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Ambulatory Care Organizations: Improving Diagnosis

by
Kathryn Mack McDonald

A dissertation submitted in partial satisfaction of the
requirements for the degree of

Doctor of Philosophy
in
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in the
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of the

University of California, Berkeley

Committee in charge:

Professor Stephen M. Shortell, Chair
Professor Hector P. Rodriguez
Professor Thomas G. Rundall
Professor Urmimala Sarkar

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Abstract

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Kathryn Mack McDonald

Doctor of Philosophy in Health Policy

University of California, Berkeley

Professor Stephen M. Shortell, Chair

Ambulatory care comprises a major and increasingly important part of the U.S. and other countries' health care sectors. Every year in the U.S., about 80% of the population seeks care at a doctor's office, amounting to one billion visits. These visits divide almost equally between primary care and specialty clinic organizations. Diagnostic work is part of most ambulatory care, and central to over 40% of patient visits that originate due to a new problem or a flare-up of an ongoing chronic problem. Yet, the risks associated with diagnostic failures have not garnered much attention from health care leaders and policy makers until a recent National Academy of Medicine (NAM 2015) report synthesized research data with the statement that "most people will experience at least one diagnostic error in their lifetime, sometimes with devastating consequences." This dissertation first reviews organizational theories and measurement challenges relevant to diagnostic safety and quality in the context of ambulatory care, and then presents three papers analyzing specific organizational factors hypothesized to enable or thwart an accurate and timely diagnosis. The first paper targets delayed diagnosis from missed evidence-based monitoring in high-risk conditions (e.g., cancer) within five specialty clinics in an urban publicly funded health system. The second paper analyzes staff-reported office problems that could lead to diagnostic error (e.g., not having test results when needed) in over 900 primary and specialty clinics across the nation. The third paper examines the associations between two types of time pressure (i.e., encounter-level and practice-level), organizational factors, and patient effects including perceptions of missed diagnostic opportunities. The three primary conclusions from this work are 1) organizational vulnerabilities for missed monitoring common to the different clinics included challenges with data systems, communications handoffs, population-level tracking, and patient activities, leading to the development of 'design seeds' for context-flexible solutions to improve diagnostic quality; 2) two organizational factors – stage of health information technology (HIT) deployment and patient safety culture are associated with diagnostic-related office problems, and 3) encounter and practice-level time stressors in primary care clinics are associated with perceptions of greater adverse effects on diagnosis and treatment, and worse patients' experiences of chronic care from the clinic team, respectively, as well as associated with several organizational factors including HIT, patient-centered culture, relational coordination for interdependent teamwork, and leadership facilitation of changes to address frontline practice challenges. Taken together, the dissertation papers also demonstrate the applicability of the NAM Improving Diagnosis Conceptual Framework for research on ambulatory care organizations.

Dedicated to

All of us when we or loved ones occupy the role of patient and need organized care



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LIST OF ABBREVIATIONS

AHRQ = Agency for Healthcare Research and Quality
EHR = electronic health record
ENT = ear nose and throat
f/u = follow-up
GI = gastroenterology
HIT = Health Information Technology
HROs = High Reliability Organizations
MO-SOPS = Medical Office Survey on Patient Safety Culture
NAM = National Academy of Medicine
PCORI = Patient Centered Outcomes Research Institute
PCP = primary care provider
SEIPS = Systems Engineering Initiative for Patient Safety

CHAPTER 1

Introduction: The Nexus of Ambulatory Care and Diagnosis

Starting with cases, as patients are anonymously referenced by physicians, is a long tradition for learning and scholarly work in health care.

Case 1: Delayed Diagnosis, long enough delay for devastating consequences	Case 2: Delayed Diagnosis, short enough delay to improve prognosis
<p>January 2005: A 17-year-old boy goes to the emergency room by himself</p> <p><i>Complaint: severe pain in his left ankle</i></p> <p><i>The doctor finds nothing to explain the pain, and tells him he probably twisted his ankle without realizing it. "Go home, it will get better." He thinks the doctor must know, and decides not to complain about his pain anymore.</i></p> <p>April 2005: The boy is rushed to emergency room with severely labored breathing. Imaging shows cancer in his ankle and spread to his lungs. Ewing's sarcoma. He undergoes treatment.</p> <p>November 2006: Soon after his 18th birthday, the boy dies.</p>	<p>January 2005: A 17-year-old girl goes to the emergency room with her mother</p> <p><i>Complaint: severe pain in her left knee</i></p> <p><i>The doctor can find nothing to explain the pain, and says she probably bumped it on the soccer field and doesn't remember. She objects to this assessment. Her mother asks what to do about the pain. The doctor writes a prescription.</i></p> <p>February 2005: When the pain intensifies, the mother calls the pediatrician, who refers the girl to an orthopedic doctor, who orders an MRI, which shows a tumor in her tibia. Her lungs are checked and clear.</p> <p>March 2005: She undergoes a year of treatment for Ewing's sarcoma, and meets the boy in the hospital. They become friends.</p> <p>.....</p> <p>March 2015: Ten years later, the girl remains cancer-free.</p>
<p><i>He had a 30% survival chance at diagnosis because cancer had spread to his lungs</i></p>	<p><i>She had a 70% survival chance at diagnosis</i></p>

These contrasting cases of diagnostic delays, one more devastating than the other, motivate attention to the broad landscape of ambulatory care settings that patients traverse as they seek an accurate and timely explanation for their health care concerns. As medical knowledge expands the diagnostic labels available and the health care delivery system grows ever more complex, patients and their informal caregivers can play critical roles in navigating each diagnostic journey. But they expect help from organizations where they seek care.

With an organizational lens, this research targets two interwoven areas of importance to health care policy makers, health care professionals, and delivery system managers who aim to assure high quality care for patients. First, this research focuses on patient care outside of the hospital, the ambulatory care setting. Second, this research delves into the realm of diagnostic activity within this setting, and especially an emerging area of patient safety concern—diagnostic error, or its flipside, diagnostic quality and safety.

Ambulatory Care

Ambulatory care comprises a major part of the U.S. and other countries' health care sectors. According to the U.S. Department of Labor, the ambulatory care subsector has grown steadily over the last decade from approximately 500,000 to 585,000 establishments, mostly private facilities.(1) For comparison, the other two subsectors have also grown with close to 9000 hospital and 80,000 nursing and residential care facilities in the U.S. at the end of 2015.(2)

Over 900 million patient visits occur annually in ambulatory care offices throughout the U.S., with almost half to primary care physicians (general, internal medicine and pediatrics).(3) For all care—to specialists and primary care offices—a significant proportion of visits are for new problems (34.7%), chronic care routine problems (30.1%), and chronic care flare-ups (7.7%).(3) The average time that doctors report spending on a patient encounter is 22.6 minutes, with a range on the mean time from 16.6 to 33.0 minutes, depending on specialty.(3)

From an economic perspective, the outpatient setting accounts for 30.7% of health care expenditures in the U.S, only slightly below the inpatient level of 33.8%.(4) The Organization for Economic Development (OECD) reported that annual per capita growth rates for health care spending in OECD countries increased more for outpatient care compared to inpatient care (i.e., 3.9% versus 2.4% for 2005 to 2009, and 1.8% growth versus 0.7% from 2009 to 2013).(5) The absolute percentage of spending dedicated to outpatient care tends to be lower for most other OECD countries compared to the U.S.(4) A McKinsey Global Institute multi-country comparison found that in the U.S., the proportion of estimated excess spending for value, adjusting for wealth, concentrated in the outpatient setting. (6) In 2006, the U.S. spent almost \$650 billion more than expected for health care, with two-thirds of the excess attributed to outpatient care (e.g., \$436 of the \$850 billion in U.S. ambulatory spending).(6) Such estimates provided the impetus for health care reform targeted in part on innovations in primary care, the ambulatory setting more generally, and coordination of care across all settings. In response to policy-making and an aging, more chronically ill population, from 2010 to 2015, the U.S. health care sector added 1.0 million jobs in the ambulatory setting compared to 0.4 million in other settings.(7) The dynamics around ambulatory care organizations make them increasingly important in efforts to improve care and reduce unnecessary costs.

Organization-level research directed at ambulatory care, and in particular, the quality and safety of the care, has received relatively less attention compared to that conducted in the more circumscribed and homogeneous hospital environment. (8,9) Some research conducted

within or across hospital settings may translate to the outpatient environment, but there are key differences across these two major settings of care that could influence quality and safety outputs. For example, organizational structures are decidedly different between hospitals and clinics, such that hospitals have quality departments, while clinics typically do not have this function centralized or even available. In terms of patient care, logistical complexity and information exchange burden for high quality outpatient teamwork is greater compared to hospital care, while support systems for such challenges are less well developed.(9,10) Since decisions to seek care and the management of care extend beyond any given encounter in a doctor's office, the patient role in care is also more significant, and can have important consequences for quality and safety.(10,11) While a systematic review showed that patient safety incidents in primary care have a lower chance of long-term harm compared to events during hospitalization,(12) Sarkar noted that "the sheer volume of service delivery translates into a substantial public health burden from patient safety incidents in primary care." (13) Safety concerns in the hospital environment center around prevention of errors related to treatment, as opposed to diagnosis.(8,12)

Diagnostic Safety

According to a recent technical brief, significant gaps exist in ambulatory safety research, notably a lack of studies on patient engagement and timely and accurate diagnosis.(14) These two areas intertwine, as underscored by the patient-centered definition of diagnostic error put forth in a National Academy of Medicine (NAM, previously called the Institute of Medicine) report, *Improving Diagnosis*, released in 2015:

"The failure to: (a) establish an accurate and timely explanation of the patient's health problem(s), or (b) communicate that explanation to the patient." (15)

The definition incorporates the notion that diagnosis is both an event where a label is given, even if temporary and based on information available at the time, and also a process by which members of the health care system work to determine and communicate what health problems can be explained. It does not speak to preventability of an error because the NAM Committee oriented the definition and the entire report to a systems approach to improving diagnosis for patients. The systems approach follows on years of patient safety research and practice.

When patients see a doctor, go to the hospital, stay in a nursing home or otherwise have an exposure to the health care system, they may experience iatrogenic adverse events or other untoward effects. The mere exposure to health care, during diagnosis or treatment, carries risk. Starting about 25 years ago, some leaders of health care characterized these iatrogenic events as a problem, a risk that the system should reduce. Some of the attention arose from anesthesiologists in response to increasing costs of medical malpractice insurance. In the late 1990's, the Institute for Medicine (now called the National Academy of Medicine) developed its first report on patient safety, *To Err is Human*, the title reflecting the futility of punishing individuals in order to stop errors, and setting up the need for a broader perspective to tackle a

systems problem.(16) The report received significant media attention with the image of the lives lost from iatrogenic events being equivalent to a jumbo jet falling out of the sky every day. Since then, much activity has occurred to label many types of patient safety problems or iatrogenic adverse effects, determine underlying causes, and find remedies including attempts to infuse health care with a culture of other “high reliability organizations” such as nuclear power plants or aircraft carrier operations where terrible risks are top of mind for those running their systems. But the risks associated with diagnostic failures are only recently garnering action by health care leaders and policy makers (e.g., a Coalition to Improve Diagnosis formed in 2015^a).

Diagnostic errors are pervasive – about five percent of U.S. adults seeking outpatient care in a given year experience a diagnostic error.(17) Errors in diagnosis are also the most common type of paid medical malpractice claim and lead to 40,000 – 80,000 deaths per year.(18) Depending upon the data source, 25% to 59% of malpractice claims are attributable to diagnostic errors.(18–21) A study of over 90,000 diagnosis-related malpractice claims from 1986 to 2005 estimated payments summing to \$34.5 billion (inflation-adjusted to 2010 U.S. dollars).(18) Among almost 11,000 malpractice claims from the 2005–2009 National Practitioner Data Bank, diagnosis related problems accounted for 45.9% of paid claims from outpatient settings and 21.1% of paid claims from inpatient settings.(22) The NAM Improving Diagnosis Committee stated that “most people will experience at least one diagnostic error in their lifetime, sometimes with devastating consequences.”(15) Strategies to mitigate these errors are quite limited, particularly in the ambulatory care setting.(14,23)

Widespread research across specialties demonstrates that inadequate monitoring in high-risk outpatients leads to delayed diagnosis, one type of diagnostic error, responsible for preventable and significant patient harm.(24–26) For example, patients who have a positive fecal blood test but no follow-up colonoscopy within a reasonable time period may experience a missed opportunity to detect and successfully treat colon cancer. More research is needed to guide organizational strategies to detect and respond robustly to such high-risk situations in ambulatory care.

To galvanize the research community and in response to the NAM Committee’s recommendations for addressing research gaps, the Agency for Healthcare Research and Quality (AHRQ) held a research summit in September 2016 on improving diagnosis. The sessions focused on measurement, organizational factors, and health information technology (HIT), as each relates to diagnostic safety and quality.^b These three areas signal national research priorities, based on known gaps in the evidence that if filled, would be expected to contribute to improvements in diagnostic performance.(15)

^a For current details: <http://www.improvediagnosis.org/?page=CID>

^b Details at <http://www.ahrq.gov/news/events/ahrq-research-summit-diagnostic-safety.html>

Organizational Lens

Quality has been viewed historically as an organizational problem from the perspective of evaluating it, assuring it, and improving it. Safety, as a part, sister or daughter of quality, depending upon how these related areas are conceptualized, is also an organizational problem. Kimberley and Minvielle argue that concerns about quality in health care have moved “from the reflection of professional bureaucracy to a vehicle for fundamental change” whereby delivery systems undergo reorganization to manage, rather than simply assure quality.(27) Patient-centeredness also has early roots with the quality management perspective.

The prominence of quality and safety, particularly from the patient and payer perspectives, continues to increase with major shifts in payment policies and delivery system arrangements in the U.S. and abroad. (7,28–31) However, there are only the beginnings of attention to the role of ambulatory care organizations – specifically primary care and specialty care clinics—in assuring quality and safety, especially that which relates to the diagnostic aspects of health care.(14)

This study aims to tackle a corner of that void by developing three research papers tied to organizational theory and linked to the following three distinct ambulatory care settings: 1) five different specialty clinics in San Francisco serving mostly poor people and other vulnerable populations; 2) over 900 primary and specialty clinics across the United States that participated in a survey on organizational culture, HIT and office problems; and 3) 16 primary care clinics from accountable care organizations in Chicago and Los Angeles, and their patients who have diabetes, cardiovascular disease, or both.

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CHAPTER 2

Organizational Theory and Links to Three Papers' Research Questions

Organizational Theories

This background leads to a central question: What extant organizational theories are critical to understanding diagnostic safety and quality in the context of ambulatory care? Four organizational theories are particularly pertinent to understanding how organizations influence better or worse diagnostic performance: 1) human factors, 2) high reliability organizations, 3) relational coordination for interdependent teamwork, and 4) complex adaptive systems.

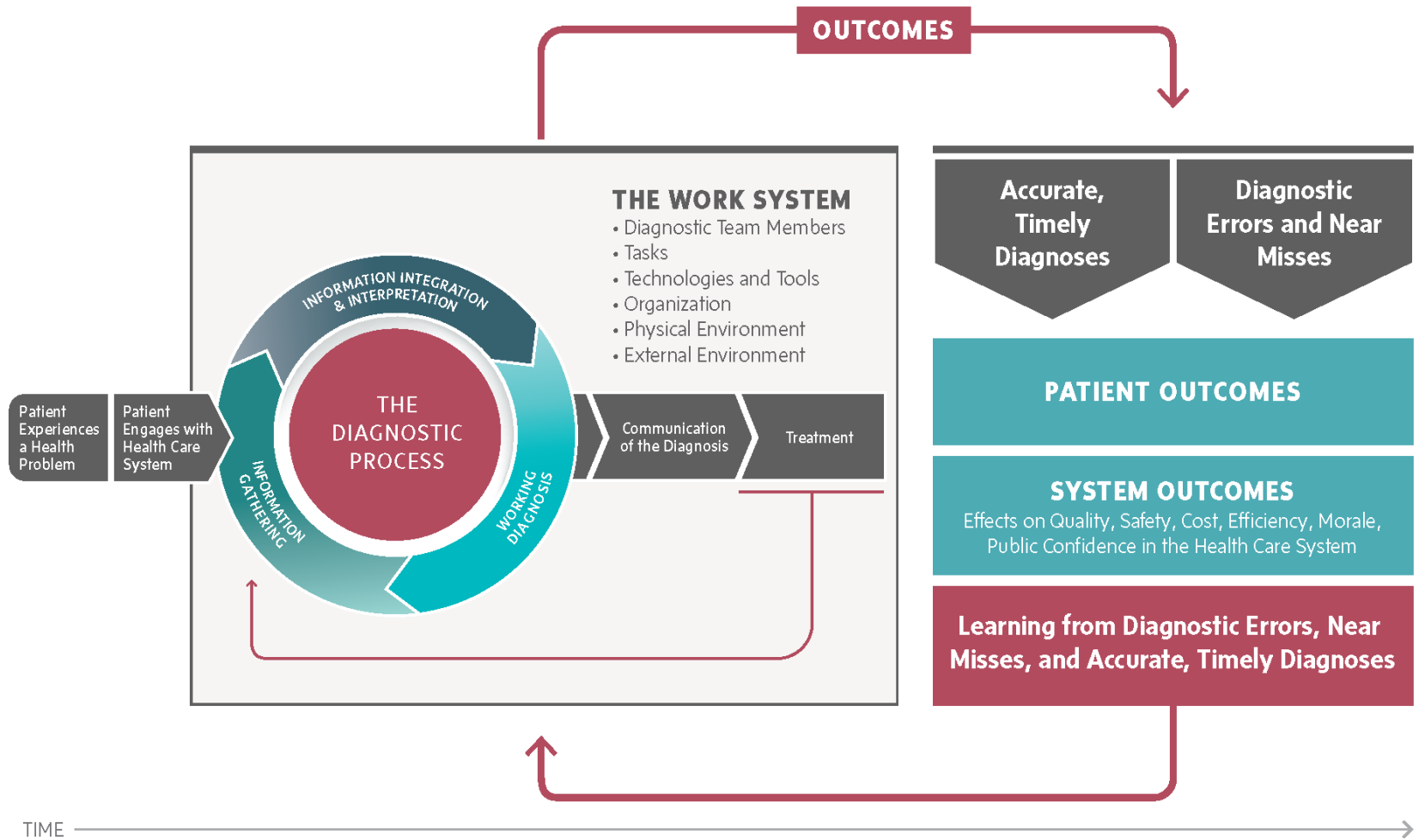
Human Factors Theory: NAM Conceptual Framework for Improving Diagnosis

The NAM Improving Diagnosis Framework (Figure 1) draws heavily from human factors approaches and theory in relationship to patient safety and quality, and serves as the guiding conceptual model for the three research papers.(1,2) From an organizational theory perspective, human factors ties to organizational design and systems approaches, based on the early contingency theorists' explication of the central issue of fit between environment, organizational structure and performance.(3,4) The NAM Framework has three main components – the diagnostic process, the work system, and outcomes. A feedback system is proposed whereby outcomes provide opportunities for learning at the level of individual patients as they move through the diagnostic process, and at the level of the organization as it works to improve care for its population of patients. The diagnostic process is conceptualized as a collaborative activity, centered on the patient and involving a cyclic decision making process of information gathering and clinical reasoning to determine a patient's health problem. The process transpires over time, within the context of a larger work system that influences the diagnostic process. The work system is composed of diagnostic team members (patients, families, all health care professionals), tasks (goal-oriented actions), technology and tools (including HIT), the organizational characteristics (including culture, rules, procedures, leadership), the physical environment (such as layout, noise and other distractions), and the external environment (including prevailing legal, payment, reporting, and accreditation circumstances).(1)

All components of the work system interact, and each component can affect the diagnostic process (e.g., a change in leadership may affect the assignment of tasks and the tools available), and consequently the outcomes for the patient and system. The work system can correspond to specific settings (or combinations thereof) in which the diagnostic process can occur—for example, primary care clinics, specialty care clinics, emergency departments, hospitals and other sites of care (including virtual, non-traditional and new forms of organizing, such as accountable care organizations). Each setting includes the six components of a work system with natural differences that depend on decisions and the environment applicable to a given setting.

