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Advancing Mechanisms of Implementation to Accelerate Sustainable Evidence-Based Practice Integration: Protocol for Generating a Research Agenda

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Advancing Mechanisms of Implementation to Accelerate Sustainable Evidence-Based Practice Integration: Protocol for Generating a Research Agenda

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Abstract

Introduction: Mechanisms explain how or why implementation strategies exert their effects. Implementation research requires careful operationalization and empirical study of the causal pathway(s) by which strategies effect change, and factors that may amplify or weaken their effects. Understanding mechanisms is critically important to replicate findings, learn from negative studies, or adapt an implementation strategy developed in one setting to another. Without understanding implementation mechanisms, it is difficult to design strategies to produce expected effects across contexts, which may have disproportionate effects on settings in which priority populations receive care. This manuscript outlines the protocol for an Agency for Healthcare Research and Quality-funded initiative to: (1) establish priorities for an agenda to guide research on implementation mechanisms, and (2) actively disseminate the agenda to research, policy, and practice audiences.

Methods and Analysis: A network of scientific experts will convene in “Deep Dive” meetings across three years. A research agenda will be generated through analysis and synthesis of information from six sources: (1) systematic reviews, (2) review network members’ approaches to studying mechanisms, (3) new proposals presented in implementation proposal feedback sessions, (4) working group sessions conducted in a leading implementation research training institute, (5) breakout sessions at the Society for Implementation Research Collaboration’s (SIRC) 2019 conference, and (6) SIRC conference abstracts. Two members will extract mechanism-relevant text segments from each data source and a third member will generate statements as an input for concept mapping. Concept mapping will generate unique clusters of challenges, and the network will engage in a nominal group process to identify priorities for the research agenda.
**Ethics and Dissemination:** This initiative will yield an actionable research agenda to guide designing and conducting mechanistic implementation research. The agenda will be disseminated via multiple channels to solicit feedback and pursue strategies to facilitate new research to carry out the agenda.

**Keywords:** psychiatry, primary care, health services administration and management, public health

**Strengths and Limitations of this Study**

- This study will synthesize multiple data sources to uncover key challenges to studying implementation mechanisms
- This study will yield a research agenda outlining challenges, priorities, and activities that will advance the study of implementation mechanisms
- This study will disseminate a mechanisms-focused research agenda for implementation science and invite international feedback
Advancing Mechanisms of Implementation to Accelerate Sustainable Evidence-Based Practice Integration: Protocol for Generating a Research Agenda

Mechanisms are broadly defined as processes that are responsible for change (1). Defining, testing, and establishing mechanisms is increasingly a priority across fields of study where interventions (2, 3) (biological, psychological, or social) or behavior change is the focus. In the context of implementation science, mechanisms explain how or why implementation strategies exert their effects on outcomes. Implementation strategies are defined as methods used to facilitate the adoption, implementation, sustainment, or scale-up of evidence-based practices (EBPs) (4, 5). Despite advances that catalog 73 expert-defined implementation strategies across nine categories (e.g., engage consumers, change infrastructure) (6, 7), we know little about the mechanisms through which these strategies generate change (8, 9). A recent systematic review of implementation mechanisms in health identified 46 studies assessing mechanisms (9). The majority of studies were not designed to formally establish implementation mechanisms per recommended criteria (1, 10). In an earlier systematic review of nine randomized implementation trials, Williams (8) observed similar methodological deficiencies, and no trials supported a hypothesized mediator. Both reviews identified numerous challenges impeding the study of mechanisms in implementation science, including conceptual (e.g., lack of harmony in defining constructs and their roles), theoretical (i.e., few theories exist), methodological (e.g., poor quality measures, design challenges), and practical (e.g., difficult to power studies for mediation analyses) challenges. More work is needed to identify barriers to mechanistic implementation science and to propose concrete, actionable steps to overcome these barriers.

The Impact of Limited Implementation Mechanisms Research on Achieving Health Equity
Insufficient or incomplete understanding of implementation mechanisms precludes successful efforts to systematically design and tailor implementation strategies to meet heterogeneous contexts and stakeholder needs and resources, to replicate positive findings in research and practice, to learn from negative studies, and to successfully adapt an implementation strategy developed in one setting to another. These difficulties weaken implementation effectiveness and efficiency and can exacerbate health disparities when implementation efforts are poorly adapted for safety net and other settings where under-served populations are found (11). Eliminating health disparities may require careful design and tailoring of implementation strategies to the unique circumstances and needs of specific priority populations and the contexts in which they receive care. For example, a clinic may engage in an implementation effort and begin to offer a new EBP with fidelity, but social factors (e.g., access to transportation, childcare) might need to be addressed through provider- and patient-focused implementation strategies (e.g., via telehealth) to improve implementation outcomes such as “reach”(12). Contexts serving priority populations might not respond to certain implementation strategies, such as external consultation, or be able to afford robust strategies, such as practice facilitation. A fundamental understanding of implementation mechanisms will enable implementers to design and, as necessary, tailor implementation strategies to locally relevant determinants while retaining their core function (13, 14).

Developing and Disseminating an Implementation-Focused Research Agenda: Conference Series Aims

Given ongoing challenges associated with tailoring and delivering implementation strategies previously found to be effective (15-18), research reporting guidelines emphasize the need to justify the selection of specific implementation strategies(4, 19, 20). This, in turn,
requires identifying the barrier(s) to be addressed and the selected strategy's mechanism of action. Table 1 provides examples of how strategies may work to address determinants and influence specific implementation outcomes. Identifying the mechanisms through which implementation strategies exert their effects, rather than focusing solely on whether or not they are effective, is an important step forward for the field of implementation science(5, 21).

Accordingly, we are undertaking an initiative to advance the study of mechanisms in implementation science. We will conduct a 3-year meeting series with between-meeting activities designed to achieve two aims: (1) establish priorities to guide a research agenda on implementation mechanisms, and (2) actively disseminate the research agenda to research, policy, and practice audiences. This protocol paper outlines our plans to engage a network of experts across three years to produce detailed guidance and identify research approaches and tools needed to test hypotheses related to strategy, mechanism, and outcome linkages and whether they vary with respect to target problems, EBPs, priority populations, and contexts.

Ultimately, the implementation research and practice efforts guided by our resulting agenda may be more actionable, practical, and equitable given their clear focus on mechanisms.

Methods

A variety of methods will be leveraged to identify challenges, priorities, and activities related to advancing the field’s understanding of how and why implementation strategies work, pulling in learnings from numerous sources. The methods include qualitative content analysis (22), which will generate the inputs for concept mapping (23), followed by nominal group technique (24) to prioritize the research agenda. Table 2 provides a brief overview of the steps in our effort to develop a research agenda, which are described in more detail below.

Partnership with the Society for Implementation Research Collaboration
In 2017, the Society for Implementation Research Collaboration (SIRC) hosted its 4th biennial conference with the following theme: “Implementation Mechanisms: What Makes Implementation Work and Why?” (25). This conference was inspired by the realization that the field of implementation science was in a position to pivot from characterizing implementation efforts (e.g., qualitative exploration of barriers and facilitators) and evaluating the general effectiveness of strategies (i.e., empirical treatment approach) to examining the causal mechanisms by which strategies achieve their effects. Given SIRC’s commitment to advancing mechanistic implementation science and its engaged global membership (26), we partnered with SIRC to pursue funding from the Agency for Healthcare Research and Quality (AHRQ) to shape the developing agenda both during and between meetings. In addition to leveraging several SIRC activities as sources and inputs for our research agenda, we will conclude our meeting series in collaboration with SIRC in 2022 where we will disseminate the agenda and invite feedback from attendees. A summary of our proposed work can be found on the SIRC website (27).

**Mechanisms Network of Expertise**

In preparing this proposal, we convened 26 implementation scientists from the United States to form a Mechanisms Network of Expertise (MNoE). We have expanded the MNoE to include international experts and bring in early career researchers, and plan to continue to do so as this work progresses. This network approach allows us to leverage the collective wisdom of key stakeholders who have been contributing to the study of implementation mechanisms and to engage in a collaborative immersion across three years to achieve our aims. By convening the MNoE regularly, roughly quarterly in virtual meetings, and annually for Deep Dive retreats, we will be able to develop a shared understanding, build momentum, and generate products for the larger field to refine and apply. We intend for the network to represent expertise in studying
implementation mechanisms and to display diversity across several dimensions (e.g., geography, gender, race/ethnicity, work with priority populations, settings in which they worked). In the initial phases, the MNoE will be organized into four workgroups that will focus initial network activities: (1) Measurement; (2) Design and Analysis; (3) Causal Theory and Context; and (4) Strategy, Mechanism, Outcome linkages (26). However, we plan to reorganize the workgroups into the conceptually distinct areas of the research agenda that emerge from the concept mapping work described below.

**Patient and Public Involvement**

This initiative is not human subjects research; no patients were involved in this process.

**Data Sources**

In collaboration with the MNoE, we will synthesize information from six sources to generate the research agenda. This broad sourcing will ensure that the agenda is grounded in the empirical literature, informed by SIRC’s global membership, and curated by our MNoE. Table 3 provides an overview of the six sources and offers examples of the types of research agenda items we might obtain from each. We believe the selected sources allow for a systematic and relatively comprehensive approach to generating a research agenda that will encompass challenges, priorities, and specific activities to guide the study of implementation mechanisms; however, we also note limitations in the discussion.

1) **Systematic Reviews.** Our work will be informed by two systematic reviews of mechanisms in implementation. The only mechanisms-focused systematic review published prior to our grant funding focused on multilevel mechanisms of implementation strategies in the context of randomized-controlled trials in mental health (8). That review included nine randomized trials that formally tested mediators linking an implementation strategy to an
implementation or clinical outcome. Mediation analysis is one quantitative approach to studying mechanisms in which the total effect of an implementation strategy on an outcome is divided into an indirect effect that occurs through a proposed mediating variable and a direct effect that is not explained by the mediating variable (28). None of the trials provided sufficient evidence to support a plausible mediator primarily because there was no evidence that the implementation strategies changed the targeted mediating variables. This review also identified several issues in mediation studies of implementation strategies, including study designs that were not conducive to detecting a relationship between the implementation strategy and candidate mediator, insufficient measurement, and underuse or misuse of theory to link implementation strategies to outcomes. We will draw upon the findings of this review, including Williams’(8) suggestions for future research when populating our research agenda. For instance, Williams (8) suggested investigating theory-informed constructs as potential mediators, improving theoretical links between implementation strategies and hypothesized mediators, enhancing study designs and analytical methods to detect and analyze mediators in multilevel contexts, and further study of implementation strategy change processes to better target candidate mechanisms.

A second systematic review conducted by several members of the MNoE built on Williams’(8) work by expanding the scope to include implementation studies across health, a wide array of study designs, and the investigation of moderators. This review included 46 studies (including the nine from Williams’(8) review), and applied seven criteria for establishing a mechanism (1, 10): (i) strong associations between the implementation strategy and mechanism and between the mechanism and outcome, (ii) specificity (demonstration that one construct and not others influencing change), (iii) consistency (replication across studies), (iv) experimental manipulation of the strategy or proposed mechanism, (v) timeline (change in mechanisms
precede change in outcomes), (vi) gradient (dose-response relationship between level of mechanism and level of outcome), and (vii) plausibility/coherence (process-outcome relationship is reasonable or supported by other research). This review found only one study that met six criteria (29); the vast majority of included studies (n=38) met three or fewer. Fewer than half of studies in the review included an implementation strategy as the independent variable of interest. As with Williams (8) this review concluded underuse of theory and overuse of study designs and analytical methods that do not afford the opportunity to establish mechanisms. We will draw upon the findings of this review, including the authors’ suggestions for future research, when populating our research agenda. The authors underscore the need for work across conceptual, theoretical, methodological, measurement, and analytic domains to advance the field.

2) Matrix Mapping of Ongoing Research. To understand how members of our network (i.e., the MNoE) are currently studying mechanisms and to identify persistent gaps in this area of inquiry, we will synthesize the data obtained in an online Matrix Mapping exercise. Matrix mapping allows members to report on recently completed and in-progress implementation projects that include the study of mechanisms (e.g., mediation studies and other studies of implementation strategies), and for us to map, or identify, saturated versus thin areas of the matrix. To this end, the matrix is organized by the following: priority populations (coded using categories identified by AHRQ), target problem (disease, disorder, symptom, or risk factor), EBP intended to improve target problem, context/setting in which the EBP was delivered, guiding theory or framework, implementation strategies, mechanism(s) under investigation (or hypothesized mechanisms), implementation outcome(s), study status (planned, in progress, or complete), and references for the project. The matrix will be coded using the Expert Recommendations for Implementing Change implementation strategies compilation (6, 7) and
the Implementation Outcomes Framework (30). We will calculate frequencies and proportions of responses occurring in each category to determine areas where there is representation (e.g., commonly used implementation strategies) and areas for which there are gaps (e.g., understudied implementation outcomes, dearth of interventions to improve the health of certain target populations) to inform the research agenda.

3) Implementation Development Workshop (IDW). The IDW is a half-day, pre-conference event that is regularly part of the biennial SIRC conference, in which SIRC Network of Expertise members (i.e., practitioners, students, new and established investigators) are invited to present “works in development” to receive expert feedback from colleagues (31). Based on the Behavioral Research in Diabetes Group Exchange model used by the Psycho-Social Aspects of Diabetes research group (32), the format includes 10-20 minutes for each presenter to orally (without technology) describe their project/proposal and 20-40 minutes for feedback coordinated by a facilitator. A note-taker records notes of the feedback so the presenter can be involved in the discussion. Qualitative content analysis (22) of the notes reflecting each proposal discussion will serve as a third source for the research agenda to capture challenges and possibilities in the study of implementation mechanisms among a unique group of experts beyond the MNoE. That is, we will learn how mechanisms are being considered (if at all) in project proposals and uncover the challenges researchers face when considering mechanism evaluation.

4) Implementation Research Institute. The Implementation Research Institute (33) is a 2-year interdisciplinary training program funded by the U.S. National Institutes of Health that focuses on developing and nurturing a network of scholars who focus on researching the implementation of effective practices within the field of behavioral health (34, 35). Every summer features a week-long training institute in which fellows convene with core and expert
faculty to engage with emerging issues in implementation science. Working sessions to advance the field are often conducted and one focused specifically on challenges to conducting mechanistic implementation science will serve as our fourth source for the research agenda. As a precursor to the exercise, a general overview of implementation strategy research was provided as well as specific content related to the concept of mechanisms (e.g., What is a mechanism? What do we know about mechanisms in implementation science?). Faculty and fellows were then split into three groups: 1) Theories, Frameworks, and Context, 2) Design and Analysis, and 3) Measurement. Each group considered two questions related to their focus area: 1) What are the major challenges to advancing our understanding of mechanisms?, and 2) What do you view as promising paths forward to advance our understanding of mechanisms? The groups were given 30 minutes to discuss and asked to assign one or more note-takers to document ideas. Following this exercise, each group reported their results to the larger group. We will use qualitative content analysis (22) to code the notes for unique challenges and opportunities generated through this exercise to inform the research agenda.

5) SIRC Breakout Sessions. All SIRC 2019 conference attendees were invited to participate in two breakout sessions facilitated by R13 investigative team members. These sessions were advertised as opportunities for the MNoE to learn from the experiences of global researchers, policy makers, practitioners, and intermediaries. In order to participate, attendees agreed to complete one hour of preparatory work, including viewing a recorded webinar (36) and reviewing an overview handout. These requirements were set to ensure all attendees would enter the breakout with the same foundational knowledge (e.g., What is an implementation mechanism?) and to encourage active participation by breakout session attendees. Participants had the option of attending one or both breakout sessions (over 90 attendees attended each
session), and they were informed that their input would be used to ultimately shape the research agenda.

The first breakout session focused on challenges of using theory to understand context and to inform the study of implementation strategies, mechanisms, and outcome linkages. It began with an introduction and discussion of the current landscape of implementation mechanisms and then moved to a conversation about key challenges and gaps associated with studying implementation mechanisms through the lens of the four workgroups. Attendees then split into four groups: (1) Causal Theory and Context; (2) Connections from Implementation Strategies to Mechanisms and Outcomes; (3) Design and Analysis; and (4) Measurement. Attendees were instructed to select the group that best fit their expertise or interests, and the majority of the session was spent in facilitated discussion. At the end of the breakout session, one member of each group presented a summary of their discussion to the larger group. Notetakers were embedded throughout to document and permit subsequent complication of challenges and opportunities relevant to the research agenda.

The second breakout session began with brief “stimulus talks” from the MNoE workgroup leads and a case study. The 3-minute stimulus talks and 13-minute case study focused on thorny issues related to the study of implementation mechanisms. Following these talks, as with the first breakout session, attendees separated into four groups: (1) Causal Theory and Context, (2) Connections from Implementation Strategies to Mechanisms and Outcomes, (3) Design & Analysis, and (4) Measurement. Participants spent most of the time discussing the case study through the lens of their workgroup’s topic area, coming together at the end of the session for summary discussion. Small group discussion was designed to elevate additional issues not raised in the presentations, and to use the case study to address the issues raised by the presenters.
through the lens of their workgroup. At the end of the breakout session, one member of each of
the four workgroups presented a summary of their discussion to the larger group. Note-takers
were embedded throughout to allow for data extraction of qualitative data that could inform the
research agenda. We will use qualitative content analysis (22) to mine the notes of these two
breakout sessions to identify challenges and opportunities in the study of implementation
mechanisms that will directly inform the research agenda.

6) SIRC abstracts. Our final source will be the 2019 presentations. The purpose of this
input is to understand the extent to which implementation mechanisms were represented in the
SIRC 2019 program (37), uncover gaps in the study of implementation mechanisms, and reveal
exemplar studies that may not be yet captured in the published literature. All 205 abstracts from
the 2019 SIRC conference program will be qualitatively coded for implementation mechanism-
related content. If authors make mention of mechanisms (or mediators and moderators) in their
abstract, the coder will record the mechanisms reported and the measurement method if
available. Abstracts will also be coded for setting and project design (9); priority populations
(38); guiding theories/frameworks (39); implementation strategies (6, 7); service outcomes,
implementation outcomes, and clinical/client outcomes (30); and barriers to implementation (40).
Abstract information will be entered into REDCap, and three coders will independently extract
data from a random sample of abstracts with 5% coded by all three members of the team to
assess for inter-rater reliability. The results of the abstract coding will directly inform the
research agenda.

