Methods Research Report

Contextual Frameworks for Research on the Implementation of Complex System Interventions

Agency for Healthcare Research and Quality
Advancing Excellence in Health Care • **www.ahrq.gov**

Methods Research Report

Contextual Frameworks for Research on the Implementation of Complex System Interventions

Prepared for:
Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
540 Gaither Road
Rockville, MD 20850
www.ahrq.gov

Contract No. 290-2007-10056-I

Prepared by:
RTI International–University of North Carolina at Chapel Hill Evidence-based Practice Center
Research Triangle Park, NC

Investigators:
Lucia Rojas Smith, Dr.P.H., M.P.H.
Mahima Ashok, Ph.D., M.S.
Sydney Morss Dy, M.D., M.Sc.
Roberta C. Wines, M.P.H.
Stephanie Teixeira-Poit, M.S.

AHRQ Publication No. 14-EHC014-EF
March 2014

This report is based on research conducted by the RTI International–University of North Carolina at Chapel Hill Evidence-based Practice Center (EPC) under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. 290-2007-10056-I). The findings and conclusions in this document are those of the authors, who are responsible for its contents; the findings and conclusions do not necessarily represent the views of AHRQ. Therefore, no statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

The information in this report is intended to help health care decisionmakers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

This report may be used, in whole or in part, as the basis for development of clinical practice guidelines and other quality enhancement tools, or as a basis for reimbursement and coverage policies. AHRQ or U.S. Department of Health and Human Services endorsement of such derivative products may not be stated or implied.

This document is in the public domain and may be used and reprinted without permission except those copyrighted materials that are clearly noted in the document. Further reproduction of those copyrighted materials is prohibited without the specific permission of copyright holders.

Persons using assistive technology may not be able to fully access information in this report. For assistance contact EffectiveHealthCare@ahrq.hhs.gov.

None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

Suggested citation: Rojas Smith L, Ashok M, Dy SM, Wines RC, Teixeira-Poit S. Contextual Frameworks for Research on the Implementation of Complex System Interventions. Methods Research Report. (Prepared by the RTI International– University of North Carolina at Chapel Hill Evidence-based Practice Center under Contract No. 290-2007-10056-I.) AHRQ Publication No. 14-EHC014-EF. Rockville, MD: Agency for Healthcare Research and Quality; March 2014. www.effectivehealthcare.ahrq.gov/reports/final.cfm.

Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies and strategies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To improve the scientific rigor of these evidence reports, AHRQ supports empiric research by the EPCs to help understand or improve complex methodologic issues in systematic reviews. These methods research projects are intended to contribute to the research base in and be used to improve the science of systematic reviews. They are not intended to be guidance to the EPC program, although may be considered by EPCs along with other scientific research when determining EPC program methods guidance.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality. The reports undergo peer review prior to their release as a final report.

We welcome comments on this Methods Research Project. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to epc@ahrq.hhs.gov.

Richard G. Kronick, Ph.D.
Director
Agency for Healthcare Research and Quality

Jean Slutsky, P.A., M.S.P.H.
Director, Center for Outcomes and Evidence
Agency for Healthcare Research and Quality

Stephanie Chang, M.D., M.P.H.
Director, EPC Program
Center for Outcomes and Evidence
Agency for Healthcare Research and Quality

Michael I. Harrison, Ph.D.
Senior Social Scientist, Organizations and Systems
Center for Delivery, Organization, and Markets
Agency for Healthcare Research and Quality

Christine Chang, M.D., M.P.H.
Task Order Officer
Center for Outcomes and Evidence
Agency for Healthcare Research and Quality

Acknowledgments

We gratefully acknowledge the support of the following AHRQ staff—Stephanie Chang, M.D., M.P.H., Christine Chang, M.D., M.P.H, and Michael Harrison, Ph.D., Janice Genevro, Ph.D., Dina Moss, M.P.A., and our Associate Editor, Barbara Mauger, Ph.D. We extend our appreciation to our Senior Advisors (listed below), Technical Expert Panel members (listed below), and Peer Reviewers (listed below), all of whom provided thoughtful advice and input during our assessment process.

We express our gratitude to the following individuals at RTI for their technical contributions to this project: Amy Roussel, Ph.D., Asta Sorensen, M.A., Amy Chepaitis, Ph.D., and Nancy McCall, Sc.D., S.M. The investigators deeply appreciate the considerable support, commitment, and contributions of Carol Offen and Jennifer Drolet, our scientific editors; Susan Beck and Loraine Monroe, our EPC publications specialists; Maria Ashbaugh, our graphic specialist; Christiane Voisin, M.S.L.S., our EPC librarian; Linda Lux, M.P.A., Program Manager; and Allen Zhang, Jennifer Cook Middleton, Ph.D., and Ellen Shanahan, M.A., Research Associates. We extend as well our most sincere gratitude to Laura Damschroder, M.S., M.P.H., Co-Implementation Research Coordinator, Diabetes QUERI at the U.S. Department of Veterans Affairs for her assistance in orienting the Technical Expert Panel members and the investigative team to the Consolidated Framework for Implementation Research (CFIR) and her thoughtful input and engagement throughout the development of this work.

Senior Advisors

Tim Carey, M.D., M.P.H.
Kenan Professor of Medicine
Director, Cecil G. Sheps Center for Health Services Research
University of North Carolina at Chapel Hill
Chapel Hill, NC

Sam Cykert, M.D.
Professor of Medicine
Associate Director for Medical Education, NC Area Health Education Centers
Clinical Director, North Carolina Regional Extension Center for Health Information Technology
University of North Carolina at Chapel Hill
Chapel Hill, NC

Timothy Daaleman, D.O., M.P.H.
Professor and Vice Chair of Family Medicine
Research Fellow in the Program on Aging, Disability, and Long-Term Care, Cecil G. Sheps Center for Health Services Research
University of North Carolina at Chapel Hill
Chapel Hill, NC

Meera Viswanathan, Ph.D.
Director, RTI-UNC Evidence-based Practice Center IV
RTI International
Research Triangle Park, NC

Brian Weiner, Ph.D.
Professor, Department of Health Policy and Management, Gillings School of Global Public Health
Director, Program on Health Care Organization, Cecil G. Sheps Center for Health Services Research
University of North Carolina at Chapel Hill
Chapel Hill, NC

Technical Expert Panels

In developing the contextual frameworks, the EPC consulted several technical and content experts. Broad expertise and perspectives were sought. Divergent and conflicted opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant report. Therefore, in the end, methodologic approaches, the content of the frameworks and/or conclusions do not necessarily represent the views of individual technical and content experts.

Technical Experts must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

The lists of Technical Experts who participated in developing this report follow.

Patient-Centered Medical Home Technical Expert Panel

Robert Berenson, M.D.
Institute Fellow, Urban Institute
Washington, DC

Stephan Fihn, M.D., M.P.H., FACP
Director, Office of Analytics and Business Intelligence
Department of Veterans Affairs
Professor, Departments of Medicine and of Health Services
Head, Division of General Internal Medicine
University of Washington
Seattle, WA

Charles Homer, M.D., M.P.H.
President and CEO, National Initiative for Children's Healthcare Quality
Boston, MA

Brian Mittman, Ph.D.
Senior Advisor, U.S. Department of Veterans Affairs Center for Implementation Practice and Research Support
Senior Scientist, Kaiser Permanente Southern California Department of Research and Evaluation
Los Angeles, CA

Michael Parchman, M.D., M.P.H.
Director, MacColl Center
Group Health Research Institute
Seattle, WA

Debra Peikes, Ph.D.
Senior Researcher, Mathematica Policy Research
Princeton, NJ

Process Redesign Technical Expert Panel

Laura Damschroder, M.P.H., M.S., B.S.
Co-Implementation Research Coordinator, Diabetes QUERI
U.S. Department of Veterans Affairs
Ann Arbor, MI

Kenneth M. Davis, M.D., M.Sc.H.P.&M.
Chief Medical Officer, San Antonio Methodist Health System
San Antonio, TX

Kelly Devers, Ph.D.
Senior Fellow, Health Policy Center, Urban Institute
Washington, DC

Bradley Doebbeling, M.D., M.Sc.
Chair, Department of Biohealth Informatics
Professor of Informatics, Medicine and Biomedical Engineering
Indiana University School of Informatics & Computing, IUPUI
Indianapolis, IN

Richard Holden, Ph.D.
Assistant Professor, Department of Medicine, Department of Biomedical Informatics
Vanderbilt University School of Medicine
Nashville, TN

Cerry Klein, Ph.D.
Professor, Industrial and Manufacturing Systems Engineering
University of Missouri
Columbia, MO

Brian Mittman, Ph.D.
Senior Advisor, U.S. Department of Veterans Affairs Center for Implementation Practice and Research Support
Senior Scientist, Kaiser Permanente Southern California Department of Research and Evaluation
Los Angeles, CA

John Ovretveit, Ph.D.
Director of Research, Professor of Health Improvement, Implementation and Evaluation,
Medical Management Centre, The Karolinska Institutet
Stockholm, Sweden

Care Transitions Technical Expert Panel

Mary Blumberg, M.S., R.D.
Atlanta Regional Commission
Atlanta, GA

Amy Boutwell, M.D., M.P.P.
President, Collaborative Healthcare Strategies
Lexington, MA

Jane Brock, M.D., M.S.P.H.
Chief Medical Officer, Colorado Foundation for Medical Care
Englewood, CO

David Dietz, M.S.W., M.H.S.A.
Senior Public Health Analyst, Hospital State Division, Office of Rural Health Policy
Health Resources and Services Administration
Rockville, MD

Brian Jack, M.D.
Professor and Chair, Department of Family Medicine
Boston University School of Medicine
Boston, MA

Margaret (Peggy) Leonard, M.S., R.N.-B.C., FNP
Senior Vice President, Clinical Services
Hudson Health Plan
Tarrytown, NY

Kathleen (Kathy) McCauley, Ph.D., R.N., A.C.N.S.-B.C., FAAN, FAHA
Associate Dean for Academic Programs
University of Pennsylvania School of Nursing
Philadelphia, PA

Sumant Ranji, M.D.
Associate Professor of Clinical Medicine
Associate Program Director, Internal Medicine Residency Program
University of California, San Francisco
San Francisco, CA

Anne E. Sales, Ph.D., R.N.
Research Scientist, Center for Clinical Management Research, VA Ann Arbor Healthcare System
Professor, University of Michigan School of Nursing
Ann Arbor, MI

Juliana Tiongson, M.P.H.
Social Science Research Analyst
Centers for Medicare & Medicaid Services
Baltimore, MD

Mark Williams, M.D.
Professor & Director, Center for Health Services Research
University of Kentucky
Lexington, KY

Patient-Centered Medical Home Usability Technical Expert Panel

Melinda Abrams, M.S.
Vice President, Patient Centered Coordinated Care Program
Commonwealth Fund
New York, NY

Janice L. Genevro, Ph.D..
Lead, Improving Primary Care Initiative
Center for Primary Care, Prevention, & Clinical Partnerships
Agency for Healthcare Research & Quality
Rockville, MD

Marci Nielsen, Ph.D., M.P.H.
Chief Executive Officer
Patient Centered Primary Care Collaborative
Washington, DC

Claire Tanner, Ph.D.
Program Director, Center for Data Management and Translational Research
Michigan Public Health Institute
Okemos, MI

Suzanne Wensky, Ph.D.
Social Science Research Analyst
Division of Research on Payment and Accountability
Research and Rapid-Cycle Evaluation Group
Center for Medicare and Medicaid Innovation
Centers for Medicare & Medicaid Services
Baltimore, MD

Elizabeth M. Yano, Ph.D., M.S.P.H.
Director, VA HSR&D Center for the Study of Healthcare Innovation, Implementation & Policy
VA Greater Los Angeles Healthcare System
Sepulveda, CA

Process Redesign Usability Technical Expert Panel

Ruth Boaden, Ph.D.
Professor of Service Operations Management, Manchester Business School
Director, National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care (CLAHRC) Greater Manchester
Manchester, United Kingdom

Pascale Carayon, Ph.D.
Procter & Gamble Bascom Professor in Total Quality, Department of Industrial and Systems Engineering
Director, Center for Quality and Productivity Improvement
University of Wisconsin
Madison, WI

Craig Froehle, M.B.A., Ph.D.
Associate Professor, Operations Management
Linder College of Business
University of Cincinnati
Cincinnati, OH

Joanna Omi, M.P.H.
Senior Vice President, Organizational Innovation and Effectiveness
New York City Health and Hospitals Corporation
New York, NY

Lucy Savitz, Ph.D., M.B.A.
Director of Research and Education, Institute for Health Care Delivery Research
Intermountain Healthcare
Research Professor, Clinical Epidemiology
Director, CCTS Patient Centered Research Methods Core
University of Utah
Salt Lake City, UT

Peer Reviewers

Prior to publication of the final evidence report, EPCs sought input from independent Peer Reviewers without financial conflicts of interest. However, the conclusions and synthesis of the scientific literature presented in this report do not necessarily represent the views of individual reviewers.

Peer Reviewers must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential nonfinancial conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential nonfinancial conflicts of interest identified.

The list of Peer Reviewers follows:

Shannon Bolon, M.D., M.P.H.
Chief, Primary Care Medical Education Branch, Division of Medicine and Dentistry, Bureau of Health Professions
Health Resources and Services Administration
Rockville, MD

Signe Flottorp
Senior Researcher
Norwegian Knowledge Center for Health Sciences
Oslo, Norway

Caroline Ryan, M.A.
Aging Services Program Specialist
Office of Program Innovation and Demonstration
U.S. Administration on Aging
Washington, DC

Lucy Savitz, Ph.D., M.B.A.
Director of Research and Education, Institute for Health Care Delivery Research
Intermountain Healthcare
Research Professor, Clinical Epidemiology
Director, CCTS Patient Centered Research Methods Core
University of Utah
Salt Lake City, UT

Paul Shekelle, M.D., M.P.H., Ph.D.
Director, Southern California Evidence-Based Practice Center
RAND Corporation
Santa Monica, CA

Contextual Frameworks for Research on the Implementation of Complex System Interventions

Structured Abstract

Objectives. This report presents the adaptation of the Consolidated Framework for Implementation Research (CFIR) to three complex system interventions involving (1) process redesign for improved efficiency and reduced costs (PR); (2) patient-centered medical homes (PCMH); and (3) care transitions. The purpose of the adapted frameworks— the PR Framework, PCMH Framework, and Care Transitions Framework—is to guide research on *how*, *why*, and *where* these interventions succeed or fail to achieve intended outcomes.

Data sources. MEDLINE™. Additional studies were identified through the gray literature and technical experts.

Methods. The adaptation was informed by the findings from a scan of selected literature on PR, PCMH, and care transitions, which included articles in MEDLINE, the published and gray literature, and recommendations of content experts at the Agency for Healthcare Research and Quality. A Technical Expert Panel (TEP) for each topic reviewed the draft of the contextual frameworks and provided input on the structure and content through a series of 2-hour calls. In addition, the PR and PCMH Frameworks were reviewed by two separate TEPs for usability. In total, five TEPs were convened for this work.

Results. While retaining much of the CFIR's original structure and most of its original concepts, the revised frameworks address distinctive features of each of the three interventions. We added concepts relevant to each topic area, and more explicitly addressed the iterative and interactive nature of complex system change. We also modified nearly all the definitions of the CFIR constructs to incorporate terminology and examples tailored to the specific interventions. Two new domains were added to each of the frameworks—one for intermediary outcomes related to the implementation and one for outcomes of the interventions themselves. Several CFIR domains and constructs were renamed to be more resonant with the intervention's research target group. None of the original CFIR constructs were dropped, but several dozen new constructs were added across the three new frameworks. As these were iterative products, with initial PR and PCMH Frameworks informing the Care Transitions Framework, many of these new constructs overlap across the frameworks.

Conclusions. These contextual frameworks provide a foundational taxonomy and conceptualization of key implementation constructs that researchers can use across studies to enhance their comparability and synthesis, thereby better informing the generalizability and replicability of specific interventions. In adapting the CFIR for complex system interventions, we thought it critical to include input from both research and practice stakeholders to ensure that the content is understandable and applicable to the intervention strategy of interest.

Contents

Tables

Figures

Appendixes

Executive Summary

Background

In January 2012, the RTI International (RTI)–University of North Carolina at Chapel Hill Evidence-based Practice Center initiated a project to develop integrative contextual frameworks that would guide researchers and evaluators of two types of complex systems of intervention: process redesign for improved efficiency and reduced costs (PR), and patient-centered medical homes (PCMH). Under a follow-on contract initiated in September 2012, a similar effort was launched for care transitions[a] between hospital and ambulatory care settings (care transitions). The Agency for Healthcare Research and Quality (AHRQ) supports these three interventions in its research portfolio as investments in strategies that hold the potential to improve health care and delivery. Thus, the context of implementation; the processes underlying these interventions; and the implications for sustainability, replicability, and generalizability deserve as much attention as the outcomes of these interventions. However, the lack of common understanding or awareness of context among researchers and evaluators of these interventions poses a significant barrier to evidence building. The integrated frameworks are intended to address this barrier and provide a common point of reference to guide future work.

A technical expert in implementation research advising RTI during the planning stages of this work identified the Consolidated Framework for Implementation Research (CFIR)[1] as a practical model amenable to complex systems intervention research. Numerous theories of implementation and context existed in the literature but had differing and overlapping terminologies and constructs. The CFIR synthesizes these various terminologies, definitions, and constructs into a consolidated framework and a common taxonomy for implementation research on health service delivery. It draws from a wide range of disciplines and does not confine itself to any one theory.[1] The CFIR addressed the needs of researchers and evaluators to assess and maximize the effectiveness of implementation within a specific context, and promote dissemination to other contexts.

As the goal of this effort was to create an *integrated* framework, starting with a framework that already resulted from review and synthesis of existing frameworks was an obvious choice. Moreover, the broad range of constructs in the CFIR encompassed most of the contextual dimensions relevant to PR, PCMH, and care transitions. We determined at the outset that some degree of adaptation would be required because the CFIR, as a general model of implementation within bounded organizational settings, might not speak to some of the unique and distinct attributes of complex system interventions.

The CFIR consists of 5 domains and 26 more discrete elements (constructs) that describe the internal and external context of implementation. The domains are Intervention Characteristics, Outer Setting, Inner Setting, Characteristics of Individuals, and Process. Table A presents these domains categorized into constructs. The domains interact with one another in a multidirectional fashion (the outer setting influences the inner setting and vice versa) and include multilevel influences (e.g., individual, organizational). The focus of the framework is on the interaction between context and processes, so it does not posit a causal pathway to specific outcomes.

[a]In this document, we use the term "care transitions" to refer to a broad class of interventions and initiatives designed to enhance the patient's transition from a hospital to an ambulatory care setting, including but not limited to the Care Transitions Program© developed by Dr. Eric Coleman (www.caretransitions.org/).

Table A. Consolidated Framework for Implementation Research (CFIR) domains and constructs

Domain	Construct
Intervention Characteristics	Intervention Source Evidence Strength and Quality Relative Advantage Adaptability Trialability Complexity Design Quality and Packaging Cost
Outer Setting	Patient Needs and Resources Cosmopolitanism Peer Pressure External Policy and Incentives
Inner Setting	Structural Characteristics Networks and Communications Culture Implementation Climate Readiness for Implementation
Characteristics of Individuals	Knowledge and Beliefs About the Intervention Self-Efficacy Individual Stage of Change Individual Identification With Organization Other Personal Attributes
Process	Planning Engaging Executing Reflecting and Evaluating

Source: Damschroder LJ, Aron DC, Keith RE, et al. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci. 2009;4(1):50. PMID: 19664226.

Investigators can use the PR, PCMH, and Care Transitions Frameworks to examine in depth the conditions under which implementation occurs. The frameworks bring to the fore *how*, *why*, *where*, and *for whom* an intervention succeeds or fails. Equally important, these frameworks offer a general taxonomy and conceptualization of key implementation constructs. Investigators engaged in similar fields of study could use them as a sort of universal guide to enhance the comparability of studies and the synthesis of findings. The benefit to intervention designers, implementers, and decisionmakers is a greater understanding of the generalizability and replicability of specific interventions.

The frameworks, due to the breadth and relevance of the constructs included, should acquaint the researcher or the implementing organization with the large range of contextual variables that are possible and important to consider in a study or evaluation. The frameworks can be used by investigative teams planning multisite studies or funders supporting a portfolio of grants to deliberate on the core constructs needed for cross-site analysis. However, we recognize that the sheer number of constructs can be overwhelming; at the suggestion of the Technical Expert Panels (TEPs), we added a general roadmap to guide in the selection of a parsimonious set of constructs. As every study is unique, there is no simple recipe for construct selection. The decision to include or leave out specific constructs should be rooted in the context of the study itself.

Scope

Our task was to build upon the CFIR by examining its suitability and adapting it as necessary to the unique research and evaluation requirements of PR, PCMH, and care transitions through

literature scans and a series of intervention-specific TEPs. We assessed the suitability and fit of each CFIR component to the research and evaluation needs of each of the three interventions. Using the input of the TEP members and AHRQ technical experts, and a brief literature update, we modified the elements of the CFIR (e.g., definitions, terms, organization, and structure) to enhance usability and relevance.

We did not systematically assess the validity or weight of evidence of each construct or identify their measures; these remain important next steps in the development of the frameworks. As a research and evaluation tool, the frameworks remain limited to a taxonomy of domains and their related constructs and subconstructs; they do not address study design, data collection methods, or statistical analyses.

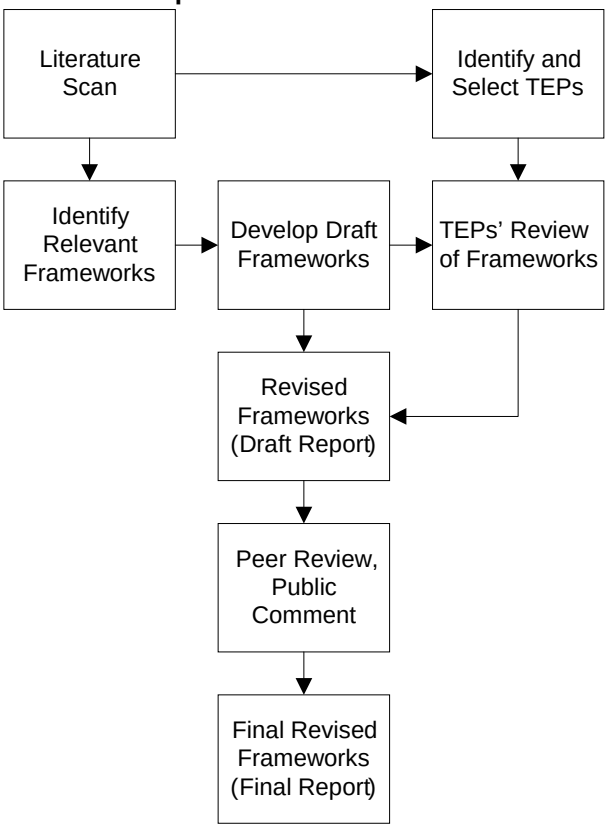
Methods

In this section, we briefly describe the four methods used for the adaptation and refinement of the CFIR: (1) a brief literature scan, (2) TEPs to inform the content and use of each of the three draft contextual frameworks, (3) TEPs to inform the usability of modified frameworks, and (4) a self-assessment of the first-phase project.

The work was carried out in two discrete phases: phase 1 (January 2012 through June 2012) and phase 2 (September 2012 to September 2013). In phase 1, we developed the draft PR and PCMH Frameworks. In phase 2, we conducted a self-assessment of phase 1, refined the frameworks, and modified the process for the adaptation of the Care Transitions Framework. The project's timeframe did not allow for a TEP to assess the usability of the Care Transitions Framework.

Our framework adaptation process was iteratively built from a set of sequential activities, as depicted in Figure A. The first activity, the literature scan, informed the initial draft of the adapted framework. This draft was subsequently revised using the feedback from the TEPs and then finalized through the input of Peer Reviewers and public comments.

Figure A. Contextual framework development



Note: TEP = Technical Expert Panel.

Literature Scan

The three literature scans began with a search of articles in MEDLINE™, the published and gray literature, and articles recommended by content experts at AHRQ. We chose to limit our search to articles published after January 2005 so as to overlap but not duplicate the review conducted for the CFIR (published in 2009). Our goal was to identify relevant topic-specific contextual and theoretical frameworks. We used 50 search terms for the PR and PCMH literature scan singly and in combination (e.g., patient care management, health care redesign, implementation theory), and we used 18 terms for care transitions (e.g., hospital, transitional care, ambulatory care). A general set of questions guided the abstraction of the included articles. The investigative team used the results of the literature scans to develop the two primary components of each framework: a graphical representation and a table listing domains and constructs, their definitions, and examples (for selected constructs). The questions for the care transitions abstraction were tailored to identify content not already captured in the contextual frameworks.

Technical Expert Panels

We convened two TEPs in 2012, one each for PR (8 members) and PCMH (7 members). Individuals recruited to each TEP included researchers with extensive experience in one or more of the following three areas relevant to the intervention: research and evaluation, management and practice, and general implementation research. A similar protocol was followed to recruit the 11-member Care Transitions TEP, convened in 2013. We sought to include individuals with a

range of professional perspectives. These subject matter experts were identified through the literature scan, AHRQ project officers, and the experts themselves, who recommended colleagues to the team. For each topic, we held two rounds of TEP conference calls, with each group call lasting 2 hours. We held 1-hour individual calls with experts who were not available for the group calls. A set of structured questions guided each TEP discussion to examine the relevance and suitability of the framework graphics, constructs, definitions, examples, and case studies. We used detailed notes from each call to revise the framework materials.

Two additional TEPs evaluated the usability of the PR and PCMH Frameworks using a similar approach. Because the focus was on the usability of the framework, the members of these TEPS differed from those in the first round. Besides researchers, we recruited health care executives and providers, who would be potential users of the frameworks. The PR usability TEP had five members and the PCMH usability TEP had six members.

Self-Assessment

In addition to receiving feedback from the usability TEPs, we conducted a self-assessment of the initial phase of the project prior to developing the Care Transitions Framework. The purpose of the self-assessment was twofold: to further the development of the PR and PCMH Frameworks, and to apply the lessons learned from the initial work to the care transitions effort.

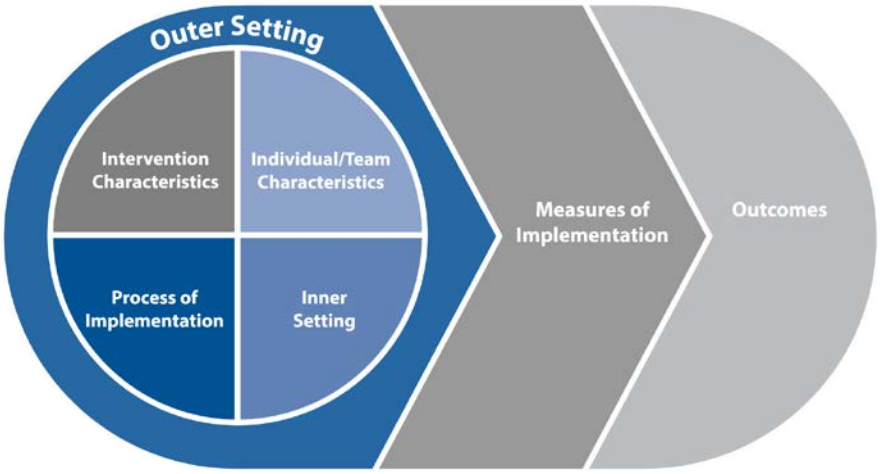
Upon deliberation, we selected a set of recommendations that were feasible to complete within the timeframe of this project. These included the majority of suggestions made by the TEPs; only a few suggestions (such as moving the frameworks online) were not addressed. In addition to making changes to the original versions of the PR and PCMH Frameworks, we used these recommendations as we developed the Care Transitions Framework.

Adapted Contextual Frameworks

The three adapted contextual frameworks maintained many of the essential elements of the CFIR; although a number of domains (the highest taxonomic category in the framework) and constructs (sub-elements of a domain) were renamed, none of the constructs were dropped entirely. A number of noteworthy modifications are described below.

