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Primary Care Practice Transformation Is Hard Work:

Insights From a 15-Year Developmental Program of Research

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Abstract

Background—Serious shortcomings remain in clinical care in the United States despite widespread use of improvement strategies for enhancing clinical performance based on knowledge transfer approaches. Recent calls to transform primary care practice to a patient-centered medical home present even greater challenges and require more effective approaches.

Methods—Our research team conducted a series of National Institutes of Health funded descriptive and intervention projects to understand organizational change in primary care practice settings, emphasizing a complexity science perspective. The result was a developmental research effort that enabled the identification of critical lessons relevant to enabling practice change.

Results—A summary of findings from a 15-year program of research highlights the limitations of viewing primary care practices in the mechanistic terms that underlie current or traditional approaches to quality improvement. A theoretical perspective that views primary care practices as dynamic complex adaptive systems with “agents” who have the capacity to learn, and the freedom to act in unpredictable ways provides a better framework for grounding quality improvement strategies. This framework strongly emphasizes that quality improvement interventions should not only use a complexity systems perspective, but also there is a need for continual reflection, careful tailoring of interventions, and ongoing attention to the quality of interactions among agents in the practice.

Conclusions—It is unlikely that current strategies for quality improvement will be successful in transforming current primary care practice to a patient-centered medical home without a stronger guiding theoretical foundation. Our work suggests that a theoretical framework guided by complexity science can help in the development of quality improvement strategies that will more effectively facilitate practice change.

Keywords

primary care practice; organizational change; complexity science; complex adaptive systems; quality improvement

Tremendous time and resources have been dedicated to enhancing quality of care, including major reports¹ and an ongoing commitment from the National Institutes of Health and Agency for Healthcare Research and Quality for implementation and dissemination research. These and other sources have documented major shortcomings in primary medical care in the United States,² including serious difficulties in providing high quality chronic care,³ preventive services,⁴ and care for mental health and emotional problems.^{5,6} In response to these shortcomings, evidence-based guidelines have been constructed and new models of care proposed that are intended to be more responsive to changing patient demographics and multiple chronic health problems.⁷ Much effort has been placed on knowledge transfer strategies that focused on improving clinical performance. Some of these have focused on a single health problem or clinical process, while others have focused on overall organizational change. A variety of system change strategies, derived from Total Quality Improvement methods and Total Quality Improvement application to hospital care,⁸ have been used to stimulate improvements in primary care; however, these have been disappointing.^{9,10}

Several characteristics of community-based primary care practices prevent them from realizing their potential to provide high quality care. First, current configurations of primary care practices evolved from an acute care model based on the primacy of the physician role, archaic information systems, and a preponderance of patients with time limited acute illnesses, and have not adapted to accommodate the longitudinal, prospective, population-based nature of chronic illness care.^{7,11} For example, practices often lack office systems to support improved chronic illness patient self-management, delegation, care management, and systematic tracking to assure optimal processes and outcomes of diabetes care. Practices operate on a narrow financial margin, have minimal flexibility in resource use, and are quite different from those systems in which adoption of chronic care management components have been demonstrated.^{12,13} Many mixed-payor primary care practices do not have sophisticated management teams, are nearly consumed by survival in the current health care environment, and are not equipped for the challenge of managing the fundamental practice changes needed to improve care.¹⁴ Finally, primary care physicians deal with a wide range of interdependent comorbid conditions and are hesitant to adopt best-practice models on a disease-by-disease basis.

