

Using Implementation Research

to Guide Adaptation, Implementation,
and Dissemination of
Patient-Centered Medical Home Models



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This brief focuses on using implementation research methods in studies of patient-centered medical home (PCMH) models. It is part of a series commissioned by the Agency for Healthcare Research and Quality (AHRQ) and developed by Mathematica Policy Research under contract, with input from other nationally recognized thought leaders in research methods and PCMH models. The series is designed to expand the toolbox of methods used to evaluate and refine PCMH models. The PCMH is a primary care approach that aims to improve quality, cost, and patient and provider experience. PCMH models emphasize patient-centered, comprehensive, coordinated, accessible care, and a systematic focus on quality and safety.

I. Implementation Research

Implementation research focuses on understanding how programs are implemented, translated, replicated, and disseminated in “real-world” settings. It expands the focus of traditional research from discovering *what* works to also discovering *how* the implementation works *in specific contexts*. In traditional medical or health services research, studies testing the efficacy and effectiveness of interventions, such as randomized, controlled trials, focus on internal validity by attempting to control dynamic and complex contextual factors. In contrast, implementation research emphasizes establishing external validity so that knowledge about how to effectively implement programs can be applied to a wide range of settings (Kessler and Glasgow, 2011). The field arose to explain why models shown to be efficacious in clinical trials and controlled settings are often less effective when implemented elsewhere and, perhaps even more importantly, to disseminate recognized high quality policies, practices, and services for widespread use in real-world settings. This gap between the highest quality services and those that are actually delivered is well documented (McGlynn, Asch, Adams, et al., 2003; Laws, St. George, Rychetnik, et al., 2012).

Undertaking a comprehensive analysis of implementation is particularly important when studying the PCMH because the model is complex, includes multiple interacting components, and is intended to be adapted to fit the needs of a practice setting and patient population. Additionally, the practices in which the PCMH is being introduced are complex adaptive systems, meaning that they are dynamic settings that co-evolve with the PCMH as it is implemented. The form of the PCMH intervention is affected by multilevel contextual factors such as provider, patient, practice, and community characteristics, as well as by broader policies such as payment approaches and incentives for meaningful use of electronic health records.

Applying the theories and methods of implementation research helps program developers and evaluators make sense of the challenges in implementing multifaceted interventions like the PCMH. Assessing how and whether the PCMH model can improve quality, cost, and patient and provider experience depends in part on understanding what happened—evaluators must first describe *what*

was implemented and *how* implementation aligned with or departed from the planned intervention. Most studies of PCMHs have focused on evaluating their effectiveness and have paid little attention to understanding implementation, including how PCMH components are operationalized, characteristics of the setting in which the PCMH is implemented, and the interaction between the PCMH components, setting characteristics, and other factors. Implementation research uses systematic approaches to understand these concepts and could be used to build knowledge about how to successfully implement the PCMH and improve key outcomes in different settings.

II. Uses of Implementation Research

Implementation research is an important approach to guide adaptation, implementation, continuous improvement, and replication of programs by model developers, implementers, and evaluators. We describe five broad applications of the approach below.

Conduct descriptive analyses of implementation. Implementation research is used to document and understand the implementation process and to determine level of fidelity to the intervention model. This helps to identify the core features of the intervention model and characteristics of implementation that must be in place in order to achieve desired outcomes.

Understand how context affects implementation. Implementation research is used to define the context in which implementation occurred and the ways the context may have affected implementation processes and outcomes.

Provide formative feedback for program improvement. Implementation research provides information about how to refine or adapt the intervention so implementation is successful in various settings, and it helps determine whether particular adaptations were useful. It also can identify problems in early implementation that can be corrected quickly to improve outcomes.

Link implementation to impacts. Implementation research supports systematic exploratory analysis of associations between the model features that were implemented and impacts, to begin investigating how and under what conditions programs can be effective (Kessler and Glasgow, 2011). It helps researchers and practitioners understand what works, where, and how, and how to improve the model.

Support replication and dissemination of effective programs. Knowing the details of successful implementation is critical to any future replication and dissemination. Reproducing desired effects requires knowing what was implemented, where, and how context affected implementation.

In addition, evaluators can use implementation theory or frameworks to guide the collection of data about the implementation of complex innovations like the PCMH. They can use implementation theory to inform data collection methodologies, ensure that common elements for successful implementation are studied, specify relationships between elements and observed outcomes, and provide critical information for future replication and dissemination. Just as outcomes researchers use theory to design and test the outcomes of clinical or behavior change innovations, implementation researchers use theory to design and test how the innovation was implemented.