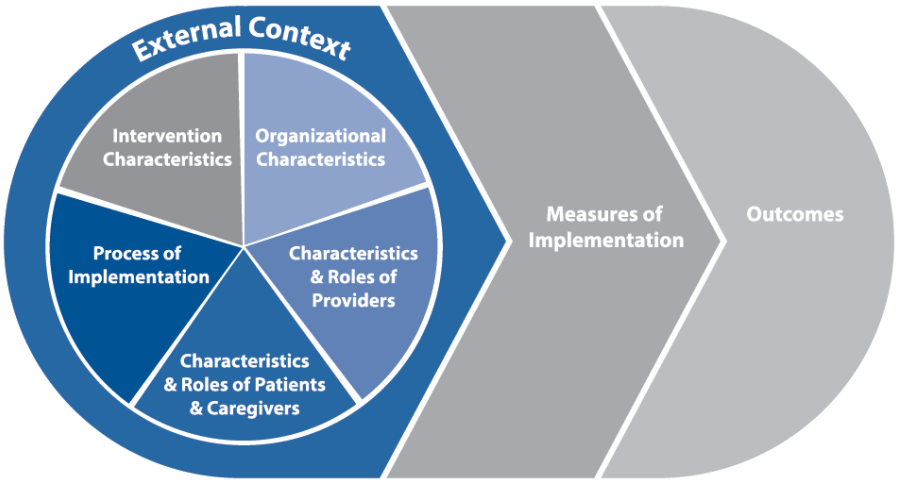
- A Measures of Implementation domain was added to describe the quality or success of the implementation.
- An Outcomes domain was added. The outcomes vary by intervention, although they share some similarities, particularly between the PCMH and Care Transitions Frameworks.
- The CFIR graphic was reconceptualized. The original CFIR graphic attempted to convey the dynamic and permeable interaction among the five CFIR domains (Intervention Characteristics, Inner Setting, Outer Setting, Characteristics of Individuals, and Process). The TEPs' input led us to reconceptualize the graphic and add measures of implementation and outcomes domains. We also expanded the Characteristics of Individuals to include Teams. Figure B presents the final graphic for the PCMH Framework, which is similar to the graphic for the PR Framework (Figure 2 under Process Redesign Framework).

Figure B. Framework for Implementation Research on Patient-Centered Medical Homes



- The graphics for the individual frameworks were reconceptualized. Figure C presents the graphic for the Care Transitions Framework, the furthest departure from the original CFIR. Some TEP members felt the frameworks could better highlight patient needs, preferences, and characteristics, and recommended highlighting patients and providers as discrete entities. To address this feedback, the graphic has separate domains for patients/caregivers and for providers. These domains were further modified by the inclusion of "roles" of providers and patients/caregivers. The PCMH TEP also thought the framework should emphasize the patient more strongly but did not recommend creating a separate domain for patients and providers. The Care Transitions Framework dropped the term "settings," so Outer Setting was renamed External Context and Internal Setting was renamed Organizational Characteristics.

Figure C. Framework for Implementation Research on Care Transitions



- Several dozen new constructs were added as part of the adaptation. Many of these new constructs overlap, as the frameworks were developed iteratively. About half of the new constructs are the result of adding the Implementation and Outcome domains. These new constructs and subconstructs are further detailed in Table B using the domain heads for the PR and PCMH Frameworks.

Table B. New framework constructs

Domain	Construct (Subconstruct)	PR	PCMH	Care Transitions
Intervention Characteristics	Vision and change strategy	✓[a]	✓	✓
	Feasibility	✓[a]	✓	✓
	Compatibility	✓[a]	✓	✓
	Radicalness	✓[a]	✓	✓
	User control	✓[a]	✓	✓
	Location of PCMH activity (location of intervention activity in Care Transitions Framework)	N/A	✓[a]	✓
	Workflows	✓[a]	✓	✓
	Task/process standardization	✓[a]	✓	✓
	History	✓	✓[a]	✓
Outer Setting	Technological environment	✓[a]	✓	✓
	Population needs and resources	N/A	✓[a]	✓
	Community resources	N/A	✓	✓[a]
Inner Setting	(Staff commitment)	✓[a]	✓	✓
	IT and HIT resources	✓[a]	✓	✓
	(Human factors; HIT/IT accessibility in PCMH Framework)	✓[a]	✓	N/A
	Physical space and equipment	✓[a]	✓	N/A
	Staff time	✓[a]	✓	N/A
	Patient self-management infrastructure	N/A	✓[a]	✓
	Continuity	N/A	✓	✓[a]
	Patient centeredness	N/A	✓[a]	✓
Characteristics of Individuals and Teams	Skills and competencies	✓[a]	✓	✓
	Role	✓	✓[a]	✓
	Authority	✓	✓[a]	✓
	Collective efficacy	✓	✓[a]	✓
	Socioeconomic demographics	N/A	✓[a]	✓
	Patient needs and resources	✓	✓	✓[a]
	Caregiver needs and resources	N/A	✓	✓[a]
Process of Implementation	Assessing	✓	✓[a]	✓
	Acquiring and allocating resources	✓	✓[a]	✓
	Process ownership	✓	✓	✓
	Engaging organizations, external context	N/A	✓	✓[a]
	(Organizational leaders)	✓	✓[a]	✓
	(Facilitator)	✓	✓[a]	✓
	(Frontline staff)	✓	✓[a]	✓
	(Integrators)	N/A	N/A	✓[a]
	(Patients and other stakeholders)	✓	✓[a]	✓
	(Decisionmaking)	✓	✓[a]	✓
	(Staging and iteration)	✓[a]	✓	✓
	(Measurement capability and data availability)	✓	✓	✓[a]

Table B. New framework constructs (continued)

Domain	Construct (Subconstruct)	PR	PCMH	Care Transitions
Measures of Implementation	Acceptability	✓	✓	✓
	Adoption/abandonment	✓	✓	✓
	Appropriateness	✓	✓	✓
	Implementation cost	✓	✓	✓
	Fidelity	✓	✓	✓
	Reach	✓	✓	✓
	(Reach within the population)	✓	✓	✓[a]
	(Reach within the organization)	✓	✓	✓[a]
	Penetration	✓	✓	✓
	Replicability	✓[a]	✓	✓
	Sustainability	✓	✓	✓
	Evolvability	✓	✓	✓[a]
Outcomes	Cost effects/impact	✓[a]	✓	✓
	Perceived value	✓[a]	✓	✓
	Unintended consequences	✓[a]	✓	✓
	Processes of care	N/A	✓[a]	✓
	Patient centered	N/A	✓[a]	✓
	(Coordinated)	N/A	✓[a]	✓
	(Comprehensive)	N/A	✓[a]	✓
	(Accessible)	✓	✓[a]	✓
	(Quality)	✓	✓[a]	✓
	(Safety)	✓	✓[a]	✓
	(Effectiveness)	✓[a]	✓	✓
	(Timeliness)	✓[a]	✓	✓
	(Efficiency)	✓[a]	N/A	N/A
	Patient- and caregiver-centered outcomes	N/A	✓	✓[a]
	Productivity	✓[a]	N/A	N/A
	Equitable	✓[a]	✓	N/A
	Patient/caregiver experience	✓	✓[a]	✓
	Provider experience	✓	✓[a]	✓
	Clinical outcomes	N/A	✓[a]	✓
	Health care utilization	✓	✓[a]	✓

[a]Indicates the original source of the construct or subconstruct.

Note: Subconstructs are shown in parentheses. HIT = health information technology; IT = information technology; N/A = not added; PCMH = patient-centered medical home; PR = process redesign.

Discussion

Capturing the context of complex system interventions can be daunting, especially because we lack a common taxonomy to describe and understand how the interplay of people, settings, technology, and policy may affect some desired outcome or impact. The CFIR, adapted to the requirements of three types of complex system interventions, is a potential solution to this dilemma.

Using the CFIR to conceptualize the multiple layers of interactions and networks that characterize complex system interventions was difficult because many of the elements of context can vary by time, location, and organizational unit (e.g., individual, team, practice, organization, system). The frameworks in their current form, confined to text-based two-dimensional tables, do not lend themselves to the multiple levels of analysis possible with complex systems. A Web-based tool would make navigation and exploration of the framework easier by allowing the user

to adjust views of the framework by domain, construct, and subconstruct, and providing links to their definitions and examples. Other possibilities for examining complex relationships might include exploring the organizational hierarchies (e.g., individual, unit, practice, organization, and system) within a construct and juxtaposing them against one or more dimensions (e.g., practice by location).

The TEPs raised a number of conceptual challenges specific to their intervention area, but a number of the issues they noted are crosscutting and are likely to arise in any similar exercise to describe and conceptualize the context of implementation. These issues include—

- *Components of the intervention*. A complex system intervention can include an overall redesign strategy (e.g., applying Lean/Toyota Production Systems); tactics (e.g., process mapping); and specific projects (e.g., conducting a rapid-cycle improvement exercise to improve patient throughput in a clinic). Researchers will have to decide where to focus their attention.
- *Component of the intervention versus target of the intervention*. Elements of the contextual frameworks that are usually thought of as the context within which the intervention occurs, such as climate or leadership, can also become the targets of an intervention.
- *Bundled nature of interventions.* The interventions can have multiple components (e.g., a practice facilitator coupled with a case manager to coordinate care). A key aim for evaluators is assessing which parts of the bundle were implemented, which parts are associated with outcomes, and the relative importance of the components.
- *Intervention timing and research timeframe*. The meaning and relevance of constructs are likely to change across stages of implementation. Researchers who follow an intervention over time might retain some core constructs across the entire study but select others that apply chiefly to one stage in the life course of the intervention. Moreover, implementation may be more of an iterative process than a linear one that proceeds sequentially through clear stages.
- *Organizational units and level of analysis. C*omplex system interventions operate at multiple organizational levels (i.e., levels of analysis). Relevant levels may include individual participants, teams, units, organizations (including autonomous practices), and delivery systems. The frameworks may inform research by alerting researchers to the following:
  - The importance of conceptualization and measurement at appropriate levels of analysis, and attention to and conceptualization of interactions across levels of analysis and among actors at the *same* level.
  - The importance of weighing potential contributions of multilevel analysis against the need to keep the research within manageable proportions.
- *Interaction effects.* Several TEP members noted that interactions among elements within the framework may be as important as the effects of isolated variables.
- *Alignment of constructs with stakeholder and practice roles.* The CFIR distinguishes among the various roles that individuals can assume in implementing an intervention (e.g., leading, facilitating, championing), and our discussion with the TEPs led to the addition of yet other roles. We recognize that constructs may take on different meanings or measured values when applied to different roles.
- *Conceptualizing the framework around settings or organizations.* Complex system interventions may be broader than a particular practice or integrated health care setting

(where patients receive care and treatment) and can include community-based organizations, such as community coalitions, agencies, and collaboratives. These are often the effector arm and critical to care transitions or PCMH interventions. Hence, interventions may be based upon layers of organizations, rather than embedded in a single setting or group of settings.

- *Indicators of implementation success*. Proctor et al.[2] define outcomes of the implementation (e.g., acceptability, adoption, appropriateness, costs, feasibility, preservation, sustainability) as distinct from outcomes of an intervention. The TEP agreed that specifying these implementation outcomes is a useful addition to the framework. To avoid confusion with clinical outcomes, we opted for the term "indicators of implementation success" to refer to Proctor's implementation "outcomes."
- *Intervention outcomes*. The PR and PCMH TEPs recommended adding outcomes to the CFIR, although they did not completely agree on which outcomes to include or what to call them. We added intervention-specific outcomes to each of the three frameworks. (Several of the outcomes overlap.) We kept the outcome constructs general to keep the focus of the framework on context and implementation. A large body of literature on many of these outcomes can be used to conceptualize them in more detail.
- *Patient-centered/population health perspectives.* A number of the PCMH and Care Transitions TEP members thought the draft contextual frameworks should be more patient centered. However, some members of the Care Transitions TEP pointed out that institutional outcomes such as readmissions and cost, rather than patient-centered outcomes such as quality of life, may be a dominant goal. Another consideration related to context is the influence of population health on the intervention design and outcomes.
- *Applicability of contextual frameworks to practice*. Although originally designed to guide research and evaluation, the PCMH Framework could also incorporate issues of concern to practitioners and managers, and has the possibility of becoming a useful tool for practice.

Conclusion

The investigative team took a very open approach to this effort, beginning with a literature scan and discussions with AHRQ. Much of the adaptation protocol was developed during the project. We considered other approaches involving more systematic methods (e.g., Delphi) but concluded that a highly systematic approach would not move us toward our desired goal. We did not seek to establish a consensus on every element of the framework; rather, we sought to generate qualitative feedback on the general utility of the framework for complex system interventions. In adapting the CFIR for complex system interventions, we thought it critical to include input from both research and practice stakeholders to ensure that the content is understandable and applicable to the intervention strategy of interest.

Given more time and resources, the frameworks could have been vetted with a broader set of stakeholders and their content honed with more systematic methods. However, we believe the goal of adaptation is not perfection, and care must be taken not to make a framework "endlessly complex"[1] for the sake of completeness. We encourage researchers to approach the adaptation process and the frameworks themselves iteratively, and to document and share their experiences with colleagues. Our collective understanding of the complex phenomena we are striving to define, measure, and explain can only increase through such efforts.

References

1. 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. PMID: 19664226.

2. Proctor E, Silmere H, Raghavan R, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. Adm Policy Ment Health. 2011 Mar;38(2):65-76. PMID: 20957426.

Introduction

Background

In January 2012, the Agency for Healthcare Research and Quality (AHRQ) contracted with the RTI International–University of North Carolina at Chapel Hill Evidence-based Practice Center to develop integrative contextual frameworks that would guide implementation researchers and evaluators of two types of complex systems of intervention: process redesign for improved efficiency and reduced cost (PR) and patient-centered medical homes (PCMH). Under a follow-on contract initiated in September 2012, a similar effort was launched for care transitions between hospital and ambulatory care settings. These three interventions are supported by AHRQ in its research portfolio as an investment in strategies that hold the potential to improve health care and delivery. Thus, the context of implementation, the processes underlying these interventions; and the implications for sustainability and replicability deserve as much attention as the outcomes of these interventions. However, the lack of common understanding or awareness of context among researchers and evaluators of these interventions poses a significant barrier to evidence building. These integrated frameworks seek to address this barrier and provide a common point of reference to guide future work.

The focus on complex system interventions is part of AHRQ's ongoing effort to bring new and useful perspectives to bear on how researchers conceptualize health care organization and delivery. In its report *Crossing the Quality Chasm*,[1] the Institute of Medicine put forth a case for incorporating the perspectives of complexity science, specifically Complex Adaptive Systems, in the design of health care interventions. The care systems in which PR, PCMH, and care transitions seek to intervene bear many of the defining attributes and features of a Complex Adaptive System. These systems are "complex," meaning they are diverse both in their constituent parts and general form. They are capable of changing in response to feedback and experience and are thus "adaptive." Their structure aligns to that of a "system," which is a set of interdependent entities enmeshed and embedded within one another.

Context is a critical factor within this highly adaptive and dynamic environment because all potential confounding variables cannot be controlled through randomization and stratification. Even clinical interventions, tested under highly controlled settings, may eventually be scaled to settings and populations very unlike those in which they were originally tested. Therefore, the key question for any kind of intervention applied to a Complex Adaptive System is not only, "Does it work?" but under what conditions and for which populations these interventions are more or less effective. Implicit in these questions is the notion that the context will change the intervention and vice versa. However, no common definition of context exists. Shekelle et al., speaking about patient safety practices, note: "There is no standard definition of 'context.' It may include detailed information about processes of implementation, as well as barriers and facilitators related to the organizational and policy environment in which a patient safety practice is implemented."[2, p.9]

We identified the Consolidated Framework for Implementation Research (CFIR)[3] as a practical model for furthering the definition and conception of context for complex systems interventions. As the goal of our effort was to create an *integrated* framework, starting with a framework that had already reviewed and synthesized existing frameworks was an obvious choice. At the time, to our knowledge, the CFIR was the only integrated framework of its kind. The CFIR addressed the need of researchers and evaluators to assess the effectiveness of implementation within a specific context, and to not only maximize the benefit within that

context but also promote dissemination to other contexts. Numerous theories of implementation and context existed in the literature but had differing and overlapping terminologies and constructs. The CFIR synthesizes these various terminologies, definitions, and constructs into a consolidated framework and a common taxonomy for implementation research on health service delivery. Drawing on 19 different theories, the CFIR consists of five domains that describe the internal and external context of implementation: Intervention Characteristics, Outer Setting, Inner Setting, Characteristics of the Individuals, and Process. The CFIR does not posit any particular set of hypotheses or causal pathways and does not confine itself to any one theory.[3]

Table 1 presents these domains categorized into more discrete elements (constructs). These domains interact with one another in a multidirectional fashion (the outer setting influences the inner setting and vice versa) and include multilevel influences (e.g., individual, organizational). The focus of the framework is on the interaction between context and processes, so it does not posit a causal pathway to specific outcomes.

Table 1. Consolidated Framework for Implementation Research (CFIR) domains and constructs

Domain	Construct
Intervention Characteristics	Intervention Source
	Evidence Strength and Quality
	Relative Advantage
	Adaptability
	Trialability
	Complexity
	Design Quality and Packaging
	Cost
Outer Setting	Patient Needs and Resources
	Cosmopolitanism
	Peer Pressure
	External Policy and Incentives
Inner Setting	Structural Characteristics
	Networks and Communications
	Culture
	Implementation Climate
	Readiness for Implementation
Characteristics of Individuals	Knowledge and Beliefs About the Intervention
	Self-Efficacy
	Individual Stage of Change
	Individual Identification With Organization
	Other Personal Attributes
Process	Planning
	Engaging
	Executing
	Reflecting and Evaluating

Source: Damschroder LJ, Aron DC, Keith RE, et al. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci. 2009;4(1):50. PMID: 19664226.

The contextual frameworks described here are comprehensive, heuristic tools designed for researchers for the purpose of generating novel and compelling questions, as well as to glean fresh insights for research and evaluation design. Investigators can use the contextual frameworks to examine in depth the conditions under which implementation occurs and the multitude of factors (and the complex web of relationships among them) that determine whether the intended outcomes are achieved. In short, these contextual frameworks bring to the fore *how, why, where,* and *for whom* an intervention succeeds or fails. Equally important, these contextual frameworks offer a general taxonomy and conceptualization of key implementation constructs. Used as a sort of universal guide by investigators engaged in similar fields of study, these

contextual frameworks could enhance the comparability of these studies and the synthesis of their findings. Intervention designers, implementers, and decisionmakers will gain a greater understanding of the generalizability and replicability of specific interventions.

The frameworks, due to the breadth and relevance of the constructs included, should acquaint the researcher or the implementing organization with the large range of contextual variables that are possible and important to consider in a study or evaluation. The frameworks can be used by investigative teams planning multisite studies or funders supporting a portfolio of grants to deliberate on the core constructs needed for cross-site analysis. However, we recognize that the sheer number of constructs can be overwhelming and, at the suggestion of our Technical Expert Panels (TEPs), we added a general roadmap to guide in the selection of a parsimonious set of constructs. As every study is unique, there is no simple recipe for construct selection. The decision to include or leave out specific constructs should be rooted in the context of the study itself.

Scope

Our task was to build upon the CFIR, by examining its suitability and adapting it as necessary to the unique research and evaluation requirements of PR, PCMH, and care transitions through literature scans and a series of intervention-specific TEPs. We determined at the outset that some degree of adaptation would be required because the CFIR, as a general model of implementation within bounded organizational settings, might not speak to the unique and distinct attributes of complex system interventions. For each intervention, we used TEP input about enhancing usability and relevance to modify the CFIR (e.g., definitions, terms, organization, and structure). We did not systematically assess the validity or weight of evidence of each construct or identify their measures; although this remains an important next step in the development of the frameworks. As a research and evaluation tool the frameworks remain limited to a taxonomy of domains and their related constructs and subconstructs, and do not address study design, the data collection methods, or statistical analyses.

Users of the resulting adapted frameworks—the PR Framework, PCMH Framework, and Care Transitions Framework—should view them as works in progress intended to evolve and adapt to the context in which they are applied.

Organization of the Report

The remainder of the report is composed of six chapters. The first of these is a general Methods chapter, which describes the general procedures for framework adaptation. The three chapters that follow present the PR, PCMH, and Care Transitions Frameworks, respectively. These chapters are organized similarly and present: (1) a brief overview of the intervention topic; (2) a brief summary of framework modifications; (3) the contextual framework itself, represented in a conceptual graphic and detailed tables; (4) guidance for using the contextual framework; and (5) a case study application of the contextual framework. In the final two chapters, the Discussion highlights the cross-cutting conceptual and methodological issues the TEPs considered during the adaptation process, and the Conclusion presents recommendations for continued framework adaptation and refinement.

We suggest readers direct their attention to the framework closest to their interests. The chapters containing the frameworks are stand-alone documents, and the first two sections are nearly identical across the three frameworks. The content of the frameworks, though they have been tailored to the interventions, is also quite similar and the differences may not be readily

apparent. A list of the differences is presented in Table B in the Executive Summary and Table 25 in the Discussion chapter. The frameworks are comprehensive but not exhaustive, and users should apply them in the manner that is most practical to their needs.

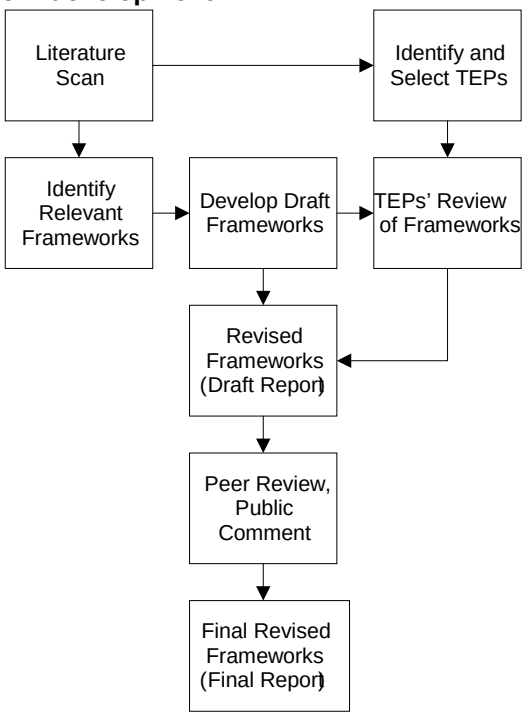
Methods

Adaptations of the Consolidated Framework for Implementation Research (CFIR) to process redesign for efficiency and reduced cost (PR), patient-centered medical homes (PCMH), and care transitions were modified using the feedback obtained from a literature scan, consultation with the original CFIR developer and experts familiar with that work, and two Technical Expert Panels (TEPs) that examined the framework objectively during a series of calls. In this section, we briefly describe the four methods used for the adaptation and refinement: (1) a brief literature scan, (2) TEPs to inform the content and use of each of the three draft contextual frameworks, (3) TEPs to inform the usability of the PR and PCMH Frameworks, and (4) a self-assessment of the first-phase project.

The work was carried out in two discrete phases: phase 1 (January 2012 through June 2012) and phase 2 (September 2012 to September 2013). In phase 1, we developed the draft PR and PCMH Frameworks. In phase 2, we conducted a self-assessment of phase 1, refined the frameworks, and modified the process for the adaptation of the Care Transitions Framework. The project's timeframe did not allow for a TEP to assess the usability of the Care Transitions Framework.

Our framework adaptation process was iteratively built from a set of sequential activities, as depicted in Figure 1. Much of this adaptation process was developed during the project rather than a priori. The first activity, the literature scan, informed the initial draft of the adapted framework. This draft was subsequently revised using feedback from the TEPs and then finalized through the input of peer reviewers and public comments.

Figure 1. Contextual framework development



Note: TEP = Technical Expert Panel.

Upon deliberation, we selected a set of recommendations that were feasible to complete within the timeframe of this project. These included the majority of suggestions made by the

TEPs; only a few suggestions (such as moving the frameworks online) were not addressed. In addition, we used these recommendations as we developed the initial drafts of the Care Transitions Framework. Likewise, a number of the recommendations from the Care Transitions TEP influenced the content of the final PR and PCMH Frameworks.

Literature Scan

The adaptation process for each of the intervention-specific frameworks began with a scan of the literature, which included MEDLINE™, the published and gray literature, and articles recommended by content experts at AHRQ. We focused on articles published after January 2005 so as to overlap but not duplicate the period covered by the CFIR (published in 2009). We sought to identify relevant topic-specific contextual and theoretical frameworks, theories, and models that had not been covered in the CFIR. Furthermore, we conducted the literature scan so as to ensure that the frameworks were comprehensive in scope and captured the unique attributes and considerations of the intervention itself.

We used 50 search terms for the PR and PCMH literature scan singly and in combination (e.g., patient care management, health care redesign, implementation theory), and we used 18 terms for care transitions (e.g., hospital, transitional care, ambulatory care). The complete set of single search terms is listed in Appendix A**.** Using a set of structured abstraction questions, we reviewed each selected article to identify intervention-relevant components (an input, output, process, or outcome) not already included in the original CFIR that we could add as new constructs or use to refine and augment existing ones. The number of articles the literature scan identified and we selected for review and the methods we used for abstraction are shown in Appendix A. The articles included in the literature scan are listed in Appendix B**.**

The investigative team used the results of the literature scans–the abstracted components from reviewed articles that could adapt or refine the CFIR–to develop the two primary components of each framework: a table listing domains and constructs, their definitions, and examples (for selected constructs) and a graphical representation of the framework components. Knowing the literature scan might overlook important literature, we relied on the AHRQ technical experts and TEP members throughout the development process to identify additional papers not identified in the initial review.

Content and Use Technical Expert Panels

We recruited three TEPs, one each for PR (8 members), PCMH (7 members), and Care Transitions (11 members), to assess the content and use of the draft contextual frameworks. Individuals recruited to each TEP had extensive experience in the intervention in one of the following three capacities: research and evaluation, management and practice, or general implementation research. The goal of TEP recruitment was to include individuals with diverse professional perspectives and ensure representation in these three capacity areas. For the Care Transitions TEP, we also sought to include key organizations involved in care transitions interventions and initiatives—Re-Engineered Discharge (RED), State Action on Avoidable Rehospitalization (STAAR), and the Community-Based Care Transitions Program (CCTP). These subject-matter experts were identified through the literature scan, AHRQ project officers, and the experts themselves, who recommended colleagues to the team. For each topic, we held two rounds of TEP conference calls, with each group call lasting 2 hours. We held 1-hour individual calls with experts who were not available for the group calls.

A set of structured questions guided each TEP discussion, with a focus on examining the relevance and suitability of the framework graphics, constructs, definitions, examples, and case studies. We used detailed notes from each call to revise the framework materials. Input from the PCMH TEP was used to refine the PR Framework and vice versa. Working in tandem, the TEPs identified issues that might not have been raised by each TEP on its own and produced greater depth and breadth of input for the adaptation process. The Care Transitions TEP completed their work after the PR and PCMH TEPs, but a number of their recommendations influenced the content of the PR and PCMH Frameworks.

Usability Technical Expert Panels

After framework development, we convened two TEPS to assess the usability of the PR and PCMH Frameworks. TEP members represented researchers, health care executives, and providers who would be potential users of the frameworks. We used criteria for framework utility (familiarity, resonance, parsimony, coherence, and differentiation)[4] to guide our discussions. Further details are found in Appendix C**.**

Self-Assessment

During the second phase of the project, we conducted a self-assessment early on to apply lessons learned to the Care Transitions TEP and to gather final recommendations for the PR and PCMH Frameworks. The self-assessment included a self-assessment questionnaire we emailed to the initial TEP members to gather feedback on the procedures and materials we had used during their calls. In addition, a member of the investigative team not involved in the first phase reviewed the procedures and materials for clarity and effectiveness in meeting TEP aims.

Peer and Public Review

Experts in the PR, PCMH, and Care Transitions fields as well as individuals representing stakeholder and user communities were invited to provide external peer review of this report, and AHRQ and an associate editor also provided comments. The draft report was posted to the AHRQ Web site for 4 weeks to elicit public comment. We addressed all reviewer comments, revised the text as appropriate, and documented the items in a disposition-of-comments report.

Process Redesign Framework

Overview[b]

Process redesign (PR) involves changing the way care is delivered by "conceptualizing, mapping, refining, and continuing to improve the many processes of healthcare." Further, redesign may "challenge existing practices, data structures, roles, and management practices, and it results in continuous change."[1] The focus of our work was to develop an integrative framework that would guide implementation research on PR for improved efficiency and reduced costs: the PR Framework. A few examples of these kinds of interventions include changes to an office or clinic workflow to allow administrative tasks to be carried out more easily and with less time, the introduction of new equipment or technology to improve clinical procedures, or streamlining billing procedures.

The purpose of this PR Framework is to guide research and evaluation of PR implementation within a broad range of organizational settings. The primary users of this framework are investigators and practitioners who wish to understand why implementation succeeds or fails and whether the PR intervention or its components can be replicated and scaled to other settings. Investigators can apply the PR Framework to a whole intervention with various distinct parts or to one or more of those parts.

This chapter is organized into six sections. The first section briefly describes the domains of the PR Framework. It is followed by a discussion of the most noteworthy changes we made from the Consolidated Framework for Implementation Research (CFIR). The PR Framework is next presented in two forms, a graphic followed by a full explication of the domains, constructs, and subconstructs in Tables 2 through 8. The How To Use section gives users a step-by-step roadmap for approaching the multiple and complex dimensions of the framework. This chapter concludes with a case study of a PR implementation that applies the roadmap. See the Glossary for important terms.

Organization of the Process Redesign Framework

Tables 2 through 8 show the entire PR Framework that we adapted from the CFIR.[3] The content is organized into seven domains that represent families of constructs we subdivided into more precise subconstructs. These elements are summarized with their definitions in the first columns of the tables; those elements labeled "new" were not part of the original CFIR. The PR Framework domains, adapted from the CFIR, are —

- **Intervention Characteristics:** The characteristics and features of the intervention being implemented into a particular organization or organizations, including core components (the essential and indispensable elements of the intervention itself). These may be fixed or mutable attributes; they are considered and assessed prior to implementation and influence adoption decisions.
- **Outer Setting**: Includes the economic, political, and social context within which an organization resides.

