly visible death of a politician by someone with a mental illness as well as some other negative events that were profiled in the media (problem stream). These events increased the visibility of mental health as a policy issue and the government at the time was receptive to further investments in the sector (politics stream). One of the outcomes of this was a national inquiry led by Anders Milton, a prominent politician and Ing-Marie Wieselgren,a prominent psychiatrist and who became the content lead for the

TABLE 3 Factors that influenced the decision to create intermediaries, drawing from the Multiple Streams framework (41).

Factors	Description of factors that influenced decision to create intermediaries by case				
	New Zealand Te Pou (est. 2006)	Ontario, Canada			Sweden Mission Mental Health (est. 2008)
		OCoECYMH (est. 2004)	PSSP (est. 2011)	SMH Assist (est. 2011)	
Problems stream	**Focusing Events** A number of "dreadful" events involving people with mental illness happened with a lot of public attention in 1990s **Feedback About a Problem/ Change in Indicator** First national epidemiological study conducted, that shed light on the full scale of the problem (mental health issues)	**Feedback About a Problem/ Change in Indicator** Visibility about mental health increasing in general (internationally, nationally and provincially) and children and youth mental health in particular Federal Senator Michael Kirby labels children's mental health as the most neglected area of health care and dubs it "*the orphan of the orphan*" Government elites needed to be perceived as investing on the heels of hospital amalgamations, including changes to mental health services *ON Auditor General 2003* identified many problems in child & youth mental health Key study (Waddell et al. 2002) and key report (Health Canada 2002) identified scale and scope of child and youth mental health problems in Canada	**Feedback About a Problem/ Change in Indicator** ***Government*** Receiving feedback through Select Committee on Mental Health and Addictions and other government activities that people were 'falling through the cracks' of systems when transitioning between them (e.g., from child and youth to adult services etc) ***CAMH*** New CEO looking to restructure the organization and was getting feedback to consider the provincial capacity that was available through policy legacies through the merger of 4 mental health and addictions facilities in Toronto and ensuring it was put to good use	**Feedback About a Problem/Change in Indicator** Provincial government was receiving feedback from multiple directions that more needed to be done to support mental health of children and youth in schools e.g., Mental Health Commission of Canada issued RFP for work on school-based MH in 2008; efforts by OCoECYMH to increase visibility of issue	**Focusing Events** Murder of Anna Lindh, former Swedish Foreign Minister by individual thought to be mentally ill (2003) and several other incidents of harm by persons with mental illness profiled in media around the same time **Feedback About a Problem/ Change in Indicator** Government Bill 1993/ 94:218—*Mentally Ill People's Conditions* identified separation of care for mental health between counties & municipalities. This resulted in problems of coordination across organizations that left gaps in the system. Mental health viewed broadly (not just mental illness)—this view increased visibility of coordination problems across levels of government and sectors
Policy stream	A great deal of policy activity in decade before establishment, identifying the need for major system reforms, including an increasing focus on workforce development. Examples: -Mason Inquiry (1996) -*Blueprint 1* (Mental Health Commission, 1998) -*Mental Health (Alcohol and Other Drugs) Workforce Development Framework*, Ministry of Health, 1992) -*Te Tāhuhu: Looking forward, moving forward Improving mental health 2005–2010* (Ministry of Health, 2005) *Strategic Principles for Workforce Development in New Zealand* (Health Workforce Advisory Committee, 2005)	Activity at the national level (e.g., consultations to develop *Out of the Shadows at Last: Transforming Mental Health, Mental Illness and Addiction Services in Canada* (2006) Final Report of The Standing Senate Committee on Social Affairs, Science and Technology led by Senators Michael Kirby & Wilbert Joseph Leon) and provincially (e.g., Ontario Auditor General's report (1993) increased visibility of the need for changes to the child and youth mental health sector. "Centres of Excellence" as a policy concept was attractive across different policy areas	Respect, Recovery, Resilience: *Recommendations for Ontario's Mental Health and Addictions Strategy* (2010) developed by the Minister's Advisory Group identified need to work across services & sectors. Direct proposal from CAMH to government repositioning some of its capacity as policy implementation support (2010/ 2011) Ministry of Health & Long-Term Care was looking for implementation partners to support their initiatives in the upcoming 10-year mental health strategy, *Open Minds, Healthy Minds* (2011)	A process that brought policy makers together to support the development of the document: *Taking mental health to school: A policy-oriented paper on school-based mental health for Ontario* (Santor, Short, & Ferguson 2009) increased salience & acceptability of idea Policy documents began to identify schools as a key location to support early identification/ intervention and school graduation rates as key outcome K. Short already running technical assistance centre in HWDSB (government saw idea had credibility and could be scaled) MED sought proposal from Short	Government strikes a *National Coordination of Mental Health Services* Commission led by Ing-Marie Wieselgren and Anders Milton Policy documents identified a need for better coordination across actors and levels of government Policy decision by national government made to contract differently with local authorities and regions for mental health services through direct agreements
Politics stream	**Swing in national mood** Increasing visibility of the issue and decrease in stigma created widespread support for investments in mental health	**Changes in the balance of organized forces** Hospital amalgamations in early 2000s caused an even greater need for strong community services	**Events within government** Striking of All-Party Committee Needed to find partner(s) to support implementation of key policy initiative on transitions between services and sectors	**Events within government** Striking of All-Party Committee & MAG who were taking a broader perspective on mental health including more focus on prevention/promotion and early intervention	**Swing in national mood** Increased visibility of the issue due to publicity related to Anna Lindh and aided by advances in information technology

(*Continued*)