Advocates of the widely touted Chronic Care Model suggest that scarce resources be spent reorganizing office processes and systems to encourage and enable clinicians to improve care among all chronic diseases rather than implementing parallel systems for every deserving condition.^{9,15} Similarly, major primary care professional organizations and the National Committee for Quality Assurance or NCQA emphasize the need for more wholesale primary care practice transformation to create what is referred to as the “patient-centered medical home” (PCMH).^{16,17} The concept of a PCMH has been propelled into the national debate on health care reform making understanding the change process of critical interest to health care systems, funders, and others involved in health care reform.^{18,19}

This manuscript highlights critical findings derived from a collaborative teams' 15-year developmental program of research aimed at enhancing quality of care in primary care practices. In a recent series of publications, quality improvement research has been criticized for not capturing a sufficient understanding of the organizational change process or why interventions do or do not work.²⁰ This is due in part because research is often conceived of as individual, largely independent studies or series of studies; however, this conceptualization fails to capture the potential learning that can only be gleaned from implementing research as an ongoing, longitudinal development process with multiple interdependencies among investigators and projects. Collaborative multidisciplinary teams working across projects and over time have built the capacity to learn well beyond what would have been possible by individual investigators or investigative teams working on a single project.²¹ Since much of the important learning from studies derives from the way sequential and concurrent studies are able to inform each other, the evolution of the program of research and the context for key findings gained along the way is critically important. The goal of this article is to describe the cumulative and synergistic learning that arises using a longitudinal, collaborative, mixed methods developmental design that facilitates a more comprehensive and richer understanding of practice development than would be possible even with tightly linked sequential studies. These studies not only inform each other in the traditional way, but were developmental in terms of research questions, theory development, research methodologies, and interpretation of findings.

PROGRAM OF RESEARCH

Emergent Longitudinal Mixed Methods Developmental Collaborative Design

The program of research described in this manuscript has studied over 350 primary care practices in an interdependent developmental progression of multimethod observational and intervention studies that informed each other in an “emergent design,” whereby learning from each study was informed and influenced by the other studies as shown in Figure 1. A hallmark of this program of research was the use of a diverse transdisciplinary collaborative team that continually met together to develop strategies for integrating qualitative and quantitative methods.²¹ This collaborative team spanned across all the studies in Figure 1, but additional expertise was brought in as needed. The following describes the evolution of the studies in Figure 1, highlighting the key findings from each and how each subsequent study was developed from previous ones.

Early Formative Studies

The early work laying the foundation for this program of research was based on the then common assumptions that quality of health care could be improved by focusing on the physician and assisting her/him in acquiring knowledge, organizing time, addressing competing demands, and becoming more efficient.²² These early studies encompassed a wide range of topics including pain and pain management,²³ approaches to diabetes care,²⁴ depression management,²⁵ mammography and breast cancer screening,²⁶ and tobacco cessation efforts.²⁷ Results of this work led our research team to challenge underlying assumptions about variation in clinical practice and the conventional wisdom of focusing improvement efforts on individual physician behavior and by isolating specific health problems. It was recognized that physicians were part of larger systems (eg, practices) and that care of specific health problems were not independent of the total care of the patient, who often has a complex array of multiple problems.²⁸ It was further recognized that barriers to improved primary care were not necessarily physician knowledge deficits, but were often founded in more complex interplay of physicians, patients, practice members, and communities. These understandings were grounded in the realities of busy primary care practices, and led to a belief that efforts to improve practice should be preceded by efforts to

understand practice and that for practice improvement interventions, one size does not fit all.
28,29

The Direct Observation of Primary Care Study (DOPC)

The first iteration of this multimethod research strategy was implemented in the National Cancer Institute (NCI) funded “Direct Observation of Primary Care” (DOPC) project, which used a combination of direct observation, survey, chart audit, and descriptive fieldnotes.³⁰ DOPC collected data from the direct observation of 4454 outpatient visits to 138 family physicians in 84 practices in which pairs of research nurses worked several days in each practice and collected data on the content and context of each outpatient visit, using a combination of direct observation of the patient visit using a modification of the Davis Observation Code³¹; an observation checklist of services delivered during the patient visit; a patient exit questionnaire; a medical record review; and a summary of billing data using CPT codes. A practice level observational checklist, clinician questionnaires, and ethnographic fieldnotes dictated at the end of each day were used to capture practice features and characteristics. The DOPC data indicated that primary care practice was much more complex than generally acknowledged and that this had implications for practice change efforts.³² For example, DOPC data provided valuable insights into a diversity of physician, patient, and practice characteristics that needed to be understood, such as the fact that 4 to 5 problems were addressed in the typical 10 to 15 minute visit and that primary care physicians delivered a wide range of services and often did this opportunistically in illness visits.^{32–34} These data also identified the necessity for understanding practices as complex adaptive systems.³⁵