[b]Because the three frameworks are described in stand-alone chapters, the Overview and Organization sections are similar across the chapters.

- **Inner Setting:** Tangible and intangible manifestation of characteristics of the organizations involved in the intervention, including structural characteristics, networks and communications, culture, climate, and readiness, which all interrelate and influence implementation.
- **Characteristics of Individuals and Teams**: The individuals (as carriers of cultural, organizational, professional, and individual mindsets, norms, interests, and affiliations) involved with the intervention and/or implementation process. Includes patients and caregivers.
- **Process of Implementation**: Refers here to the course of *actions* (e.g., planning, engaging, and reflecting) to achieve individual- and organizational-level use of the intervention as designed.
- **Measures of Implementation**: Refer to what Proctor et al.[5] call "implementation outcomes"; they are intermediary outcomes that describe how well the implementation was carried out and the prospects for sustainability.
- **Outcomes**: The results of the PR implementation, defined as the targets of the PR intervention.

The PR Framework provides a comprehensive menu of contextual domains and constructs. Users of the framework may find it useful to refine the subconstructs even further for specific research purposes. Researchers could use these frameworks to define and review the range of potentially relevant concepts and variables as they prepare an implementation study. Additionally, they may engage in prestudy to determine which constructs are likely to be most useful. During their research, they may refine their selection of constructs and construct specifications in response to data that emerge from the field or in response to changes in the intervention process and context that take place during the life course of the intervention.

Modifications in the Process Redesign Framework

The CFIR served as the foundation for the PR Framework. In addition, the PR and patient-centered medical home (PCMH) Frameworks were developed simultaneously, and therefore additions to one framework resulted in similar additions to the other when appropriate. All construct and subconstruct additions are noted in Table B in the Executive Summary and Table 25 in the Discussion. Descriptions and examples of the original CFIR have been modified to enhance their resonance to PR researchers and evaluators. Below, we briefly list some of the constructs, by domain, that were added to the PR Framework based on the input of the PR Technical Expert Panel or our review of the PR literature. For definitions of these constructs, we direct the reader to the PR Framework tables that follow.

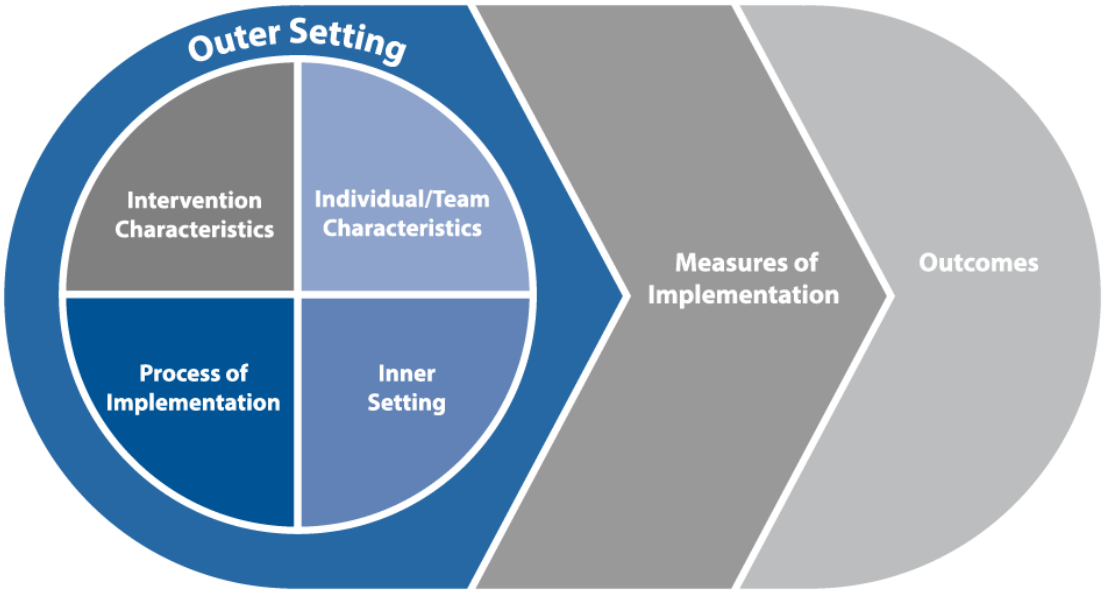
- Intervention Characteristics: The PR Framework includes the following new constructs reflecting characteristics of a PR intervention, which often focuses on changing a process involving technology or workflow: *vision and change strategy, feasibility, compatibility, radicalness, user control, workflows,* and *task/process standardization.*
- Outer Setting: *Technological environment* reflects the importance of technological trends and updates in the development and implementation of a PR intervention.
- Inner Setting: New constructs related to features of the inner setting that may impact the PR implementation include *staff commitment* (a subconstruct under *readiness for implementation), information technology (IT) and health information technology (HIT) resources, human factors, physical space and equipment,* and *staff time*.

- Characteristics of Individuals and Teams: New constructs include *skills and competencies* that add additional dimensions beyond *knowledge and beliefs.*
- Process of Implementation: We defined the *executing* construct with more detail, adding *staging and iteration* as a subconstruct.
- Measures of Implementation: This is a new domain. The PR Framework made a few modifications to those described in Proctor et al.[5] To *adoption,* we added *abandonment,* since the decision to stop an implementation can be as important to consider in implementation research as the decision to begin an implementation. *Feasibility* was moved to Intervention Characteristics, as it is an attribute of the intervention to be considered in the decision to implement, but it can change over the course of implementation. *Replicability* in process redesign is often an explicit goal; an intervention must be successful not only in one setting but multiple settings. *Cost* was further clarified by adding *implementation* to distinguish it from other cost outcomes.
- Outcomes: In order to provide users with a comprehensive list of outcomes related to PR, we included the following constructs: *cost effects/impact, perceived value,* and *unintended consequences.* Furthermore, we capture the aims outlined by the Institute of Medicine (IOM) in its seminal 2001 report[1] by including the following outcomes: *safety, effectiveness, timeliness, efficiency,* and *equitable* (originally termed equity in the IOM report).

Graphic Representation of the Process Redesign Framework

Figure 2 shows the relationships of five of the domains to measures of implementation success and various PR outcomes. On the left side of the figure is an inner circle with four domains: Intervention Characteristics, Individual/Team Characteristics, Inner Setting, and Process of Implementation. Surrounding this inner circle is an outer ring named the Outer Setting that may influence these four domains. An arrow to the right of the inner and outer circles points to the Measures of Implementation, which influence Outcomes.

Figure 2. Framework for Implementation Research on Process Redesign

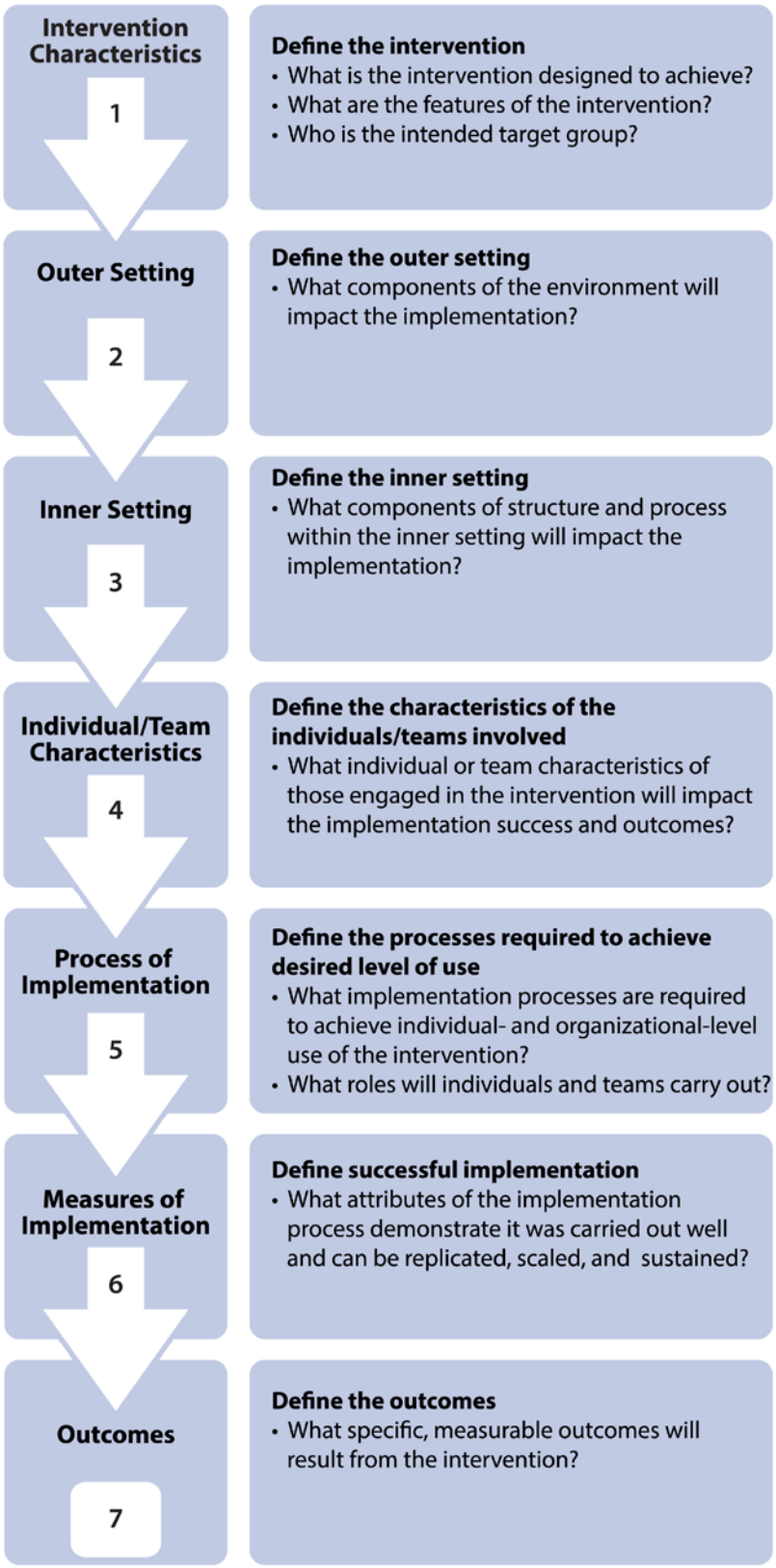


How To Use the Process Redesign Framework

The flowchart in Figure 3 presents step-by-step guidance on how the PR Framework may be used. The flowchart presents a series of questions, and each set of questions is tied to a particular domain in the framework (Tables 2 through 8). As these questions are considered, the user should refer to the appropriate domain in the framework table to see which constructs are relevant. For example, Step 1 corresponds to the Intervention Characteristics domain; as users consider the various issues related to this domain, they should refer to the framework to choose those constructs relevant to them.

As mentioned, the framework does not prescribe which constructs must be selected due to the diversity of research objectives and to variations between different PR interventions. The frameworks are designed to be a practical tool for research and evaluation, and it would be unfeasible to include all or even most of the constructs described. While following this step-by-step process of using the framework, we recommend that users of the framework select qualities, features, or characteristics that are closely tied to intervention outcomes and aligned to the goal, questions, theory, or model guiding the research or evaluation. Doing so will help the user prioritize the constructs, remain focused on the essential aims of the investigation, and keep the number of constructs to a manageable size.

Figure 3. How to use the Process Redesign Framework



Content of the Process Redesign Framework

We present the PR Framework in Tables 2 through 8 with brief definitions of the constructs and subconstructs, and examples. Constructs labeled "new" are additions to the original CFIR.[3] Based on Technical Expert Panel input, we added clarifying examples for those constructs and subconstructs that were unclear or complex. Each construct or subconstruct is independent and should be applied, as appropriate, to the research questions and objectives.

Table 2. Process Redesign Framework—Intervention Characteristics

Construct	Description	Examples
A. Vision and change strategy (NEW)	The proposed changes envisioned by the PR and the theory of change: how the intervention is supposed to work, what it is meant to achieve or do.[6] May be explicated in logic models, goals, outcomes, and performance measures.	According to sociotechnical theory, engaging end-users in the design of the process will result in greater utility and adoption.[7]
B. Targeted groups	The staff and others (vendors, patients) who will be impacted by the intervention.	—
C. Intervention source	Identifying who (which individuals or groups) originated the PR initiative and/or from which source the components of the initiative were derived.	—
D. Evidence strength and quality	Target group and other stakeholders' perceptions of the quality and validity of evidence supporting the belief that the PR will have the desired outcomes.[8]	Peer-reviewed published literature; Institute of Medicine Consensus Study Reports.
E. Relative advantage	Target group and other stakeholders' perception of the advantage of the PR instead of other possible interventions or maintaining the status quo.[7]	—
F. Adaptability	Target group and other stakeholders' perception of the degree to which PR strategies, techniques, and practices can be adapted to local needs.	—
G. Feasibility (NEW)	Target group and other stakeholders' perception of the extent to which the PR can be successfully used or carried out within a given organization or setting.	—
H. Trialability	Target group and other stakeholders' perception of the ability to test and refine components of the PR on a small scale in the organization.	—
I. Complexity	Target group and other stakeholders' perception of duration, scope, centrality, and intricacy, and number of steps required to implement.	—
J. Compatibility (NEW)	Target group and other stakeholders' perceptions regarding the alignment of values and norms attached to PR with those of the practice or organization.	—
K. Radicalness (NEW)	Target group and other stakeholders' perception of the degree of difference between the change envisioned and the current state.[9]	—
L. User control (NEW)	The degree to which the intervention relies on the end-users' authority/skill to implement the PR on their own vs. reliance on experts.	Implementation of Lean requires use of consultants trained in Lean methods.
M. Workflows (NEW)	Tasks and workflows, including interdependencies between them that are the focus of the change strategy or that will be affected by it.[7]	—
N. Task /process standardization (NEW)	Degree to which the PR seeks to standardize selected tasks and/or processes that require iterative consultation.	—
O. History (NEW)	Experiences with similar interventions within the setting and within the target population.	The maturity, breadth, and depth of quality improvement processes used within an integrated physician network to increase the efficiency of referral appointments.[10,11]

Note: PR = process redesign.

Table 3. Process Redesign Framework—Outer Setting

Construct	Description	Examples
A. External networks	Degree to which an organization is networked with other external organizations that are engaged in similar types of PR development activities. *(Termed "cosmopolitanism" in the CFIR.)*	—
B. External pressure	Pressure emanating from outside the organization to implement a PR intervention.	Key peer or competing organizations have already implemented PR; there is competitive pressure to secure a better share of the market.
C. External policy and incentives/ disincentives	Laws and regulations (governmental or other central entity), recommendations and guidelines, and payment schemes that affect the decision to adopt or abandon the PR.	—
D. Technological environment (NEW)	Technological trends and movements, and the availability of technological innovations that may affect the intervention and its context.	Software product trends, health information exchanges, cloud computing, social media mobile applications.

Note: CFIR = Consolidated Framework for Implementation Research; PR = process redesign.

Table 4. Process Redesign Framework—Inner Setting

Construct	Description	Examples
A. Structural characteristics	Social architecture; age; maturity; size; mix of occupations of team, unit, organization, or system; and the employment status of physicians.	—
B. Team and network characteristics	Influence, breadth, depth, and role diversity of teams and networks engaged in the PR.[11]	—
B1. Teams, networks, and communications	Nature and quality of teams and social networks; formal/informal communication and information exchange within an organization or between organizations.	—
B2. Team and network self-organization	Capacity to arrange and organize for a defined (nonrandom) purpose without external pressure or mandate.	—
C. Culture	Norms, values, and beliefs within a team, unit, or practice that affect views of PR and its implementation.	—
D. Implementation climate	Capacity or reserve[12] for change and the shared receptivity of involved individuals to the intervention.	—
D1. Tension for change	Degree to which stakeholders perceive the current situation as intolerable or needing change.	—
D2. Mandate	Whether compliance with the PR initiative is expected.	—
D3. Accountability	Whether entities are subject to tangible consequences for noncompliance.	—
D4. Relative priority	Individuals' shared perception of the importance of the PR implementation within the organization.	—
D5. Organizational incentives	Extrinsic incentives offered to adopt PR.	Gain-sharing awards, promotions, increased stature, or respect.
D6. Learning climate	The organization's willingness to promote trial and error, test new methods, and innovate.[11]	Routine and structured quality improvement activities.
E. Readiness for implementation	Tangible and immediate indicators of organizational commitment to its decision to implement PR.	—
E1. Leadership commitment	Degree of commitment, involvement, and accountability of leaders and managers to quality and safety improvement and the PR initiative.	—
E2. Staff commitment (NEW)	Degree of commitment, involvement, and accountability of physicians, nurses, and other staff to efficiency and waste reduction and to the PR specifically.	Provider involvement in setting and monitoring efficiency targets.
F. Access to information, training, education	Ease of access for staff to digestible, applicable information and knowledge about PR. Resources dedicated to training and education.	Online training tools, time given for training and education, funding for training.
G. IT and HIT resources (NEW)	Technological infrastructure in place to support electronic information management and redesign of patient care.	—
G1. HIT systems (NEW)	Electronic information management infrastructure and technologies available to clinicians to manage patient care, data, and communications.	Decision support tools, e-prescribing, electronic health records.

Table 4. Process Redesign Framework—Inner Setting (continued)

Construct		Description	Examples
	G2. IT systems (NEW)	Technological systems and capabilities to support PR.	Server space, bandwidth, interoperability, health information exchange.
	G3. Human factors (NEW)	Features of the physical and technical environment of the practice that determine the use, accessibility, and acceptability of technology in patient care.[13]	Repositioning the blood pressure station to create more rapid intake flow.
H.	Physical space and equipment (NEW)	Physical space and equipment dedicated to or impacted by the PR intervention.[14]	—
I.	Staff time (NEW)	Time dedicated to implement the PR intervention.	Paid time given to implementation staff to attend trainings, and adjust and adapt to new processes.

Note: HIT = health information technology; IT = information technology; PR = process redesign.

Table 5. Process Redesign Framework—Characteristics of Individuals and Teams

Construct	Description	Examples
A. Knowledge and beliefs	Views regarding the PR, as well as familiarity with facts, truths, and principles related to the intervention.	—
B. Skills and competencies (NEW)	Degree of relevant subject matter expertise, skills, and competencies within the implementing team, unit, and organization.	—
C. Role (NEW)	Individual's or team's role and responsibilities, and extent of multiple or shared roles.	—
D. Authority (NEW)	Perceived and actual degree of authority to make decisions and act autonomously.[15]	—
E. Self-efficacy	Confidence in the capacity to execute the courses of action necessary to achieve PR goals.	—
F. Collective efficacy (NEW)	Conviction of individuals and teams involved that the PR transformation can be carried out in cooperation with others.[16]	—
G. Stage of change	Phase an individual or team is in; characterizes progress toward skilled, enthusiastic, and sustained application of PR strategies.	—
H. Identification with organization	How individuals or teams perceive the organization, and their relationship and degree of attachment with the organization.	—
I. Patient needs and resources (NEW)	Patient priorities for health and health care, and the social and economic capital to address those priorities.	—
J. Other personal attributes	Other personal traits not captured elsewhere.	Tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, learning style.

Note: PR = process redesign.

Table 6. Process Redesign Framework—Process of Implementation

Construct	Description	Examples
A. Planning	Degree to which implementation steps or tasks are developed in advance and take into account various scenarios; the quality of those schemes or methods.	Contingency planning.
A1. Assessing (NEW)	Formal assessment of the problem or condition to be changed, including needs of users and barriers and facilitators of change.	Root cause analysis.
A2. Goal-setting	Written goals, objectives, benchmarks, and timelines for PR activities, and their feasibility and adequacy.	—
A3. Feedback	Procedures used to provide feedback to stakeholders and their adequacy.	—
B. Acquiring and allocating resources (NEW)	Staff time, space, equipment, and other resources dedicated to implementing the PR; the adequacy of those allocations.	—
C. Process ownership (NEW)	The diversity of practice roles involved in processes of implementation; authority and accountability for these activities.	—
D. Practice roles	Roles of those involved in the decision to adopt, execute, and facilitate the intervention.	—
D1. Organizational leaders (NEW)	Managers and others with the authority to dedicate resources and make decisions to maintain or abandon the implementation.	—
D2. Opinion leaders	Individuals who influence (positively or negatively) the attitudes and beliefs of their colleagues.[17,18]	Experts and peers.[19]
D3. Implementation leaders	Individuals formally appointed with responsibility for implementing the PR.	Project manager, team leader, project coordinator.
D4. Champions	Individuals who dedicate themselves to galvanizing and maintaining support for the PR and overcoming indifference or resistance.	—
D5. External change agents	Individuals outside the organization who can facilitate or undermine decisions about PR adoption and implementation.	Individuals from health plans, other health care systems, consultants, policymakers.
D6. Facilitator (NEW)	A formally appointed role that provides reflective, empathetic, and interactive counsel.	Experts who model and teach new skills and practices.[16]
D7. Frontline staff (NEW)	Administrative staff and providers (within and outside the organization) who will implement the PR or be impacted by it.	—
D8. Patients and other stakeholders (NEW)	Individuals and their caregivers who are impacted by the PR.	—
E. Engaging	Processes involved in attracting and involving appropriate individuals in the implementation and use of the intervention.[10]	Capitalizing on relationships between leaders and frontline staff.
F. Executing	Manner in which those involved carry out and accomplish the implementation according to plan; the role and authority to execute.[15]	—
F1. Decisionmaking (NEW)	The frequency, duration and timing of the activities involved in making decisions about the intervention.[11] The directionality of those activities.[20]	Decisions made top down vs. bottom up.

Table 6. Process Redesign Framework—Process of Implementation (continued)

Construct	Description	Examples
F2. Staging and iteration (NEW)	Whether the implementation is carried out in incremental steps, refined iteratively, or implemented in its entirety within a specified period.	—
F3. Facilitating and coaching	Use of experts to teach new processes, model best practices, and develop solutions; the structure, formality, and adequacy of these activities.	—
G. Reflecting and evaluating	Quantitative and qualitative feedback on the quality of the implementation process[21]—"reflexive monitoring" and the degree to which it is attained.	Project monitoring, systematic feedback processes.
G1. Measurement capability and data availability (NEW)	Availability of data and capacity to use them for monitoring, evaluation, and process improvement. Includes measurement differences between organizations; sharing; accountability for collection, documentation, and analysis; and timeliness.	

Note: PR = process redesign.

Table 7. Process Redesign Framework—Measures of Implementation (new domain)

Construct	Description	Examples
A. Acceptability (NEW)[2]	Degree to which PR goals, strategies, tactics, and specific activities are agreeable, palatable, or satisfactory.	—
B. Adoption/abandonment (NEW)[2]	Intention, initial decision, or action to employ or cease PR.	—
C. Appropriateness (NEW)[2]	Suitability of the PR intervention to the specific issues or problems to be addressed.	—
D. Intervention cost (NEW)[2]	Costs of the PR interventions and costs associated with implementation, ongoing maintenance costs, and opportunity costs.	Investment costs for training, staffing, and IT updates.
E. Fidelity (NEW)[2]	Degree to which PR was implemented as intended by those who developed and/or introduced it to the organization.	—
F. Reach (NEW)	Absolute number, proportion, and representativeness of entities willing to participate in the PR.[22]	—
F1. Reach within the population (NEW)	Number of patients exposed to or participating in the PR intervention.	—
F2. Reach within the organization (NEW)	Absolute number, proportion, and representativeness of individuals and subcomponents within an organizational setting exposed to or participating in the PR.[22]	Percentage of practices within a network that adopt open scheduling.
G. Penetration (NEW)[2]	Depth of integration of a process design implementation within a service setting and its subsystems.	Among practices with e-prescribing, the percentage of patients who receive e-prescriptions.
H. Replicability (NEW)	Degree to which the PR implementation process and outcomes can be reproduced beyond the adopting site or setting.	—
I. Sustainability (NEW)[2]	Degree to which changes resulting from PR are maintained or institutionalized within a service setting.	—
J. Evolvability (NEW)	Degree to which the change is sustained through adaptation and refinement.	—

Note: IT = information technology; PR = process redesign.

Table 8. Process Redesign Framework—Outcomes (new domain)

Construct	Description	Examples
A. Patient experience (NEW)	Impact on patient experiences with care, including satisfaction with care and patient-provider interactions at the same or lower cost.[21]	—
B. Provider experience (NEW)	Effect(s) on a provider's burden of effort and quality of work life, communication, and interactions with patients and colleagues.[21]	—
C. Accessible (NEW)	Extent to which PR delivers access to routine/urgent care and clinical advice during and after business hours, provides electronic access.[23]	—
D Quality (NEW)	Extent to which PR shows an ongoing commitment to high quality through the use of performance measurement, evidence-based strategies, etc.[24]	—
E. Safety (NEW)[3]	Extent to which the intervention contributes to providing safe care for patients; avoiding injuries.	—
F. Effectiveness (NEW)[3]	Extent to which the intervention contributes to providing services to all who could benefit, without providing services to those who would not.	—
G. Timeliness (NEW)[3]	Extent to which the intervention contributes to reducing wait times and delays, both for those who provide care and those who receive it.	—
H. Efficiency (NEW)	Improvement in an outcome without added resource inputs or with less resources/cost than previously required.[25]	Reduction in equipment, supplies, provider time, or patient time (without harm to quality).
I. Productivity (NEW)	Degree to which the intervention results in greater output of a service or good in the same or less amount of time.	Number of tests processed per hour.
J. Equitable (NEW)	Extent to which disparities in care are reduced or eradicated.[1]	—
K. Health care utilization (NEW)	Changes in the frequency, type, timing, and duration of use of health care services.[1]	—
L. Cost effects/impact (NEW)	Cost impact (summative or incremental) to the unit or organization resulting from changes in health care utilization and efficiency. Fixed and variable costs; offsets of the cost of implementation.	—
M. Perceived value (NEW)	Perceived worth, utility, and importance of the benefits of efficiency and cost saving to the organization.	—
N. Unintended consequences (NEW)	Emergent, interim, or longer term outcomes that were unanticipated and usually not desired.	—

Note: PR = process redesign.

Applying the Process Redesign Framework: A Case Study

To illustrate how the PR Framework may be applied, we present below a brief case study. It is based on a published case study by E. L. McCarthy, "Physician office productivity improvement through operations analysis and process redesign."[26]

Practice Scheduling Redesign Case Study

Eleven hospital-owned physician practices connected with a multihospital system implemented a process redesign of key scheduling and prescription filling processes. These were multiprovider practices engaged in a mix of primary care specialties, including pediatrics, family, and internal medicine practices. These physician practices had large patient panels of approximately 195,000 patient encounters per year. The overall focus of the process redesign was on improving patient access to timely appointments (offices were booked 3 to 5 months in advance) and improving systems for faster throughput. The scope of the project included a step-by-step analysis of all the workflow processes in each practice. Here, we focus on the following processes:

- Patient appointment scheduling
- Physician/patient scheduling templates
- Pharmacy refills and prescriptions
- Patient check-in

The process redesign involved mapping individual functions at each practice and then comparing them with other offices to identify process improvements that could be replicated widely across the network. These process improvements included—

- **Patient appointment scheduling.** Wave scheduling blended routine office visits, physicals, and sick visits so as to eliminate periods of extremely high and low activity. Available time slots were thus maximized and patient throughput enhanced.
- **Physician/patient scheduling templates.** The scheduling templates for each specialty, with the same number and type of office visits scheduled in any given hour, were standardized. This change was implemented concurrently with the wave scheduling.
- **Pharmacy refills and prescriptions**. The existing manual telephone call process to place prescription orders was replaced with a single prescription form for multiple patients that was faxed to each pharmacy.
- **Patient check-in.** A standard best-practice list for check-in functions was developed that included the printing of encounter forms and charts, collection of demographic and insurance information, and collection of copayments.

Applying the Process Redesign Framework

Below, we walk through the how-to-use flowchart detailed in Figure 3. For illustrative purposes, we examine this study at a high level with a short list of constructs. In real-world implementations, many more constructs may be relevant. Researchers will have to select a workable subset of potentially relevant constructs. This selection will likely be influenced by previous experience and research, current research aims, and practical considerations.

Step 1—Define the Intervention

In this step, the user of the framework examines the first major domain in the PR Framework: *Intervention Characteristics*.

- What is the intervention designed to achieve?
  The PR intervention strategy in this case study consists of a step-by-step analysis and operational improvement of scheduling, prescription filling, and check-in processes at each physician practice under consideration to improve patient access and throughput. The PR techniques employed include:
  (a) Mapping individual functions performed at each office, assessing their efficiency, and comparing levels of efficiency across offices;
  (b) Identifying best practices; and
  (c) Streamlining procedures to implement best practices at all offices.
  In addition, the user examines the following issues, while selecting relevant constructs from the domain.
- What are the features of the intervention?
  Here, the user considers the details of the various intervention steps mentioned above (a, b, and c), such as the steps involved in mapping the criteria for a best practice and methods for streamlining. Relevant constructs that may be used include *feasibility*, *trialability*, and *complexity.* See Table 2 for definitions of constructs.
- Who is the intended target group?
  Relevant constructs that may be used include *targeted groups* and *workflows*, including interdependencies. See Table 2.

