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Executive Summary

The way health services research is conducted is changing, as the health care delivery system evolves to be more integrated vertically through hospital and insurance company integrated models and horizontally via accountable care organizations (ACOs). As quality improvement (QI) teams address clinical problems, research teams study implementation, and awareness for prompt assessment and actionable adaptations accrues, the methods for pursuing rapid-cycle research are emerging. This document explores the breadth of methodologies conventionally associated with QI in primary care settings, discusses the appropriateness of such strategies across evaluation objectives, and provides practical discussions about tools to accelerate the assessment-to-adoption cycle.

Purpose: This document is designed as a practical guide to the uses of and methods for conducting rapid-cycle research. It was developed by the Agency for Healthcare Research and Quality (AHRQ) Practice-Based Research Network (PBRN) Resource Center to:

- address a demand of researchers and implementers, including the primary care PBRN community to describe the process of identifying opportunities to pursue rapid-cycle research, and
- provide in-depth exploration of some methodologies of interest.

Audience: Research teams conducting health services research in primary care and other health settings; quality improvement staff in health care settings, and physicians and other providers involved in practice-based research networks.

Definition of Rapid-Cycle Research: The working definition of rapid-cycle research for this document is a process by which practical problems are identified and addressed using analysis methods that are incremental and contextually informed. Six phases by which to conduct this rapid iterative process are outlined and described with the emphasis on the preparation phases of designing a study.

The phases in the process are:

- 1. **Preparation:** The preparation phase involves identifying partner organizations and the individuals within those partner organizations who will champion the study. It also means identifying potential opponents within the system and understanding their perspectives.
- Problem Exploration: The problem exploration phase involves understanding patient/provider problems that are important to solve. Four tools to help develop deeper understanding of the problems that need solving or questions that need answering are provided: 1) the walk-through, 2) the nominal group technique, 3) the critical incident technique, and 4) dialogue.

"Applying the rapidcycle research framework enhances one's ability to find home-run solutions...strikeouts are expected sometimes and hone one's skills, too." *-Bernard Ewigman*











- 3. Knowledge Exploration: The knowledge exploration phase explores the problem from different perspectives. The four steps of knowledge exploration are: 1) characterize the problem in the most general way possible, 2) identify other industries that face the same problem as it is characterized in a general way, 3) identify organizations in those industries that have best addressed the problem, and 4) identify the processes or activities that differentiate the best organizations from others by how they addressed the problem and determine what makes them so much better at this than their peers.
- 4. **Solution Development:** The solution development phase identifies the simplest possible solutions that can be applied. Applying an engineering process called "ideal design" is recommended to devise the simplest, least invasive, and most scalable solution to the problem.
- 5. **Solution Testing:** The solution testing phase is the process for determining if the identified solution works. It can be done in a rapid-cycle pilot testing method as in QI or may be conducted with more traditional research methods. The testing method used is determined by the question that is asked and the uses of the answer. This section also highlights some research methods being used in practice-based research settings that may accelerate the research-to-implementation cycle.
- 6. **Implementation and Dissemination** are the final steps in the rapid-cycle research process. We provide several resources to support implementation and dissemination. These resources help research and QI teams scale up their efforts once their solution is found effective, and address implementation issues providers might encounter.

The appendix contains an annotated bibliography and several resources that research and QI teams can use to adopt more rapid-cycle research methods.













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1. Introduction

1.1 Purpose

This document is a practical guide to the uses of and methods for conducting rapid-cycle research. It was developed by the Agency for Healthcare Research and Quality (AHRQ) Practice-Based Research Network (PBRN) Resource Center to:

- address a demand of researchers and implementers, including primary care PBRN community to describe the process of identifying opportunities to pursue rapid-cycle research, and
- provide in-depth exploration of some methodologies of interest.

This document will help research teams accelerate the research cycle from concept development to implementation in practice. Greater depth of discussion is provided on the preparation and pre-study phases of the research cycle because, despite being essential to accelerating the research process and ensuring that findings from research are adopted, they are often underexplored due to pressures to "get started" in the field. The framework of phases presented is oriented around the "Secrets of Rapid Research Framework," based on the work of David H. Gustafson.¹ This framework outlines steps in the QI/research process and links these to tools and resources that accelerate these processes.

Target Audience 1.2

Research teams conducting health services research in primary care and other health settings, guality improvement staff in health care settings, physicians, and other providers involved in practice-based research networks.

This guide is for primary care PBRNs and other ambulatory research organizations. The target audience is anyone who wants to learn about conducting health care research in a rapid-cycle manner.

1.3 **Objectives**

- 1. Define rapid-cycle research.
- 2. Describe a process for conducting rapid-cycle research.
- 3. Use tools for conducting rapid-cycle research.
- 4. Provide examples of where rapid-cycle research has been used.

Why Rapid-Cycle Research Is Important 1.4

Rapid-cycle research is important to ambulatory care research settings such as PBRNs because it results in better care faster.²













PBRNs were designed in the late 1970s to address the concern that research was not used in practice. They engaged individual and small groups of clinicians in practical research; but today's practices have changed. Clinicians now are often organized as large groups under hospital or vertically integrated payer/provider systems. In these systems, administrators not just clinicians—must approve participation in studies. Also, clinicians in large systems must know and manage the outcomes for populations, not just individual patients. Productivity expectations limit their time to design research projects, collect data, and perform other research-related activities. Efficiency has become as important as effectiveness in practices. Clinicians may avoid participating in research that does not fit into routine workflows or address problems that they perceive.

PBRN Membership Demographics

Across the 173 Registered PBRNs...

- 29,325 member practices or clinics
 - On average, each PBRN has **170** member practices.
 - The median number of practices per PBRN is 43.
- PCMH Designation
 - 94 PBRNs have practices with PCMH designation.
 - **78 PBRNs** have practices pursuing PCMH designation.
- 153,629 clinicians across practices



As our health care delivery system changes, roles and responsibilities of different players evolve. The widespread use of QI staff and processes blurs the distinction between QI and research methods. While quality improvement staff focus most of their efforts on rapid-cycle QI using proven methods (e.g., Plan-Do-Check-Act [PDCA] cycles), they may also identify issues that need a clinical instead of a process response. They may use research methods to answer their questions, or blend QI and research methods. When quality monitoring identifies research questions, research can be designed to address practical problems. Research designed to answer practical questions raised in clinical practice may be

conducted differently from research using the current grant-funded model (i.e., research addressing a single question, taking years to plan, fund, study, and publish).

Another change that has occurred in the past 10 years is the availability of a vast quantity of data via electronic health records (EHRs), patient recorded data from activity trackers and other monitors, and self-management support tools. These data sources provide an "Practice-based research is an iterative design process. We introduce change, learn about what works and what doesn't, we incorporate what we learn in the next cycle.... Rapid results can (only) be seen if there is followup and learning is supported." -Lynne Nemeth

opportunity for research to be quickly conducted at a population level.













In summary, changes in system design, staffing, and data collection and management require us to rethink how we conduct research in primary care settings. This guide gives researchers and primary care staff tools to quickly conduct practical research within the opportunities and constraints that exist in their current delivery structure.













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2. What Is Rapid-Cycle Research?

In their 2014 paper, C.J. Peek and his colleagues identified five criteria for research (the "Five Rs"³) to address the problem of making research relevant in a rapidly changing

Five Rs of Health Care Delivery Research

- 1. Is relevant to stakeholders
- 2. Is rapid and recursive in application
- 3. Redefines rigor
- 4. Reports on resources required
- 5. Is replicable

standard in primary care health services research.⁴

The literature defines rapid-cycle improvement as a process that can be done in a brief period (i.e., a month or less) and includes multiple cycles of small changes to address a problem. In the early days of implementing rapid-cycle improvement in health care, cycle times of 90 or fewer days were described as rapid. Experience using and adapting the methods reduced the perception of how much time a QI process should take. Elements that were changed in process improvement methods to speed up the

environment. One of their Five Rs is rapid and recursive research design. This design accelerates the research-to-practice process by using real-time clinical data, engaging stakeholders to identify research questions, and designing studies that can operate like the PDCA cycles used in QI processes. The Five R model has been promoted as a general

> "I prefer not to think of rapidcycle research as a one-step journey, a two-step journey or a journey of a thousand steps, but rather as taking the next step rapidly." *-Bernard Ewigman*

process are also relevant for accelerating research today. These elements include solving key problems; minimizing meeting time; being selective about measures; and considering the ability of each tested solution to be scaled up, disseminated, or continued outside of the experimental time frame and conditions before it is tested.⁵

There is a growing body of literature on rapid-cycle evaluation. Rapid-cycle evaluation applies program evaluation methods early and often in a pilot program's or policy's implementation process. Then, rapid-cycle improvement methods are used to change the program or policy to address issues raised by the early findings.⁶ Because researchers collect and analyze data early in the process rather than waiting until the end of a pilot or study, the intervention can be adapted, the change tested, and iterative improvements made. While this method is best known for how the Centers for Medicare & Medicaid Services (CMS) deploy it in their study of health care finance and delivery system models, it can also be applied to clinical research. Examples of this include applying rapid-cycle evaluation to assess technologies^{7,8} and care improvement processes.⁹

Rapid-cycle research is still a relatively new term. As in the early days of rapid-cycle improvement, the experts consulted clearly understand which processes take too long, but they do not necessarily have a clear definition of rapid-cycle research. However, there is great interest in shortening the research-to-adoption cycle and in applying the knowledge gained from rapid-cycle improvement processes to the research arena. The definition of rapid













and how to include cyclical processes in research design are points still being debated and tested.

A Working Definition of Rapid-Cycle Research

This document's working definition of rapid-cycle research is: a process by which practical problems are identified and addressed using analysis methods that are incremental and contextually informed. Six phases used to conduct this rapid iterative process are outlined in a graphic depiction of the Framework for Rapid-Cycle Research in Exhibit 1.1. A bicycle gear highlighting the six phases depicts rapid-cycle research's cyclical nature. At any point in the research process, methods from earlier phases may be incorporated to make adaptations based on new information. The contextual awareness examined in each phase of this process enables the mechanisms of change to be identified efficiently, thus rapidly accelerating the assessment, adaptation, and adoption of solutions.













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Figure 1.1. A Graphic Depiction of the Framework for Rapid-Cycle Research

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2.1 Framework for Rapid-Cycle Research

We based our framework for rapid-cycle research on the work of David H. Gustafson (see Exhibit 2.1.) in process improvement and research.¹ The framework outlines six phases of the QI/research process, from conceptualization through implementation, and provides a set of tools that improve each phase's efficiency and effectiveness. By thoughtfully executing each phase of the process, researchers may accelerate both the research and adoption timeframes. Although this framework is organized from the first steps of preparing for the research process through the implementation of research findings, some of its tools and resources can be used in more than one phase.

Preparation	Committed Team	Influential change leader	Simplicity
Problem Exploration	Nominal Group Technique	Walk-Through	Critical Incident
Plan Do Check Act*			
Knowledge Exploration	Reach outside	Essential ingredients	What makes you so good?
Solution Development	Improve customer lives	Ideal systems	Make staff lives better
Solution Testing	Limited number of measures	Rapid-cycle testing	RE-AIM
Implementation and Dissemination	Address environmental and organizational factors	Monitor and Alert	Stories

Figure 2.1. Dr. Gustafson's "Secrets of Rapid Research" Framework

* The Plan Do Check Act Model can be used during the Knowledge Exploration, Solution Development, and Solution Testing phases.

3. Applying the Phases of Rapid-Cycle Research

3.1 Preparation Phase

The preparation phase involves identifying partner organizations and the individuals within those partner organizations who will champion the study. This phase also involves identifying potential opponents within the system and understanding their perspectives.

Research from AHRQ's integrated delivery system research network (IDSRN, now replaced with the ACTION III network

http://www.ahrq.gov/research/findings/fa

There are some tools for a project's Preparation Phase. The DARTNet Institute's "Toolkit for Developing and Conducting Multisite Clinical Trials in Practice Based Research Networks" (see <u>http://www.dartnet.info/clinicaltrialsPBRNtoolkit.htm</u>)¹⁰ includes information on partnering with clinical practices, budgeting, and planning for dissemination.

<u>ctsheets/translating/action/index.html</u>) showed the value of a carefully planned preparation phase in rapid-cycle research. In evaluating the IDSRN model, four factors were identified as facilitating successful research-to-practice efforts:

- 1. having a research team employed by the health system <u>or</u> a champion in the health system when the research team was external,
- 2. the study's responding to delivery system needs,
- 3. ongoing funding, and
- 4. creating tools (e.g., decision support tools) to facilitate adoption.

Factors that hindered success were multiple demands that drew the clinical team away from the research process and failing to address the correct audience.¹¹

Our own experience suggests that, in addition to the factors identified in the Gold¹¹ study, having a strong leader for the research team and having clear timeframes and objectives improve the probability of moving research findings into practice.

These concerns must be addressed in the preparation phase before a study is begun. We cannot overemphasize that simplifying the study process during the planning phase increases the likelihood of developing strategies that will provide sustained improvement in care.

3.2 Problem Exploration Phase

Identifying key problems for stakeholders (e.g., clinicians, funders, and especially patients) engages them in the problem-solving process. It accelerates recruitment of study participants and adoption of study results. Figure 3.1. below reflects the importance of engaging clinicians in rapid-cycle research.

Four different techniques to identify problems worth solving that also engage stakeholders from the earliest phases of designing a research or QI project are listed and described below. Each has its own purpose, and may be used alone or in combination with the others.