Prevention and Competing Demands in Primary Care (P&CD)

Building on the DOPC study, a more detailed study was designed to better understand the organization context of primary care practices and the variation seen in the delivery of preventive services. The “Prevention and Competing Demands in Primary Care” study (P&CD) was funded by Agency for Healthcare Research and Quality to study 18 family practices in detail using a multimethod ethnographic design, which involved extensive observational field notes of clinical encounters and the office system.³⁶ A field researcher trained in qualitative methods was sent to each practice where she used a variety of data collection methods to produce a comprehensive picture of each practice as a functioning organization. Data were collected through observation of the practice, the use of structured checklists of the office environment, observation of patient encounters, graphing patient pathways as they made office visits, individual depth interviews with physicians and other key staff members, and chart audits. These data contained detailed descriptions of the clinic location and environment, patient characteristics, nursing station, examination rooms, waiting areas, physician offices, bulletin boards, posters, and patient education materials. Existing practice personnel, their roles and duties, and their relationships and interactions with other staff members were characterized in a practice genogram.³⁷ Physical office systems including charts, flow sheets, and computer systems were described, as well as functional office routines and procedures. This adaptation of case study methods was structured into a Multimethod Assessment Process (MAP) and developed into an important research tool and a fundamental component of interventions in subsequent studies.³⁶ For example, as described later, the STEP-UP (Study to Enhance Prevention by Understanding Practice) study facilitators used the MAP to collect data for identifying particular values, structures, and processes that were used in helping practices select specific intervention options that best fit existing contexts, while in ULTRA (Using Learning Teams for Reflective Adaptation) the facilitators used MAP to collect data to generate reports that could be discussed with practices to stimulate motivation and intervention targets.

Early analyses of the DOPC and P&CD studies led to the realization that traditional theoretical frameworks for understanding the data were not adequate if the purpose of collecting the data was to develop strategies and tactics for organizational improvement. This eventually led to the use of complexity science as an organizing framework for interventions.^{35,38–41} Complexity science principles provided a framework for understanding how complex behaviors emerge from relationships among agents in a practice and increased the research team's focus on the larger context in which practices operate. The data from DOPC and P&CD provided evidence that practices coevolved with their environment in ways that were often highly dependent on the initial conditions within which they operated. Practices were not best described in mechanistic terms, because all the parts and people of a practice were interconnected and interdependent in terms of both relationships and functions. Additionally, it was noted that changes in one part of the practice often had ripple effects through other parts of a practice. Those ripple effects often created tension and problems that could be barriers to change. A key P&CD result was that what worked in one practice may not work in another, and that there were many different ways of achieving good outcomes.⁴²

Further analyses and a more in-depth review of the complexity science literature identified key principles of complex adaptive systems (CAS) that are very useful for characterizing primary care practices. These included: (1) a CAS consists of “agents” with capacity to learn and freedom to act in unpredictable ways; (2) the agents are often individuals, but they also may be teams, organizational processes, technical components; (3) agents are connected in nonlinear ways such that one agent's actions changes the context for other agents; and (4) the quality of the interactions among agents is more important than the quality of the agents. Basic properties of a complex system include: *self-organization*, which describes how systems generate new structures and patterns over time as a result of their own internal dynamics (order emerges from patterns of relationships among agents)⁴³; *emergence*, the process by which nonlinear interactions among agents results in new patterns of behavior (the system that evolves over time is more than the sum of its parts)⁴⁴; and *coevolution*, the process of mutual transformation of the agent and the environment in which it exists.⁴⁵