Step 2—Define the Outer Setting

- What components of the environment will impact the implementation?
  Here, the user examines various relevant outer setting constructs that may include, for example, *external pressure* (e.g., from competing hospital systems that have successfully implemented similar PR interventions) and *technological environment* (e.g., new software that facilitates faster processing of patients at check-in). See Table 3.

Step 3—Define the Inner Setting

- What components of structure and process within the inner setting will impact the implementation?
  These may be tangible and intangible manifestations of structural characteristics, networks and communications, culture, climate, readiness, and so on. Relevant constructs here include *culture* (e.g., how staff will adapt to changing longstanding pharmacy refill processes and whether there will be significant pushback from staff) and *knowledge* (e.g., knowledge gained by involved staff who have experience with similar interventions in the past). See Table 4.

Step 4—Define the Characteristics of the Individuals/Teams Involved

- What are the characteristics of individuals (or teams) and patients that will help in making the PR intervention and/or implementation successful?
  A relevant construct may include *skills and competences* (e.g., whether staff members have the skills needed to effectively conduct wave scheduling or require additional training). *Patient needs and resources* might include access to transit, ability to make

appointments during work and school hours, and need for translation services. See Table 5.

Step 5—Define the Processes Required To Achieve Desired Level of Use

- What are the implementation processes that are required to achieve individual- and organizational-level use of the intervention?
  Relevant constructs to consider may include *planning* (e.g., whether the rollout has clear milestones, timelines, and dedicated staff accountable for actions) and *staging and iteration* (e.g., whether changes are being introduced slowly and refined in one site before scaling to another site or are being implemented across the board with each site responsible for adapting to local conditions). See Table 6. This step does not cover how completely an intervention was used; this concept is covered under the Measures of Implementation domain.

Step 6—Define Successful Implementation

- What are the attributes of the implementation process that demonstrate it was carried out well and can be replicated, scaled, and sustained?
  Constructs here include *acceptability* (e.g., whether staff members believe that the goals of the intervention are acceptable), *intervention cost* (e.g., the financial costs of the implementation), *reach* (percentage of offices that use wave scheduling 6 months after implementation), and *penetration* (proportion of staff within each practice using the wave scheduling). See Table 7.

Step 7—Define the Outcomes

- What are the specific measurable outcomes that will result from the intervention?
  Relevant constructs, representing outcomes, may be *accessibility, patient experience, provider experience*, *timeliness*, and *efficiency*. The user is encouraged to revisit previous domains to ensure that the outcomes selected in this step are supported by the intervention. In particular, the user would tie these outcomes back to the goals of the intervention (improving patient access and throughput), listed under the first step. See Table 8.

Note: Constructs in the PR Framework, because they represent the components of a complex system intervention, can be explored at multiple levels (i.e., at the individual, team, or organizational level). In Table 9, we show how a handful of constructs applicable to this case study are relevant across multiple organizational levels. For brevity, we show only three levels, but other levels may be relevant, depending on the scenario. For example, in some cases, a "unit" might be a level that comprises groups of "teams." However the levels may be defined, the important aspect is to ensure that users of the framework appreciate that each construct may (and in most cases should) be applied at various levels, and not just at one.

Table 9. Example of application of Process Redesign Framework constructs to diverse levels of analysis by organizational level

Construct	Individual	Team	Organization
External pressure	N/A	N/A	✓
Workflows	N/A	✓	✓
Planning	N/A	✓	✓
Accessibility	✓	N/A	N/A

Note: N/A = not added.

Patient-Centered Medical Home Framework

Overview[c]

A patient-centered medical home (PCMH), as defined by the Agency for Healthcare Research and Quality, is an organizational model of primary care with the following functions and attributes: comprehensive, patient centered, coordinated, accessible, high quality,[24] and safe. Achieving these functions and attributes requires a complex set of changes and innovations that go well beyond the boundaries of the practice setting and include provider and hospital networks, insurers, and Federal agencies. Examples of PCMH interventions within the practice setting include team-based care, the use of facilitation and coaching to develop skills, and disease registries that allow the provider to see patients not just as individuals but as part of a larger population with common needs and concerns.

The purpose of the PCMH Framework is to guide research and evaluation of PCMH implementation within a broad range of organizational settings. The primary users of this framework are investigators and practitioners who wish to understand why PCMH implementation succeeds or fails and whether the PCMH intervention or its components can be replicated and scaled to other settings. The PCMH Framework is intended to guide users in the design of a study or evaluation project. Some practitioners, because of the comprehensiveness of the PCMH Framework, may also find it useful for intervention design and continuous quality improvement. Investigators can apply the PCMH Framework to a whole intervention with various distinct parts or to one or more of those parts.

This chapter is organized into six sections. The first section briefly describes the domains of the PCMH Framework. It is followed by a discussion of the most noteworthy changes we made. The PCMH Framework is next presented in two forms, a graphic followed by a full explication of the domains, constructs, and subconstructs in Tables 10 through 16. The How To Use section gives users a step-by-step roadmap for approaching the multiple and complex dimensions of the PCMH Framework. This chapter concludes with an application of the roadmap to a PCMH case study. See the Glossary for important terms.

Organization of the Patient-Centered Medical Home Framework

Tables 10 through 16 show the PCMH Framework. The content is organized into seven domains and further subdivided into precise categories of constructs and subconstructs. The elements are summarized with their definitions in the first two columns of the tables; those elements labeled "new" were not part of the original Consolidated Framework for Implementation Research (CFIR).[3] The PCMH Framework domains, adapted from CFIR, are—

- **Intervention Characteristics:** The characteristics and features of the intervention being implemented into a particular organization or organizations, including core components (the essential and indispensable elements of the intervention itself). These may be fixed or mutable attributes; they are considered and assessed prior to implementation and influence adoption decisions.

[c] Because the three frameworks are described in stand-alone chapters, the Overview and Organization sections are similar across the chapters.

- **Outer Setting**: The economic, political, and social context within which an organization resides.
- **Inner Setting:** Tangible and intangible manifestations of characteristics of the organizations involved in the intervention, including structural characteristics, networks and communications, culture, climate, and readiness, which all interrelate and influence implementation.
- **Characteristics of Individuals and Teams**: The individuals (as carriers of cultural, organizational, professional, and individual mindsets, norms, interests, and affiliations) involved with the intervention and/or implementation process. Includes patients and caregivers.
- **Process of Implementation**: Refers here to the course of *actions* (e.g., planning, engaging, and reflecting) to achieve individual- and organizational-level use of the intervention as designed.
- **Measures of Implementation**: Refer to what Proctor et al.[5] call "implementation outcomes"; they are intermediary outcomes that describe how well the implementation was carried out and prospects for sustainability.
- **Outcomes**: The results of the PCMH implementation, defined as the targets of the PCMH intervention.

Users of the framework may find it helpful to refine these subconstructs even further for specific research purposes. Researchers could use these frameworks to define and review the range of potentially relevant concepts and variables as they prepare an implementation study. Additionally, they may engage in prestudy to determine which constructs are likely to be most useful. During their research, they may refine their selection of constructs and their specifications of them in response to data that emerge from the field or in response to changes in the intervention process and context that take place during the life course of the intervention.

Modifications in the Patient-Centered Medical Home Framework

The CFIR served as the foundation for the PCMH Framework. In addition, the PR and PCMH Frameworks were developed simultaneously, and therefore additions to one framework resulted in similar additions to the other when appropriate. All construct and subconstruct additions are noted in Table B in the Executive Summary and Table 25 in the Discussion. Below, we briefly list by domain the constructs added to the PCMH Framework as a result of the adaptation work (i.e., not present in the original CFIR or in the PR Framework). For definitions of these constructs, we direct the reader to the PCMH Framework tables, which begin with Table 10.

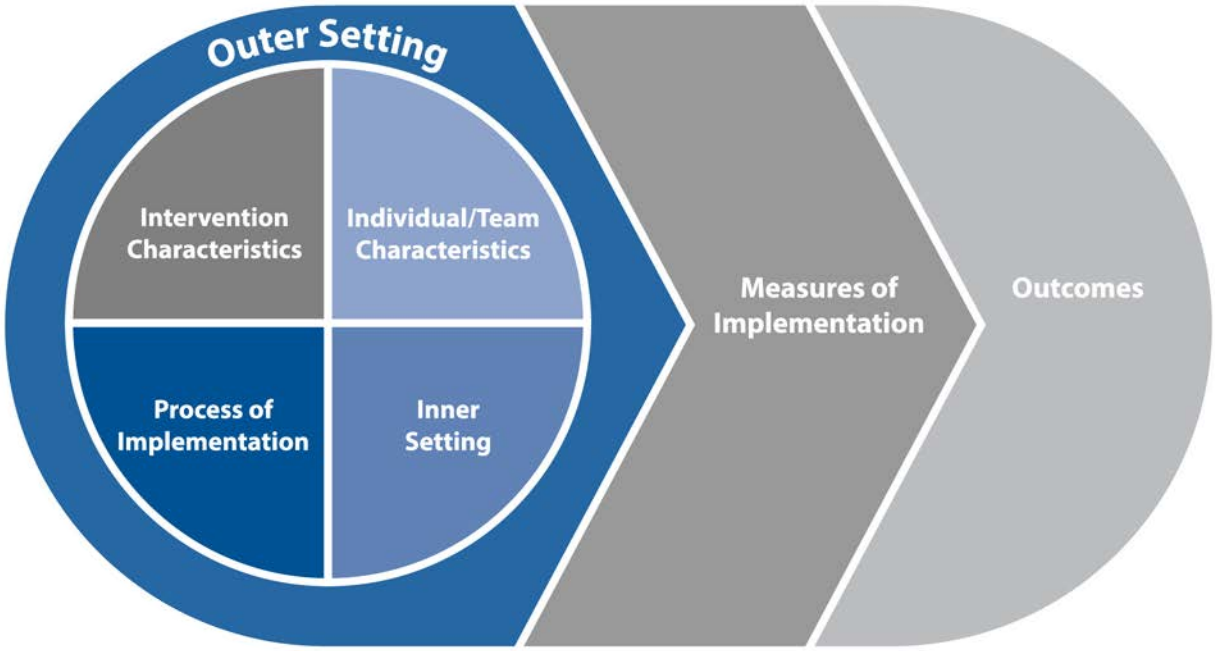
- Intervention Characteristics: Some models of PCMH rely extensively on vendors and consultants to carry out PCMH activities such as case management or outreach. Thus, the *location of the intervention* may be partially outside the practice setting. The practice's *history* with similar PCMH interventions was deemed a potentially important factor in seeking to engage in these activities and ease of implementation.
- Outer Setting: A new construct, *population needs and resources*, was added because these needs may influence the kinds of services and care innovations the practice may pursue.

- Inner Setting: *Patient-centeredness* was added to capture the degree to which the practice is aware of patient needs and seeks to addresses them. *Patient self-management infrastructure* represents the resources made available to patients in the PCMH. The construct *human factor* that was added in the PR Framework was renamed *HIT/IT* (health information technology/information technology) *accessibility* to better resonate with PCMH users.
- Characteristics of Individuals and Teams: The new construct *socioeconomic demographics* provides a place for users to capture important information on patient groups. *Role, authority,* and *collective efficacy* are elements important to teaming and collaboration.
- Process of Implementation: We expanded on the *planning* construct and added the subconstruct *assessing* to cover activities designed to identify needs and barriers. *Acquiring and allocating resources* is typically a part of the process of implementation. To *practice roles,* we added *organizational leaders, frontline staff, facilitator,* and *patients and other stakeholders* to better articulate the focus on patients. Under *execution,* we added *decisionmaking*.
- Measures of Implementation: This is a new domain. The PCMH Framework does not contain any new constructs in this domain in addition to those described in the PR Framework.
- Outcomes: This is a new domain. The PCMH Framework added a number of PCMH-specific outcomes that the interventions seek to achieve for patients, providers, and health care utilization. These outcomes include *process of care* (further subdivided by six subconstructs: *patient-centered, coordinated, comprehensive, accessible, quality,* and *safety), patient/caregiver experience, clinical outcomes,* and *health care utilization.* The Technical Expert Panel raised the issue of the high burden of PCMH implementation, which provided the rationale for adding *provider experience*.

Graphic Representation of the Patient-Centered Medical Home Framework

Figure 4 is a graphic representation of the PCMH Framework. It shows the relationships of five of the domains to measures of implementation success and various PCMH outcomes. On the left side of the figure is an inner circle with four domains: Intervention Characteristics, Individual/Team Characteristics, Inner Setting, and Process of Implementation. Surrounding this inner circle is an outer ring named the Outer Setting that may influence these four domains. An arrow to the right of the inner and outer circles points to the Measures of Implementation, which influence Outcomes.

Figure 4. Framework for Implementation Research on Patient-Centered Medical Homes



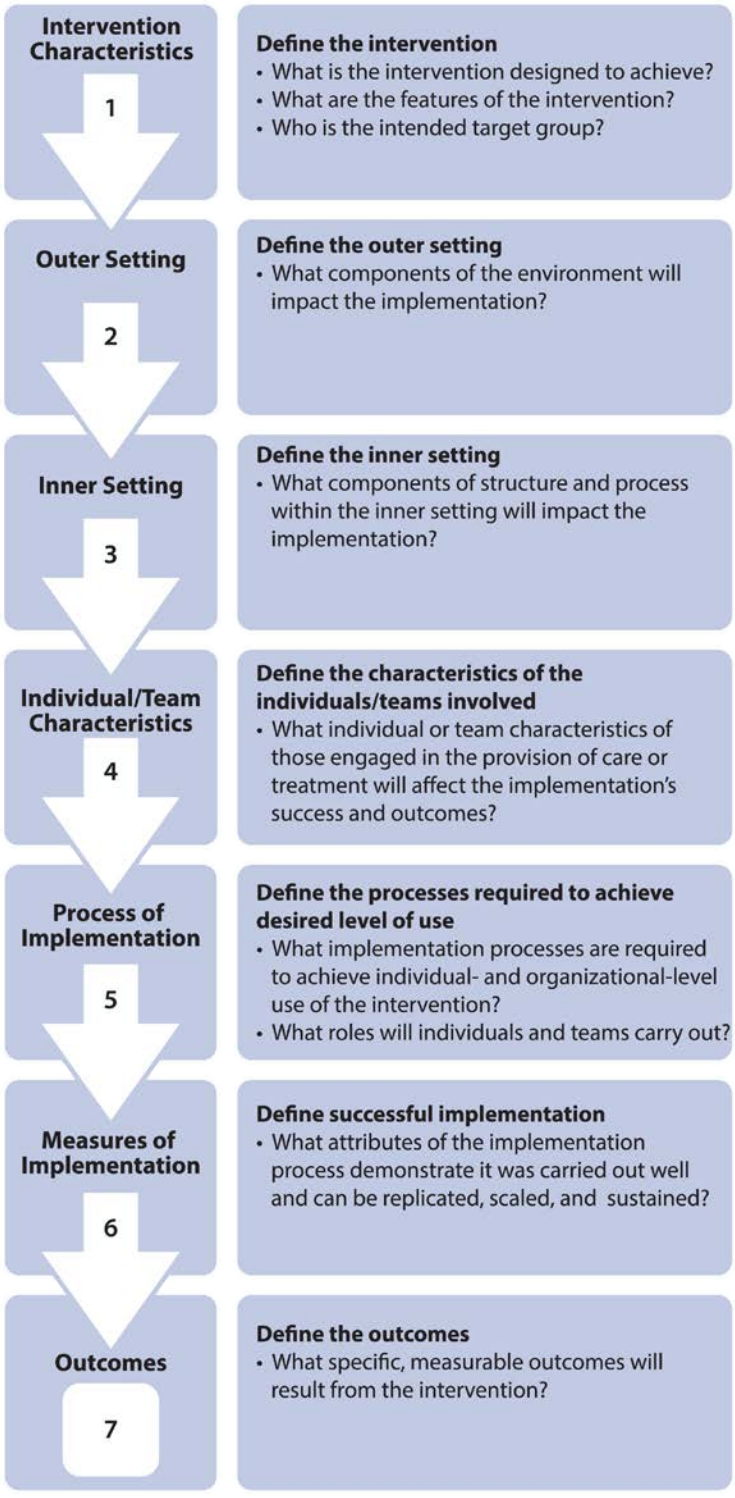
How To Use the Patient-Centered Medical Home Framework

The evolving nature of PCMH interventions and the heterogeneity of the settings in which the PCMH model may be applied are such that the details of implementation will vary from one setting to another. Therefore, the PCMH Framework does not prescribe a set of normative constructs that must be considered; rather, it provides a large set of potential constructs within major domains, from which investigators can choose those constructs relevant to their particular intervention and goals, questions, theory, or model guiding the research or evaluation.

The flowchart in Figure 5 presents step-by-step guidance on how this framework may be used. The flowchart presents a series of questions, and each set of questions is tied to a particular domain in the framework (Tables 10 through 16). As these questions are considered, the user should refer to the appropriate domain in the framework table to see which constructs are relevant. For example, Step 1 corresponds to the Intervention Characteristics domain; as users consider the various issues related to this domain, they should refer to the framework to choose those constructs relevant to them.

As mentioned previously, the framework does not prescribe which constructs must be selected due to the diversity of research objectives and to variations between different PCMH interventions. The frameworks are designed to be a practical tool for research and evaluation, and it would be unfeasible to include all or even most of the constructs described. While following this step-by-step process of using the framework, we recommend that users of the framework select qualities, features, or characteristics that are closely tied to intervention outcomes and aligned to the goal, questions, theory, or model guiding the research or evaluation. Doing so will help the user prioritize the constructs, remain focused on the essential aims of the investigation, and keep the number of constructs to a manageable size.

Figure 5. How to use the Patient-Centered Medical Home Framework



Abbreviations: PCMH = Patient-Centered Medical Home.

Content of the Patient-Centered Medical Home Framework

We present the PCMH Framework in Tables 10 through 16 with brief definitions of the constructs and subconstructs, and examples. Constructs labeled "new" are additions to the original CFIR.[3] Based on Technical Expert Panel input, we added clarifying examples and comments for those constructs and subconstructs that were unclear or complex. Each construct or subconstruct is independent and should be applied as appropriate to the research questions and objectives.

Table 10. Patient-Centered Medical Home Framework—Intervention Characteristics

Construct	Description	Examples
A. Vision and change strategy (NEW)	The proposed changes envisioned by the PCMH and the theory of change: how the intervention is supposed to work, what it is meant to achieve or do.[6] May be explicated in logic models, goals, outcomes, and performance measures.	According to Complex Adaptive System (CAS) theory, a trained facilitator can help overcome barriers to change and improvement.[27]
B. Targeted groups	Practice staff, patients, caregivers, and others who are the intended recipients or beneficiaries of PCMH.	—
C. Intervention source	Identifying who (which individuals or groups) originated the PCMH initiative and/or from which source the components of the initiative were derived.	—
D. Evidence strength and quality	Target group and other stakeholders' perceptions of the quality and validity of evidence supporting the belief that the PCMH will have the desired outcomes.[8]	Standards and recommendations from the National Committee for Quality Assurance.
E. Relative advantage	Target group and other stakeholders' perception of the advantage of PCMH instead of other possible interventions or maintaining the status quo.[7]	—
F. Feasibility (NEW)	Target group and other stakeholders' perception of the extent to which the PCMH can be successfully used or carried out within a given organization or setting.	—
G. Adaptability	Target group and stakeholders' perception of the degree to which PCMH strategies, techniques, and practices can be adapted to meet local needs.	—
H. Trialability	Target group and stakeholders' perception of the ability to test and refine components of the PCMH on a small scale.	—
I. Complexity	Target group and stakeholders' perception of the duration, scope, centrality, and intricacy, and number of steps required to implement the intervention.	Team-based care coordination with multiple organizations vs. a disease registry within a single practice.
J. Compatibility (NEW)	Target group and stakeholders' perception of the alignment of the meaning, values, and norms attached to PCMH with those held by members of the practice or organization.	—
K. Radicalness (NEW)	Target group and stakeholders' perception of the degree of difference between the change envisioned and the current state.[9]	—
L. User control (NEW)	The degree to which the intervention relies on staff authority/skill to implement PCMH on its own vs. reliance on external consultants.	—
M. Location of intervention (NEW)	Components of the intervention conducted outside the clinic/office setting using external service providers and organizations.	Case-management, home visits.
N. Workflows (NEW)	Office tasks and workflows, including interdependences between them that will be intentionally redesigned or impacted by the PCMH transformation.[7]	—
O. Task/process standardization (NEW)	Degree to which the PCMH seeks to standardize selected tasks and/or processes that require iterative consultation.	—
P. History (NEW)	Experiences of similar interventions within the setting and within the target population.	Patients' experience with a patient navigator prior to PCMH.

Note: PCMH = patient-centered medical home.

Table 11. Patient-Centered Medical Home Framework—Outer Setting

Construct	Description	Examples
A. External networks	Practice's involvement with networks and partnerships that support the transition to PCMH and are involved in similar efforts.	Improvement collaborative.
B. External pressure	Pressure emanating from outside the organization to implement a PCMH intervention.	Key peer or competing organizations have already implemented PCMH; there is competitive pressure to secure a better share of the market.
C. External policy and incentives/ disincentives	Laws and regulations (governmental or other central entity), recommendations and guidelines, and payment schemes that affect the decision to adopt or abandon PCMH.	Payer provides incentives for National Committee for Quality Assurance PCMH certification.
D. Technological environment (NEW)	Technological trends and movements, and the availability of technological innovations that may affect the intervention and its context.	Health information exchanges.
E. Population needs and resources (NEW)	Prevalence of conditions and disease in the population served and the characteristics of the community that are determinants of health status.	Environmental quality, poverty, transportation, employment, health determinants.
F. Community resources (NEW)	Availability and access to service providers, aging resources, and multiple levels of community services and supports not directly a part of the PCMH.	—

Note: PCMH = patient-centered medical home.

Table 12. Patient-Centered Medical Home Framework—Inner Setting

Construct	Description	Examples
A. Structural characteristics	Social architecture; age; maturity; size; composition of the team, unit, organization, or system; and the patient panel served.	Staffing mix, clinician demographics, clinician training, employment status of physicians.
B. Team and network characteristics	Influence, breadth, depth, and role diversity of teams and networks engaged in implementation of the PCMH.[11]	—
B1. Teams, networks, and communications	Nature and quality of teams and social networks; formal/informal communication and information exchange within practice setting, with patients and caregivers.	—
B2. Team and network self-organization	Capacity to arrange and organize for a defined (nonrandom) purpose without external pressure or mandate.	
C. Culture	Norms, values, and beliefs within a team, unit, or practice that affect views of PCMH and its implementation.	—
D. Implementation climate	Capacity or reserve[12] for change and the shared receptivity of involved individuals to the intervention.	—
D1. Tension for change	Degree to which stakeholders perceive the current situation as intolerable or needing change.	—
D2. Mandate	Whether compliance with the PCMH initiative is expected.	—
D3. Accountability	Whether entities are subject to tangible consequences for noncompliance.	—
D4. Relative priority	Individuals' shared perception of the importance of the PCMH implementation within the organization.	—
D5. Organizational incentives	Extrinsic incentives and rewards offered to adopt PCMH.	Shared savings, promotions, increased stature, or respect.
D6. Learning climate[11]	Organization's willingness to promote trial and error, test new methods, and innovate.	Routine and structured quality improvement activities.
E. Readiness for implementation	Tangible and immediate indicators of organizational commitment to its decision to implement PCMH.	—
E1. Leadership commitment	Degree of commitment, involvement, and accountability of leaders and managers to patient-centered care and the PCMH initiative.	—
E2. Staff commitment (NEW)	Degree of commitment, involvement, and accountability of physicians, nurses, and other staff for patient-centered care and to the PCMH.	—
F. Access to information, training, education.	Ease of access to digestible, applicable information about PCMH. Resources dedicated to training and education available within the organization.	Online training tools, time given for training and education, funding for training.
G. IT and HIT resources (NEW)	Technological infrastructure in place to support electronic information management and the redesign of patient care.	—
G1. HIT systems	Electronic information management infrastructure and technologies available to clinicians to manage patient care, data, and communications.	Patient portals, disease registries, mobile applications.

Table 12. Patient-Centered Medical Home Framework—Inner Setting (continued)

Construct		Description	Examples
	G2. IT systems	Technological systems and capabilities to support PCMH.	Hardware, software, server space, bandwidth, interoperability, health information exchange.
	G3. HIT/IT accessibility (NEW)	Features of the physical, technical, and spatial environment of the practice that determine the use, accessibility, and acceptability of technology in patient care.[13]	—
H.	Physical space and equipment (NEW)	Physical space and equipment dedicated for or impacted by the PCMH intervention.[14]	—
I.	Staff time (NEW)	Time dedicated to implement the PCMH intervention.	Time given to staff to attend trainings and learn PCMH techniques and strategies; time allowed for adjustment and adaptation.
J.	Patient self-management infrastructure (NEW)	Training, counseling, and education available to patients prior to PCMH within the practice setting or affiliated organizations.	—
K.	Continuity (NEW)	Information continuity (exchange of information) and relationship continuity, both with provider and patients/caregivers and across organizations.	—
L.	Patient-centeredness (NEW)	Extent to which the practice knows and prioritizes patient goals, needs, and preferences, and has the resources and services to meet them.	Patient needs assessments, patient portals, mobile health applications.

Note: HIT = health information technology; IT = information technology; PCMH = patient-centered medical home.

Table 13. Patient-Centered Medical Home Framework—Characteristics of Individuals and Teams

Construct	Description	Examples
A. Knowledge and beliefs	Views regarding the PCMH, as well as familiarity with facts, truths, and principles related to the intervention.	—
B. Skills and competencies (NEW)	Degree of relevant subject matter expertise, skills, and competencies within the implementing team, unit, and organization.	—
C. Role (NEW)	Individual's or team's role and responsibility, and extent of multiple or shared roles.	—
D. Authority (NEW)	Perceived and actual degree of authority to make decisions and act autonomously.[15]	—
E. Self-efficacy	Confidence in the capacity to execute the courses of action necessary to achieve PCMH goals.	Patient confidence in accessing and using a patient portal.
F. Collective efficacy (NEW)	Conviction of individuals and teams involved that the PCMH can be carried out in cooperation with others.[16]	Individual team members desire to become a PCMH but nursing staff believe they will have to do all the work.
G. Stage of change	Phase an individual or team is in; characterizes progress toward skilled, enthusiastic, and sustained application of PCMH strategies.	—
H. Identification with organization	How individuals or teams perceive the organization, and their relationship and degree of attachment with the organization.	—
I. Socioeconomic demographics (NEW)	Characteristics related to the individual's socioeconomic status.	—
J. Patient needs and resources (NEW)	Patient priorities for health and health care, and the social and economic capital to address those priorities.	—
K. Caregiver needs and resources (NEW)	Caregiver priorities for health and health care, and the social and economic capital to address those priorities.	—
L. Other personal attributes	Other personal traits not captured elsewhere.	Tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, learning style.

Note: PCMH = patient-centered medical home.

Table 14. Patient-Centered Medical Home Framework—Process of Implementation

Construct	Description	Examples
A. Planning	Degree to which implementation steps or tasks are developed in advance and in response to various scenarios; the quality of those schemes or methods.	Contingency planning.
A1. Assessing (NEW)	Formal assessment of the problem or condition to be changed, including barriers and facilitators to change.	—
A2. Goal-setting	Written goals, objectives, benchmarks, and timelines for PCMH activities, and their feasibility and adequacy.	—
A3. Feedback	Procedures used to provide feedback to stakeholders and their adequacy.	—
B. Acquiring and allocating resources (NEW)	Staff time, space, equipment, and other resources dedicated to implementing the PCMH intervention; the adequacy of those allocations.	—
C. Process ownership (NEW)	The diversity of practice roles involved in processes of implementation; authority and accountability for these activities.	—
D. Practice roles	Roles of individuals involved in the decision to adopt, execute, and facilitate PCMH.	—
D1. Organizational leaders (NEW)	Managers and others with the authority to dedicate resources and make decisions to adopt, maintain, or abandon the implementation.	—
D2. Opinion leaders	Individuals who influence (positively or negatively) the attitudes and beliefs of their colleagues.[17,18]	Experts and peers.[19]
D3. Implementation leaders	Individuals formally appointed with responsibility for implementing an intervention.	Coordinator, project manager, team leader.
D4. Champions	Individuals who dedicate themselves to galvanizing and maintaining support for PCMH and overcoming indifference or resistance.	—
D5. External change agents	Individuals outside the practice who can facilitate or undermine decisions about PCMH adoption and implementation.	Individuals from health plans, other health care systems, consultants, and policymakers.