The conceptual framework aligns well with findings from a focus group study that explored physician perspectives on improving the diagnostic process in ambulatory care settings.(5) In

Figure 1. NAM Improving Diagnosis Framework



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the study, the discussions were analyzed using the Systems Engineering Initiative for Patient Safety (SEIPS) model,(2) a foundation for the NAM Improving Diagnosis framework. Barriers perceived to timely and accurate diagnosis included factors related to organizational culture, information availability, and communication. Although cognitive factors have received much attention in the research literature on diagnostic problems, this ambulatory care study found greater concern about health system structure and interactions among health care professionals and with patients affecting the diagnostic process.(5)

The NAM report and others have highlighted teamwork among health care professionals, co-production with the patient, and HIT as highly relevant to the often complex and time-sensitive cognitive work related to diagnosis.(1,5–13) From this vantage, two work conditions are particularly applicable to diagnostic teamwork in the ambulatory setting and in patient transitions across settings – 1) level of time pressure experienced by the health care team and 2) capabilities (and limits) of HIT. Further study of these factors (part of the three papers) is important to understanding some mechanisms by which modern health care organizations impact the genesis and trajectory of each patient’s journey in the territory surrounding a new illness label.

High Reliability Organizations Theory

Extensive field work on industries facing hazardous conditions (e.g., nuclear power) resulted in a theory of High Reliability Organizations (HROs).(14,15) These organizations are characterized as having nearly error-free operations in contexts that are extremely complex, dynamic, interdependent and time-pressured, often features found in health care work. Weick and Sutcliffe identified five principles that undergird the ways HROs organize mindfully to anticipate, respond and contain unexpected events: preoccupation with failure, reluctance to simplify interpretations, sensitivity to operations, commitment to resilience, and deference to expertise.(16) Current organizational manifestations of these organizational approaches include Lean Six Sigma, Robust Performance Improvement (a recent Joint Commission initiative) and other variants to eliminate waste and reach zero defects.

Across these organizations, safety culture is prominent, and thought to produce high reliability.(17) A safety culture is the product of the shared values, attitudes, and patterns of behavior that determine the observable degree of effort with which all organizational members direct their attention and actions towards minimizing patient harm that may result from the process of care delivery. Building from earlier measurement research outside health care by Roberts et al(18) and within hospital units by Shortell et al,(19) Singer and colleagues developed the first hospital-wide measure of safety culture.(20) They demonstrated safety culture variation across hospitals and by type of personnel (e.g. leaders seem to have rose colored glasses compared to frontline workers).(20) The Agency for Healthcare Research and Quality (AHRQ) has developed and fielded an office-based safety culture survey. Vogus and colleagues have developed a safety culture framework of enabling, enacting and elaborating in a system of feedback about safety outcomes.(21) For patient safety, Walshe and Shortell highlight

challenges with learning resulting from the “culture of secrecy and protectionism” in health care settings, which they referred to as “endemic”.(22) The barriers to disclosure, and subsequently learning, may be stronger for diagnostic errors, though efforts to introduce apology and disclosure interventions, mostly in the hospital setting, may help. A systematic review of the literature on interventions to improve patient safety culture in primary care identified only two studies (electronic medical record implementation, physician workshops on risk management and event audits) with low evidence of effects.(23) Vogus and colleagues point to the interactions between elements of their framework suggesting the need for an emergent approach, which brings us to the next applicable source of pertinent organizational theory, complex adaptive systems. They also note the relevance of relational coordination (more below) as a mechanism to balance efficiency and safety concerns in the health care domain.(21)

Relational Coordination for Interdependent Teamwork Theory

Relational coordination is a mutually reinforcing process of communicating and relating for the purpose of task integration, for example, task related to making a diagnosis by all members of the team, including the patient (and family).(24) More specifically, relational coordination is the coordination of work across organizational boundaries through relationships of shared goals, shared knowledge and mutual respect, supported by frequent, timely, accurate, problem-solving communication.(25) Better relational coordination is theorized to improve performance of a work process, such as the diagnostic process, by improving the work relationships between people (shared goals, shared knowledge, mutual respect) who perform different functions in that work process, leading to higher quality communication. This enables task interdependencies to be managed more directly, in a more seamless way, with fewer redundancies, lapses, errors and delays. According to relational coordination theory, organizational structures serve to strengthen or weaken relational coordination depending on their design.(26,27) Relational coordination in turn is theorized to drive performance outcomes including quality and safety, particularly when work is highly interdependent, uncertain and time constrained, which can be the case for diagnostic work.(24)

This simple structure, process and outcomes model is highly linear and as such may not capture processes of change (e.g., interventions, planned or emergent) and their implications for outcomes (e.g., quality, safety). Gittell, Edmonson and Schein have proposed a relational model of organizational change, arguing that new organizational structures are not sufficient for creating new levels of relational coordination and new levels of performance.(24,28) Instead, they hypothesize that change agents may need to begin with *relational interventions* to foster new working relationships characterized by shared goals, shared knowledge and mutual respect, and *work process interventions* that create new ways of working together. *Structural interventions* then emerge from participants themselves, informed by their new working relationships and new ways of doing the work.

Complex Adaptive Systems Theory

Begun, Zimmerman and Dooley assert that “improvement of health care organizations individually and collectively, and research on those organizations, will best be facilitated by comprehensive application of the metaphor of the system as a living organism, rather than that of the system as a machine.”(29) Others have echoed this view, and increasingly place health care organizational research within a complex adaptive systems perspective, where emergent properties, variations, interactions, networks, robust responsiveness, and relationships take precedence over past constructs from earlier organizational theory (e.g. standardization, vertical integration, resource dependence, etc.). Begun and colleagues generated a useful list of implications for organizational research methods in light of a complexity perspective that includes: study emergence, patterns of interactions among agents, coevolution of the organization and environment, quality of relationships, and conditions that facilitate change.(29)

A new model developed by Sittig and Singh for studying HIT in complex adaptive systems is particularly relevant to health care quality and safety. In aiming to develop a comprehensive model integrating technological and measurement dimensions of HIT with socio-technical dimensions, they combined and extended four models (including Carayon’s Systems Engineering Initiative for Patient Safety (SEIPS) model(2) that served as a foundation for the NAM conceptual framework). The model features eight interdependent and inter-related dimensions reflecting the composition complex adaptive systems: hardware/software, clinical content, human computer interface, people, workflow and communication, internal organizational features (e.g., procedures, culture), external rules and regulations, that facilitate or constrain the preceding dimensions, and systems measurement and monitoring of both intended and unintended consequences of HIT implementation and use. They provide an example of applying the model to the complex adaptive system surrounding follow-ups of alerts related to abnormal diagnostic imaging results during various stages of development and implementation of HIT.(30)

Research Questions and Links to Key Frameworks

The research proceeds with three papers directed at the problem of quality and safety gaps related to the diagnostic phase of care emanating from the ambulatory setting. Subsequent sections are dedicated to the specific details for each paper. At a macro level, the research questions for the three papers are related to the conceptual framework from the National Academy of Medicine (Figure 1) as follows, with elements of the framework shown in *italics*.

Paper #1 “Implementation science for ambulatory care safety: A novel method to develop context-sensitive interventions to reduce quality gaps in monitoring high-risk patients”

- What *Work System* factors produce robust monitoring (*Systems Outcomes*) and fewer diagnostic errors (*Patient Outcomes*)?

Paper #2 “Health information technologies, patient safety culture and medical office problems that could lead to diagnostic errors”

- What are the associations between *Tools* (health information technology [HIT]), *Organization* (patient safety culture), and *Diagnostic Process* (medical office problems that could lead to diagnostic errors)?

Paper #3 “Organizational influences on time pressure stressors and potential patient consequences in primary care”

- Do *Diagnostic Team Members* perceive adverse effects from time pressure on the *Diagnostic Process*? What *Work System* and *Diagnostic Team Member* factors are associated with these effects?

The NAM framework also includes the critical role of time for achieving diagnostic quality and safety (Figure 1, *Time* arrow at the bottom of the diagram). The three papers also explore time as a work condition that is particularly salient in the current ambulatory care environment. Studying time from an organizational perspective is tricky, with contributing literatures from numerous vantage points spanning the philosophy of time to the social psychology of time to the experience of time in organizations. Ancona and colleagues reviewed this diverse literature from a managerial sciences perspective, and proposed three categories of interconnected variables —conceptions of time, mapping activities to time, and actors relating to time.(31) According to Ancona et al, “the (three-category) framework presented is meant to provide a starting point to begin a dialogue that spans the existing work and sets a new research agenda in the field of time and organizations.”(31)

This study’s time-related variables are described later, but in brief:

- Paper #1: exploring the impact of new work designs on *time spent* corresponds to Ancona’s activities category;
- Paper #2: analyzing *work pace* (as a sub-dimension of culture) relates to all three of Ancona’s categories; and
- Paper #3: defining chaotic versus calm work conditions as a *practice-level time pressure* links to how actors (practice team members) relate to time; and assessing perceived effects of *encounter-level time pressure* on patient safety corresponds to activity mapping, specifically how activities performed (or missed) may be subject to time pressure effects (overlooking a chance to diagnose).

Situating this study’s time-related variables within Ancona’s temporal framework could enable future contributions to organizational theory about time. For the diagnostic improvement field, such linkages could enrich characterizations of the NAM framework’s time dimension.

Critical Literature Gaps

While relatively strong foundations exist for the set of research papers from a theoretical perspective, the literature base is extremely limited for research related to two key elements of this study: time pressure effects and diagnostic performance in ambulatory care settings. The limited work is summarized as background about the need for research, as well as to position this study's contributions to these areas within a realistic range of possibility.

Time Pressure Research Base

Experimental studies on time pressure effects on judgment between choices (say among potential diagnoses suspected) point to different possible information processing adaptations and responses to experiencing a faster pace or just feeling rushed, especially outside of laboratory settings.(32) Cognitive processing by experts making decisions under uncertainty or ambiguity (as is the case for diagnosis) seem to use intuitive processing more prominently than analytic thinking with increased time pressure.(33) Under these circumstances, expertise is an important variable, likely moderating the decrements in performance with increasing expertise. However, the evidence about time pressure effects in light of level of expertise and complexity of the task is mixed for physician decision-making.(34–37)

The range of cognitive contributions to diagnostic error suggests a need for research on time pressure effects in actual practice, and in relationship to potential failure modes present in actual cases – faulty knowledge, faulty data gathering (e.g. ineffective or incomplete workup), faulty information processing (e.g., detection or perception of a symptom that was noticeable being missed), and faulty verification (e.g., premature closure on an initial diagnosis, not following up to gather new data about whether the situation has changed).(8,38) Picking up important contextual cues related to diagnosis may also be harder with time pressure, and secret patients offer a method for studying such potential effects.(39) In addition, the NAM Committee on Improving Diagnosis recommended attention to diagnostic teamwork,(1) an area where research on time pressure effects is also lacking (though some simulation studies include teamwork in time-sensitive clinical situations, such as obstetric emergencies which require some diagnostic decision-making).(40)

Tsiga et al conducted an experimental study on time pressure effects on general practitioners' adherence to guidelines for diagnostically relevant aspects of care (e.g., history taking, clinical examination, lab testing referrals, likelihood and certainty of the final diagnosis) as well as treatment recommendations for viral respiratory tract infections.(41) They found a threat to patient safety under the time pressure condition: physicians were less likely to ask questions and or examine the nervous system to consider a differential diagnosis of meningitis. Accuracy of this fairly routine diagnosis was not different between the two conditions, but physicians were less confident in their diagnosis under time pressure. Participants received all of the scenarios and time conditions, with a counterbalancing technique for order of presentation. (41)

Research on time pressure within ambulatory care is limited, but some studies have explored whether time spent with patients has a positive effect on patient care. A large study in the Netherlands of 239 general practices showed strong positive association between the amount of time spent with patient's face-to-face, as well as time spent in the practice outside of direct care, and patient's evaluations of the physician performance.(42) Another study by Chen et al in the United States found some evidence that increasing duration of primary care visits confers a modest association with quality of care.(43) But neither of these studies assess time pressure per se.

Linzer and colleagues have conducted several studies on the effects of time pressure, as well as a related work condition—chaotic practice environment, on physician and patient wellbeing.(44–46) In the Physician Worklife Study, Linzer et al surveyed over 5,000 primary and specialty care physicians from 1996-98, and found that time pressure diminished job satisfaction.(44) Time pressure was assessed based on a ratio of reported time needed to provide quality care compared to time allotted. Time pressure ratios were similar across specialties, with doctors reporting needing one to six extra minutes per patient to provide quality care.(44) A primary care study (MEMO- Minimizing Error, Maximizing Outcomes) from 2001-2005 of over 100 ambulatory clinics in the U.S. assessed physicians and their patients with chronic conditions (diabetes, hypertension, or heart failure) to determine associations between work conditions, physician reactions and quality of patient care.(45) Roughly half of the physicians (53%) reported time pressure during office visits and a chaotic work pace (48%). Adverse workflow (time pressure and chaotic environments), as well as low work control and unfavorable organizational culture were strongly associated with poor physician reactions (e.g., high stress, burnout). Time pressure ratios were assessed for two different appointment types. Time pressure for physical examination appointments was modestly associated with lower quality (based on medical record review), but there was no association between time pressure for follow-up visits and quality.(45)

Measurement of Diagnostic Safety and Quality

Diagnostic errors often go unrecognized, and even the most sophisticated health systems lack measurement capabilities much less the feedback mechanisms necessary for improving diagnosis.(47) The science of quality and safety measurement, itself in its infancy, must be deepened.(48) A system for the assessment of the validity and reliability of diagnostic performance measures needs to be established and made transparent.(47) There are many challenges that must be overcome in order to establish a reliable and sustainable measurement infrastructure for improving diagnosis, or researching it head on. However, some efforts are underway on measure concepts for diagnostic quality drawing from Donabedian's framework of identifying structures and processes related to outcomes of diagnostic safety. (49–51) Targeted condition-specific measures have also been used in interventional studies aimed at mitigating diagnostic error.(52) Studying diagnostic safety and quality will remain a challenge

without well-validated measures, but the National Quality Forum has work underway to establish a framework for measures in this area.^c

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^c Additional information: <http://www.qualityforum.org/ProjectDescription.aspx?projectID=83357>

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CHAPTER 3

Paper 1—Implementation science for ambulatory care safety: A novel method to develop context-sensitive interventions to reduce quality gaps in monitoring high-risk patients

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Introduction

A seminal National Academy of Medicine (NAM) report asserts that most people will experience at least one diagnostic error – a delayed or inaccurate diagnosis—in a lifetime, “sometimes with devastating consequences.”(1) In ambulatory care, one of 20 patients in the United States experience potentially preventable diagnostic errors annually.(2, 3) Missed cancer diagnoses are the leading reason for paid medical malpractice claims in the ambulatory setting.(4, 5)

Widespread research across specialties demonstrates that inadequate monitoring in high-risk outpatients leads to preventable high-risk events and significant patient harm.(5, 6) For example, patients who have a positive fecal blood test but do not follow up colonoscopy within a reasonable time period may experience a missed opportunity to detect and successfully treat colon cancer.(7, 8) The National Comprehensive Cancer Network has monitoring guidelines for screening (active and initial) as well as post-treatment cancer recurrence surveillance.(7, 9–17) Proactive and efficient strategies to respond to high-risk situations—such as overdue imaging or blood tests—are urgently needed to reduce the safety gap in evidence-based monitoring for cancer.(18–23)

Safety-net populations are particularly prone to failures in patient monitoring, given high prevalence of limited health literacy and lower English proficiency, as well as barriers like lack of transportation, inability to leave work for medical appointments, and a myriad of other obstacles to engaging with the health care system.(24–27) At the same time safety-net health systems often lack critical HIT infrastructure and resources (e.g., personnel time) to devote to monitoring these vulnerable populations.(28) Common software development practices favor mass production and rapid adoption over user-specified customization necessary for long-term sustainability in a safety-net setting.(29, 30) To accomplish robust patient monitoring and prevent adverse events, it is critical to identify setting- and population-specific vulnerabilities and needed attributes of effective interventions, whether technical, social, organizational or a combination.

Theories for complex delivery system interventions stress the importance of studying human and contextual aspects of change.(31, 32) The NAM Improving Diagnosis conceptual framework includes these factors, among others such as clinical reasoning and teamwork that contribute to diagnostic safety and improvement.(1) The framework explicates that patient and systems outcomes are produced by the diagnostic process which evolves over time, within the context of a larger work system composed of diagnostic team members, tasks, technologies and tools, organizational elements, and the physical environment.(33–35) To reduce the chance of missing a cancer diagnosis, vulnerabilities need to be addressed within both the ambulatory care’s diagnostic process and work system. In other words, what work system factors produce robust monitoring (systems outcomes) and fewer diagnostic errors (patient outcomes)? Research in this area is nascent, with many unknowns about specific vulnerabilities, patient

safety intervention opportunities, and subsequent implementations.(1, 36) Taylor et al identified four theoretical domains of contextual features determined by expert consensus as important for patient safety intervention implementations: safety culture, teamwork and leadership involvement; structural organizational characteristics; external factors; and availability of implementation and management tools.(37)

To develop theory-based, context-informed organizational interventions for closing the safety gap, our study introduces a unique integration of user experience and human factors methodologies: journey mapping and design seeds. We apply journey mapping to clinician-centered workflow focused on patients at high risk for a missed monitoring opportunity to diagnose cancer.(38) Previous applications have taken the perspective of an individual patient's journey within a health care setting.(39–41) Design seeds are solution attributes that separate the goal of a modular intervention (e.g., alerting patients that they need to return to the clinic) from the means for achieving it (e.g., use of a web portal messaging system).(42) They have the advantage of generating multiple solutions to the same problem so unknown vulnerabilities and preferences can be uncovered, interventions can be tailored to different contexts, and more solution variations can be considered to evaluate correct fit.(43) To apply design seeds to patient monitoring^d, we draw from a somewhat analogous situation studied outside of health care: intelligence analysts who experience time pressure and data overload as they cull through numerous documents to identify national security threats.(44) Our approach will inform prototyping, piloting and full-scale testing of technical and organizational interventions, with the aim of producing robust population-level monitoring solutions for widespread implementation.