TABLE 3 Continued

Factors	Description of factors that influenced decision to create intermediaries by case				
	New Zealand Te Pou (est. 2006)	Ontario, Canada			Sweden Mission Mental Health (est. 2008)
		OCoECYMH (est. 2004)	PSSP (est. 2011)	SMH Assist (est. 2011)	
	Changes in the balance of organized forces Formation of Mental Health Commission **Events within government** Treasury willing to make investments in mental health "And, in part, because the money was flowing. The money was really flowing at that point, so we could afford to build infrastructure." Hired Dr Janice Wilson as Director of Mental Health	The striking of mental health implementation task forces engaged stakeholders in solution-finding **Events within government** Government was not polling well and looking to hold power prior to next election through investments after years of cutbacks. This was unsuccessful and the government changed in 2003 but the idea of a Centre of Excellence remained relevant. Lack of opposition to investments in children's mental health (clear "win" and concept of "centre of excellence" was politically palatable)	Fit—CAMH already had capacity and could get up and running quickly	Congruent with provincial mood Needed to be seen as doing something regarding mental health in schools	**Changes in the balance of organized forces** Creation of Swedish Association of Local Authorities & Regions SALAR (Sveriges Kommuner och Landsting as a coordination body between local/regional levels and national government provided natural "home" for an intermediary **Events within government** Health and Social Care minister who was willing to invest and believed that while you can't win an election based on mental health as a policy issue, you can lose one
Participants	**Policy entrepreneur** Dr Janice Wilson, psychiatrist and first Director of Mental Health for NZ government **Other visible participants** Judge Kenneth Mason (led 2 inquiries) Barbara Disley (first Mental Health Commissioner)	**Policy entrepreneurs** Dr Simon Davidson, prominent child psychiatrist who was an expert advisor to government on hospital amalgamations related to children's services and considered an innovator in the field Peggy Taillon, key figure in mental health implementation task force work and an advisor to government on this and other health reforms, suggested a "centre of excellence" to government officials **Hidden participants** Dr Ian Manion, CPsyc who became co-executive director of the OCoECYMH Peter Finkle, Regional Director, MOHLTC	**Visible participants** Dr Bob Bell, Deputy Minister of Health Dr Catherine Zahn, President and CEO of CAMH **Hidden participants** Susan Paetkau, MOHLTC Director - key decision maker in appointing PSSP as lead for service collaboratives initiative Susan Pigott, VP at CAMH—reporting line for PSSP and liaison with MOHLTC Dr Nick Kates, physician & member of MAG, originally developed service collaboratives concept	**Visible participants** Dr Kathy Short, school psychologist, and now lead of SMH ASSIST Dr Bruce Ferguson, psychologist, member of the MAG and expert advisor to government **Hidden participants** Barry Finlay, MED Director—key decision maker John Malloy—Director of Education, Hamilton-Wentworth District School Board	**Policy entrepreneur** Dr Ing-Marie Wieselgren, psychiatrist and co-lead of national inquiry. Then became first chief executive for Mission Mental Health **Other visible participants** Dr Anders Milton—prominent physician and co-lead of national inquiry Goran Hägglund—Minister for Health and Social Affairs who understood the political value of the mental health agenda **Hidden participants** Karin Johansson, state secretary, Ministry of Health and Social affairs

Bolding indicates elements drawn from the Multiple Streams framework (41).

inquiry. The inquiry made many recommendations including a need to focus on children and youth, which was seen as a large gap (policy stream). Dr. Wieselgren also acted as the policy entrepreneur, coupling the streams, and once the inquiry work was completed, she became the leader of Mission Mental Health.

Sweden is a good example of how the influence of the policy entrepreneur can continue beyond the decision to establish the intermediary itself. In this case, Dr. Wieselgren was intimately aware of the policy issues based on her work on the national inquiry as well as through her previous roles. She had also established a wide array of relationships with different actors across Sweden. This likely enabled the establishment of Mission Mental Health by increasing its acceptability and ensuring that its work aligned with the policy issues that surfaced during the inquiry.

How are intermediaries structured and what strategies do they use to support the implementation of policy directions?

The structure and organizational characteristics of the intermediaries are summarized in Table 4. Generally, there is a great deal of variation in the structures and organizational

TABLE 4 Structure and organizational characteristics of intermediaries.

	Intermediary				
	Te Pou o te Whakarro Nui (including Matua Raki)	Ontario Centre of Excellence for Child and Youth Mental Health	Provincial System Support Program	School Mental Health Assist	Mission Mental Health
Country	New Zealand	Ontario, Canada			Sweden
Public vs. private	Private, not-for-profit (highly regulated)	Private, not-for-profit (highly regulated)	Private, not-for-profit (highly regulated)	Public (highly regulated)	Public (highly regulated)
Setting	Non-governmental organization (Wise Group)	Service delivery organization (Children's Hospital of Eastern Ontario, CHEO)	Service delivery organization (Centre for Addiction and Mental Health, CAMH)	Service delivery organization (Hamilton-Wentworth District School Board)	Peak organization (Swedish Association of Local Authorities and Regions, SALAR)
Main funding source	National government: NZ Ministry of Health (Health Workforce NZ)	Provincial government: Ontario Ministry of Children & Youth Services[a] (MCYS)	Provincial government: Ontario Ministry of Health and Long-Term Care	Provincial government: Ontario Ministry of Education	National government: Swedish Ministry of Health and Social Affairs
Focus	Adults and older adults	Children & youth	Youth, adults & older adults	School-aged children & youth	Full age continuum
Boundaries of mandate	Mental health, addictions and disability	Mental health	Mental health and addictions (including problem gambling)	Mental health and addictions	Mental health
Primary target audience	Mental health and addictions workforce (focus on District Health Boards)	Child & youth serving community mental health agencies funded by MCYS	Organizations serving people with mental health and/or addictions problems across sectors	School boards	Cross-sectoral regional and local authorities working with mental health in social care, education and health care
Governance structure	Board of Directors	CHEO's Board of Trustees	CAMH's Board of Trustees	Hamilton Wentworth District School Board of Trustees. Reports directly to Director of Education	SALAR's Board (who report to a congress of politically elected officials) & different political committees
Advisory structure (s)	Clinical Sector Reference Group (27 members, including people with lived experience, family/whanau, service sector leaders, and researchers)	Strategic Advisory Council (12 members, including youth, parents/family members and organizational leaders)	Project-specific advisory structures (e.g., EENet persons with lived experience & family panel, provincial collaborative advisory group)	No formal ongoing advisory structure. With co-creation model, regularly receive input from a range of stakeholders	SALAR steering group comprised of internal and external stakeholders
Size (approx.)	43 people	50 people	150 people	13 people provincially supporting 72 mental health leaders in schools	40 people
Annual budget[b] (approx.)	$20 million NZD	$5.9 million CAD	$19 million CAD	$2.2 million CAD (does not include funding for mental health leaders)	60 million SEK/5.7 million EUR
# Offices & locations	2 offices (Auckland & Wellington)	1 office (Ottawa)	10 offices (Barrie, Hamilton, Kenora, Kingston, London, Ottawa, Sudbury, Thunder Bay, Toronto Central & Toronto Regional)	1 office (Hamilton)	1 office (Stockholm)
Service model	Distributed (travel as needed, particularly to South Island)	Centralized (travel as needed to other locations)	Highly distributed (less travel required based on number of regional offices)	Highly distributed (coaches located across province; mental health leaders in each school board in province)	Centralized (travel as needed to other locations)
High-level description	National centre of evidence-based workforce development for the mental health, addiction and disability sectors in New Zealand	Drive high-quality child and youth mental health services by setting the bar for excellence and collaborating with others to pursue continuous quality improvement	Works with communities, service providers and other partners across Ontario to move evidence to action to create sustainable, system-level change	Provincial implementation support team designed to help Ontario school boards to promote student mental health and well-being using evidence-based approaches	
Stated goal(s)	To improve the workforce performance of mental health, addiction and disability services	Working to strengthen Ontario's mental health programs and services for all children, youth, families and caregivers	Transforming mental health and addictions systems to improve the lives of Ontarians	Enhance quality and coherence in mental health promotion and prevention programming in schools	Create conditions for a sustainable mental health system by encouraging the improvement and enhancement of services and supports, and by increasing accessibility and equality