- 1. *The Walk-Through*—Purpose: understand the experience of care from the "customer" perspective.
- 2. *Nominal Group Technique*—Purpose: engage the research/care provision team in identifying possible causes of problems.
- 3. *Critical Incident Technique*—Purpose: help the "customer" describe an experience so researchers and care providers can better understand needs and strengths within the context of the experience of using the health care system.
- 4. *Dialogue*—Purpose: develop a common understanding of a problem based on sharing different perspectives.

3.2.1 The Walk-Through

The walk-through tool has been used in a number of industries including manufacturing,¹² restaurants,¹³ and health care.¹⁴ It is a process of "walking" through the experience in which problems have been identified. For example, in manufacturing, managers walk through the factory to better understand how bottlenecks and defects occur. In restaurants, the manager approaches the

It is important to engage patients in the problem exploration process.

¹ Reprinted with permission from Paul Nutting, MD, MSPH, Director of Research, Center for Research Strategies.

restaurant as though she were a customer and walks through the whole experience to identify issues from signage, service, meal preparation, etc., from a customer perspective. The idea in each case is to better understand the process and how it works or does not work. Ultimately, this identifies what can be done to create a better product or improve the customer experience or increase efficiency and reduce mistakes. In health care, walk-throughs have been used to identify access and utilization issues.¹⁵ The walk-through can also be used to identify research problems that address patient and provider concerns.

How to do a Walk-Through:

- 1. Identify the process one wants to walk-through. Specify the beginning and ending points.
- 2. Let staff know one will be conducting a walk-through and tell them it is to understand the process and "customer" experience, not to find out what they are doing wrong. Note that during the process, the staff will be asked to suggest changes that will make things better for them and their customers. The walk-through is a joint effort (researcher and staff).
- 3. Develop a character based on the process one is trying to understand: for example, "I am a 50-year-old female going for her first chemotherapy appointment for stage three breast cancer," or "I am the partner of a 50-year-old female with breast cancer" or "I am a nurse with 20 years of experience trying to implement a new electronic health record population management tool."
- 4. Conduct the walk-through by completing each step of the process as though one were the character created. One should ask to be treated as if they were that character and act exactly as they would for that character. Completely fill out all forms and go through every step of the process. Think about what the experience feels like from that character's perspective. Ask staff questions about what they are doing and why. Ask the questions in an open way to assure them that one wants to understand how the process works, not to catch them doing things wrong or making mistakes. Take notes. Since two sets of eyes are usually better than one, ask a second person to play the role of family member or another relevant role and take notes.
- 5. Discuss the experience with one's change/research team. What was learned that might be a problem that is worth solving or what is a question that is worth asking? What strengths were identified that might be used as part of the solution?

Done properly, the walk-through gives management or the research team a patient's view of a specific treatment and the care delivery system that provides it. Patient concerns may be process-oriented, but they may also be treatment-specific. This tool can also be used to better understand other stakeholder perspectives by, for example, standing in the shoes of a clinician or a nurse to identify why a certain process is not being adopted and deciding how it might be changed to be better incorporated into the normal work flow (or how the work flow needs to change to adopt the practice).

3.2.2 Nominal Group Technique

The nominal group technique (NGT) is a proven tool for identifying problems. Over 40 years ago, Van de Ven¹⁶ proposed it as a way to identify worthwhile health research questions. A relatively simple process that engages members of health care delivery teams, it can help identify both the causes of problems and their potential solutions. Van de Ven suggests a researcher use the NGT to clearly define the dimensions of the problem so that data collection is relevant, valid and reliable. The nominal group process has five steps¹⁷ (see Appendix D for a detailed description). The strength of NGT are that it reduces the risk of one person (or a few people) dominating a discussion.¹⁸ It does so by limiting and controlling conversation. For instance, prior to any discussion, the facilitator asks that each person in a group silently think through the task and generate his/her own list of ideas. Rather than having an open discussion, each person is asked to give only one idea and then move to the next person and continue around the table until all ideas are out, allowing each person an equal opportunity to contribute.

The Nominal Group Technique¹⁹ has five steps:

- 1. Step 1: Preparation
- 2. Step 2: Silent idea-generation
- 3. Step 3: Round-robin recording of ideas
- 4. Step 4: Serial discussion of ideas
- 5. Step 5: Preliminary voting
 - a. Rating method
 - b. Ranking method

3.2.3 Critical Incident Technique

The critical incident technique (CIT) was developed in the 1940s for psychological studies.²⁰ The CIT originated in studies to better understand decisionmaking and to develop assessment tools that could objectively identify capabilities (e.g., piloting and leadership) in the military. It was later used to identify the criteria for assessing the ability to perform a variety of roles.

CIT has been used to understand patient experiences in health care,²¹ to view how health care teams function,²² and to identify and reduce medical errors.²³

Critical Incident Technique has five stages:

- 1. Identify the aim and research question.
- 2. Plan (e.g., identify incidents to examine and the means to access them).
- 3. Collect data by direct observation or in interviews. The goal is usually to better understand what a person is thinking or experiencing during an incident. Thus, surveys may work, but they often do not collect data at the level of depth desired.
- 4. Identify themes by analyzing data using qualitative research methods.
- 5. Interpret and report results.

The CIT's purpose is to get someone to talk about an experience in detail. Figure 3.2. outlines the distribution of PBRN communication modalities as reported in the 2015 PBRN Registration Responses.

Figure 3.2. Distribution of PBRN Communication Modalities (N=173)

Ultimately, that data will help the researcher guess the person's needs. People often do not know what their needs are, but they can describe an experience and how they felt about it, and researchers can work effectively from there. Below is an example.

Example of Critical Incident Technique to Understand Needs of a Breast **Cancer Patient:** Instead of asking a breast cancer patient what she needs, Dr. Gustafson and colleagues asked: "What is it like to be a woman with breast cancer?" There are several important points to consider when phrasing the question. First, even for health care providers whose interest is improving their cancer service, it is important to get a broader picture of their *customer*. Asking patients what L it is like to be a patient in a clinic may help improve a clinic's internal processes, but it limits the scope of solution finding. Three types of service L gualities exist: expected, desired, and unexpected. Expected gualities address the things that are assumed to be present. United Airlines does not advertise using the slogan, "We don't crash," since customers would not fly with them if they expected United's planes to crash. Similarly, patients expect that practices will have skilled clinicians. If someone experiences a crash or encounters a medical error, the cost can be enormous. Desired qualities of service, in contrast, are ones customers know to hope for, but realize they may not get. Examples of desired qualities include easy parking, minimal delays, nice people, and tasty food. Unexpected qualities are different: patients do not know that they need these in their health service experience, but they are often L overjoyed when they experience them. For providers to deliver unexpected qualities, they must know their patients. Asking what it is like to be a patient within a particular practice may help improve expected and desired qualities, but that question does not give a broad enough picture of a provider's customer to address unexpected qualities. To get at unexpected qualities, providers and researchers must know what it is like to be that woman with breast cancer, including being aware of critical incidents that have deeply affected her life both within and outside of the health care delivery system. The point is to probe to really understand the experience of being the person with that condition. Dr. Gustafson and colleagues probed about what the experience was like: what she felt, wanted, hoped for, and worried about to better understand how to deliver the unexpected qualities that would improve her condition. This deeper understanding was important as Dr. Gustafson and colleagues developed information communication technologies for patients with breast cancer in the early days of personal computers.²⁴

3.2.4 Dialogue

Dialogue is a uniquely powerful methodology for achieving shared understanding and common purpose. As a formal method for group communication, Dialogue emerged from Bohm,²⁵ a theoretical physicist, who observed that many of the world's intractable social problems stemmed from distorted thinking, fixed beliefs, and a lack of shared understanding between people with fundamentally different life experiences. The techniques and attitudes that characterize formal Dialogue have evolved and are well described in books by Isaacs²⁶ and Ridings.²⁷ The methods of formal Dialogue have been successfully used to improve the working environment for health care workers,²⁸ resolving longstanding and bitter disputes between management and labor,²⁹ and facilitating deeper appreciation of unconscious racial bias among individuals with diverse experiences of privilege, power, and discrimination.³⁰ Dialogue requires suspension of judgment, respect for differences of opinion, intentional listening, and giving voice to different perspectives.

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There are several steps to Dialogue:

- 1. One or more outside facilitators set the expectations.
- 2. Participants sit in a circle with no table or other objects in the middle, with each person having full view of each other person, speaking to the "center" rather than to each other.
- 3. Participants remain silent when not speaking.
- 4. Participants are not allowed distractions such as papers, mobile phones or tablet computers.

Many researchers know the value of open conversation and careful listening. Working productively with research or QI colleagues or stakeholders from diverse educational, ethnic, racial, or socioeconomic backgrounds requires openness, patience, and the desire to listen carefully. In particular, researchers who work on multi-

Individuals with formal training and experience with the Dialogue technique find great value in its use in all conversations, including oneon-one and group meetings, since it fosters deeper understanding.

disciplinary or transdisciplinary teams; use multi-method approaches (e.g., qualitative and quantitative methodologies); or engage patients, communities, or stakeholders to develop research questions and hypotheses, collect and interpret data, and disseminate and implement findings must be adept at communicating. One might call this a "dialogic" approach to communication, regardless of the setting, circumstances, or people involved.

Dialogue as a method refers to a more specified, complex, and formalized process of communicating in groups. Individuals with formal training and experience with Dialogue bring a dialogic approach to all conversations, including one-on-one and group meetings. Having a dialogic orientation and well-developed dialogic skills leads to very effective communication.

Dialogue as an explicit method of obtaining a common understanding and learning from the collective intelligence of a group promotes a deep understanding. The level of understanding achieved with Dialogue is deeper and richer than what individuals can achieve alone or in ordinary conversations or discussions.

3.3 Knowledge Exploration Phase

Many research projects inadequately explore alternative solutions. Once a problem is identified, people often coalesce around a single

solution without adequately exploring alternatives.

Exploring alternative solutions may seem to be an added step that increases time in a research cycle. However, spending time in this phase may increase the odds of finding a successful solution and significantly reduce time in later phases. Researchers may identify more easily tested Exploring alternative solutions may seem to be an added step that increases time in a research cycle. However, spending time in this phase may significantly reduce time in later phases by identifying a more workable solution.

solutions or solutions that are more easily adopted if additional time is spent in this phase of a QI/research project.

One way to do knowledge exploration is by a stepwise process that begins with the most general level of characterization of the problem, and then narrows the focus to identify elements that must exist in any successful solution.

Knowledge exploration has four steps:

- 1. Characterize the problem in the most general way possible.
- 2. Identify other industries that face the same problem as it is characterized in a general way.
- 3. Identify organizations in those industries that have best addressed the problem.
- 4. Identify the processes or activities that differentiate the best organizations from others in terms of addressing the problem. Determine what makes them so much better at this than their competitors.

*Knowledge Exploration-Population Management Characterized as a Hand-off Problem:*A population management system identified the problem that patients with diabetes have a
lower rate of blood sugar control than meets CMS criteria. After further data analysis, the
problem of a low rate of follow-through on referrals to the dietician and endocrinologist was
identified. One way to characterize the problem is the failure in making a hand-off. Many
industries have hand-offs. Manufacturers have hand-offs on the assembly line, sports teams
(e.g., basketball, relay races) have hand-offs. Even airplanes are handed off between air traffic
control towers. Football is an example of an unrelated industry where good hand-offs? There are
critical to success. What makes a football team have great success with hand-offs? There are
clear signals for which play is going to be called, and each player knows where to go. Because
everyone is in the designated place, the quarterback knows where to throw the ball, or to whom
he should hand the ball at the right moment. These actions occur smoothly because the
players practice so often.

We see similarities in how good hand-offs occur if we take the football teams' solutions and apply them to hand-offs of airplanes between air traffic control towers. Air traffic controllers have a manual for conducting hand-offs of planes. They practice the process many times daily. The roles and activities of each air traffic controller are clearly defined in the manual, and the hand-off is not complete until both air traffic controllers acknowledge it.

controllers acknowledge it.

How can we use these ideas to solve the problem of patient follow-through with referrals? Patients are not inanimate objects that can be handed off like a football. Yet, patients benefit significantly from a clear process in which each member of the health care team has a defined role and responsibility. Communication is clear concerning where each team member is in the process, and it is the team members, not the patient, who must ensure the

patient gets appropriate and safe care. These are the essential ingredients of a good hand-off that can be used regardless of the industry.

This process of knowledge exploration accelerates the research-to-adoption cycle in two ways.

- 1. First, by using the same tools used in problem identification (i.e., nominal group technique, critical incident technique), knowledge exploration engages stakeholders in identifying solution components that make sense to them.
- 2. Second, stepping away from the problem, looking at it in a general way, and thinking about how other industries have addressed it may help identify more creative solutions that have a greater effect.

Using ideas from other industries may also increase the probability of generating solutions that medical practices can easily adopt.

3.4 Solution Development Phase

Innovations that are widely adopted have characteristics that Everett Rogers identified in his work with the University Extension Systems.³¹ Combining relative advantage, compatibility with current processes and beliefs, simplicity of implementation, trialability, and observability increases the probability that an innovative solution will be adopted. In other words, these are attributes of solutions worth testing. In health care systems, because of the rapid pace of change in things beyond clinician control, providers need solutions that decrease their workload rather than adding to it. Solutions that meet the criteria for having a higher probability of adoption are also easier to test (trialability is one of the criteria). The concept of ideal solutions is one tool to develop a solution that meets the criteria listed above. This process allows one to address the fundamental dimensions of a solution design: purpose, inputs, outputs, sequence of steps, environment, human resources, equipment, data, and capability to improve.

3.4.1 Ideal Systems

A systems engineering approach to solution development is to think in terms of an *ideal* system. How would the procedure ideally be delivered? How would the process function if cost were not a consideration, if there were no waits, and no special effort were needed on the customer's or staff's part? This gives researchers a target that may be unrealistic, but one's goal is to see how close they can come to the ideal. When designing an intervention with the starting point that the ideal solution would require no effort, time, and costs, one is likely to come up with very innovative ideas. Of course they will not be realistic, but moving from the ideal to the realistic is the next step.