Synthesizing Findings Across Data Sources

We will conduct qualitative content analysis (22) to code each of the six sources
described above across two categories: (1) challenges in conducting mechanistic implementation
science and (2) priorities for improving the study of implementation mechanisms. Data analysis will occur in three phases: immersion, reduction, and interpretation. During the immersion phase, study team members will obtain a sense of “the whole” before rearranging it into smaller segments (22). This will be accomplished by reviewing each of the six inputs described above to gain a better sense of these data. The reduction phase will involve condensing data into text segments by coding each of the six data sources. To increase reliability and reduce bias (41, 42), two researchers will use an electronic spreadsheet to independently extract text segments that represent challenges or priorities related to studying implementation mechanisms. These coders will regularly debrief during project meetings to ensure a common frame of reference for each input and to discuss and resolve discrepancies. A third researcher will work with BJP and CCL to examine all text extracted text segments to eliminate redundancies and ensure that each segment is worded clearly and concisely. Rather than identifying themes across text segments, each text segment describing challenges related to researching implementation mechanisms will be used in the concept mapping (23, 43) study described below. This will generate conceptually distinct clusters of challenges that will need to be addressed to advance the field’s understanding of implementation mechanisms, and it will constitute the interpretation phase of the qualitative content analysis approach. Although coders will also extract possibilities or opportunities for the field, these will be tabled for consideration until the Deep Dive retreat when the results of the concept mapping are turned into an actionable research agenda.

**Generating the Research Agenda through Concept Mapping**

The members of the MNoE will be engaged in a concept mapping study to further develop and refine the emerging research agenda to advance the study of mechanisms in implementation. Concept mapping is a structured process designed to organize concepts into
conceptually distinct categories and to generate ratings of specified dimensions such as importance and feasibility (23, 43, 44). As noted by Powell et al. (45), concept mapping is particularly useful for structuring the ideas of diverse groups of stakeholders and has been leveraged by implementation researchers to identify and prioritize implementation barriers and facilitators (46, 47), implementation strategies (7), training needs (48), dimensions of pragmatic measures (45), and an agenda for studying sustainability of EBPs (49). Concept mapping is a mixed methods, multi-step approach that typically involves: the identification of specific statements through brainstorming or other sources, statement analysis and synthesis, statement rating, unstructured sorting of statements, multidimensional scaling and hierarchical cluster analysis, and the generation of interpretable maps and data displays. Concept mapping is described in more detail by Trochim and Kane (23) and Kane and Trochim (43).

The Concept mapping process will be completed via the Group Wisdom software platform (50). Statement identification, analysis, and synthesis will occur via the consolidation of the six research agenda sources as described above. Statements describing challenges to advancing research on implementation mechanisms will entered into the Group Wisdom software platform. To ensure feasibility and to remain consistent with recommendations for the overall number of statements for concept mapping studies (44, 51), we will keep the number of statements to no more than 100. Members of the MNoE will then be invited to engage in the concept mapping study via the Group Wisdom platform (50). MNoE members will be asked to complete a brief demographic survey and then be presented with the list of statements to engage in rating and sorting tasks (in any order they so choose). They will be asked to rate each statement on a 5-point Likert scale across two dimensions, including criticality (i.e., how important the challenge is to advancing the science and achieving health equity) and
pervasiveness of the challenges. They will also be asked to sort each of the statements into piles or categories that make sense to them and will be given the opportunity to label each of the categories they create.

We will utilize multidimensional scaling to generate a point map depicting each of the statements and relationships between them based upon a summed square similarity matrix (23). Statements that are sorted together more frequently will be placed closer together on the map. Model fit will be assessed using the stress value, an indication of goodness of fit between the point map and the total similarity matrix (23, 43). Hierarchical cluster analysis will be used to partition the point map into non-overlapping clusters (23). We will convene the MNoE to consider a range of cluster solutions produced by the analysis to determine the number of clusters that best represents the core domains of our emerging research agenda. The Group Wisdom software platform (50) will aid in the labeling process by suggesting potential cluster labels based upon participant responses; however, the MNoE will engage in discussion to determine the names for each cluster in our final cluster map. Descriptive statistics of MNoE members’ ratings of criticality and pervasiveness will be presented at the statement and cluster levels.

Once the optimal concept map is identified, the majority of the Deep Dive retreat will be focused on engaging the MNoE in small workgroups organized by the conceptually distinct clusters that emerged from the concept mapping. The workgroups will consider the discrete challenges in their cluster(s), examine how they are related, and reflect on their degree of criticality and pervasiveness. They will then engage in a facilitated nominal group process (24) to brainstorm broad priorities and specific activities for addressing each challenge. Nominal group process is a structured method of small-group discussion to reach consensus in problem-
solving, idea generation, and priority setting (24). Nominal group process brings structure to what is often described in vague terms in published reports as an “iterative process” for developing insights and exhausting the expertise of a group. Once all challenges have been subjected to the nominal group process, the resulting opportunities and activities will be captured in a structured research agenda. The research agenda will be comprised of challenges, priorities, and specific activities that will be organized according to the clusters identified through the concept mapping study. We will disseminate the research agenda via the SIRC website, conference presentations, and open access publications and build opportunities to seek feedback from international stakeholders from the implementation research, practice, and policy communities.

Discussion

Understanding how and why implementation strategies achieve their effects will enable stakeholders to deploy these strategies with more precision retaining their core functions, to develop multifaceted and multilevel implementation strategies that combine component strategies in a synergistic manner (52), to systematically match strategies to high-priority determinants, and to tailor strategies to diverse and under-resourced contexts. This is particularly important as a means of addressing health disparities by ensuring that implementation efforts address social, political, and environmental factors that contribute to inequitable outcomes for underserved populations (53). However, there are significant challenges to advancing the study of implementation mechanisms that cut across conceptual, methodological, analytical, and practical spaces. By partnering with the Society for Implementation Research Collaboration, convening a Mechanisms Network of Expertise, and hosting Deep Dive retreats, we will clarify and collate the challenges to studying implementation mechanisms and develop a research
agenda that pairs challenges with priorities and specific activities that are needed to advance the field.

We acknowledge several limitations to our planned approach to developing this research agenda. First, although we recently expanded our MNoE to include international members, we are primarily based in the United States, which may limit the relevance of our research agenda internationally where researchers and implementers may face different challenges or generate unique opportunities. We will continue to seek opportunities to obtain feedback from international experts in implementation research, practice, and policy. This may occur through expanding our MNoE to include more international participants, and by seeking international dissemination outlets that will afford the opportunity to receive feedback on the developing research agenda. Second, our sources are not exhaustive but are intended to capture diverse and expert perspectives, which may result in missed challenges and approaches that are important but not included in the six sources described above. Third, our 2020 in-person Deep Dive was postponed due to the threat of COVID-19, but we will continue the work virtually, and have identified virtual, asynchronous platforms for all planned activities, including the nominal group process.

We will disseminate the resulting research agenda through presentations at SIRC’s 6th conference in 2022, in presentations and webinars, and in a series of open access manuscripts in the service of stimulating more and better research related to the development and optimization of implementation strategies. This represents a tremendous opportunity to initiate international discourse about how we can develop more precise, scalable, and effective implementation strategies capable of improving the quality of health and social care delivery. We welcome input.
from the practice, policy, and research communities on the development and dissemination of this research agenda.
List of Abbreviations

AHRQ: Agency for Healthcare Research and Quality; EBP: evidence-based practice; IDW: Implementation Development Workshop; MNoE: Mechanisms Network of Expertise; SIRC: Society for Implementation Research Collaboration

Declarations

Ethics Approval and Consent to Participate

Not applicable.

Consent for Publication

Not applicable.

Availability of Data and Materials

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

CCL drafted the majority of the introduction and discussion. BJP drafted content throughout the manuscript, but primarily contributed to the methods section. SKB, AMN, SFV, and CWB each drafted paragraphs of the Method section. GAA, RB, ARL, BJW, NW, and BM
all reviewed and heavily edited an early draft of the manuscript. All authors reviewed and approved the final version.

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References

1. Kazdin AE. Mediators and mechanisms of change in psychotherapy research. Annual Review of Clinical Psychology. 2007;3:1–27.

2. Proctor EK, Powell BJ, McMillen JC. Implementation strategies: Recommendations for specifying and reporting. Implementation Science. 2013;8:1–11.

3. Powell BJ, Fernandez ME, Williams NJ, Aarons GA, Beidas RS, Lewis CC, et al. Enhancing the impact of implementation strategies in healthcare: A research agenda. Frontiers in Public Health. 2019;7:1–9.

4. Powell BJ, Waltz TJ, Chinman MJ, Damschroder LJ, Smith JL, Matthieu MM, et al. A refined compilation of implementation strategies: Results from the Expert Recommendations for Implementing Change (ERIC) project. Implementation Science. 2015;10:1–14.

5. Waltz TJ, Powell BJ, Matthieu MM, Damschroder LJ, Chinman MJ, Smith JL, et al. Use of concept mapping to characterize relationships among implementation strategies and assess their feasibility and importance: Results from the Expert Recommendations for Implementing Change (ERIC) study. Implementation Science. 2015;10:1–8.

6. Williams NJ. Multilevel mechanisms of implementation strategies in mental health: Integrating theory, research, and practice. Administration and Policy in Mental Health and Mental Health Services Research. 2016;43:783–98.

7. Lewis CC, Boyd MR, Walsh-Bailey C, Lyon AR, Beidas R, Mittman B, et al. A systematic review of empirical studies examining mechanisms of implementation in health. Implementation Science. 2020;15:1–25.

8. Hill AB. The environment and disease: Association or causation? Proceedings of the Royal Society of Medicine. 1965;58:295–300.

9. Smith S, Johnson L, Wesley D, Turner KB, McCray G, Sheats J, et al. Translation to practice of an intervention to promote colorectal cancer screening among African Americans. Clinical and Translational Science. 2012;5:412–5.

10. Shelton RC, Chambers DA, Glasgow RE. An extension of RE-AIM to enhance sustainability: Addressing dynamic context and promoting health equity over time. Frontiers in Public Health. 2020;8:1–8.

11. Patient Centered Outcomes Research Institute. PCORI standards for studies of complex interventions. 2019. https://www.pcori.org/research-results/about-our-research/research-methodology/pcori-methodology-standards#Complex. Accessed 11 Feb 2021.

12. Perez Jolles M, Lengnick-Hall R, Mittman BS. Core functions and forms of complex health interventions: A patient-centered medical home illustration. Journal of General Internal Medicine. 2019;34:1032–8.
13. Bosch M, van der Weijden T, Wensing M, Grol R. Tailoring quality improvement interventions to identified barriers: A multiple case analysis. Journal of Evaluation in Clinical Practice. 2007;13:161–8.

14. Baker R, Comosso-Stefinovic J, Gillies C, Shaw EJ, Cheater F, Flottorp S, et al. Tailored interventions to address determinants of practice. Cochrane Database of Systematic Reviews. 2015;4:1–118.

15. Wensing M. The Tailored Implementation in Chronic Diseases (TICD) project: Introduction and main findings. Implementation Science. 2017;12:1–4.

16. Bird KA, Castleman BL, Denning JT, Goodman J, Lamberton C, Rosinger KO. Nudging at scale: Experimental evidence from FAFSA completion campaigns. Journal of Economic Behavior and Organization. 2021;183:105–28.

17. Hoffman TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: Template for intervention description and replication (TIDieR) checklist and guide. BMJ. 2014;348:1–12.

18. Bragge P, Grimshaw JM, Lokker C, Colquhoun H, The AIMD Writing/Working Group. AIMD - a validated, simplified framework of interventions to promote and integrate evidence into health practices, systems, and policies. BMC Medical Research Methodology. 2017;17:1–11.

19. Hamilton AB, Mittman BS, Brownson RC, Colditz GA, Proctor E k. Implementation science in health care. In: Dissemination and implementation research in health; Translating science to practice. 2nd edition. New York: Oxford University Press; 2018. p. 385–400.

20. Forman J, Damschroder L. Qualitative content analysis. In: Jacoby L, Siminoff LA, editors. Empirical methods for bioethics: A primer. Amsterdam: Elsevier; 2008. p. 39–62.

21. Trochim WMK, Kane M. Concept mapping: An introduction to structured conceptualization in health care. International Journal for Quality in Health Care. 2005;17:187–91.

22. Van de Ven AH, Delbecq AL. The nominal group as a research instrument for exploratory health studies. American Journal of Public Health. 1972;62:337–42.

23. Lewis CC, Stanick C, Lyon A, Darnell D, Locke J, Puspitasari A, et al. Proceedings of the Fourth Biennial Conference of the Society for Implementation Research Collaboration (SIRC) 2017: Implementation mechanisms: What makes implementation work and why? Part 1. Implementation Science. 2018;13 Suppl 2:1–5.

24. Landes SJ, Kerns SEU, Pilar MR, Walsh-Bailey C, Yu SH, Byeon YV, et al. Proceedings of the Fifth Biennial Conference of the Society for Implementation Research Collaboration (SIRC) 2019: Where the rubber meets the road: The intersection of research, policy, and practice - Part 1. Implementation Science. 2020;15(Suppl 3):1–5.
25. Society for Implementation Research Collaboration. Mechanisms network of expertise. 2021. https://societyforimplementationresearchcollaboration.org/mechanisms-network-of-expertise/. Accessed 11 Feb 2021.

26. Hayes AF, Preacher KJ. Quantifying and testing indirect effects in simple mediation models when the constituent paths are nonlinear. Multivariate Behavioral Research. 2010;45:627–60.

27. Williams NJ, Glisson C, Hemmelgarn A, Green P. Mechanisms of change in the ARC organizational strategy: Increasing mental health clinicians’ EBP adoption through improved organizational culture and capacity. Administration and Policy in Mental Health and Mental Health Services Research. 2017;44:269–83.

28. Proctor EK, Silmere H, Raghavan R, Hovmand P, Aarons GA, Bunger A, et al. Outcomes for implementation research: Conceptual distinctions, measurement challenges, and research agenda. Administration and Policy in Mental Health and Mental Health Services Research. 2011;38:65–76.

29. Marriott BR, Rodriguez AL, Landes SJ, Lewis CC, Comtois KA. A methodology for enhancing implementation science proposals: Comparison of face-to-face versus virtual workshops. Implementation Science. 2016;11:1–11.

30. PsychoSocial Aspects of Diabetes Group. Behavioral Research in Diabetes Group Exchange. http://www.psad-easd.eu/bridge/. Accessed 8 Feb 2021.

31. Implementation Research Institute. 2021. https://iristl.org. Accessed 11 Feb 2021.

32. Proctor EK, Landsverk J, Baumann AA, Mittman BS, Aarons GA, Brownson RC, et al. The Implementation Research Institute: Training mental health implementation researchers in the United States. Implementation Science. 2013;8:1–12.

33. Landsverk J, Proctor EK. From research training to scientific advancement - Contributions from the Implementation Research Institute: An introduction to the special issue. Administration and Policy in Mental Health and Mental Health Services Research. 2020;47:169–75.

34. Chambers D, Williams N, Lewis CC. Setting the stage for understanding mechanisms of implementation. 2019. https://societyforimplementationresearchcollaboration.org/wp-content/uploads/2019/04/SIRC-mechanisms-webinar-slides.pdf. Accessed 11 February 2021.

35. Society for Implementation Research Collaboration. Proceedings of the Fifth Biennial Conference of the Society for Implementation Research Collaboration (SIRC) 2019: Where the rubber meets the road: The intersection of research, policy, and practice - Part 2. Implementation Science. 2020;15(Suppl 2):1–85.

36. Agency for Healthcare Research and Quality. Priority populations. 2021. https://www.ahrq.gov/priority-populations/index.html. Accessed 8 Feb 2021.
37. Tabak RG, Khoong EC, Chambers DA, Brownson RC. Bridging research and practice: Models for dissemination and implementation research. American Journal of Preventive Medicine. 2012;43:337–50.

38. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: A consolidated framework for advancing implementation science. Implementation Science. 2009;4:1–15.

39. Bernard HR. Research methods in anthropology: Qualitative and quantitative approaches. 5th edition. Lanham, Maryland: AltaMira Press; 2011.

40. Krippendorff K. Content analysis: An introduction to its methodology. 2nd edition. Thousand Oaks, CA: Sage Publications; 2003.

41. Kane M, Trochim WMK. Concept mapping for planning and evaluation. Thousand Oaks, CA: Sage; 2007.

42. Rosas SR, Kane M. Quality and rigor of the concept mapping methodology: A pooled study analysis. Quality and rigor of the concept mapping methodology: A pooled study analysis. 2012;35:236–45.

43. Powell BJ, Stanick CF, Halko HM, Dorsey CN, Weiner BJ, Barwick MA, et al. Toward criteria for pragmatic measurement in implementation research and practice: A stakeholder-driven approach using concept mapping. Implementation Science. 2017;12:1–7.

44. Aarons GA, Wells RS, Zagursky K, Fettes DL, Palinkas LA. Implementing evidence-based practice in community mental health agencies: A multiple stakeholder analysis. American Journal of Public Health. 2009;99:2087–95.

45. Lobb R, Pinto AD, Lofters A. Using concept mapping in the knowledge-to-action process to compare stakeholder opinions on barriers to use of cancer screening among South Asians. Implementation Science. 2013;8:1–12.

46. Tabak RG, Padek MM, Kerner JF, Stange KC, Proctor EK, Dobbins MJ, et al. Dissemination and implementation science training needs: Insights from practitioners and researchers. American Journal of Preventive Medicine. 2017;52:S322–9.

47. Proctor EK, Luke D, Calhoun A, McMillen JC, McCrary S, Padek M. Sustainability of evidence-based healthcare: research agenda, methodological advances, and infrastructure support. Implementation Science. 2015;10:1–13.

48. Concept Systems Incorporated. groupwisdom. 2021. https://groupwisdom.com. Accessed 8 Feb 2021.

49. Trochim W. Reliability. 10 Mar 2020. In: Research Methods Knowledge Base [Internet]. Sydney, Australia: Conjoint.ly, https://conjointly.com/kb/measurement-reliability/. Accessed 11 Feb 2021.
50. Weiner BJ, Lewis MA, Clauser SB, Stitzenberg KB. In search of synergy: Strategies for combining interventions at multiple levels. JNCI Monographs. 2012;44:34–41.