(*Continued*)

TABLE 4 Continued

	Intermediary				
	Te Pou o te Whakarro Nui (including Matua Raki)	Ontario Centre of Excellence for Child and Youth Mental Health	Provincial System Support Program	School Mental Health Assist	Mission Mental Health
Investment areas	1. Practice & leadership 2. Information & outcomes 3. Training & development 4. Workforce planning	1. Support evidence-based practice & knowledge in use 2. Maximize capacity in training, research & evaluation 3. Collaborate with stakeholders	1. Knowledge exchange 2. Implementation 3. Information management 4. Health equity & engagement 5. Evaluation	1. Leadership & guidance 2. Implementation coaching 3. Tailored resources 4. Community of practice	1. Coordinate local improvement work 2. Analysis & implementation of local and regional conditions 3. Support development of data collection template for reporting of data and action plans
Recent EIPP foci	• Reducing the use of seclusion & restraints • Increasing the use of talking therapies • Service user, consumer and peer workforce capacity building • Addressing co-existing mental health and addiction problems • Improving the physical health of people experiencing mental health or addiction problems	• Enhancing family engagement in services • Enhancing youth engagement in services • Improving service quality and performance • Promoting community-based suicide prevention and life promotion through coaching • Coordinating a Lead Agency Community of Practice	• Developing service collaboratives to supports transitions of people across services and sectors • Implementing Ontario Perception of Care Mental Health and Addictions tool • Implementing Staged Screening and Assessment protocol • Supporting knowledge exchange for Early Psychosis Intervention Ontario Network • Developing an Opioid Resource Hub	• Enhancing the organizational conditions for mental health in schools • Improving mental health literacy for educators • Addressing tragic events in schools • Decision support for school boards for mental health programming selection • Life promotion and suicide prevention	• Mental health for asylum seekers and new arrivals • Supporting the implementation of social investment • Workplace mental health • Creation of a multi-region infrastructure for knowledge sharing and improvement • Mental health in schools
Use of knowledge exchange and/or implementation theory to underpin work	No Does not draw for any theory in particular but will integrate concepts as deemed appropriate (e.g., PDSA cycles)	Somewhat • Concept of co-production used in youth and family engagement work • Created toolkits for sector on knowledge mobilization and implementation based on theory	Yes • Network theory (EENet) • NIRN's Active Implementation Frameworks	Yes • Co-production • NIRN's Active Implementation Frameworks	No Does not draw for any theory in particular but will integrate concepts as deemed appropriate (e.g., incorporating IHI's model for improvement)

[a] In 2018 the Ontario government dissolved the Ministry of Children & Youth Services. Responsibility for this portfolio now rests with the Ministry of Health and Long-Term Care.

[b] In many cases, the intermediary acts as a flow through for funds to others in the system. The full annual budget is not necessarily retained and used directly by the intermediary.

characteristics of the intermediaries in our cases, with differences across most of the domains. Key differences include: the settings in which intermediaries are located (e.g., NGO, service delivery organization or peak organization), the age-related focus of the intermediary (e.g., children & youth, adult, full age continuum), the mandate and how far it extends beyond mental health (e.g., addictions, problem gambling, disability), the primary target audience of the intermediary (e.g., hospital, community, schools or cross-sectoral) and the service model (e.g., centralized or distributed). Each intermediary also has very different stated areas of investment and often focused on quite different EIPPs. They also varied around how closely they drew upon implementation or knowledge exchange models, theories or frameworks to guide their work.

In terms of similarities, three of the five intermediaries were around the same size (40–50 people), although PSSP was much larger (150 people) and SMH ASSIST was much smaller (13 core team members). All of the intermediaries also identified their respective government ministry as their primary funding source. On the whole, intermediaries differed more than they were similar with respect to their descriptive characteristics and this lack of commonality contributes to intermediaries continuing to be a "fuzzy" construct.

Interestingly, there was a high level of consistency in the strategies employed by the intermediaries, despite the large variation in intermediary structure and organizational characteristics stated above (Table 5). We did, however, observe a qualitative difference in where the emphasis of the activities

TABLE 5 Implementation strategies used by intermediaries by target and by case.

Target	Implementation strategy	Powell et al. (2012) Typology	Use of strategy by case				
			New Zealand	Ontario			Sweden
			Te Pou & Matua Raki	Ontario Centre of Excellence for Child and Youth Mental Health	Provincial System Support Program	School Mental Health Assist	Mission Mental Health
Synthesis and translation system	Developing and disseminating products and tools to support the use evidence in policy/practice	Educate strategy - develop materials (develop effective educational materials) - educate (distribute materials)	✓	✓	✓	✓	✓
	Conducting research and/or contracting with researchers/ research organizations	Plan strategy - develop relationships (develop academic partnerships) Quality management strategy - use data experts - capture and share local knowledge	✓	✓	✓	✓	✓
	Bringing exemplars of best practice/evidence from other provinces or countries	Educate strategy - develop materials - educate - educate through peers	✓	✓	✓	✓	✓
	Supporting capacity development for knowledge exchange/implementation	Plan strategy - build buy-in (identify and prepare champions; involve patients/ consumers and family members) Educate strategy - develop materials (related to knowledge exchange/ implementation)	✓	✓	✓	✓	✓
Delivery system	Training	Educate strategy - educate (develop educational meetings; conduct ongoing training; make training dynamic)	✓	✓	✓	✓	✓
	Consultation and technical assistance	Educate strategy - educate (provide ongoing consultation) Quality management strategy - centralize technical assistance	✓ limited	✓	✓	✓	✓
	Quality assurance/quality improvement	Quality management strategy - develop and organize quality monitoring systems - develop tools for quality monitoring	✓	✓	✓	x	✓
	Leadership development/ capacity-building	Plan strategy - initiate leadership (recruit, designate or train for leadership)	✓	✓ limited	x	✓	✓ Goal, but no direct program

(*Continued*)