Here is the six-step process for developing interventions that meet the criteria of minimizing cost, time, and effort:

- 1. Eliminate as many functions/processes/steps in the process as possible.
- 2. Use the minimum number, lowest cost inputs (e.g., minimizing the number of times a patient needs to take medications).
- 3. Automate everything that can reasonably be automated.
- 4. Use staff skills 100% of the time (e.g., use the physician's time for activities that are only related to providing patient care—someone with a different skill set can perform other activities).
- 5. Design the system for normal conditions before considering what to do about exceptional cases.
- 6. Include control systems that identify and automatically respond to exceptions/outliers.

The point is to say: "Here is our customer, and here is what it is like to be that customer." More than anything, what does that customer need that he or she does not currently have? Now, assume that anything is possible to meet that need. Cost is not a consideration. Limitations of current technology are not a consideration. One can have anything they want to meet that customer's needs. But making the patient's life more difficult is a limitation. Creating bureaucratic burden for staff is a limitation. What, in the ideal world, would that look like? That ideal world becomes the starting point for thinking about possible solutions to test.

Example of using Ideal Systems Design:

In the late 80s Dr. Gustafson and colleagues were trying to help women cope with a diagnosis | of breast cancer. The team conducted several critical incident interviews to understand their I needs (e.g., One woman said, "The surgeon told me I had breast cancer. S/he said, 'You need I to have either a mastectomy or a lumpectomy with radiation. Here are the advantages and I disadvantages of each. I can't tell you what to do, but you should decide within a couple of I weeks.' I felt so lonely.") Dr. Gustafson and colleagues convened a group of seven women I with breast cancer who were considered to be very innovative thinkers. They were asked, I using a nominal group, to silently generate descriptions of the ideal help that would meet their I needs. One woman wanted an 18 wheeler left at her home. It would be filled with all the I literature on breast cancer translated into a language she could understand. Another had an extra bedroom, and she wanted her personal oncologist to move in. Another wanted five I women just like her (except that they were at different points in their journey—just diagnosed, 5 years out, etc.) to move in with her so that she could talk to them at any time. Of course, I none of that was possible. They then convened a group of technological visionaries and asked I them to come up with a solution that was as close to the ideal as possible. By the mid-1990s, I hundreds of women were using a computer system (CHESS) that had an instant library (instead of an 18 wheeler), an anonymous ask-the-expert (instead of a personal oncologist), and a I bulletin board discussion group (instead of the women moving in), and there was a decision analysis program to help them think through the type of surgery they might have.²⁴

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3.4.2. Using Change Concepts

Another way to simplify solution development without settling on one solution too rapidly is to consider the types of solutions that have been developed in other studies or to solve other problems. Similar to using the steps in the knowledge exploration phase, this process identifies the possible solutions in high-level conceptual categories that may be applied to

multiple types of problems, then considers how they might work to address the current problem. After identifying a category of solutions, the concept can be refined to fit the specific problem being solved.

For example, Langley et al³² identified nine categories of change concepts (such as improve workflow) with a total of 72 specific ways (e.g., minimize hand-offs) to think about how a problem could be solved. Providing a selection of ways to categorize a problem (e.g., this could be a work flow problem) and solutions (e.g., what if we "I've heard it said that most of the problems in today's systems are created by yesterday's solutions³³." *-Lloyd Provost*

reduced the number of hand-offs?) may help QI and study team members rethink a problem and develop more creative solutions.

Using a list like the one in appendix E, the options to using this method of solution development are:

- 1. Select a group of change concepts that are related to the aim of the improvement effort. Then randomly choose one of the change concepts in that category.
- 2. Or choose a change concept someone on the team thinks might generate some ideas that would be useful to the aim of the improvement effort.
- 3. Or choose change concepts that have not been previously considered by the team.
- 4. Or randomly choose a specific change concept from the list of 72.

3.5 Solution Testing Phase

Campbell and Stanley,³⁴ in their classic 71-page text on research designs, focus on the importance of deciding what kinds of things are likely to interfere with one's ability to confidently state whether the intervention being tested is really having an effect.

Below we have listed 10 threats to internal validity that impact one's ability to state that the intervention is what is causing the effect. The first seven are important if one is not trying to generalize beyond the people being studied. The last three are also critical if one hopes to generalize. One should take a few minutes to sit back and think about the study: the interventions, the subjects, the measures, the environment. One should go over the 10 threats and circle how worried one should be about each.

1- None Some Very. *History*: the world will change around you (e.g., maybe a change in leadership?).

- 2- None Some Very. *Maturation:* the subjects will change (e.g., age out of the problem, leave town, become more infirm). 3- None Some Very. *Testing*: just by completing the pretest, the subjects will have learned things that will affect their performance on the posttests. 4- None Some Very. Instrumentation: the measurement methods may change (e.g., a new format; an old measure is replaced by a "better" but different one). 5- None Some Very. *Regression:* the study group is selected because group members recently performed particularly well or poorly (e.g., I might have one good day at golf, but the next time I will not be so lucky). 6- None Some Very. Biases in selection: It you are comparing one group to another, are there reasons to believe that one of those groups is different from the other to start with? 7- None Some Very. *Experimental mortality*: If you are comparing two groups, is there reason to believe that subjects from one group will be more likely to drop out of the study? 8- None Some Very. Selection-intervention interaction: If you are comparing two groups, is one group more likely to respond to the intervention than the other (e.g., if one set of subjects comes from football players and another from horse thieves, and the intervention is teaching them to ride a horse, the horse thieves are more likely to be experienced in riding in the first place)? 9- None Some Very. *Reacting to the testing:* the pretest will change the patient in ways that makes them different from real-world people who would not be taking that test (e.g., suppose the pretest was time to complete an obstacle course. Just taking the pretest may make these people feel that they need to improve their conditioning. Even if the intervention
- 10- None Some Very. *Reacting to being in an experiment*: Could the way the experiment is being conducted be so different from the real world that results will not be the same in the real world? (e.g., the Hawthorn studies measured whether productivity improved when lighting improved. It did. Once the lighting was at the highest level, they measured what happened when lighting was reduced. Productivity improved further. It was not the lighting. It was that they were being studied).

itself has no effect at all, the subject may improve anyway.).

Once the biggest threats are identified, one can select a design that will protect from those threats. Campbell and Stanley³⁴ provide tables that allow 16 different study designs to be compared in terms of their ability to protect against the various threats. For instance, they show that the classic randomized controlled trial (RCT) is great as long as one does not try to generalize from the results. Whereas separate sample pretest-posttest designs are great for generalizing, but are not nearly as good for the first seven criteria. The nature of the research

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aim—whether explanatory or pragmatic—should also be considered. Figure 3.5. "Flow of Analytical Methods" is a whimsical illustration of the choices in research objectives and flow of resources that should be activated based on data resources, research objectives, and anticipated application of findings. The selection of the appropriate combination of qualitative and quantitative analytical methods to apply is determined based on the objectives of the study and contextual factors that explain the intent and implementation of the intervention. An appropriate combination of qualitative and quantitative methods also provides data to support replicability and translation of study findings to other situations and settings.

Figure 3.5. Flow of Analytical Methods

3.5.1 RE-AIM as a framework

Once potential solutions and testing strategies have been identified, it is worth using RE-AIM³⁵ as a framework for considering how well one's proposed solution addresses all the issues that might hinder wide adoption. RE-AIM stands for reach, efficacy, adoption, implementation, and maintenance. The model was developed as a tool for assessing and comparing interventions in their likelihood to achieve a sustainable improvement. Glasgow³⁶ recommends that researchers attend to issues of external validity equally with internal validity and provides a list of things to consider. The RE-AIM Web site (<u>http://www.re-aim.hnfe.vt.edu/index.html</u>) has turned this list into an online tool and checklist for

"Other industries are more accustomed to a continuous process of feedback and adaptation...What is the right balance of rigor, flexibility and adaptation for the setting and the question?" -Jonathan Tobin

evaluating a study plan within the RE-AIM framework. For a presentation on using the RE-

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AIM framework in assessing the level of pragmatism in a study, see the AHRQ PBRN Resource Center Webinar *How pragmatic is it? Lessons learned using PRECIS and RE-AIM for determining pragmatic characteristics of research* at <u>http://pbrn.ahrq.gov/events/how-</u> <u>pragmatic-it-lessons-learned-using-precis-and-re-aim-determining-pragmatic.</u>

Not all guestions need to be answered using an RCT. Other methods may be adequate to answer a particular question and may be executed more rapidly than a typical RCT. Campbell and Stanley³⁴ explain that either more data or more assumptions are necessary to assert causation via quasi-experimental designs. They recommend more data over more assumptions. The large quantities of data that are available now via electronic health records (EHRs)—and that will soon be widely available via patient self-monitoring tools (e.g., wearable devices) and through communication via mobile applications-make it possible to have the quantity and type of data needed to assess the impact of different interventions. Some PBRNs are using data from EHRs to conduct multisite studies designed to address care delivery quality. These large-scale projects use data from the EHR to identify common practice issues, test practice improvements, and assess the targeted interventions. For example, the Wisconsin Research Education Network (WREN) combined data from EHRs and community data regarding population density and air quality to predict asthma control and identify targets for improving asthma control with predictive analytics.³⁷ The Canadian Primary Care Sentinel Surveillance Network used EHR data to identify variation in practice and outcomes, develop and test clinical algorithms to address that variation, and assess sustainability of improved practices.³⁸

In a presentation at the North American Primary Care Research Group (NAPCRG) on July 1, 2014, Wilson Pace³⁹ described the advantages of "big data" to practice-based research (the presentation slides are available here: (PDF - 900 KB).

- The ability to randomize using baseline practice performance and characteristics.
- The ability to balance multiple criteria at once, even with small groups of practices.
- The presence of historical data allows tailoring of academic detailing to each site if needed.
- Measurement of a broad spectrum of outcomes, cost analysis, and intervention effectiveness can be completed without asking clinical staff to do more than their usual data collection.
- Providing a feedback loop to practitioners creates an adaptive health care system.

However, researchers who have begun using EHR data have raised issues about data quality. They caution that EHR data may need to be carefully cleaned before it is useable in research or QI projects. A recorded Webinar from DartNet on using clinical records for research is available at

<u>https://altarum.adobeconnect.com/_a758956138/enrich120612archive/</u>. This presentation covers issues of data quality, pluses and minuses of EHR data and examples of studies that successfully used EHR data.

3.5.2 Research-Quality Data

The concept of data quality includes accuracy (validity), precision, completeness, and consistency and appropriateness. Data quality problems can occur from lack of

standardization of the data collection processes, poor design of questions and definitions, lack of understanding by patients, difficult data collection forms, poor handwriting, measurement equipment errors, improper rounding of measures, miscalculations, human error, or database errors. Data quality control and improvement are the processes of detecting, fixing, and preventing poor data quality. With electronic data systems, most of these processes can be automated, including duplicate entry, data audits, comparisons to reference data, checks for boundaries and reasonableness, and other matches to pre-programed expectations.

Regardless of the research design used, considering data quality through all phases of the research project is important. Data quality control is part of ensuring the integrity of the research results. Rapid-cycle research designs have some advantages over traditional research relative to data quality. Using rapid-cycle methods where data is reviewed early and often deals with data quality issues early, making it easier to solve the current problems and to prevent other problems from recurring.

QI and research projects can take advantage of a registry where data describing both the patient and the care processes are entered in real time (or close to real time) during a patient visit. Sometimes this can be done directly from the EHR. Exception reports can thus be created in real time and actions taken to mitigate data quality problems even before the visit is complete. Monthly reports may include data quality statistics for review and action. These actions create quality data that are useful for research purposes.

3.5.3 Rapid-Cycle Testing Designs

Use of any of the testing strategies described below to accelerate the research-to-practice cycle depends on two factors. The first factor is that the study design is appropriate to the question being asked or the problem being addressed and the use to which one will put the answer.

The second factor is a focus on the first four steps of the rapid-cycle testing process. Testing methods alone will not accelerate the research-to-adoption cycle. Addressing problems that matter with solutions that work for patients and practitioners is more important than using new models of statistical analysis or study design. Some of these methods may actually extend the testing phase, but will provide more information than a standard RCT. Some may take as long as an RCT, but refine the intervention during the study period so that multiple cycles of RCTs are unnecessary. The list is not meant to be exhaustive or prescriptive, but provides a list of examples of research methods that have been employed in pragmatic studies by the experts consulted in development of this document. Another resource that describes study designs in pragmatic trials is available on AHRQ's Patient-Centered Medical Home (PCMH) Resource Center at http://pcmh.ahrq.gov/page/evidence-and-evaluation.

1. Time Series Studies

Repeated measures are the cornerstone of process improvement efforts where measures are taken before a change and then again after a change to see if there is a difference. Time series studies using frequent measures are more feasible now that electronic means of capturing data can reduce both patient and provider burden.

Statistical process control (SPC) is an engineering method that uses repeated measures to tease out normal variation from real improvement.⁴⁰ It was originally created by Shewhart⁴¹ to assess manufacturing processes. The idea in a research context is to understand the range of normal variation and to see how an intervention affects the pattern.

Basic principles of Statistical Process Control (SPC)

- 1. Any process will exhibit variation.
- 2. If the data come from a stable common cause process, their variability is predictable within a range that can be computed from a statistical model such as the Gaussian, binomial, or Poisson distribution.
- 3. If a change actually is having an effect, measured values will deviate in some observable way from the expected distribution.
- 4. Assuming the data are in control, we can establish statistical limits and test for data that deviate from predictions, providing statistical evidence of a change.