51. Baumann AA, Cabassa LJ. Reframing implementation science to address inequities in healthcare delivery. BMC Health Services Research. 2020;20:1–9.
Table 1. Examples of Links Between Determinants, Implementation Strategies, Mechanisms, and Implementation Outcomes

| Determinant                      | Implementation Strategy                                      | Mechanism                                      | Implementation Outcome                  |
|---------------------------------|-------------------------------------------------------------|------------------------------------------------|----------------------------------------|
| Provider knowledge deficit       | Education (provision of information)                        | Awareness-building, knowledge-acquisition      | Feasibility, acceptability, appropriateness, adoption |
| Provider skill deficit           | Training (teaching and practice with corrective feedback)   | Skill acquisition, refinement, mastery         | Fidelity to EBP                        |
| Provider views EBP unfavorably   | Audit and Feedback provision of descriptive social norms indicating peer use of EBP | Social pressure/norms                          | Adoption                               |
| Turnover                        | Train-the-trainer                                           | Real-time training and consultation            | Sustainability                         |
| Competing clinical demands       | Leadership training                                         | Growing leadership support/perseverance        | Adoption, Sustainability               |
Table 2. Overview of Steps in Developing the Research Agenda

| Step | Description |
|------|-------------|
| 1)   | Develop strategic partnership with the Society for Implementation Research Collaboration (SIRC) |
| 2)   | Recruit members of the Mechanisms Network of Expertise (MNoE) |
| 3)   | Identify challenges and opportunities related to the study of mechanisms in implementation science across six different data sources |
| 4)   | Engage MNoE members in a Concept Mapping study to generate conceptually distinct clusters of challenges related to studying mechanisms, and generate ratings of the criticality and pervasiveness of challenges (at both the item and cluster level) |
| 5)   | Employ the nominal group technique with MNoE members to identify priorities and specific activities for advancing research on implementation mechanisms |
| 6)   | Disseminate the research agenda via the SIRC website, conference presentations, and open access publications |
| 7)   | Refine the agenda over time and encourage original research to advance understanding of how and why implementation strategies work |
| Input                                      | Data Represented                                      | Global | Examples of Expected Data in Form of Challenge Statements                                                                                                                                                                                                 |
|-------------------------------------------|-------------------------------------------------------|--------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Systematic Reviews (8, 9)                 | Peer reviewed literature                              | Y      | • Lack of shared terminology (linguistic inconsistencies) and definitions (lack of conceptual clarity)  
• Number of determinants make it unrealistic to isolate impact  
• Majority of studies focus on intrapersonal mechanisms, and few studies examined multilevel relationships |
| Matrix Mapping                            | Expert input from investigators’ recent and ongoing studies | N      | • Several investigators use “conduct educational meetings” across numerous studies and upwards of 20 different mechanisms are being studied  
• The majority of studies do not indicate a theory to guide their evaluation  
• Very few investigators explore system-level mechanisms  
• There is insufficient attention to several priority populations (e.g., minoritized populations, low-income families) |
| Implementation Development Workshop (31) | Expert input from investigators proposing new studies | Y      | • Very few proposals study implementation mechanisms because their budget is not equipped to power for these analyses  
• Investigators do not choose strategies based on their putative mechanisms of action  
• An equity lens is rarely integrated |
| Implementation Research Institute (34, 35)| Expert input from researchers                          | N      | • Available measures might drive conceptualization of what is important  
• It is difficult to decide how often we need to measure each putative mechanism to measure the change trajectory or sequence |
| SIRC Breakout Sessions (37)              | Novice to Expert input including practitioners, policy makers, purveyors, students, and researchers | Y      | • Unevenness in availability of measures across constructs  
• Often context is invoked retrospectively and is insufficiently measured  
• Longitudinal, iterative nature of mechanisms evaluations make it difficult to measure and analyze |
| SIRC Abstracts (37) | Novice to Expert input including practitioners, policy makers, purveyors, students, and researchers | Y |
|--------------------|--------------------------------------------------------------------------------------------------|---|
|                    | • [Despite ubiquitous nature of training and post-training consultation], few studies evaluate their mechanisms of action |
|                    | • Within a complex social-ecological system, there are multiple mechanisms by which an intervention could have its effect on the distal implementation outcome |
|                    | • Descriptions of implementation strategies are too general and do not include full and consistent descriptions of their active ingredients |

*Note.* “Global” refers to including global participants or data
References

1. Kazdin AE. Mediators and mechanisms of change in psychotherapy research. Annu Rev Clin Psychol. 2007;3(1):1-27.
2. Reiss D, Price RH. National research agenda for prevention research: The National Institute of Mental Health report. American Psychologist. 1996;51(11):1109-15.
3. Michie S, Carey RN, Johnston M, Rothman AJ, de Bruin M, Kelly MP, et al. From Theory-Inspired to Theory-Based Interventions: A Protocol for Developing and Testing a Methodology for Linking Behaviour Change Techniques to Theoretical Mechanisms of Action. Annals of Behavioral Medicine. 2017;52(6):501-12.
4. Proctor EK, Powell BJ, McMillen JC. Implementation strategies: recommendations for specifying and reporting. Implement Sci. 2013;8:139.
5. Powell BJ, Fernandez ME, Williams NJ, Aarons GA, Beidas RS, Lewis CC, et al. Enhancing the Impact of Implementation Strategies in Healthcare: A Research Agenda. Frontiers in Public Health. 2019;7:3.
6. Powell BJ, Waltz TJ, Chinman MJ, Damschroder LJ, Smith JL, Matthieu MM, et al. A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. Implement Sci. 2015;10:21.
7. Waltz TJ, Powell BJ, Matthieu MM, Damschroder LJ, Chinman MJ, Smith JL, et al. Use of concept mapping to characterize relationships among implementation strategies and assess their feasibility and importance: results from the Expert Recommendations for Implementing Change (ERIC) study. Implement Sci. 2015;10:109.
8. Williams NJ. Multilevel mechanisms of implementation strategies in mental health: integrating theory, research, and practice. Adm Policy Ment Health. 2016;43(5):783-98.
9. Lewis CC, Boyd MR, Walsh-Bailey C, Lyon AR, Beidas R, Mittman B, et al. A systematic review of empirical studies examining mechanisms of implementation in health. Implement Sci. 2020;15(1):21.
10. Hill AB. The Environment and Disease: Association or Causation? Proc R Soc Med. 1965;58:295-300.
11. Smith S, Johnson L, Wesley D, Turner KB, McCray G, Sheats J, et al. Translation to practice of an intervention to promote colorectal cancer screening among African Americans. Clin Transl Sci. 2012;5(5):412-5.
12. Shelton RC, Chambers DA, Glasgow RE. An Extension of RE-AIM to Enhance Sustainability: Addressing Dynamic Context and Promoting Health Equity Over Time. Front Public Health. 2020;8:134.
13. Institute PCOR. PCORI standards for studies of complex interventions. 2019.
14. Perez Jolles M, Lengnick-Hall R, Mittman BS. Core functions and forms of complex health interventions: A patient-centered medical home illustration. J Gen Intern Med. 2019;34:1032-8.
15. Bosch M, Van Der Weijden T, Wensing M, Grol R. Tailoring quality improvement interventions to identified barriers: a multiple case analysis. J Eval Clin Pract. 2007;13(2):161-8.
16. Baker R, Camosso-Stefinovic J, Gillies C, Shaw EJ, Cheater F, Flottorp S, et al. Tailored interventions to address determinants of practice. Cochrane Database Syst Rev. 2015(4).
17. Wensing M. The Tailored Implementation in Chronic Diseases (TICD) project: introduction and main findings. Implement Sci. 2017;12(1):5.
18. Bird KA, Castleman BL, Denning JT, Goodman J, Lamberton C, Rosinger KO. Nudging at scale: Experimental evidence from FAFSA completion campaigns. Journal of Economic Behavior and Organization. 2021;183:105–28.

19. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. British Medical Journal. 2014;348.

20. Bragge P, Grimshaw JM, Lokker C, Colquhoun H, Group AWW. AIMD - a validated, simplified framework of interventions to promote and integrate evidence into health practices, systems, and policies. BMC Medical Research Methodology. 2017;17(1):38.

21. Brownson RC, Colditz GA, Proctor EK. Implementation science in health care. In: Brownson RC, Colditz GA, Proctor EK, editors. Dissemination and implementation research in health; Translating science to practice. 2nd edition ed. New York: Oxford University Press; 2018. p. 385–400.

22. Forman J, Damschroder L. Qualitative content analysis. In: Jacoby L, Siminoff LA, editors. Empirical methods for bioethics: A primer. 11. Amsterdam, NL: Elseivier; 2008. p. 39-62.

23. Trochim W, Kane M. Concept mapping: an introduction to structured conceptualization in health care. Int J Qual Health Care. 2005;17(3):187-91.

24. Van de Ven AH, Delbecq AL. The nominal group as a research instrument for exploratory health studies. Am J Public Health. 1972;62(3):337-42.

25. Lewis CC, Stanick C, Lyon A, Darnell D, Locke J, Puspitasari A, et al. Proceedings of the Fourth Biennial Conference of the Society for Implementation Research Collaboration (SIRC) 2017: implementation mechanisms: what makes implementation work and why? part 1. Implement Sci. 2018;13(2):30.

26. Landes SJ, Kerns SEU, Pilar MR, Walsh-Bailey C, Yu SH, Byeon YV, et al. Proceedings of the Fifth Biennial Conference of the Society for Implementation Research Collaboration (SIRC) 2019: where the rubber meets the road: the intersection of research, policy, and practice - part 1. Implement Sci. 2020;15(Suppl 3):76.

27. Collaboration SFIR. Mechanisms network of expertise 2021 [Available from: https://societyforimplementationresearchcollaboration.org/mechanisms-network-of-expertise/.

28. Hayes AF, Preacher KJ. Quantifying and Testing Indirect Effects in Simple Mediation Models When the Constituent Paths Are Nonlinear. Multivariate Behav Res. 2010;45(4):627-60.

29. Williams NJ, Glisson C, Hemmelgarn A, Green P. Mechanisms of Change in the ARC Organizational Strategy: Increasing Mental Health Clinicians' EBP Adoption Through Improved Organizational Culture and Capacity. Adm Policy Ment Health. 2017;44(2):269-83.

30. Proctor E, Silmere H, Raghavan R, Hovmand P, Aarons G, Buenger A, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. Adm Policy Ment Health. 2011;38(2):65-76.

31. Marriott BR, Rodriguez AL, Landes SJ, Lewis CC, Comtois KA. A methodology for enhancing implementation science proposals: comparison of face-to-face versus virtual workshops. Implement Sci. 2016;11:62.

32. PsychoSocial Aspects of Diabetes Group. Behavioral Research in Diabetes Group Exchange [cited 2020 Oct 1]. Available from: http://www.psad-easd.eu/bridge/.

33. Implementation Research Institute 2021 [Available from: https://iristl.org.
34. Proctor EK, Landsverk J, Baumann AA, Mittman BS, Aarons GA, Brownson RC, et al. The implementation research institute: training mental health implementation researchers in the United States. Implement Sci. 2013;8:105.
35. Landsverk J, Proctor EK. From Research Training to Scientific Advancement-Contributions from the Implementation Research Institute: An Introduction to the Special Issue. Adm Policy Ment Health. 2020;47(2):169-75.
36. Chambers D, Williams N, Lewis CC. Setting the stage for understanding mechanisms of implementation. 2019.
37. Collaboration SfIR. Proceedings of the Fifth Biennial Conference of the Society for Implementation Research Collaboration (SIRC) 2019: Where the rubber meets the road: The intersection of research, policy, and practice - Part 2. Implementation Science : IS. 2020;15(Suppl 2)(2):1-85.
38. Quality AfHRa. Priority populations 2021 [Available from: https://www.ahrq.gov/priority-populations/index.html.
39. Tabak RG, Khoong EC, Chambers DA, Brownson RC. Bridging research and practice: models for dissemination and implementation research. Am J Prev Med. 2012;43(3):337-50.
40. Damschroder LJ, Aron D, Keith R, Kirsh S, Alexander J, Lowery J. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci. 2009;4:50.
41. Bernard HR. Research methods in anthropology: Qualitative and quantitative approaches. 5th edition ed. Lanham, Maryland: AltaMira Press; 2011.
42. Krippendorff K. Content analysis: An introduction to its methodology. 2nd edition ed. Thousand Oaks, CA: Sage Publications; 2003.
43. Kane M, Trochim W. Concept mapping for planning and evaluation Thousand Oaks, CA: Sage; 2007.
44. Rosas SR, Kane M. Quality and rigor of the concept mapping methodology: a pooled study analysis. Eval Program Plann. 2012;35(2):236-45.
45. Powell BJ, Stanick CF, Halko HM, Dorsey CN, Weiner BJ, Barwick MA, et al. Toward criteria for pragmatic measurement in implementation research and practice: a stakeholder-driven approach using concept mapping. Implement Sci. 2017;12(1):118.
46. Aarons GA, Wells RS, Zagursky K, Fettes DL, Palinkas LA. Implementing evidence-based practice in community mental health agencies: a multiple stakeholder analysis. Am J Public Health. 2009;99(11):2087-95.
47. Lobb R, Pinto AD, Lofsters A. Using concept mapping in the knowledge-to-action process to compare stakeholder opinions on barriers to use of cancer screening among South Asians. Implement Sci. 2013;8:37.
48. Tabak RG, Padek MM, Kerner JF, Stange KC, Proctor EK, Dobbins MJ, et al. Dissemination and Implementation Science Training Needs: Insights From Practitioners and Researchers. Am J Prev Med. 2017;52(3 Suppl 3):S322-S9.
49. Proctor E, Luke D, Calhoun A, McMullen C, Brownson R, McCrary S, et al. Sustainability of evidence-based healthcare: research agenda, methodological advances, and infrastructure support. Implement Sci. 2015;10(1):88.
50. Concept Systems Inc. groupwisdom. 2021.
51. Trochim W. Reliability Sydney, Australia: Conjoint.ly; 2020 [Available from: https://conjointly.com/kb/measurement-reliability/.
52. Weiner BJ, Lewis MA, Clauser SB, Stitzenberg KB. In search of synergy: strategies for combining interventions at multiple levels. J Natl Cancer Inst Monogr. 2012;2012(44):34-41.
53. Baumann AA, Cabassa LJ. Reframing implementation science to address inequities in healthcare delivery. BMC Health Serv Res. 2020;20(1):190.
## Standards for Reporting Implementation Studies: the StaRI checklist for completion

The StaRI standard should be referenced as: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths CJ, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor SJC for the StaRI Group. Standards for Reporting Implementation Studies (StaRI) statement. *BMJ* 2017;356:i6795

The detailed Explanation and Elaboration document, which provides the rationale and exemplar text for all these items is: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths C, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor S, for the StaRI group. Standards for Reporting Implementation Studies (StaRI). *BMJ Open* 2017;7:e013318

Notes: A key concept of the StaRI standards is the dual strands of describing, on the one hand, the implementation strategy and, on the other, the clinical, healthcare, or public health intervention that is being implemented. These strands are represented as two columns in the checklist.

The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed. The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations.

The StaRI standards refers to the broad range of study designs employed in implementation science. Authors should refer to other reporting standards for advice on reporting specific methodological features. Conversely, whilst all items are worthy of consideration, not all items will be applicable to, or feasible within every study.

| Checklist item | Implementation Strategy | Intervention |
|----------------|-------------------------|--------------|
| **Title and abstract** | | |
| Title | **Implementation strategy** refers to how the intervention was implemented | **Intervention** refers to the healthcare or public health intervention that is being implemented. |
| Abstract | | |
| Introduction | | |
| Introduction | Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address. | |
| Rationale | The scientific background and rationale for the implementation strategy (including any underpinning theory/framework/model, how it is expected to achieve its effects and any pilot work). | The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects). |
| Aims and objectives | 5 | 7 | The aims of the study, differentiating between implementation objectives and any intervention objectives. |
|---------------------|---|---|--------------------------------------------------------------------------------|

### Methods: description

| Design | 6 | 7-19 | The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons |
|--------|---|------|----------------------------------------------------------------------------------------------------------------------------------|
| Context | 7 | NA | The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere). |
| Targeted ‘sites’ | 8 | NA | The characteristics of the targeted ‘site(s)’ (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria. | The population targeted by the intervention and any eligibility criteria. |
| Description | 9 | NA | A description of the implementation strategy | A description of the intervention |
| Sub-groups | 10 | NA | Any sub-groups recruited for additional research tasks, and/or nested studies are described |

### Methods: evaluation

| Outcomes | 11 | NA | Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets | Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets |
|----------|---|---|--------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| Process evaluation | 12 | NA | Process evaluation objectives and outcomes related to the mechanism by which the strategy is expected to work |
| Economic evaluation | 13 | NA | Methods for resource use, costs, economic outcomes and analysis for the implementation strategy | Methods for resource use, costs, economic outcomes and analysis for the intervention |
| Sample size | 14 | NA | Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate) |
| Analysis | 15 | NA | Methods of analysis (with reasons for that choice) |
| Sub-group analyses | 16 | NA | Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks |

### Results
| Characteristics | 17 | NA | Proportion recruited and characteristics of the recipient population for the implementation strategy | Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention |
|-----------------|----|----|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|
| Outcomes        | 18 | NA | Primary and other outcome(s) of the implementation strategy                                     | Primary and other outcome(s) of the Intervention (if assessed)                                   |
| Process outcomes| 19 | NA | Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work |                                                                                                 |
| Economic evaluation | 20 | NA | Resource use, costs, economic outcomes and analysis for the implementation strategy              | Resource use, costs, economic outcomes and analysis for the intervention                          |
| Sub-group analyses | 21 | NA | Representativeness and outcomes of subgroups including those recruited to specific research tasks |                                                                                                 |
| Fidelity/adaptation | 22 | NA | Fidelity to implementation strategy as planned and adaptation to suit context and preferences    | Fidelity to delivering the core components of intervention (where measured)                       |
| Contextual changes | 23 | NA |                                                                                                 | Contextual changes (if any) which may have affected outcomes                                     |
| Harms           | 24 | NA |                                                                                                 | All important harms or unintended effects in each group                                          |

**Discussion**

| Structured discussion | 25 | NA | Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications |                                                                                                 |
|-----------------------|----|----|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|
| Implications          | 26 | NA | Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability) | Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability) |

**General**

| Statements | 27 | NA | Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest |                                                                                                 |
Advancing Mechanisms of Implementation to Accelerate Sustainable Evidence-Based Practice Integration: Protocol for Generating a Research Agenda

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Advancing Mechanisms of Implementation to Accelerate Sustainable Evidence-Based Practice Integration: Protocol for Generating a Research Agenda

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Abstract

Introduction: Mechanisms explain how implementation strategies work. Implementation research requires careful operationalization and empirical study of the causal pathway(s) by which strategies effect change, and factors that may amplify or weaken their effects. Understanding mechanisms is critically important to replicate findings, learn from negative studies, or adapt an implementation strategy developed in one setting to another. Without understanding implementation mechanisms, it is difficult to design strategies to produce expected effects across contexts, which may have disproportionate effects on settings in which priority populations receive care. This manuscript outlines the protocol for an Agency for Healthcare Research and Quality-funded initiative to: (1) establish priorities for an agenda to guide research on implementation mechanisms in health and public health, and (2) disseminate the agenda to research, policy, and practice audiences.