Methods

Design

We conducted formative research, following a 6-stage co-development process between the research team and frontline clinicians (attending doctors, residents, nurse practitioners, registered nurses) to identify solution attributes of a comprehensive intervention for more robust monitoring of high-risk cancer conditions over time (Figure 2). The research team applied human factors strategies and organizational theory about complex adaptive systems within five specialty clinics to identify vulnerabilities and generate desirable solution attributes for interventions. (1, 37, 45, 46)

^d Patient monitoring for cancer, in this paper, is broadly construed to include an expansive set of diagnostic opportunities, not just one definitive and staged cancer diagnosis. Ambulatory safety risk in this context includes identification of high-risk patients, pre-diagnosis testing, definitive diagnostic procedures (e.g., biopsies), and even longitudinal post-diagnosis follow up (e.g., keeping track of patients for whom treatment is delayed on purpose, or following patients after treatment for cancer recurrence).

Ethical approval for semi-structured interviews and feedback sessions with clinic personnel for quality improvement purposes was reviewed and waived by the institutional review board of the University of California, San Francisco.

Figure 2. Co-Development Research Process

<p>Key Questions Based on NAM Improving Diagnosis Framework <i>PROBLEM: What vulnerabilities exist in monitoring outpatients for high risk conditions (e.g., cancer)?</i> <i>SOLUTION: What elements of work systems and the diagnostic process are important to produce robust monitoring & thereby reduce diagnostic errors?</i></p>
<p>Stage 1: Identify 5 High-risk Populations</p> <ul style="list-style-type: none"> • Review literature • Corroborate with local clinicians taking care of these patients
<p>Stage 2: Develop Journey Maps</p> <ul style="list-style-type: none"> • Identify key participants to learn about workflows for each high-risk population • Elicit with semi-structured interview a description of the patient and data flow from worker’s vantage • Visualize this information into swim lanes or “clusters” of activities • Show swim lanes to participants and revise (as needed) • Visit clinic sites to observe critical parts of process (as needed)
<p>Stage 3: Generate Vulnerability List</p> <ul style="list-style-type: none"> • Abstract vulnerabilities from interview notes and journey maps • Return to clinic participants to validate the list (one or more clinic has indeed experienced vulnerability) • Map validated list of items to theory domains from applicable patient safety frameworks [1, 56]
<p>Stage 4: Analyze Journey Maps for Commonalities</p> <ul style="list-style-type: none"> • Categorize types of activities in the journey using human factors method of process tracing (novel extension to derive tracings from journey maps) • Generate process trace sequences for each clinic’s workflow [57] • Look for patterns of workflow that are similar and variable across the 5 populations
<p>Stage 5: Develop Design Seeds for Interventions and Link to Implementation Theory</p> <ul style="list-style-type: none"> • State what a solution would need to do to address vulnerabilities identified from previous stage • Reduce the list to solution attributes (design seeds) that address common problems and needs across clinics • Aim for design seeds that meet the generic needs of robust monitoring and that enable evaluation • Hypothesize which contexts are likely to affect the effectiveness of the implementation of the interventions emanating from the design seeds using Taylor et al’s contextual domains and features [37]
<p>Stage 6: Seek Reactions from Clinics on Design Seeds</p> <ul style="list-style-type: none"> • Assess anticipated impact (improved monitoring of patients, reduced time spent by clinic team) and relative priority of each design seed (see Appendix 1 and 2 for script and data collection used in each clinic)

Setting

The San Francisco Health Network is a publicly funded, integrated health network operating under the auspices of San Francisco’s Department of Public Health and includes 14 primary care clinics, urgent care, and specialty care at Zuckerberg San Francisco General Hospital.

Patients seen within the network are diverse: of those seen at the network's main clinic and hospital, 18% are African American, 31% are Latino, 22% are White, and 21% are Asian. Services are provided in over 20 languages. Based on outpatient days, only 1% of the population has commercial insurance, 14% uninsured, 16% Healthy San Francisco (a citywide sliding scale health access program), 42% Medi-Cal, 17% Medicare, and the remaining 10% covered by other mostly public sources.(47) Others have categorized hospitals according to safety-net burden, with high-burden ranging from 33 or 36% to 100% of patients as those with Medicaid or no coverage.(48, 49)

Like many safety-net systems and ambulatory practices nationwide, the health system does not have a comprehensive electronic health record system and struggles with information transfer as well as fragmentation of health information across over 50 electronic platforms. Despite some of the HIT challenges and known workarounds typical of these safety-net settings, the organization has a longstanding commitment to both human-centered strategies (patient-centered medical home, plan-do-study-act cycles) and Lean management methods.(50)

Evidence-based Safety Gaps Targeted (Stage 1)

Based on literature about missed and delayed diagnoses, including reports from medical malpractice, we selected five high-risk cancer situations—incidentally-discovered pulmonary nodules, and monitoring for breast, colorectal, prostate, and ear, nose, and throat (ENT) cancers—for which coordination and timely use of data are important for patient safety surveillance but challenging to implement, particularly in safety-net settings.(4, 5, 51) These challenging high-risk situations require recurring and timely follow-up care to prevent harm.(7, 9–17, 52)

Our team (GS, SL, KM) conducted a series of theoretically informed semi-structured interviews with participants from each of five specialty clinics responsible for these high-risk patients: pulmonary medicine, breast cancer, gastroenterology, urology and otolaryngology. As part of these interviews, we corroborated the specific safety targets by asking frontline clinicians: “What keeps you up at night?” and “What are your clinical hunches about who might fall through the cracks?” Although providers talked about the types of patients lost to follow-up, none of the clinics were enabled with a standardized and efficient method for quantifying how many patients were lost to follow-up, why patients were lost to follow-up, or even which patients were lost to follow-up. Many other health networks share similar struggles with incomplete documentation and measuring the real-time scope of patient safety problems.(53)

Mapping and Analyzing Clinical Workflows (Stage 2 through 4)

The interviews in each of the five cancer clinical settings followed a user-centered design approach called journey mapping, a tool widely used across multiple industries.(38, 54, 55) Journey mapping derives from user experience initiatives in industry that informed the

improving diagnosis framework proposed in the recent NAM Improving Diagnosis report.(1, 34, 56) The method articulates and documents a process through a specific point of view (typically, a customer). In the health care field, it has been applied to elicit individual patient journeys through the clinical workflow.(40) Our team-based variation of journey mapping has a patient population management view. We elicit specialty care management through the experiences of the clinical team as they try to track the host of patient data required to monitor their high-risk population. To our knowledge, this technique has seldom been applied to the ambulatory setting, and has not been targeted to clinic workflow efficiency or patient safety intervention development.

We directed these journey mapping sessions to: (1) isolate the steps in the patient monitoring journey that are the most critical, time-intensive, and risky relative to the safety gap, (2) identify critical data elements needed to effectively and safely monitor patients, and (3) gather potential attributes of organizational and technical interventions to ameliorate workflow problems. To construct the journey maps, investigators probed clinical participants with questions such as: “What are you working on?” to elicit actions taken; “Who is responsible for which task?” to learn about monitoring-related activities; “Are there external stakeholders?” and “How important are they?” to surface coordination challenges outside of the clinic. Based on what participants articulated, we constructed a journey map for each clinical pathway with their review and endorsement. The maps focus on the transfer of patient data throughout the patient’s monitoring experience, starting with the initial diagnostic assessment and ending with the ongoing follow-up. Whenever participants verbalized elements of the pathway that were particularly vulnerable to error or poor monitoring, we marked the activity with a bull’s eye target, also referred to by clinicians as a ‘pain point’.

From the journey mapping sessions, we generated a comprehensive list of vulnerabilities experienced by at least one clinic. To verify the list and gauge how many of the clinics experienced each of the vulnerabilities, we returned to the clinic with a data collection instrument (Appendix 1). We also mapped the vulnerabilities corroborated by at least one clinic to domains from patient safety theoretical frameworks.(1, 56)

Using standard process tracing techniques from human factors, we categorized and summarized the sequence of activities described in journey maps.(57) The trace sequences are used to determine the similarity of activity flow among clinics that monitor high-risk populations as well as any differences between clinics to inform well-designed interventions.

Developing Design Seeds and Linking to Implementation Theory (Stages 5)

Design seeds and the human factors approaches from which they stem have been used outside of health care for development of complex socio-technical interventions.(44, 58) They serve as bridges to technical and organizational solution options that can be designed differently depending upon context, but that use common attributes. As such, they offer an appealing addition to the implementation science toolkit. In simple terms this approach replaces the

typical technical approach (Figure 3) with a theoretically based socio-technical system understanding (Figure 4). As shown in Figure 4, design seeds link the vulnerabilities experienced to potential solutions in a specific and evaluable way. This promotes the evaluation of a “seed” to a solution, rather than a full-fledged solution itself as is practiced in software development cycles often used in HIT.(59) By jumping directly from “problem” to “solution,” one opens the door to various misdirected applications that do not appropriately mediate the diverse instantiations of a problem. The evaluation of design seeds prior to the development of a solution creates an opportunity for more cost-effective and user-customized solutions.(44)

Since a design seed features a series of evaluable statements, the approach enables intervention testing at the right point in the pathway for a specific action (e.g., does the intervention work according to the design seed criteria? yes, no, or partially). In order to set up theory-based implementation, we (KM, SL) independently used these statements to hypothesize which contexts are likely to affect the effectiveness of implementation of the interventions emanating from the design seeds. We used Taylor et al’s four contextual domains and 13 specific features that a technical expert panel judged as high priority for assessment (as opposed to simple description) in the evaluation of a varied range of patient safety intervention implementations. (37)

Figure 3. Technical Intervention Development Cycle

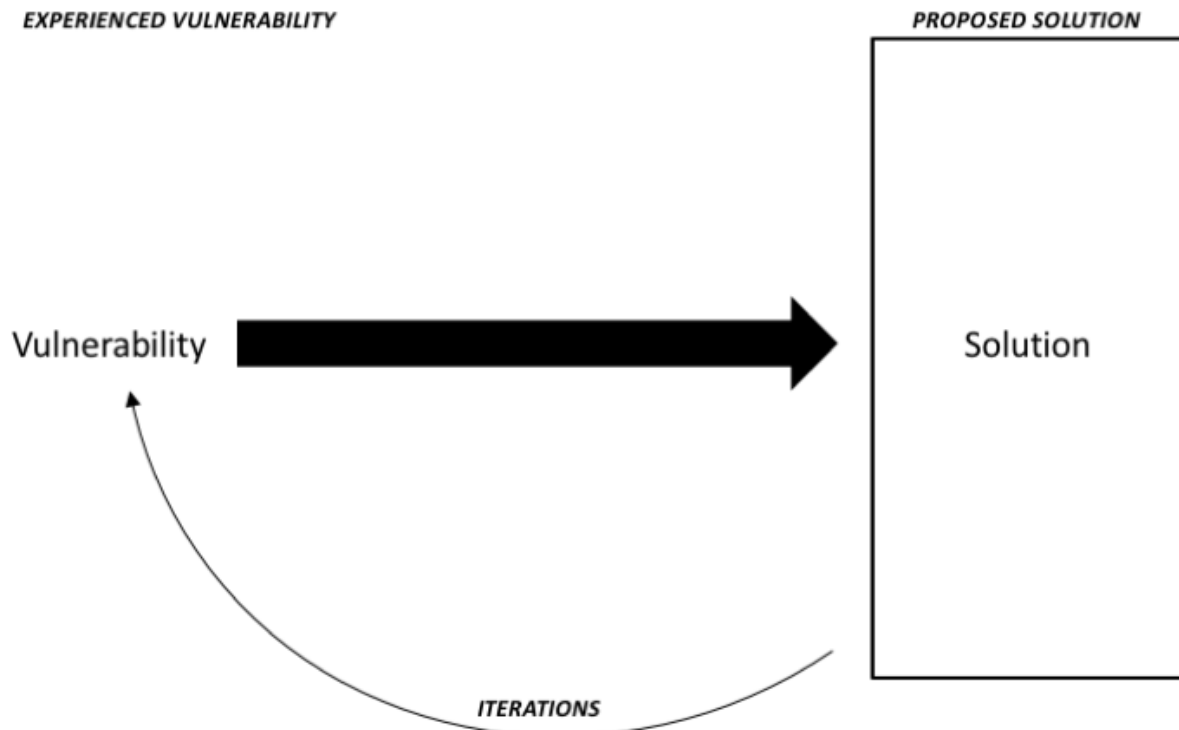
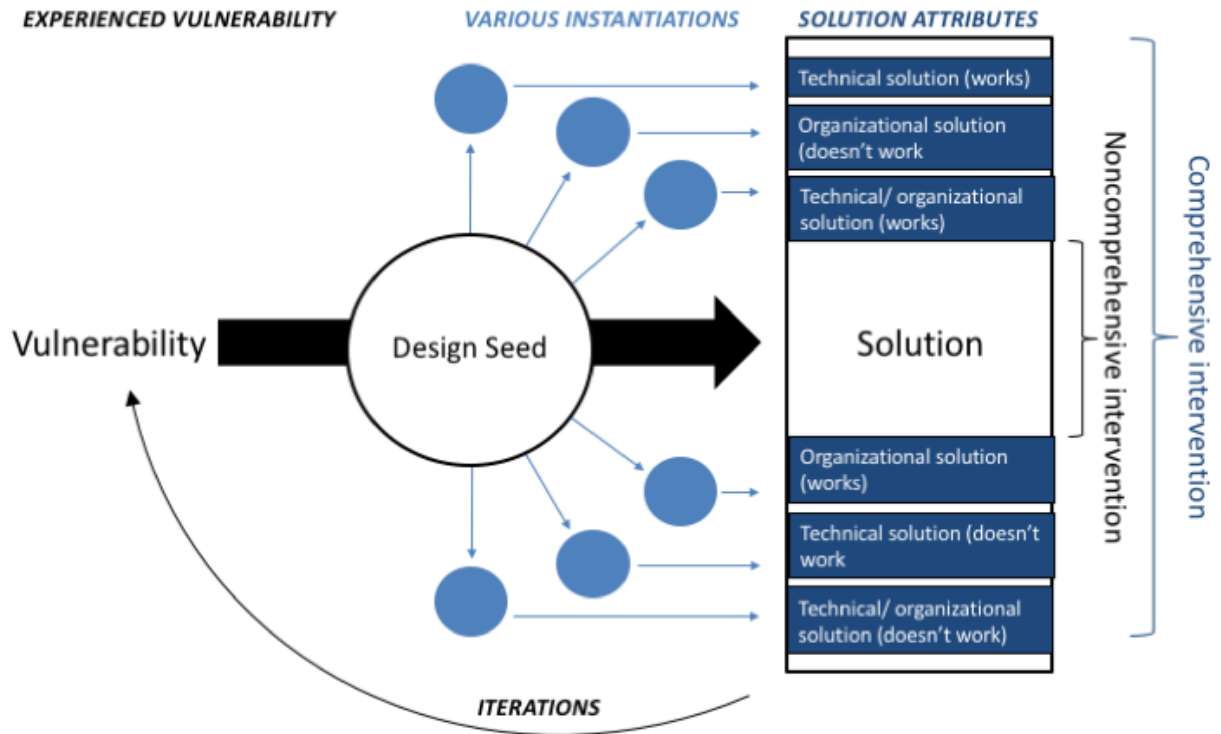


Figure 4. Socio-Technical Intervention Development Cycle: Design Seed Theory



Assessing Clinician Reactions to Design Seeds (Stage 6)

To gain insight about the importance of the design seeds, we developed and tested a data collection script and instrument (Appendix 1 and 2). A clinician participant from each clinic reviewed each design seed, assessed likelihood of improved monitoring and likelihood of reducing time spent monitoring, and ranked the set of seeds for relative overall importance.

Results

From January 2015 to February 2016, we convened one or more journey mapping sessions with clinicians and staff at five specialty clinics to establish the workflow for monitoring high-risk patients. As expected, all clinics participate in teaching alongside patient care, have similar safety-net patient demographics with accompanying operational challenges (e.g., translation services, transportation needs), and use the same underlying electronic health record system but work within a larger system of fragmented record-keeping systems (e.g. different specialty-specific EHRs, electronic systems restricted to on-site devices, paper-based systems). The mapping process also revealed variability in organizational approaches to monitoring high-risk patients, including the types of personnel involved in various monitoring-related tasks (e.g. resident versus nurse responsibility for tracking) and the specific steps taken to monitor high-

risk patients (e.g., use of notebook-based list of patients versus lack of a structured tracking tool).

Journey Maps: How Specialty Clinics Monitor High-Risk Patients

For each clinic, we constructed a journey map as shown in Figure 5, the abnormal colonoscopy workflow, and Figure 6, the ENT cancer workflow. These journey maps follow the management of patients with concerning conditions requiring cancer surveillance, diagnosis, monitoring and treatment, starting with referral to the respective subspecialty clinic. Each journey map contains swim lanes (visual columns) to group similar activities, flow arrows to represent patient and information movement, and targets to highlight areas of vulnerability for monitoring as expressed by clinic personnel.

For example, an abnormal colonoscopy triggers entry into the gastroenterology clinic workflow (Figure 5), which is adjudicated by the attending doctor. The first swim lane clusters the activities related to referrals. The next two swim lanes separate two different levels of diagnostic concern and coordination – one for benign lesions which just require notifying the primary care doctor, and the other for “sinister” lesions which precipitate a series of actions within the specialty clinic, as well as coordination with others based on subsequent findings (e.g., pathology, primary care, oncology). The bull’s eye target on the box -- “if no-show, patient falls off the list” -- means that the clinic is aware of this vulnerability, but does not have any further, regular steps to reduce the risk of losing a patient to follow-up. The bottom of the diagram illustrates that patient-related contacting happens throughout the workflow; the associated target conveys the challenges in reaching patients outside of clinic and assuring that they can make it to follow-up encounters.

The ENT clinic (Figure 6) reported similar challenges contacting patients monitored and treated for cancer, as did all other clinics (Appendix 3). The activities performed by the ENT clinic for cancer monitoring cluster into four swim lanes—case identification and referral, coordination, consultation, and care pathway. In this clinic, the coordination activities do not follow from a particular clinical scenario (the benign versus sinister lesion), but instead relate to a particular role, the chief resident. As a result, this clinic identified four separate vulnerabilities related to the busy chief resident’s responsibility to keep patients on the “ENT Radar” without any specific tools besides paper notecards, while also coordinating resources such as transportation for patients, tumor board presentations, and communication of follow-up requirements to primary care providers (PCPs). The care pathway swim lanes sketch out a series of diagnostic activities and pre-treatment preparation. The last stage of this clinic’s care pathway is patient surveillance after treatment. No specific responsibility assignment exists for patients who require regular surveillance to monitor for cancer recurrence, so the ongoing surveillance activity box is labeled with a bull’s eye target, indicating another vulnerability.