SPC has been used as a tool to test whether a change really had an impact in a rapidcycle study to reduce methicillin-resistant Staphylococcus aureus infection in hospitals,⁴² improve glucose control,⁴³ and reduce the number of inappropriately scheduled births.⁴⁴ All of these studies used SPC to measure improvement within sites that were implementing rapid-cycle testing of practice changes.

Diaz⁴⁵ notes that using SPC is preferred to conducting a RCT under some conditions because it may be faster and cheaper, and, using the example of the change in time to death as the outcome for the rabies vaccine, demonstrates statistical significance with a very small sample. The Institute for Health Improvement offers an online course on the use of SPC in health care (see

http://www.ihi.org/education/WebTraining/OnDemand/Run_ControlCharts/Pages/default. aspx).

Single case experimental design (SCED) is an example of an experimental method that has been improved by the availability of electronic data collection tools.⁴⁶ In single case, or n-of-one studies, individuals act as their own control. The individual could be a single person, practice, or even community that is under study. In this study design, one or more interventions are given to a single "case" over a period of time, and the difference in response for that single case is observed. The results from a group of single cases can be aggregated to test hypotheses about the effect of interventions. Single case trials have been used to better describe variation in response to treatments and to understand the change process.⁴⁶ For this reason, they have been recommended as a tool to study behavioral interventions and assess improvement in chronic disease.⁴⁷ There are many variations on the basic pre-post (AB) design that have been developed to address some of the potential threats to validity of this type of design. AHRQ has developed a guidance document on conducting n-of-one trials with checklists to guide researchers who are considering this methodology; *Design and Implementation of N-of-One Trials: A User's Guide* is accessible here: (PDF – 900 KB).

In community-based research, **multiple baseline studies**, a variation of single case design, have implemented an intervention at different points in time in different communities to reduce the possibility the outcome includes secular trends or bias due to timing of data collection.⁴⁸ These studies use a basic single case pre-post (AB) design, but introduce the intervention to each individual or site at a different point in time and aggregate the results of the individual outcomes to better generalize to a broader population.

2. Point-of-Care Randomized Controlled Trials (RCT)

Point-of-care RCTs use randomization to address selection bias concerns, but uses a rapid-cycle process more like that of a quality improvement process to compare existing treatments in usual care settings. This type of study uses existing data collection tools, existing treatment protocols, and has few exclusion criteria to minimize the burden on patients and providers. Point-of-care RCTs were first described by Fiore et al⁴⁹ in their work to improve care within a group of Veterans Administration hospitals. By incorporating randomization of patients to specific treatments into the QI process, they developed a method to conduct rapid-cycle research that includes the strength of randomization with the pace of QI. This method of solution testing is also being used to design a trial to assess which medication is best for treating neonatal abstinence syndrome.⁵⁰

An example of point-of-care RCT:

One example (http://www.research.va.gov/services/csrd/point-of-care.cfm) comes from the I first test of the model in a study conducted by eight U.S. Department of Veterans Affairs (VA) hospitals in New England. When a patient entered the hospital needing insulin, the L EHR presented the physician with three choices of how to dose the medication. The first was no preference, the second and third were traditional protocols of either weight-based or sliding scale dosing. The no-preference option led to the offer to participate in the study comparing weight-based and sliding scale dosing protocols. If the doctor had no preference and the patient consented, s/he was randomized to one of the two protocols. This particular study used adaptive randomization hinged to a Bayesian analysis model that increased the percentage of people randomized to the study arm with the best outcomes until it was randomizing 99% of participants into the preferred arm. By the end of the study, they had not only demonstrated which protocol was best, but had also I moved most of their practitioners to using that protocol via the study randomization process.

3. Factorial Design

Factorial designs compare the effect of several interventions at the same time. Factorial designs are efficient because they can use a sample size similar to that used for an RCT that compares only two interventions. Factorial designs are particularly useful in assessing what the individual effect of different parts of a complex intervention is or to understand how the different components interact with one another. A good example of how to plan a factorial study is available at Penn State's Methodology Center (see http://methodology.psu.edu/ra/most/factorial).

A variation on factorial design that PBRNs have used is the efficient orthogonal design.⁵¹ In this study design, each practice is assigned a unique combination of the components under study. Each practice is randomly assigned one of the combinations of interventions or components. A study or QI team that wishes to use this method must carefully select the combinations of components to be tested because as a fractional factorial design, efficient orthogonal design is prone to confounding by unmeasured interaction effects.

Factorial designs and their variations may be used to identify the most likely to succeed components of a complex intervention that may later be tested in a randomized trial such as the Multiphase Optimization Strategy (MOST),^{52,53} or they may stand alone as a way of conducting comparative effectiveness studies across multiple intervention strategies or implementation models⁵⁴ or best combinations of interventions that have been previously demonstrated to be efficacious.⁵⁵

4. Stepped Wedge Design

Stepped wedge designs may actually take longer than RCTs where the comparison group and the intervention group are observed at the same time. However, there are situations for which the stepped wedge design is more efficient, more ethical, and may decrease implementation time, thereby decreasing the overall research-to-practice cycle time.⁵⁶ Stepped wedge designs are a form of cluster randomized trials where all clusters eventually receive the intervention, but the intervention is introduced at different

"Adaptive trials can begin with iterative explorations of problem and workable solutionsthen test those solutions in more settings." -*Miriam Dickinson*

times for different clusters. Stepped wedge studies can be designed as repeated measure cross sectional studies or as cohort studies. They work best when the outcome measured is a short term outcome or is an interim measure so that patients do not need to be followed for long periods of time. They are useful when there are only a small number of clusters that are available to participate in a study. Stepped wedge designs are being used to study knowledge translation methods in cardiac arrest,⁵⁷ a nutritional intervention to reduce weight loss in hospital patients,⁵⁸ and the treatment of sexually transmitted disease.⁵⁹ The primary benefit of a stepped wedge design comes in the implementation phase. Since all study sites will have been introduced to the intervention during the testing phase, the first step in implementing the new practice and training practitioners in using the new practice have already been completed at all of the sites. More information and a presentation on designing stepped wedge studies and how to analyze the data are available on AHRQ's PBRN Resource Center Web site at http://pbrn.ahrq.gov/events/advanced-methods-primary-care-research-stepped-wedge-design.⁶⁰

5. Adaptive Trial Designs

Adaptive trial designs are RCTs that have a process of adaptation of the intervention designed into the study. These trials can be briefer and require a smaller sample size depending on the specific adaptations that are proposed. Adaptive trial designs plan for adaptation either at certain endpoints or based on certain findings.⁶¹ Many adaptive trial designs use Bayesian analysis to adjust the randomization process based on prior findings (as was used in the Fiore study⁴⁹ above). There are at least 10 different types of adaptive trial designs,⁶² and PCORI offers a set of standards for conducting adaptive clinical trials (PDF – 381 KB).

3.5.4 Accelerating RCTs

PBRNs and other research networks are well positioned to accelerate the process of conducting an RCT. One of the ways that researchers inadvertently extend the time that a clinical trial takes to recruit subjects is by asking a question that is confined to too narrow a population. Researchers must balance the ability to have statistically significant differences between the treatment and control group by limiting the population under study and developing treatments and protocols that can be generalized to real treatment populations. Following the steps in this document's preparation, problem identification and knowledge exploration sections will help researchers design studies that can recruit adequate samples in reasonable time, particularly when multiple sites are used for recruitment.

Following the processes described above for engaging practices and patients in all aspects of study design should also help research teams in other ways. They avoid developing study protocols that are difficult to implement or require significant investments in training and audit of whether the practice is being implemented with fidelity. By working to fully understand the patient's and the primary care provider's needs, researchers can design interventions that can be adopted within existing workflows and address problems that practices would like to solve, thereby increasing the probability of dissemination.

3.6 Implementation and Dissemination Phases

3.6.1 Implementation

Once a research or a QI project has demonstrated results, ensuring implementation within the organization(s) that conducted the testing can be the first step in a dissemination process. The reasons that the practices involved in the research sometimes do not adopt recommendations based on the outcomes of studies in which they were involved are often related to concerns that can be addressed using the tools in this document's preparation, problem identification, solution-finding, and testing sections. Questions about whether the patients in the practice are generally like the patients in the study or whether the study patients were a small sub group (e.g., they had heart disease but no other chronic conditions), whether the clinicians involved were really representative of the population of physicians expected to implement the practice, and how the clinical and administrative leadership feel about the change can all affect adoption of a new practice, even within organizations that are introduced to a new practice without having been involved in the study.

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Implementation is another area in which the RE-AIM framework may prove useful. Clinical studies often do not adequately address organizational barriers to adoption of a new practice and therefore underestimate the ease with which a new practice will be adopted. By considering organizational issues during the early phases of planning a study and selecting a solution, the QI/research team will be better prepared for implementation when they have a positive outcome to their study. Study designs that involve implementation activities as part of the testing protocol, such as the Bayesian randomization algorithm used in the Fiore⁴⁹ study in the VA (described above), can move an organization toward adoption during the study process.

Problems also arise because of assumptions that good practices will automatically be adopted. In fact there is overwhelming evidence that most people and organizations are highly risk averse and will not change practice even in the face of overwhelming evidence that the change is an improvement.⁶³ Consequently, clinical settings do not prepare to adopt new practices. Informing/educating appropriate staff is only one step. Changes in organizational processes may also be necessary. A tool to assess an organization's readiness to implement an innovation may identify the organizational facilitators and barriers that need to be addressed to successfully implement an innovation. One tool that was created for health care providers⁶⁴ is available at http://networkofpractice.org/ris/getstarted/. One of the benefits of a PBRN or of a large integrated health system is the availability of practice facilitators who use QI techniques and implementation science to ensure fidelity in the adoption of new practices. For additional information and resources, download AHRQ's Developing and Running a Primary Care Practice Facilitation Program: A How-to Guide accessible here (PDF – 2.9 MB)

Sustaining a practice improvement is not guaranteed even once it is implemented. One tool that is available to assess an organization's ability to sustain a practice change once it has been adopted is the sustainability index⁶⁵ developed for the British National Health Service. The tool is available in an electronic format at

<u>http://www.niatx.net/Content/ContentPage.aspx?NID=156</u>. This model outlines three levels of intervention and support that are necessary for a new practice to be sustained in an organization: (1) staff including leadership, (2) organizational structure and culture, and (3) the process including the evidence base of the new intervention and the process of implementing it. It uses a simple 10-question survey to assess strengths and weaknesses of a specific change within a health care practice.

External factors may affect whether a new practice is adopted. Regulation, funding, and perception of peers may all affect whether and to what extent an organization adopts a particular practice. While academic researchers may not think that addressing these levers of change is under their purview, other industries consider these things critical to ensuring that their products and services are adopted.

3.6.2 Dissemination

Researchers are expected to disseminate the findings of their projects. While publication in peer-reviewed journals is often the goal of academic scientists, publication in scientific journals rarely promotes the dissemination of findings beyond the small circle of researchers

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interested in the topic. Funders now expect researchers to have a plan for how study findings will be disseminated to people who can use them.

There are many ways to disseminate information in today's electronically connected world. The three most common types of dissemination used by PBRNs are (1) publications in peerreviewed medical journals; (2) professional society meetings; and (3) local, regional, national, and international meetings. Word of mouth using stories is a powerful means of dissemination that is frequently disregarded. Sometimes natural diffusion via word of mouth just happens. More often than not, an active process using tools such as influence analysis and social network mapping to facilitate word of mouth dissemination is necessary. Stories from a patient or provider perspective are often a more effective means of communicating information than scientific presentations of study outcomes. For most audiences, data is better used as a way to back up a claim demonstrated by an anecdote. University extension offices and marketers of commercial products and services have developed a deep understanding of how to use influential social network members to accelerate dissemination of innovations via word of mouth. Research teams may benefit from contacting their local public university extension office for guidance.

While academic research teams and organizational QI/research staff generally lack the resources to actively disseminate their findings on a large scale, there are mechanisms to help health care providers adopt new practices. For example, the National Area Health Education Centers (AHEC) Organization has resources on their Web site here: http://www.nationalahec.org/ to help disseminate and implement new practice guidelines in health care practices. Researchers who wish to disseminate new discoveries to practices beyond their research network may find that the technology transfer centers funded by HHS, such as the AHECs, have tools and resources to support their efforts.

On Wednesday, July 22nd 2015, the AHRQ PBRN Resource Center hosted *Dissemination and Implementation Research in Health: Translating Science to Practice* authors Drs. Ross Brownson and Graham Colditz on a Webinar to discuss their new book. View the Webinar recording on AHRQ's PBRN Events page here:

<u>https://pbrn.ahrq.gov/events/dissemination-and-implementation-research-health-translating-science-practice</u>⁶⁶.

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Appendices

Appendix A. Reference List

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Appendix B. Annotated Bibliography of Select Publications on "Rapid-Cycle" Research

This appendix presents an annotated bibliography of publications relevant to rapid-cycle research in the PBRN context. The term "rapid-cycle research" may mean different things to different people, and other terminology is often used to describe the concept of conducting studies that can be completed quickly and produce results that are easily incorporated into clinical practice. This annotated bibliography lists select articles on rapid-cycle research, quality improvement, and the different phases of Dr. Gustafson's "Secrets of Rapid Research" Framework (see Exhibit 1.1.)