Study to Enhance Prevention by Understanding Practice (STEP-UP)

Principles of CAS were applied in the NCI funded STEP-UP trial, a group randomized quality improvement trial to improve cancer screening services among 80 randomly assigned family practices in Ohio. A focused MAP procedure developed from the P&CD study was used in this intervention by a trained facilitator who observed practice operations and patient visits, while also conducting key informant interviews that focused on the practice's values, structures, and processes. The MAP data were used to help practices reflect on their goals and to alter their structures and processes to enhance preventive service delivery in ways that were congruent with their core values. The intervention itself concentrated on having practices choose and implement from a menu of tools and approaches that had been found to be effective in previous studies.

The STEP-UP tailored approach resulted in substantial increases in a global measure of preventive service delivery, with significant increases in both screening and health habit counseling subscores.⁴⁶ Whereas most intervention effects decay toward baseline after the outside intervention stimulus ends, remarkably, the STEP-UP effect was sustained over 2 years of follow up.⁴⁷ The sustainability of the intervention effect was likely due to the tailoring of the intervention to the unique values, structures, and processes of each practice which allowed the changes to become incorporated into the culture of the organization. For example, in practices where it was discovered that there were already valued processes in place for delivering nonprevention services, these same process could often be adapted to deliver preventive services.

Insights From Multimethod Assessment of Change Over Time (IMPACT)

Although the STEP-UP intervention resulted in some practices making dramatic and sustained changes in their cancer screening,^{46,47} other practices seemed unaffected. Thus, the NCI-funded IMPACT study performed a systematic comparative case analysis of STEP-UP qualitative MAP data to develop a refined model of organizational change. The research team developed a series of models for understanding and enhancing practice change which built on prior understandings of complexity science and interrelationships affecting practice change.⁴⁸ The “IMPACT” model (Fig. 2) depicts coevolutionary process factors that were important for understanding and facilitating a complex change in primary care practices.⁴⁹ The model suggests that interventions must simultaneously integrate interrelationships among different model elements. Key stakeholders were people who have an investment in the practice and capacity to influence how the practice acts, with motivation of key stakeholders being defined as the desire or interest of key stakeholders to make an effort toward a particular target. Resources for change are qualities and characteristics that enable a primary care practice to modify both technical aspects of the practice and the practice's values and/or beliefs regarding how they operate. These resources include a wide array of strengths, skills, resources, and competencies such as leadership and decision making, culture, communication and relationships, management infrastructure, and information mastery (access to and use of information). Opportunities for change included how practices understand the opportunities that were available at any given time. Outside motivators were the outside systems, events and environmental characteristics, including healthcare system and community agents that could influence and be influenced by the practice. These forces shaped how practices saw themselves and their opportunities for change. The model depicts a dynamic system with multiple interdependencies among model elements. The character of these interactions, and the perceptions attached to them, can become more apparent during change efforts and can enhance or impede change. An important feature of primary care practices (and all organizations) is that practice resources and capabilities are highly interconnected; a change in one area can reverberate throughout the system, thereby altering the landscape of the practice.

Using Learning Teams for Reflective Adaptation (ULTRA)