Methods and Analysis: A network of scientific experts will convene in “Deep Dive” meetings across three years. A research agenda will be generated through analysis and synthesis of information from six sources: (1) systematic reviews, (2) network members’ approaches to studying mechanisms, (3) new proposals presented in implementation proposal feedback sessions, (4) working group sessions conducted in a leading implementation research training institute, (5) breakout sessions at the Society for Implementation Research Collaboration’s (SIRC) 2019 conference, and (6) SIRC conference abstracts. Two members will extract mechanism-relevant text segments from each data source and a third member will generate statements as an input for concept mapping. Concept mapping will generate unique clusters of challenges, and the network will engage in a nominal group process to identify priorities for the research agenda.
**Ethics and Dissemination:** This initiative will yield an actionable research agenda to guide research to identify and test mechanisms of change for implementation strategies. The agenda will be disseminated via multiple channels to solicit feedback and promote rigorous research on implementation mechanisms.

**Keywords:** Implementation Research, Implementation Strategies, Mechanisms, Healthcare, Public Health

**Strengths and Limitations of this Study**

- This study will synthesize multiple data sources to uncover key challenges to studying implementation mechanisms
- This study will yield a research agenda outlining challenges, priorities, and activities that will advance the study of implementation mechanisms
- This study will disseminate a mechanisms-focused research agenda for implementation science and invite international feedback
- The generation of this research agenda is largely informed by stakeholders from the United States, potentially limiting its relevance internationally; however, the network has been expanded to obtain global perspectives
- Given the focus on advancing research methods, stakeholder engagement in this effort focuses primarily upon researchers, limiting opportunities for patients and policy makers to inform the research agenda
Mechanisms and What We Know About Them in Implementation Science

Mechanisms are broadly defined as processes that are responsible for change [1]. Defining, testing, and establishing mechanisms is increasingly a priority across fields of study where biological, psychological, or social intervention or behavior change is the focus [2,3]. In the context of implementation science, mechanisms explain how or why implementation strategies exert their effects on outcomes [4]. Implementation strategies are defined as methods used to facilitate the adoption, implementation, sustainment, or scale-up of evidence-based practices (EBPs) [5,6]. While over 70 implementation strategies have been identified and defined for use in healthcare settings [7,8], we know little about the mechanisms through which these strategies generate change [9,10]. A recent systematic review of implementation mechanisms in health identified 46 studies assessing mechanisms [9]. The majority of studies were not designed to formally establish implementation mechanisms per recommended criteria [1,11]. In an earlier systematic review of nine randomized implementation trials, Williams [10] observed similar methodological deficiencies, and no trials supported a hypothesized mediator. Both reviews identified numerous challenges impeding the study of mechanisms in implementation science, including conceptual (e.g., lack of harmony in defining constructs and their roles), theoretical (i.e., few theories exist), methodological (e.g., poor quality measures, design challenges), and practical (e.g., difficult to power studies for mediation analyses) challenges. More work is needed to identify barriers to identifying and testing mechanisms in implementation science and to propose concrete, actionable steps to overcome these barriers.

The Impact of Limited Implementation Mechanisms Research on Achieving Health Equity

Insufficient understanding of implementation mechanisms stymies the field. First, it hinders efforts to systematically design and tailor implementation strategies to meet the needs of
heterogeneous contexts and stakeholders. Second, it limits our ability to learn from negative studies and to replicate positive findings. Third, it prevents the successful adaptation of an implementation strategy developed in one setting to another. These difficulties weaken implementation effectiveness and efficiency and can exacerbate health disparities when implementation efforts are poorly adapted for safety net and other settings where under-served populations are found [12]. Eliminating health disparities may require careful design and tailoring of implementation strategies to the unique circumstances and needs of specific priority populations and the contexts in which they receive care. For example, a clinic may begin to offer a new EBP with fidelity, but social factors (e.g., access to transportation, childcare) might need to be addressed through provider- and patient-focused implementation strategies (e.g., via telehealth) to improve “reach” [13]. Contexts serving priority populations might not respond to certain implementation strategies, such as external consultation, or be able to afford robust strategies, such as practice facilitation. A fundamental understanding of implementation mechanisms will enable implementers to design and, as necessary, tailor implementation strategies to locally relevant determinants while retaining their core function [14,15].

**Developing and Disseminating a Research Agenda: Conference Series Aims**

Given ongoing challenges associated with delivering and tailoring implementation strategies previously found to be effective [16–19], research reporting guidelines emphasize the need to justify the selection of specific implementation strategies [5,20,21]. This requires identifying the barrier(s) to be addressed and the selected strategy’s mechanism of action. Table 1 provides examples of how strategies may work to address determinants and influence specific implementation outcomes. Identifying the mechanisms through which implementation strategies
exert their effects, rather than focusing solely on whether or not they are effective, is an important step forward for the field of implementation science [6,22].

Accordingly, we are undertaking an initiative to advance the study of mechanisms of implementation strategies in healthcare and public health. We will conduct a 3-year meeting series with between-meeting activities designed to achieve two aims: (1) establish priorities to guide a research agenda on implementation mechanisms, and (2) actively disseminate the research agenda to research, policy, and practice audiences. This protocol outlines our plans to engage a network of experts to produce detailed guidance and identify research approaches and tools needed to study mechanisms of implementation strategies and whether they vary with respect to target problems, EBPs, priority populations, and contexts. Ultimately, the research and practice efforts guided by this agenda may be more actionable, practical, and equitable given their clear focus on mechanisms.

Methods

A variety of methods will be used to identify challenges, priorities, and activities related to the study of implementation mechanisms, drawing upon data from numerous sources. The methods include qualitative content analysis [23], which will generate the inputs for concept mapping [24], followed by nominal group technique [25] to prioritize the research agenda. Table 2 provides an overview of the steps of developing the research agenda, which are described in more detail below.

Step 1: Partnership with the Society for Implementation Research Collaboration (SIRC)

In 2017, SIRC hosted its 4th biennial conference with the following theme: “Implementation Mechanisms: What Makes Implementation Work and Why?” [26]. This conference was inspired by the realization that the field of implementation science was in a
position to pivot from characterizing implementation efforts (e.g., qualitative exploration of barriers and facilitators) and evaluating the general effectiveness of strategies (i.e., empirical treatment approach) to examining the causal mechanisms by which strategies achieve their effects. Given SIRC’s commitment to this work and its engaged global membership [27], we partnered with them to pursue funding from the Agency for Healthcare Research and Quality (AHRQ) to shape the developing agenda. In addition to leveraging several SIRC activities as inputs for our research agenda, we will conclude our meeting series in collaboration with SIRC in 2022, where we will disseminate the agenda and invite feedback from attendees. A summary of our proposed work can be found on the SIRC website [28].

**Step 2: Mechanisms Network of Expertise**

In preparing this proposal, we convened 26 implementation scientists from the United States to form a Mechanisms Network of Expertise (MNoE). We have expanded the MNoE to over 40 individuals to include international experts and early career researchers, and plan to continue to do so as this work progresses. This network approach allows us to leverage the collective wisdom of key stakeholders who have been contributing to the study of implementation mechanisms and to engage in a collaborative immersion across three years to achieve our aims. By convening the MNoE regularly, roughly quarterly in virtual meetings, and annually for Deep Dive retreats, we will be able to develop a shared understanding, build momentum, and generate products for the larger field to apply and refine. We intend for the MNoE to represent expertise in studying implementation mechanisms and to display diversity across several dimensions (e.g., geography, gender, race/ethnicity, work with priority populations, settings in which they worked). In the initial phases, the MNoE will be organized into four workgroups that will focus initial network activities: (1) Measurement; (2) Design and...
Analysis; (3) Causal Theory and Context; and (4) Strategy, Mechanism, Outcome linkages [28].

However, we plan to reorganize the workgroups into the conceptually distinct areas of the research agenda that emerge from the concept mapping work described below.

**Patient and Public Involvement**

This effort is primarily focused on challenges and opportunities related to research methods; thus, the primary stakeholder involvement in this effort is from healthcare researchers and there is no explicit patient or public involvement. Many members of the MNoE have experience not only as researchers, but as clinicians and patients. Moreover, there will be opportunities for individuals with a diverse array of experiences to provide input to the research agenda (e.g., the SIRC breakout sessions) and respond to initial iterations (e.g., see Steps 6 & 7 below).

**Step 3: Identifying Challenges Across Six Data Sources**

In collaboration with the MNoE, we will synthesize information from six sources to inform the research agenda. This broad sourcing will ensure that the agenda is grounded in the empirical literature, informed by SIRC’s global membership, and curated by our MNoE. Table 3 provides an overview of the six sources and offers examples of the types of research agenda items we might obtain from each. We believe the selected sources allow for a systematic and relatively comprehensive approach to generating a research agenda; however, we note several limitations in the discussion.

**1) Systematic Reviews.** Our work will be informed by two systematic reviews of mechanisms in implementation. The only mechanisms-focused systematic review published prior to our grant funding focused on multilevel mechanisms of implementation strategies in the context of randomized-controlled trials in mental health [10]. That review included nine
randomized trials that formally tested mediators linking an implementation strategy to an implementation or clinical outcome. Mediation analysis is one quantitative approach to studying mechanisms in which the total effect of an implementation strategy on an outcome is divided into an indirect effect that occurs through a proposed mediating variable and a direct effect that is not explained by the mediating variable [29]. None of the trials provided sufficient evidence to support a plausible mediator primarily because there was no evidence that the implementation strategies changed the targeted mediating variables. This review also identified several issues in mediation studies of implementation strategies, including study designs that were not conducive to detecting a relationship between the implementation strategy and candidate mediator, insufficient measurement, and underuse or misuse of theory to link implementation strategies to outcomes. We will draw upon the findings of this review, including Williams’ [10] suggestions for future research when populating our research agenda. For instance, Williams [10] suggested investigating theory-informed constructs as potential mediators, improving theoretical links between implementation strategies and hypothesized mediators, enhancing study designs and analytical methods to detect and analyze mediators in multilevel contexts, and further study of implementation strategy change processes to better target candidate mechanisms.

A second systematic review conducted by several members of the MNoE built on Williams’ [10] work by expanding the scope to include implementation studies across health, a wide array of study designs, and the investigation of moderators [9]. This review included 46 studies (including the nine from Williams’ [10] review), and applied seven criteria for establishing a mechanism [1,11]: (i) strong associations between the implementation strategy and mechanism and between the mechanism and outcome, (ii) specificity (demonstration that one construct and not others influencing change), (iii) consistency (replication across studies), (iv)
experimental manipulation of the strategy or proposed mechanism, (v) timeline (change in mechanisms precede change in outcomes), (vi) gradient (dose-response relationship between level of mechanism and level of outcome), and (vii) plausibility/coherence (process-outcome relationship is reasonable or supported by other research). This review found only one study that met six criteria [30]; the vast majority of included studies (n=38) met three or fewer. Fewer than half of studies included an implementation strategy as the independent variable of interest. As with Williams [10], this review identified underuse of theory and overuse of study designs and analytical methods that do not afford the opportunity to establish mechanisms. We will draw upon the findings and suggestions from this review when generating the research agenda.

2) Matrix Mapping of Ongoing Research. To understand how members of the MNoE are studying mechanisms and to identify gaps in this area of inquiry, we will synthesize the data obtained from ~30 researchers in an online Matrix Mapping exercise. Matrix mapping allows members to report on recently completed and in-progress projects that include the study of mechanisms (e.g., mediation studies and other studies of implementation strategies), and for us to map, or identify, saturated versus thin areas of the matrix. To this end, the matrix is organized by the following: priority populations (coded using categories identified by AHRQ) [31], target problem (disease, disorder, symptom, or risk factor), EBP intended to improve target problem, context/setting in which the EBP was delivered, guiding theory or framework, implementation strategies, mechanism(s) under investigation (or hypothesized mechanisms), implementation outcome(s), study status (planned, in progress, or complete), and references for the project. The matrix will be coded using the Expert Recommendations for Implementing Change (ERIC) implementation strategies compilation [7,8] and the Implementation Outcomes Framework [32]. We will calculate frequencies and proportions of responses occurring in each category to
determine areas where there is representation (e.g., commonly used implementation strategies) and areas for which there are gaps (e.g., understudied implementation outcomes, dearth of interventions to improve the health of certain target populations) to inform the research agenda.

3) Implementation Development Workshop (IDW). The IDW is a half-day, pre-conference event that is regularly part of the biennial SIRC conference, in which SIRC Network of Expertise members (i.e., practitioners, students, new and established investigators) are invited to present “works in development” to receive expert feedback from colleagues (31). Based on the Behavioral Research in Diabetes Group Exchange model used by the Psycho-Social Aspects of Diabetes research group [33], the format includes 10-20 minutes for each presenter to orally (without technology) describe their project/proposal and 20-40 minutes for feedback coordinated by a facilitator. A note-taker records notes of the feedback so the presenter can be involved in the discussion. In 2019, 54 researchers and/or practitioners participated. Qualitative content analysis [23] of the notes reflecting each proposal discussion will serve as a third source for the research agenda to capture challenges and possibilities in the study of implementation mechanisms among a unique group of experts beyond the MNoE. That is, we will learn how mechanisms are being considered (if at all) in project proposals and uncover the challenges researchers face when considering mechanism evaluation.

4) Implementation Research Institute. The Implementation Research Institute [34] is a 2-year interdisciplinary training program funded by the U.S. National Institutes of Health that focuses on developing and nurturing a network of scholars who focus on researching the implementation of effective practices within the field of behavioral health [35,36]. Every summer features a week-long training institute in which fellows convene with core and expert faculty to engage with emerging issues in implementation science. Working sessions to advance
the field are often conducted and one focused specifically on challenges to studying implementation mechanisms will serve as our fourth data source. As a precursor to the exercise, a general overview of implementation strategy research was provided as well as specific content related to the concept of mechanisms (e.g., What is a mechanism? What do we know about mechanisms in implementation science?). Faculty (n = ~10) and fellows (n = ~20) were then split into three groups: 1) Theories, Frameworks, and Context, 2) Design and Analysis, and 3) Measurement. Each group considered two questions related to their focus area: 1) What are the major challenges to advancing our understanding of mechanisms?, and 2) What do you view as promising paths forward to advance our understanding of mechanisms? The groups were given 30 minutes to discuss and asked to assign one or more note-takers to document ideas. Following this exercise, each group reported their results to the larger group. We will use qualitative content analysis [23] to code the notes for unique challenges and opportunities to inform the research agenda.

5) SIRC Breakout Sessions. All SIRC 2019 conference attendees were invited to participate in two breakout sessions facilitated by investigative team members. These sessions were advertised as opportunities for the MNoE to learn from the experiences of global researchers, policy makers, practitioners, and intermediaries. To participate, attendees agreed to complete one hour of preparatory work, including viewing a recorded webinar and reviewing an overview handout. These requirements were set to ensure all attendees would enter the breakout with the same foundational knowledge (e.g., What is an implementation mechanism?) and to encourage active participation by breakout session attendees. Participants had the option of attending one or both breakout sessions (over 90 attendees attended each session), and they were informed that their input would be used to ultimately shape the research agenda.
The first breakout session focused on challenges of using theory to understand context and to inform the study of implementation strategies, mechanisms, and outcome linkages. It began with an introduction and discussion of the current landscape of implementation mechanisms and then moved to a conversation about key challenges and gaps associated with studying implementation mechanisms through the lens of the four workgroups. Attendees then split into four groups: (1) Causal Theory and Context; (2) Connections from Implementation Strategies to Mechanisms and Outcomes; (3) Design and Analysis; and (4) Measurement. Attendees were instructed to select the group that best fit their expertise or interests, and the majority of the session was spent in facilitated discussion. At the end of the breakout session, one member of each group presented a summary of their discussion to the larger group. Notetakers were embedded throughout to document and permit subsequent generation of challenges and opportunities relevant to the research agenda.

The second breakout session began with brief “stimulus talks” from the MNoE workgroup leads and a case study. The 3-minute stimulus talks and 13-minute case study focused on thorny issues related to the study of implementation mechanisms. Following these talks, as with the first breakout session, attendees separated into four groups: (1) Causal Theory and Context, (2) Connections from Implementation Strategies to Mechanisms and Outcomes, (3) Design & Analysis, and (4) Measurement. Participants spent most of the time discussing the case study through the lens of their workgroup’s topic area, coming together at the end of the session for summary discussion. Small group discussion was designed to elevate additional issues not raised in the presentations, and to use the case study to address the issues raised by the presenters through the lens of their workgroup. At the end of the breakout session, one member of each of the four workgroups presented a summary of their discussion to the larger group. Note-takers
were embedded throughout to allow for data extraction of qualitative data that could inform the research agenda. We will use qualitative content analysis [23] to mine the notes of these two breakout sessions to inform the research agenda.

6) SIRC abstracts. Our final source will be the 2019 presentations. The purpose of this input is to understand the extent to which implementation mechanisms were represented in the SIRC 2019 program [27], uncover gaps in the study of implementation mechanisms, and reveal exemplar studies that may not be yet captured in the published literature. All 205 abstracts from the 2019 SIRC conference program will be qualitatively coded for implementation mechanism-related content. If authors make mention of mechanisms (or mediators and moderators) in their abstract, the coder will record the mechanisms reported and the measurement method if available. Abstracts will also be coded for setting and project design; priority populations [31]; guiding theories/frameworks [37]; implementation strategies [7,8]; service outcomes, implementation outcomes, and clinical/client outcomes [32]; and barriers to implementation [38]. Abstract information will be entered into REDCap, and three coders will independently extract data from a random sample of abstracts with 5% coded by all three members of the team to assess for inter-rater reliability. The results of the abstract coding will directly inform the research agenda.

Step 4: Synthesizing & Prioritizing Challenges via Content Analysis and Concept Mapping

We will conduct qualitative content analysis [23] to code each of the six sources described above across two categories: (1) challenges in conducting mechanistic implementation science and (2) priorities for improving the study of implementation mechanisms. Data analysis will occur in three phases: immersion, reduction, and interpretation. During the immersion phase, study team members will obtain a sense of “the whole” before rearranging it into smaller
segments [23]. This will be accomplished by reviewing each of the six inputs described above to gain a better sense of these data. The reduction phase will involve condensing data into text segments by coding each of the six data sources. To increase reliability and reduce bias [39,40], two researchers will use an electronic spreadsheet to independently extract text segments that represent challenges or priorities related to studying implementation mechanisms. These coders will regularly debrief during project meetings to ensure a common frame of reference for each input and to discuss and resolve discrepancies. A third researcher will work with BJP and CCL to examine all extracted text segments to eliminate redundancies and ensure that each segment is worded clearly and concisely. Rather than identifying themes across text segments, each text segment describing challenges related to researching implementation mechanisms will be used in the concept mapping [24] study described below. This will generate conceptually distinct clusters of challenges that will need to be addressed to advance the field’s understanding of implementation mechanisms, and it will constitute the interpretation phase of the qualitative content analysis approach. Although coders will also extract possibilities or opportunities for the field, these will be tabled for consideration until the Deep Dive retreat when the results of the concept mapping are turned into an actionable research agenda.