Annotated Bibliography of Select Resources by Rapid-Cycle and Quality Improvement Phase		
Citation	Summary	
Resources Relevant	to Quality Improvement	
Gustafson D, Johnson K The NIATx Model: Process Improvement in Behavioral Health. Madison: University of Wisconsin; 2011. Funded by: The authors received no financial support for the research, authorship, and/or publication of this book.	This book outlines the simple process improvement model developed at NIATx by Dr. Gustafson and his colleagues.	
 Plsek PE. Quality improvement methods in clinical medicine. Pediatrics 1999;103(Supplement E1):203-14. PMID: 9917464. Funded by: The author received no financial support for the research, authorship, and/or publication of this article. 	This article surveys the methods and tools of quality improvement used today in health care. Specifically, the article describes how clinicians can use these methods to impact the clinical practice of medicine.	
Starr SR, Kautz JM, Sorita A, et al. Quality improvement education for health professionals: a systematic review. Am J Med Qual 2015 Jan. PMID: 25583877. http://www.ncbi.nlm.nih.gov/pubmed/25583877. Funded by: The authors received no financial support for the research, authorship, and/or publication of this article.	This systematic review describes the use of clinical measures in quality improvement education for health professionals. The research team used clinical measures to evaluate the prevalence of QI curricula, and their association with several curricular features. Though effective QI education should measurably improve patient care, the research team found that little more than half of the published QI curricula studies included clinical measures. Health care curricula that predicted success included learner buy-in, adequate teacher expertise, role-modeling, mixed teaching methods, adequate curricular time to finish a project, and a supportive institutional culture. [Also relevant for: implementation phase]	

Annotated Bibliography of Select Resources by Rapid-Cycle and Quality Improvement Phase		
Citation	Summary	
Posources Polovant	to the Proparation Phase	
Baldwin L-M, Graham D, Schmit K, et al. Toolkit for Developing and Conducting Multi- site Clinical Trials in Practice Based Research Networks. <u>http://www.dartnet.info/clinicaltrialsPBRNtoolkit.</u> <u>http://www.dartnet.info/clinicaltrialsPBRNtoolkit.</u> <u>httm</u> . Funded by: This toolkit was developed in collaboration with the DARTNet Institute Research Steering Committee and the Clinical Translational Science Award (CTSA) Practice Based Research Network Workgroup of the Community Engagement Key Function Committee.	This toolkit offers considerations for researchers interested in conducting clinical trials in a PBRN setting. Questions related to clinical effectiveness, comparative effectiveness, and safety are addressed.	
Gold M, Taylor EF. Moving research into practice: lessons from the US Agency for Healthcare Research and Quality's IDSRN program. Implement Sci 2007 Mar;29:2-9. PMID: 17394644. Funded by: The research upon which this article is based was supported by a contract from the Agency for Healthcare Research and Quality of the U.S. Department of Health and Human Services.	This article describes an evaluation of AHRQ's Integrated Delivery Systems Research Network (IDSRN) program. Interviews and case studies helped identify several factors import to and limiting success of projects in influencing operations.	
Thorpe K. PRECIS Tool: Understanding your Research Intentions, the Pragmatic- Explanatory Continuum. AHRQ PBRN Resource Center Webinar. 2014. <u>http://pbrn.ahrq.gov/events/precis-tool-</u> <u>understanding-your-research-intentions-</u> <u>pragmatic-explanatory-continuum</u> . Funded by: AHRQ Contract No. HHSA290- 2010-00004I, Task Order No. 32006T	This Webinar details the pragmatic-explanatory continuum indicator summary (PRECIS) tool. It focuses on the development of the tool and the methods for its use by trialists to determine whether one's research design decisions are consistent with the stated purpose of one's research trial.	
Resources Relevant to the	e Problem Exploration Phase	
Bergman D, Arnetz B, Wahlström R, et al. Effects of dialogue groups on physicians' work environment. J Health Organ Manag 2007;21(1):27-38. PMID: 17455810. Funded by: Funding source unknown.	This article examines whether dialogue groups for physicians can improve their psychosocial work environment.	
Bhasale AL, Miller GC, Reid SE et al. Analysing potential harm in Australian general practice: an incident-monitoring study. Med J Aust, 1998 Jul;169(2):73-6. PMID: 9700340. Funded by: The Commonwealth Review of Professional Indemnity Arrangements for Health Care Professionals.	This article is an observational study of incidents of potential harm based on a modified critical incident technique. A non-random sample of general practitioners anonymously submitted incident reports contemporaneously.	
Bohm D. On dialogue. New York: Routledge; 1996. <u>http://www.amazon.com/Dialogue-</u> <u>Routledge-Classics-David-</u> <u>Bohm/dp/0415336414</u> . Funded by: The authors reported no funding assistance for the preparation of this book.	This is the original text describing the dialogue technique developed by Bohm.	

Annotated Bibliography of Select Resources by Rapid-Cycle and Quality Improvement Phase		
Citation	Summary	
Delbecq AL, Van deVen AH. A Group Process Model for Problem Identification and Program Planning. J Appl Behav Sci 1971;July/August 7(4):466-92. Funded by : The authors reported no funding assistance for the preparation of this article.	This article demonstrates the application of group process approach by administrators for program planning.	
Fitzsimmons JA, Maurer GB. A walk-through audit to improve restaurant performance. The Cornell Hotel and Restaurant Administration Quarterly 1991 Feb;31(4):95-100. http://cqx.sagepub.com/content/31/4/95. Funded by: The authors express their appreciation to Kent Hughes and the Texas Restaurant Association for supporting this project, and to Mona J. Fitzsimmons for her assistance.	This article reports on the findings of a "walk- through audit" for a restaurant. The audit, which consists of 42 questions, was developed as a management tool for the systematic evaluation of a customer's view of the service provided in a restaurant.	
Flanagan JC. The critical incident technique. Psychol Bull 1954 Jul;51(4):327-58. PMID: 13177800. Funded by: The authors reported no funding assistance for the preparation of this manuscript.	This article discusses the development, fundamental principles, and original uses of the critical incident technique, along with a review of studies employing the technique and suggestions for further applications.	
Ford JH, Green CA, Hoffman KA et al. Process improvement needs in substance abuse treatment: Admissions walkthrough results. J Subst Abuse Treat 2007;33(4):379-89. PMID: 17499961. Funded by : The Robert Wood Johnson Foundation and the Center for Substance Abuse Treatment support the Network for the Improvement of Addiction Treatment through grants and cooperative agreements. Awards to the University of Wisconsin (RWJF 48364; CSAT-SC-04-035) and Oregon Health & Science University (RWJF 46876 and 50165; PIC-STAR-SC-03-044) supported the preparation of this manuscript.	This article outlines the findings from walk-throughs of admission processes for 327 addiction treatment agencies in the U.S.	
Gustafson DH, McTavish F, Hawkins R, et al. Computer support for elderly women with breast cancer. JAMA 1998 October;280(15):1305. PMID: 9794300. Funded by: Funding source unknown.	This letter to the editor of JAMA magazine describes an evaluation of patient education through use of a personal computer at home by elderly cancer patients.	

Annotated Bibliography of Select Resources by Rapid-Cycle and Quality Improvement Phase		
Citation	Summary	
How to Use the Nominal Group Technique. NIATx. http://www.niatx.net/content/contentpage.aspx? NID=147 Funded by: The University of Wisconsin- Madison Center for Health Enhancement Systems Studies (CHESS).	This Web site states and describes the 7 steps of the nominal group technique.	
together. Crown Business; 2008. http://www.randomhouse.com/book/85559/dial ogue-by-william-isaacs/9780307483782/. Funded by: The authors reported no funding assistance for the preparation of this book.	first described by Bohm.	
Ivarsson B, Larsson S, Sjöberg T. Patients' experiences of support while waiting for cardiac surgery. a critical incident technique analysis. Eur J Cardiovasc Nurs 2004;3(2):183-91. Funded by: Funding source unknown.	This article discusses how identifying factors that influence patients' experiences of support while they wait for heart surgery using a CIT, institutional and non-institutional health care services can improve the organization of the entire health care process and develop patient-focused support programs.	
Kvarnström S. Difficulties in collaboration: A critical incident study of interprofessional healthcare teamwork. J Interprof Care 2008;22(2):191-203. Funded by: Funding source unknown.	This article discusses 18 individual interviews using a Critical Incident Technique. These were performed with 18 Swedish professionals working in health care teams and were examined with qualitative content analysis. The main findings show difficulties related to the team dynamic that arose when team members acted towards one another as representatives of their professions and difficulties that occurred when the members' various knowledge contributions interacted in the team.	
Leonard-Barton D. The factory as a learning laboratory. Sloan Management Review 1992 Oct;34:23. <u>http://sloanreview.mit.edu/article/the-factory-as-</u> <u>a-learning-laboratory/</u> . Funded by : The study was supported by the Division of Research, Harvard Business School.	This article discusses distinguishing activities critical to a learning laboratory: (1) problem solving, (2) internal knowledge integration, (3) innovation and experimentation, and (4) integration of external information flows.	
Maemura Y. Changing stereotypes in India's garment sector through dialogue. J Conflict Resolut 2013;31(2):159-187. Funded by : The authors reported no funding assistance for the preparation of this manuscript.	This article reports on a methodology for productive dialogue and collaboration within groups experiencing tension.	

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Quality Improvement Phase		
Citation	Summary	
McCarty D, Gustafson DH, Wisdom JP, et al. The Network for the Improvement of Addiction Treatment (NIATx): enhancing access and retention. Drug Alcohol Depend 2007;88(2):138-45. PMID: 17129680. Funded by: The Network for the Improvement of Addiction Treatment (NIATx) was supported through grants from the Robert Wood Johnson Foundation and cooperative agreements from the Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment. The National Evaluation Team at Oregon Health and Science University was supported through awards from the Robert Wood Johnson Foundation (46876 and 50165), the Center for Substance Abuse Treatment (through subcontracts from Northrop Grumman Corporation PIC-STAR-SC-03-044, SAMHSA SC-05-110), and the National Institute on Drug Abuse (R01 DA018282). National Program Office activities at the University of Wisconsin were supported through awards from the Robert Wood Johnson Foundation (48364), and the Center for Substance Abuse Treatment (through a subcontract from Northrop Grumman Corporation PIC-STAR-SC-04-035).	This article discusses how small incremental changes in treatment processes can lead to significant reductions in days to treatment and consistent gains in retention in addiction treatment.	
Nagda BA, Spearmon ML, Holley LC, et al. Intergroup dialogues: An innovative approach to teaching about diversity and justice in social work programs. J Soc Work Educ 1999;35(3):433-449. Funded by: The project reported in this article was funded by a Council on Social Work Education Millennium Project grant and the University of Washington School of Social Work.	This article reports on intergroup dialogues and suggests ways to incorporate them into social work program curricula.	
Ridings A. Pause for Breath: Bringing the Practices of Mindfulness and Dialogue to Leadership Conversations. London: Live It Publishing; 2011. <u>http://www.amazon.com/Pause-Breath-</u> <u>Mindfulness-Leadership-</u> <u>Conversations/dp/1906954232</u> . Funded by: The authors reported no funding assistance for the preparation of this book.	This book further describes the dialogue process and adds the element of mindfulness to the practice.	

Annotated Bibliography of Select Resources by Rapid-Cycle and Quality Improvement Phase		
Citation	Summary	
Van de Ven AH, Delbecq AL. The nominal group as a research instrument for exploratory health studies. Am J Public Health 1972;62(3):337-42. PMID: 5011164. Funded by: The authors reported no funding assistance for the preparation of this manuscript.	This paper sets forth a group process for qualitative judgmental problem exploration that is particularly applicable to the subjective and judgmental character of many health planning efforts.	
Resources Relevant to the	e Solution Development Phase	
Langley GJ, Moen R, Nolan KM, et al. The improvement guide: a practical approach to enhancing organizational performance. 2nd ed. San Francisco: Jossey-Bass; 2009. Funded by: The authors reported no funding assistance for the preparation of this book.	This text provides tools, techniquesb and explanations for how to conduct process improvement activities to improve organizational performance. [Also relevant for: all phases, as a general resource]	
Rogers EM. Diffusion of Innovations. 5th ed. New York: Simon and Schuster; 2003. <u>http://www.amazon.com/Diffusion-Innovations-</u> Edition-Everett-Rogers/dp/0743222091. Funded by : The authors reported no funding assistance for the preparation of this book.	In this text, Rogers explores the research on innovation diffusion and dissemination.	
Senge P. The fifth discipline: The art & practice of the learning organization. United States: Doubleday; 1990. <u>http://www.amazon.com/The-Fifth-Discipline- Practice-Organization/dp/0385517254</u> . Funded by: The author reported no funding assistance for the preparation of this book.	This text outlines 11 laws of learning organization, "the fifth discipline".	
Resources Relevant to	the Solution Testing Phase	
Benneyan J, Lloyd R, Plsek P. Statistical process control as a tool for research and healthcare improvement. Qual Saf Health Care 2003 Dec;12(6):458–64. PMID: 14645763. Funded by: Funding source unknown.	This article describes statistical process control and its primary tool, the control chart, along with several practical health care applications, in the context of improvement of process performance measurement.	
Berry DA. Adaptive clinical trials: the promise and the caution. J Clin Oncol 2011;29(6):606-9. PMID: 21172875. Funded by : The author reported no funding assistance for the preparation of this manuscript	This article analyses the advantages and disadvantages of using adaptive randomization with a Bayesian perspective in multi-arm clinical trials.	
Biglan A, Ary D, Wagenaar AC. The value of interrupted time-series experiments for community intervention research. Prev Sci 2000;1(1):31-49. PMID:11507793. Funded by: This paper was supported by Grants DA09306 and DA 09678 from the National Institute of Drug Abuse and Grant No. CA38273 from the National Cancer Institute.	This paper reports on the uses of multiple baseline time-series designs and related repeated-measures time series experiments as they relate to the evaluation of community interventions and policy changes. Threats to internal validity are also described.	