TABLE 5 Continued

Target	Implementation strategy	Powell et al. (2012) Typology	Use of strategy by case				
			New Zealand	Ontario			Sweden
			Te Pou & Matua Raki	Ontario Centre of Excellence for Child and Youth Mental Health	Provincial System Support Program	School Mental Health Assist	Mission Mental Health
	Audit and provide feedback	Quality management strategy - audit and provide feedback	x	x	x	x	x
Other support system	Developing partnerships (with other intermediaries or support system infrastructure)	Plan strategy - develop relationships (build coalitions)	✓	✓	✓	✓	✓
	Undertaking collective action amongst support system infrastructure related to implementation	N/A	✓	✓	✓	✓	✓
Policy system	Formal advice/policy input	N/A	✓	✓	✓	✓	✓
	Informal linkage & exchange with policy makers	N/A	✓	✓	✓	✓	✓
	Bringing forward new policy ideas/system improvements	N/A	✓	✓	✓	✓	✓
	Providing feedback to government on implementation activities/ barriers/challenges	N/A	✓	✓	✓	✓	✓
Public	Public awareness/ education	Educate strategy - inform and influence stakeholders (use mass media)	x	x	x	x	x
Lived experience & family	Engaging PWLE and families in activities of intermediary	Plan strategy - build buy-in	✓	✓	✓	x	✓via partner
	Developing tools/resources/ training for PWLE and families	Educate strategy - develop materials (develop effective educational materials) - inform and influence stakeholders (prepare patients/consumers to be active participants)	✓	✓	✓	✓	x
Performance assessment/ system-monitoring	Hosts data collection system (s)	Quality management strategy - develop and organize quality monitoring systems - use data warehousing techniques - use data experts - capture and share local knowledge	✓	x	✓	✓	x

was placed across implementation strategies. For example, Te Pou placed a relatively high emphasis on training compared to other activities. The OCoECYMH had a strong emphasis on lived experience and family-targeted activities. The PSSP had the most well-developed link to the synthesis and translation system through EENet and the number of researchers on staff. School Mental Health ASSIST had a strong emphasis on leadership development and capacity-building for mental health within schools and at the school board level. Finally, Mission Mental Health placed a great deal of emphasis on consultation and technical assistance, although not directed toward a particular EIPP, instead, responding to needs identified by the local authorities and regions. Te Pou also had the most well-developed information management strategy, by having national responsibility for managing two data collection systems on behalf of the Ministry of Health. They were followed closely by PSSP, that hosts an information management system for the addictions sector and has been expanding its functionality to support other EIPPs.

Despite these differences in emphasis, it is remarkable that there is so much similarity in terms of the implementation strategies employed by the intermediaries given the variation in the mandates and other structural and organizational features. It is also notable that none of the intermediaries used strategies that directly targeted the public (i.e., public awareness and education) or used audit and feedback as a Delivery system strategy. This emerged as the principal policy puzzle that needed to be explained. Specifically, why do these policy intermediaries consistently choose not to engage in these two implementation strategies?

What explains the lack of use of particular implementation strategies?

Our analysis indicates that there are five reasons why the implementation strategies targeting the public and audit and feedback are not employed by the policy intermediaries: (1) their need to build and maintain healthy relationships with policy actors (public strategies); (2) their need to build and maintain healthy relationships with service delivery system actors (audit & feedback strategy); (3) role differentiation with other system actors (public strategies); (4) lack of "fit" with the role of policy intermediaries (public and audit & feedback strategies); and (5) resource limitations that preclude intensive distributed (program-level) work (audit & feedback strategy).

The first three of these reasons are aspects of Interests using the 3I + E framework. In particular, the role of intermediaries necessarily means they must develop and manage effective relationships with other system actors and as such, they must be highly sensitized to actions that may have a compromising effect on these relationships. The power held by other system actors, and in particular, policy actors in government and service delivery system actors, is exerted indirectly on the intermediaries, what Lukes (52) calls the second dimension of power, causing them to anticipate what strategies would or would not be considered acceptable to those in power and to avoid strategies that could be damaging to these relationships.

For government and policy actors, publicly targeted strategies can sometimes be viewed as supporting advocacy, and advocacy in turn can be perceived by government actors as directly pressuring the government to make changes. Because policy intermediaries often depend on government in multiple ways (e.g., as a funding source, as an implementation partner, as a target of their activities, etc), they prefer to remain as neutral as possible, being perceived as an "honest broker" or a vehicle that enables implementation, rather than specifying what should be implemented. Thus, while the policy actors have not specifically limited the implementation activities of the intermediaries, these intermediaries have shaped their activities to avoid those public-facing strategies that could compromise their relationships with policy actors.

The "honest broker" framing extends to the relationships intermediaries must cultivate with service delivery actors. In order to facilitate implementation, intermediaries must become a trusted source of implementation support for organizations, programs and individual professionals who deliver mental health services to citizens. To build this trust, they prefer implementation strategies that are perceived as facilitative rather than those that may be perceived as more of a performance monitoring or a "watchdog" function. Audit and feedback, when used at the clinical level or at a systems level (e.g., public reporting) can be perceived as falling into the performance-monitoring category and thus, is not a preferred strategy of these intermediaries. Interestingly, some of these intermediaries still play a role in other performance monitoring strategies, by collecting data on behalf of the service delivery system. However, even when they are responsible for this strategy, their approach is often focused on enabling the service delivery sector to use its own data for improvement, or to provide policy makers with additional context for appropriate interpretation of the data and tend not to engage directly in public reporting.

The lack of "fit" of both public strategies and audit and feedback, falls under the Ideas element of the 3I + E framework. This relates to the normative assumptions held by intermediaries and their stakeholders about what policy-focused intermediaries "should" be doing and where there are seen as adding value (and conversely, where they aren't). Finally, past policies (including deinstitutionalization and decisions to offer mental health services across a continuously expanding range of service environments) makes the institutional landscape of mental health services in all three cases large in number and complex for implementation efforts at scale. All of the intermediaries face capacity constraints related to time and money. The strategy of audit and feedback can be cost and time intensive when applied at the individual program level and the intermediaries in our study did not feel they could accomplish this strategy effectively with their existing resources and scope of activity.

Discussion

Our study sheds further light on policy intermediaries supporting the implementation of EIPPs across mental health systems. These findings help to advance our understanding of the factors that lead to the development of intermediaries in terms of the problems (e.g., negative events involving people with mental illness), policies (e.g., feedback on effectiveness of existing policies) and political events (e.g., changes in government) that are salient in each case. It also presents an in-depth description of the similarities and differences in intermediary structure, organization and use of implementation strategies (e.g., the wide range of structures and organizational mandates contrasting with the striking similarities in terms of implementation strategies employed). Finally, our study provides five reasons why these intermediaries do not use audit and feedback or strategies targeting the public in their work, drawing from explanatory frameworks.

Beyond the contribution of further understanding of intermediaries and their role in facilitating implementation, this study contributes to the literature in two ways. First, our study answers the call made by Nilsen (53) and others to integrate the field of policy implementation with the field of implementation science. We did this by drawing on established theories from political science and through our focus on policy intermediaries. While we found that using these theories was not always a perfect "fit" with questions that relate to the implementation phase of the policy cycle, they were useful in generating unique insights that would not be available from implementation science. Second, we have noted that the vast majority of the literature on intermediaries, and those focusing on mental health and addictions in particular, come from the USA, which has health and social system arrangements that are fairly unique in the world. Our study expands the focus to policy intermediaries in three other countries that each have their own unique health and social system arrangements.