The members of the MNoE will be engaged in a concept mapping study to further develop and refine the emerging research agenda to advance the study of mechanisms in implementation. Concept mapping is a structured process designed to organize concepts into conceptually distinct categories and to generate ratings of specified dimensions such as importance and feasibility. As noted by Powell et al. [41], concept mapping is particularly useful for structuring the ideas of diverse groups of stakeholders and has been leveraged by implementation researchers to identify and prioritize implementation barriers and facilitators
implementation strategies [8], training needs [44], dimensions of pragmatic measures [41], and an agenda for studying sustainability of EBPs [45]. Concept mapping is a mixed methods, multi-step approach that typically involves: the identification of specific statements through brainstorming or other sources, statement analysis and synthesis, statement rating, unstructured sorting of statements, multidimensional scaling and hierarchical cluster analysis, and the generation of interpretable maps and data displays. Concept mapping is described in more detail by Trochim and Kane [24] and Kane and Trochim [46].

The Concept mapping process will be completed via the Group Wisdom software platform [47]. Statement identification, analysis, and synthesis will occur via the consolidation of the six research agenda sources as described above. Statements describing challenges to advancing research on implementation mechanisms will entered into the Group Wisdom software platform. To ensure feasibility and to remain consistent with recommendations for the overall number of statements for concept mapping studies [48,49], we will keep the number of statements to approximately 100 statements or less. Members of the MNoE will then be invited to engage in the concept mapping study via the Group Wisdom platform [47]. MNoE members will be asked to complete a brief demographic survey and then be presented with the list of statements to engage in rating and sorting tasks (in any order they so choose). They will be asked to rate each statement on a 5-point Likert scale across two dimensions, including criticality (i.e., how important the challenge is to advancing the science and achieving health equity) and pervasiveness of the challenges. They will also be asked to sort each of the statements into piles or categories that make sense to them and will be given the opportunity to label each of the categories they create.
We will utilize multidimensional scaling to generate a point map depicting each of the statements and relationships between them based upon a summed square similarity matrix [46]. Statements that are sorted together more frequently will be placed closer together on the map. Model fit will be assessed using the stress value, an indication of goodness of fit between the point map and the total similarity matrix [46,49]. Hierarchical cluster analysis will be used to partition the point map into non-overlapping clusters [46]. We will convene the MNoE to consider a range of cluster solutions produced by the analysis to determine the number of clusters that best represents the core domains of our emerging research agenda. The Group Wisdom software platform [47] will aid in the labeling process by suggesting potential cluster labels based upon participant responses; however, the MNoE will engage in discussion to determine the names for each cluster in our final cluster map. Descriptive statistics of MNoE members’ ratings of criticality and pervasiveness will be presented at the statement and cluster levels.

**Step 5: Identifying Research Priorities via Nominal Group Technique**

The Deep Dive retreat will be focused on engaging the MNoE in small workgroups organized by the conceptually distinct clusters that emerged from the concept mapping. The workgroups will consider the discrete challenges in their cluster(s), examine how they are related, and reflect on their degree of criticality and pervasiveness. They will then engage in a facilitated nominal group process [25] to brainstorm broad priorities and specific activities for addressing each challenge. Nominal group process is a structured method of small-group discussion to reach consensus in problem-solving, idea generation, and priority setting [25]. Nominal group process brings structure to what is often described in vague terms in published reports as an “iterative process” for developing insights and exhausting the expertise of a group.
Once all challenges have been subjected to the nominal group process, the resulting opportunities and activities will be captured in a structured research agenda. The research agenda will be comprised of *challenges, priorities*, and *specific activities* that will be organized according to the clusters identified through the concept mapping study.

**Steps 6 & 7: Dissemination, Discovery & Refinement**

We will disseminate the research agenda via multiple channels to maximize reach to research, practice, and policy communities. This includes (but is not limited to) conference presentations, peer reviewed publications, webinars, policy briefs, and short video clips. For the research community, we will present our findings at multiple national and international conferences (e.g., SIRC 2022, AcademyHealth/NIH Conference on the Science of Dissemination and Implementation, etc.) and webinars (e.g., the U.S. Department of Veterans Affairs Health Services Research & Development Cyberseminar series). We will also publish a special issue or collection of peer reviewed articles, which will include commentaries and critiques from internationally renowned implementation scientists. For policy and practice audiences, we will develop policy briefs and short video clips for dissemination via the SIRC website, relevant listservs, and social media channels. Both the MNoE and SIRC 2022 attendees will have opportunities to inform the dissemination of the agenda to diverse research, policy, and practice communities internationally. These dissemination activities and the pursuit of the priorities outlined in the research agenda will inevitably lead to ongoing refinement as our understanding of implementation mechanisms deepens.

**Discussion**

Understanding how and why implementation strategies achieve their effects will enable stakeholders to deploy these strategies with more precision retaining their core functions, to
develop multifaceted and multilevel implementation strategies that combine component strategies in a synergistic manner [50], to systematically match strategies to high-priority determinants, and to tailor strategies to diverse and under-resourced contexts. This is particularly important as a means of addressing health disparities by ensuring that implementation efforts address social, political, and environmental factors that contribute to inequitable outcomes for underserved populations [51]. However, there are significant challenges to advancing the study of implementation mechanisms that cut across conceptual, methodological, analytical, and practical spaces. By partnering with SIRC, convening an MNoE, and hosting Deep Dive retreats, we will clarify these challenges and develop a research agenda that pairs challenges with priorities and activities that will advance the field.

We acknowledge several limitations to our planned approach. First, although we recently expanded our MNoE to include international members, we are primarily based in the United States, which may limit the relevance of our research agenda internationally where researchers and implementers may face different challenges or generate unique opportunities. We will continue to seek opportunities to obtain feedback from international experts in implementation research, practice, and policy by expanding our MNoE and by seeking international dissemination outlets that will afford the opportunity to receive feedback on the developing research agenda. Second, given the focus on advancing research methods, stakeholder engagement in this effort focuses primarily upon researchers. While we believe this is appropriate for our aims, it does limit opportunities for patients and policy makers to inform the research agenda. Finally, our sources are not exhaustive but are intended to capture diverse and expert perspectives, which may result in missed challenges and approaches that are important but not included in the six sources described above.
The development of this research agenda represents a tremendous opportunity to initiate international discourse about how we can develop more precise, scalable, and effective implementation strategies capable of improving the quality of health and social care delivery. We welcome input from the practice, policy, and research communities on the development and dissemination of this research agenda.
List of Abbreviations

AHRQ: Agency for Healthcare Research and Quality; EBP: evidence-based practice; ERIC: Expert Recommendations for Implementing Change; IDW: Implementation Development Workshop; MNoE: Mechanisms Network of Expertise; SIRC: Society for Implementation Research Collaboration

Declarations

Ethics Approval and Consent to Participate
Not applicable.

Consent for Publication
Not applicable.

Availability of Data and Materials
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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Authors' contributions
CCL, BJP, GAA, RB, ARL, BJW, NW, and BM all contributed to the design and conceptualization of the protocol. SKB, AMN, SFV, SHS, and CWB contributed to the conceptualization, design, and execution of the data sources. CCL drafted the majority of the
introduction and discussion. BJP drafted content throughout the manuscript, but primarily contributed to the methods section. SKB, AMN, SFV, SHS, and CWB each drafted paragraphs of the Method section. GAA, RB, ARL, BJW, NW, and BM all reviewed and heavily edited an early draft of the manuscript. All authors reviewed and approved the final version.

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References

1 Kazdin AE. Mediators and mechanisms of change in psychotherapy research. *Annual Review of Clinical Psychology* 2007;3:1–27. doi:10.1146/annurev.clinpsy.3.022806.091432

2 Reiss D, Price RH. National research agenda for prevention research: The National Institute of Mental Health report. *American Psychologist* 1996;51:1109–15. doi:10.1037/0003-066X.51.11.1109

3 Michie S, Carey RN, Johnston M, *et al.* From theory-inspired to theory-based interventions: A protocol for developing and testing a methodology for linking behaviour change techniques to theoretical mechanisms of action. *Annals of Behavioral Medicine* 2018;52:501–12. doi:10.1007/s12160-016-9816-6

4 Lewis CC, Klasnja P, Powell BJ, *et al.* From classification to causality: Advancing Understanding of Mechanisms of change in implementation science. *Frontiers in Public Health* 2018;6:1–6. doi:10.3389/fpubh.2018.00136

5 Proctor EK, Powell BJ, McMillen JC. Implementation strategies: Recommendations for specifying and reporting. *Implementation Science* 2013;8:1–11. doi:10.1186/1748-5908-8-139

6 Powell BJ, Fernandez ME, Williams NJ, *et al.* Enhancing the impact of implementation strategies in healthcare: A research agenda. *Frontiers in Public Health* 2019;7:1–9. doi:10.3389/fpubh.2019.00003

7 Powell BJ, Waltz TJ, Chinman MJ, *et al.* A refined compilation of implementation strategies: Results from the Expert Recommendations for Implementing Change (ERIC) project. *Implementation Science* 2015;10:1–14. doi:10.1186/s13012-015-0209-1

8 Waltz TJ, Powell BJ, Matthieu MM, *et al.* Use of concept mapping to characterize relationships among implementation strategies and assess their feasibility and importance: Results from the Expert Recommendations for Implementing Change (ERIC) study. *Implementation Science* 2015;10:1–8. doi:10.1186/s13012-015-0295-0

9 Lewis CC, Boyd MR, Walsh-Bailey C, *et al.* A systematic review of empirical studies examining mechanisms of implementation in health. *Implementation Science* 2020;15:1–25.

10 Williams NJ. Multilevel mechanisms of implementation strategies in mental health: Integrating theory, research, and practice. *Administration and Policy in Mental Health and Mental Health Services Research* 2016;43:783–98. doi:10.1007/s10488-015-0693-2

11 Hill AB. The environment and disease: Association or causation? *Association or causation? Proceedings of the Royal Society of Medicine* 1965;58:295–300.

12 Smith S, Johnson L, Wesley D, *et al.* Translation to practice of an intervention to promote colorectal cancer screening among African Americans. *Clinical and Translational Science* 2012;5:412–5. doi:10.1111/j.1752-8062.2012.00439.x
13 Shelton RC, Chambers DA, Glasgow RE. An extension of RE-AIM to enhance sustainability: Addressing dynamic context and promoting health equity over time. *Frontiers in Public Health* 2020;8:1–8.

14 Patient Centered Outcomes Research Institute. PCORI standards for studies of complex interventions. 2019.https://www.pcori.org/research-results/about-our-research/research-methodology/pcori-methodology-standards#Complex (accessed 16 Mar 2019).

15 Perez Jolles M, Lengnick-Hall R, Mittman BS. Core functions and forms of complex health interventions: A patient-centered medical home illustration. *Journal of General Internal Medicine* 2019;34:1032–8. doi:10.1007/s11606-018-4818-7

16 Bosch M, van der Weijden T, Wensing M, *et al.* Tailoring quality improvement interventions to identified barriers: A multiple case analysis. *Journal of Evaluation in Clinical Practice* 2007;13:161–8. doi:10.1111/j.1365-2753.2006.00660.x

17 Baker R, Comosso-Stefinovic J, Gillies C, *et al.* Tailored interventions to address determinants of practice. *Cochrane Database of Systematic Reviews* 2015;4:1–118. doi:10.1002/14651858.CD005470.pub3

18 Wensing M. The Tailored Implementation in Chronic Diseases (TICD) project: Introduction and main findings. *Implementation Science* 2017;12:1–4. doi:10.1186/s13012-016-0536-x

19 Bird KA, Castleman BL, Denning JT, *et al.* Nudging at scale: Experimental evidence from FAFSA completion campaigns. *Journal of Economic Behavior and Organization* 2021;183:104–28.

20 Hoffman TC, Glasziou PP, Boutron I, *et al.* Better reporting of interventions: Template for intervention description and replication (TIDieR) checklist and guide. *BMJ* 2014;348:1–12. doi:10.1136/bmj.g1687

21 Bragge P, Grimshaw JM, Lokker C, *et al.* AIMD - a validated, simplified framework of interventions to promote and integrate evidence into health practices, systems, and policies. *BMC Medical Research Methodology* 2017;17:1–11. doi:10.1186/s12874-017-0314-8

22 Hamilton AB, Mittman BS. Implementation science in health care. In: Brownson RC, Colditz GA, Proctor EK, eds. *Dissemination and implementation research in health: Translating science to practice*. New York: : Oxford University Press 2018. 385–400.

23 Forman J, Damschroder L. Qualitative content analysis. In: Jacoby L, Siminoff LA, eds. *Empirical methods for bioethics: A primer*. Amsterdam: : Elsevier 2008. 39–62.

24 Trochim WMK, Kane M. Concept mapping: An introduction to structured conceptualization in health care. *International Journal for Quality in Health Care* 2005;17:187–91. doi:10.1093/intqhc/mzi038
25 Van de Ven AH, Delbecq AL. The nominal group as a research instrument for exploratory health studies. *American Journal of Public Health* 1972;**62**:337–42.

26 Lewis CC, Stanick C, Lyon A, *et al.* Proceedings of the Fourth Biennial Conference of the Society for Implementation Research Collaboration (SIRC) 2017: implementation mechanisms: what makes implementation work and why? part 1. *Implementation Science* 2018;**13**(Suppl 2):1–5. doi:10.1186/s13012-018-0714-0

27 Landes SJ, Kerns SEU, Pilar MR, *et al.* Proceedings of the Fifth Biennial Conference of the Society for Implementation Research Collaboration (SIRC) 2019: where the rubber meets the road: the intersection of research, policy, and practice - part 1. *Implementation Science* 2020;**15**(Suppl 3):1–5. doi:10.1186/s13012-020-01034-7

28 Society for Implementation Research Collaboration. Mechanisms Network of Expertise. 2021.https://societyforimplementationresearchcollaboration.org/mechanisms-network-of-expertise/ (accessed 20 Aug 2021).

29 Hayes AF, Preacher KJ. Quantifying and testing indirect effects in simple mediation models when the constituent paths are nonlinear. *Multivariate Behavioral Research* 2010;**45**:627–60.

30 Williams NJ, Glisson C, Hemmelgarn A, *et al.* Mechanisms of change in the ARC organizational strategy: Increasing mental health clinicians’ EBP adoption through improved organizational culture and capacity. *Administration and Policy in Mental Health and Mental Health Services Research* 2017;**44**:269–83.

31 Agency for Healthcare Research and Quality. Priority populations. 2021.https://www.ahrq.gov/priority-populations/index.html (accessed 20 Aug 2021).

32 Proctor EK, Silmere H, Raghavan R, *et al.* Outcomes for implementation research: Conceptual distinctions, measurement challenges, and research agenda. *Administration and Policy in Mental Health and Mental Health Services Research* 2011;**38**:65–76. doi:10.1007/s10488-010-0319-7

33 PsychoSocial Aspects of Diabetes Group. Behavioral Research in Diabetes Group Exchange. http://www.psad-easd.eu/bridge/ (accessed 11 Feb 2021).

34 Implementation Research Institute. 2021.https://iristl.org (accessed 20 Aug 2021).

35 Proctor EK, Landsverk J, Baumann AA, *et al.* The Implementation Research Institute: Training mental health implementation researchers in the United States. *Implementation Science* 2013;**8**:1–12. doi:10.1186/1748-5908-8-105

36 Landsverk J, Proctor EK. From research training to scientific advancement: Contributions from the Implementation Research Institute: An introduction to the special issue. *Administration and Policy in Mental Health and Mental Health Services Research* 2020;**47**:169–75.
37 Tabak RG, Khoong EC, Chambers DA, et al. Bridging research and practice: Models for dissemination and implementation research. *American Journal of Preventive Medicine* 2012;43:337–50. doi:10.1016/j.amepre.2012.05.024

38 Damschroder LJ, Aron DC, Keith RE, et al. Fostering implementation of health services research findings into practice: A consolidated framework for advancing implementation science. *Implementation Science* 2009;4:1–15.

39 Bernard HR. *Research methods in anthropology: Qualitative and quantitative approaches*. 5th ed. Lanham, Maryland: AltaMira Press 2011.

40 Krippendorff K. *Content analysis: An introduction to its methodology*. 2nd ed. Thousand Oaks, CA: Sage Publications 2003.