Figure 5. Abnormal Colonoscopy Journey Map

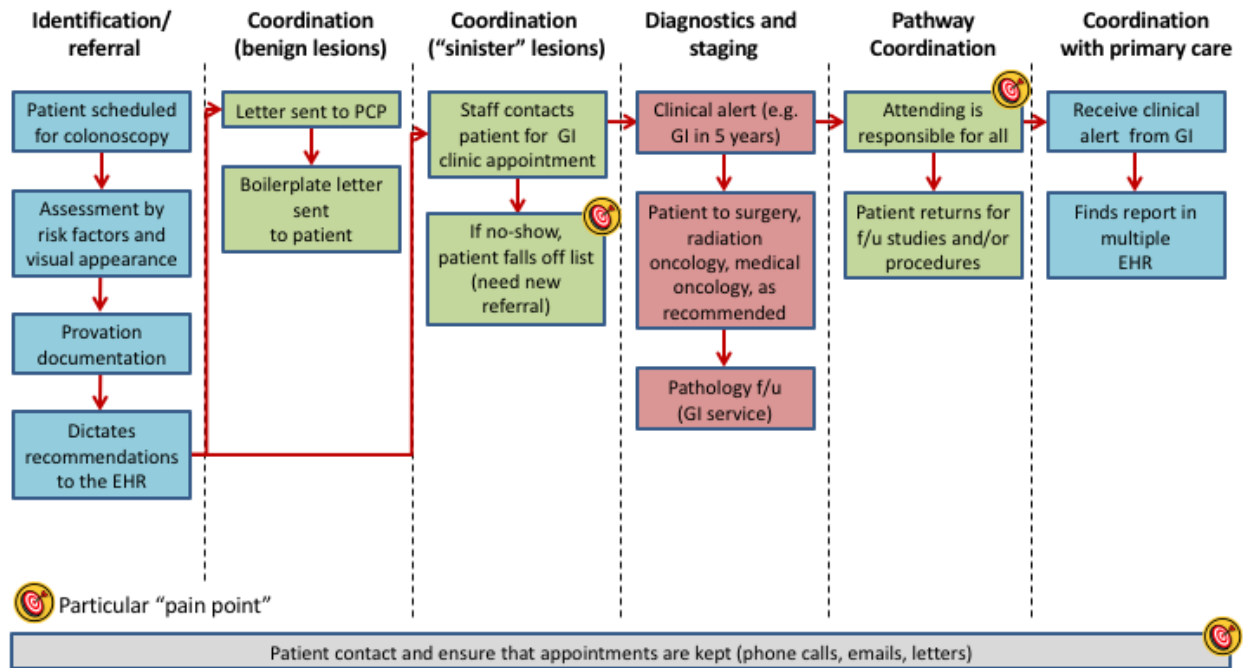
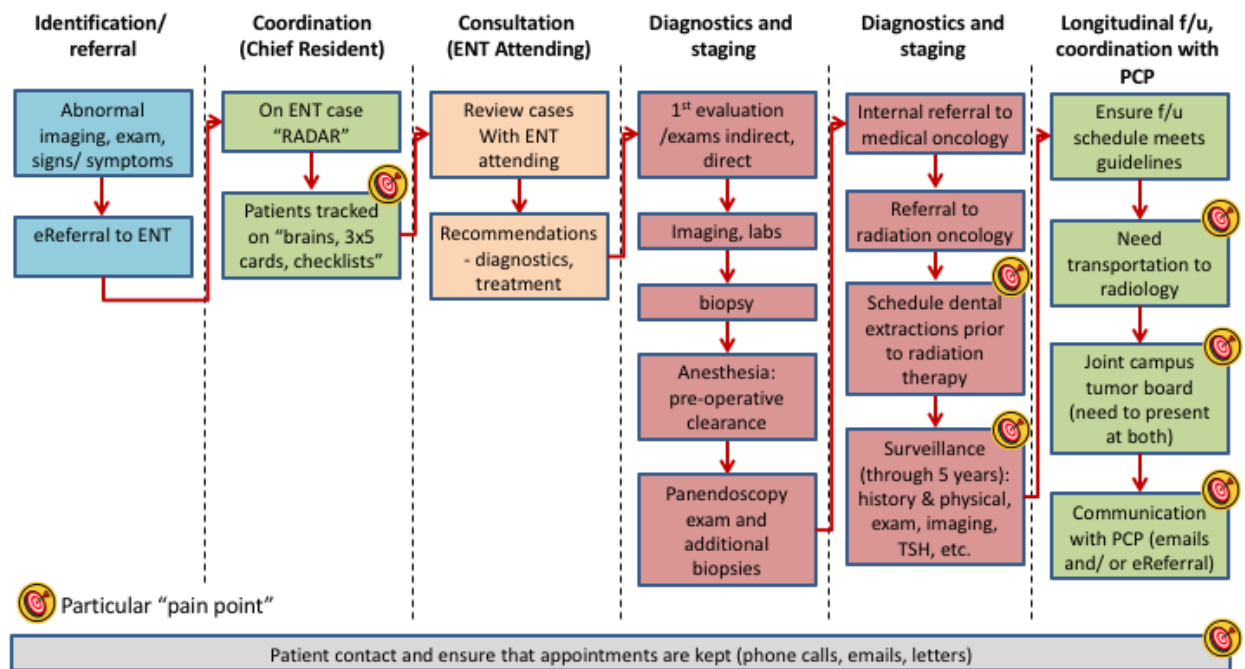


Figure 6. Ear Nose and Throat (ENT) Cancer Journey Map



The journey maps intentionally tell only part of the story as they represent the journey told from a single clinic's perspective. For example, all of the subspecialty clinics have interactions with PCPs, but only when an individual clinic spoke about dependencies on the PCP for the patients that they monitor did we include the PCP in a journey map. For incidental lung nodules, breast cancer oncology navigation service, and abnormal colonoscopies, the specialty clinics rely on the PCP to remind patients to follow-up at the necessary intervals since they have minimal contact with these patients.

Challenges Experienced in the Clinics

Based on the interview notes and journey maps from all five clinics we developed a comprehensive list of vulnerabilities described by at least one clinic (see Table 1). We identified 45 distinct vulnerabilities, and mapped these to domains from patient safety theoretical frameworks: 36 relate to work system factors that are inherent to environment, task, technology, organization and people, while 9 vulnerabilities correspond to process factors that reflect interactions between people or with systems.(1, 56) Each clinic reviewed the list at least four months after journey mapping to validate high-priority vulnerabilities that persist over time despite ongoing organizational changes and to record differences between clinics. Only two vulnerabilities—1) have to track some patients in own mind or side system, and 2) creating list of patient requiring monitoring takes time – were experienced by all five clinics. At least two clinics (in varying combinations) experienced most of the vulnerabilities. Four of the five clinics verified multiple problems related to the time expended on tasks related to monitoring. The breast cancer clinic experienced only 7% of the full list of possible vulnerabilities, while the others experienced 12% to 34%. This lighter vulnerability burden is perhaps because the breast clinic has separate philanthropic funding that supports patient navigation services, referred to by a participant as a “human tracking system”.

Several broad work system challenges emerged from the clinic visits:

- Organized for visit-based care (as opposed to patient management over time)
- Rotating care providers from visit-to-visit due to being a teaching environment (as opposed to having doctors with long-term organizational know-how)
- Lack of clear ownership for the monitoring-over-time function (as opposed to task responsibility and adequate time allocated for this population management function)
- No aggregated real-time lists of those who require follow-up monitoring (as opposed to supportive tools)
- Lack of systematic and transparent approach to patient's care plan (as opposed to widely known and specified benchmarks and timing for monitoring follow-ups)
- Substantial time pressure limits frontline attention to learning from missed monitoring incidents (as opposed to efforts to analyze data about misses, understand vulnerabilities and develop organization-wide solutions)

This work environment analysis that utilizes the NAM framework underscores the lack of infrastructure and processes organized to support population-level tracking of patients undergoing diagnosis of initial cancer, progressing cancer or recurring cancer. One noteworthy finding was the lack of population-level descriptions of the different types of monitoring care pathways commonly used within a given clinic. For example, the urology clinic participants – an attending doctor, a resident and a nurse – described a composition book where the resident logs all urologic patients who had a pathology result. The composition book is a starting point for population-level tracking of those who are at some risk for being lost to follow-up despite likelihood of needing it. However, the list is not sub-divided or categorized based on findings, conditions, anticipated follow-up pathway (e.g., testing, timing of next visit). The clinic participants noted that they preferred a system to monitor for all urologic cancers rather than restricting to prostate cancer monitoring (journey map focus) and that the composition book re-emerged as a workaround after a technical monitoring system was unsuccessful.

Table 1. Vulnerabilities Experienced by Each Clinic

Vulnerability from Specialty Clinician Perspective <i>Classified by Framework Domain*</i>	# of Clinics Experiencing	Clinic⁺ (X = experienced)				
		B	P	GI	E	U
Work System: Task						
Have to track some patients in own mind or side system	5	X	X	X	X	X
Creating list of patients requiring monitoring takes time	5	X	X	X	X	X
Looking up each patient's information takes time	4		X	X	X	X
Maintaining list of patients requiring monitoring takes time	4		X	X	X	X
Outside of visit-based care, don't always know when patients need follow-up monitoring	4	X	X		X	X
Manually monitoring patients is time intensive	4		X	X	X	X
Don't always know which patients need to be called back for monitoring	3		X		X	X
Have to spend too much time scheduling	2		X		X	
Manually monitoring patients is error-prone	2				X	X
Work System: Technology and Tools						
Analyzing data in ad hoc manner is time intensive	4		X	X	X	X
Inefficient system to create personal, siloed reminders for follow-up	4		X	X	X	X
List of patients we use outdated quickly	3			X	X	X
Can't divert alerts to other providers	3		X	X	X	
Analyzing data in ad hoc manner is error-prone	3		X		X	X
Don't always know when patient data is missing	2		X		X	
Can't find missing data from outside clinic	1				X	
Don't always want alert when patient status changes	1					X
Don't have adequate real-time data	1				X	
Can't edit patient's care pathway as needed based on frontline data	1		X			
Can't find missing data within clinic	1				X	
Work System: Organization						
Systems don't talk to each other	4		X	X	X	X
Don't have a system that puts patients into subgroups for more efficient monitoring	4		X	X	X	X

Vulnerability from Specialty Clinician Perspective <i>Classified by Framework Domain*</i>	# of Clinics Experiencing	Clinic⁺ (X = experienced)				
		B	P	GI	E	U
Can't share patient list with entire care team	3		X		X	X
Don't always have the time to perform the assigned role	2		X		X	
Hard to stratify patients into subgroups for monitoring due to many individual patient differences	2		X		X	
Care plan is poorly documented	2		X		X	
Don't know what types of scheduling challenges occur most often	1				X	
Work System: People						
Overlapping efforts	4	X		X	X	X
Don't always know when the loop closes	3			X	X	X
Everyone inputs data differently	2		X		X	
Knowing who is managing at each stage is unclear	2				X	X
Mapping patient to care plan requires clinical judgment	2		X		X	
Work System: Environment						
Coordinating scheduling efforts across care teams is difficult	3		X		X	X
Little or no performance data about monitoring so don't know where to focus any improvement efforts	3	X	X		X	
Stretched for resources to reach out to all patients in need of follow-up	3		X	X	X	
Unaware of clinic's performance in patient monitoring	2	X			X	
Process: System-Patient Interaction						
Don't know when patient misses appointment	4		X	X	X	X
Don't always know when patient doesn't have PCP	4	X	X		X	X
Don't always know patient's vulnerabilities relevant to monitoring (e.g. patient's work schedule, can't get to clinic, substance abuse)	3		X		X	X
Difficulty communicating patient needs with entire care team	2		X		X	
Don't know when patient changes status	2		X		X	
Process: System-Provider Interaction						
Inconsistent process for informing PCP	3		X		X	X
Can't use patient data for operational improvement	2		X		X	
Involving PCP when not necessary	1	X				
Process: Patient-Provider Interaction						
PCP doesn't have overview of all patient info/ care pathway	3		X		X	X

*Adapted from the National Academy of Medicine Improving Diagnosis Framework, 2015 and Sarkar et al's System-related Factors, 2014 to classify each reported vulnerability into Work System versus Process, as well as subdomains of these two framework categories (1, 56)

⁺Clinics designated as B=Breast, P=Pulmonary, G=GI, E=Ear Nose and Throat, U=Urology

Process Trace Sequences: Four Critical Activities for Monitoring High-Risk Patients

To simplify the journey maps and enable pattern recognition across clinics (see Appendix 4 for color-coded journey maps), we categorized each action into one of three functional clusters:

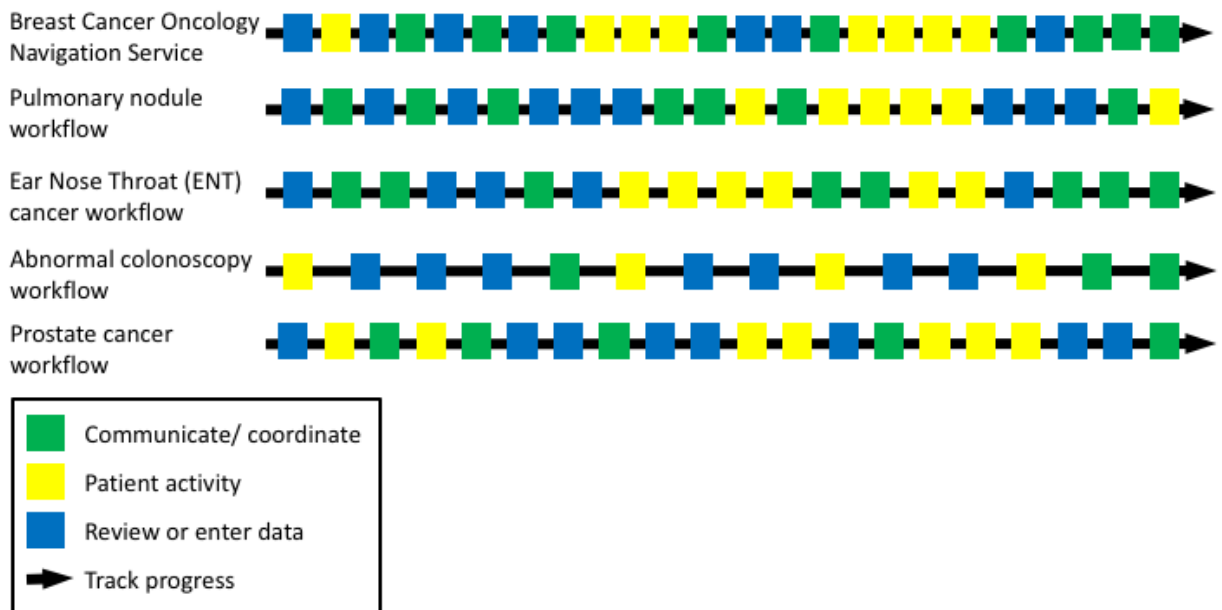
- Communicate/coordinate

- Patient activity (contact patient, patient shows up)
- Review or enter data/ data systems

Figure 7 shows the resultant process trace sequences derived from the journey maps for each of the five clinics. The workflows have similar patterns: review and entering data at the beginning of the journey; a couple activities to communicate and coordinate within the clinic team before seeing a patient, a series of tests and appointments where the patient has to show up, and some patient contact outside the appointments punctuating the middle of the journey; and more communication or coordination actions marking the end of the journey. As noted in the thematic analysis, a fourth critical activity weaves through the sequence:

- Track progress related to patients and their follow-up needs

Figure 7. Process Trace Sequences



Design Seeds: Elements of a Comprehensive and Adaptable Intervention to Save Lives and Time

To inform intervention development, we looked for leverage points to alleviate the vulnerability areas that held the highest consequence for failure. We generated a list of 13 leverage points, called design seeds, which correspond to the critical activities for robust patient monitoring, as shown in Table 2. One of the clinics, urology, told us that they had a registry but it was not used. This situation exemplifies the typical solutions pathway, as shown

in Figure 8. In contrast, based on socio-technical theory, stating simply that a registry “is needed” is too minimalistic and fails to take the organizational context and its potential variations into account. Figure 9 provides an example of the design seed description for functions needed in a population registry of high-risk patients requiring monitoring. The design seed communicates the intent behind the recommendation resulting in a modular - therefore more evaluable - set of solution attributes. Each of the four functions (e.g., groups patients by PCP) shown can support different components of an intervention. In addition, each design seed functional statement can easily be converted into an evaluation question, such as “does the intervention use data visualization in a way that enables rapid identification of patients in need of follow-up?” or “does the intervention allow our clinic to prioritize work in a way that assures that the highest risk patients receive follow-up first?” (Appendix 2 has an example of the detailed functional descriptions for one design seeds, as presented to the clinics for feedback.) These descriptions also support hypothesis-generation about contextual features that may have variable effects on whether the intervention is able to achieve its intended design goals (Table 2).

Table 2. Design Seeds Relationship to Critical Activity Categories and Implementation Context

Critical activity category	Design seed*	Relevant Context Domains (37)			
		Safety Culture, Teamwork, Leadership	Structural Organizational Characteristics	External Factors	Implementation/ Management Tools
Communicate/ coordinate	Ability to control data access	X	X	X	X
	Scheduling functionality	X	X		X
	Assign roles and responsibilities	X	X		X
	Triggered notifications	X	X	X	X
Patient activity	Patient support	X	X	X	X
	Complete patient information	X	X		X
Review or enter data	Keeps list up-to-date	X	X		X
	Standardized data entry			X	X
	Complete data capture		X	X	X
	Performance data	X	X	X	X
Track progress	Population registry functionality for high-risk patients	X			X
	Figure out what patients are “on the list”	X	X	X	X
	Customize the patient list	X	X		X

*Design seeds correspond to the four critical activities performed by clinics. To maximize effectiveness in diverse and dynamic settings, designed interventions are considered within the context of a larger work system, split into four major domains by Taylor et al.(37) Hypothesized relationships between context features (e.g., leadership at unit level, local tailoring of intervention) are show for the four context domains and each design seed.