Table 14. Patient-Centered Medical Home Framework—Process of Implementation (continued)

Construct	Description	Examples
D6. Facilitator (NEW)	Formally appointed role that provides reflective, empathetic, and interactive counsel.	Experts who model and teach new skills and practices.[16]
D7. Frontline staff (NEW)	Administrative staff and providers (within and outside the organization) who will implement the PCMH or be impacted by it.	—
D8. Patients and other stakeholders (NEW)	Patients and other stakeholders impacted by the PCMH.	Family members, advocates, and social service providers.
E. Engaging	Processes involved in attracting and involving appropriate individuals in the implementation and use of the intervention.[10]	Social marketing, various outreach activities.
E1. Engaging organizations, external context (NEW)	Developing and capitalizing on relationships with providers, leaders, and frontline staff in the implementing organizations, and with external providers, resources, funders.	—
F. Executing	Manner in which those involved carry out and accomplish the implementation according to plan; the role and authority to execute.[15]	—
F1. Decisionmaking (NEW)	Frequency, duration, and timing of the activities involved in making decisions.[11] The directionality of these activities.[20]	Decisions directed from the top down vs. the bottom up.
F2. Staging and iteration (NEW)	Whether the implementation is carried out in incremental steps, refined iteratively, or implemented in its entirety within a specified period	—
F3. Facilitating and coaching	Use of experts to teach new processes, model best practices, and develop solutions; the structure, formality, and adequacy of these facilitative activities.	—
G. Reflecting and evaluating	Quantitative and qualitative feedback on the quality of the implementation process[21]—"reflexive monitoring" and the degree to which it is attained.	Project monitoring; systematic feedback processes.
G1. Measurement capability and data availability (NEW)	Availability of timely data. Capacity for monitoring, evaluation, and process improvement. Includes measurement differences; accountability for collection, documentation, and analysis.	—

Note: PCMH = patient-centered medical home.

Table 15. Patient-Centered Medical Home Framework—Measures of Implementation (new domain)

Construct	Description	Examples
A. Acceptability (NEW)[2]	Degree to which PCMH goals, strategies, tactics, and specific activities are agreeable, palatable, or satisfactory.	—
B. Adoption/abandonment (NEW)[2]	Intention, initial decision, or action to try to employ or cease PCMH.	—
C. Appropriateness (NEW)[2]	Suitability of the PCMH intervention to the specific issues or problems to be addressed.	—
D. Intervention cost (NEW)[2]	Costs of the PCMH interventions and costs associated with implementation, including investment, ongoing maintenance costs, and opportunity costs.	Training, staffing, IT updates.
E. Fidelity (NEW)[2]	Degree to which PCMH was implemented as intended by those who developed and/or introduced it to the practice.	—
F. Reach (NEW)	Absolute number, proportion, and representativeness of targeted entities willing to participate in a given PCMH intervention.[22]	—
F1. Reach within the population (NEW)	Number of patients within the targeted setting exposed to or participating in the PCMH intervention.	—
F2. Reach within the organization (NEW)	Absolute number, proportion, and representativeness of individuals and subcomponents within an organization exposed to or participating in the PCMH intervention.[22]	Percentage of practices within a network that provide email consultations.
G. Penetration (NEW)[2]	Depth of integration of a PCMH implementation within a service setting and its subsystems.	Among providers who have e-prescribing, the percentage of patients who receive e-prescriptions.
H. Replicability (NEW)	Degree to which the PCMH implementation process and outcomes can be reproduced beyond the adopting practice sites.	—
I. Sustainability (NEW)[2]	Degree to which changes resulting from PCMH are maintained or institutionalized within a practice.	—
J. Evolvability (NEW)	Extent to which the change is capable of being sustained through adaptation and refinement.	—

Note: IT = information technology; PCMH = patient-centered medical home.

Table 16. Patient-Centered Medical Home Framework—Outcomes (new domain)

Construct	Description	Examples
A. Patient- and caregiver-centered outcomes (NEW)	Patient- and caregiver-defined goals and care consistent with patient and caregiver preferences.	Patient and caregiver would rather be seen by a physician than by a nurse practitioner.
B. Patient/caregiver experience (NEW)	Impact of PCMH on patient and caregiver experiences with care, including satisfaction with care and patient-provider interactions.[21]	—
C. Provider experience (NEW)	Effect(s) of PCMH on a provider's burden of effort and quality of work life, communication, and interactions with patients and colleagues.[21]	—
D. Process of care (NEW)	Key measurable processes of PCMH interventions.[23,24]	—
D1. Patient-centered (NEW)	Extent to which PCMH engages patients and family in care decisions, provides resources for self-management, and is culturally and linguistically appropriate.[23]	—
D2. Coordinated (NEW)	Extent to which practice tracks, follows up on, and manages tests, referrals, and care at other facilities; follows up with discharged patients; and ensures continuity of care.[23]	—
D3. Comprehensive (NEW)	Extent to which the intervention satisfies all the health care needs of a patient, including prevention and specialty care.[24] Includes access and ability to pay.	—
D4. Accessible (NEW)	Extent to which PCMH delivers routine/urgent care and clinical advice during and after business hours, provides electronic access.[23]	—
D5. Quality (NEW)	Extent to which PCMH shows an ongoing commitment to high quality through the use of performance measurement, evidence-based strategies, etc.[24]	—
D6. Safety (NEW)	Extent to which PCMH collects and uses safety data, and shares such data publicly as a marker of ongoing commitment to safety and quality.[24]	—
E. Effectiveness (NEW)[3]	Extent to which the intervention contributes to providing services to all who could benefit, without providing services to those who would not.	—
F. Timeliness (NEW)[3]	Extent to which the intervention contributes to reducing wait times and delays, both for those who provide care and those who receive it.	—
G. Equitable (NEW)	Extent to which disparities in care are reduced or eradicated.[1]	—
H. Clinical outcomes (NEW)	Result of a medical intervention as captured by changes in health status.	—
I. Health care utilization (NEW)	Changes in the frequency, type, timing, and duration of health care services due to PCMH.	—
J. Cost effects/impact (NEW)	Cost impact (summative or incremental) to the practice/organization resulting from PCMH changes. Fixed and variable costs; offsets of the cost of implementation.	—
K. Value (NEW)	Perceived worth, utility, and importance of PCMH outcomes to the practice, the providers, and patients.	—
L. Unintended consequences (NEW)	Emergent, interim, or longer term outcomes that were unanticipated and usually not desired.	Staff burnout from burden of balancing "day job" with PCMH activities.

Note: PCMH = patient-centered medical home.

Applying the Patient-Centered Medical Home Framework: A Case Study

To illustrate how the PCMH Framework may be applied, we present below a brief case study based on Driscoll et al., "Process and outcomes of patient-centered medical care with Alaska Native people at Southcentral Foundation."[28]

Alaska Southcentral Foundation Case Study

The Southcentral Foundation (SCF) provides health care services to nearly 60,000 Alaska Native and American Indian people living in south-central Alaska, including Anchorage and 50 rural villages. SCF was formerly managed by the Indian Health Service. In 1997, SCF assumed responsibility for the primary care services at the Alaska Native Medical Center. Two years later the SCF began implementing key components of the PCMH model. The tailored model is based on several key characteristics of a PCMH. These are described below:

- **Team-based care**. Coordinated care is delivered by multidisciplinary teams rather than by individual clinicians. These teams include primary care physicians or physician assistants, nurses, certified medical assistants, and other clinicians. Over time, behavioral health consultants, nutritionists, and appointment schedulers were added.
- **Empanelment.** Patients are matched, either by self-selection or assignment, to an integrated and comprehensive care team. Patients schedule primary care appointments with their team members.
- **Open access.** To the extent possible, patients' barriers to access are mitigated through open scheduling, expanded office hours, and increased availability of electronic communication between patients and team members.

In the remainder of the case study, we will use the example of SCF to demonstrate how the PCMH Framework may be used to evaluate this intervention.

Applying the Patient-Centered Medical Home Framework

Below, we walk through the how-to-use flowchart detailed in Figure 5. For illustrative purposes we have used a brief case study and examine this study at a high level. In real-world implementations, the level of detail will be significantly greater. For each step, we have selected a few constructs as examples.

<u>Step 1—Define the Intervention</u>

In this step, the user of the framework examines the first major domain in the PCMH Framework, *Intervention Characteristics*.

- What is the intervention designed to achieve?
  The goal of the PCMH intervention is to improve access to and coordination of care among patients served by SCF's primary care services.
- What are the features of the intervention?
  Here, the user considers the details of the various intervention components specified above, which have three main components: empanelment, open access, and team-based care. In this case, we address all three, but another option is to limit the focus to only one of these components. The user may consider *evidence strength and quality* as a potential construct to include (e.g., perceptions of the quality and validity of the three components

selected among key stakeholders at SCF; whether there are existing standards and/or publications that can provide supporting evidence).

- Who is the intended target group?
  Relevant constructs that may be used include *targeted groups* and *workflows.* See Table 10.

Step 2—Define the Outer Setting

- What components of the environment will impact the implementation?
  These may include political context, social context (including Native American subcultures), economic context, and *population needs and resourc*es (e.g., the specific health needs, if any, of the local Alaskan population and how the PCMH intervention will ensure that these needs are well served). See Table 11.

Step 3—Define the Inner Setting

- What components of structure and process within the inner setting will impact the implementation?
  These may be networks and communications, culture, climate, readiness, and so on. Relevant constructs here include *structural characteristics* (e.g., how many physicians are employed by the SCF; in how many buildings services are provided) and provider *culture* (e.g., how staff will adapt to the concept of team-based care, which will include more frequent communication and coordination between individuals; how comfortable physicians are with increased communications and how the transitions can be made smoother). See Table 12.

Step 4—Define the Characteristics of the Individuals/Teams Involved

- What are the characteristics of individuals (or teams) that will help in making the PCMH intervention and/or implementation successful?
  Here, the user could examine *patient needs and resources* (e.g., whether patients are able to schedule appointments during various hours when they need to do so; whether they can make appointments online or by email). Other relevant constructs here include *skills and competences* (e.g., whether staff members have the skills needed to successfully form integrated and comprehensive care teams; whether staff members require training); *role* (who is responsible for which tasks under the new team-based care); and *authority* (which physicians have override authority if there are multiple physicians involved in care for a patient). See Table 13.

Step 5—Define the Processes Required To Achieve Desired Level of Use

- What are the implementation processes that are required to achieve individual- and organizational-level use of the intervention?
  Relevant constructs to consider may include *planning* (e.g., whether the PCMH intervention has clear milestones, timelines, and dedicated staff accountable for actions) and *staff time* (e.g., whether staff are given sufficient time to implement various changes, while not compromising the various functions they are currently responsible for). See Table 14. This step does not cover how completely an intervention was used; this concept is covered under the Measures of Implementation domain.

Step 6—Define Measures of Implementation

- What are the attributes of the implementation process that demonstrate it was carried out well and can be replicated, scaled, and sustained?
  Relevant constructs here may include *acceptability* (e.g., the degree to which stakeholders find SCF's PCMH implementation agreeable and satisfactory), *intervention cost* (e.g., the total cost of implementing the three components of PCMH, and whether this stays within a set budget), and *reach within the organization* (e.g., the number of units within SCF where empanelment is functioning as expected 6 months after completion of intervention). See Table 15.

Step 7— Define the Outcomes

- What are the specific measurable outcomes that will result from the intervention?
  Relevant constructs, representing outcomes, may include *process of care* (e.g., whether the SCF is able to provide care that satisfies relevant defining attributes of PCMH, such as being *coordinated, accessible,* and *patient centered*). The user is encouraged to revisit previous domains to ensure that the outcomes selected in this step are logically supported by the intervention. In particular, the user would tie these outcomes back to the goals of the intervention (improving access and coordination of care) listed under the first step. See Table 16.

Note: The constructs in the PCMH Framework, because they represent components of a complex system intervention, can be explored at multiple levels (i.e., at the individual, team, or organizational level). The number of levels and their definitions will vary based on the specific scenario. In Table 17, we show how a handful of constructs applicable to this case study are relevant across multiple organizational levels. For brevity, we show only three levels, but other levels may be relevant, depending on the scenario. For example, in some cases, a "unit" might be a level composed of groups of "teams." However the levels may be defined, the important aspect is to ensure that users of the framework appreciate that each construct may (and in most cases should) be applied at various levels, and not just at one.

Table 17. Example of application of Patient-Centered Medical Home Framework constructs to diverse levels of analysis by organizational level

Construct	Individual	Team	Organization
Evidence strength and quality	✓	N/A	N/A
Population needs and resources	N/A	N/A	✓
Culture	✓	✓	✓
Process of care	✓	✓	✓

Note: N/A = not added.

Care Transitions Framework

Overview[d]

Care transitions can be defined as "the movement patients make between health care practitioners and settings as their condition and care needs change during the course of a chronic or acute illness."[29] Interventions to improve transitions or transitional care are "a set of actions designed to ensure the coordination and continuity of health care as patients transfer between different locations or different levels of care within the same location."[30]

The Care Transitions Framework presented here builds on previous adaptations of the Consolidated Framework for Implementation Research (CFIR)[3] for process redesign for efficiency and cost reduction (PR Framework) and patient-centered medical homes (PCMH Framework). The purpose of the framework is to guide research and evaluation of care transitions implementation within a broad range of organizational settings to address questions of *how, why,* and *where* care transitions interventions succeed or fail to achieve intended outcomes, and whether the framework components can be replicated and scaled to other settings. Investigators can apply the Care Transitions Framework to a whole intervention with various distinct parts, or to one or more of those parts. The primary users of this framework are investigators and practitioners who wish to design a study or evaluation project.

A key focus of current health care policy is interventions for transitions from the acute hospital to the ambulatory setting, which can involve predischarge interventions in the hospital setting, such as patient/caregiver education; postdischarge interventions, such as outreach to patients; and bridging interventions, which include both types of elements. The Center for Medicare & Medicaid Innovation (CMMI) has also recently funded projects that integrate community-based organizations and services into new care delivery models for beneficiaries. The inclusion of a strong community component to these models requires close attention to the context and interactions of organizational stakeholders.

The taxonomy used in several previous systematic literature reviews on care transitions[31] categorizes different types of transitional care interventions and includes key activities (or components) from the perspective of the hospital. Importantly, because this taxonomy (and most current research) is from the hospital perspective and therefore does not address community-based interventions comprehensively, we have not included the development of relationships with common postdischarge followup sources, outpatient-based care management, or primary care interventions.

This chapter is organized into six sections. The first section briefly describes the domains of the Care Transitions Framework. It is followed by a discussion of how we adapted and refined the PR and PCMH Frameworks to care transitions interventions. The Care Transitions Framework is next presented in two forms, a graphic followed by a full explication of the domains, constructs, and subconstructs in Tables 18 through 24. The How To Use section gives users a step-by-step roadmap for approaching the multiple and complex dimensions of the framework. This chapter concludes with a case study of a care transitions intervention that applies the roadmap. See the Glossary for important terms.

[d]Because the three frameworks are described in stand-alone chapters, the Overview and Organization sections are similar across the chapters.

Organization of the Care Transitions Framework

The Care Transitions Framework is a comprehensive menu of implementation research factors, organized into eight domains and subdivided into more specific categories of constructs and subconstructs. The domains differ from the CFIR and the PR and PCMH Frameworks in several ways. Care transition interventions often cover multiple settings, so the Outer Setting is redefined here as the External Context, and because the intervention can involve more than just settings (e.g., community-based organizations), the Inner Setting is redefined as Organizational Characteristics. The Outcomes domain, which was added for the PCMH Framework, is also included. The eight domains, adapted from CFIR and the PR and PCMH Frameworks, are defined as follows:

- **Intervention Characteristics:** The characteristics and features of the intervention being implemented in a particular organization(s), including core activities or components (the essential and indispensable elements of the intervention itself). These may be fixed or mutable attributes; they are considered and assessed prior to implementation and influence adoption decisions.
- **External Context:** The economic, political, and social context within which an organization or organizations reside and that may affect the implementation process.
- **Organizational Characteristics:** Redefined from the CFIR "Inner Setting" domain. Tangible and intangible manifestations of characteristics of the organizations involved in the intervention, including structural characteristics, networks and communications, culture, climate, and readiness, which all interrelate and influence implementation. The construct includes hospital and ambulatory organizations involved in the care transitions intervention, as well as other organizations that are core to the intervention (e.g., community-based organizations). Can include the transferring and receiving organizations.
- **Characteristics and Roles of Providers**: Attributes of the individuals (as carriers of cultural, organizational, professional, and individual mindsets, norms, interests, and affiliations) who are engaged in the provision of care or treatment. They may or may not be directly involved in the intervention and/or implementation process.
- **Characteristics and Roles of Patients and Caregivers:** Attributes (individual mindsets, norms, interests, and affiliations) of the individuals and caregivers who are the recipients of care or treatment in the given intervention setting.
- **Process of Implementation**: Processes (including planning, engaging, and reflecting) to achieve individual- and organizational-level use of the intervention as designed.
- **Measures of Implementation**: Qualities of the implementation and descriptions of how the intervention components are actually implemented within and between organizations, and changes over time. Measurement should involve not just the number and type of interactions with patients and caregivers or between providers, but the content and quality of those interactions. These elements refer to the Proctor et al.[5] "implementation outcomes"; they are intermediate outcomes.
- **Outcomes**: The results of the implementation, defined as implementation dimensions, and the targets of the intervention overall.

Researchers could use this framework to define and review the range of potentially relevant concepts and outcomes as they prepare an implementation study. Additionally, they could conduct initial investigations with hospital and ambulatory care providers, administrators, and

implementers to determine which constructs are likely to be most useful in the evaluation. During their research, they may refine their selection of constructs and their specifications of them in response to data that emerge from the field or in response to changes in the intervention process and context that take place during the life course of the intervention. They may also find it useful to refine the subconstructs even further for specific research purposes.

Modifications in the Care Transitions Framework

The original intent of the Care Transitions Framework was to focus on transitions from hospital to ambulatory care settings; however, the Technical Expert Panel recommended including community-based service organizations because these entities play central roles in the successful transition to the home. Ultimately we chose to broaden the focus and emphasize interactions between organizations, reframing constructs to include different organizations within an intervention, increasing emphasis on patients and engagement, and adding and separating out caregiver issues. Below, we provide a brief discussion of domains and constructs that were developed or modified substantially for the Care Transitions Framework. All construct and subconstruct additions/modifications are noted in Table B in the Executive Summary and Table 25 in the Discussion. For definitions of these constructs, see the Care Transitions Framework tables, which begin with Table 18.

- Intervention Characteristics: The CFIR construct *adaptability* was adapted to reflect the frequent need to choose different components that are contained within a "bundled" intervention in care transitions interventions. Organizations using a named intervention such as STAAR (State Action on Avoidable Rehospitalizations) have frequently customized it. Rather than using labels, it is better for the researcher to precisely describe what is being done.
- External Context: This domain was renamed from Outer Setting, as these interventions will often include different settings. Care transitions rely heavily on *community resources,* so this construct was added.
- Organizational Characteristics: The Technical Expert Panel agreed that the framework should be broader than practice or integrated health care settings (where patients receive care and treatment) and include community-based organizations, such as community coalitions, agencies, and collaboratives. Thus, this domain was renamed from Inner Setting, as these interventions can include different settings as well as other organizations, such as community-based organizations or collaboratives. We also had numerous modifications and additions to this domain.
    - *Accountability* was modified to reflect the shared accountability for implementation and success across and within organizations that are part of the intervention. Within an organization, certain disciplines or units may be more involved than others, and some may not be involved (e.g., nursing leadership, hospitalists, emergency department). External organizations and networks may be categorized as belonging to the outer setting but nonetheless involve accountability in order for the intervention to succeed.
    - *Continuity* was added to emphasize the importance of exchange of information and relationships between organizations and with patients/caregivers.
- Characteristics and Roles of Providers: "Roles" was added to this domain to emphasize the importance of provider roles in care transition interventions. For parsimony,

characteristics of providers, patients, and caregivers are combined in the table but remain separate in the graphic to emphasize their unique contributions.

- Characteristics and Roles of Patients and Caregivers: Technical Expert Panel members agreed patients should be emphasized in the framework; moreover, caregivers have roles and needs unique from those of patients. We created two new constructs, *patient needs and resources* and *caregiver needs and resources*, to emphasize this distinction.
- Process of Implementation: This domain had a number of notable construct modifications and additions.
  - *Physical space* was adapted to also include *presence of organizations*, as the physical presence of providers/facilitators from other organizations may be key to building and sustaining collaborations.
  - *Engaging organizations, external context* was added to highlight the significance of the external context in care transitions.
  - *Practice roles* was renamed *transition roles* to enhance its resonance to care transitions researchers and evaluators.
  - *Integrators* was added as a subconstruct under *transition roles.* Integrators are responsible for building relationships/collaborations between organizations; their role is central to many sponsored care transitions programs, such as Better Outcomes for Older Adults through Safe Transitions (BOOST).
  - *Measurement capability and data availability* was added as a subconstruct of *reflecting and evaluating.* Lack of data or of quality data often leads to failure of the project. Common issues go beyond barriers related to information technology and include measurement differences between organizations; lack of availability or sharing; accountability for collection, documentation, and analysis; and timeliness.
- Measures of Implementation: The construct of *evolvability* was added to reflect description of adaptations made to the intervention components and how these were implemented. The construct *reach* was further broken down into *reach within the population* and *reach within the organization*, as the intervention may aim to do one but not the other, or both.
- Outcomes: There was no consensus on what patient-centered outcomes should be included and whether adverse drug outcomes should be considered patient centered or clinical. We chose to maintain the outcomes developed for the PCMH Framework, as they aligned well to the outcomes for care transitions. The only change was to redefine *patient-centered outcomes* to include caregivers, and to emphasize achievement of goals and care consistent with preferences.

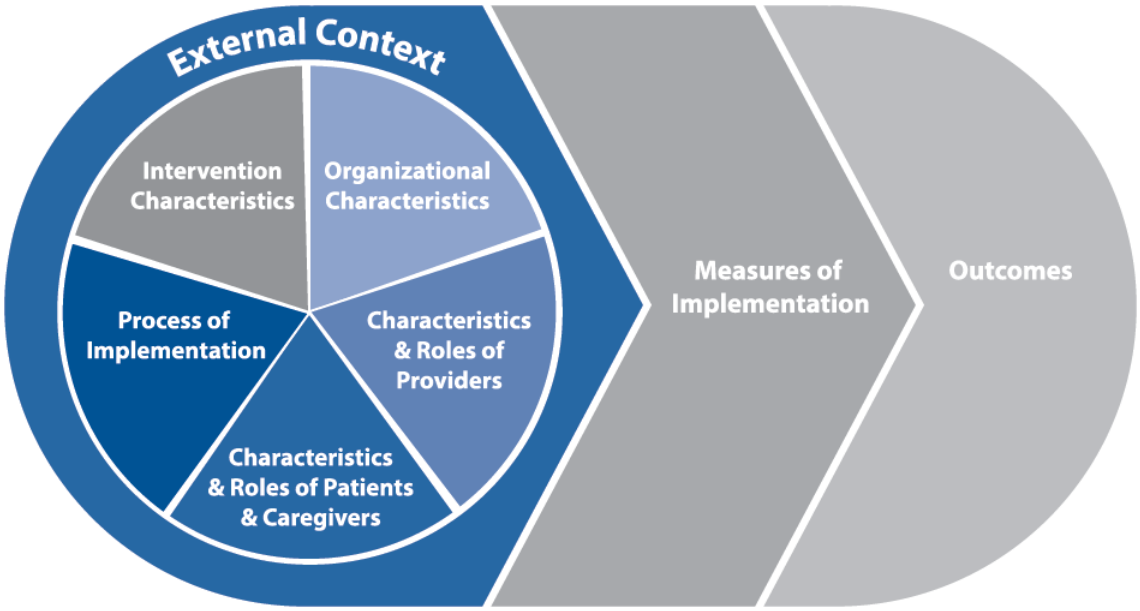
Graphic Representation of the Care Transitions Framework

Figure 6 is a graphic representation of the Care Transitions Framework. Although all Technical Expert Panel members agreed that patient-centeredness is the ideal, they had different perspectives on whether the graphic should have patients and caregivers at the center. Some argued that intervention design is usually centered around organizations, based on issues such as policies, payment, speed, funding, and research opportunities, and that organizations are the leaders of this work; institutional outcomes such as readmissions and cost, rather than patient-centered outcomes such as quality of life, are usually the primary goal. For others, the primary reason for the intervention is the patient, and if the intervention cannot be personalized to

heterogeneous patient and caregiver needs, it will not be effective. We addressed these comments by creating two distinct areas within the graphic for providers and patients.

On the left side of the figure, the five domains of care transition interventions are shown in a circle that includes the attributes of the intervention itself, and the individuals and organizations or systems carrying out the intervention or the target of the intervention. These domains are Intervention Characteristics, Organizational Characteristics, Characteristics & Roles of Providers, Characteristics & Roles of Patients and Caregivers, and Process of Implementation. The outer ring of the circle represents the External Context, outside the domains of intervention, organizations, individuals, and process. An arrow to the right of the circle points to the Measures of Implementation, which influence Outcomes.

Figure 6. Framework for Implementation Research on Care Transitions



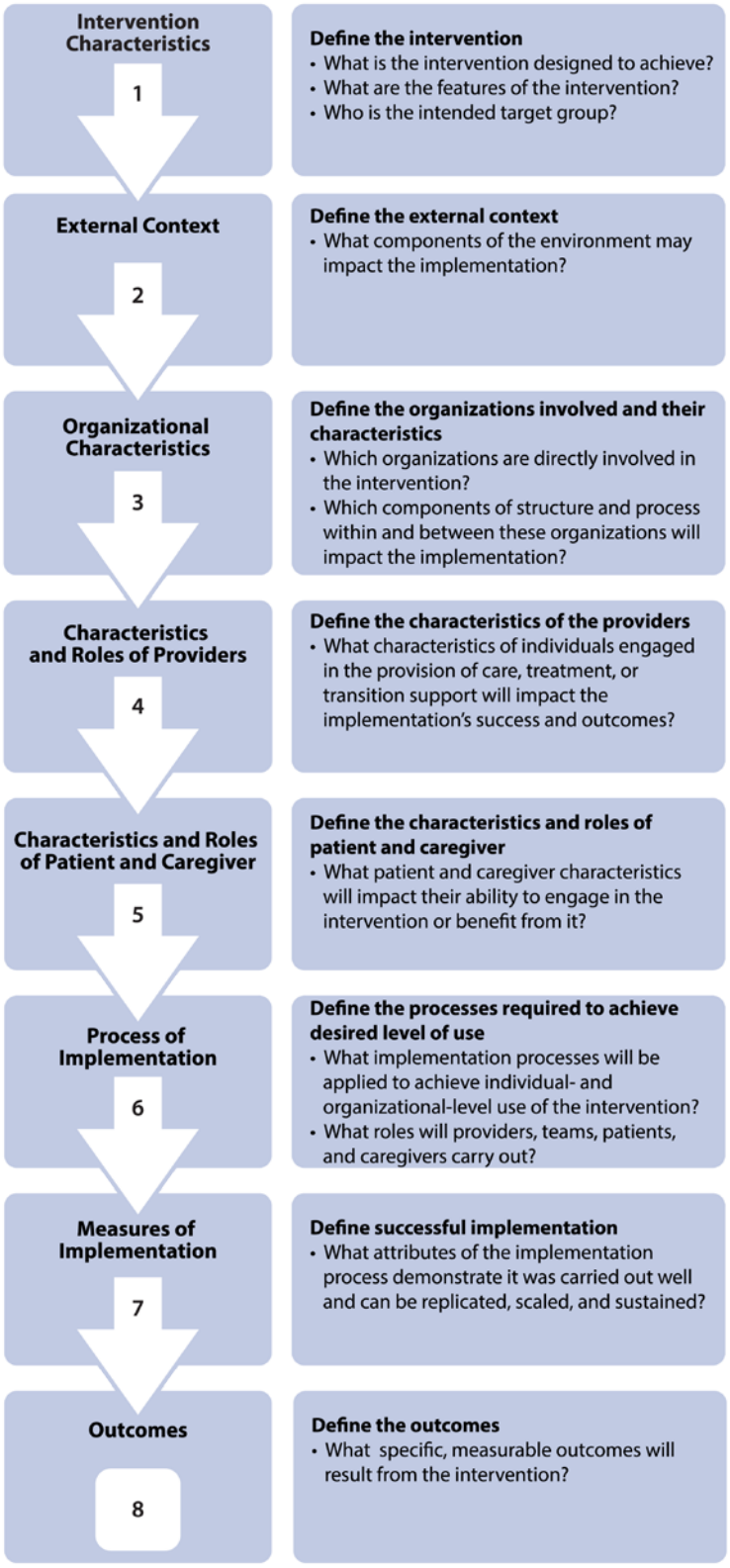
How To Use the Care Transitions Framework

The nature of care transitions interventions is such that details of development and implementation vary from one context to another, depending on a variety of issues. Therefore, the framework does not prescribe a set of domains or constructs that must be considered during evaluation; rather it provides a comprehensive, though not exhaustive, set of potential items that teams working on care transitions interventions research can choose, depending on the nature of the research or evaluation goals and questions.

The following flowchart (Figure 7) presents step-by-step guidance on how this framework can be used. The flowchart presents a series of questions, and each set of questions is tied to a particular domain in the framework (Tables 18 through 24). As these questions are considered, the user should refer to the appropriate domain in the framework table to see which constructs are relevant. For example, Step 1 corresponds to the Intervention Characteristics domain; as the team considers the various issues related to this domain, they should refer to the framework to choose those constructs relevant to them. In particular, in many interventions, the discharging or receiving setting will have little control or relationship with the other setting, as well as little control over the external context. Ideally, interventions would try to create these relationships or links between settings. While following this step-by-step process of using the framework, we

recommend that users of the framework select qualities, features, or characteristics that are closely tied to intervention outcomes such as utilization (e.g., readmissions, completion of followup tests) and patient satisfaction with the discharge process (see Outcomes domain in Table 24). Furthermore, the user is advised to use the goals, research questions, and theories guiding the investigation to prioritize the constructs for inclusion. Doing so will ensure the investigation remains focused on its essential purpose and keep the number of constructs to a manageable size.