Annotated Bibliography of Select Resources by Rapid-Cycle and Quality Improvement Phase		
Citation	Summary	
Birtwhistle R. How can PBRNs use Big Data to Create a Learning Health System: The Canadian Primary Care Sentinel Surveillance Network (CPCSSN). Proceedings of North American Primary Care Research Group (NAPCRG) Practice-based Research Network Conference; 2014 Jun 30– Jul 1; Bethesda. Bethesda: North American Primary Care Research Group; 2014. (PDF – 1.38 MB). Funded by: CPCSSN is funded by the Public Health Agency of Canada, Health Canada and Canada Health Infoway and the Canadian Institute for Health Research.	This presentation describes how PBRNs can use 'big data' in creating a learning health system and discusses three uses of CPCSSN EMR data.	
Campbell DT, Stanley JC, Gage, NL. Experimental and Quasi-Experimental Designs for Research. Boston: Houghton Mifflin Company; 1963. (<u>PDF – 6.64 MB</u>). Funded by: The authors reported no funding assistance for the preparation of this book.	This is the classic text on experimental and quasi- experimental design; it outlines the various ways of setting up a study, what assumptions are made with each design, and what conclusions can be drawn from each design.	
Chakraborty B, Collins LM, Strecher VJ, et al. Developing multicomponent interventions using fractional factorial designs. Stat Med 2009;28(21):2687-708. PMID:19575485. Funded by: Support for this project was received from the National Institutes of Health grants RO1 MH080015, P50 DA10075, and P50 CA101451.	This report operationalizes screening studies and evaluates the efficacy of using factorial designs to screen out the least active component of multicomponent interventions.	
Chow SC, Chang M. Adaptive design methods in clinical trials – a review. Orphanet Journal of Rare Diseases 2008 May;2:3-11. PMID: 18454853. Funded by: The authors reported no funding assistance for the preparation of this journal article.	This article reviews the adaptive trial design and briefly describes all 10 ways in which trials have been adapted	
Dainty KN, Scales DC, Brooks SC, et al. A knowledge translation collaborative to improve the use of therapeutic hypothermia in post- cardiac arrest patients: protocol for a stepped wedge randomized trial. Implement Sci. 2011;6:4. PMID: 21235799. Funded by: This study was funded by the Heart and Stroke Foundation of Canada, the Canadian Institutes of Health Research, and by the Laerdal Foundation for Acute Medicine (Norway). The trial is registered under ClinicalTrials.gov Trial Identifier: NCT00683683.	This article outlines a proposed stepped wedge randomized trial design to evaluate a knowledge translation strategy designed to increase the utilization rate of induced hypothermia in survivors of cardiac arrest across a network of Canadian hospitals.	

Annotated Bibliography of Select Resources by Rapid-Cycle and Quality Improvement Phase		
Citation	Summarv	
D'Avolio L, Ferguson R, Goryachev S, et al. Implementation of the Department of Veterans Affairs' first point-of-care clinical trial. J Am Med Inform Assoc 2012;19(e1), e170-176. PMID: 22366293. Funded by: This work was supported by the VA Office of Research and Development and the VA Cooperative Studies Program. Phillip Lavori was supported by grants UL1 RR025744 and R01 MH051481 to Stanford University.	This article describes the development of the point- of-care clinical trial methods.	
Design and Implementation of N-of-One Trials: A User's Guide. Final. Prepared by Brigham and Women's Hospital DEcIDE Methods Center under Contract No. 290-2005-0016-I. AHRQ Publication No. 13(14)-EHC122-EF. Rockville, MD: Agency for Healthcare Research and Quality; February 2014. (PDF – 900 KB). Funded by: AHRQ Contract No. 290-2005- 0016-I.	This AHRQ-developed tool outlines the purposes of n-of-one trials, the best uses of this methodology and provides some examples and tools for deciding whether and how to conduct n-of-one studies	
Detry MA, Lewis RJ, Broglio KR, et al. Standards for the Design, Conduct, and Evaluation of Adaptive Randomized Clinical Trials. <u>http://www.pcori.org/assets/Standards-for-the-Design-Conduct-and-Evaluation-of-Adaptive-Randomized-Clinical-Trials.pdf</u> . Funded by : The Patient-Centered Outcomes Research Institute (PCORI) through a contract to support the Methodology Committee's development of a report to outline existing methodologies for conducting patient centered outcomes research, propose appropriate methodological standards, and identify important methodological gaps that need to be addressed.	This document contains standards for conducting adaptive trials in terms of study design, analysis, and implementation.	
Diaz M, Neuhauser D. Pasteur and parachutes: when statistical process control is better than a randomized controlled trial. Qual Saf Health Care 2005 Apr;14(2):140–3. Funded by: This article was funded by the Charles Elton Blanchard MD Endowment, Medical School, Case Western Reserve University, Cleveland, OH.	This article demonstrates the application of statistical process control by use of control charts in several examples, including one regarding rabies vaccination and another about parachute jumping.	

Annotated Bibliography of Select Resources by Rapid-Cycle and		
Citation	Summary	
Dickinson M, Bartlett-Esquilant G, Kwan B, et al. Advanced Methods for Primary Care Research: The Stepped Wedge Design. Video. AHRQ PBRN Resource Center Webinar. 2015. <u>http://pbrn.ahrq.gov/events/advanced-methods-</u> <u>primary-care-research-stepped-wedge-design</u> . Funded by : AHRQ Contract No. HHSA290- 2010-00004I, Task Order No. 32006T	This Web site provides a number of articles describing the pros and cons of stepped wedge design, when to use a stepped wedge design and studies that are using this study design. It also has slides and a link to a presentation on how to do stepped wedge studies, including setting up the analysis.	
Donovan EF, Lannon C, Bailit J, et al. A statewide initiative to reduce inappropriate scheduled births at 36 0/7–38 6/7 weeks' gestation. Am J Obstet Gynecol 2010;202(3):243.e1-8. PMID: 20207241. Funded by: This article was supported in part by Grant No. 1U0CMS030227/01 from the Center for Medicare & Medicaid Services (CMS) administered by the Ohio Department of Job and Family Services.	This article describes the effect of a statewide quality collaborative, specifically Institute for Healthcare Improvement Breakthrough Series interventions, in reducing the number of scheduled births lacking a documented medical indication.	
Eslami 1, Abu-Hanna A, de Keizer NF, et al. Implementing glucose control in intensive care: a multicenter trial using statistical process control. Intensive Care Med 2010 Sep;36(9):1556-65. PMID: 20533024. Funded by: Funding source unknown.	This article describes a study that investigated glucose control (GC) performance over time in three intensive care units and in routine clinical practice during implementation of GC strategies.	
Fiore LD, Brophy M, Ferguson R, et al. A point- of-care clinical trial comparing insulin administered using a sliding scale versus a weight-based regimen. Clin Trials 2011;8(2):183-95. PMID: 21478329 Funded by: This study was supported by the Department of Veterans Affairs Cooperative Studies Program. Dr Lavori's efforts have been supported by grants UL1 RR025744 and R01 MH051481 to Stanford University.	This article describes a point-of-care randomized controlled trial to improve diabetes treatment.	
Glasgow RE, Klesges LM, Dzewaltowski DM, et al. The future of health behavior change research: what is needed to improve translation of research into health promotion practice? Ann Behav Med 2004;27(1):3-12. PMID: 14979858. Funded by: National Cancer Institute, Agency for Healthcare Research and Quality, and NIH Office of Behavioral and Social Science Research.	This article describes how to use the RE-AIM model for assessing studies and has a set of questions for researchers and research funders to consider to improve the use of research findings in practice	

Annotated Bibliography of Select Resources by Rapid-Cycle and Quality Improvement Phase	
Citation	Summary
Glasgow RE., Lichtenstein E, Marcus AC. Why don't we see more translation of health promotion research to practice? Rethinking the efficacy-to-effectiveness transition. Am J Public Health 2003 August;93(8):1261–67. PMID: 12893608. Funded by : This project was funded by The Robert Wood Johnson Foundation (grant 030102) and the Agency for Healthcare Research and Quality (grant HS10123).	This article offers recommendations to help close the gap between research and practice by addressing one of the reasons for this gap: the assumption that successful efficacy research naturally leads to effectiveness research. The article recommends greater attention be paid to documentation to guide evaluation and possible adoption of new programs.
Golden MR, Kerani RP, Stenger M, et al. Uptake and population-level impact of expedited partner therapy (EPT) on chlamydia trachomatis and neisseria gonorrhoeae: The Washington State Community-Level Randomized Trial of EPT. PLoS Med 2015;12(1):e1001777. PMID: 25590331. Funded by: The authors reported no funding assistance for the preparation of this manuscript.	This article discusses the methods and findings of a stepped-wedge, community-level randomized trial to evaluate the efficacy of a public health intervention promoting expedited partner therapy to decrease chlamydia test positivity and gonorrhea incidence in women.
Hanrahan L. Clinical Big Data and Practice- Based Research Networks are the Foundations for a Rapid Learning Health System. Proceedings of North American Primary Care Research Group (NAPCRG) Practice-based Research Network Conference; 2014 Jun 30– Jul 1; Bethesda. Bethesda: North American Primary Care Research Group; 2014. (PDF – <u>1.88 MB</u>). Funded by: This project was supported through the University of Wisconsin School of Medicine and Public Health Block Grant Fund.	This presentation discusses the use of health systems intelligence and analytics to provide advice for how PBRNs can use big data for creation of a learning health system.
 Harrington G, Watson K, Bailey M, et al. Reduction in hospitalwide incidence of infection or colonization with methicillin-resistant Staphylococcus aureus with use of antimicrobial hand-hygiene gel and statistical process control charts. Infect Control Hosp Epidemiol 2007 Jul;28(7):837-44. PMID: 17564987. Funded by: This article was funded in part by Les Entreprises Solumed, Medical Specialities Australia, and Ansell Limited. 	This article describes a longitudinal observational study in which a series of interventions were carried out to reduce the incidence of methicillin- resistant Staphylococcus aureus.
Harvey G, Kitson A. Implementing Evidence- Based Practice in Healthcare: A Facilitation Guide. New York: Routledge; 2015. Funded by: The authors reported no funding assistance for the preparation of this book.	This book delves into possible facilitation methods to use across health care settings, including real- time implementation projects.

Annotated Bibliography of Select Resources by Rapid-Cycle and Quality Improvement Phase	
Citation	Summarv
Improving Care Delivery Through Lean: Implementation Case Studies: Contract Report. November 2014. Agency for Healthcare Research and Quality, Rockville, MD. <u>http://www.ahrq.gov/professionals/systems/syst</u> <u>em/systemdesign/leancasestudies/index.html</u> Funded by: AHRQ Contract No. HHSA290200600019	This AHRQ-funded report includes six in-depth case studies that explain how Lean principles were applied in 13 implementation projects. These included: improving patient flow during hospital care, electronic prescribing of medicines, reducing the cost of hip and knee replacement surgery, and preventing urinary tract infection, amongst others. [Also relevant for: implementation phase]
Institute for Healthcare Improvement. How to Improve: IHI Model for Improvement. <u>http://www.ihi.org/resources/Pages/HowtoImprove/default.aspx.</u> Funded by: This Web site is funded by the Institute for Healthcare Improvement.	This Web site outlines the Model for Improvement, developed by Associates in Process Improvement to accelerate improvement. The plan-do-study-act cycles are outlined as an example of how to test changes on a small scale. [Also relevant for: implementation and dissemination phase]
Lauer MS, D'Agostino RB, Sr. The randomized registry trialthe next disruptive technology in clinical research? N Engl J Med 2013;369(17):1579-81. Funded by : The authors reported no funding assistance for the preparation of this journal article.	This article discusses the possibilities for using EHR data to recruit participants and assess study outcomes in an RCT with fewer resources, and in a shorter time than is typical but adds a caution about data quality.
Lloyd R. On Demand: Using Run and Control Charts to Understand Variation. Video. <u>http://www.ihi.org/education/WebTraining/OnD</u> <u>emand/Run_ControlCharts/Pages/default.aspx</u> . Funded by: This Web site is funded by the Institute for Healthcare Improvement.	This link is to the Institute for Healthcare Improvement's online course in using statistical process control tools for process improvement and research
Pace W. Linking PBRN Research and Big Data: The DARTNet Experience. Proceedings of North American Primary Care Research Group (NAPCRG) Practice-based Research Network Conference; 2014 Jun 30– Jul 1; Bethesda. Bethesda: North American Primary Care Research Group; 2014. (PDF – 900 KB). Funded by: The authors reported no funding assistance for the preparation of this presentation.	This presentation utilizes DARTNet as a case study to describe how big data can be linked to patient outcomes and provider decision making in PBRN research.
Shewhart WA. Economic control of quality of manufactured product (Vol. 509). ASQ Quality Press; 1931. Funded by: The authors reported no funding assistance for the preparation of this book.	This book discusses the control chart and the principles behind it, which draw from the disciplines of statistics, engineering, and economics.
Shrank W. The Center For Medicare and Medicaid Innovation's blueprint for rapid-cycle evaluation of new care and payment models. Health Aff (Millwood) 2013;32(4):807-12. Funded by: The authors reported no funding assistance for the preparation of this journal article.	This article describes the approaches this group will take as it evaluates new delivery and payment models launched by the Innovation Center under the Affordable Care Act.