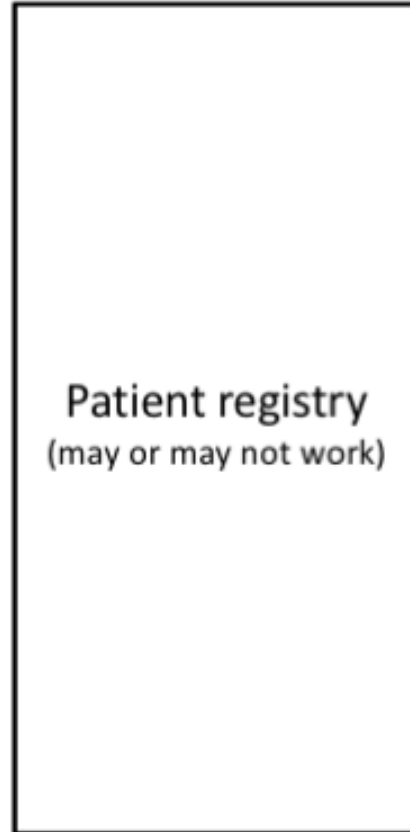
Figure 8. Technical Intervention Development Cycle: Example

EXPERIENCED VULNERABILITY

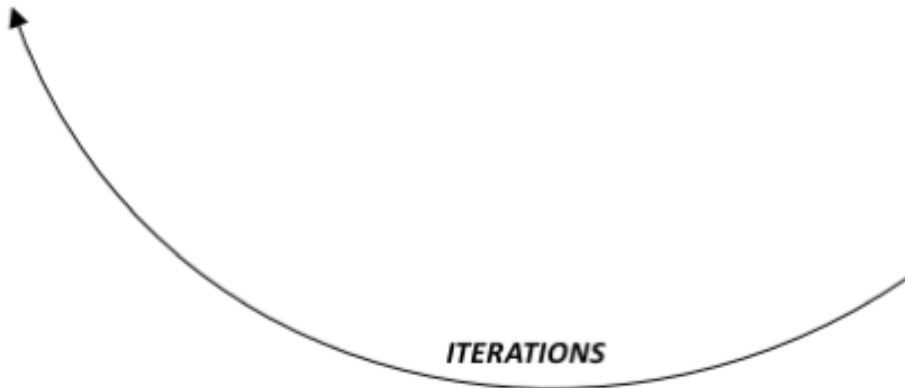
“Our clinic doesn’t have an accurate list of all patients that need monitoring”



PROPOSED SOLUTION

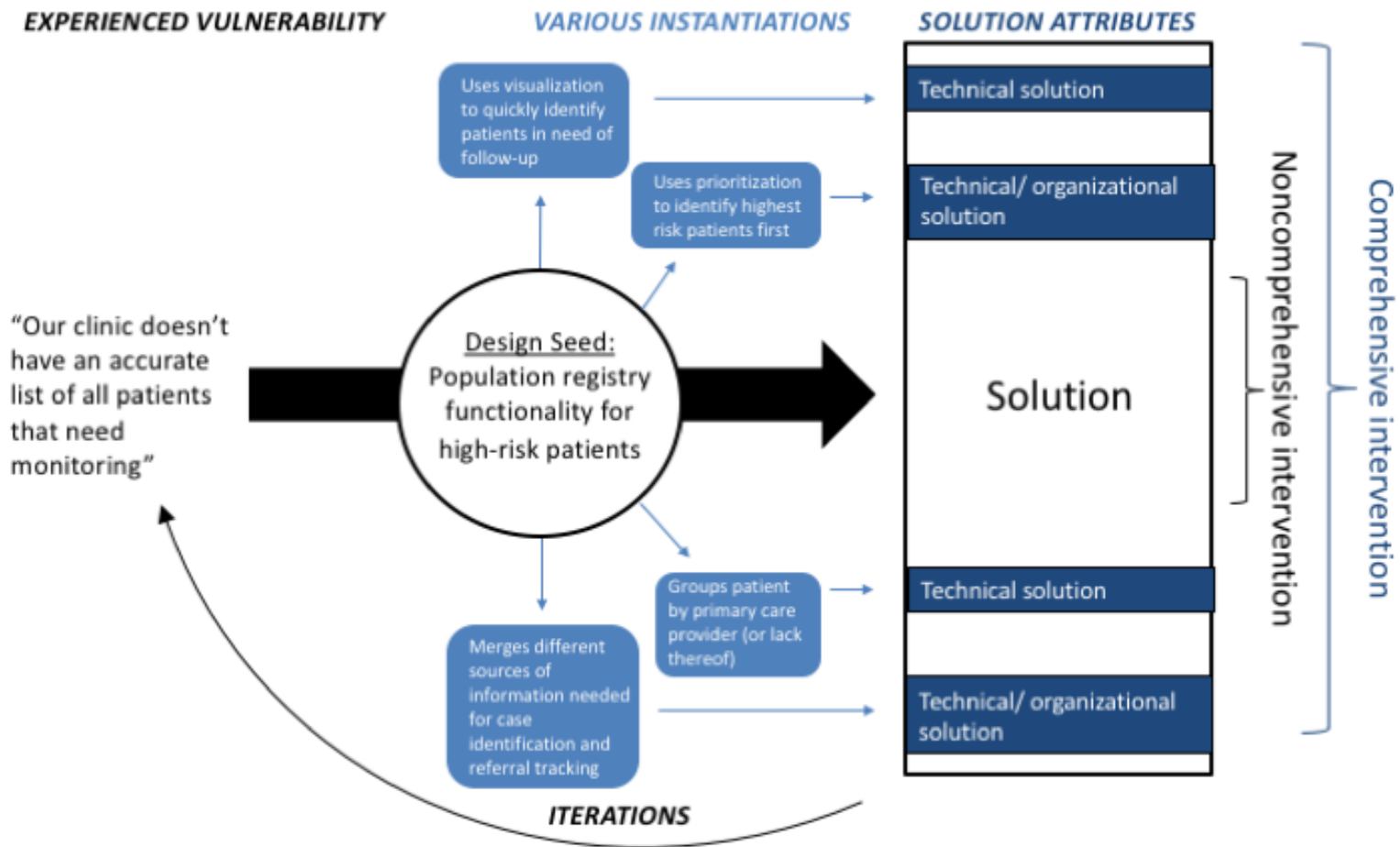


Patient registry
(may or may not work)



ITERATIONS

Figure 9. Socio-Technical Intervention Development Cycle: Design Seed Example



When clinic participants were presented the preliminary findings from this formative research, they were asked to prioritize the design seeds and suggest revisions of the design seed descriptions. Twelve of the 13 design seeds received ranking in the top 5 in at least one clinic (Table 3). Although the design seed for scheduling functionality did not receive a top 5 ranking, four clinics ranked it seventh, right in the middle of the list, so it was hardly a low priority. The design seed for keeping the list of patients who need monitoring up-to-date received top three or better ranking at four clinics. Three other design seeds – triggered notifications, customize the patient list, and population registry functionality – were ranked in the top 5 by three or more clinics. As noted by one participant, the high priority seeds or solution attributes “were those that bring the right information to the right person at the right time.” Some design seeds had higher salience for only one clinic. Complete data capture, for example, is more problematic for clinics whose patients receive some of their care at other institutions that use other record-keeping systems and EHRs. In these instances, patient data is either inaccessible or must be faxed between sites.

Based on average ratings shown in Table 3, as well as individual clinic ratings, the design seeds received agreement that they would improve monitoring and save time in most clinics. Only one design seed (assigning roles) received disagreement for improving monitoring and reducing time in one clinic because all monitoring is performed by a “one-woman show” (a registered nurse). All design seeds except one (patient support) received the most favorable rating (5) for time saved by at least one clinic. No clinic provided very strong agreement (5) that the design seed for performance data would improve monitoring, although representatives of three clinics (breast, GI and urology) agreed that it would improve monitoring (ratings of 4 on 5-point scale). As one respondent noted, “the scope of the problem would be good to know, but secondary to other needs.” This view is consistent with other studies showing frontline concern that monitored activities will be artificially prioritized over core clinical work.(60) Design seeds viewed as having higher impact potential for saving time and improving monitoring were generally ranked closer to the top by more clinics.

Table 3. Importance Ranking of Design Seeds from Five Specialty Clinics

Design Seed	Ranked in Top 5*	Rank (Avg)	Improved Monitoring (Avg)	Reduce Time Spent (Avg)
Keeps list up-to-date	P, G, E, U	3.4	4.6	4.8
Triggered notifications	B, G, E	4.2	4.8	4.8
Customize the patient list	B, P, G, U	5.2	4.2	4.6
Ability to control data access	E, U	6.2	4.4	4.2
Population registry functionality for high-risk patients	P, E, U	6.6	4.4	4.2
Complete patient information	G, E	7.2	4.6	4.6
Standardized data entry	G	7.2	4.2	4.4
Performance data	B	7.2	3.6	3.8

Patient support	B, P	7.8	4.2	3.6
Complete data capture	B	8	3.8	4.2
Scheduling functionality	-	8.4	4	4
Figure out what patients are "on the list"	P	9.8	4.2	4.2
Assign roles and responsibilities	U	9.8	3.4	3.6

*Clinics designated as B=Breast, P=Pulmonary, G=GI, E=Ear Nose and Throat, U=Urology

Discussion

This research highlights the unique and innovative integrated application of methods drawn from human factors engineering (design seeds, process tracing analysis) and user experience studies (journey mapping) to derive context-sensitive and theory-based interventions at the local level. Such focused and potentially scalable work is particularly needed for patients who may be lost to follow-up in systems that are stretched for dollars and time. This project focused on high-risk patients, both clinically due to a potentially concerning finding during an outpatient visit, and due to challenges from a socio-demographic viewpoint. When a patient has a warning signal for a serious condition that has yet to materialize, but may in the future, the ability of a clinical team to watch the patient closely over time hinges on incredible vigilance on the part of individual clinicians - hardly an ideal solution.

These challenges mirror those reported in other health settings with incomplete documentation and limited knowledge of the magnitude of patient safety problems.(53) Providers will often create informal workarounds in response to the lack of comprehensive and coordinated record-keeping systems, which can result in errors as well as redundant efforts.(61, 62) Accompanied by an understanding of these workarounds, safety-net settings offer a unique opportunity to apply user-centered approaches to redesign socio-technical strategies by integrating user and client needs, the possibilities of technology, and requirements for economic viability.(63)

Through mapping how patients are currently monitored for specific high-risk conditions according to evidence-based practice in five specialty clinics in our safety-net setting, we identified 45 different vulnerabilities. Repeatedly, we heard that clinicians worry about properly tracking these patients, and are troubled by the significant personnel time required in carrying out patient-level monitoring activities without tools and organizational approaches for population-level monitoring. In addition, no ongoing performance data currently exists related to the frequency of missed opportunities to monitor these high-risk patients, though efforts are underway.(27)

To ameliorate the difficulties identified, we worked iteratively with the clinics to develop the basis for a sound approach to population management of diagnostically high-risk patients. We adapted the journey mapping technique to capture activities and experiences of the clinic team as they manage cohorts of such patients, focusing on the clinician's monitoring journey.

Previous applications have focused on patient journeys and experiences. While each clinic had a different journey map, all teams carried out the same four basic functions with some variation in sequencing and specifics. For example, one function, 'patient activities', includes scheduling the patient, assisting patients with barriers to making it to a critical test, seeing the patient when they come into the clinic, conducting an imaging study, and so forth.

Once we understood the clinic teams' many concerns, particularly the time implications of the current monitoring workload, as well as the potential for errors, we did not jump straight to solutions. The use of design seeds, as a bridge between problems and effective organizational interventions, offers three advantages to leaping over this step. First, design seeds are simple descriptions that state what a solution needs to do, and can be described in a way that allows validation by the users, those on the frontlines at the clinics. For example, clinicians can easily imagine scenarios where patients might not be monitored according to evidence-based guidelines because of ambiguity in who is responsible for tracking high-risk situations (i.e., addressed by the design seed for assigning roles and responsibilities between primary care practitioner and specialist for a patient flagged for further follow-up). Second, design seeds can be supplied to other clinics to learn whether they have face validity outside of this particular safety-net setting. Design seeds support flexibility and tailoring to context, a critical feature for effective implementation of patient safety interventions in different settings.(37, 64) Other clinics could use the feedback exercise to determine whether the 13 design seeds are perceived to improve monitoring and save time in their setting prior to investing in a solution. As a result, one organization could implement and test interventions based on one set of design seeds (e.g., #3, 5, and 7), while another might choose another set (e.g., #2, 3, 4, 6) based on differing contextual enablers and barriers. Third, design seeds are, by definition, an assessment tool during testing of potential solutions. Does the solution do what the design seed prescribed? Some of the design seeds may result in primarily HIT solutions (triggered notifications), while others may need significant organizational changes (patient support). But most, if not all, will likely require both technical and organizational change.

The use of design seeds, previously applied for complex cognitively rich tasks outside of health care, is adaptive to any organizational setting coordinating layers of cognitively taxing activities meant to accomplish a particular organizational goal.(65, 66) Health networks fragmented by technology, location, and organizational elements are ripe environments for the design seed method as it captures differences in context while moving towards a cohesive end-goal: a solution that works across settings while also targeting specific needs to provide the high value to local settings. In our case, we sought to use journey mapping coupled with process tracing and design seeds to identify features of population management interventions for high-risk conditions and treatments to reduce diagnostic error. The flexible structure of these tools, anchored to touch points with end users, enable a generalizable strategy for identifying leverage points, reducing diagnostic delays related to suboptimal monitoring, and increasing organizational effectiveness.

Limitations

While designed for adaptability across systems, our proposed strategy for developing design seeds would be strengthened by further assessment within other health care systems. At this stage, we know from testing in multiple specialty settings that common themes and variations exist. While each of the clinics in this study has its own leadership, electronic and paper-based systems, and organizational design, we showed that journey mapping paired with process tracing captured both differences and similarities across five settings.

An additional limitation is that our design seeds have not received feedback from stakeholders outside the specialty clinic workforce (e.g. patients, information technology providers, caregivers). By focusing on the “holders” of the patient data – those stakeholders that most frequently engage with, and bear responsibility for, patient monitoring activities – we have established a foundation from which to build. The approach used fosters an iterative process for data collection that will loop in other stakeholders. Our adaptation of journey mapping and design seeds summarizes a broad, but possibly incomplete, list of activities related to patient monitoring when approached from a cohort perspective.

Future Work

We sought to draw from organizational analysis used outside of the healthcare setting to inform a practical and scalable intervention geared to reduce missed and delayed diagnosis in high-risk patient populations. Ideally, this approach would be replicated in other specialty areas and sites, including those that are better resourced. We will translate the validated design seeds into a prioritized list of solution attributes to use in development and evaluation of socio-technical interventions. During the organizational change process, we intend to continually reference and iterate journey maps. One of the design seeds – figure out what patients are “on the list” – will require work within the clinics as well as literature reviews targeted to trigger algorithms for identifying patients in need of close, but not urgent, follow-up during their diagnostic journeys.(67-69) We anticipate that interventions evaluated against user needs that are generated with intention and context will be more sustainable, user-friendly, and implemented more successfully than those generated without this human factors approach.

As a nascent area of research, strategies to close gaps in diagnostic safety built from the ground up, as in this study, will first be followed by pilot testing, and ultimately full-scale implementation evaluations with additional measures related to the people (patient, provider), organizational, technology and structural factors predicting desired implementation outcomes.(70) The NAM Improving Diagnosis framework shares a similar multi-level structure with those of implementation science, anticipating future research to improving diagnostic care in an organizationally effective and sustainable way.

Conclusions

We carried out a multi-stage research process with specialty clinics at an urban publicly funded health system to address an important evidence-based safety gap in ambulatory care: potentially preventable and consequential diagnostic and monitoring delays. Based on surfacing a large number of common vulnerabilities among the clinics, we specified and validated key attributes for a robust socio-technical approach to improving outpatient monitoring that is geared to enable context-sensitive implementation, utilizing industrial and human factors methods linked to implementation theory.

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CHAPTER 4

Paper 2—Health information technologies, patient safety culture and medical office problems that could lead to diagnostic errors

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Introduction

As EHRs are adopted more widely for ambulatory care, and physician clinics continue to HIT systems, it is increasingly important to evaluate both the positive and negative effects of HIT implementation on clinic processes and communication that may impact patient safety.(1-2) In addition to EHRs, examples of HIT applications in a clinic include computerized provider order entry systems, computerized clinical decision support systems, electronic reporting of laboratory or imaging results, and electronic exchange of health information with other health care facilities. In the ambulatory setting, these systems are becoming increasingly integral to a range of patient care-related activities such as test and medication ordering, results reporting, diagnosis, clinical decision-making, care planning, patient communication, and care coordination with other providers.

HIT and Patient Safety

There is evidence that effective use of HIT can improve healthcare quality and safety in the inpatient setting.(3-4) For example, Furukawa et al found that cardiovascular, pneumonia and surgery hospitalized patients exposed to fully electronic EHRs had 17-30 percent lower odds of an adverse event.(5) However, the evidence on the impact of HIT on quality and safety in physician clinics is mixed, with both positive and negative effects reported.(6-10) Studies have pointed to the implementation phase of new or upgraded HIT systems as a particularly risky time that can negatively impact office processes that can lead to HIT-related errors.(11-15)

A HIT-related error occurs when data are lost, incorrectly entered, displayed or transmitted.(16-17) These errors can occur due to system malfunctions, system or internet down-time, user interface error (poor usability and/or learnability), information display issues, or non-interoperability across systems.(18-22) A systematic review of ambulatory care safety publications over 10 years found that HIT was a contributing factor to the three most common safety concerns: 1) medication errors, 2) diagnostic errors, and 3) patients in transition.(23) For example, in a study that reviewed critical imaging alert notifications, the researchers found that nearly all abnormal results lacking timely follow-up at 4 weeks were eventually found to have measurable clinical impact in terms of further diagnostic testing or treatment.(24)

Diagnostic Errors

Singh et al. have estimated that one in 20 ambulatory patients will experience a diagnostic error every year, and half of those errors could potentially result in harm.(25) Diagnostic errors may cause harm to patients by preventing or delaying appropriate treatment or by providing unnecessary or harmful treatment.(26) There is currently a national focus on addressing the problem of diagnostic errors.(27-28) EHRs and electronic results reporting have the potential to improve decision support and to assist in finding, exchanging, and analyzing the data needed

during the diagnostic process. However, this potential has not been widely met.(29) Data-gathering and synthesis problems, inaccuracies and information overload from electronic “copy and paste” functionality, and the unintended consequences of alert and/or reminder fatigue are just a few of the examples of how HIT is not currently supporting the diagnostic process.(30-31)

Patient Safety Culture

The National Patient Safety Foundation describes a culture of safety as “one in which health care professionals are held accountable for unprofessional conduct, yet not punished for human mistakes; errors are identified and mitigated before harm occurs; and systems are in place to enable staff to learn from errors and near-misses and prevent recurrence.”(32) Health care providers measure culture through staff surveys to determine areas that need improvement, to conduct internal and external comparisons, and to evaluate quality improvement initiatives and other interventions.

Studies have shown that better patient safety culture is generally associated with safer care.(33-35) However the ability of better safety culture to mitigate the potential risks of HIT, especially during the implementation phase, has not been well studied.(36)

This study aims to better understand the relationship between HIT implementation and office problems that can lead to a diagnostic error, and to test the hypothesis that culture is a mediating factor in that relationship. The measures included in the Agency for Healthcare Research and Quality’s (AHRQ) Medical Office Survey on Patient Safety Culture (MO-SOPS) provide a unique opportunity to quantitatively assess the associations between a clinic’s staff perceptions of culture and the frequency of office problems that can lead to diagnostic error, and to link those results with clinic characteristics and each clinic’s HIT implementation level.

Methods

Data Source

Since 2009, health care organizations have been using the MO-SOPS to ask providers and staff for their opinions about the culture of patient safety in their clinics. The MO-SOPS survey instrument can be found on-line at <http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/medical-office/index.html>. In addition to questions about patient safety culture, the MO-SOPS survey includes questions about the frequency of office quality and safety issues related to the diagnostic process as described below. Furthermore, during 2012, the survey included data about the level of implementation of several electronic types of HIT system tools within a clinic.