Figure 7. How to Use the Care Transitions Framework



Content of the Care Transitions Framework

In Tables 18 through 24**,** we present the Care Transitions Framework with brief definitions of the constructs, subconstructs, and examples. Constructs added to the CFIR are labeled as "New," and many other constructs are adapted to better fit with care transitions; a few are named differently or included or excluded here based on differences from the PR or PCMH Frameworks, but most are similar. We added clarifying examples for those constructs and subconstructs that were unclear or complex. Each construct or subconstruct is independent and should be applied as appropriate to the research questions and objectives. Please note, as well, that because the constructs for provider, patient, and caregiver characteristics and roles are identical, we have combined them into a single section of the table to maintain parsimony. They remain separate in the graphic to highlight their distinctiveness.

Table 18. Care Transitions Framework—Intervention Characteristics

Construct	Description	Examples
A. Vision and change strategy (NEW)	The proposed changes envisioned by the intervention and the theory of change: how the intervention is supposed to work, what it is meant to achieve or do.[6] May be explicated in logic models, goals, outcomes, performance measures.	According to Complex Adaptive System (CAS) theory, a designated integrator can improve quality of communication among organizations, which will result in process improvement.[27]
B. Targeted groups	Staff and others (vendors, patients) who are the intended recipients or beneficiaries of the intervention.	—
C. Intervention source	Identifying who (which individuals or groups) originated the initiative and/or the source from which the components of the initiative were derived.	—
D. Evidence strength and quality	Target group and other stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have the desired outcomes.[8]	Peer-reviewed published literature; consensus policy statements.
E. Relative advantage	Target group and other stakeholders' perceptions of the advantage of the selected intervention instead of other possible interventions or maintaining the status quo.[7]	—
F. Feasibility (NEW)	Target group and other stakeholders' perceptions of the extent to which the intervention can be successfully used or carried out within the organization(s).	—
G. Adaptability	Target group and other stakeholders' perceptions of the degree to which the intervention can be adapted to meet local needs.	—
H. Trialability	Target group and other stakeholders' perceptions of the ability to test components of the intervention on a small scale in the organization(s).	—
I. Complexity	Target group and stakeholders' perception of the duration, scope, centrality, and intricacy, and number of steps and organizations required to implement the intervention.	Packaged bundle of complementary activities vs. single activity (e.g., discharge planning).
J. Compatibility (NEW)	Target group and stakeholder perception of the alignment of the meaning, values, and norms attached to care transitions with those held by members of the organization(s).[21]	—
K. Radicalness (NEW)	Target group and other stakeholder perceptions of the degree of difference between the change envisioned and the current state of care transitions.[9]	—
L. User control (NEW)	The degree to which the intervention relies on the end-users' authority/skill to implement the intervention on their own vs. reliance on experts.	—
M Location of intervention activity (NEW)	Components of the intervention conducted outside the hospital/clinic/office setting using external service providers and organizations.	Case management, phone followup, home visits.
N. Design quality and packaging	Degree to which interventions within a bundle or program are well specified and well aligned with one another	A standardized intervention such as Project RED (Re-Engineered Discharge).
O. Workflows (NEW)	Tasks and workflows, including interdependencies between them that are the focus of the intervention or will be affected by it.[7]	Medication reconciliation, outreach to patients.
P. Task/process standardization (NEW)	Degree to which the intervention seeks to standardize tasks and processes that require iterative consultation.	—

Table 18. Care Transitions Framework—Intervention Characteristics (continued)

Construct	Description	Examples
Q. History (NEW)	Experiences with similar interventions within the organizations or within the target groups.	The maturity, breadth, and depth of collaboration with community service agencies.

Table 19. Care Transitions Framework—External Context

Construct	Description	Examples
A. External networks	Involvement with organizations, systems, and partnerships that support and promote care transitions.	Improvement collaborative; aging and disability networks.
B. External pressure	Pressure emanating from outside the organization to implement the intervention.	Key peer or competing organizations have implemented care transitions.
C. External policy and incentives/ disincentives	Laws and regulations (governmental or other central entity), recommendations and guidelines, and payment schemes that affect decision to adopt or abandon the intervention.	Affordable Care Act; nonpayment for readmissions.
D. Technological environment (NEW)	The technological trends and movements and the availability of technological innovations that may affect the intervention and its context.	Electronic medical record compatibility, health information exchange, social media.
E. Population needs and resources (NEW)	Prevalence of conditions and disease in the population served and the characteristics of the community that are determinants of health status.	Interventions more critical in populations with high rates of chronic disease.
F. Community resources (NEW)	Availability and access of service providers, aging resources, and multiple levels of community services and supports not directly involved in the intervention.	Services for subacute rehabilitation.

Table 20. Care Transitions Framework—Organizational Characteristics

Construct	Description	Examples
A. Structural characteristics	Social architecture, age, maturity, size, and composition of the organization(s).	—
B. Team and network characteristics	Influence, breadth, depth, and role diversity of the teams and networks engaged in the intervention.[11]	Linkages between providers, units, the hospital and ambulatory setting, and other involved organizations, and ability to navigate among them.
B1. Teams, networks, and communications	Nature and quality of teams and social networks; formal/informal communication and information exchange within and across organization(s), with patients and caregivers.	—
B2. Team and network self-organization	Capacity to arrange and organize for a defined (nonrandom) purpose without external pressure or mandate.	—
C. Culture	Norms, values, and basic assumptions of given unit(s) or organization(s) that affect views of the intervention and its implementation.	—
D. Implementation climate	Capacity or reserve for change and the shared receptivity of involved individuals to the intervention.[12]	—
D1. Tension for change	Degree to which stakeholders perceive the current situation as intolerable or needing change.	—
D2. Mandate	Whether compliance with the intervention is expected within the organization.	—
D3. Accountability	Whether entities are subject to tangible consequences for noncompliance.	—
D4. Relative priority	Individuals' shared perception of the importance of the intervention and its components within the organization(s).	—
D5. Organizational incentives	Extrinsic incentives and rewards offered to implement the intervention.	—
D6. Learning climate (NEW)	Organization's willingness to promote trial and error, test new methods, and innovate.[11]	—
E. Readiness for implementation	Tangible and immediate indicators of organizational commitment to its decision to implement care transitions.	—
E1. Leadership engagement	Degree of commitment and accountability of leaders and managers to high-quality care transitions, and specifically to the intervention components.	—
E2. Staff commitment (NEW)	The degree of clinician, transitional, and community care staff, patient, and caregiver involvement in transition planning.	Degree of clinician and staff participation in training.
F. Access to information, training, education	Ease of access to digestible, applicable information about the intervention. Resources dedicated to training and education available within the organization.	Online training tools, time given for training and education, funding for training.
G. IT and HIT resources (NEW)	Technological infrastructure in place to support electronic information management, including IT that crosses organizations.	—
G1. HIT systems	Electronic information management infrastructure and technologies available to clinicians to manage patient care, data, and communications.	Decision support tools, e-prescribing, electronic health records.
G2. IT systems	Technological systems and capabilities to support care transitions.	Interoperability, health information exchange.

Table 20. Care Transitions Framework—Organizational Characteristics (continued)

Construct		Description	Examples
	G3. HIT/IT accessibility (NEW)	Includes features of the physical, technical, and social environment in the organization that determine the use, accessibility, and acceptability of technology in patient care.[13]	—
H.	Physical space and presence of organizations	Physical space and equipment dedicated to or impacted by the intervention.[14]	Designated space for team meetings. Office space for community-based transitional care staff at the hospital.
I.	Staff time	Staff time dedicated to implement the intervention.	Time given to staff to attend training and learn transition procedures.
J.	Other resources (NEW)	Resources for implementation and ongoing operations to support change and innovation, including grant or other funding specific to care transitions.	Money, physical space, equipment, staff time.
K.	Patient self-management infrastructure (NEW)	Training, counseling, and education available to patients prior to the intervention within the hospital and ambulatory setting.	—
L.	Continuity (NEW)	Information continuity (exchange of information) and relationship continuity, both with providers and patients/caregivers and across organizations.	—
M.	Patient/caregiver-centeredness (NEW)	Extent to which the organization(s) knows and prioritizes patient and caregiver goals, needs, and preferences, and has the resources and services to meet them.	—

Note: HIT = health information technology; IT = information technology.

Table 21. Care Transitions Framework—Characteristics and Roles of Providers, Patients, and Caregivers

Construct	Description	Examples
A. Knowledge and beliefs	Individual attitudes toward and value placed on the intervention as well as familiarity with facts, truths, and principles related to the intervention.	—
B. Skills and competencies (NEW)	Degree of relevant subject matter expertise, skills, and competencies within the implementing team, unit, and organization.	—
C. Role (NEW)	Individual's role and responsibility for the intervention. The degree of multiple or shared roles.	Patient is expected to meet with a patient navigator monthly and can make appointments.
D. Authority (NEW)	Individual provider's perceived and actual degree of authority to make decisions and act autonomously.[15]	—
E. Self-efficacy	Individual provider's belief and confidence in his/her capacity to execute the courses of action necessary to achieve intervention goals.	—
F. Collective efficacy (NEW)	Conviction of individuals and teams involved that the intervention can be carried out in cooperation with each other.[16]	Case manager does not believe the providers have the time to deal with patient issues.
G. Stage of change	Characterization of the phase an individual is in, as he or she progresses toward skilled, enthusiastic, and sustained application of the intervention.	—
H. Identification with organization(s)	How individuals perceive the implementing organization(s) and the degree of attachment to those organizations.	Patients' trust in their usual source of care vs. a new case management service.
I. Socioeconomic demographics (NEW)	Characteristics related to the individual's socioeconomic status.	Age, race, gender, occupation, insurance status.
J. Patient needs and resources (NEW)	Patient priorities for health and health care priorities and the social and economic capital to address those priorities.	Importance of self-management, need for care coordination. Preferences for caregiver involvement in discharge planning.
K. Caregiver needs and resources (NEW)	Caregiver priorities for health and health care, and the social and economic capital to address those priorities.	Caregivers' desire to engage with other caregivers through support groups.
L. Other personal attributes	Other personal traits not captured elsewhere.	Tolerance of change, social network support, quality of relationship between patient and caregiver.

Table 22. Care Transitions Framework—Process of Implementation

Construct	Description	Examples
A. Planning	Degree to which implementation steps or tasks are developed in advance; the quality of those schemes or methods.	—
A1. Assessing (NEW)	Formal assessment of care transitions issues; the needs of the users; barriers to change; the timing of these activities relative to implementation.	Root cause analysis.
A2. Goal-setting	Written goals, objectives, benchmarks, and timeline activities and their feasibility and adequacy.	—
A3. Feedback	Procedures used to provide feedback to stakeholders.	
A4. Contingency planning (NEW)	Plans for adaptation in response to various scenarios and outcomes.	Plans for increasing the availability of resources to meet the demands of implementation.
B. Acquiring and allocating resources (NEW)	Resources dedicated to implementing the intervention; the adequacy of those allocations.	—
C. Process ownership (NEW)	The diversity of transition roles involved in processes of implementation; authority and accountability for these activities.	—
D. Transition roles (NEW)	Roles of individuals involved in the decision to adopt, execute, and facilitate the intervention.	Case managers, navigators, social service providers.
D1. Organizational leaders (NEW)	Managers and others with the authority to dedicate resources and make decisions to adopt, maintain, or abandon the implementation.	—
D2. Opinion leaders	Individuals who influence (positively or negatively) the attitudes and beliefs of their colleagues.[17,18]	Experts and peers.[19]
D3. Formally appointed implementation leaders	Individuals formally appointed with responsibility for implementing the intervention.	Program manager.
D4. Champions	Individuals who dedicate themselves to galvanizing and maintaining support for the intervention and overcoming indifference or resistance.	—
D5. External change agents	Individuals outside the organization who can facilitate or undermine decisions about adoption and implementation.	Individuals from health plans, other health care systems, collaboratives, consultants, and policymakers.
D6. Frontline staff (NEW)	Administrative staff, providers (within and outside the organization) who will carry out the intervention or be affected by it.	—
D7. Integrators (NEW)	Individuals who build relationships between organizations and create linkages to facilitate the intervention.	—
D8. Patients, caregivers, and other stakeholders (NEW)	Patient and his/her family members, and members of the family's support network.	—
E. Engaging	Processes involved in attracting and involving appropriate individuals in the implementation and use of the intervention.[10]	Patient facilitation, navigation, outreach, and followup across organizations.
E1. Engaging organizations, external context (NEW)	Developing and capitalizing on relationships with providers, leaders, and frontline staff in the implementing organizations, and to external providers, resources, funders.	—

Table 22. Care Transitions Framework—Process of Implementation (continued)

Construct	Description	Examples
F. Executing	Extent to which those involved carry out and accomplish the implementation according to plan; the role and authority to execute.[15]	—
F1. Decisionmaking (NEW)	Frequency, duration, and timing of the activities involved in making decisions.[11] The directionality of these activities.[20]	Decisions made with the patient vs. for the patient.
F2. Staging and iteration (NEW)	Degree to which the care transition is carried out in iterative, incremental steps or implemented in its entirety within a specified period.	—
G. Reflecting and evaluating	Quantitative and qualitative feedback on the quality of the implementation process[21]—"reflexive monitoring" and the degree to which it is attained.	Project monitoring; systematic feedback processes.
G1. Measurement capability and data availability (NEW)	Availability of timely data. Capacity for monitoring, evaluation, and process improvement. Includes measurement differences; accountability for collection, documentation, and analysis.	Better Outcomes for Older adults through Safe Transitions (BOOST) includes easy-to-aggregate measures.

Table 23. Care Transitions Framework—Measures of Implementation (new domain)

Construct	Description	Examples
A. Acceptability (NEW)[2]	Degree to which intervention goals, strategies, tactics, and specific activities are agreeable, palatable, or satisfactory.	—
B. Adoption/abandonment (NEW)[2]	Intention, initial decision, or action to employ or cease the intervention.	—
C. Appropriateness (NEW)[2]	Suitability of the intervention to the specific transition issues or problems to be addressed.	—
D. Intervention cost[2]	Costs of the intervention and costs associated with implementing that intervention, including investment, supply, and opportunity costs.	—
E. Fidelity (NEW)[2]	Degree to which the intervention was implemented as originally designed by those who developed and/or introduced it to the organization.	—
F. Reach (NEW)	Absolute number, proportion, and representativeness of entities who are willing to participate in a given initiative, intervention, or program.[22]	—
F1. Reach within the population (NEW)	Number of patients within the targeted setting exposed to or participating in the intervention.	Percentage of patients who receive a discharge plan.
F2. Reach within the organization (NEW)	Absolute number, proportion, and representativeness of individuals and subcomponents within an organization setting exposed to or participating in the intervention.[22]	Percentage of units within a hospital that use discharge planning.
G. Penetration (NEW)[2]	Depth of integration of the intervention within an organization involved in the intervention and its subsystems.	Percentage of time a discharge document is transmitted to the accepting provider.
H. Replicability(NEW)	Degree to which the intervention implementation process and outcomes can be reproduced beyond the adopting sites or settings.	—
I. Sustainability (NEW)[2]	Extent to which changes resulting from the intervention are maintained or institutionalized within the organization(s)' ongoing, stable operations.	—
J. Evolvability (NEW)	Extent to which the change is capable of being sustained through adaptation and refinement.	—

Table 24. Care Transitions Framework—Outcomes (new domain)

Construct		Description	Examples
A.	Patient- and caregiver-centered outcomes (NEW)	Patient- and caregiver-defined goals and care consistent with patient and caregiver preferences.	Patient and caregiver would rather be catheterized in the hospital than at home or would rather be seen by a physician than by a nurse practitioner.
B.	Patient/caregiver experience (NEW)	Impact of the intervention on patient/caregiver experiences with care, including satisfaction with care and patient/caregiver-provider interactions.[21]	—
C.	Provider experience (NEW)	Effect(s) of the intervention on a provider's burden of effort and quality of work life, including provider communication/collaboration.[21]	—
D.	Processes of care (NEW)	Key measurable processes of care transitions interventions.	—
	D1. Patient-centered (NEW)	Extent to which intervention engages patients and family in care decisions, provides resources for self-care, and is culturally and linguistically appropriate.[23]	Collaborates with patients and family to develop care plans.
	D2. Coordinated (NEW)	Extent to which the intervention tracks discharged patients; follows up on and coordinates tests, referrals, and care across organizations/settings.[23]	—
	D3. Comprehensive (NEW)	Extent to which the intervention satisfies all the health care needs of a patient, including prevention and specialty care.[24] Includes access and ability to pay.	—
	D4. Accessible (NEW)	Extent to which routine/urgent care and clinical advice are delivered during and after business hours, and electronic access is provided.[23]	—
	D5. Quality (NEW)	Extent to which the intervention shows an ongoing commitment to high quality through the use of performance measurement, evidence-based strategies, etc.[24]	—
	D6. Safety (NEW)	Extent to which the intervention collects and uses safety data, and shares such data publicly as a marker of ongoing commitment to safety and quality.[24]	—
E.	Effectiveness (NEW)[3]	Extent to which the intervention contributes to providing services to all who could benefit, without providing services to those who would not.	—
F.	Timeliness (NEW)[3]	Extent to which the intervention contributes to reducing wait times and delays, both for those who provide care and those who receive it.	—
G.	Clinical outcomes (NEW)	Result of a medical intervention as captured by changes in health status.	—
H.	Health care utilization (NEW)	Utilization related to care transitions, such as readmissions, redundant tests/procedures, and postdischarge provider visits.	—
I.	Cost effects/impact (NEW)	Cost impact (summative or incremental) resulting from intervention changes. Fixed and variable costs; offsets of the cost of implementation.	—

Table 24. Care Transitions Framework—Outcomes (new domain) (continued)

Construct	Description	Examples
J. Value (NEW)	Perceived worth, utility, and importance of intervention outcomes for the organization, providers, and patients.	—
K. Unintended consequences (NEW)	Emergent, interim, or longer term outcomes that were unanticipated and usually not desired.	—

Applying the Care Transitions Framework: A Case Study

Below is an adapted version of a case study from the Robert Wood Johnson Foundation's Aligning Forces for Quality program.[32] We use this modified example to illustrate how the Care Transitions Framework may be used.

Reducing Readmissions and Integrating Care in Cincinnati

The Health Improvement Collaborative of Greater Cincinnati Alliance (the Collaborative), sponsored by the Robert Wood Johnson Foundation Aligning Forces for Care Quality (AF4Q), was established to improve communication and coordination among hospitals and physician groups. The Collaborative) partnered with the local hospital association and the Greater Cincinnati Health Council to reduce heart failure readmissions by 10 percent under a program called Accountable Care Transformation, or ACT.

Nineteen hospitals and health systems participate in ACT and promote five best practices to reduce readmissions—

1. Upon admission, implement a risk-assessment tool with a focus on heart failure to identify patients who are at high risk of readmission from social factors.
2. Use the teach-back method during the hospital stay from admission to discharge during key clinical interventions.
3. Provide real-time handover communications.
4. Address timely physician followup (appointment to occur within 5 to 7 days of discharge).
5. Follow up with the patient or primary caregiver (or emergency contact) within 48 to 72 hours of discharge via telephone or home visit.

The five practices draw from a variety of sources, including Project Better Outcomes for Older adults through Safe Transitions (BOOST), the STAAR Initiative, and the Institute for Healthcare Improvement. The ACT rests on two core principles: collaboration and transparency. The Collaborative is regional because patients cross routinely from one community within the Cincinnati region to another. It is not bound by hospital structures; even within a competitive environment, hospitals have to share data and communicate with one another in order to adhere to the five practices.

According to the medical director of the Collaborative, implementation and evaluation have been challenging. The Collaborative is not receiving data in real time, which creates delays in the implementation timeline. This lag in data submission also has hampered the Collaborative's ability to track dollars saved and number of readmissions reduced; however, self-reported data from hospitals participating in the ACT indicate a downward trend in readmissions. The medical director added, "But regardless of whether we meet our goal, the journey and the process has been so helpful and has improved care for patients in our communities."

Applying the Care Transitions Framework

Below, we apply the flowchart to the case study, selecting a few constructs as examples for each step.

Step 1—Define the Intervention Characteristics

- What is the intervention designed to achieve?
  The goal of this intervention is to reduce heart failure readmissions. In a broader sense, the intervention is building a collaborative and working to coordinate care across disparate organizations.
- What are the features of the intervention?
  The intervention for this case has five key elements, all adapted from established care transitions programs but rebundled for this collaborative:
  1. Implement a heart failure readmission risk assessment tool.
  2. Use the teach-back method during key clinical interventions.
  3. Provide real-time handover communications.
  4. Address timely physician followup.
  5. Follow up with the patient or primary caregiver after discharge.

  Relevant constructs may include *feasibility* (e.g., whether all these elements can realistically be carried out at all hospitals, including issues of cost-effectiveness), *complexity* (e.g., difficulty of implementing five disparate elements of the intervention, which will require involvement of a number of providers, including training), and the *workflows* and *task/process standardization* that will be needed to incorporate tasks such as teach-back into daily care. See Table 18.
- Who is the intended target group?
  The ultimate beneficiary of the changes in practices is the patient, who is thus a primary stakeholder. However, much of the intervention is focused on changes in processes and workflows within and between hospitals, so other targeted entities include providers and staff, units, and hospitals. See Table 18.

Step 2—Define the External Context

- What components of the environment will impact the implementation?
  Key constructs for external context may include *external networks*, or existing relationships with outpatient providers who will need to see the patient in a timely way to achieve timely physician followup (element #4), and the *external pressure* and policy incentives to reduce heart failure readmissions. See Table 19.

Step 3—Define the Organizations Involved and Their Characteristics

- Which organizations are directly involved in the intervention?
  For this case, the 19 hospitals and health systems are included, as well as community and national organizations: the Health Improvement Collaborative of Greater Cincinnati, Greater Cincinnati Health Council (hospital organization), and the Robert Wood Johnson Foundation.
- Which components of structure and process within and between these organizations will impact the implementation?
  Key structural characteristics may include the size and organizational resources of the various 19 hospitals, which could influence their capacity, internal support, and ability to be flexible enough to make the multiple changes needed. The implementation *climate* could affect how willing the individual organizations are to change care processes to improve care transitions. Other important constructs include individual organizational *accountability* for reducing heart failure readmissions in the larger collaborative, *relative*

priority within the organizations to dedicate to the elements of the intervention as compared to other priorities, and *leadership engagement* to support the organizations and staff in implementing the intervention. See Table 20.

Step 4—Define the Characteristics and Roles of the Providers

- What are the characteristics of individuals who are engaged in the provision of care or treatment?
  For this intervention, provider *roles* may be particularly important, as new roles (especially discharge followup) need to be developed within each organization. *Collective efficacy, belief* that the intervention can be achieved, is needed at the individual and organizational as well as the collaborative level. See Table 21.

Step 5—Define the Characteristics and Roles of Patients and Caregivers

- What are the characteristics and roles of patients and caregivers that will impact their ability to engage in the intervention or to benefit from it?
  The importance of patient goals, needs, preferences, and resources is reflected in the first element of the intervention—risk assessment for readmission, including social factors—and these factors may affect the implementation of the intervention and readmission outcomes. *Knowledge and beliefs* and *skills and competencies* are important for the effectiveness of the teach-back method and phone followup, and social factors such as access to transportation and a telephone could affect physician followup. See Table 21.

Step 6—Define the Processes Required To Achieve Desired Level of Use

- What are the implementation processes applied to achieve individual- and organizational-level use of the intervention?
  For this case, *planning* is important, with the elements of the intervention chosen from existing programs and rebundled for this collaborative. *Engaging* patients and caregivers and providers is also critical, with important information exchange in teach-back and postdischarge phone calls for patients/caregivers, and effective handoff communication with providers. *Measurement capability and data availability* are particularly important for care transitions interventions; in this case, outcomes could not be evaluated due to issues with accessing data from the various organizations involved. See Table 22. This step does not cover how completely an intervention was used; this concept is covered under the Measures of Implementation domain.

Step 7—Define Measures of Implementation

- What are the attributes of the implementation process that should be measured to determine how it was carried out and can be sustained?
  In care transitions interventions, specific elements may not be implemented as planned, or may require adjustment during implementation or after initial evaluation. Evaluating what was actually implemented and the measures of implementation is critical to understanding the intervention and outcomes. Potentially useful aspects to be measured reflect many of the constructs described above, including *acceptability* of the intervention among stakeholders and the *fidelity* to the established protocol and design within each organization. *Reach within the organization* would examine the providers involved in care of the patients, while *reach within the population* would examine patients and

caregivers. Better measurement of the implementation process might help to identify barriers as well as solutions effective in some organizations that could be helpful to others. See Table 23.

Step 8—Define the Outcomes

- What are the specific, measurable outcomes that will result from the intervention?
  In this case, the focus was on readmissions as an outcome of *health care utilization*, but many other possible outcomes could have been relevant, including those focused on patients and caregivers, such as achieving *patient- and caregiver-centered outcomes*, the *patient/caregiver experience* of care; *cost effects/impact;* and *unintended consequences* (e.g., the burden of the substantial investment required for followup postdischarge). See Table 24.

Discussion

In this chapter, we reflect on the experience of adapting the Consolidated Framework for Implementation Research (CFIR) to three different types of complex system interventions, highlighting the similarities we uncovered in the needs, issues, and concerns voiced by the Technical Expert Panels (TEPs) and guidance we can offer to researchers wishing to adapt the CFIR to other forms of complex system interventions.

The systems in which process redesign for efficiency and cost reduction (PR), patient-centered medical homes (PCMH), and care transition interventions might be applied can aptly be described as nonlinear, dynamic, and composed of a multitude of "massively entangled" entities.[33] Most researchers of these interventions (our TEP members among them) would agree that these interventions are complex. Yet we lack a common vocabulary for capturing this complexity. To understand the interplay of people, settings, technology, and policy to effect some desired outcome or impact, researchers require a common taxonomy.

We identified the CFIR, adapted to the requirements of each intervention, as a potential solution to this dilemma. The CFIR draws from a wide range of disciplines and is not tied to any specified theory–features amenable to the study of complex system interventions, which inherently benefit from a multidisciplinary approach. The CFIR's broad range of constructs encompasses most of the contextual dimensions of the three interventions we adapted.

Similarities and Differences Among the Frameworks

The TEPs found the original constructs in the CFIR to be relevant across the three adaptations. However, the literature scan and the TEP input resulted in adding several dozen new constructs to the PR and PCMH Frameworks and two new domains. The Care Transitions Framework integrated these inputs and added several new constructs of its own, splitting the Individual Characteristics domain into separate domains for providers and for patients and caregivers.

Table 25 presents these new constructs and subconstructs by framework. The original CFIR constructs required mostly modest revisions to the definitions and construct name. The CFIR construct *design quality and packaging* was dropped from the PR and PCMH Frameworks but retained in the Care Transitions Framework; care transition interventions have packages (e.g., RED [ReEngineered Discharge], Project Better Outcomes for Older adults through Safe Transitions [BOOST]) with established steps and protocols, whereas this is less the case for PR and PCMH.

Our decision to include some constructs in a framework and not others was dictated by our understanding (informed by experts and the literature scan) of the principal focus of the intervention. The PR Framework, for example, did not add many of the patient- and population-focused constructs (e.g., *population needs and resources, continuity of patient care, socioeconomic demographics*) because generally PR studies on improving efficiency and reducing costs emphasize reducing waste and producing more units of service or output with less (or the same) resources. Ensuring that the PR improves patient outcomes (or at least does not worsen them) could be an explicit outcome, as reflected in the inclusion of *patient needs and resources, patients and other stakeholders*, and patient-related PR Framework outcomes.

Similarly, efficiency as an outcome was not added to the PCMH Framework and Care Transitions Framework because the major focus of these interventions is on enhancing patient experiences and outcomes, and perhaps less on increasing the throughput of patients through the

system or decreasing the number of steps to complete a task. The *integrator* role was not added to the PR and PCMH Frameworks because central coordination of many different types of organizations and roles outside the implementing organization is not a defining feature of these interventions. The *IT/HIT* (information technology/health information technology) *accessibility* role was not added to the Care Transitions Framework because we deemed technology a facilitator but not a key driver or focus of the intervention. Obviously, the specific goals of a particular investigation may require the inclusion of a construct not added to the framework, and we encourage investigators to approach the frameworks with a degree of flexibility and openness.