The complex interdependencies noted in the STEP-UP intervention study and the understanding of the importance of relationships identified in the IMPACT observational study led to the development of the ULTRA intervention. NHLBI funding was obtained for the ULTRA intervention trial that randomized 60 practices to intervention and control conditions. The intervention involved MAP data collection that included qualitative observational fieldnotes, key-informant interviews, and audio-taped depth interview data. These data from MAP were summarized into a report that was reviewed with a practice before getting them to engage in a Reflective Adaptive Process (RAP) in which on-site change facilitators worked with an improvement team within each practice over a 6-month period with a focus on improving communications and relationships among the practice personnel. These RAP teams were made up of diverse participants including physicians, nursing staff, receptionists, and patients. All RAP meetings were audio recorded and fieldnotes were taken by the facilitator during RAP meetings. In addition, follow-up 1- to 2-day Mini-MAP observation notes were taken at 1, 2, and 3 years postintervention. Analysis of ULTRA data confirmed the fundamental importance of trusting relationships and rich conversations in the capability for making and sustaining improvement changes.^{50,51} A “dual hierarchy” was observed in many practices in which there was a purposeful separation between the physician staff and the “support organization,” creating additional challenges for the relationship system.⁵² In addition, practice leadership systems often lacked constructive attributes and were generally challenged in understanding the role and use of power in relationships. The data also provided insights into the challenges of implementing

innovations like an electronic medical record that impacted the whole system. For example, practice leadership was often not involving staff in discussions about an electronic medical record until after a system was purchased nor did leadership appreciate how a new system might impact people's work roles and, therefore, their identities.⁵³ In addition, the ULTRA data provided further understandings of strategies for implementing interventions in complex systems, particularly strategies for enhancing communication and relationships,⁵⁴ including how traditional continuous quality improvement (CQI) approaches might need to be modified.⁵⁵

National Demonstration Project Evaluation (NDP)

Over the past decade there has been a growing recognition that primary care is in need of extensive redesign. One of the outcomes of this recognition has been the development of the "New Model Practice" espoused in the Future of Family Medicine Project.⁵⁶ The American Academy of Family Physicians provided funding for an ongoing rigorously evaluated 24 month National Demonstration Project (NDP) to implement the New Model Practice in a cross-section of family medicine practices and assessed 2 approaches to practice change, one facilitated and one self-directed. The NDP was implemented by TransformMED, a wholly-owned subsidiary of the American Academy of Family Physicians (<http://www.transformed.com/>) and evaluated by an independent collaborative team with 3 aims: (1) to discover what the theoretical model looks like in real world practices; (2) to generate new knowledge about the process of practice change; and (3) to evaluate the effect of 2 approaches on practice and patient outcomes, including patient-centered care.

Thirty-six practices were selected from among more than 300 applicants and randomly assigned to either a facilitated or a self-directed group. Practices in the facilitated group received ongoing and often intense assistance with their tailored implementation strategy, ranging from consulting, coaching, and facilitation of the practice relationships.⁵⁷ Practices also participated in in-person collaborative learning sessions and monthly conference calls with other practices. Practices in the self-directed group had access to tools and information through a website to guide their implementation of components of the transformed practice model, but otherwise had minimal contact with the NDP team. Process and outcome measures of both the facilitated and the self-directed practices included data collected from medical record reviews, patient and staff surveys, and direct observation and interviews.

The evaluation of the NDP applied complexity science concepts and had preliminary findings consistent with earlier studies in the program of research. For example, as identified in ULTRA, the most successful practices seemed to have shared leadership systems rather than an individual physician leader. Despite being highly motivated, some practices had serious problems within the relationship infrastructure that resulted in dysfunctional situations that required significant time and energy on the part of the facilitator.⁵⁷ A practice's capability for change at baseline was a significant determinant of that practice's progress, and equally important was the facilitator's ability to increase that capability. Technology in the New Model, while shining with possibilities, was not by any means an easy "plug and play" interface for the practices, and in fact, due in part to the ongoing challenges of technology, even the most successful practices experienced change fatigue.⁵⁷ A comparative analysis of the facilitated and self-directed practices indicated that most practices in both groups were able to implement many of the model components, but at the same time, almost all of them would have benefited from some form of external support.