The pre-existing relationship that one author (HB) had with the intermediaries and other system leaders was both a source of strength in this study and a potential limitation. First, these relationships allowed for an IKT approach to the research and likely contributed to the strong response and participation in all three cases. However, her familiarity with the individuals, and her previous role in Ontario and internationally may have influenced how stakeholders responded in the interviews. For example, there were several instances when participants referenced previous conversations or knowledge that HB had and she was sometimes referenced as an influential actor in the development of the intermediaries. Conversely, this familiarity and being established as credible and knowledgeable, may have also meant that participants were more honest, or were likely to delve into issues with greater detail than with an unknown interviewer.

We faced two key challenges with our research. The first relates to the fact that there were no fluent Swedish speakers on the research team. We expect this could have affected the choice of words and phrases participants used in the interviews as well as limiting our ability to use triangulation of sources because many documents were not available in English. The second relates to conducting research in three constantly evolving systems. Since the data collection period, the research team has already noted some shifts in the intermediaries and their contexts making it difficult to be both precise and "current" in our analysis. The ability to adapt and change is likely an important trait for intermediaries and can offset the inherent instability that has been identified as problematic in existing literature (29) but presents a moving target for researchers.

Our study focused on a small number of intermediaries that best fit our definition, yet it was abundantly clear that the infrastructure needed for implementation efforts at a systems level is much more comprehensive. Many more organizations and programs were engaged in mental health policy implementation efforts in these jurisdictions. Some examples include the health quality bodies in New Zealand and Canada and the public health agency in Sweden. Future studies could examine the full complement of infrastructure and how different systems differentiate the implementation strategies among actors. An additional distinction that merits future exploration is the main funding sources and placement of intermediaries across settings (such as government, public sector and private sector), specifically, whether and how the proximity to legislative and regulatory restrictions affects intermediary functions.

Future studies could also use these findings as a foundation from which to build a quantitative study examining a larger number of intermediaries divided among the three sub-types (KT, practice and policy intermediaries) and explore whether and how the use of implementation strategies varies according to sub-type or which strategies are most closely tied to intended outcomes. For example, do policy intermediaries collectively rely on a different subset of implementation strategies than those focussed on implementation in practice settings? Furthermore, the role division and functions of individual team members within an intermediary organization requires further study. Working in a team environment may offset some of the challenges individuals face such as role conflict and ambiguity (29), but role distinction and specialization likely becomes more important (23). How can these roles be optimized in intermediary team settings?

Conclusions

Policy makers and other actors seeking to implement EIPPs must consider the capacity needed to do it effectively. Our study identifies how intermediaries can be developed and harnessed to support implementation and offers a number of transferrable lessons to those in other jurisdictions. When looking to build implementation infrastructure, policy makers and implementers should make explicit choices in terms of design, with appropriate consideration of the political system context and the health and social system context. They must also pay careful attention to the role of other actors in the system to ensure the intermediary(ies) add value and are optimized to work with those actors effectively. Finally, they should make active decisions about the implementation strategies they intend to employ and monitor their use and effectiveness. To date, much of the focus in implementation science has been at the intervention level, or on the implementation strategies and organizational contexts in which implementation occurs. We forward that it is equally important to consider the vehicles through which these strategies are delivered at scale in systems. This examination of policy intermediaries in mental health systems contributes to this gap in knowledge and increases our understanding of the role intermediaries play in implementation.

Data availability statement

The datasets presented in this article are not readily available because the data were derived from qualitative interviews. Individual transcripts may be identifiable when viewed in whole. Requests to access the datasets should be directed to bullochl@mcmaster.ca.

Ethics statement

Ethics approval for this study was granted by McMaster University through the Hamilton Integrated Research Ethics Board and informed consent was sought and provided by all participants.

Author contributions

HB: Conceptualization, Data curation, Formal Analysis, Funding acquisition, Investigation, Methodology, Project administration, Visualization, Writing – original draft, Writing – review & editing. JL: Writing – review & editing. GM: Writing – review & editing. MW: Writing – review & editing.

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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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APPENDIX

Interview guide for case study interviews

Ethical considerations

A description of the study will have been presented during the recruitment phase. A signed confirmation of commitment to participate will be obtained prior to engaging in the questions. Any ethical issues arising will be addressed prior to the first question and will be documented by the Interviewer.

Process

Interviews will be recorded on a digital audio device or computer, transcribed, and uploaded into a qualitative software program. Hand written notes will also be made by the interviewer into her field notebook.

✓ Denotes probes

Date:
  Time:
  Place:
  Interviewer:
  Interviewee:
  Position of Interviewee:

Questions

Do you have any questions for me before proceeding to the interview?

Before we start, I wanted to mention that we will be using the term "mental health" to refer to fields of "mental illness", "addictions", "behavioural health" and "health promotion and prevention of mental illnesses and/or addictions" inclusively. It also refers to the health of individuals across the lifespan, not just at particular life stages. Feel free to point out particular or unique features of any of these depending on how your system is arranged, if you feel they are relevant.

A—current mental health policy priorities

- Can you tell me a little bit about the current policy priorities in [your jurisdiction] that are being implemented? (top 2–4)
  - ✓ When were they identified as priorities?
  - ✓ How is the implementation of these priorities governed?
  - ✓ How are these priorities financed & funded (if at all)?
  - ✓ How are they delivered?
    - ■ Consumer-targeted
    - ■ Provider-targeted
    - ■ Organization-targeted
  - ✓ What system challenges are the policy priorities trying to address?
  - ✓ What outcomes are they meant to achieve?
  - ✓ What organizations/programs/people are responsible for implementing them?

B—structures supporting implementation of mental health priorities (support system & synthesis & translation system)

- I understand from the previous phase of my study that [organization or program] has a role in supporting the implementation of some of the mental health strategic directions/policies/ targets. Can you tell me a little more about them?
  - ✓ Who gave them this responsibility?
  - ✓ Can you describe [organization or program]'s role and how it functions?
  - ✓ What is its size? (in terms of people and funding)
- Who do they provide these activities to? (recipients)
- Do organizations/programs/people from communities voluntarily come to [organization/program] to access implementation supports or does [organization/program] proactively approach the organizations/programs/people in the community? (push vs. pull)
- How are they perceived by other organizations/programs/people in your system?
- Are there other organizations or programs that also play a role supporting the implementation of mental health priorities?