There are many theories and frameworks to guide implementation and the study of implementation. For example, the Consolidated Framework for Implementation Research (CFIR) has been used to help

understand the interplay between context and the implementation process. The CFIR builds on the seminal review by Greenhalgh et al. (2004) of factors that can promote or hinder implementation, and is an attempt to unify and consolidate terminology and concepts across theories and frameworks. It is a comprehensive taxonomy of constructs describing context that are known to affect implementation (Damschroder, Aron, Keith, et al., 2009; Damschroder and Hagedorn, 2011). The CFIR organizes implementation constructs across theories and disciplines into five major domains. This framework can be used to guide both the design of PCMH models for particular settings and the study of their implementation. Below we discuss the five domains.

Intervention characteristics may present challenges or may facilitate implementation in several ways. Complex interventions like the PCMH may include features that make them particularly difficult to implement, such as: (1) a large number of components (e.g., processes for empanelling or attributing patients to a particular physician, panel management, care team building, and patient-centered care); (2) disruptive, intricate changes (e.g., re-engineering work processes); (3) changes to fundamental primary care processes; and (4) changes that affect many people of different types, including all primary care staff. Other PCMH characteristics that are important to understand are clinical staff members' perceptions of the quality and strength of evidence supporting the PCMH (such as whether physicians believe it will result in better care for their patients), adaptability of the PCMH to the local clinic setting, and whether or not the PCMH can be pilot tested on a smaller scale before a larger rollout.

Outer setting refers to the organizational context faced by the primary care practice. For the PCMH, this includes whether the practice is independent or is part of a larger delivery system, the payment system, use of external performance incentives, participation in practice-based learning networks, availability of health information exchanges, and the nature of relationships among other providers in the medical neighborhood.

Inner setting describes the practice that is adopting the PCMH model. This includes constructs such as practice culture, the nature and quality of networks and communications among different practice clinicians and staff, priority placed on the PCMH versus other practice concerns, the degree to which leaders are committed to changes, and whether sufficient resources (such as time, space, and staff) are available to implement the changes. The importance of inner setting factors is highlighted by findings from the National Demonstration Project (NDP), the most comprehensive implementation analysis of the PCMH to date. The study found that higher adaptive reserve (supported by highly functioning working relationships and engaged leadership) promoted more successful PCMH implementations (Nutting, Crabtree, Miller, et al., 2010).

Individuals involved refers to the practice staff in the PCMH context. These staff will both implement the PCMH and be affected by the changes. Individual-level factors that influence implementation include knowledge of and attitudes toward the PCMH model, staff members' readiness and ability to change, and pre-existing level of burnout.

Implementation processes refer to the approach and intentionality of plans for implementing the PCMH. Key process factors include (1) the quality and type of planning; (2) early and intentional efforts to engage key stakeholders (such as identifying and preparing change champions, empowering a change leader, and involving key opinion leaders); (3) quality of execution of the implementation

plan; and (4) providing time, space, and infrastructure for continuous qualitative and quantitative evaluation and reflection on the progress of implementation efforts, so that adjustments can be made if needed. Highlighting the important role of this domain, the NDP found that providing expert external facilitation helped practices implement more PCMH components than self-guided transformation (Nutting, Crabtree, Stewart, et al., 2010).

Systematic use of the CFIR taxonomy across PCMH studies could help support consistent collection of information about implementation. It would also facilitate synthesis of findings from studies that are testing different variants of the PCMH model in different settings.

Although the CFIR can help guide the measurement of context, currently there is no taxonomy to guide measurement of different ways to operationalize the five key features of the medical home (that is, comprehensive care, patient-centeredness, coordinated care, accessible care, and a commitment to providing safe, high quality care). For example, if practices expand access, do they use extended office hours, agreements with after-hours clinics, on-call staff, or other approaches? A standard way to describe and measure ways of operationalizing the PCMH would help implementation researchers better explore what was implemented as well as enhance the ability to synthesize evidence across studies (Gardner, Whittington, McAteer, et al., 2010). It would also facilitate the transfer of knowledge about what works and promote further successful implementations of the PCMH.

III. Advantages

Implementation research carries many advantages for PCMH evaluators.