Table 25. New framework constructs

Domain	Construct (Subconstruct)	PR	PCMH	Care Transitions
Intervention Characteristics	Vision and change strategy	✓[a]	✓	✓
	Feasibility	✓[a]	✓	✓
	Compatibility	✓[a]	✓	✓
	Radicalness	✓[a]	✓	✓
	User control	✓[a]	✓	✓
	Location of PCMH activity (location of intervention activity in Care Transitions Framework)	N/A	✓[a]	✓
	Workflows	✓[a]	✓	✓
	Task/process standardization	✓[a]	✓	✓
	History	✓	✓[a]	✓
Outer Setting	Technological environment	✓[a]	✓	✓
	Population needs and resources	N/A	✓[a]	✓
	Community resources	N/A	✓	✓[a]
Inner Setting	(Staff commitment)	✓[a]	✓	✓
	IT and HIT resources	✓[a]	✓	✓
	(Human factors; HIT/IT accessibility in PCMH Framework)	✓[a]	✓	N/A
	Physical space and equipment	✓[a]	✓	N/A
	Staff time	✓[a]	✓	N/A
	Patient self-management infrastructure	N/A	✓[a]	✓
	Continuity	N/A	✓	✓[a]
	Patient centeredness	N/A	✓[a]	✓
Characteristics of Individuals and Teams	Skills and competencies	✓[a]	✓	✓
	Role	✓	✓[a]	✓
	Authority	✓	✓[a]	✓
	Collective efficacy	✓	✓[a]	✓
	Socioeconomic demographics	N/A	✓[a]	✓
	Patient needs and resources	✓	✓	✓[a]
	Caregiver needs and resources	N/A	✓	✓[a]
Process of Implementation	Assessing	✓	✓[a]	✓
	Acquiring and allocating resources	✓	✓[a]	✓
	Process ownership	✓	✓	✓
	Engaging organizations, external context	N/A	✓	✓[a]
	(Organizational leaders)	✓	✓[a]	✓
	(Facilitator)	✓	✓[a]	✓
	(Frontline staff)	✓	✓[a]	✓
	(Integrators)	N/A	N/A	✓[a]
	(Patients and other stakeholders)	✓	✓[a]	✓
	(Decisionmaking)	✓	✓[a]	✓
	(Staging and iteration)	✓[a]	✓	✓
	(Measurement capability and data availability)	✓	✓	✓[a]

Table 25. New framework constructs (continued)

Domain	Construct (Subconstruct)	PR	PCMH	Care Transitions
Measures of Implementation	Acceptability	✓	✓	✓
	Adoption/abandonment	✓	✓	✓
	Appropriateness	✓	✓	✓
	Implementation cost	✓	✓	✓
	Fidelity	✓	✓	✓
	Reach	✓	✓	✓
	(Reach within the population)	✓	✓	✓[a]
	(Reach within the organization)	✓	✓	✓[a]
	Penetration	✓	✓	✓
	Replicability	✓[a]	✓	✓
	Sustainability	✓	✓	✓
	Evolvability	✓	✓	✓[a]
Outcomes	Cost effects/impact	✓[a]	✓	✓
	Perceived value	✓[a]	✓	✓
	Unintended consequences	✓[a]	✓	✓
	Processes of care	N/A	✓[a]	✓
	Patient centered	N/A	✓[a]	✓
	(Coordinated)	N/A	✓[a]	✓
	(Comprehensive)	N/A	✓[a]	✓
	(Accessible)	✓	✓[a]	✓
	(Quality)	✓	✓[a]	✓
	(Safety)	✓	✓[a]	✓
	(Effectiveness)	✓[a]	✓	✓
	(Timeliness)	✓[a]	✓	✓
	(Efficiency)	✓[a]	N/A	N/A
	Patient- and caregiver-centered outcomes	N/A	✓	✓[a]
	Productivity	✓[a]	N/A	N/A
	Equitable	✓[a]	✓	N/A
	Patient/caregiver experience	✓	✓[a]	✓
	Provider experience	✓	✓[a]	✓
	Clinical outcomes	N/A	✓[a]	✓
	Health care utilization	✓	✓[a]	✓

[a]Indicates the original source of the construct or subconstruct.

Note: Subconstructs are shown in parentheses. HIT = health information technology; IT = information technology; N/A = not added; PCMH = patient-centered medical home; PR = process redesign.

Using the CFIR to conceptualize the multiple layers and complex interactions and networks that characterize complex system interventions was more difficult. Many of the elements of context can vary by time, location, and organizational unit (e.g., individual, team, practice, organization, system). This limitation of the framework became especially apparent in the care transitions area, as these interventions cannot even be characterized as having a narrowly defined location or setting. Interventions that are essentially a multiagency collaborative or a community-based entity that provides coordination across multiple providers are not bounded by place or organization. In this case the TEP had difficulty distinguishing the "outer setting" from the "inner setting." Accordingly, we dropped the term "inner setting" altogether from the Care Transitions Framework and regrouped its constituent parts into new domains.

In the initial versions of the PR and PCMH Frameworks, we included samples of constructs in two- and three-dimensional tables to orient the researcher to the multidimensional attributes of constructs and to discourage the tunnel vision that can occur when context is examined from

only one perspective. These sample tables failed to resonate with the TEPs, who found them on the whole confusing and unhelpful. The frameworks in their current form, confined to text-based two-dimensional tables, do not lend themselves to the levels of abstraction possible with complex systems. A Web-based tool that allows the user to explore the various hierarchies within a construct and juxtapose them against two or more dimensions (e.g., time by location) may come closer to achieving the original intent of our sample tables.

The frameworks, due to the breadth and relevance of the constructs included, should acquaint the researcher or the implementing organization with the large range of contextual variables that are possible and important to consider in a study or evaluation. The frameworks can be used by investigative teams planning multisite studies or funders supporting a portfolio of grants to deliberate on the core constructs needed for cross-site analysis. However, we recognize that the sheer number of constructs can be overwhelming, and at the TEPs' suggestion we added a general roadmap to guide the construct selection process. As every study is unique, there is no simple recipe for construct selection. Much like the interventions, the decision to include or leave out specific constructs is rooted in the context of the study itself.

Crosscutting Issues

CFIR was originally developed for research on highly focused clinical and practice interventions, rather than for evaluations of complex sets of interventions such as the three discussed here. Adapting the CFIR is therefore challenging but is needed if the framework is to contribute to research on the complex system interventions that are spreading and evolving rapidly.

In the remainder of this chapter, we present a number of the common issues or concerns we encountered in two or more of the adaptations. Some of these we addressed in the frameworks. Others remain unresolved or may have no clear solution, but are nevertheless important to keep in mind. These issues are as follows:

- *Components of the intervention*. Complex system interventions are typically not a single intervention but a collection of interventions, so issues of scope and boundary are critical to address early in study design. PR interventions such as Lean and Six Sigma can be especially confounding because they are organization-wide initiatives; researchers must decide whether to apply particular constructs (e.g., complexity and relative advantage of intervention) organization-wide, to specific projects, or both.
- *Components of the intervention versus targets of the intervention*. Disentangling the intervention from its context for research purposes can be an onerous task. Elements of the framework that are usually considered to be the context within which an intervention occurs can also become the targets of an intervention—for example, when PR seeks to alter team interactions or change culture and learning climate. Defining exactly what elements constitute the intervention and its objectives would seem a critical first step in using the framework. Unless the intervention specifies a specific causal pathway with well-articulated goals and objectives, the activities or outputs of the intervention could easily be confused with the outcomes. A new "vision/change strategy" construct was added to distinguish the intervention from its context.
- *Bundled nature of many interventions.* The bundling of intervention components drawn from different programs is a key element in these interventions. Bundling is important for

evaluating which parts of the bundle were implemented, which parts are associated with outcomes, and the relative importance of the components.

- *Intervention timing and research timeframe*. Complex system interventions rarely have a defined start and end date. As several TEP members noted, implementation may be more of an iterative process than a linear one that proceeds sequentially through clear stages. The PR and PCMH TEPs agreed that the contextual framework should encourage awareness of possible changes in the meaning and relevance of constructs across stages of implementation—even though very little empirical knowledge exists about the long-term implementation of complex interventions. One conceptualization that may be helpful divides the process into three stages: preimplementation, implementation, and sustainability.[34] Constructs that are relevant to one stage, such as preimplementation adoption decisions, may be less useful for studying another stage of the same intervention, such as sustainability. Researchers who follow an intervention over time might retain some core constructs across the entire study but select others that apply chiefly to one stage in the life course of the intervention. While considerations of time are relevant to selecting and applying constructs, the TEP noted that it can be difficult to determine when adoption and other stages begin and end.
- *Organizational units and level of analysis*. Complex system interventions may occur in multiple organizational units at the same time. For example, several clinics within the same organization or delivery system may implement similar redesigns aimed at enhancing patient access and throughput. Additionally, redesigns often operate at multiple organizational levels (i.e., levels of analysis). Relevant levels may include individual participants, teams, units, organizations (including autonomous practices), and delivery systems. The framework may inform research by alerting researchers to the following:
  - The importance of conceptualization and measurement at appropriate levels of analysis, and attention to and conceptualization of interactions among actors or units at the same level and across levels.
  - The importance of weighing potential contributions of multilevel analysis against the need to keep the research within manageable proportions.
- *Interaction effects*. Several TEP members noted that such interactions, along with interactions among multiple aspects of the interventions (reflected in multiple constructs within the framework), may be as important as the effects of isolated variables.
- *Alignment of constructs with stakeholder and practice roles*. The CFIR distinguishes among the various roles that individuals can assume in implementing an intervention (e.g., leading, facilitating, championing), and our discussion with the TEPs led to the addition of yet other roles and to a focus on the diverse internal and external stakeholders involved in and affected by PR, PCMH, and care transitions. We recognize that constructs may take on different meanings or measured values when applied to different roles or different stakeholders. For example, top management and nurse leaders may assess the value of an intervention of nursing roles very differently. External change agents for an intervention may assess the leadership commitment to the intervention very differently than frontline staff who participate in the initiative.
- *Indicators of implementation success*. Proctor et al.[5] define outcomes for the implementation (e.g., acceptability, adoption, appropriateness, costs, feasibility, preservation, sustainability) as distinct from the outcomes of an intervention. The TEP

agreed that specifying these implementation outcomes is a useful addition to the framework. To avoid confusion with clinical outcomes, we opted for the term "indicators of implementation success" to refer to Proctor's implementation "outcomes."

- *Intervention outcomes*. The PR and PCMH TEPs recommended adding outcomes to the CFIR, although they did not completely agree on which outcomes to include or what to call them. We added intervention-specific outcomes to each of the three frameworks. (Several of the outcomes overlap.) We kept the outcome constructs general so as to keep the focus of the framework on context and implementation. A large body of literature on many of these outcomes can be used to conceptualize them in more detail.
- *Patient-centered/population health perspectives.* Neither the PCMH nor the Care Transitions TEPs thought the frameworks were sufficiently patient centered. On the one hand, intervention design is usually centered around organizations, based on issues such as policies, payment, speed, funding, and research opportunities, and organizations are the leaders of this work; institutional outcomes such as readmissions and cost, rather than patient-centered outcomes such as quality of life, are usually the primary goal. On the other hand, the primary reason for a PCMH or care transitions intervention is the patient, and if the intervention cannot be personalized to heterogeneous patient and caregiver needs, it will not be effective. The PCMH and Care Transitions TEP members also felt that the framework should emphasize the role of population health. Taking into account these perspectives, we added constructs relevant to patient-, caregiver-, and population-level contexts. We also included patient outcomes.
- *Conceptualizing the framework around settings or organizations.* Complex system interventions are broader than a particular practice or integrated health care setting (where patients receive care and treatment) and typically can include community-based organizations, such as community coalitions, agencies, and collaboratives. These are often the effector arm and critical to a care transitions or PCMH intervention. A key concept to consider is that the intervention is based upon layers of organizations, rather than embedded in a single setting or group of settings.
- *Broader applicability*. Although the primary purpose of the frameworks is to guide research and evaluation, a number of TEP members thought they incorporated issues of concern to implementers and might become a useful tool for practice.

Limitations

The comprehensive series of methods used to develop the PR, PCMH, and Care Transitions Frameworks has a number of strengths, including a set of literature reviews and TEP input sessions. Limitations include the scope of the literature reviews, which could have missed some relevant resources (e.g., by focusing on hospital-ambulatory transitions or searching after 2005 for care transitions interventions), and limitations on the size of the TEPs to group sizes amenable to discussion, which may have not included some viewpoints. The qualitative, descriptive nature of the input allowed for a rich discussion of the issues, but interpretations of recommendations were made based on discussion; no surveys or other quantitative input was obtained from the TEP. The scope of this project did not include a formal assessment of the validity of each construct or identification and development of measures. We point investigators interested in measurement to the Seattle Implementation Research Collaborative, which has undertaken a formal evaluation of over 400 instruments for implementation research (www.seattleimplementation.org/sirc-projects/sirc-instrument-project/). Finally, although we

asked the TEPs to consider carefully if and how they would apply the frameworks to their implementation research, real evaluation of these frameworks depends on application in actual practice.

Next Steps

The adoption and use of the frameworks could be facilitated through a number of next steps. First, a Web-based version of the frameworks that allows users to drill down to the level of detail desired would allow the frameworks to be as comprehensive as needed without being overwhelming in detail. Second, evaluation of the user experience with the framework in a real-world research setting would provide valuable feedback for improving and developing the framework further. Third, the evaluation could be used to create an interactive roadmap that would provide users with tailored guidance on which constructs to select for specific research goals, as well as to link constructs to candidate measures. Transforming a static two-dimensional framework into a decision support tool for investigators would be a significant undertaking, but one well worth considering in view of the potential for improving the comparability and rigor of implementation studies.

Conclusion

The investigative team took a very open approach to this effort, with a literature scan and discussions with the Agency for Healthcare Research and Quality and our Technical Expert Panels. Much of the adaptation protocol was developed during the project. We considered other approaches involving more systematic methods (e.g., Delphi), but concluded that a highly systematic approach would not move us toward our desired goal. We did not seek to establish a consensus on every element of the framework; rather, we sought to generate qualitative feedback on the general utility of the framework for complex system interventions. In adapting the Consolidated Framework for Implementation Research (CFIR) for complex system interventions, we thought it critical to include input from both research and practice stakeholders to ensure that the content is understandable and applicable to the intervention strategy of interest.

The process of adapting the CFIR to three complex system interventions proved to be a daunting but stimulating challenge, and it pushed the investigative team to think creatively about how to produce a usable product for research implementation with rigor and efficiency. Given more time and resources, the frameworks could have been vetted with a broader set of stakeholders and their content honed with more systematic methods. However, we believe the goal of adaptation is not perfection, and care must be taken not to make a framework "endlessly complex"[3] for the sake of completeness. We encourage researchers to approach the adaptation process, and the frameworks themselves, iteratively and to document and share their experiences with colleagues. Our collective understanding of the complex phenomena we are striving to define, measure, and explain can only increase through such efforts.

References

1. Committee on Quality of Health Care in America, Institute of Medicine. Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, DC: The National Academies Press; 2001.
2. Shekelle PG, Pronovost PJ, Wachter RM, et al. Assessing the Evidence for Context-Sensitive Effectiveness and Safety of Patient Safety Practices: Developing Criteria. (Prepared under Contract No. 290-2009-0001C.) AHRQ Publication No. 11-0006-EF. Rockville, MD: Agency for Health Care Research and Quality; December 2010. www.ahrq.gov/research/findings/final-reports/contextsensitive/context.pdf.
3. 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. PMID: 19664226.
4. Gerring J. What makes a concept good? A critical framework for understanding concept formation in the social sciences. Polity. 1999 Spring;31(3):357-93.
5. Proctor E, Silmere H, Raghavan R, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. Adm Policy Ment Health. 2011 Mar;38(2):65-76. PMID: 20957426
6. Foy R, Ovretveit J, Shekelle PG, et al. The role of theory in research to develop and evaluate the implementation of patient safety practices. BMJ Qual Saf. 2011 May;20(5):453-9. PMID: 21317181.
7. Clegg CW. Sociotechnical principles for system design. Appl Ergon. 2000;31:463-77.
8. Stetler CB, Damschroder LJ, Helfrich CD, et al. A Guide for applying a revised version of the PARIHS framework for implementation. Implement Sci. 2011;6:99. PMID: 21878092.
9. Gustafson DH, Sainfort F, Eichler M, et al. Developing and testing a model to predict outcomes of organizational change. Health Serv Res. 2003 Apr;38(2):751-76. PMID: 12785571.
10. Harrison MI, Kimani J. Building capacity for a transformation initiative: system redesign at Denver Health. Health Care Manage Rev. 2009 Jan-Mar;34(1):42-53. PMID: 19104263.
11. Kaplan HC, Provost LP, Froehle CM, et al. The Model for Understanding Success in Quality (MUSIQ): building a theory of context in healthcare quality improvement. BMJ Qual Saf. 2012 Jan;21(1):13-20. PMID: 21835762.
12. Nutting PA, Crabtree BF, Miller WL, et al. Transforming physician practices to patient-centered medical homes: lessons from the national demonstration project. Health Aff (Millwood). 2011 Mar;30(3):439-45. PMID: 21383361.
13. Henriksen K, Joseph A, Zayas-Caban T. The human factors of home health care: a conceptual model for examining safety and quality concerns. J Patient Saf. 2009 Dec;5(4):229-36. PMID: 22130216.
14. Carayon P, Schoofs Hundt A, Karsh BT, et al. Work system design for patient safety: the SEIPS model. Qual Saf Health Care. 2006 Dec;15 Suppl 1:i50-8. PMID: 17142610.
15. Kanter R. Men and Women of the Corporation (2nd ed.). New York: Basic Books 1977.
16. Helfrich CD, Li YF, Sharp ND, et al. Organizational readiness to change assessment (ORCA): development of an instrument based on the Promoting Action on Research in Health Services (PARIHS) framework. Implement Sci. 2009;4:38. PMID: 19594942.
17. Greenhalgh T, Robert G, Macfarlane F, et al. Diffusion of innovations in service organizations: systematic review and recommendations. Milbank Q. 2004;82(4):581-629. PMID: 15595944.
18. Rogers EM. Diffusion of Innovations. 5th ed., New York: Free Press; 2003.
19. Locock L, Dopson S, Chambers D, et al. Understanding the role of opinion leaders in improving clinical effectiveness. Soc Sci Med. 2001 Sep;53(6):745-57. PMID: 11511050.

20. Burston S, Chaboyer W, Wallis M, et al. A discussion of approaches to transforming care: contemporary strategies to improve patient safety. J Adv Nurs. 2011 Nov;67(11):2488-95. PMID: 21627678.

21. Murray E, Burns J, May C, et al. Why is it difficult to implement e-health initiatives? A qualitative study. Implement Sci. 2011;6:6. PMID: 21244714.

22. Glasgow R, Boles S, Vogt T. Reach Effectiveness Adoption Implementation Maintenance-RE-AIM Framework. Blacksburg, VA: Human Nutrition, Foods and Exercise, College of Agriculture and Life Sciences, Virginia Polytechnic Institute and State University; 2012. www.re-aim.org/about_re-aim/what_is_re-aim/index.html. Accessed July 16, 2012.

23. National Committee for Quality Assurance. NCQA's Patient-Centered Medical Home (PCMH). 2011 www.ncqa.org/Portals/0/Programs/Recognition/PCMH_2011_Overview_5.2.pdf. Accessed July 11, 2013.

24. Agency for Healthcare Research and Quality. Patient Centered Medical Home Resource Center. Rockville, MD: Agency for Healthcare Research and Quality; 2012. http://pcmh.ahrq.gov/portal/server.pt/community/pcmh__home/1483/pcmh_home_v2. Accessed June 19, 2013.

25. James B, Bayley KB. Cost of Poor Quality or Waste in Integrated Delivery System Settings. Final Report. AHRQ Publication No. 08-0096-EF. Rockville, MD: Agency for Healthcare Research and Quality; September 2006. www.ahrq.gov/research/findings/final-reports/costpqids/index.html.

26. McCarthy EL. Physician office productivity improvement through operations analysis and process redesign. J Ambul Care Manage. 2002 Oct;25(4):37-52. PMID: 12371018.

27. Parchman ML, Pugh JA, Culler SD, et al. A group randomized trial of a complexity-based organizational intervention to improve risk factors for diabetes complications in primary care settings: study protocol. Implement Sci. 2008;3:15. PMID: 18321386.

28. Driscoll DL, Hiratsuka V, Johnston JM, et al. Process and outcomes of patient-centered medical care with Alaska Native people at Southcentral Foundation. Ann Fam Med. 2013 May-Jun;11 Suppl 1:S41-9. PMID: 23690385.

29. Coleman EA. The Care Transitions Program. Aurora, CO: Division of Health Care Policy and Research, University of Colorado Denver. www.caretransitions.org. Accessed February 8, 2013.

30. Coleman EA, Boult C, American Geriatrics Society Health Care Systems Committee. Improving the quality of transitional care for persons with complex care needs. J Am Geriatr Soc. 2003 Apr;51(4):556-7. PMID: 12657079.

31. Rennke S, Shoeb MH, Nguyen OK, et al. Chapter 37. Interventions to improve care transitions at hospital discharge. In: Shekelle PG, Wachter RM, Pronovost RH, et al., eds. Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices. Evidence Reports/Technology Assessments, No. 211. Prepared by the Southern California-RAND Evidence-based Practice Center under Contract No. Rockville, MD; 2013.

32. Robert Wood Johnson Foundation. Care Across Settings: Challenges, Successes and Opportunities. 2013. www.rwjf.org/content/dam/farm/reports/issue_briefs/2013/rwjf404875. Accessed June 11 2013.

33. Begun JW, Zimmerman B, Dooley K. Health care organizations as complex adaptive systems. In: Mick SM, Wyttenbach M, eds. Advances in Health Care Organization Theory. San Francisco: Jossey-Bass; 2003:253-88.

34. Chamberlain P, Brown CH, Saldana L. Observational measure of implementation progress in community based settings: The Stages of implementation completion (SIC). Implement Sci. 2011;6:116. PMID: 21974914.

Glossary

Term	Definition
Adoption	Adoption is the intention, initial decision, or action to use the intervention. Adoption helps prepare for implementation.
Constructs	Constructs are operational definitions of theoretical concepts. Constructs may involve different meanings or measured values when applied to different practice roles.
Context	Context involves the interrelations and interactions between constructs that condition the individual and organizational use of the intervention as designed.
Domains	Domains are groupings of related constructs. Frameworks often include multiple domains.
Framework	A framework systematically identifies and organizes potential constructs and relationships to provide a conceptual tool for integrating the elements of the intervention; the environment impacting the intervention; the individuals/teams involved in the intervention; and the structures, processes, and outcomes of the intervention.
Implementation	Implementation involves deliberately initiated processes to achieve use of the intervention as designed or deliberately initiated PR to guide system-wide changes of complex sociotechnical systems.
Intervention	An intervention is a specific, discrete activity, action, or technique intended to achieve a desired health or health care outcome. These may be implemented singly, as combinations or bundles, or as a strategy. A strategy later encompasses a set of practices, techniques, or interventions sharing an underlying logic or approach for achieving the desired outcome.
PCMH	"The patient-centered medical home (PCMH) is a promising primary care approach that emphasizes patient-centered, comprehensive, coordinated, accessible care, with a systematic focus on quality and safety. The goal of these models is to improve quality, cost, and patient and provider experience."[e]
PR	PR examines interactions among components of complex sociotechnical systems (e.g., health care delivery systems) and provides resources and tools to guide system-wide changes that improve care value and its safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity of care.[f]
Practice Roles	Practice roles include the individuals within and outside the practice, network, or organizations involved in the decision to adopt, execute, and facilitate the intervention. Examples of practice roles include external change agents, organizational leaders, and frontline staff.
Process	Process involves a course of actions (e.g., planning, engaging, and reflecting) to achieve individual- and organizational-level use of the intervention as designed.
Transitional Care	"Transitional care is defined as a set of actions designed to ensure the coordination and continuity of health care as patients transfer between different locations or different levels of care within the same location. Representative locations include (but are not limited to) hospitals, sub-acute and post-acute nursing facilities, the patient's home, primary and specialty care offices, and long-term care facilities."[g]

Note: PCMH = patient-centered medical home; PR = process redesign.

[e]**Source**: Agency for Healthcare Research and Quality. Expanding the Toolbox: Methods To Study and Refine Patient-Centered Medical Home Models. PCMH Research Methods Series. AHRQ Publication No. 13-0012-EF. 2013.

[f]**Source:** Agency for Healthcare Research and Quality. System Design: AHRQ Resources. www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/systemdesign.html#process. 2013. Accessed June 14, 2013.

[g]**Source:** Coleman EA, Boult CE, on behalf of the American Geriatrics Society Health Care Systems Committee. Improving the quality of transitional care for persons with complex care needs. J Am Geriatr Soc. 2003;51(4):556-7. PMID: 12657079.

Appendix A. Detailed Methods and Results of the Literature Scans

We used 50 search terms singly and in combination to identify potentially relevant process redesign (PR) and patient-centered medical home (PCMH) literature and used 18 terms for care transitions literature. These terms are listed in Table A-1.

Table A-1. Literature search terms

PR and PCMH Search Terms
1. advanced primary care
2. CFIR
3. consolidated frameworks for implementation research
4. Costs and Cost Analysis
5. Delivery of Health Care, Integrated
6. efficiency
7. Efficiency, Organizational
8. guided care
9. health care redesign
10. Health Services Misuse
11. health-care home
12. implement sci
13. implementation effectiveness
14. implementation framework(s)
15. implementation model(s)
16. implementation theory
17. lean
18. Lean thinking
19. model for understanding success in quality
20. MUSIQ
21. operations research
22. Operations Research
23. patient aligned care team
24. patient care
25. patient care
26. patient care management
27. patient care redesign
28. Patient Care Team
29. patient safety
30. Patient Safety
31. Patient-Centered Care
32. patient-centered medical home(s)
33. PCMH
34. practical, robust implementation and sustainability model
35. PRISM
36. Process Assessment (Health Care)
37. process redesign
38. process redesign
39. quality improvement
40. Quality Improvement
41. Quality of Health Care/organization and administration
42. quality of healthcare
43. redesign
44. relationship-centered care
45. relationship-centered health care (healthcare)
46. six sigma

Table A-1. Literature search terms (continued)

PR and PCMH Search Terms
47. system redesign
48. theoretical framework(s)
49. theoretical model(s)
50. Utilization Review
Care Transitions Search Terms
1. ambulatory
2. Ambulatory Care
3. ambulatory care
4. care transition(s/ing)
5. Episodes of Care Measurement Framework
6. framework(s)
7. Hospital(s)
8. Hospitalization/hospitalization
9. model(s)
10. transition record(s)
11. transitional care
12. Transitional Care Intervention
13. Transitional Care Intervention Framework
14. Transitional Care Model
15. transitions in care
16. transitions of care
17. Transitions of Care Measures
18. uncoordinated transition(s)

During the title, abstract, and full-text reviews, we excluded articles for any of the reasons listed in Table A-2.

Table A-2. Abstract and full text exclude reasons

1. Not English language
2. No framework or theory
3. Topic is not PR, PCMH, or Care Transitions
4. Does not discuss efficiency, costs, or business case elements (for PR Framework only)
5. Does not concern hospital to ambulatory Care Transitions for adults (for Care Transitions Framework only)
6. Published before January 2005
7. Letter to the editor
8. Other (e.g., full text not available, evaluates/applies rather than develops model, protocol or methods paper)

A general set of questions guided the abstraction of the included articles. The questions were tailored to identify content not already captured in the frameworks. The questions we used for abstraction were as follows:

- What components (inputs, processes, outputs, outcomes) of the model are not included in the Consolidated Framework for Implementation Research (CFIR)?
- What components are unique or applicable to PCMH, PR, or care transitions features?
- Are the specified categories/relationships among the components different from those in the CFIR and if so, how?
- Which components or relationships should be considered for inclusion in the frameworks for PCMH, PR, or Care Transitions?