  - ✓ Do they differ from [organization or program]? How?
    - ○ Generating guidelines
    - ○ Generating research & synthesizing it (not just primary research)
    - ○ Data systems
    - ○ Continuing education

C—delivery methods and approaches to change being utilized

- What types of activities does [organization/program] engage in? (list from EBSIS, HSE, Franks & Bory & phase 1 of this study)
  - ✓ General capacity building
  - ✓ Knowledge translation/exchange/mobilization
  - ✓ Specific implementation supports (e.g., for a particular Evidence Based Practice, also called technical assistance)
  - ✓ Education and training
  - ✓ Coaching
  - ✓ Research & Evaluation
  - ✓ Quality improvement
  - ✓ Convening people (in-person/virtual)
  - ✓ Consultation
  - ✓ Policy & Systems Building

  - ✓ Best practice model development
  - ✓ Public awareness and education
  - ✓ Opinion leaders
  - ✓ Audit and feedback
  - ✓ Train-the-trainer
  - ✓ Other
- Are the activities targeted at the organizational level, the provider level or the consumer/patient level?
- What is the frequency with which they provide these activities?
- Are the people who deliver these activities from [organization/program] located in the communities in which they are delivered? If not, where are they from? (central vs. regional)
- Are there any particular over-arching methods or approaches the [organization or program] utilizes?

  - ✓ Implementation science (IS) and the specific IS model
  - ✓ Getting-To-Outcomes
  - ✓ Quality improvement methods such as LEAN or the IHI model
  - ✓ Any other specific methods or approaches that you haven't already mentioned?

D—value, challenges & outcomes

- Do you have a sense of what the strengths of this structure and methods might be?
  - ✓ Institutions (e.g., government structures, policy legacies, networks), interests (e.g., citizen groups, professional associations, etc), ideas (e.g., values, research, etc)
- Do you feel [organization or program] is valued by the system?
  - ○ Who in the system values them?
  - ○ Why?
- What are some of the barriers or challenges that are faced in this work?
  - ✓ Institutions (e.g., government structures, policy legacies, networks), interests (e.g., citizen groups, professional associations, etc), ideas (e.g., values, research, etc)
- Is [organization/program] able to help achieve the identified policy goals?
- Are there evaluation or outcome data available?

Prompt for documents, presentations or other items that might address any of the topics discussed

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Reimagining policy implementation science in a global context: a theoretical discussion

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policy, implementation science, global context, policy cycle, global health

Introduction

Policy implementation science (IS) is defined here as generating knowledge and deploying implementation strategies to effectively adopt and integrate evidence-based interventions (EBIs) into policy designs and improve policy implementation and effectiveness (1–3). Most existing policy IS scholarly works originate from the Global North (United States, Canada, and Western Europe) and describe or evaluate strategies to increase the uptake of EBIs (4). The existing Global North-generated frameworks focus less on the critical resources needed to formulate and implement a policy in diverse settings. Current approaches to policy IS lack sufficient contextual nuance to be applicable to a broader global population and limit the potential impact of policy IS in low-resource settings. Globally, there are differences in the emphasis of universal healthcare (UHC) vs. individualized healthcare, the value of affordability vs. gross domestic product (GDP) or per capita spending on health, and access to health insurance and availability of primary care vs. specialized care. Many countries of the Global South have mixed healthcare systems, comprising both public and private sectors, with the majority of the population relying on public health services. The governance of health systems is often a mix of centralized and decentralized models with shared responsibilities between the national government and subnational systems either as states, regions, or counties. These subnational levels have some degree of autonomy to make localized policies. Health systems in many Global South countries are characterized by considerable resource scarcity in funding, workforce, medicines and medical technologies, and equipment (5). However, there are still some variations within the Global South. For example, Colombia, a middle-income country with a mixed public–private healthcare system, has high insurance coverage. Nearly all Colombians (99%) are enrolled in a collection of state and private insurance companies; they receive annual allocations depending on their number of enrollees from a centrally managed government pool fund, giving the national government substantial oversight authority and responsibility in regulating insurers (6). Similarly, variations exist in the

Global North systems. For example, the United States has a privatized system, whereas the United Kingdom has a system more focused on the public sector. These governance and sociopolitical differences—especially in health system decentralization, resources, and prioritization of outcomes (7–9), as well as the history of colonization and resulting international donor power—mean that the direct application of a Global North-generated policy IS framework may be less effective in a global context.

Utilizing the policy cycle heuristic of agenda setting, policy formulation, and policy implementation and evaluation (10), we highlight domains within policy IS frameworks that could be strengthened with traditional IS frameworks and political science scholarship to be more applicable within heterogeneous settings. Numerous IS frameworks have been robustly informed by scholarship in the Global South, which reflect many types of power differentials and emphasize the criticality of stakeholder input and reciprocal collaboration (11, 12). However, these traditional IS frameworks often lack explicit considerations for agenda setting, policy formulation, and policy implementation (13, 14). Although political science scholarship has focused extensively on the policy cycle, particularly agenda setting, with dozens of relevant theories, few (15) have been developed explicitly outside of a Global North setting. The unique case of international donors in health policy processes is less reflected in these theories. The policy IS frameworks developed to bridge this gap between policy and IS have opportunities for refinement to adequately reflect the policy processes (16) and the evolving role of donors as unique stakeholders (17). Therefore, more work is needed to expand policy IS frameworks by incorporating more traditional IS and political science theories to make global policy implementation scientists better stewards in global policy processes. By outlining potential concepts for future scholarship, we hope to advance the use of policy IS globally to address global goals such as reducing inequities, moving forward to a more just world, and decolonizing global health.

Agenda setting

Policy IS frameworks—including those by Crable et al. and Bullock et al. (16, 17)—often assume, either implicitly or explicitly, that the role of the researcher (or potentially the funder) is to persuade the policymaker (18, 19). This results in a focus on disseminating research findings to policymakers, with less attention on other relevant stakeholders in the process. The unidirectional assumption may be particularly inappropriate in global health settings where the policy process can be either more or less centralized, include diverse sets of stakeholders, and where the history of colonization and the outsized power of international donors are acutely likely to influence the development of national and subnational health agendas. In contrast, existing political science theories on agenda setting describe policy and policy implementation as non-linear processes. The HIV guideline and policy development process in Kenya is a good example of reciprocal relationships between researchers, donors, policymakers, community members, and other stakeholders. This multiorganizational and multidisciplinary process involves multiple actors convened as a technical working group or task force, a deep review of existing literature on topics presented by researchers, a review of lessons learned from demonstration projects, mapping of available resources at subnational levels, and identifying additional questions to be subsequently included in the research agenda. One notable example is the public sector adoption and scale-up of oral pre-exposure prophylaxis (PrEP) in Kenya from 2016 onward. Local scientists were involved in generating the evidence that led to the global adoption of PrEP, and large-scale demonstrations were conducted in the country. This contributed to a high level of trust and goodwill toward the evidence that supported the introduction of PrEP, which played a part in facilitating the acceptance and scaling of the PrEP program (20).