Approval for use of clinic-level aggregated data was granted by AHRQ pursuant to Westat's data use agreement (DUA) with organizations that submit data to the comparative database. The data provided for this study was de-identified -- clinic geographic location and other provider identifiers were not provided. The 2012 AHRQ MO-SOPS User Comparative Database Report, presenting data from 934 U.S. clinics nationwide, contains detailed comparative data for various clinic characteristics (number of providers, specialty, ownership, and region) and staff position. (37)

Study Sample

Survey results from 934 clinics were analyzed from data voluntarily submitted in 2012 to the AHRQ MO-SOPS database. Participating clinics administered the MO-SOPS to their staff (including doctors, management, nurses, and other staff) between November 2009 and October 2011. Eight clinics were excluded from this analysis: five clinics with response rates less than 15% and three that did not answer the implementation of electronic tools question. Among the remaining 926 clinics, response rates at the clinic level ranged from 18-100%, averaging 72%, with a total of 23,597 staff respondents in this study.

Measures

Implementation of electronic tools

Although not part of the survey taken by staff members, in 2012, when a clinic submitted data to the database, they were asked a question about HIT implementation. This five-item question asked: "To what extent has this medical office implemented the following electronic (computer-based) tools?": a) appointment scheduling, b) ordering of medications, c) ordering of tests/images, d) access to patients' results, and e) electronic health records. The four response options were: 1) not implemented and no plans to implement in the next 12 months, 2) not implemented but implementation planned in the next 12 months, 3) implementation in process (only partial implementation), and 4) fully implemented. We grouped the responses into three categories by combining the two not implemented response options.

This study focuses on two of the IT tools relevant to the diagnostic process: access to patients' laboratory and imaging results ("E-reporting") and EHRs. E-reporting represents computer-generated reports and images that are transferred electronically from the laboratory and from radiologists (respectively) to the patient's attending providers. Data collected and stored in an EHR include demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology.

Office problems related to diagnostic process

As part of the MO-SOPS survey, each clinic staff respondent is asked "How often did the following things happen in your medical office over the past 12 months?" The listed items were:

incorrect patient information, not having results available when needed, untimely follow-up of abnormal test results, and problems exchanging accurate, complete, and timely information with other provider types. The six response options are: 1) daily, 2) weekly, 3) monthly, 4) several times in the past 12 months, 5) once or twice in the past 12 months, and 6) not in the past 12 months. For each clinic and each problem, we calculated the percent of a clinic’s total responses that were daily and weekly (referred to as “Percent Daily or Weekly”).

Culture score

The MO-SOPS survey includes 38 items that measure ten psychometrically-sound dimensions of organizational culture pertaining to patient safety. (38) The questions within a culture dimension are led with these instructions: “How much do you agree or disagree with the following statements:...?” An example item is: “Our office processes are good at preventing mistakes that could affect patients.” Responses are a 5-item Likert scale with 1=strongly disagree, 2= disagree, 3= neither agree nor disagree, 4 = agree, 5 = strongly agree. Respondents can also choose “Does not apply / don’t know”. An overall culture score was calculated by taking the average of the 10-dimension mean scores (range 1 to 5, with 5 representing highest level of clinic safety culture). Clinics were ranked and categorized into relative equal-size thirds (“tiers”). The survey items within each dimension can be found in on AHRQ’s website at <http://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/patientsafetyculture/medical-office/userguide/medoffitems.pdf>.

Clinic characteristics (Table 4) and statistical analysis

Analyses were performed using SAS version 9.3. For each office problem, we compared the adjusted means of Percent Daily or Weekly across the three implementation levels of EHR and E-Reporting. We also performed statistical testing and analysis to determine model covariates. For example, for a few of the office problems, higher survey response rates at the clinic level were correlated with Percent Daily or Weekly frequency of clinic problems.

We found, upon investigation, that higher response rates were correlated with the percent of clinic responses that were from physicians ($r=12.5$; $p < .0001$). Therefore, we chose to include percent of respondents who were physicians in the models.

Table 4. Office characteristics (n=926)

Characteristic	Percent or Mean
EHR Implementation Level	
None	25.4%
Partial	12.7%
Full	61.9%
E-Reporting Implementation Level	
None	16.2%

Partial	15.2%
Full	68.6%
Number of Doctors in Clinic	
1-3	27.7%
4-9	41.5%
10+	30.9%
Clinic is a multi-specialty practice	30.9%
Clinic mainly owned by an Academic Medical Center	5.7%
Clinic only has one location (vs. more than one)	59.9%
% of responses that were physicians (mean of clinics)	12.6%
Overall culture score*	3.80
Mean score in low culture tier (n=308)	3.46
Mean score in middle culture tier (n=309)	3.80
Mean score in high culture tier (n=309)	4.13

* Note: Main model includes an indicator of a clinic’s culture score tier, not the score.

Regression Analysis

For each of the 8 office problems, we used a multivariate regression model (PROC GLIMMIX) to estimate the effect of HIT implementation level on each office problem Percent Daily or Weekly while controlling for clinic characteristics and overall culture tier. Lastly, we ran the full model with the 10 culture dimension scores replacing the culture tier.

The SAS GLIMMIX procedure with a lognormal distribution was used to model the dependent variables (office problems) because the distribution of the positive values was skewed. Restricted maximum likelihood (REML) was used for variance estimation. The majority of our dependent variables had a mixture of a large spike at zero and a continuous distribution. For example, for the problem “results from a lab or imaging test were not available when needed”, 35% of the clinics had a Percent Daily or Weekly value equal to 0%. However, among the remaining 65% of clinics, the Percent Daily or Weekly was normally distributed.

We performed sensitivity analysis using other regression models such as the use of a two-step model to predict the odds of not zero coupled by a linear regression (both with normal and lognormal distributions) on only non-zero dependent variable values. For each problem-specific model, the results of the sensitivity analysis of various regression models confirmed the same direction and strength of the covariates as those reported from the GLIMMIX lognormal model.

Results

Findings before controlling for safety culture

Office problems that are relevant to the diagnostic process were reported to have occurred daily or weekly by an average of 1.2% to 14.6% of clinic respondents, depending on the specific

problem (Table 5). Having the incorrect patient record was reported least frequently, while not having the results for a lab or imaging test in a timely enough manner had the highest frequency. These reports varied widely with some clinics at over 80% of staff surveyed reporting one or more of the problems occurring daily or weekly.

Table 5. Medical Office Problems Measured in MO-SOPS

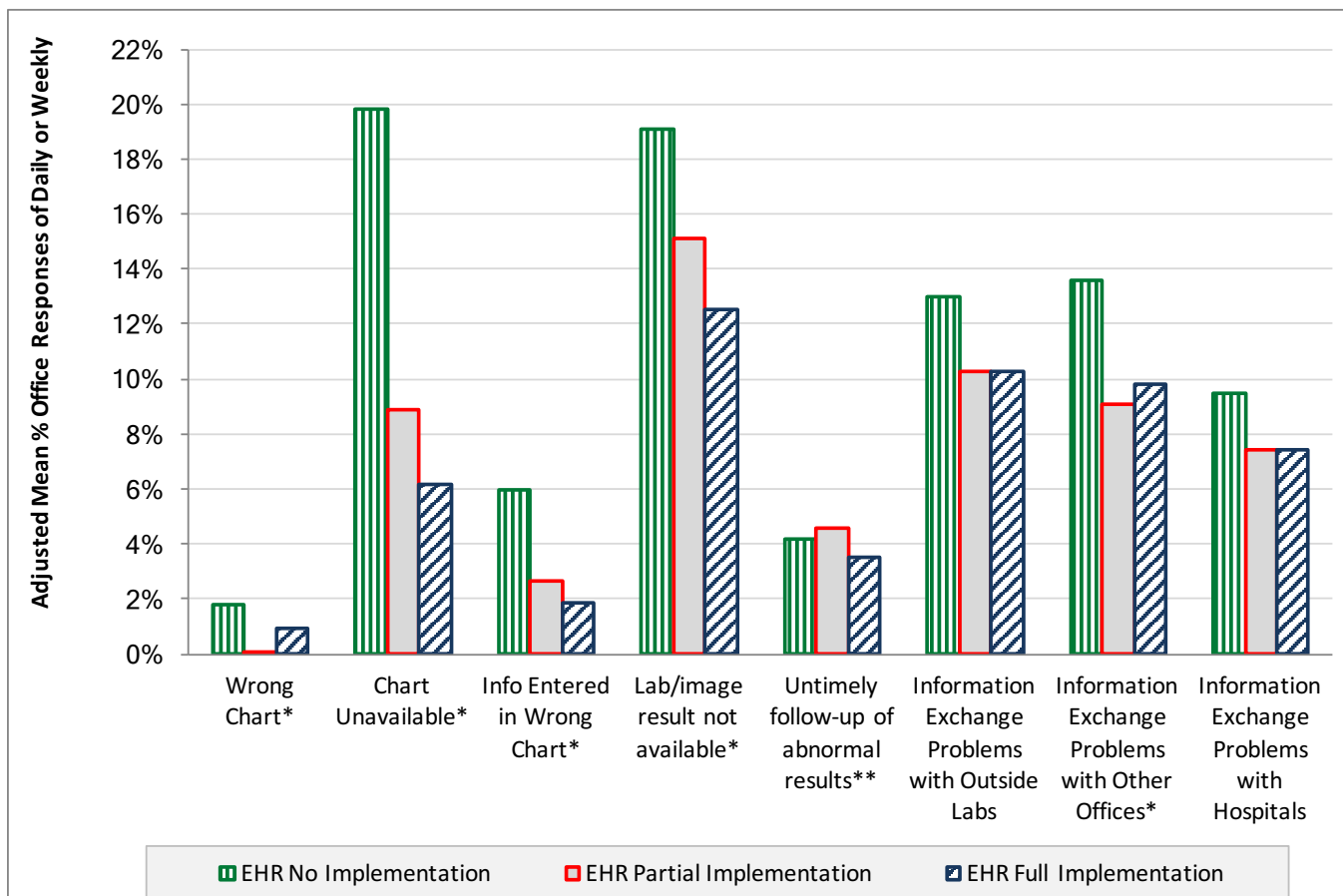
Problem	Of all responses in an office the Percent Daily or Weekly		
	Mean ^a	Standard Deviation	Range
1) The results from a lab or imaging test were not available when needed	14.6%	15.3%	0 – 83.3%
2) Patient’s medical record was not available when needed	10.1%	15.9%	0 – 88.9%
3) A critical abnormal result from a lab or imaging test was not followed up within 1 business day.	3.8%	7.5%	0 – 66.7%
4) Medical information was filed, scanned, or entered into the wrong patient’s chart	3.1%	6.8%	0 – 55.6%
5) Wrong chart/medical record was used for a patient	1.2%	3.5%	0 – 37.5%
6) Information exchange problems with outside imaging or labs	11.1%	13.2%	0 – 85.7%
7) Information exchange problems with other medical offices	10.7%	12.8%	0 – 83.3%
8) Information exchange problems with hospitals	8.0%	11.1%	0 – 80.0%

^aNote: Mean of 926 clinics’ percent of total responses Daily or Weekly when staff asked about problem frequency over the past 12 months.

As shown in Figure 10, for five of the eight office problems, the adjusted mean Percent Daily or Weekly was significantly lower for EHR full implementation in comparison to no implementation. For untimely follow-up of abnormal results, the Percent Daily or Weekly was higher for clinics implementing EHRs.

With respect to E-Reporting (Figure 11), for five of the eight office problems, the adjusted mean Percent Daily or Weekly was highest for partial implementation. However, clinics with full implementation of E-Reporting had the lowest Percent Daily or Weekly for chart unavailable, information in wrong chart, lab/image result not available, and information exchange problems with other offices.

Figure 10. Percent of Office Staff that Reported Problem as Happening Daily or Weekly by EHR Implementation Level



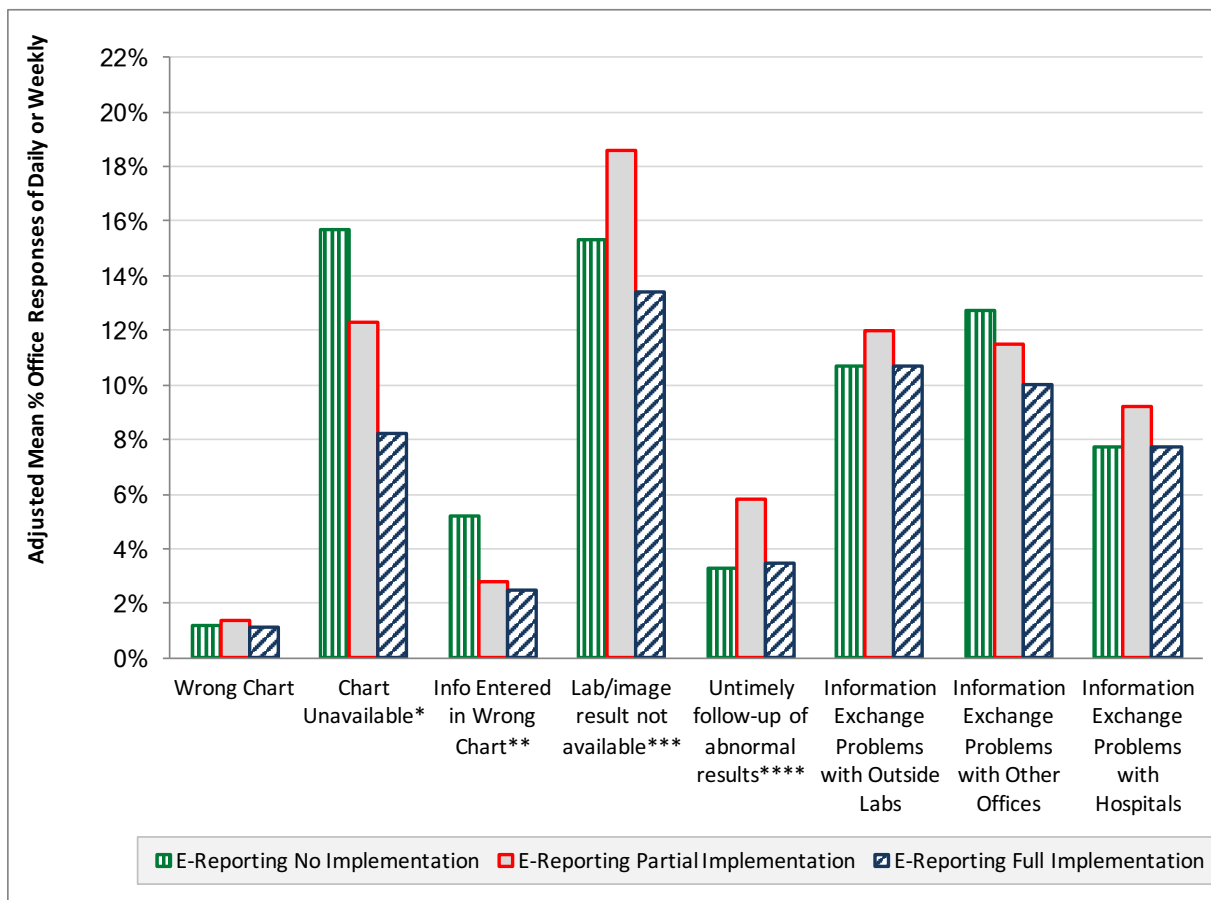
SOURCE: 2012 Medical Office Survey of Patient Safety Culture Database (N=926 offices)

* The adjusted mean for full implementation is significantly different than no implementation.

** The adjusted mean for partial Implementation is significantly different than full implementation.

Means are adjusted for # of physicians per office, multi-specialty or not, academic medical center ownership status, one or more locations, and the % of physician responses.

Figure 11. Percent of Office Staff that Reported Problem as Happening Daily or Weekly by E-Reporting Implementation Level



SOURCE: 2012 Medical Office Survey of Patient Safety Culture Database (N=926 offices)

* The adjusted mean for full Implementation is significantly different than none and partial implementation.

** The adjusted means for partial and full implementation are significantly different than no implementation.

*** The adjusted mean for full implementation is significantly different than partial implementation.

**** The adjusted mean for partial Implementation is significantly different than none and full implementation.

Means are adjusted for # of physicians per office, multi-specialty or not, academic medical center ownership status, one or more locations, and the % of physician responses.

Findings after controlling for culture: full model

Multivariate Regression Results (Table 6)

The Percent Daily or Weekly for seven out of the eight office problems was lower for clinics with full implementation of EHRs, three of them statistically significantly lower: patient chart not available when needed; patient medical information filed, scanned, or entered into the wrong patient’s chart; and lab or imaging results not available when needed ($p < .0001$ for each problem). The Percent Daily or Weekly for seven out of the eight office problems was higher for clinics undergoing implementation of E-reporting of lab or imaging results, one of them statistically significantly higher: critical abnormal result not followed up within 1 business day ($p = .006$). Clinics with full implementation of E-reporting had higher Percent Daily or Weekly of patient information in wrong patient’s chart in comparison to clinics with no E-reporting ($p = .01$). Neither EHR nor E-reporting implementation level was associated with the frequency of information exchange problems across facilities.

Compared to the medium culture tier clinics, on average, clinics in the lowest tier had significantly higher Percent Daily or Weekly for of all eight problems, while the highest tier clinics had significantly lower Percent Daily or Weekly for all eight problems. Larger clinics had higher Percent Daily or Weekly for seven of the eight problems in comparison to smaller clinics (i.e., with less than 4 doctors). Increased physician representation in a clinic’s total survey respondents was associated with higher Percent Daily or Weekly for the three information exchange problems ($p < .001$).

Table 6. Regression Result: Percent Daily or Weekly Problem Frequency (Dependent Variable)

Effect*	Wrong pt chart		Chart not avail		Info wrong chart		Results not avail	
	Estimate	Pr > t	Estimate	Pr > t	Estimate	Pr > t	Estimate	Pr > t
Intercept	-8.57	<.0001	-5.13	<.0001	-7.36	<.0001	-4.99	<.0001
EHR Full	-0.61	0.0201	-2.75	<.0001	-2.14	<.0001	-0.73	<.0001
EHR Partial	-0.54	0.1097	-1.39	0.0049	-1.06	0.0117	-0.30	0.0117
E-reporting Full	0.42	0.1680	0.82	0.0657	0.93	0.0135	0.75	0.0135
E-reporting Partial	0.50	0.1546	0.28	0.5798	0.17	0.7024	1.33	0.7024
10 or more doctors	0.69	0.0013	1.81	<.0001	1.20	<.0001	0.91	<.0001
4-9 doctors	0.55	0.0039	1.08	<.0001	0.69	0.0031	0.95	0.0031
Multispecialty	0.66	0.0004	0.22	0.4041	0.33	0.1510	0.07	0.1510
AMC ownership	-0.49	0.1413	-0.63	0.1987	-0.30	0.4691	0.73	0.4691
One location	-0.13	0.4291	-0.01	0.9724	0.11	0.5705	-0.33	0.5705
% Doc Responses	-0.29	0.6555	-0.30	0.7567	1.345	0.0972	2.22	0.0972
High culture tier	-0.58	0.0021	-1.60	<.0001	-1.15	<.0001	-1.53	<.0001
Low culture tier	0.70	0.0002	0.95	0.0005	0.81	0.0004	1.11	0.0004

* Note: Reference categories include EHR none, E-reporting none, 1-3 doctors and middle culture tier.