41 Powell BJ, Stanick CF, Halko HM, et al. Toward criteria for pragmatic measurement in research and practice: A stakeholder-driven approach using concept mapping. *Implementation Science* 2017;12:1–7. doi:10.1186/s13012-017-0649-x

42 Aarons GA, Wells RS, Zagursky K, et al. Implementing evidence-based practice in community mental health agencies: A multiple stakeholder analysis. *American Journal of Public Health* 2009;99:2087–95. doi:10.2105/AJPH.2009.161711

43 Lobb R, Pinto AD, Lofters A. Using concept mapping in the knowledge-to-action process to compare stakeholder opinions on barriers to use of cancer screening among South Asians. *Implementation Science* 2013;8:1–12. doi:10.1186/1748-5908-8-37

44 Tabak RG, Padek MM, Kerner JF, et al. Dissemination and implementation science training needs: Insights from practitioners and researchers. *American Journal of Preventive Medicine* 2017;52:S322–9. doi:10.1016/j.amepre.2016.10.005

45 Proctor EK, Luke D, Calhoun A, et al. Sustainability of evidence-based healthcare: research agenda, methodological advances, and infrastructure support. *Implementation Science* 2015;10:1–13. doi:10.1186/s13012-015-0274-5

46 Kane M, Trochim WMK. *Concept mapping for planning and evaluation*. Thousand Oaks, CA: Sage 2007.

47 Concept Systems Incorporated. groupwisdom. 2021.https://groupwisdom.com

48 Trochim WMK. The reliability of concept mapping. Dallas, Texas: 1993. http://www.socialresearchmethods.net/research/Reliable/reliable.htm

49 Rosas SR, Kane M. Quality and rigor of the concept mapping methodology: A pooled study analysis. *Quality and rigor of the concept mapping methodology: A pooled study analysis* 2012;35:236–45.
50 Weiner BJ, Lewis MA, Clauser SB, et al. In search of synergy: Strategies for combining interventions at multiple levels. *JNCI Monographs* 2012;44:34–41. doi:10.1093/jncimonographs/lgs001

51 Baumann AA, Cabassa LJ. Reframing implementation science to address inequities in healthcare delivery. *BMC Health Services Research* 2020;20:1–9. doi:10.1186/s12913-020-4975-3
## Table 1. Examples of Links Between Determinants, Implementation Strategies, Mechanisms, and Implementation Outcomes

| Determinant                        | Implementation Strategy                                      | Mechanism                                         | Implementation Outcome                        |
|-----------------------------------|-------------------------------------------------------------|---------------------------------------------------|-----------------------------------------------|
| Provider knowledge deficit        | Education (provision of information)                        | Awareness-building, knowledge-acquisition         | Feasibility, acceptability, appropriateness, adoption |
| Provider skill deficit            | Training (teaching and practice with corrective feedback)   | Skill acquisition, refinement, mastery            | Fidelity to EBP                               |
| Provider views EBP unfavorably    | Audit and Feedback provision of descriptive social norms indicating peer use of EBP | Social pressure/norms                             | Adoption                                       |
| Turnover                         | Train-the-trainer                                           | Real-time training and consultation               | Sustainability                                |
| Competing clinical demands        | Leadership training                                         | Growing leadership support/perseverance           | Adoption, Sustainability                      |
Table 2. Overview of Steps in Developing the Research Agenda

| Step | Focus:                      | Brief Description:                                                                 |
|------|-----------------------------|-------------------------------------------------------------------------------------|
| 1    | Partnership                  | Develop strategic partnership with SIRC                                            |
| 2    | Network Recruitment          | Recruit members of the Mechanisms Network of Expertise (MNoE)                     |
| 3    | Identifying Challenges       | Identify challenges and opportunities related to the study of mechanisms in implementation science across six different data sources |
| 4    | Synthesizing & Prioritizing Challenges via Content Analysis and Concept Mapping | Engage MNoE members to generate conceptually distinct clusters of challenges related to studying mechanisms, and generate ratings of the criticality and pervasiveness of challenges (at both the item and cluster level) |
| 5    | Identifying Research Priorities via Nominal Group Technique | Employ the nominal group technique with MNoE members to identify priorities and specific activities for advancing research on implementation mechanisms |
| 6    | Dissemination                | Disseminate the research agenda via the SIRC website, conference presentations, open access publications and briefs, and videos |
| 7    | Discovery & Refinement       | Refine the agenda over time and encourage original research to advance understanding of how and why implementation strategies work |
Table 3. Summary of Data Sources Informing Concept Mapping and Nominal Group Technique

| Input                        | Data Represented                                      | Global | Examples of Expected Data in Form of Challenge Statements                                                                                                                                                                                                 |
|------------------------------|-------------------------------------------------------|--------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Systematic Reviews           | Peer reviewed literature                              | Y      | • Lack of shared terminology (linguistic inconsistencies) and definitions (lack of conceptual clarity)                                                   • Number of determinants make it unrealistic to isolate impact • Majority of studies focus on intrapersonal mechanisms, and few studies examined multilevel relationships |
| Matrix Mapping               | Expert input from investigators’ recent and ongoing studies | N      | • Several investigators use “conduct educational meetings” across numerous studies and upwards of 20 different mechanisms are being studied • The majority of studies do not indicate a theory to guide their evaluation • Very few investigators explore system-level mechanisms • There is insufficient attention to several priority populations (e.g., minoritized populations, low-income families) |
| Implementation Development Workshop | Expert input from investigators proposing new studies | Y      | • Very few proposals study implementation mechanisms because their budget is not equipped to power for these analyses • Investigators do not choose strategies based on their putative mechanisms of action • An equity lens is rarely integrated |
| Implementation Research Institute | Expert input from researchers                           | N      | • Available measures might drive conceptualization of what is important • It is difficult to decide how often we need to measure each putative mechanism to measure the change trajectory or sequence |
| SIRC Breakout Sessions       | Novice to Expert input including practitioners, policy makers, purveyors, students, and researchers | Y      | • Unevenness in availability of measures across constructs • Often context is invoked retrospectively and is insufficiently measured • Longitudinal, iterative nature of mechanisms evaluations make it difficult to measure and analyze |
| SIRC Abstracts | Novice to Expert input including practitioners, policy makers, purveyors, students, and researchers | Y |
|---------------|-----------------------------------------------------------------------------------|---|
|               | • [Despite ubiquitous nature of training and post-training consultation], few studies evaluate their mechanisms of action |
|               | • Within a complex social-ecological system, there are multiple mechanisms by which an intervention could have its effect on the distal implementation outcome |
|               | • Descriptions of implementation strategies are too general and do not include full and consistent descriptions of their active ingredients |

*Note.* “Global” refers to including global participants or data
Standards for Reporting Implementation Studies: the StaRI checklist for completion

The StaRI standard should be referenced as: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths CJ, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor SJC for the StaRI Group. Standards for Reporting Implementation Studies ([StaRI] statement). BMJ 2017;356:i6795

The detailed Explanation and Elaboration document, which provides the rationale and exemplar text for all these items is: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths C, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor S for the StaRI group. Standards for Reporting Implementation Studies ([StaRI]. Explanation and Elaboration document). BMJ Open 2017;7:e013318

Notes: A key concept of the StaRI standards is the dual strands of describing, on the one hand, the implementation strategy and, on the other, the clinical, healthcare, or public health intervention that is being implemented. These strands are represented as two columns in the checklist.

The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed. The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations.

The StaRI standards refers to the broad range of study designs employed in implementation science. Authors should refer to other reporting standards for advice on reporting specific methodological features. Conversely, whilst all items are worthy of consideration, not all items will be applicable to, or feasible within every study.

| Checklist item | Reported on page # | Implementation Strategy | Reported on page # | Intervention |
|----------------|--------------------|------------------------|--------------------|--------------|
| **Title and abstract** | | | | |
| Title | 1 | Identification as an implementation study, and description of the methodology in the title and/or keywords |
| Abstract | 2 | NA | Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes. |
| **Introduction** | | | | |
| Introduction | 3 | 5-6 | Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address. |
| Rationale | 4 | 5-6 | The scientific background and rationale for the implementation strategy (including any underpinning theory/framework/model, how it is expected to achieve its effects and any pilot work). |

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml
| Aims and objectives | 5 | 7 | The aims of the study, differentiating between implementation objectives and any intervention objectives. |
|---------------------|---|---|--------------------------------------------------------------------------------------------------|
| Methods: description | | | | |
| Design | 6 | 7-19 | The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons |
| Context | 7 | NA | The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere). |
| Targeted ‘sites’ | 8 | NA | The characteristics of the targeted ‘site(s)’ (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria. |
| Description | 9 | NA | A description of the implementation strategy |
| Sub-groups | 10 | NA | Any sub-groups recruited for additional research tasks, and/or nested studies are described |
| Methods: evaluation | | | | |
| Outcomes | 11 | NA | Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets |
| Economic evaluation | 13 | NA | Methods for resource use, costs, economic outcomes and analysis for the implementation strategy |
| Sample size | 14 | NA | Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate) |
| Analysis | 15 | NA | Methods of analysis (with reasons for that choice) |
| Sub-group analyses | 16 | NA | Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks |

**Results**
| Characteristics | NA | Proportion recruited and characteristics of the recipient population for the implementation strategy | Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention |
|-----------------|----|---------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| Outcomes        | NA | Primary and other outcome(s) of the implementation strategy                                       | Primary and other outcome(s) of the intervention (if assessed)                                    |
| Process outcomes| NA | Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work |
| Economic evaluation | NA | Resource use, costs, economic outcomes and analysis for the implementation strategy               | Resource use, costs, economic outcomes and analysis for the intervention                           |
| Sub-group analyses | NA | Representativeness and outcomes of subgroups including those recruited to specific research tasks |
| Fidelity/ adaptation | NA | Fidelity to implementation strategy as planned and adaptation to suit context and preferences | Fidelity to delivering the core components of intervention (where measured)                        |
| Contextual changes | NA | Contextual changes (if any) which may have affected outcomes                                       |
| Harms           | NA | All important harms or unintended effects in each group                                           |

**Discussion**

| Structured discussion | NA | Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications |
|-----------------------|----|---------------------------------------------------------------------------------------------------|
| Implications          | NA | Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability) | Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability) |

**General**

| Statements | NA | Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest |
|------------|----|---------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|
Advancing Mechanisms of Implementation to Accelerate Sustainable Evidence-Based Practice Integration: Protocol for Generating a Research Agenda

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Advancing Mechanisms of Implementation to Accelerate Sustainable Evidence-Based Practice Integration: Protocol for Generating a Research Agenda

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Abstract

Introduction: Mechanisms explain how implementation strategies work. Implementation research requires careful operationalization and empirical study of the causal pathway(s) by which strategies effect change, and factors that may amplify or weaken their effects. Understanding mechanisms is critically important to replicate findings, learn from negative studies, or adapt an implementation strategy developed in one setting to another. Without understanding implementation mechanisms, it is difficult to design strategies to produce expected effects across contexts, which may have disproportionate effects on settings in which priority populations receive care. This manuscript outlines the protocol for an Agency for Healthcare Research and Quality-funded initiative to: (1) establish priorities for an agenda to guide research on implementation mechanisms in health and public health, and (2) disseminate the agenda to research, policy, and practice audiences.

Methods and Analysis: A network of scientific experts will convene in “Deep Dive” meetings across three years. A research agenda will be generated through analysis and synthesis of information from six sources: (1) systematic reviews, (2) network members’ approaches to studying mechanisms, (3) new proposals presented in implementation proposal feedback sessions, (4) working group sessions conducted in a leading implementation research training institute, (5) breakout sessions at the Society for Implementation Research Collaboration’s (SIRC) 2019 conference, and (6) SIRC conference abstracts. Two members will extract mechanism-relevant text segments from each data source and a third member will generate statements as an input for concept mapping. Concept mapping will generate unique clusters of challenges, and the network will engage in a nominal group process to identify priorities for the research agenda.
**Ethics and Dissemination:** This initiative will yield an actionable research agenda to guide research to identify and test mechanisms of change for implementation strategies. The agenda will be disseminated via multiple channels to solicit feedback and promote rigorous research on implementation mechanisms.

**Keywords:** Implementation Research, Implementation Strategies, Mechanisms, Healthcare, Public Health

**Strengths and Limitations of this Study**

- This study will synthesize multiple data sources to uncover key challenges to studying implementation mechanisms
- This study will yield a research agenda outlining challenges, priorities, and activities that will advance the study of implementation mechanisms
- This study will disseminate a mechanisms-focused research agenda for implementation science and invite international feedback
- The generation of this research agenda is largely informed by stakeholders from the United States, potentially limiting its relevance internationally; however, the network has been expanded to obtain global perspectives
- Given the focus on advancing research methods, stakeholder engagement in this effort focuses primarily upon researchers, limiting opportunities for patients and policy makers to inform the research agenda
Mechanisms and What We Know About Them in Implementation Science

Mechanisms are broadly defined as processes that are responsible for change [1]. Defining, testing, and establishing mechanisms is increasingly a priority across fields of study where biological, psychological, or social intervention or behavior change is the focus [2,3]. In the context of implementation science, mechanisms explain how or why implementation strategies exert their effects on outcomes [4]. Implementation strategies are defined as methods used to facilitate the adoption, implementation, sustainment, or scale-up of evidence-based practices (EBPs) [5,6]. While over 70 implementation strategies have been identified and defined for use in healthcare settings [7,8], we know little about the mechanisms through which these strategies generate change [9,10]. A recent systematic review of implementation mechanisms in health identified 46 studies assessing mechanisms [9]. The majority of studies were not designed to formally establish implementation mechanisms per recommended criteria [1,11]. In an earlier systematic review of nine randomized implementation trials, Williams [10] observed similar methodological deficiencies, and no trials supported a hypothesized mediator. Both reviews identified numerous challenges impeding the study of mechanisms in implementation science, including conceptual (e.g., lack of harmony in defining constructs and their roles), theoretical (i.e., few theories exist), methodological (e.g., poor quality measures, design challenges), and practical (e.g., difficult to power studies for mediation analyses) challenges. More work is needed to identify barriers to identifying and testing mechanisms in implementation science and to propose concrete, actionable steps to overcome these barriers.

The Impact of Limited Implementation Mechanisms Research on Achieving Health Equity

Insufficient understanding of implementation mechanisms stymies the field. First, it hinders efforts to systematically design and tailor implementation strategies to meet the needs of
heterogeneous contexts and stakeholders. Second, it limits our ability to learn from negative studies and to replicate positive findings. Third, it prevents the successful adaptation of an implementation strategy developed in one setting to another. These difficulties weaken implementation effectiveness and efficiency and can exacerbate health disparities when implementation efforts are poorly adapted for safety net and other settings where under-served populations are found [12]. Eliminating health disparities may require careful design and tailoring of implementation strategies to the unique circumstances and needs of specific priority populations and the contexts in which they receive care. For example, a clinic may begin to offer a new EBP with fidelity, but social factors (e.g., access to transportation, childcare) might need to be addressed through provider- and patient-focused implementation strategies (e.g., via telehealth) to improve “reach” [13]. Contexts serving priority populations might not respond to certain implementation strategies, such as external consultation, or be able to afford robust strategies, such as practice facilitation. A fundamental understanding of implementation mechanisms will enable implementers to design and, as necessary, tailor implementation strategies to locally relevant determinants (i.e., factors that enable or obstruct changes in professional behaviors or healthcare delivery processes [14]) while retaining their core function [15,16].

Developing and Disseminating a Research Agenda: Conference Series Aims

Given ongoing challenges associated with delivering and tailoring implementation strategies previously found to be effective [17–20], research reporting guidelines emphasize the need to justify the selection of specific implementation strategies [5,21,22]. This requires identifying the barrier(s) to be addressed and the selected strategy’s mechanism of action. Table 1 provides examples of how strategies may work to address determinants and influence specific
implementation outcomes. Identifying the mechanisms through which implementation strategies exert their effects, rather than focusing solely on whether or not they are effective, is an important step forward for the field of implementation science [6,23].

Accordingly, we are undertaking an initiative to advance the study of mechanisms of implementation strategies in healthcare and public health. We will conduct a 3-year meeting series with between-meeting activities designed to achieve two aims: (1) establish priorities to guide a research agenda on implementation mechanisms, and (2) actively disseminate the research agenda to research, policy, and practice audiences. This protocol outlines our plans to engage a network of experts to produce detailed guidance and identify research approaches and tools needed to study mechanisms of implementation strategies and whether they vary with respect to target problems, EBPs, priority populations, and contexts. Ultimately, the research and practice efforts guided by this agenda may be more actionable, practical, and equitable given their clear focus on mechanisms.

**Methods**

A variety of methods will be used to identify challenges, priorities, and activities related to the study of implementation mechanisms, drawing upon data from numerous sources. The methods include qualitative content analysis [24], which will generate the inputs for concept mapping [25], followed by nominal group technique [26] to prioritize the research agenda. Table 2 provides an overview of the steps of developing the research agenda, which are described in more detail below.

**Step 1: Partnership with the Society for Implementation Research Collaboration (SIRC)**

In 2017, SIRC hosted its 4th biennial conference with the following theme: “Implementation Mechanisms: What Makes Implementation Work and Why?” [27].
conference was inspired by the realization that the field of implementation science was in a position to pivot from characterizing implementation efforts (e.g., qualitative exploration of barriers and facilitators) and evaluating the general effectiveness of strategies (i.e., empirical treatment approach) to examining the causal mechanisms by which strategies achieve their effects. Given SIRC’s commitment to this work and its engaged global membership [28], we partnered with them to pursue funding from the Agency for Healthcare Research and Quality (AHRQ) to shape the developing agenda. In addition to leveraging several SIRC activities as inputs for our research agenda, we will conclude our meeting series in collaboration with SIRC in 2022, where we will disseminate the agenda and invite feedback from attendees. A summary of our proposed work can be found on the SIRC website [29].

**Step 2: Mechanisms Network of Expertise**

In preparing this proposal, we convened 26 implementation scientists from the United States to form a Mechanisms Network of Expertise (MNoE). We have expanded the MNoE to over 40 individuals to include international experts and early career researchers, and plan to continue to do so as this work progresses. This network approach allows us to leverage the collective wisdom of key stakeholders who have been contributing to the study of implementation mechanisms and to engage in a collaborative immersion across three years to achieve our aims. By convening the MNoE regularly, roughly quarterly in virtual meetings, and annually for Deep Dive retreats, we will be able to develop a shared understanding, build momentum, and generate products for the larger field to apply and refine. We intend for the MNoE to represent expertise in studying implementation mechanisms and to display diversity across several dimensions (e.g., geography, gender, race/ethnicity, work with priority populations, settings in which they worked). In the initial phases, the MNoE will be organized
into four workgroups that will focus initial network activities: (1) Measurement; (2) Design and Analysis; (3) Causal Theory and Context; and (4) Strategy, Mechanism, Outcome linkages [29]. However, we plan to reorganize the workgroups into the conceptually distinct areas of the research agenda that emerge from the concept mapping work described below.

**Patient and Public Involvement**

This effort is primarily focused on challenges and opportunities related to research methods; thus, the primary stakeholder involvement in this effort is from healthcare researchers and there is no explicit patient or public involvement. Many members of the MNoE have experience not only as researchers, but as clinicians and patients. Moreover, there will be opportunities for individuals with a diverse array of experiences to provide input to the research agenda (e.g., the SIRC breakout sessions) and respond to initial iterations (e.g., see Steps 6 & 7 below).

**Step 3: Identifying Challenges Across Six Data Sources**

In collaboration with the MNoE, we will synthesize information from six sources to inform the research agenda. This broad sourcing will ensure that the agenda is grounded in the empirical literature, informed by SIRC’s global membership, and curated by our MNoE. Table 3 provides an overview of the six sources and offers examples of the types of research agenda items we might obtain from each. We believe the selected sources allow for a systematic and relatively comprehensive approach to generating a research agenda; however, we note several limitations in the discussion.

1) **Systematic Reviews.** Our work will be informed by two systematic reviews of mechanisms in implementation. The only mechanisms-focused systematic review published prior to our grant funding focused on multilevel mechanisms of implementation strategies in the
context of randomized-controlled trials in mental health [10]. That review included nine randomized trials that formally tested mediators linking an implementation strategy to an implementation or clinical outcome. Mediation analysis is one quantitative approach to studying mechanisms in which the total effect of an implementation strategy on an outcome is divided into an indirect effect that occurs through a proposed mediating variable and a direct effect that is not explained by the mediating variable [30]. None of the trials provided sufficient evidence to support a plausible mediator primarily because there was no evidence that the implementation strategies changed the targeted mediating variables. This review also identified several issues in mediation studies of implementation strategies, including study designs that were not conducive to detecting a relationship between the implementation strategy and candidate mediator, insufficient measurement, and underuse or misuse of theory to link implementation strategies to outcomes. We will draw upon the findings of this review, including Williams’ [10] suggestions for future research when populating our research agenda. For instance, Williams [10] suggested investigating theory-informed constructs as potential mediators, improving theoretical links between implementation strategies and hypothesized mediators, enhancing study designs and analytical methods to detect and analyze mediators in multilevel contexts, and further study of implementation strategy change processes to better target candidate mechanisms.