In the absence of agenda-setting-oriented IS frameworks, multiple researchers have used Kingdon's "multiple streams" theory to explore health priorities in the Global South. This theory centers on the opening of a "policy window" when the appropriate problem, policy, and political streams align, which allows for a policy change (21). This framing is easy to comprehend when the power structures for the actors within those streams ebb and flow relatively equally over time. However, in practice, the balance of power among stakeholders (both internally and externally) differs in countries in the Global South due to governance structures, health system infrastructure, varied levels of resources, sources of funding, and histories of colonization (22). The power and roles of individual actors and external stakeholders (including bilateral and multilateral institutions, philanthropic actors, normative guidance institutions (e.g., World Health Organization), and communities vary. The involvement of these multilayered actors starts early and spans from testing evidence-based interventions to their implementation and scale-up. External actors may have their own agendas and be less susceptible to influence by local actors, echoing the dynamics of colonialism and international development. For example, while local actors have advocated for chronic diseases to feature prominently in the health policy agenda, external actors continue to prioritize and fund infectious disease programs (23). Often, this decision-making power is linked to resource availability to fund programs. To more effectively advance the locally led health agenda-setting process, policy IS frameworks and practitioners need a better understanding of how to navigate entrenched power structures. To address this, policy IS theories and frameworks should be expanded to include reciprocal relationships between policy actors and account for varying governance structures (Figure 1).

Policy formulation

Across policy formulation, there is an acknowledgment that policies need to be adapted when transferred to different country contexts. However, the process for doing this has not received the same intensity of study as the adaptation and translation of evidence-based interventions, which is common in IS frameworks

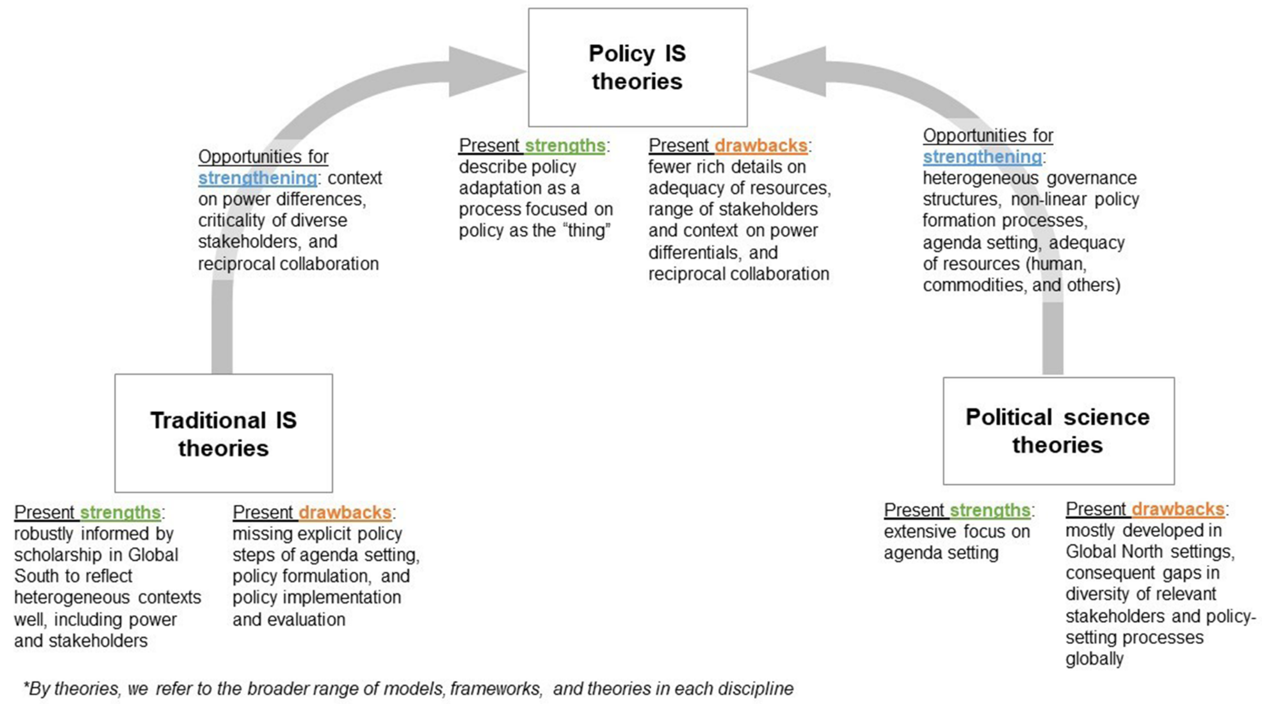

FIGURE 1
Strengths and opportunities for improvements in theories from the related disciplines of political science research, traditional implementation science theories, and policy implementation science. The arrows demonstrate how strengths from one discipline can help improve existing policy implementation science theories.

(24, 25). Typically, policy adaptation is conceptualized as a technocratic process—updating targets and implementation instructions based on country-specific data.

Current approaches to a benefits package design, adapted heavily from experiences in the United Kingdom (NICE), Thailand, and other European health systems, assume highly centralized, data-intensive, nominally apolitical governance structures for health, with policy formulation decision-making centered within a central figure or office, disseminating guidance to other local entities. This approach has proven insufficient for decentralized systems, where significant autonomy is reserved for local or subnational levels, with broader guidelines established by a central figure or office. While countries with differing governance structures have created and implemented UHC policies, implementation in the Global South has lagged due to a lack of financial and human resources (26, 27), which remain key contextual factors that need to be considered when adapting policies for heterogeneous settings.

We present two case studies that highlight the need to adapt a general policy to fit different governance structures for health and various financial and human resource contexts when developing a universal health coverage essential benefits package. In the most recent revision to its Essential Package of Health Services for the 12th Five-Year Plan, Pakistan identified efficiencies and alignment with evidence-based recommendations by using the normative package proposed in the 3rd edition of Disease Control Priorities (DCP3) as a framework. Through a year-long collaborative process led by the Ministry of National Health Services, Regulations & Coordination, the initial policies proposed in the DCP3 package were narrowed and adapted into a set targeted to the needs of the Pakistani population and aligned with the health system structure that centers on a community-focused delivery model (28, 29). Rwanda, on the other hand, approached the achievement of universal health coverage by strengthening its primary healthcare infrastructure and implementing a community-based health insurance program (*Mutuelle de santé*) (30). The program provides health insurance coverage to more than 90% of its population, resulting in improved health outcomes. This success is attributed to strong leadership and community partnerships, as evidenced by the increasing government spending on health, exceeding the regional average, and the role of the community in its implementation (31–33). The approaches taken by these two countries in developing UHC demonstrate the necessary adaption of this general policy to fit the local context.