Table 6. Continued

Effect	Untimely Followup		Info X Rad /Lab		Info X Offices		Info X Hospitals	
	Estimate	Pr > t	Estimate	Pr > t	Estimate	Pr > t	Estimate	Pr > t
Intercept	-7.97	<.0001	-6.06	<.0001	-5.84	<.0001	-6.95	<.0001
EHR Full	0.15	0.6570	-0.56	0.1433	-0.64	0.0906	-0.08	0.8323
EHR Partial	0.14	0.7470	-0.67	0.1785	-0.79	0.1086	-0.16	0.7378
E-reporting Full	0.18	0.6523	0.49	0.2739	-0.11	0.8093	0.15	0.7363
E-reporting Partial	1.27	0.0062	1.00	0.0551	0.38	0.4517	0.72	0.1595
10 or more doctors	1.10	<.0001	1.61	<.0001	2.08	<.0001	1.55	<.0001
4-9 doctors	0.07	0.7638	1.12	<.0001	1.16	<.0001	0.76	0.0055
Multispecialty	0.23	0.3289	0.15	0.5781	0.49	0.0670	0.25	0.3472
AMC ownership	1.10	0.0101	0.23	0.6356	0.25	0.6046	1.28	0.0077
One location	-0.38	0.0702	-0.19	0.4181	-0.23	0.3205	-0.30	0.1927
% Doc Responses	1.99	0.0204	4.60	<.0001	3.39	0.0004	3.38	0.0004
High culture tier	-1.27	<.0001	-1.57	<.0001	-1.03	0.0002	-1.42	<.0001
Low culture tier	0.91	0.0002	0.73	0.0080	1.03	0.0001	1.37	<.0001

Note: pt= patient, avail = available, info =information, Info X = information exchange

Sub-Analysis Results of the Ten Culture Dimensions

Table 7 shows the mean score for each safety culture dimension, and the problems for which each dimension had a significant, independent effect in each problem-specific regression model. These models included all ten safety culture dimensions and controlled for EHR and E-reporting implementation levels and clinic characteristics.

Table 7. Culture Dimensions and Related Office Problems*

Dimension**	Mean Score	Significant Effect on Percent Daily or Weekly <i>A higher score on culture dimension was significantly associated with a</i>
1) Work Pressure and Pace	2.8	<ul style="list-style-type: none"> Decrease in Results not available when need (p=.002)
2) Office Processes and Standardization	3.3	N/A
3) Management / Leadership Support for Patient Safety	3.5	<ul style="list-style-type: none"> Increase in Info exchange problems with imaging / labs (p < .0001) Increase in Info exchange problems with offices (p < .003)
4) Communication Openness	3.5	N/A
5) Communication About Error	3.6	N/A
6) Staff Training	3.6	N/A

Dimension**	Mean Score	Significant Effect on Percent Daily or Weekly <i>A higher score on culture dimension was significantly associated with a</i>
7) Overall Perceptions of Patient Safety and Quality	3.7	<ul style="list-style-type: none"> • Decrease in Wrong chart used (p < .0001) • Decrease in Info entered in wrong chart (p < .0001) • Decrease in Info exchange problems with hospitals (p = .0002)
8) Organizational Learning	3.7	N/A
9) Teamwork	3.9	N/A
10) Patient Care Tracking/Follow-up	4.0	<ul style="list-style-type: none"> • Decrease in Results not available (p < .0001) • Decrease in Abnormal - untimely follow-up (p < .0001) • Decrease in Info exchange problems with hospitals (p= .003)

* Regression model included all ten dimensions and controlled for HIT implementation levels and clinic characteristics. Dependent variable per problem was Percent Daily or Weekly

** MO-SOPS Survey Dimension mean scores range from 1-5, with 5 reflecting higher/better safety culture

*** Significant at p < .005. N/A is not applicable; no significant association with frequency of a problem.

Limitations

The EHR and E-reporting implementation-level information at each clinic was not independently verified, which may lead to some misspecification. However, it seems unlikely that a clinic respondent would have difficulty reflecting the situation accurately. In addition, possible differences in timing between the completion of data about HIT implementation level and staff responses about culture and office problems may lead to some degree of mismatching in those types of responses. Also, we did not have access to information about the patient populations at the clinics, which may influence the relationships studied. Lastly, although we found in our study that clinics with EHRs seem to have better coordinated care and more reliable office processes, our cross-sectional analysis does not prove causation. It is quite possible that clinics with better processes of care were “early adopters” and, thus, more likely to have EHR and E-reporting implemented by 2012.

Discussion

The results of this study generate new evidence on the effects of HIT on patient safety in the ambulatory setting. We found that the implementation of electronic laboratory and imaging results reporting was associated with an increase in results not available and untimely follow-up of abnormal results. This association may indicate vulnerabilities during the diagnostic process that can cause serious lapses in diagnosis and patient care.(30,39) With so much emphasis on the inpatient setting, software vendors may not optimize electronic reporting software and products to support the needs of ambulatory care clinicians for timely and accurate diagnosis and treatment.(40-41) However, these results show that clinic diagnostic

processes are susceptible during the implementation phase of new or upgraded HIT systems.(42-44)

Our study showed that that subscales of patient safety culture demonstrate associations with office problems, linkages worthy of further exploration in ambulatory care. (45) Notably, we also found that clinics where staff perceived better management and/or leadership support for patient safety also reported more frequent information exchange problems. The items in this dimension ask about resources for quality, process improvement, and doing what is best for the patient. Possibly, in a clinic where management and/or leadership is strongly focused on patient-centered care, the clinic staff has higher expectations for care coordination and information exchange, or is more likely to report problems in these areas. Not surprisingly, as shown in Table 7, when staff perceived unfavorable work pressure and pace, clinics were less likely to have imaging and lab results available when needed. Patient safety culture is often viewed as a contextual factor that shapes staff behaviors and attitudes in ways that may influence the quality and efficacy of health care processes.

Pre-implementation risk assessments, monitoring during implementation, measurement, and post-implementation evaluations are crucial for the prevention of HIT-related errors.(46) Frameworks, models and toolkits are available to HIT professionals to understand and assess the safety implications of EHR implementation.(47-49) Furthermore, the ONC's Safety Assurance Factors for EHR Resilience (SAFER) Guides, that include pre-implementation checklists and planning tools, are available for the implementation of specific electronic technologies.(50) More specifically, the Test Results Reporting and Follow-Up SAFER Guide can help assess whether an organization's communication of diagnostic test results with HIT works as it should and is designed and implemented to minimize the potential errors. Practices can also assess the impact of HIT on their patients' experiences through use of the CG-CAHPS supplemental items.(51-52)

Our study findings add to the evidence base for three of the eight goals in the National Academies' 2015 report, *Improving Diagnosis*.(28) First, the committee recommended establishing a work system and culture that supports the diagnostic process and improvements in diagnostic performance. Second, the committee highlighted the importance of HIT in enabling patients and health care professionals in the diagnostic process. Third, the committee recommended a teamwork approach to diagnosis. To achieve all of these goals, HIT vendors, clinicians, and patients need an understanding of the interactions between organizational structures, processes and tools that relate to ensuring effective and timely communication of diagnostically salient information (e.g., imaging results, patient records, etc.). In addition, our findings underscore the need for ambulatory care organizations to focus on promoting a culture that values open discussion and feedback on impediments to improving diagnostic performance.(32)

Consistent with recommendations from the Institute of Medicine in 2011, the NQF-led HIT Safety Committee recommends better clinical documentation and more timely transmission of

high-quality clinical information as patients move across care settings.(1,53) Additionally, technology-based interventions aimed at identifying potential patient safety concerns and those that can reduce diagnostic errors should be tested and improved.(54) Diagnostic improvement work needs to address clinical reasoning, workflow, and system-level solutions with involvement from physicians and their teams, diagnostic service providers, and health care organizations in all settings.(46,55-56)

Conclusions

As measured by the AHRQ Medical Office Survey on Patient Safety Culture, full implementation of EHRs was associated with less frequent office problems, but not associated with cross-entity information exchange problems. The implementation of electronic reporting of images and lab results was associated with more frequent diagnostic-related office problems. Clinics with low patient safety culture reported office problems more frequently. More research is needed to understand the underlying risks and causes of errors that can lead to diagnostic error during and after HIT implementation in the ambulatory setting.

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CHAPTER 5

Paper 3—Organizational influences on time pressure stressors and potential patient consequences in primary care

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Introduction

Over 900 million patient visits occur annually in ambulatory care clinics throughout the U.S., with almost half to primary care physicians.(1) Primary care teams face daily time pressures in attempting to meet the needs of their patients.(2,3) Time constraint stressors occur both within a patient encounter,(4,5) and more globally as the clinical team manages work outside of appointments.(6,7)

Time pressure can affect altruistic behaviors, as seen dramatically in a seminal laboratory study on seminarians who when rushed were less likely to stop and help a man who appeared to need to go to an emergency room.(8) A meta-analysis of studies with similar manipulations to create time stress conditions (e.g., pressure from instructions to go faster, a deadline or a controlled pace for tasks) compared to no time pressure showed modest detrimental effects on performance.(9) Despite the salience of time stress to primary care clinicians and their staff, scant evidence exists about types of time stress, the organizational factors that shape such stressors in routine care settings, and consequences for patients and practitioners alike.

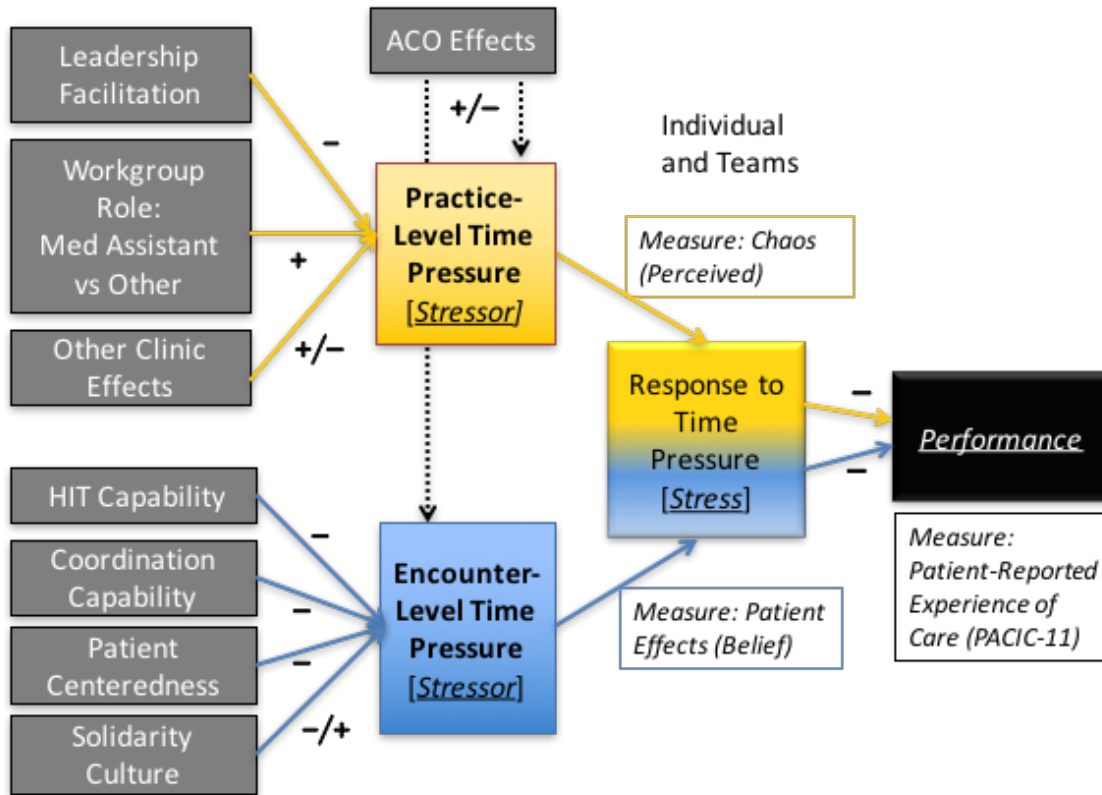
In response, we assess the extent to which two types of time stressors – encounter-level and practice-level time pressure—are associated with poorer patient reported experiences of care and the role of selected organizational strategies in mitigating this relationship. As part of a study of 16 randomly selected primary care practices from two large Accountable Care Organizations (ACOs) and their adult patients with cardiovascular disease (CVD), diabetes, or both,(10) we analyzed team perceptions and patient-reported effects of time stressors on patient care.

Theoretical Model of Time Stressors, Organizational Predictors and Patient Consequences

Organizational performance of a work team is affected by the way it handles stressors that come from environmental demands. For primary clinics operating within ACOs, this relationship is shown in Figure 12, and adapted from a synthesis of stressor-stress-performance theories applied to the military context. (11) The environment is outside the picture, but shapes corporate and clinic responses, which in turn result in higher or lower levels of time pressure stressors, which when experienced as stress by the team, translate to effects on performance.

Figure 12. Stressor-Stress-Performance in the Ambulatory Care Context

ACO/Clinic Responses to Environment Stressors → Team Stress Response → Patient Outcomes



Based on this broad theory, we posit that primary care clinics respond organizationally to demands from the environment such as new payment and regulatory requirements and from their corporate parent organization to stay solvent and perform well on quality metrics. Clinic organizational level responses in terms of staffing models, leadership approach, work processes and support infrastructure may be more or less adaptive to the environmental pressures, resulting in higher or lower levels of stressor exerting force on the team members. We posit that specific clinic and corporate responses to the environment translate into two types of stressors related to time pressure: practice-level time pressure and encounter-level time pressure.(12,13) The stressor condition is similar to the weather – determined by both barometric pressure and temperature – in potentially different ways. We hypothesize that the ways in which the clinic or its corporate parent organization shape the two distinct forms of time pressure differ, motivating an exploration of both the ways these constructs may be distinct, as well as the ways in which they may be malleable in influencing a clinic’s potential to change stressor levels.

Greater time pressure resulting from activities *outside* of the individual patient encounter is reflected in higher levels of practice-level pace, operationalized as chaos in previous studies of

clinic work conditions.(14,15) Previous studies restricted assessments to physicians, and this study extends the operational approach to include perceptions of all clinic personnel, thereby reflecting a broader concept of practice-level time pressure. Production pressure to see more patients more quickly is conceptualized as time pressure *within* encounters. While previous studies have sought physician estimations of time allocated to appointments versus time needed to provide high quality care, (15,16) our study operationalizes patient encounter-level time pressure for the entire team, using a measure of perceived effects of time pressure within appointments on missing important care opportunities for screening, diagnosis and treatment. (12) This measure choice provides an assessment of perceived patient safety effects of encounter-level time pressure. Both forms of the time pressure stressor – within and outside of encounters with patients—are hypothesized to create a stress response at the individual and team level. In turn, their responses to time pressure (stress) will affect the clinic’s performance on patient reported experiences. In summary, we address three questions:

- 1) What clinic factors are associated with Practice-Level Time Pressure?
- 2) What clinic factors are associated with Encounter-Level Time Pressure?
- 3) Are these Time Pressure constructs associated with Patient-Reported Experience of Care?

For the first question, environmental stressors exert force on the clinic as a whole, creating practice-level time pressure to varying degrees that depend on clinic leadership and workgroup role within the practice team. We hypothesize that those occupying lower status positions in the team, such as Medical Assistants [MA], will report higher levels of practice chaos because they may experience more practice-level time pressure from covering multiple operational tasks with low control to make practice-level improvements, relative to those in higher status positions such as Primary Care Physicians, Nurse Practitioners and other Nursing personnel. (17–19) More leadership responsiveness to frontline needs related to challenges underway from primary care transformation to patient-centered medical homes, so called leadership facilitation, will be associated with less practice-level time pressure.(20,21)

For the second research question, encounter-level time pressure may be perceived by the clinic team to adversely affect patient care. As shown in Figure 12, we posit that practices that are more patient-centered, that coordinate their interdependent work better (relational coordination), and that use more HIT capabilities will be less likely to report adverse time pressure effects during patient encounters. Solidarity among team members could produce better team flexibility and be associated with less adverse time pressure effects, or such a group-oriented culture could distract attention away from patient care and be associated with more adverse encounter-level effects. From the human factors and organizational systems literature, (22–24) perceived patient safety effects of time pressure are hypothesized to be similar regardless of whether concern expressed relates to missing important *diagnostic and screening* opportunities or missing *treatment* opportunities.

To address the third research question, we theorize that practice-level time pressure (as measured by practice chaos) and encounter-level time pressure effects (missed opportunities,

as perceived by the team members) each adversely influence patient reported experiences of care (11-question PACIC instrument) (25) Adequate time within an encounter and time capacity to organize supportive resources are potential prerequisites necessary, but perhaps not sufficient for clinic teams to provide all of the necessary actions to meet patient's chronic care needs. We hypothesize that patients receiving care from more time stressed practices (both encounter-level and practice-level) will report experiencing lower levels of support from the practice in managing their chronic conditions.

Methods

Study Design Overview

We analyzed cross-sectional survey data collected from primary care teams and their patients, participating in the second wave (January-August, 2016) of the ACTIVATE longitudinal study of 16 practices. The ACTIVATE parent study protocol, the characteristics of the two large regional ACOs from which the clinics were drawn, and the first wave of data analysis on patient engagement and patient-reported outcomes have been previously reported. (10) In brief, 16 practices were selected at random, evenly split from each ACO's top and bottom quartile of clinics based on patient engagement activities undertaken by the practices at baseline. Patients were randomly sampled from the subset of each clinic's patient population that met inclusion criteria (adults, English or Spanish or unknown primary language, at least one visit to the practice in the previous year, and clinical evidence of diabetes or cardiovascular disease based on ICD-9-CM diagnosis codes or prescriptions filled).

The study received approval prior to data collection by the institutional review board (IRB) of the University of California, Berkeley.

Team Assessment Practice Survey and Time Stressor Measures

All physicians, nurses, medical assistants, receptionists and others in each clinic's practice team received a 20-question survey starting January 27, 2016, with data collection closing on April 25, 2016 at a response rate of 84.37% (N=353). The survey repeated the initial wave's items reported previously,(10) including multiple questions on patient-centeredness, (26) solidarity culture,(27) leadership efforts to facilitate change and support the frontline workers,(28) and relational coordination among the people on the team in their respective roles related to patient care. (29) The survey also included questions about HIT capabilities, not included in the first wave. (14) (See Appendix 5)

The survey also incorporated additional questions about time stressors for the current study's primary aim. Based on the work of Linzer et al, (12,15) we incorporated questions about the perception by practice members of time pressure (encounter-level) affecting patient care and practice site chaos (practice-level time stressor).