A second systematic review conducted by several members of the MNoE built on Williams’ [10] work by expanding the scope to include implementation studies across health, a wide array of study designs, and the investigation of moderators [9]. This review included 46 studies (including the nine from Williams’ [10] review), and applied seven criteria for establishing a mechanism [1,11]: (i) strong associations between the implementation strategy and mechanism and between the mechanism and outcome, (ii) specificity (demonstration that one
construct and not others influencing change), (iii) consistency (replication across studies), (iv) experimental manipulation of the strategy or proposed mechanism, (v) timeline (change in mechanisms precede change in outcomes), (vi) gradient (dose-response relationship between level of mechanism and level of outcome), and (vii) plausibility/coherence (process-outcome relationship is reasonable or supported by other research). This review found only one study that met six criteria [31]; the vast majority of included studies (n=38) met three or fewer. Fewer than half of studies included an implementation strategy as the independent variable of interest. As with Williams [10], this review identified underuse of theory and overuse of study designs and analytical methods that do not afford the opportunity to establish mechanisms. We will draw upon the findings and suggestions from this review when generating the research agenda.

2) Matrix Mapping of Ongoing Research. To understand how members of the MNoE are studying mechanisms and to identify gaps in this area of inquiry, we will synthesize the data obtained from ~30 researchers in an online Matrix Mapping exercise. Matrix mapping allows members to report on recently completed and in-progress projects that include the study of mechanisms (e.g., mediation studies and other studies of implementation strategies), and for us to map, or identify, saturated versus thin areas of the matrix. To this end, the matrix is organized by the following: priority populations (coded using categories identified by AHRQ) [32], target problem (disease, disorder, symptom, or risk factor), EBP intended to improve target problem, context/setting in which the EBP was delivered, guiding theory or framework, implementation strategies, mechanism(s) under investigation (or hypothesized mechanisms), implementation outcome(s), study status (planned, in progress, or complete), and references for the project. The matrix will be coded using the Expert Recommendations for Implementing Change (ERIC) implementation strategies compilation [7,8] and the Implementation Outcomes Framework [33].
We will calculate frequencies and proportions of responses occurring in each category to determine areas where there is representation (e.g., commonly used implementation strategies) and areas for which there are gaps (e.g., understudied implementation outcomes, dearth of interventions to improve the health of certain target populations) to inform the research agenda.

3) Implementation Development Workshop (IDW). The IDW is a half-day, pre-conference event that is regularly part of the biennial SIRC conference, in which SIRC Network of Expertise members (i.e., practitioners, students, new and established investigators) are invited to present “works in development” to receive expert feedback from colleagues (31). Based on the Behavioral Research in Diabetes Group Exchange model used by the Psycho-Social Aspects of Diabetes research group [34], the format includes 10-20 minutes for each presenter to orally (without technology) describe their project/proposal and 20-40 minutes for feedback coordinated by a facilitator. A note-taker records notes of the feedback so the presenter can be involved in the discussion. In 2019, 54 researchers and/or practitioners participated. Qualitative content analysis [24] of the notes reflecting each proposal discussion will serve as a third source for the research agenda to capture challenges and possibilities in the study of implementation mechanisms among a unique group of experts beyond the MNoE. That is, we will learn how mechanisms are being considered (if at all) in project proposals and uncover the challenges researchers face when considering mechanism evaluation.

4) Implementation Research Institute. The Implementation Research Institute [35] is a 2-year interdisciplinary training program funded by the U.S. National Institutes of Health that focuses on developing and nurturing a network of scholars who focus on researching the implementation of effective practices within the field of behavioral health [36,37]. Every summer features a week-long training institute in which fellows convene with core and expert
faculty to engage with emerging issues in implementation science. Working sessions to advance the field are often conducted and one focused specifically on challenges to studying implementation mechanisms will serve as our fourth data source. As a precursor to the exercise, a general overview of implementation strategy research was provided as well as specific content related to the concept of mechanisms (e.g., What is a mechanism? What do we know about mechanisms in implementation science?). Faculty (n = ~10) and fellows (n = ~20) were then split into three groups: 1) Theories, Frameworks, and Context, 2) Design and Analysis, and 3) Measurement. Each group considered two questions related to their focus area: 1) What are the major challenges to advancing our understanding of mechanisms?, and 2) What do you view as promising paths forward to advance our understanding of mechanisms? The groups were given 30 minutes to discuss and asked to assign one or more note-takers to document ideas. Following this exercise, each group reported their results to the larger group. We will use qualitative content analysis [24] to code the notes for unique challenges and opportunities to inform the research agenda.

5) SIRC Breakout Sessions. All SIRC 2019 conference attendees were invited to participate in two breakout sessions facilitated by investigative team members. These sessions were advertised as opportunities for the MNoE to learn from the experiences of global researchers, policy makers, practitioners, and intermediaries. To participate, attendees agreed to complete one hour of preparatory work, including viewing a recorded webinar and reviewing an overview handout. These requirements were set to ensure all attendees would enter the breakout with the same foundational knowledge (e.g., What is an implementation mechanism?) and to encourage active participation by breakout session attendees. Participants had the option of
attending one or both breakout sessions (over 90 attendees attended each session), and they were informed that their input would be used to ultimately shape the research agenda.

The first breakout session focused on challenges of using theory to understand context and to inform the study of implementation strategies, mechanisms, and outcome linkages. It began with an introduction and discussion of the current landscape of implementation mechanisms and then moved to a conversation about key challenges and gaps associated with studying implementation mechanisms through the lens of the four workgroups. Attendees then split into four groups: (1) Causal Theory and Context; (2) Connections from Implementation Strategies to Mechanisms and Outcomes; (3) Design and Analysis; and (4) Measurement. Attendees were instructed to select the group that best fit their expertise or interests, and the majority of the session was spent in facilitated discussion. At the end of the breakout session, one member of each group presented a summary of their discussion to the larger group. Notetakers were embedded throughout to document and permit subsequent generation of challenges and opportunities relevant to the research agenda.

The second breakout session began with brief “stimulus talks” from the MNoE workgroup leads and a case study. The 3-minute stimulus talks and 13-minute case study focused on thorny issues related to the study of implementation mechanisms. Following these talks, as with the first breakout session, attendees separated into four groups: (1) Causal Theory and Context, (2) Connections from Implementation Strategies to Mechanisms and Outcomes, (3) Design & Analysis, and (4) Measurement. Participants spent most of the time discussing the case study through the lens of their workgroup’s topic area, coming together at the end of the session for summary discussion. Small group discussion was designed to elevate additional issues not raised in the presentations, and to use the case study to address the issues raised by the presenters.
through the lens of their workgroup. At the end of the breakout session, one member of each of
the four workgroups presented a summary of their discussion to the larger group. Note-takers
were embedded throughout to allow for data extraction of qualitative data that could inform the
research agenda. We will use qualitative content analysis [24] to mine the notes of these two
breakout sessions to inform the research agenda.

6) SIRC abstracts. Our final source will be the 2019 presentations. The purpose of this
input is to understand the extent to which implementation mechanisms were represented in the
SIRC 2019 program [28], uncover gaps in the study of implementation mechanisms, and reveal
exemplar studies that may not be yet captured in the published literature. All 205 abstracts from
the 2019 SIRC conference program will be qualitatively coded for implementation mechanism-
related content. If authors make mention of mechanisms (or mediators and moderators) in their
abstract, the coder will record the mechanisms reported and the measurement method if
available. Abstracts will also be coded for setting and project design; priority populations [32];
guiding theories/frameworks [38]; implementation strategies [7,8]; service outcomes,
implementation outcomes, and clinical/client outcomes [33]; and barriers to implementation [39].
Abstract information will be entered into REDCap, and three coders will independently extract
data from a random sample of abstracts with 5% coded by all three members of the team to
assess for inter-rater reliability. The results of the abstract coding will directly inform the
research agenda.

Step 4: Synthesizing & Prioritizing Challenges via Content Analysis and Concept Mapping

We will conduct qualitative content analysis [24] to code each of the six sources
described above across two categories: (1) challenges in conducting mechanistic implementation
science and (2) priorities for improving the study of implementation mechanisms. Data analysis
will occur in three phases: immersion, reduction, and interpretation. During the immersion phase, study team members will obtain a sense of “the whole” before rearranging it into smaller segments [24]. This will be accomplished by reviewing each of the six inputs described above to gain a better sense of these data. The reduction phase will involve condensing data into text segments by coding each of the six data sources. To increase reliability and reduce bias [40,41], two researchers will use an electronic spreadsheet to independently extract text segments that represent challenges or priorities related to studying implementation mechanisms. These coders will regularly debrief during project meetings to ensure a common frame of reference for each input and to discuss and resolve discrepancies. A third researcher will work with BJP and CCL to examine all extracted text segments to eliminate redundancies and ensure that each segment is worded clearly and concisely. Rather than identifying themes across text segments, each text segment describing challenges related to researching implementation mechanisms will be used in the concept mapping [25] study described below. This will generate conceptually distinct clusters of challenges that will need to be addressed to advance the field’s understanding of implementation mechanisms, and it will constitute the interpretation phase of the qualitative content analysis approach. Although coders will also extract possibilities or opportunities for the field, these will be tabled for consideration until the Deep Dive retreat when the results of the concept mapping are turned into an actionable research agenda.

The members of the MNoE will be engaged in a concept mapping study to further develop and refine the emerging research agenda to advance the study of mechanisms in implementation. Concept mapping is a structured process designed to organize concepts into conceptually distinct categories and to generate ratings of specified dimensions such as importance and feasibility. As noted by Powell et al. [42], concept mapping is particularly useful
for structuring the ideas of diverse groups of stakeholders and has been leveraged by implementation researchers to identify and prioritize implementation barriers and facilitators [43,44], implementation strategies [8], training needs [45], dimensions of pragmatic measures [42], and an agenda for studying sustainability of EBPs [46]. Concept mapping is a mixed methods, multi-step approach that typically involves: the identification of specific statements through brainstorming or other sources, statement analysis and synthesis, statement rating, unstructured sorting of statements, multidimensional scaling and hierarchical cluster analysis, and the generation of interpretable maps and data displays. Concept mapping is described in more detail by Trochim and Kane [25] and Kane and Trochim [47].

The Concept mapping process will be completed via the Group Wisdom software platform [48]. Statement identification, analysis, and synthesis will occur via the consolidation of the six research agenda sources as described above. Statements describing challenges to advancing research on implementation mechanisms will entered into the Group Wisdom software platform. To ensure feasibility and to remain consistent with recommendations for the overall number of statements for concept mapping studies [49,50], we will keep the number of statements to approximately 100 statements or less. Members of the MNoE will then be invited to engage in the concept mapping study via the Group Wisdom platform [48]. MNoE members will be asked to complete a brief demographic survey and then be presented with the list of statements to engage in rating and sorting tasks (in any order they so choose). They will be asked to rate each statement on a 5-point Likert scale across two dimensions, including criticality (i.e., how important the challenge is to advancing the science and achieving health equity) and pervasiveness of the challenges. They will also be asked to sort each of the statements into piles
or categories that make sense to them and will be given the opportunity to label each of the categories they create.

We will utilize multidimensional scaling to generate a point map depicting each of the statements and relationships between them based upon a summed square similarity matrix [47]. Statements that are sorted together more frequently will be placed closer together on the map. Model fit will be assessed using the stress value, an indication of goodness of fit between the point map and the total similarity matrix [47,50]. Hierarchical cluster analysis will be used to partition the point map into non-overlapping clusters [47]. We will convene the MNoE to consider a range of cluster solutions produced by the analysis to determine the number of clusters that best represents the core domains of our emerging research agenda. The Group Wisdom software platform [48] will aid in the labeling process by suggesting potential cluster labels based upon participant responses; however, the MNoE will engage in discussion to determine the names for each cluster in our final cluster map. Descriptive statistics of MNoE members’ ratings of criticality and pervasiveness will be presented at the statement and cluster levels.

**Step 5: Identifying Research Priorities via Nominal Group Technique**

The Deep Dive retreat will be focused on engaging the MNoE in small workgroups organized by the conceptually distinct clusters that emerged from the concept mapping. The workgroups will consider the discrete challenges in their cluster(s), examine how they are related, and reflect on their degree of criticality and pervasiveness. They will then engage in a facilitated nominal group process [26] to brainstorm broad priorities and specific activities for addressing each challenge. Nominal group process is a structured method of small-group discussion to reach consensus in problem-solving, idea generation, and priority setting [26].
Nominal group process brings structure to what is often described in vague terms in published reports as an “iterative process” for developing insights and exhausting the expertise of a group. Once all challenges have been subjected to the nominal group process, the resulting opportunities and activities will be captured in a structured research agenda. The research agenda will be comprised of challenges, priorities, and specific activities that will be organized according to the clusters identified through the concept mapping study.

**Steps 6 & 7: Dissemination, Discovery & Refinement**

We will disseminate the research agenda via multiple channels to maximize reach to research, practice, and policy communities. This includes (but is not limited to) conference presentations, peer reviewed publications, webinars, policy briefs, and short video clips. For the research community, we will present our findings at multiple national and international conferences (e.g., SIRC 2022, AcademyHealth/NIH Conference on the Science of Dissemination and Implementation, etc.) and webinars (e.g., the U.S. Department of Veterans Affairs Health Services Research & Development Cyberseminar series). We will also publish a special issue or collection of peer reviewed articles, which will include commentaries and critiques from internationally renowned implementation scientists. For policy and practice audiences, we will develop policy briefs and short video clips for dissemination via the SIRC website, relevant listservs, and social media channels. Both the MNoE and SIRC 2022 attendees will have opportunities to inform the dissemination of the agenda to diverse research, policy, and practice communities internationally. These dissemination activities and the pursuit of the priorities outlined in the research agenda will inevitably lead to ongoing refinement as our understanding of implementation mechanisms deepens.

**Discussion**
Understanding how and why implementation strategies achieve their effects will enable stakeholders to deploy these strategies with more precision retaining their core functions, to develop multifaceted and multilevel implementation strategies that combine component strategies in a synergistic manner [51], to systematically match strategies to high-priority determinants, and to tailor strategies to diverse and under-resourced contexts. This is particularly important as a means of addressing health disparities by ensuring that implementation efforts address social, political, and environmental factors that contribute to inequitable outcomes for underserved populations [52]. However, there are significant challenges to advancing the study of implementation mechanisms that cut across conceptual, methodological, analytical, and practical spaces. By partnering with SIRC, convening an MNoE, and hosting Deep Dive retreats, we will clarify these challenges and develop a research agenda that pairs challenges with priorities and activities that will advance the field.

We acknowledge several limitations to our planned approach. First, although we recently expanded our MNoE to include international members, we are primarily based in the United States, which may limit the relevance of our research agenda internationally where researchers and implementers may face different challenges or generate unique opportunities. We will continue to seek opportunities to obtain feedback from international experts in implementation research, practice, and policy by expanding our MNoE and by seeking international dissemination outlets that will afford the opportunity to receive feedback on the developing research agenda. Second, given the focus on advancing research methods, stakeholder engagement in this effort focuses primarily upon researchers. Unfortunately, the limited opportunities for patients and the general public to inform the research agenda may have negative unintended consequences. To fill the potential gaps in this protocol, we will draw on
findings from a related, recently funded Center grant from the U.S. National Institute of Mental Health (P50MH126219) where we have robust stakeholder participation (e.g., youth and family advocates, providers, organizational leaders, and policy makers). Finally, our sources are not exhaustive but are intended to capture diverse and expert perspectives, which may result in missed challenges and approaches that are important but not included in the six sources described above.

The development of this research agenda represents a tremendous opportunity to initiate international discourse about how we can develop more precise, scalable, and effective implementation strategies capable of improving the quality of health and social care delivery. We welcome input from the practice, policy, and research communities on the development and dissemination of this research agenda.
List of Abbreviations

AHRQ: Agency for Healthcare Research and Quality; EBP: evidence-based practice; ERIC: Expert Recommendations for Implementing Change; IDW: Implementation Development Workshop; MNoE: Mechanisms Network of Expertise; SIRC: Society for Implementation Research Collaboration

Declarations

Ethics Approval and Consent to Participate

Not applicable.

Consent for Publication

Not applicable.

Availability of Data and Materials

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

CCL, BJP, GAA, RB, ARL, BJW, NW, and BM all contributed to the design and conceptualization of the protocol. SKB, AMN, SFV, SHS, and CWB contributed to the conceptualization, design, and execution of the data sources. CCL drafted the majority of the
introduction and discussion. BJP drafted content throughout the manuscript, but primarily contributed to the methods section. SKB, AMN, SFV, SHS, and CWB each drafted paragraphs of the Method section. GAA, RB, ARL, BJW, NW, and BM all reviewed and heavily edited an early draft of the manuscript. All authors reviewed and approved the final version.

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References

1 Kazdin AE. Mediators and mechanisms of change in psychotherapy research. *Annual Review of Clinical Psychology* 2007;3:1–27. doi:10.1146/annurev.clinpsy.3.022806.091432

2 Reiss D, Price RH. National research agenda for prevention research: The National Institute of Mental Health report. *American Psychologist* 1996;51:1109–15. doi:10.1037/0003-066X.51.11.1109

3 Michie S, Carey RN, Johnston M, *et al.* From theory-inspired to theory-based interventions: A protocol for developing and testing a methodology for linking behaviour change techniques to theoretical mechanisms of action. *Annals of Behavioral Medicine* 2018;52:501–12. doi:10.1007/s12160-016-9816-6

4 Lewis CC, Klasnja P, Powell BJ, *et al.* From classification to causality: Advancing Understanding of Mechanisms of change in implementation science. *Frontiers in Public Health* 2018;6:1–6. doi:10.3389/fpubh.2018.00136

5 Proctor EK, Powell BJ, McMillen JC. Implementation strategies: Recommendations for specifying and reporting. *Implementation Science* 2013;8:1–11. doi:10.1186/1748-5908-8-139

6 Powell BJ, Fernandez ME, Williams NJ, *et al.* Enhancing the impact of implementation strategies in healthcare: A research agenda. *Frontiers in Public Health* 2019;7:1–9. doi:10.3389/fpubh.2019.00003

7 Powell BJ, Waltz TJ, Chinman MJ, *et al.* A refined compilation of implementation strategies: Results from the Expert Recommendations for Implementing Change (ERIC) project. *Implementation Science* 2015;10:1–14. doi:10.1186/s13012-015-0209-1

8 Waltz TJ, Powell BJ, Matthieu MM, *et al.* Use of concept mapping to characterize relationships among implementation strategies and assess their feasibility and importance: Results from the Expert Recommendations for Implementing Change (ERIC) study. *Implementation Science* 2015;10:1–8. doi:10.1186/s13012-015-0295-0

9 Lewis CC, Boyd MR, Walsh-Bailey C, *et al.* A systematic review of empirical studies examining mechanisms of implementation in health. *Implementation Science* 2020;15:1–25.