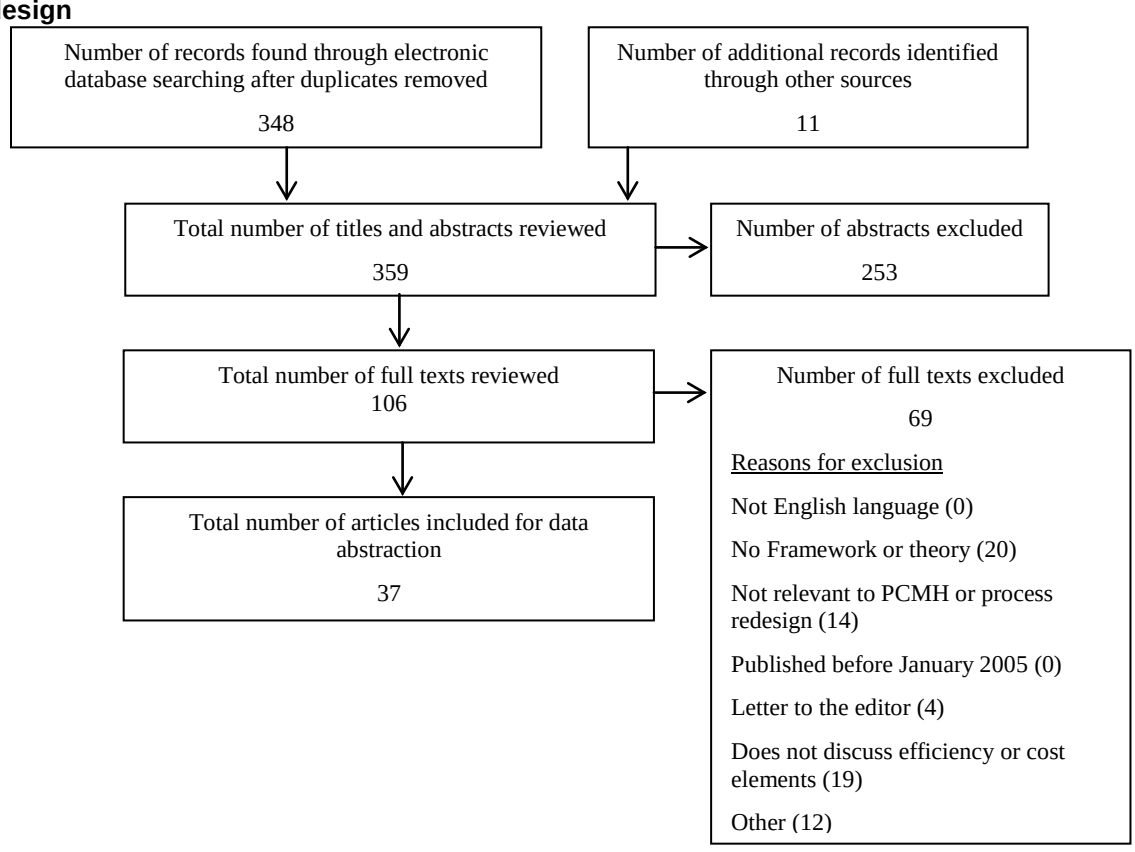
- What components and constructs listed in the article are more applicable to models of Care Transitions from hospitals to ambulatory compared with other types of transitions? (For Care Transitions Framework only)

Process Redesign and Patient-Centered Medical Homes

Figure A-1 shows the flow diagram for included articles from the initial literature scan for the PCMH and PR Framework adaptations. After the completion of the literature scan, the project team continued to identify and receive literature that aided in the refinement and adaptations of the frameworks throughout the multiphase process. These additional resources are cited within the report as appropriate, but they are not included in the tallies for the literature scan because they did not go through the same review and data abstraction process as the articles identified by the team during the time period of the literature scan.

The main MEDLINE search yielded 226 citations and the table of contents search yielded 122 citations after removing duplicates. Technical Expert Panel recommendations and a search of the AHRQ Web site provided 11 more articles. After title and abstract review, we excluded 253 citations. Among the 107 full-text articles reviewed, we included 37 for data abstraction. At the full-text stage, 69 citations were excluded because they did not include a framework or theory, described activities that were not directly applicable to PCMH or PR, did not include cost or efficiency (if a citation pulled for PR), or was a letter to the editor.

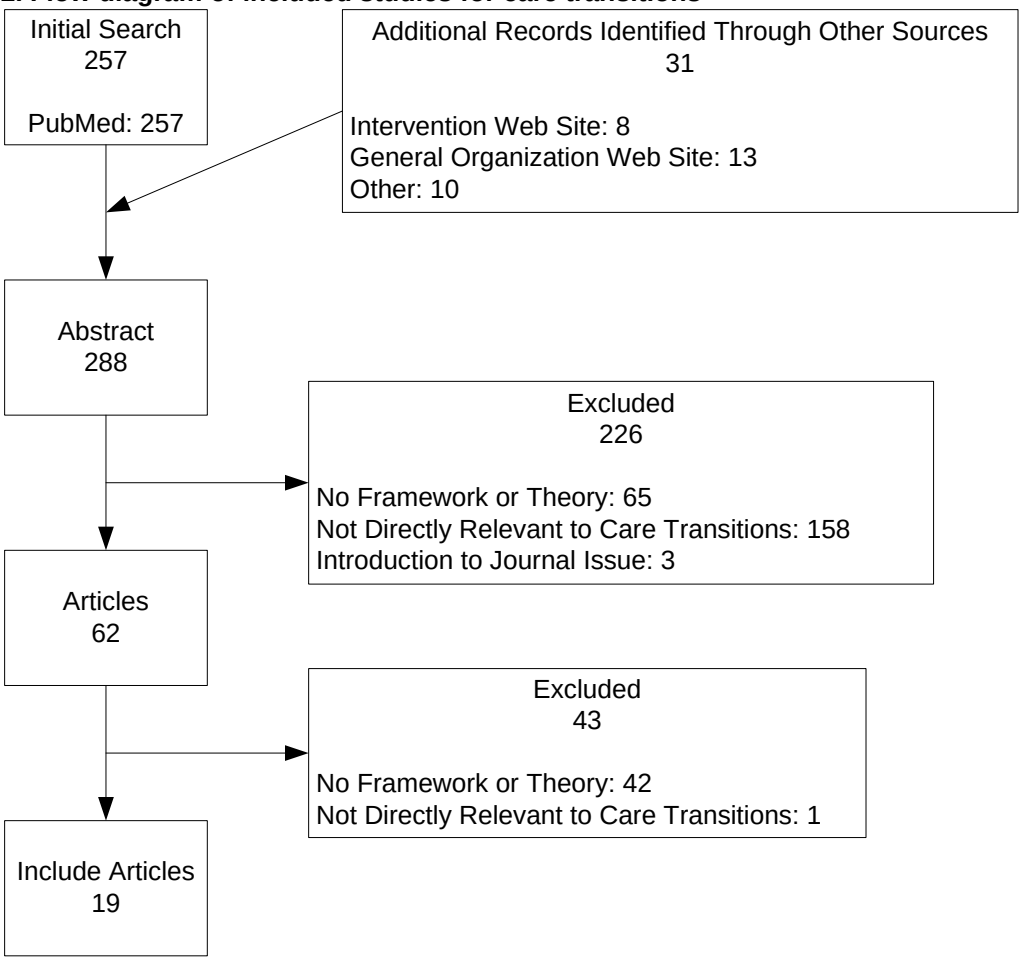
Figure A-1. Flow diagram of included studies for patient-centered medical home and process redesign



Care Transitions

The literature scan for Care Transitions focused on identifying contextual and theoretical frameworks related to transition interventions, specifically hospital-ambulatory transitions, and to medical illnesses. Figure A-2 shows the flow diagram for included articles. The main MEDLINE search yielded 257 citations, and the gray literature search yielded another 31 citations after removing duplicates. After title and abstract review, we excluded 226 citations. Among the 62 full-text articles reviewed, we included 19 for data abstraction. The most common reasons for exclusion were the absence of a framework or theory and a focus on activities not directly applicable to Care Transitions.

Figure A-2. Flow diagram of included studies for care transitions



Appendix B. Included Articles From Literature Scans

Process Redesign and Patient-Centered Medical Home Literature

1. Alexander JA, Hearld LR. The science of quality improvement implementation: developing capacity to make a difference. Med Care. 2011 Dec;49 Suppl:S6-20. PMID: 20829724.
2. Arora VM, Johnson JK, Meltzer DO, et al. A theoretical framework and competency-based approach to improving handoffs. Qual Saf Health Care. 2008 Feb;17(1):11-4. PMID: 18245213.
3. Ben-Tovim DI, Bassham JE, Bennett DM, et al. Redesigning care at the Flinders Medical Centre: clinical process redesign using "lean thinking". Med J Aust. 2008 Mar 17;188(6 Suppl):S27-31. PMID: 18341473.
4. Bray P, Roupe M, Young S, et al. Feasibility and effectiveness of system redesign for diabetes care management in rural areas: the eastern North Carolina experience. Diabetes Educ. 2005 Sep-Oct;31(5):712-8. PMID: 16203855.
5. Burston S, Chaboyer W, Wallis M, et al. A discussion of approaches to transforming care: contemporary strategies to improve patient safety. J Adv Nurs. 2011 Nov;67(11):2488-95. PMID: 21627678.
6. Carayon P, Schoofs Hundt A, Karsh BT, et al. Work system design for patient safety: the SEIPS model. Qual Saf Health Care. 2006 Dec;15 Suppl 1:i50-8. PMID: 17142610.
7. Damschroder L, Aron D, Keith R, et al. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implementation Science. 2009;4(1):50. PMID: doi:10.1186/1748-5908-4-50.
8. Duckers ML, Wagner C, Vos L, et al. Understanding organisational development, sustainability, and diffusion of innovations within hospitals participating in a multilevel quality collaborative. Implement Sci. 2011;6:18. PMID: 21385467.
9. Feeley TW, Fly HS, Albright H, et al. A method for defining value in healthcare using cancer care as a model. J Healthc Manag. 2010 Nov-Dec;55(6):399-411; discussion -2. PMID: 21166323.
10. Feldstein AC, Glasgow RE. A practical, robust implementation and sustainability model (PRISM) for integrating research findings into practice. Jt Comm J Qual Patient Saf. 2008 Apr;34(4):228-43. PMID: 18468362.
11. Franx G, Oud M, De Lange J, et al. Implementing a stepped care approach in primary care. Results of a qualitative study. Implement Sci. 2012 Jan 31;7(1):8. PMID: 22293362.
12. Glasgow RE, Dickinson P, Fisher L, et al. Use of RE-AIM to develop a multi-media facilitation tool for the patient-centered medical home. Implement Sci. 2011;6:118. PMID: 22017791.
13. Harrison MI, Kimani J. Building capacity for a transformation initiative: system redesign at Denver Health. Health Care Manage Rev. 2009 Jan-Mar;34(1):42-53. PMID: 19104263.
14. Harwood L, Ridley J, Lawrence-Murphy JA, et al. Nurses' perceptions of the impact of a renal nursing professional practice model on nursing outcomes, characteristics of practice environments and empowerment--Part I. CANNT J. 2007 Jan-Mar;17(1):22-9. PMID: 17405392.
15. Helfrich CD, Li YF, Sharp ND, et al. Organizational readiness to change assessment (ORCA): development of an instrument based on the Promoting Action on Research in Health Services (PARIHS) framework. Implement Sci. 2009;4:38. PMID: 19594942.
16. Henriksen K, Joseph A, Zayas-Caban T. The human factors of home health care: a conceptual model for examining safety and quality concerns. J Patient Saf. 2009 Dec;5(4):229-36. PMID: 22130216.

17. Holden RJ. Lean Thinking in emergency departments: a critical review. Ann Emerg Med. 2011 Mar;57(3):265-78. PMID: 21035904.

18. Jasovsky DA, Morrow MR, Clementi PS, et al. Theories in action and how nursing practice changed. Nurs Sci Q. 2010 Jan;23(1):29-38. PMID: 20026725.

19. Kaplan HC, Provost LP, Froehle CM, et al. The Model for Understanding Success in Quality (MUSIQ): building a theory of context in healthcare quality improvement. BMJ Qual Saf. 2012 Jan;21(1):13-20. PMID: 21835762.

20. King HB, Battles J, Baker DP, et al. TeamSTEPPS™: Team Strategies and Tools to Enhance Performance and Patient Safety. Rockville, MD: 2008.

21. Kirsh S, Watts S, Pascuzzi K, et al. Shared medical appointments based on the chronic care model: a quality improvement project to address the challenges of patients with diabetes with high cardiovascular risk. Qual Saf Health Care. 2007 Oct;16(5):349-53. PMID: 17913775.

22. Kirsh SR, Lawrence RH, Aron DC. Tailoring an intervention to the context and system redesign related to the intervention: a case study of implementing shared medical appointments for diabetes. Implement Sci. 2008;3:34. PMID: 18533021.

23. Kochevar LK, Yano EM. Understanding health care organization needs and context. Beyond performance gaps. J Gen Intern Med. 2006 Feb;21 Suppl 2:S25-9. PMID: 16637957.

24. Lanham HJ, McDaniel RR, Jr., Crabtree BF, et al. How improving practice relationships among clinicians and nonclinicians can improve quality in primary care. Jt Comm J Qual Patient Saf. 2009 Sep;35(9):457-66. PMID: 19769206.

25. Lemmens KM, Nieboer AP, van Schayck CP, et al. A model to evaluate quality and effectiveness of disease management. Qual Saf Health Care. 2008 Dec;17(6):447-53. PMID: 19064661.

26. Luck J, Hagigi F, Parker LE, et al. A social marketing approach to implementing evidence-based practice in VHA QUERI: the TIDES depression collaborative care model. Implement Sci. 2009;4:64. PMID: 19785754.

27. Martin CM. Chronic disease and illness care: adding principles of family medicine to address ongoing health system redesign. Can Fam Physician. 2007 Dec;53(12):2086-91. PMID: 18077734.

28. Murray E, Burns J, May C, et al. Why is it difficult to implement e-health initiatives? A qualitative study. Implement Sci. 2011;6:6. PMID: 21244714.

29. Ovretveit J, Scott T, Rundall TG, et al. Improving quality through effective implementation of information technology in healthcare. Int J Qual Health Care. 2007 Oct;19(5):259-66. PMID: 17717038.

30. Peikes D, Zutshi A, Genevro J, et al. Early Evidence on the Patient-Centered Medical Home Final Report (Prepared by Mathematica Policy Research, under Contract Nos. HHSA290200900019I/HHSA29032002T and HHSA290200900019I/HHSA29032005T). Rockville, MD: Agency for Healthcare Research and Quality; February 2012.

31. Post EP, Kilbourne AM, Bremer RW, et al. Organizational factors and depression management in community-based primary care settings. Implement Sci. 2009;4:84. PMID: 20043838.

32. Profit J, Typpo KV, Hysong SJ, et al. Improving benchmarking by using an explicit framework for the development of composite indicators: an example using pediatric quality of care. Implement Sci. 2010;5:13. PMID: 20181129.

33. Rippen HE, Pan EC, Russell C, et al. Organizational framework for health information technology. Int J Med Inform. 2012 Feb 27PMID: 22377094.

34. Siminerio LM. The role of technology and the chronic care model. J Diabetes Sci Technol. 2010 Mar;4(2):470-5. PMID: 20307409.

35. Singh R, Singh A, Fox C, et al. Computer visualisation of patient safety in primary care: a systems approach adapted from management science and engineering. Inform Prim Care. 2005;13(2):135-44. PMID: 15992498.

36. Vest JR, Gamm LD. A critical review of the research literature on Six Sigma, Lean and StuderGroup's Hardwiring Excellence in the United States: the need to demonstrate and communicate the effectiveness of transformation strategies in healthcare. Implement Sci. 2009;4:35. PMID: 19570218.

37. Walsh K, Antony J. An assessment of quality costs within electronic adverse incident reporting and recording systems: a case study. Int J Health Care Qual Assur. 2009;22(3):203-20. PMID: 19537183.

Care Transitions Literature

1. Transitions of Care Measures. National Transitions of Care Coalition. http://www.ntocc.org/Portals/0/PDF/Resources/TransitionsOfCare_Measures.pdf. Accessed on February 8, 2013.

2. Care Transitions Performance Measurement Set. AMA; 2009. www.ama-assn.org/ama/pub/physician-resources/physician-consortium-performance-improvement.page. Accessed on February 8, 2013.

3. Allen KR, Hazelett SE, Jarjoura D, et al. The after discharge care management of low income frail elderly (AD-LIFE) randomized trial: theoretical framework and study design. Popul Health Manag. 2011 Jun;14(3):137-42. PMID: 21323461.

4. Almaden S, Freshman B, Quaye B. Case management redesign in an urban facility. Prof Case Manag. 2011 Jul-Aug;16(4):199-209. PMID: 21646895.

5. Babcock CW, Robinson LE. A novel approach to hospital palliative care: an expanded role for counselors. J Palliat Med. 2011 Apr;14(4):491-500. PMID: 21410337.

6. Coleman EA, Parry C, Chalmers S, et al. The care transitions intervention: results of a randomized controlled trial. Arch Intern Med. 2006 Sep 25;166(17):1822-8. PMID: 17000937.

7. Geary CR, Schumacher KL. Care transitions: integrating transition theory and complexity science concepts. ANS Adv Nurs Sci. 2012 Jul;35(3):236-48. PMID: 22869210.

8. Graham CL, Ivey SL, Neuhauser L. From hospital to home: assessing the transitional care needs of vulnerable seniors. Gerontologist. 2009 Feb;49(1):23-33. PMID: 19363001.

9. Holland DE, Harris MR. Discharge planning, transitional care, coordination of care, and continuity of care: clarifying concepts and terms from the hospital perspective. Home Health Care Serv Q. 2007;26(4):3-19. PMID: 18032197.

10. Manser T, Foster S, Gisin S, et al. Assessing the quality of patient handoffs at care transitions. Qual Saf Health Care. 2010 Dec;19(6):e44. PMID: 21127094.

11. McCarthy D, Cohen A, Johnson M. Case study series synthesis: Innovations in care transitions. Gaining ground: Care management programs to reduce hospital admissions and readmissions among chronically ill and vulnerable patients. The Commonwealth Fund; 2013. http://www.commonwealthfund.org/Publications/Case-Studies/2013/Jan/Care-Transitions-Synthesis.aspx. Accessed on February 8, 2013.

12. Moore C, McGinn T, Halm E. Tying up loose ends: discharging patients with unresolved medical issues. Arch Intern Med. 2007 Jun 25;167(12):1305-11. PMID: 17592105.

13. Naylor M. Transitional care conceptual model. Transitional Care Model. www.transitionalcare.info. Accessed on February 8, 2013.

14. Naylor MD. Transitional care: a critical dimension of the home healthcare quality agenda. J Healthc Qual. 2006 Jan-Feb;28(1):48-54. PMID: 16681300.

15. Naylor MD, Sochalski JA. Scaling up: bringing the transitional care model into the mainstream. Issue Brief (Commonw Fund). 2010 Nov;103:1-12. PMID: 21053533.

16. Prvu Bettger J, Alexander KP, Dolor RJ, et al. Transitional care after hospitalization for acute stroke or myocardial infarction: a systematic review. Ann Intern Med. 2012 Sep 18;157(6):407-16. PMID: 22986378.

17. Rennke S, Shoeb M, Nguyen O, et al. Interventions to Improve Care Transitions at Hospital Discharge. AHRQ; 2013. http://www.ahrq.gov/research/primarix.htm. Accessed on February 8, 2013.

18. Snow V, Beck D, Budnitz T, et al. Transitions of Care Consensus Policy Statement American College of Physicians-Society of General Internal Medicine-Society of Hospital Medicine-American Geriatrics Society-American College of Emergency Physicians-Society of Academic Emergency Medicine. J Gen Intern Med. 2009 Aug;24(8):971-6. PMID: 19343456.

19. Wong FK, Chan MF, Chow S, et al. What accounts for hospital readmission? J Clin Nurs. 2010 Dec;19(23-24):3334-46. PMID: 21029227.

Appendix C. Technical Expert Panel Composition, Methods, and Input on Usability

Process Redesign and Patient-Centered Medical Home Technical Expert Panels

Table C-1 shows the distribution of expertise in each TEP. The PCMH TEP included 7 members, and the PR TEP included 8 members (2 individuals served on both TEPs).

Table C-1. Representation on the Process Redesign and Patient-Centered Medical Home Technical Expert Panels

PCMH TEP Member	Research and Evaluation	Management and Practice	General Implementation Research Expertise	Served on Both TEPs
1	—	—	X	X
2	X	X	—	—
3	X	—	—	—
4	X	X	—	—
5	X	X	—	—
6	—	—	X	X
7	X	—	—	—
PR TEP Member	**Research and Evaluation**	**Management and Practice**	**General Implementation Research Expertise**	**Served on Both TEPs**
1	—	—	X	X
2	X	—	—	—
3	X	—	—	—
4	X	—	—	—
5	X	—	—	—
6	—	X	—	—
7	X	—	—	—
8	—	—	X	X

Abbreviations: PCMH = Patient-Centered Medical Home; PR = process redesign; TEP = Technical Expert Panel.

To prepare the TEP for the first discussion, we sent the draft contextual frameworks a week in advance for the members to review. During the first call, a member of the team that developed the CFIR oriented the TEPs to the CFIR and answered their questions. Using the feedback from the initial discussion, we made modifications to the draft frameworks and reviewed these with the TEP on the second call. In addition, we asked the TEP to provide feedback on a set of multilevel analyses tables we created to accompany the frameworks. These tables were intended to help the user apply the constructs in the framework to multiple levels of analysis.

We used the following set of questions to elicit feedback to guide the adaptation of the CFIR:

- Is the CFIR in its original form an appropriate guide for the study of PCMH/PR implementation?
- What are the most important changes that need to be made to the CFIR?
- What are the most important constructs for PCMH/PR implementation research?
- Are some CFIR constructs related to *adoption vs. implementation*; are adoption constructs appropriate for an implementation framework?

- Are there entire domains or specific "variables" where we need to take into account *change* during the life course of an intervention/system change?
- Could one *level of analysis* be chosen as the focal level for a given study, with the others then seen as interacting with the focal level?
- Should *"implementation outcomes"* (Proctor et al.[1]) and *final outcomes* be included in the framework?
- Is there a manageable way of addressing the way context and the intervention interact and co-evolve?

Care Transitions Technical Expert Panel

Similar to the composition of TEPs for PCMH and PR earlier, we aimed to include individuals with diverse professional perspectives for the Care Transitions TEP encompassing research and evaluation, health care providers, and those engaged in developing and implementing Care Transitions interventions. The Care Transitions TEP included 11 members. Table C-2 shows the distribution of perspectives among the TEP.

Table C-2. Representation on the Care Transitions Technical Expert Panel

—	Perspective	
TEP Member	**Provider/Researcher**	**Association**
1	—	X
2	X	—
3	X	X
4	—	X
5	X	—
6	—	X
7	X	—
8	X	—
9	—	X
Co10	X	—
11	—	X

Abbreviations: TEP = Technical Expert Panel.

Using a similar protocol to the PCMH and PR TEPs, materials were sent to the Care Transitions TEP to review 1 week in advance of the first call. During the first call, a senior member of the investigative team gave a brief presentation on the CFIR. The orientation to the CFIR was followed by a structured discussion focused on the applicability of the draft Care Transitions Framework with the goal of addressing several overarching questions:

- Is the CFIR in its adapted form an appropriate guide for Care Transitions implementation research?
- Are the domains and constructs of the CFIR adapted appropriately for Care Transitions implementation research?
- What modifications are needed to the draft graphic (Care Transitions Framework) to provide a useful and accurate representation of Care Transitions implementation research?
- What important aspects of Care Transitions implementation research are missing from the constructs in the framework?
- How should the Care Transitions Framework frame issues of patient- or caregiver-centered care (including the key area of patient and family engagement)?

- How should links or integration between the settings for Care Transitions best be used to adapt the CFIR?
- How can the adapted CFIR best represent the concept of accountability or the home of coordination (that can rest in either or both settings)?

Based on the results of these TEP calls, we summarized input on the adaptation of the framework and developed a set of recommendations and questions for additional clarification in the second set of calls. The following questions were the focus of this second set of calls:

- Does the framework help you as a researcher identify and define the core components of the intervention?
- Does making a distinction between Inner (Core) Settings and Outer Context help you define the intervention?
- How can the framework best represent the concepts of accountability and coordination at the patient level?
- How can the framework best represent the concept of collaboration at the organizational level?
- What important aspects of Care Transitions implementation research are missing from the constructs in the framework?
- Are the domains and constructs of the framework adapted appropriately for Care Transitions implementation research?
- How should the framework frame issues of patient- or caregiver-centered care?

We also developed two case studies to evaluate the utility of the framework for designing the evaluation or a study of a typical Care Transitions intervention. The subject of the first case study was the Health Improvement Collaborative of Greater Cincinnati; the second case study featured the transition of a fictional patient named "Mrs. Davis" from hospital to home. These cases were drawn from a policy brief of the Aligning Forces for Quality Initiative.[2]

Usability Technical Expert Panel

In a second phase of this project, the team evaluated the usability of the PCMH and PR Frameworks by convening two new TEPs, one to assess each framework. The PCMH TEP consisted of 6 members, and the PR TEP had 5 members. Table C-3 shows the distribution of perspectives in each TEP.

Table C-3. Representation on the patient-centered medical home and process redesign usability Technical Expert Panels

PCMH Usability TEP Member	Researcher	Health Care Executive and/or Provider
1	X	—
2	X	—
3	X	—
4	X	X
5	X	—
6	X	—
PR Usability TEP Member	**Researcher**	**Health Care Executive and/or Provider**
1	X	—
2	X	—
3	X	—
4		X
5	X	—

Abbreviations: PCMH = Patient-Centered Medical Home; PR = process redesign; TEP = Technical Expert Panel.

Each TEP met twice. During these TEP calls, members discussed the effectiveness and ease of use of the PCMH and PR Frameworks. Effectiveness discussions focused on the following questions:

- How useful is the PCMH Framework (or PR Framework) for implementation research?
- Does the framework meet the following criteria?[3]
  - Familiarity
  - Resonance
  - Parsimony
  - Coherence
  - Differentiation

Ease of use discussions centered on the following questions:

- How can the structure and organization of the PCMH Framework (or PR Framework) be improved to enhance ease of use?
- What the pros and cons of various formats for viewing the framework (hardcopy, online, etc.) and which formats are preferred?

We followed up this TEP call with a second set of TEP calls where we provided experts with two case studies, and asked them to share their experiences while applying the PCMH or PR Frameworks to these case studies. The PCMH TEP received two case studies of PCMH implementation initiatives: the first in a pediatric practice in Saginaw, Michigan,[4] and the second in an integrated provider network in Seattle, Washington.[5] The PR TEP also received two case studies: a productivity improvement activity carried out by a hospital-owned physician practice[6] and a lean implementation in a large federally qualified health center in California.[7] The following questions guided our case study discussions.

- What contextual factors are important to this case study?
- Does the PCMH Framework (or PR Framework) contain all the relevant contextual factors needed to evaluate the outcomes of interest? Are any factors missing?

- What were the challenges you encountered while applying the PCMH Framework (or PR Framework) to this case study?
- Considering the contextual factors you selected for each study:
  - At what levels of analysis (e.g., individual, family, team, organization, and system) should these contextual factors be measured?
  - How might these contextual factors change over time?
  - At what stage of research might these contextual factors be less or more important?
  - Should anything be added to the framework that would help the researcher think through these issues?
- Did the structure and format of the adapted PCMH Framework (or PR Framework) make it easy for you to search for domains and constructs? Do you have any suggestions to improve the structure and format?
- How would you have approached the research design question if you had not been asked to use the modified CFIR? Did the addition of the framework add value to your design?

Input on Usability

The Self-Assessment and the Usability TEP conferences together provided rich information that allowed the project team to assess the processes and materials used in developing the initial PR and PCMH Frameworks. As we compiled the various recommendations for the frameworks, a few stood out as being repeated in various scenarios regarding both the PCMH and PR Frameworks (e.g., during multiple TEP calls, as a major discussion point during one TEP call, during a TEP call, and through the document review). In Table C-4, we present these recommendations. They represent solutions to some of the more frequently encountered challenges to using the framework and heavily influenced the methods for adaptation of CFIR to Care Transitions. The frameworks contained in this document are the refined versions, and already include a majority of the changes suggested below.

Table C-4. Major recommendations to update the Patient-Centered Medical Home and Process Redesign Frameworks

• The purpose of the frameworks and intended target group is not clear and needs to be provided. • The various tables in the frameworks documents need modifications. The main construct table may be made clearer by reducing lengthy descriptions, streamlining the level of analysis, clarifying ambiguous terms, and adding brief examples. The multilevel analysis table and the stages of implementation table are not clear in their current form and require accompanying text to clarify their purpose. • The graphical representation is extremely useful, and needs to be expanded and moved ahead of the framework table. • A roadmap or how-to-use guide is necessary for new users to understand the purpose of the framework and steps to use it effectively. A case study may also be added to the framework document as part of this how-to-use guide. • Regarding format of the frameworks, an interactive online format, with the ability to read and print from a PDF document, would be most useful because it would provide multiple modes of interaction for users. In addition, small usability-related changes to the document (such as color coding domains) can help make the framework easier to read and understand.

Abbreviations: PCMH = Patient-Centered Medical Homes; PR = process redesign.

References

1. Proctor E, Silmere H, Raghavan R, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. Adm Policy Ment Health. 2011 Mar;38(2):65-76. PMID: 20957426.
2. Robert Wood Johnson Foundation. Care across settings: challenges, successes and opportunities. 2013 www.rwjf.org/content/dam/farm/reports/issue_briefs/2013/rwjf404875. Accessed June 11 2013.
3. Gerring J. What makes a concept good? A critical framework for understanding concept formation in the social sciences. Polity. 1999 Spring;31(3):357-93.
4. Michigan State Medical Society. Innovation in Physician Practices: 13 Case Studies to Guide Michigan Physicians. 2011 www.msms.org/AM/Template.cfm?Section=Your_Practice&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=17061. Accessed June 11, 2013.
5. Hsu C, Coleman K, Ross TR, et al. Spreading a patient-centered medical home redesign: a case study. J Ambul Care Manage. 2012 Apr-Jun;35(2):99-108. PMID: 22415283.
6. McCarthy EL. Physician office productivity improvement through operations analysis and process redesign. J Ambul Care Manage. 2002 Oct;25(4):37-52. PMID: 12371018.
7. Stephens J, Carman K, Smeeding L, et al. Implementing Lean in a safety-net clinic: a case study summary. American Institutes for Research; 2012 www.chcf.org/~/media/MEDIA%20LIBRARY%20Files/PDF/I/PDF%20ImplementingLeanSafetyNetSummary.pdf. Accessed June 11, 2013.