Recent policy IS frameworks uniquely describe policy as the focus of adaptation. In the original Exploration, Preparation, Implementation, and Sustainment (EPIS) framework, policy was conceptualized as a contextual "bridging factor" that connects outer and inner contexts (34). In the policy-optimized version of the EPIS framework, policy is conceptualized as the "thing" to be tailored (16) (Figure 1). These frameworks also present an opportunity for expansion to reflect contextual factors such as governance structures and the role and power of external actors—areas better articulated by more traditional implementation science frameworks informed by Global South scholarship (11, 12) (Figure 1).

Policy implementation and evaluation

Arguably, most theoretical and empirical work in policy IS to date has been conducted on the latter phases of the policy cycle. While the integration of implementation science concepts into policy implementation research has made great strides since Nilsen et al. (35) first lamented their incompatibility, the language used in IS research on policy still reflects assumptions of the political economy of the Global North. Current frameworks stress the role of advocacy coalitions, organizational networks and capacity, and the influence of types of policy levers but gloss over the impact of extreme resource scarcity on implementation outcomes. Policy implementation in any context, particularly in health, is affected by substantial heterogeneity in capacity (workforce, resources, commodities) at national, subnational, and facility levels, and in the Global South, this heterogeneity is amplified not only by an acute lack of funding compared to need but also by the stark lack of fungibility of resources (36). Bullock et al. (17), in their seminal work on policy implementation theory, note that the overrepresentation of studies from the United States limits the field's consideration of other resource allocation models. However, their final determinants framework does not include resource adequacy in the model (Figure 1). Finally, while there is little published scholarship on whether implementation outcomes should differ between resource-rich and resource-constrained settings, this has been a topic at recent dissemination and implementation conferences (37).

As with agenda setting and formulation, in the Global South, external funders and program implementers exert unique influence on policy implementation outcomes. Development agencies and international non-governmental organizations (NGOs) acting in the Global South limit the extent to which governments can fully manage the policy implementation process. This may be driven by government expenditures on health. For example, in 2021, health expenditure in high-income countries stood at 13.13% of their GDP, while the corresponding figure was 5.25% in low-income countries (38). Country-level comparisons reveal even more stark differences in health expenditures. For example, the United States spent 17.36% of its GDP on health, while two of Africa's most populous countries, Ethiopia and Nigeria, only spent 3.21% and 4.08%, respectively (5). Countries with low health expenditures are dependent on financial assistance from high-income countries, and this commonly comes with their set of policy priorities. Paina et al. (39), Qiu et al. (40), and Carbaugh (41) documented how the 2015 President's Emergency Plan for AIDS Relief (PEPFAR) directive to their country missions to transition HIV/AIDS funding away from low-burden areas to increase efficiencies in programming had an undeniable influence on HIV policy implementation in the respective countries. Government and external funders play a significant role especially in geographical prioritization and transition efforts requiring government financing. NGOs play an outsized role in policy implementation and evaluation, and these NGOs are accountable to governments in complex and varying ways, directly reflecting the history and aftermath of colonial rule. Solutions to these challenges will be multifactorial and relate to governance and power shifting, similar to how decolonizing global health involves critically revising power and governance relationships and structures.

With regard to areas for further improvement in policy implementation and evaluation, policy IS frameworks could be refined to reflect the role and power of external actors using insights from more traditional implementation science frameworks (Figure 1).

Discussion

It is clear from our discussion that we need to continue refining policy implementation science frameworks to fully embrace a global perspective addressing differences in governance, resources, and stakeholder relationships. This presents an opportunity to reduce inequities and prioritize decolonizing global health. By expanding policy IS frameworks through the incorporation of more traditional IS and political science theories and advancing an intersectionality approach that recognizes complex relationships and the impact of power dynamics on policymaking in a global setting, countries can better adapt policies to their local socio-cultural, economic, and political contexts. This should occur not only at the policy implementation and evaluation stages but also at all upstream stages in the policy cycle, such as agenda setting and policy formulation. It will be essential to move beyond this theoretical work and toward empirical research to make this agenda a reality. We propose that the future roadmap for this research includes engaging with diverse stakeholders using formative and consensus-driving methodologies to integrate policy frameworks, implementation science frameworks, and policy IS frameworks with a global health lens. We then propose a review of this integrated work by individuals in diverse contexts, applying these integrated frameworks to previous case studies to determine whether they resonate more strongly than the unadapted versions. Finally, we would propose the prospective application of such frameworks to policy IS work in global contexts.

Ultimately, using policy implementation science to promote the uptake and adoption of evidence-based policymaking presents a unique opportunity available to countries and needs to be broadened to ensure effectiveness in the Global South. It will be essential to move beyond this theoretical work toward empirical research to make this agenda a reality. This will require more interdisciplinary work, bringing together experts in implementation science, public policy, social science, and health equity, among others, to further advance the global application of policy implementation science.

Author contributions

KL: Conceptualization, Project administration, Writing – original draft, Writing – review & editing. PA: Conceptualization, Project administration, Writing – original draft, Writing – review & editing. DA: Conceptualization, Writing – review & editing. PC: Writing – review & editing. KD: Conceptualization, Project administration, Writing – review & editing. JK: Writing – review & editing. AM: Conceptualization, Writing – review & editing. IM: Writing – review & editing. NN: Writing – review & editing. YS: Conceptualization, Writing – review & editing. AW: Conceptualization, Project administration, Writing – review & editing. BW: Writing – review & editing. SM: Conceptualization, Project administration, Writing – original draft, Writing – review & editing.

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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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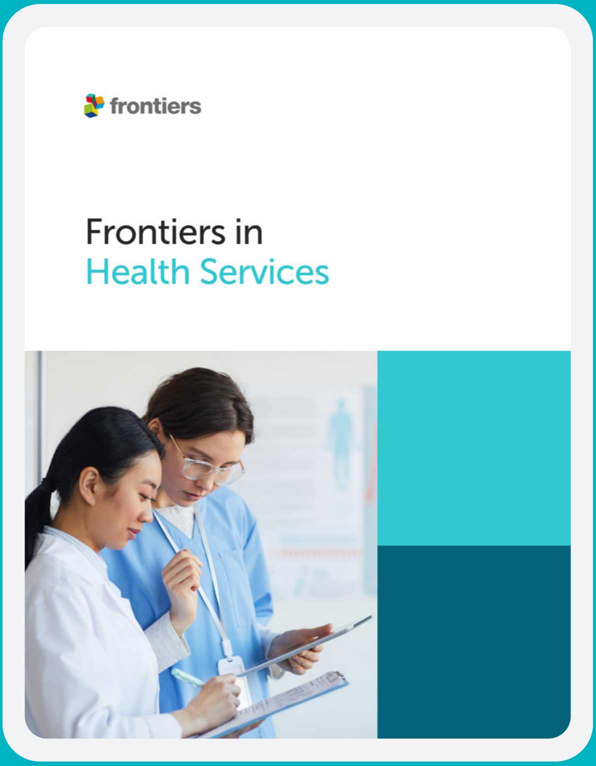
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