10 Williams NJ. Multilevel mechanisms of implementation strategies in mental health: Integrating theory, research, and practice. *Administration and Policy in Mental Health and Mental Health Services Research* 2016;43:783–98. doi:10.1007/s10488-015-0693-2

11 Hill AB. The environment and disease: Association or causation? *Association or causation? Proceedings of the Royal Society of Medicine* 1965;58:295–300.

12 Smith S, Johnson L, Wesley D, *et al.* Translation to practice of an intervention to promote colorectal cancer screening among African Americans. *Clinical and Translational Science* 2012;5:412–5. doi:10.1111/j.1752-8062.2012.00439.x
13 Shelton RC, Chambers DA, Glasgow RE. An extension of RE-AIM to enhance sustainability: Addressing dynamic context and promoting health equity over time. *Frontiers in Public Health* 2020;8:1–8.

14 Krause J, Van Lieshout J, Klomp R, *et al.* Identifying determinants of care for tailoring implementation in chronic diseases: An evaluation of different methods. *Implementation Science* 2014;9. doi:10.1186/s13012-014-0102-3

15 Patient Centered Outcomes Research Institute. PCORI standards for studies of complex interventions. 2019. https://www.pcori.org/research-results/about-our-research/research-methodology/pcori-methodology-standards#Complex (accessed 16 Mar 2019).

16 Perez Jolles M, Lengnick-Hall R, Mittman BS. Core functions and forms of complex health interventions: A patient-centered medical home illustration. *Journal of General Internal Medicine* 2019;34:1032–8. doi:10.1007/s11606-018-4818-7

17 Bosch M, van der Weijden T, Wensing M, *et al.* Tailoring quality improvement interventions to identified barriers: A multiple case analysis. *Journal of Evaluation in Clinical Practice* 2007;13:161–8. doi:10.1111/j.1365-2753.2006.00660.x

18 Baker R, Comosso-Stefinovic J, Gillies C, *et al.* Tailored interventions to address determinants of practice. *Cochrane Database of Systematic Reviews* 2015;4:1–118. doi:10.1002/14651858.CD005470.pub3

19 Wensing M. The Tailored Implementation in Chronic Diseases (TICD) project: Introduction and main findings. *Implementation Science* 2017;12:1–4. doi:10.1186/s13012-016-0353-x

20 Bird KA, Castleman BL, Denning JT, *et al.* Nudging at scale: Experimental evidence from FAFSA completion campaigns. *Journal of Economic Behavior and Organization* 2021;183:104–28.

21 Hoffman TC, Glasziou PP, Boutron I, *et al.* Better reporting of interventions: Template for intervention description and replication (TIDieR) checklist and guide. *BMJ* 2014;348:1–12. doi:10.1136/bmj.g1687

22 Bragge P, Grimshaw JM, Lokker C, *et al.* AIMD - a validated, simplified framework of interventions to promote and integrate evidence into health practices, systems, and policies. *BMC Medical Research Methodology* 2017;17:1–11. doi:10.1186/s12874-017-0314-8

23 Hamilton AB, Mittman BS. Implementation science in health care. In: Brownson RC, Colditz GA, Proctor EK, eds. *Dissemination and implementation research in health: Translating science to practice.* New York: : Oxford University Press 2018. 385–400.

24 Forman J, Damschroder L. Qualitative content analysis. In: Jacoby L, Siminoff LA, eds. *Empirical methods for bioethics: A primer.* Amsterdam: : Elsevier 2008. 39–62.
25 Trochim WMK, Kane M. Concept mapping: An introduction to structured conceptualization in health care. *International Journal for Quality in Health Care* 2005;**17**:187–91. doi:10.1093/intqhc/mzi038

26 Van de Ven AH, Delbecq AL. The nominal group as a research instrument for exploratory health studies. *American Journal of Public Health* 1972;**62**:337–42.

27 Lewis CC, Stanick C, Lyon A, *et al.* Proceedings of the Fourth Biennial Conference of the Society for Implementation Research Collaboration (SIRC) 2017: implementation mechanisms: what makes implementation work and why? part 1. *Implementation Science* 2018;**13**(Suppl 2):1–5. doi:10.1186/s13012-018-0714-0

28 Landes SJ, Kerns SEU, Pilar MR, *et al.* Proceedings of the Fifth Biennial Conference of the Society for Implementation Research Collaboration (SIRC) 2019: where the rubber meets the road: the intersection of research, policy, and practice - part 1. *Implementation Science* 2020;**15**(Suppl 3):1–5. doi:10.1186/s13012-020-01034-7

29 Society for Implementation Research Collaboration. Mechanisms Network of Expertise. 2021.https://societyforimplementationresearchcollaboration.org/mechanisms-network-of-expertise/ (accessed 20 Aug 2021).

30 Hayes AF, Preacher KJ. Quantifying and testing indirect effects in simple mediation models when the constituent paths are nonlinear. *Multivariate Behavioral Research* 2010;**45**:627–60.

31 Williams NJ, Glisson C, Hemmelgarn A, *et al.* Mechanisms of change in the ARC organizational strategy: Increasing mental health clinicians’ EBP adoption through improved organizational culture and capacity. *Administration and Policy in Mental Health and Mental Health Services Research* 2017;**44**:269–83.

32 Agency for Healthcare Research and Quality. Priority populations. 2021.https://www.ahrq.gov/priority-populations/index.html (accessed 20 Aug 2021).

33 Proctor EK, Silmere H, Raghavan R, *et al.* Outcomes for implementation research: Conceptual distinctions, measurement challenges, and research agenda. *Administration and Policy in Mental Health and Mental Health Services Research* 2011;**38**:65–76. doi:10.1007/s10488-010-0319-7

34 PsychoSocial Aspects of Diabetes Group. Behavioral Research in Diabetes Group Exchange. http://www.psad-easd.eu/bridge/ (accessed 11 Feb 2021).

35 Implementation Research Institute. 2021.https://iristl.org (accessed 20 Aug 2021).

36 Proctor EK, Landsverk J, Baumann AA, *et al.* The Implementation Research Institute: Training mental health implementation researchers in the United States. *Implementation Science* 2013;**8**:1–12. doi:10.1186/1748-5908-8-105
37 Landsverk J, Proctor EK. From research training to scientific advancement: Contributions from the Implementation Research Institute: An introduction to the special issue. *Administration and Policy in Mental Health and Mental Health Services Research* 2020;47:169–75.

38 Tabak RG, Khoong EC, Chambers DA, et al. Bridging research and practice: Models for dissemination and implementation research. *American Journal of Preventive Medicine* 2012;43:337–50. doi:10.1016/j.amepre.2012.05.024

39 Damschroder LJ, Aron DC, Keith RE, et al. Fostering implementation of health services research findings into practice: A consolidated framework for advancing implementation science. *Implementation Science* 2009;4:1–15.

40 Bernard HR. *Research methods in anthropology: Qualitative and quantitative approaches*. 5th ed. Lanham, Maryland: AltaMira Press 2011.

41 Krippendorff K. *Content analysis: An introduction to its methodology*. 2nd ed. Thousand Oaks, CA: Sage Publications 2003.

42 Powell BJ, Stanick CF, Halko HM, et al. Toward criteria for pragmatic measurement in implementation research and practice: A stakeholder-driven approach using concept mapping. *Implementation Science* 2017;12:1–7. doi:10.1186/s13012-017-0649-x

43 Aarons GA, Wells RS, Zagursky K, et al. Implementing evidence-based practice in community mental health agencies: A multiple stakeholder analysis. *American Journal of Public Health* 2009;99:2087–95. doi:10.2105/AJPH.2009.161711

44 Lobb R, Pinto AD, Lofters A. Using concept mapping in the knowledge-to-action process to compare stakeholder opinions on barriers to use of cancer screening among South Asians. *Implementation Science* 2013;8:1–12. doi:10.1186/1748-5908-8-37

45 Tabak RG, Padek MM, Kerner JF, et al. Dissemination and implementation science training needs: Insights from practitioners and researchers. *American Journal of Preventive Medicine* 2017;52:S322–9. doi:10.1016/j.amepre.2016.10.005

46 Proctor EK, Luke D, Calhoun A, et al. Sustainability of evidence-based healthcare: research agenda, methodological advances, and infrastructure support. *Implementation Science* 2015;10:1–13. doi:10.1186/s13012-015-0274-5

47 Kane M, Trochim WMK. *Concept mapping for planning and evaluation*. Thousand Oaks, CA: Sage 2007.

48 Concept Systems Incorporated. groupwisdom. 2021. https://groupwisdom.com

49 Trochim WMK. The reliability of concept mapping. Dallas, Texas: 1993. http://www.socialresearchmethods.net/research/Reliable/reliable.htm
50 Rosas SR, Kane M. Quality and rigor of the concept mapping methodology: A pooled study analysis. *Quality and rigor of the concept mapping methodology: A pooled study analysis* 2012;35:236–45.

51 Weiner BJ, Lewis MA, Clauser SB, et al. In search of synergy: Strategies for combining interventions at multiple levels. *JNCI Monographs* 2012;44:34–41. doi:10.1093/jncimonographs/lgs001

52 Baumann AA, Cabassa LJ. Reframing implementation science to address inequities in healthcare delivery. *BMC Health Services Research* 2020;20:1–9. doi:10.1186/s12913-020-4975-3
Table 1. Examples of Links Between Determinants, Implementation Strategies, Mechanisms, and Implementation Outcomes

| Determinant                  | Implementation Strategy                                                                 | Mechanism                                           | Implementation Outcome                           |
|------------------------------|----------------------------------------------------------------------------------------|-----------------------------------------------------|--------------------------------------------------|
| Provider knowledge deficit   | Education (provision of information)                                                    | Awareness-building, knowledge-acquisition           | Feasibility, acceptability, appropriateness, adoption |
| Provider skill deficit       | Training (teaching and practice with corrective feedback)                                | Skill acquisition, refinement, mastery              | Fidelity to EBP                                   |
| Provider views EBP unfavorably| Audit and Feedback provision of descriptive social norms indicating peer use of EBP     | Social pressure/norms                                | Adoption                                          |
| Turnover                     | Train-the-trainer                                                                       | Real-time training and consultation                 | Sustainability                                    |
| Competing clinical demands   | Leadership training                                                                     | Growing leadership support/perseverance             | Adoption, Sustainability                          |
Table 2. Overview of Steps in Developing the Research Agenda

| Step | Focus: | Brief Description: |
|------|--------|--------------------|
| 1    | Partnership | Develop strategic partnership with SIRC |
| 2    | Network Recruitment | Recruit members of the Mechanisms Network of Expertise (MNoE) |
| 3    | Identifying Challenges | Identify challenges and opportunities related to the study of mechanisms in implementation science across six different data sources |
| 4    | Synthesizing & Prioritizing Challenges via Content Analysis and Concept Mapping | Engage MNoE members to generate conceptually distinct clusters of challenges related to studying mechanisms, and generate ratings of the criticality and pervasiveness of challenges (at both the item and cluster level) |
| 5    | Identifying Research Priorities via Nominal Group Technique | Employ the nominal group technique with MNoE members to identify priorities and specific activities for advancing research on implementation mechanisms |
| 6    | Dissemination | Disseminate the research agenda via the SIRC website, conference presentations, open access publications and briefs, and videos |
| 7    | Discovery & Refinement | Refine the agenda over time and encourage original research to advance understanding of how and why implementation strategies work |
Table 3. Summary of Data Sources Informing Concept Mapping and Nominal Group Technique

| Input                          | Data Represented                           | Global | Examples of Expected Data in Form of Challenge Statements                                                                                     |
|-------------------------------|--------------------------------------------|--------|-------------------------------------------------------------------------------------------------------------------------------------------------|
| Systematic Reviews            | Peer reviewed literature                    | Y      | • Lack of shared terminology (linguistic inconsistencies) and definitions (lack of conceptual clarity)                                          |
|                               |                                            |        | • Number of determinants make it unrealistic to isolate impact                                                                               |
|                               |                                            |        | • Majority of studies focus on intrapersonal mechanisms, and few studies examined multilevel relationships                                       |
| Matrix Mapping                | Expert input from investigators’ recent and ongoing studies | N      | • Several investigators use “conduct educational meetings” across numerous studies and upwards of 20 different mechanisms are being studied        |
|                               |                                            |        | • The majority of studies do not indicate a theory to guide their evaluation                                                                  |
|                               |                                            |        | • Very few investigators explore system-level mechanisms                                                                                  |
|                               |                                            |        | • There is insufficient attention to several priority populations (e.g., minoritized populations, low-income families)                         |
| Implementation Development Workshop | Expert input from investigators proposing new studies | Y      | • Very few proposals study implementation mechanisms because their budget is not equipped to power for these analyses                        |
|                               |                                            |        | • Investigators do not choose strategies based on their putative mechanisms of action                                                         |
|                               |                                            |        | • An equity lens is rarely integrated                                                                                                         |
| Implementation Research Institute | Expert input from researchers               | N      | • Available measures might drive conceptualization of what is important                                                                       |
|                               |                                            |        | • It is difficult to decide how often we need to measure each putative mechanism to measure the change trajectory or sequence                   |
| SIRC Breakout Sessions        | Novice to Expert input including practitioners, policy makers, purveyors, students, and researchers | Y      | • Unevenness in availability of measures across constructs                                                                                   |
|                               |                                            |        | • Often context is invoked retrospectively and is insufficiently measured                                                                      |
|                               |                                            |        | • Longitudinal, iterative nature of mechanisms evaluations make it difficult to measure and analyze                                           |
SIRC Abstracts | Novice to Expert input including practitioners, policy makers, purveyors, students, and researchers | Y
---|---|---
- [Despite ubiquitous nature of training and post-training consultation], few studies evaluate their mechanisms of action
- Within a complex social-ecological system, there are multiple mechanisms by which an intervention could have its effect on the distal implementation outcome
- Descriptions of implementation strategies are too general and do not include full and consistent descriptions of their active ingredients

Note. “Global” refers to including global participants or data
Standards for Reporting Implementation Studies: the StaRI checklist for completion

The StaRI standard should be referenced as: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths CJ, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor SJ for the StaRI Group. Standards for Reporting Implementation Studies (StaRI) statement. BMJ 2017;356:i6795

The detailed Explanation and Elaboration document, which provides the rationale and exemplar text for all these items is: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths C, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor S, for the StaRI group. Standards for Reporting Implementation Studies (StaRI). Explanation and Elaboration document. BMJ Open 2017 2017;7:e013318

Notes: A key concept of the StaRI standards is the dual strands of describing, on the one hand, the implementation strategy and, on the other, the clinical, healthcare, or public health intervention that is being implemented. These strands are represented as two columns in the checklist. The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed. The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations.

The StaRI standards refers to the broad range of study designs employed in implementation science. Authors should refer to other reporting standards for advice on reporting specific methodological features. Conversely, whilst all items are worthy of consideration, not all items will be applicable to, or feasible within every study.

| Checklist item | Implementation Strategy | Interveneion |
|----------------|-------------------------|--------------|
| **Title and abstract** | | |
| Title | Identification as an implementation study, and description of the methodology in the title and/or keywords | “Implementation strategy” refers to how the intervention was implemented |
| Abstract | Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes | “Intervention” refers to the healthcare or public health intervention that is being implemented. |
| **Introduction** | | |
| Introduction | Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address. | |
| Rationale | The scientific background and rationale for the implementation strategy (including any underpinning theory/framework/model, how it is expected to achieve its effects and any pilot work). | The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects). |
### Aims and objectives

| 5 | 7 | The aims of the study, differentiating between implementation objectives and any intervention objectives. |

### Methods: description

| Design | 6 | 7-19 | The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons |
| --- | --- | --- | --- |
| Context | 7 | NA | The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere). |
| Targeted ‘sites’ | 8 | NA | The characteristics of the targeted ‘site(s)’ (e.g. locations/personnel/resources etc.) for implementation and any eligibility criteria. | The population targeted by the intervention and any eligibility criteria. |
| Description | 9 | NA | A description of the implementation strategy | A description of the intervention |
| Sub-groups | 10 | NA | Any sub-groups recruited for additional research tasks, and/or nested studies are described |

### Methods: evaluation

| Outcomes | 11 | NA | Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets | Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets |
| Process evaluation | 12 | NA | Process evaluation objectives and outcomes related to the mechanism by which the strategy is expected to work |
| Economic evaluation | 13 | NA | Methods for resource use, costs, economic outcomes and analysis for the implementation strategy | Methods for resource use, costs, economic outcomes and analysis for the intervention |
| Sample size | 14 | NA | Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate) |
| Analysis | 15 | NA | Methods of analysis (with reasons for that choice) |
| Sub-group analyses | 16 | NA | Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks |
| Characteristics | 17 | NA | Proportion recruited and characteristics of the recipient population for the implementation strategy | Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention |
|-----------------|----|----|-----------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|
| Outcomes        | 18 | NA | Primary and other outcome(s) of the implementation strategy | Primary and other outcome(s) of the Intervention (if assessed) |
| Process outcomes| 19 | NA | Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work |  |
| Economic evaluation | 20 | NA | Resource use, costs, economic outcomes and analysis for the implementation strategy | Resource use, costs, economic outcomes and analysis for the intervention |
| Sub-group analyses | 21 | NA | Representativeness and outcomes of subgroups including those recruited to specific research tasks |  |
| Fidelity/adaptation | 22 | NA | Fidelity to implementation strategy as planned and adaptation to suit context and preferences | Fidelity to delivering the core components of intervention (where measured) |
| Contextual changes | 23 | NA | Contextual changes (if any) which may have affected outcomes |  |
| Harms           | 24 | NA | All important harms or unintended effects in each group |  |

**Discussion**

| Structured discussion | 25 | NA | Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications |  |
|-----------------------|----|----|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|
| Implications          | 26 | NA | Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability) | Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability) |

**General**

| Statements | 27 | NA | Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest |  |