A practice's capability for change at baseline was a huge determinant of its response to a change intervention or an implementation process.⁵⁷ The capability for change, in turn, was highly dependent on a healthy relationship system.⁵¹ Even when highly motivated for improvement, some practices had a seriously dysfunctional relationship infrastructure that

impeded change and frustrated change champions. Thus, initial efforts at change should assess and pay more attention to the quality of the interactions among staff than on the quality of the staff. To address dysfunctional relationship systems required significant time and energy on the part of a facilitator to address conflict that surfaced when change was attempted, but in many cases relationship systems appeared to be amenable to improvement.

DISCUSSION

The results that emerged during this 15-year program of research convincingly shows that primary care practices are very complicated small organizations with multiple competing demands, dual hierarchies, and challenging relationship systems. As Alexander and Hearld discuss elsewhere in this Medical Care supplement, grasping the intricacies of quality improvement implementation in a primary care practice requires moving from cross-sectional, independent effects to conceptualizing practices as integrated holistic systems with complex relationships and nonlinear interdependencies.⁵⁸ Thus, a useful metaphor is to think of a practice like a jazz combo, which encourages cognitive diversity among staff and constantly leverages this diversity to foster learning, emergence, and innovation.⁴¹

People working in practices are well educated and want to do well; however, they need support in finding ways to interact and collaborate with colleagues.⁵⁹ The data examined in this program of research indicates that most practices spend surprisingly little time on reflection and relationship building; for example, most have few, if any, meetings.⁶⁰ Thus, practices have great difficulty in developing ways to reflect on what they do and how they work together. A key component of interventions needs to be strategies and tactics to help practices develop time and space for thinking about what they do. Unfortunately, most practices are resistant to protecting time for reflection. They see it as an intrusion, thus, “forcing” time and space for reflection may be one of the more important components of a change management strategy.

Calls for transformation from the current status of primary care practice to the idealized vision of the PCMH will likely prove to be a greater challenge than merely achieving incremental improvement in clinical quality indicators or implementation of technology solutions.^{57,61} In fact, findings from our program of research suggest that changes to the PCMH cannot be achieved by even the most enlightened set of carefully engineered, sequential steps if it is not consistent with CAS notions of emergence and self-organization. The results of change efforts are often unpredictable and may, in fact, be negative, suggesting that patience is required to successfully manage change. True transformation often requires major changes in identities of agents, which in turn requires not just a change in roles (such as the job description of a medical assistant), but an interdependent and emergent change in relationships among agents. Emerging processes will not be the same in every practice, and the exact developmental pathway to transformation will be unique for each. Change often implies an endpoint; however, complexity science and coevolution lead us to understand that change is ongoing, and so processes need to be put in place to guard against change fatigue to maintain momentum. This may be in the form of reflective meetings,^{59,60} or the use of external resources from health systems, insurers, or state academies.

Adoption of CAS theory creates a theoretical framework for practice improvement that is neutral to specific tools such as Plan-Do-Study-Act cycles, run charts, and Pareto charts. In fact, the RAP strategy used in ULTRA is a variation on Plan-Do-Study-Act, but encourages attention to organizational characteristics such as relationship systems, communication, and leadership systems.⁵⁵ Many widely cited improvement strategies use staged change processes, where change is thought to take place through implementation of sequential steps,

or stages, to achieve a set of objectives. In fact, this has been considered the optimal approach to implementing change in primary care settings. For example, among staged change processes, CQI has been a particularly popular approach. Although CQI employs well-articulated aims, methods, and tools designed to achieve documented and measurable outcomes, the use of a theoretical framework for change based on complexity science will lead to a different view of how and when these might be implemented. Because any given change actually alters the conditions under which subsequent steps take place, all change strategies require frequent reassessment and tailoring. Thus, CAS suggests that even most relatively simple changes, more or less whole practice transformation, cannot be a carefully engineered, stepwise process, but rather will need to be the result of emergent properties, processes, and structures that evolve from a robust and resilient relationship system among agents.

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FIGURE 1.
The 15-year program of research.

FIGURE 2.
Organizational change model adapted from Cohen et al.⁴⁹