Annotated Bibliography of Select Resources by Rapid-Cycle and Quality Improvement Phase		
Citation	Summary	
Smith JD. Single-case experimental designs: A systematic review of published research and current standards. Psychol Methods 2012;17(4):510-50. PMID: 22845874. Funded by: Research support for the author was provided by research training grant MH20012 from the National Institute of Mental Health, awarded to Elizabeth A. Stormshak.	This article describes the research design, measurement, and analysis domains distinctive to the single-case experimental design (SCED) and provides updated benchmarks for key SCED characteristics.	
Strecher VJ, McClure JB, Alexander GL, et al. Web-based smoking-cessation programs: results of a randomized trial. Am J Prev Med 2008;34(5):373-81. PMID: 18407003 Funded by: This grant was funded from National Cancer Institute grants P50 CA101451 and R01 CA101843. This project was conducted in collaboration with the Cancer Research Network (CRN). The CRN is a consortium of research organizations affiliated with nonprofit integrated health care delivery systems and the National Cancer Institute. Nicotine replacement therapy was provided by GlaxoSmithKline.	This article discusses the use of a novel fractional factorial design to evaluate study aims relating to improving smoking cessation interventions. Fractional factorial designs will be important for evaluating eHealth activities moving forward.	
The Pennsylvania State University. Introduction to Factorial Experimental Designs. <u>http://methodology.psu.edu/ra/most/factorial</u> . Funded by: This Web site is funded by the Institute for Healthcare Improvement.	This Web site provides a primer for conducting factorial study designs	
Virginia Polytechnic Institute and State University. Reach Effectiveness Adoption Implementation Maintenance (RE-AIM). <u>http://www.re-aim.hnfe.vt.edu/index.html</u> . Funded by: This Web site is funded by Virginia Tech.	This Web site provides tools for assessing a study or project implementation through the RE-AIM lens. [Also relevant for: implementation and dissemination phase]	
 Winhusen TC, Wilder C, Wexelblatt SL, et al. Design considerations for point-of-care clinical trials comparing methadone and buprenorphine treatment for opioid dependence in pregnancy and for neonatal abstinence syndrome. Contemp Clin Trials 2014;39(1):158-65. PMID: 25183042. Funded by: The authors reported no funding assistance for the preparation of this journal article. 	This article describes the study design for a point- of-care RCT to treat pregnant women with opioid dependence and their newborns. It includes the design and the rationale for using this design.	
Woertman W, de Hoop E, Moerbeek M, et al. Stepped wedge designs could reduce the required sample size in cluster randomized trials. J Clin Epidemiol. Jul 2013;66(7):752-758. PMID: 23523551. Funded by: The authors received no financial support for the research, authorship, and/or publication of this article.	This article discusses a sample size formula for cluster randomized stepped wedge designs.	

Annotated Bibliography of Select Resources by Rapid-Cycle and Quality Improvement Phase	
Citation	Summary
Wyrick DL, Rulison KL, Fearnow-Kenney M, et al. Moving beyond the treatment package approach to developing behavioral interventions: addressing questions that arose during an application of the Multiphase Optimization Strategy (MOST). Transl Behav Med 2014;4(3):252-9. PMID: 25264465. Funded by: This project was funded by the National Institute on Drug Abuse (NIDA): 3R44DA023735.	This article reports on the first-ever iterative application of Multiphase Optimization Strategy to an online program to prevent substance use among college student athletes.
Zurovac J, Moreno L, Crosson J, et al. Using multifactorial experiments For comparative effectiveness research in physician practices with electronic health records. EGEMS 2013;1(3):1037. PMID: 25848579 Funded by: The authors reported no funding assistance for the preparation of this article.	This article recommends the use of multifactorial designs and electronic health record data to evaluate quality improvement efforts in physician practices.
Zurovac J, Peikes D, Zutshi A, Brown R. Efficient Orthogonal Designs: Testing the Comparative Effectiveness of Alternative Ways of Implementing Patient-Centered Medical Home Models. Rockville, MD: Agency for Healthcare Research and Quality. February 2013. AHRQ Publication No. 13-0024-EF. (PDF – 6.64 MB). Funded by: AHRQ Contract No. HHSA290200900019I Task Order 5.	This brief describes a study that used an efficient orthogonal design, a variation on factorial design. It discusses the pros and cons of the study design for comparative effectiveness research.
Resources Relevant to the Imple	mentation and Dissemination Phase
Brownson RC, Colditz GA, Proctor EK. Dissemination and Implementation Research in Health: Translating Science to Practice. AHRQ PBRN Resource Center Webinar. 2015. https://pbrn.ahrq.gov/events/dissemination- and-implementation-research-health- translating-science-practice. Funded by: AHRQ Contract No. HHSA290- 2010-00004I, Task Order No. 32006T	In this Webinar, the discuss how to evaluate the evidence base on effective interventions; which strategies will produce the greatest impact; how to design an appropriate study; and how to track a set of essential outcomes as outlined in their book, <i>Dissemination and Implementation Research in</i> <i>Health: Translating Science to Practice.</i>
Cody S, Asher A. Proposal 14: Smarter, Better, Faster: The Potential for Predictive Analytics and Rapid-Cycle Evaluation to Improve Program Development and Outcomes. In Kearney MS, Harris BH (Eds.). Policies to Address Poverty in America. Washington, DC: Brookings; 2014. Funded by : The authors reported no funding assistance for the preparation of this book.	This book discusses opportunities for applying analytic techniques from the private sector to public sector work. As government agencies invest in data warehouses and business intelligence capabilities, it becomes feasible to employ analytic techniques used more commonly in the private sector. Predictive analytics and rapid-cycle evaluation are analytical approaches that are used to do more than describe the current status of programs: in both the public and private sectors, these approaches provide decision-makers with guidance on what to do next.

Annotated Bibliography of Select Resources by Rapid-Cycle and		
Citation	Summary	
Gold M, Helms D, Guterman S. Identifying, monitoring, and assessing promising innovations: using evaluation to support rapid- cycle change. Issue Brief (Commonw Fund) 2011;12:1-12. PMID: 21682057. Funded by: This paper was developed as part of a project funded by The Commonwealth Fund to AcademyHealth, with a subcontract to Mathematica Policy Research.	This issue brief suggests rapid-cycle evaluation, among other strategies, as a means of identifying desirable payment model innovations more quickly for CMS's Center for Medicare and Medicaid Innovation (CMMI).	
Khanamen D. Thinking fast and slow. Cambridge University Press: New York; 2012. Funded by : The author reported no funding assistance for the preparation of this book.	This book reports on human judgment and decisionmaking using concepts from psychology.	
Lehmann CU, Conner KG, Cox JM. Preventing provider errors: online total parenteral nutrition calculator. Pediatrics 2004;113(4):748-53. PMID: 15060223. Funded by: This work was supported by the Center for Innovation and Quality Patient Care at the Johns Hopkins Hospital.	This article discusses how low-cost, pragmatic approaches using Internet technology in the design of medical information systems can reduce medical errors and might pose a viable option for the prevention of adverse drug events.	
Lewis CC, Stanick CF, Martinez RG, et al. The Society for Implementation Research Collaboration Instrument Review Project: a methodology to promote rigorous evaluation. Implement Sci. 2015 Jan;10(1):2. PMID: 25567126. Funded by: This manuscript was supported, in kind, through the National Institutes of Health R13 award entitled, "Development and Dissemination of Rigorous Methods for Training and Implementation of Evidence- Based Behavioral Health Treatments" granted to PI: KA Comtois from 2010 to 2015. Dr. Bryan J. Weiner's time on the project was supported by the following funding: NIH CTSA at UNC UL1TR00083.	This paper discusses a study to identify psychometrically strong instruments for the field of implementation science. The paper discusses the methodology used by the Society for Implementation Research Collaboration (SIRC), and a summary of the preliminary review of over 420 instruments and their scores, as assessed by constructs delineated in the Consolidated Framework for Implementation Research and the Implementation Outcomes Framework . Gaps in the field of dissemination and implementation science are discussed. Ultimately, SIRC hopes to develop an online repository where instruments can be reviewed by researchers and stakeholders on an ongoing basis. This will lead to the identification of psychometrically strong instruments through which to apply evidence-based implementation strategies to support widespread delivery of evidence-based care.	
NIATx. Sustainability Model. <u>http://www.niatx.net/Content/ContentPage.aspx</u> <u>?NID=156</u> . Funded by: The University of Wisconsin- Madison Center for Health Enhancement Systems Studies (CHESS).	This is a link to the Sustainability Index, a tool that can be used to assess the likelihood of an intervention or practice improvement being sustained in a health care setting.	

Annotated Bibliography of Select Resources by Rapid-Cycle and Quality Improvement Phase	
Citation	Summarv
Norman N, Bennett C, Cowart S, et al. Boot camp translation: a method for building a community of solution. J Am Board Fam Med 2013 Nov;26(3):254-63. PMID: 23657693. Funded by: This project was supported by Cooperative Agreement Number 5 U48 DP000054-02 from the Centers for Disease Control and Prevention, an implementation grant from the Caring for Colorado Foundation for Community AIR and the NIH/_NCATS Colorado CTSI Grant Number UL1 TR000154.	This article discusses the use of Boot Camp Translation in community-based settings to translate topics including asthma diagnosis and management, hypertension, and the patient- centered medical home, among others.
Pickering BW, Herasevich V, Ahmed A, et al. Novel representation of clinical information in the ICU: developing user interfaces which reduce information overload. Appl Clin Inform 2010;1(2):116-31. PMCID: PMC3632280. Funded by : This study was funded in part from intramural funds obtained through the Mayo Clinic, Critical Care Independent Multidisciplinary Practice committee and Innovation Loan Program.	This paper outlines the barriers to effective use of electronic medical records and describes the methodology, using a worked example of the output. AWARE (Ambient Warning and Response Evaluation) is a physician-led, electronic- environment enhancement program in an academic, tertiary care institution's intensive care unit (ICU). The development process focused on reducing information overload, improving efficiency and eliminating medical error in the ICU.
Srinivasan M. The innovator's DNA and healthcare improvement. J Gen Intern Med 2014;29(1):1-2. PMCID: PMC3889935. Funded by: The author received no financial support for the research, authorship, and/or publication of this article.	This article highlights the ways in which implementation science researchers currently apply the five characteristics of individuals and teams who successfully innovate from Jeff Dyer's book, <i>The Innovator's DNA</i> . The article concludes in a call to action to continue to innovate and improve health care delivery.
Stevens BJ, Yamada J, Promislow S, et al. Implementation of multidimensional knowledge translation strategies to improve procedural pain in hospitalized children. Implement Sci 2014;9(1):120. PMID: 25928349. Funded by: The Canadian Institutes of Health Research (CIHR) (CTP-79854 and MOP- 86605.	This article discusses a multifaceted knowledge translation (KT) intervention, Evidence-based Practice for Improving Quality (EPIQ), which included tailored KT strategies. This intervention was effective in improving pain practices and clinical outcomes at the unit level. The research was a prospective comparative cohort study in 32 hospital units (16 EPIQ intervention and 16 Standard Care), in eight pediatric hospitals in Canada.
Wen KY, Gustafson DH, Hawkins RP, et al. Developing and validating a model to predict the success of an IHCS implementation: the Readiness for Implementation Model. J Am Med Inform Assoc 2010;17(6):707–13. PMID: 20962135. Funded by: This research was supported by the Agency for Healthcare Research and Quality (AHRQ R01 HS10246).	This article demonstrates the use of the Readiness for Implementation Model, which predicts a health care organization's potential for success in implementing an interactive health communication system.
Genera	Resources

Annotated Bibliography of Select Resources by Rapid-Cycle and Quality Improvement Phase		
Citation	Summarv	
Auerbach AD, Landefeld CS, Shojania KG. The tension between needing to improve care and knowing how to do it. N Engl J Med. 2007;357(6):608-13. PMID: 17687138. Funded by: AHRQ Contract No. (K08 HS11416-02, to Dr. Auerbach), an Academic Leadership Award from the National Institute on Aging (K07 AG00912, to Dr. Landefeld), and funding from the Government of Canada Research Program (to Dr. Shojania).	This article argues that interventions to improve the quality and safety of health care should meet the same standards that are applied to the adoption of all medical technologies. The article discusses the pros and cons of rapid dissemination, and offers support for continuing to conduct randomized controlled trials as a tool for quality improvement.	
Centers for Medicare & Medicaid Services: 2014 Physician Quality Reporting System (PQRS): Implementation Guide. Version 8.5. 2014.1-43. <u>http://www.cms.gov/apps/ama/license.asp?file=</u> /PQRS/downloads/2014 PQRS MeasuresList ImplementationGuide_12132013.zip. Funded by: The Centers for Medicare & Medicaid Services Physician Quality Reporting System.	This document promotes understanding of how to implement 2013 PQRS claims-based reporting of measures in clinical practice, and to facilitate satisfactory reporting of quality data by eligible professionals who wish to participate in PQRS.	
Centers for Medicare & Medicaid Services: 2014 Physician Quality Reporting System (PQRS) Measures List. Version 8.1.2014.1-54. http://www.cms.gov/apps/ama/license.asp?file= /PQRS/downloads/2014_PQRS_MeasuresList ImplementationGuide_12132013.zip. Funded by: The Centers for Medicare & Medicaid Services Physician Quality Reporting System.	This document outlines the 2013 PQRS list of measures. This list is intended as a summary list to assist eligible professionals in initially reviewing the measures.	
deGruy F, Ewigman B, DeVoe J, et al. A plan for useful and timely family medicine and primary care research. Fam Med 2015;(In press). Funded by: Funding source unknown.	This manuscript outlines a vision for the next 5 to 10 years for family medicine research, including advocacy for placing "family medicine research" broadly in the context of primary care and population health research.	
Dyer JH, Gregersen HB, Christensen CM. The innovator's DNA. Harvard Business Review 2009; 87(12):60-67. PMID: 19968057. Funded by: The authors reported no funding assistance for the preparation of this article.	This article outlines five "discovery skills" that allow the most creative business executives to maximize innovation production at their companies. The five discovery skills are: (1) associating, (2) questioning, (3) observing, (4) experimenting, and (5) networking.	
Green LA, Werner JJ, Etz RS. Contextual Relevancy and Research Collaborations, PBRNs Foster Partnerships for Pragmatic, Prompt Resolutions. AHRQ PBRN Resource Center Webinar. <u>http://pbrn.ahrq.gov/events/contextual-</u> <u>relevancy-and-research-collaborations-pbrns-</u> <u>foster-partnerships-pragmatic-prompt.</u> Funded by: AHRQ Contract No. HHSA290- 2010-00004I, Task Order No. 32006T	This Webinar discusses the importance of expanding the breadth of PBRN research; redesigning research so it is more easily adoptable; and developing a primary care data model for PBRNs, with suggestions for how to do so.	