Explain implementation of complex interventions. Implementation research can help program designers and evaluators explain the “black box” of a complex intervention and its implementation. This is important in the context of the PCMH because there are variations of the model and multiple ways to achieve successful results. For example, even within the NDP, practices used different strategies to improve access. Similarly, Bitton et al. (2012) describe the variation in contexts and tactics in a different PCMH pilot. Because there are so many different ways to operate as a PCMH, using a consistent framework can help evaluators accurately describe and measure the intervention components and how they were implemented. Researchers can learn as much from failures to demonstrate improved outcomes as they can from studies resulting in improved outcomes if implementation factors and processes are documented precisely.

Strengthen interpretation of findings. Linking intervention components and processes with outcomes can facilitate analysis. Researchers who do not study the process and context of implementation may draw erroneous conclusions about the effectiveness of an intervention. For example, inadequately assessing the implementation process might lead to the erroneous conclusion that a program or practice is not effective (Damschroder and Hagedorn, 2011), when in fact it failed to achieve outcomes because of incomplete or improper implementation or the influence of contextual factors. A focus on implementation also can identify drivers of change and factors that influence outcomes that might otherwise go unnoticed in an evaluation that focuses exclusively on outcomes.

Support the spread of effective programs and practices. Reproducing the positive effects of a program requires more than simply adopting the model and meeting the initial startup requirements

(Durlak and DuPre, 2008). Instead, organizations must have key attributes, context, and conditions in place to ensure that program effects can be replicated. Identifying the contextual factors and other resources necessary to reproduce desired effects and understanding what it takes to implement them with fidelity and quality are critical to successful replication and dissemination of programs in diverse contexts (Fixsen, Naoom, Blase, et al., 2005).

IV. Limitations

Below we discuss some challenges in implementation research.

Lacks consistent terminology. Implementation research is a relatively young discipline and has not yet developed consistent terminology and definitions. In addition, there are inherent challenges with operationalizing and measuring implementation constructs because sufficiently valid measures often do not exist. The field is starting to develop measures of context but, with few exceptions (Wagner, Coleman, Reid, et al., 2012), little effort has been applied to developing a taxonomy for PCMH model components.

Requires additional resources. Additional time and costs and different researcher competencies are needed to build examination of the implementation process into research designs (Curran, Bauer, Mittman, et al., 2012). Experts in implementation analysis are needed.

Yields limited information. Implementation research is just one component needed in a strong evaluation. Used alone, it will not establish causality or the efficacy of an innovation. Implementation research can (1) support evaluation design by identifying components of implementation and context that need to be measured over time and (2) guide interpretation of evaluation results by connecting implementation characteristics to outcomes. Ideally, implementation researchers should work with outcomes researchers to support the successful delivery and testing of innovations (Curran, Bauer, Mittman, et al., 2012).

V. Conclusion

Implementation research is labor intensive, but it provides an essential contribution to understanding how variations of the PCMH model work in different contexts. The approach can be used to implement PCMH models quickly and successfully in a broad range of settings.

VI. References

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VII. Resources

Implementation Research Methods and Study Design

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Framework of Contextual Constructs

Damschroder L, Aron D, Keith R, et al. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci* 2009;4(1):50.

Practical Guides for Conducting Implementation Research

United States Department of Veterans Affairs, Health Services Research & Development Service. Cyberseminar series. <http://www.hsrd.research.va.gov/cyberseminars/catalog-archive.cfm>

Examples of Cyberseminars available include:

Damschroder L. The Role and Selection of Theoretical Frameworks in Implementation Research. Video: http://www.hsrd.research.va.gov/for_researchers/cyber_seminars/archives/video_archive.cfm?SessionID=370

Damush T. The Role and Selection of Theoretical Frameworks in Implementation Research. Video: http://www.hsrd.research.va.gov/for_researchers/cyber_seminars/archives/video_archive.cfm?SessionID=551

Hagedorn H, Young A. Evaluation Details (Outcome Measures, Formative Evaluation). Video: http://www.hsrd.research.va.gov/for_researchers/cyber_seminars/archives/video_archive.cfm?SessionID=554

Hamilton A. Pre-Implementation and Hybrid Effectiveness-Implementation Study Designs. Video: http://www.hsrd.research.va.gov/for_researchers/cyber_seminars/archives/video_archive.cfm?SessionID=549

Mittman B. EIS- Intro Program Session 1: Introduction to Implementation Science in VA. May 2012. Video: http://www.hsrp.research.va.gov/for_researchers/cyber_seminars/archives/video_archive.cfm?SessionID=548

Smith J. Evaluation Overview and Designs. Slides: http://www.hsrp.research.va.gov/for_researchers/cyber_seminars/archives/video_archive.cfm?SessionID=553

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