Annotated Bibliography of Select Resources by Rapid-Cycle and Quality Improvement Phase		
Citation	Summary	
Gustafson DH, Hundt AS. Findings of innovation research applied to quality management principles for healthcare. Health Care Manage Rev 1995;20(2):16-33. PMID: 7607882. Funded by: The Agency for Healthcare Research and Quality under the name of Agency for Health Care Policy and Research (AHCPR).	This study examined the difference between successful and failed change efforts to identify five characteristics that differentiated success from failure.	
Kairys SR, Wasserman R, Pace W. Practice- based quality improvement/research networks: full speed forward. Academic Pediatrics 2013 Nov-Dec;13(6, Supplement):S12-S13. PMID: 24268077. Funded by: AHRQ Contract No. 1R01HS019908-01	This commentary discusses the intersect of research and QI within the PBRN framework. The authors conclude that "The future may show us that networks can do it all: perform research, disseminate the results, and translate that research as well as QI efforts into sustainable improvements in health outcomes".	
Maher L, Gustafson D, Evans A. Sustainability model and guide. NHS Institute for Innovation and Improvement. PDF. British National Health Service (NHS) Institute for Innovation and Improvement. 2007. <u>http://www.institute.nhs.uk/index.php?option=c</u> <u>om_joomcart&ltemid=194&main_page=docum</u> <u>ent_product_info&cPath=67&products_id=290</u> <u>&Joomcartid=20fv0dookq7c4dfpirss3dmvi5</u> . Funded by: The British National Health Service.	This is a detailed guide to the sustainability model, including a diagnostic score system and how to use it, designed to increase the likelihood of sustainability for health care improvements.	
Mathematica Policy Research. Rapid-Cycle Evaluation. Web site. <u>http://www.mathematica-</u> <u>mpr.com/our-capabilities/Rapid-Cycle-</u> <u>Evaluation</u> . Funded by: The Brookings Institution.	This Web site serves as a landing page for Mathematica's work around "rapid-cycle evaluation," including the aforementioned <i>Smarter,</i> <i>Better, Faster White Paper.</i>	
Mold JW, Peterson KA. Primary care practice- based research networks: working at the interface between research and quality improvement. Ann Fam Med 2005 May- Jun;3(suppl 1):S12-S20. PMID: 15928213. Funded by : The authors reported no funding assistance for the preparation of this journal article.	Discusses the concept and examples of how QI processes are used to conduct research. [Also relevant for: the intersect of quality improvement (QI) and research]	
Patel DI, Puga F. Easy Approaches to Convert Quality Improvement to Research. Improvement Science Research Network Webinar. Webinar. <u>http://www.isrn.net/Oct2012webseminar</u> . Funded by: Funded in part by a grant from the Dean's Scholarly Project Award Program: Scholarship of Teaching Award from the University of Texas Health Science Center San Antonio School of Nursing.	This Webinar outlines processes and tools to build the capacity for collaboration and ensure successful work in team-based improvement research. The Webinar offers best practices for research collaboration, and describes how team- based science can increase innovation and advance knowledge.	

Annotated Bibliography of Select Resources by Rapid-Cycle and Quality Improvement Phase	
Citation	Summary
Peek CJ, Glasgow RE, Stange KC, et al. The 5 R's: an emerging bold standard for conducting relevant research in a changing world. Ann Fam Med 2014;12(5):447-45. PMID: 25354409. Funded by : NIH contract no. HHSN261200800001E.	This article addresses the assertion, "If we want more evidence-based practice, we need more practice-based evidence." The authors outline a detailed description of an emerging standard for research, the "5 Rs," and how to use them. These "5 Rs" stem from a synthesis of recommendations for care delivery research.
Wagner EH, Glasgow RE, Davis C, et al. Quality improvement in chronic illness care: a collaborative approach. Jt Comm J Qual Improv 2001;27(2):63-80. PMID: 11221012. Funded by: Robert Wood Johnson Foundation to Group Health Cooperative Grant No. 0347984.	This report discusses suggested improvements in chronic illness care. Both chart review and self- report data on care processes and clinical outcomes suggested improvement based on changes teams made in the collaborative. Many of the organizations evidencing the largest improvements were community health centers, which had the fewest resources and the most challenged populations.

Appendix C. List of Working Group Participants

Expert Name and Credentials	Affiliation
Elizabeth Waddell, PhD	Wisconsin Research and Education Network (WREN)
Geri Dino, PhD	West Virginia Practice-Based Research Network
	(WVPBRN)
Karim Keshavjee, MD	Canadian Primary Care Sentinel Surveillance Network
	(CPCSSN)
Michael Parchman, MD, MPH	Group Health Research Institute
Paul Meissner, MSPH	New York City Research Improvement Networking Group
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AHRQ PBRN Working Group on Rapid-Cycle Research Participants

Appendix D. Nominal Group Technique

Below is a detailed overview of the five steps involved in the Nominal Group Technique.

Step 1: Preparation

Before using the Nominal Group Process, the meeting facilitator must complete a set of sequential preparatory tasks that set the stage for a successful meeting:

- 1. Design preparation
 - a. Prepare the NGT question that clarifies the objective of the meeting and illustrates the desired responses in terms of the level of abstraction and scope. The facilitator will often pilot test the question before to the meeting.
 - b. Print the question on worksheets for each participant.
 - c. Select the desired voting method (e.g., ranking vs. rating).
- 2. Room preparation
 - a. Secure a room large enough to comfortably seat group participants.
 - b. Stock the room with these supplies: flip charts, masking tape, markers, pens, and paper for each participant, and either 3" x 5" index cards or post-it notes.
- 3. Meeting preparation
 - a. Prepare a welcome statement that explains the purpose of the meeting, outlines individual roles, and describes how the output will be used.
 - b. Conduct the meeting following the NGT process.

Step 2: Silent idea generation

Before starting, the facilitator should prepare and present, in writing and verbally, the question that the group will consider in their meeting. A well-thought-out question will generate a wealth of potential ideas. The facilitator will encourage participants to silently and independently write ideas in brief phrases.

The benefits of silent generation include:

- 1. Allows adequate time for thinking and reflection through recall.
- 2. Promotes social facilitation (e.g., seeing others hard at work).
- 3. Avoids interruptions; undue focus on one idea; and competition, status, and conformance pressures, or choosing prematurely between ideas.
- 4. Promotes a problem-centered focus.

Step 3: Round-robin recording of ideas

In this step, the facilitator goes around the table and records one idea from each participant on the flip chart. The ideas should be recorded verbatim with little to no paraphrasing. However, the facilitator is allowed to ask questions to clarify the idea. The process continues until all ideas have been recorded. Participants who are out of ideas can pass.

The benefits of the round-robin recording are that it:

- 1. Promotes equal participation in the presentation of ideas.
- 2. Increases problem-mindedness and the ability to deal with a large number of ideas.
- 3. Separates the ideas from the person.
- 4. Allows for the tolerance of conflicting ideas.

- 5. Encourages hitchhiking on ideas.
- 6. Provides written records of the ideas.

Step 4: Serial discussion of ideas

This involves taking each idea, one at a time (serially) and discussing or clarifying the idea before the preliminary vote. The benefits of this step are that it:

- 1. Avoids unduly focusing on any one idea or a subset of ideas.
- 2. Allows for clarification and elimination of any misunderstanding.
- 3. Outlines the arguments and disagreements over ideas.
- 4. Records differences of opinion without undue augmentation.

Step 5: Voting

During this stage, group participants begin to narrow the list of potential ideas. Building on the discussion of ideas, individual members will make an independent judgment about those ideas they consider most likely to represent the problem to be solved or the potential solution to address it.

The two voting methods, typically used, are ranking and rating.

1. Rating method

When rating the ideas, each participant distributes a set number of points (e.g., 100) across the ideas, as seen in Exhibit 1.1.:

ldea #	Joe	Sue	Kelly	Jim	Total
1				50	50
2	40		30		70
3	20	100		32	152
4					0
5			30		30
6	20		30		50
7					0
8					0
9	20		5	18	43
10			5		5
Total	100	100	100	100	400

Exhibit 1.1. Rating Method

As seen in the table above, each of the four team members distributed their points across the ten ideas they generated during Step 2 (silent idea generation). Note that participants have the option of assigning all of their points to one idea if they believe strongly that it is truly the best (i.e., Sue). From the table, note that Idea 3 has the highest point total, and the team can end the NGT process at this point, and choose this option.

In another variation of this method, participants assign colored dots to ideas, using the same process.

2. Ranking method

When ranking items, each participant is asked to choose roughly half of the total number of ideas generated and to rank these from most important to least important. This process will emphasize fewer ideas. In preparation for recording the vote, the facilitator should list the number of each idea on a separate piece of paper. When the actual votes are recorded, she/he will record the rank assigned by each participant to the idea, as seen in Exhibit 1.2.:

ldea #	Joe	Sue	Kelly	Jim	Total
1	1			5	6
2	5		5		10
3	4	5		4	13
4					0
5		3	4	1	8
6	2	4	3	2	11
7					0
8		2			2
9	3	1	2	3	9
10			1		1

Exhibit 1.2. Ranking Method

As seen in the table above, Idea 3 has the highest score. In many instances, the nominal group technique will end after this step. If greater accuracy is desired, and especially if the group has generated a large number of ideas, the group may choose to engage in additional rounds of voting and discussion.

Appendix E. Using Change Concepts

The presentation slides below were included with permission from their author, Lloyd Provost. The slides provide an overview of how to use Change Concepts, as derived from the book, *The Improvement Guide: a Practical Approach to Enhancing Organizational Performance* by Langley, et al, 2009.

Using Change Concepts (list on p.132 of Improvement Guide and Appendix A)

Change Concept: a general notion or approach to change that has been found to be useful in developing specific ideas for changes that lead to improvement.

Complete List of Change Concepts

Eliminate Waste

- Eliminate things that are not used
- Eliminate multiple entry 2 3. Reduce or eliminate overkill
- Reduce controls on the system
- 5 Recycle or reuse
- 6. Use substitution
- Reduce classifications
- 8 Remove intermediaries
- 9 Match the amount to the need
- 10 Use Sampling
- 11. Change targets or set points

Improve Work Flow

- Synchronize 13.
- Schedule into multiple processes 14 Minimize handoffs
- Move steps in the process close together 15.
- 16. Find and remove bottlenecks
- 17 Us automation
- 18 Smooth workflow
- 19 Do tasks in parallel
- 20 Consider people as in the same system
- 21 Use multiple processing units
- 22 Adjust to peak demand

Optimize Inventory

- Match inventory to predicted demand
 47. Set up timing to use dia

 Use pull systems
 48. Optimize maintenance
 23
- 24
- 25 Reduce choice of features 26
- Reduce multiple brands of the same item 50.

Change the Work Environment

- 27 Give people access to information 28
- Use Proper Measurements 29. Take Care of basics
- 30. Reduce de-motivating aspects of pay system
- 31. Conduct training
- 32. Implement cross-training
- 33. Invest more resources in improvement
- 34. Focus on core process and purpose
- 35. Share risks
- Emphasize natural and logical consequences 36
- 37. Develop alliances/cooperative relationships

Enhance the Producer/customer relationship

38. Listen to customers

- 39. Coach customer to use product/service
- 40. Focus on the outcome to a customer
- 41 Use a coordinator
- 42. Reach agreement on expectations
- 43. Outsource for "Free"
- 44. Optimize level of inspection45. Work with suppliers

Manage Time

- Reduce setup or startup time
 Set up timing to use discounts
- 49.
 - Extend specialist's time Reduce wait time

Manage Variation

- Standardization (Create a Formal Process) Stop tampering Develop operation definitions Improve predictions
- 55. Develop contingency plans
- 56 Sort product into grades
- Desensitize Exploit variation

Design Systems to avoid mistakes

- Use reminders Use differentiation 60
- Use constraints
- 62. Use affordances

Focus on the product or service

- Mass customize
- Offer product/service anytime Offer product/service anyplace 64. 65.
- 66. Emphasize intangibles
- 67. Influence or take advantage of fashion trends 68
- Reduce the number of components Disguise defects or problems
- 70. Differentiate product using quality dimensions
- Move steps in process closer together 71.
 - Manage variation, not tasks

Reference: The Improvement Guide, Langley, Nolan, Nolan, Norman and Provost, p.359

Change Concept - Example

Change Concept - #51 - Standardize

Perform the same task in the same way. Performing the same task in a variety of ways results in broad variation in practice, a reduced ability to monitor outcomes, and wasted time, effort, and money.

Examples:

a) to increase the percentage of eligible patients discharged on ACE Inhibitors, implement standing orders for initiation of ACEI's during the hospital stay for all patients admitted with a diagnosis of CHF, unless contraindicated;

b) to increase the percentage of patients with daily weights recorded, include daily weights in a CHF management protocol that includes standing orders; and

c) implement standardized discharge teaching methods, including preprinted discharge instructions that allow for customization for an individual patient; and

d) document NYSA class, EF% and euvolemic weight in discharge summary.

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