As part of the Minimizing Error, Maximizing Outcome (MEMO) study of primary care clinics, Linzer et al developed a novel scale (OSPRE-Occupational Stress and Preventable Error) to assess physicians' self-reported likelihood of future errors committed in the management of common chronic medical conditions that includes missed diagnostic and screening opportunities, as well as treatment gaps.(12) We adapted the scale to assess perceived time pressure effects by all members of the practice team, not just physicians. The dependent variable is a seven-item battery assessing how likely it is that time pressure causes the respondent's care team to overlook a proactive need to diagnose or screen a patient for a health problem (5 questions), or miss an important treatment opportunity (2 questions). For example, how likely would it be to 'overlook a diagnosis of hypertension for a patient with 2-3 elevated BPs' or 'not start an ACE inhibitor in a diabetic patient for whom it is indicated'? (The full scale is shown in Appendix 5.)

A separate single-item scale assessed practice site chaos (from calm to chaotic). The chaos scale was developed based on focus group findings from MEMO, (15) and has been reported in two subsequent studies. (30,31) Linzer et al found that physicians who rated their practice as chaotic (4 or more on the 5-point scale) were more likely to report higher stress and burnout. (15) In a more recent study by Perez et al, clinics were classified as chaotic if more than 50% of physicians rated the practice atmosphere as a 4 or 5.(31) Previous studies have not assessed chaos among non-physician frontline team members, so the extent to which relationships between time pressure and perceptions of practice site chaos differ for physicians and other primary care team members remains unclear.

Patient Survey

From May 16 to August 9, 2016, we fielded a survey by mail with telephone follow-up, and the option to administer in English or Spanish. The survey achieved a 73.48% response rate (N=1,291). As previously reported for the first wave, we collected demographic information and data on patient-reported outcomes of care,(32) patient assessment of the chronic illness care that they received (PACIC-11),(25,33) and patient-reported activation (PAM).(34) In addition, the survey included CollaboRATE, a 3-item measure of the extent that patients believe that the practice team understands what matters to them, and provides critical ingredients required for collaboration between the practice team and the patient (e.g., listening to the patient). (35) Because this measure refers to the primary care doctor and other members of the practice team, the survey also asks the patients whether members of the team in addition to the doctor played an important role in their care.

Statistical Analysis

For primary analyses, we restricted the sample to the core primary care team member roles represented in almost all of the clinics: primary care physicians (N=75), nurses (N=70), medical assistants (N=110), and diabetic nurse educators (N=19). There was minimal missing data for patient variables (average 1.1%, range 0 to 3.4%) and for most team variables (average 1.9%,

range 0 to 9.1%). As a sensitivity test, analyses were also conducted on the full sample of care team members to examine the consistency of the results.

We conducted correlation analysis on the continuous time stressor items (7 items for time pressure effects and one practice atmosphere item). For all summary dependent and independent measures, we conducted factor analysis and obtained acceptable Cronbach alpha internal consistency reliability coefficients of .82 and above.(36)

We examined the hypothesized associations between organizational factors and the two dichotomized time stressor measures using multivariate logistic regression models and robust variance estimators. We also ran a combined model with all of the organizational factors to test for hypothesized null relationships between predictors of one time stressor but not the other.

We examined the hypothesized association between each time stressor measure summarized at the clinic level (average percentage of respondents rating the clinic above the dichotomized threshold) and patient-reported experiences of care. We estimated hierarchical linear regression models to account for patients nested within clinics.(37,38) These models controlled for patient characteristics including age, educational attainment, English language proficiency, patient activation, patient reported physical, social, and emotional health status. All hierarchical regression analyses were performed with restricted maximum likelihood (REML) estimators, advantageous for a small number of clusters. Data were analyzed using Stata 14.0 (StataCorp LP, College Station, TX) and regression coefficients at a level of ≤ 0.05 were considered statistically significant.

Results

Primary Care Clinic and Patient Characteristics

Table 8 shows the descriptive statistics for key variables based on study clinic team respondents (n=353) and patient respondents (n=1291). Clinics vary in their composition of occupations (receptionist and ancillary staff as a percentage of total ranged from 0% to 40%) and size (number of respondents per clinic ranging from 5-81). For clinic characteristics, the core primary care team members (primary care, nursing, medical assistant, diabetes educator) reported similar values as the entire team of respondents for all dependent and independent variables.

The adult patients with diabetes and/or CVD established with the 16 clinics were 57.2% female, predominantly English speaking (82.5%), and over 44 years old (95.9%) with at least some college exposure (58.8%). Patient-reported outcomes for functional status averaged slightly higher than the midpoint of scales for emotional (mean 3.50, SD 0.72), physical (mean 3.93, SD 0.91) and social health (mean 3.61, SD 1.06), and patient responses spanned the entire scale from poor health at the low end to full functioning at the top end for the population.

Table 8. Descriptive Statistics for Key Variables

Practice Survey Variables	Medical Team	All	Cronbach alpha (Med Team)
	N=274	N=353	
Encounter-Level Time Pressure Effect, mean, SD [1-6]	4.94 (1.14), N=249	4.96 (1.16), N=280	.95 (7 items)
Encounter-Level Time Pressure– Highly Unlikely to Miss All Diagnostic, Screening and Treatment Opportunities [6]	78/249 (31.3%)	94/280 (33.5%)	
Encounter-Level Time Pressure, dichotomized (more vs less likely [5+])	95/249 (38.2%)	101/280 (36.1%)	
Practice Atmosphere (calm to chaotic), mean, SD [1-5]	3.29 (0.84), N=272	3.26 (0.86), N=351	
Practice-Level Time Pressure: chaos, dichotomized (more [4+] vs less)	91/272 (33.5%)	117/351 (33.3%)	
Relational coordination, mean (SD) [96-336]	256.16 (42.62)	264.04 (46.46)	0.90 (7 items)
Patient centeredness, mean (SD) [0-25]	21.01 (4.60)	20.73 (4.69)	0.92 (5 items)
Health information technology, mean (SD) [1-4]	3.52 (0.55), N=264	3.52 (0.58), N=323	0.88 (8 items)
Leadership facilitation, mean (SD) [0-35]	26.17 (7.49)	26.19 (7.71)	0.95 (7 items)
Solidarity culture, mean (SD) [0-20]	14.92 (3.88)	14.78 (3.88)	0.82 (4 items)
Workgroup Role, N			
Physician	75	75	
Nurse	70	70	
Medical Assistant	110	110	
Diabetic Educator	19	19	
Receptionist	-	74	
Other: Social Worker, Dietician	-	5	
ACO (# of respondents)			
A	185	247	
B	89	106	
Practice Sites: Clinic Anonymous ID # (ACO A or B)			Med Team %
1 (A)	15	23	65.2%
2 (A)	38	53	71.7%
3 (A)	8	11	72.7%
4 (B)	4	5	80.0%
5 (B)	10	12	83.3%
6 (B)	19	25	76.0%
7 (A)	9	15	60.0%
8 (A)	9	13	69.2%
9 (B)	10	15	66.7%
10 (B)	6	6	100.0%
11(A)	37	37	100.0%

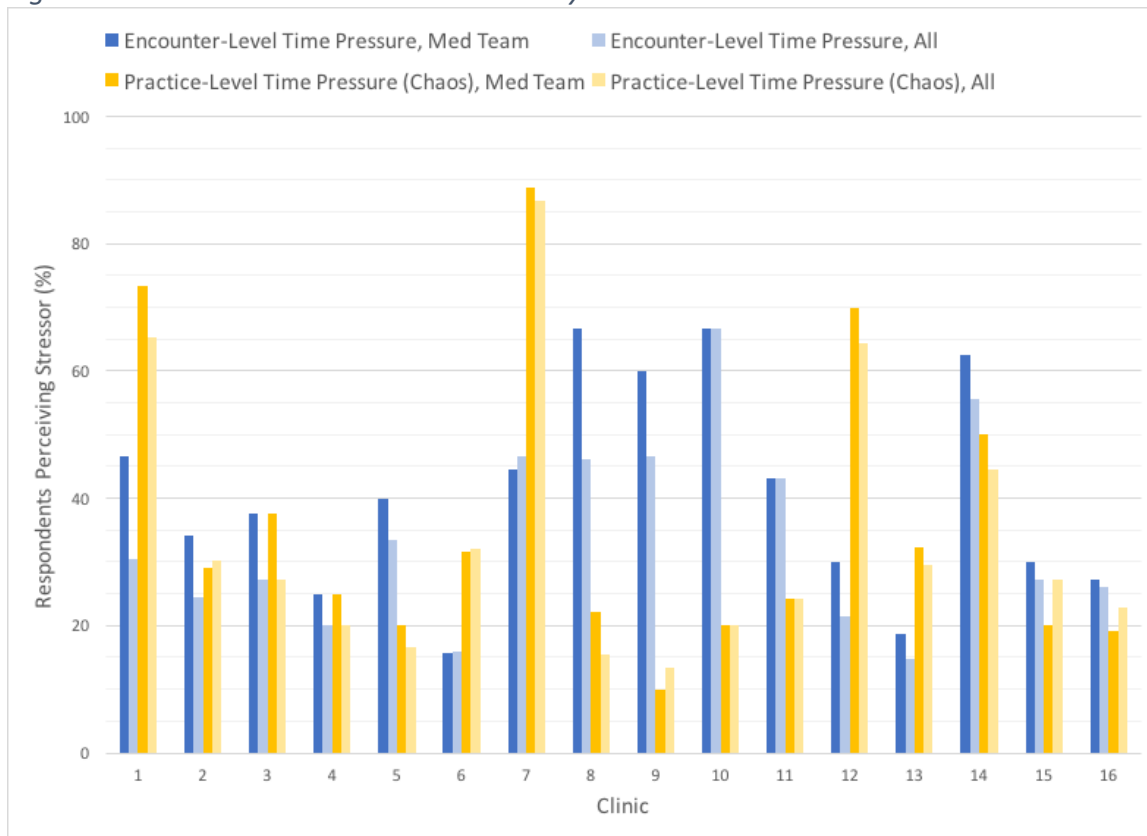
Practice Sites: Clinic Anonymous ID # (ACO A or B)			Med Team %
12 (A)	10	14	71.4%
13 (A)	59	81	72.8%
14 (B)	8	9	88.9%
15 (B)	10	11	90.9%
16 (B)	22	23	95.7%
Patient Survey Variables			
	All N=1291	Range	Cronbach alpha
Patient Assessment of Chronic Illness Care (PACIC), mean (SD) N=1282	2.73 (0.82)	1-4	0.92 (11 items)
CollaboRATE, mean (SD) N=1269	3.61 (1.08)	1-5	0.91 (3 items)
Patient Activation Measure (PAM), mean (std. dev.)	3.25 (0.51)	0-4	0.92 (13 items)
Patient-Reported Outcomes (higher scores → better function)			
Emotional Functioning (PHQ-4/Depression), mean (std. dev.) N=1284	3.50 (0.72)	1-4	0.89 (4 items)
Physical functioning, mean (SD) N=1290	3.93 (0.91)	1-5	0.93 (10 items)
Social functioning, mean (SD) N=1288	3.61 (1.06)	1-5	0.96 (8 items)
Age, years, no. (%) N=1278			
18–24	4 (0.3%)		
25–44	48 (3.8%)		
45–64	446 (34.9%)		
65+	780 (61.0%)		
Sex, no. (%) N=1282			
Female	733 (57.2%)		
Male	549 (42.8%)		
Education, no. (%) N=1269			
Grade 8 or less	152 (12.0%)		
GED or some high school	371 (29.2%)		
Four-year college degree or some college	573 (45.2%)		
More than 4-year college degree	173 (13.6%)		
English language proficiency, no. (%) N=1285			
Yes	1060 (82.5%)		
No	225 (17.5%)		
Doctor only, no. (%) N=1247			
Yes (response = 0)	561 (45.0%)		
No (others played important role = 1)	686 (55.0%)		

Time Stressors: Encounter-Level and Practice-Level

One-third (33.3%) of respondents indicated a chaotic practice atmosphere. Only 31.3% of the core medical team responded that during patient encounters it was very unlikely for the clinic team to miss all seven specific opportunities related to screening, diagnosis or treatment. These encounter-level time pressure effects were highly correlated (average 0.73, range 0.63 to 0.82 in pairwise comparisons among the seven items) indicating comparable potential for patient safety effects of missed screening, diagnosis, or treatment. Practice-level time pressure, based on atmosphere from calm to chaotic, was not correlated with any of the encounter-level time pressure effects (0.02-0.05), supporting the hypothesis that these two separate time stressor constructs are distinct.

Figure 13 displays the dichotomized stressor variables (encounter-level time pressure effect and practice-level time pressure [chaos]) by clinic for all respondents and core medical team only. The proportion of personnel from a given clinic who reported a stressor ranged from 10% to 89%. Four of 16 clinics had 50% or more medical personnel perceiving a chaotic practice-level time pressure (clinics 1, 7, 12 and 14). Clinic 14 from the chaotic subgroup, and three other clinics (8, 9 and 10) had greater than 50% of the medical respondents reporting greater likelihood of encounter-level time pressure effects on patient management.

Figure 13. Time Stressor Levels in 16 Primary Care Clinics



Organizational Factors Associated with Each Type of Time Pressure

Table 9 and 10 each show three models for practice-level (chaos) and encounter-level time pressure effects. In the ACO-only models, the ACO encounter-level time pressure effects are indistinguishable, but respondents from ACO B are less likely to report practice-level chaos (odds ratio (OR) 0.52, $p=0.03$).

The second set of multivariate models examine the impact of adding clinic organizational variables hypothesized to be related to each time stressor. As hypothesized, encounter-level time pressure adverse effects are associated with less patient-centeredness (OR 0.85, $p<0.001$), less HIT capability (OR 0.46, $p=0.003$), and less relational coordination among team members (OR 0.98, $p<0.001$). Solidarity culture, however, was not associated with encounter-level time pressure effects. Similarly, supporting the hypothesized relationships for practice-level time pressure, medical assistants were more likely to report a chaotic practice compared to primary care physicians, (OR 2.30, $p=0.03$), and greater leadership facilitation was associated with lower odds of practice-level chaos (OR 0.92, $p<0.001$).

The final set of models incorporated all independent clinic variables to test whether different organizational characteristics predict one of the two time stressors, but not the other as hypothesized (null theory). Compared to reference Clinic 1, nine clinics were much less likely to have practice-level chaos (OR 0.05 to 0.18, $p<0.05$), and three clinics were more likely to perceive adverse encounter-level time pressure effects (OR 9.3-14.3, $p<0.05$). Clinics 9 and 10 were statistically different from Clinic 1 for both practice-level chaos (less likely) and encounter-level time pressure effects (more likely). As hypothesized, leadership facilitation was not associated with encounter-level time pressure, and patient-centeredness, HIT capability, relational coordination and solidarity culture were not associated with the presence of practice-level chaos. Contrary to the hypothesized relationship, both nurses and medical assistants were significantly less likely to perceive adverse encounter-level time pressure effects on patient care compared to primary care physicians (OR 0.24, $p=0.001$ for nurses and OR 0.21, $p<0.001$ for medical assistants).

Table 9. Practice-Level Time Pressure (Chaos) Models

Practice-Level Time Pressure (Chaos)						
	Model 1: ACO		Model 2: Hypothesized		Model 3: All Factors	
	Odds Ratio	P> z	Odds Ratio	P> z	Odds Ratio	P> z
ACO A	Reference					
ACO B	0.523	0.027				
Patient Centered					1.018	0.662
HIT					1.243	0.501
RC					0.999	0.775
Solidarity					0.927	0.224
Leadership			0.922	0.000	0.937	0.068
Clinic 1			Reference		Reference	
2			0.152	0.009	0.119	0.005
3			0.181	0.095	0.168	0.086
4			0.195	0.251	0.169	0.224
5			0.048	0.011	0.050	0.012
6			0.175	0.033	0.133	0.023
7			1.916	0.609	1.463	0.767
8			0.097	0.012	0.088	0.009
9			0.048	0.024	0.037	0.020
10			0.052	0.009	0.049	0.012
11			0.151	0.012	0.145	0.012
12			0.708	0.719	0.569	0.569
13			0.135	0.005	0.114	0.004
14			0.349	0.283	0.303	0.247
15			0.105	0.022	0.080	0.015
16			1.476	1.476	1.476	1.476
Physician			Reference		Reference	
Diabetes Educator (RN/Health/Peer)			1.162	0.844	1.172	0.834
Medical Assistant			2.269	0.033	2.089	0.059
Nursing (RN, RN Care Manager, LVN)			1.589	0.292	1.477	0.394
	N	272.000	N	272.000	N	263
	Wald chi2(1)	4.890	Wald chi2(19)	44.000	Wald chi2(23)	46.64
	Prob > chi2	0.027	Prob > chi2	0.001	Prob > chi2	0.003
	Pseudo R2	0.015	Pseudo R2	0.169	Pseudo R2	0.1783

Table 10. Encounter-Level Time Pressure Models

Encounter-Level Time Pressure	Model 1: ACO		Model 2: Hypothesized		Model 3: All Factors	
	Odds Ratio	P> z	Odds Ratio	P> z	Odds Ratio	P> z
ACO A	Reference					
ACO B	1.087	0.757				
Patient Centered			0.829	0.000	0.826	0.000
HIT			0.433	0.002	0.369	0.002
RC			0.984	0.000	0.985	0.001
Solidarity			1.059	0.277	1.059	0.467
Leadership					0.948	0.144
Clinic 1					Reference	
2					1.947	0.458
3					0.589	0.727
4					3.207	0.461
5					0.930	0.950
6					0.392	0.422
7					0.364	0.341
8					5.423	0.223
9					9.252	0.042
10					11.570	0.021
11					1.194	0.834
12					0.992	0.995
13					0.605	0.576
14					14.347	0.028
15					0.670	0.766
16					1.476	1.476
Physician					Reference	
Diabetes Educator (RN/Health/Peer)					0.613	0.503
Medical Assistant					0.210	0.000
Nursing (RN, RN Care Manager, LVN)					0.236	0.001
	N	274	N	264	N	264
	Wald chi2(1)	0.1	Wald chi2(4)	45.22	Wald chi2(23)	69.82
	Prob > chi2	0.7573	Prob > chi2	0.000	Prob > chi2	0.000
	Pseudo R2	0.0003	Pseudo R2	0.1974	Pseudo R2	0.3343

Two Types of Time Pressure and Patient-Reported Experience of Chronic Care

Greater practice-level time pressure (chaos) was associated with lower PACIC-11 mean scores (OR 0.719, p<0.05) and remained significant in multivariate analysis including patient-reported characteristics and other experiences with the clinic (OR 0.743, p<0.01) (Table 11). Encounter-level time pressure was not associated with PACIC-11 scores in either unadjusted or adjusted analyses, though the effect trended in the expected direction.

Among control variables (Table 11, Models 3 and 4), women reported lower PACIC scores than men, and those with an 8th grade education or less had higher PACIC scores than those with more education. PACIC scores did not vary significantly by patient condition or symptoms (patient-reported functioning), age or English proficiency, all else equal. Patients who indicated that team members in the primary care practice besides the doctor played an important role in their care reported higher PACIC scores. Higher levels of collaboration with the practice team, and greater patient activation levels were also significantly associated with higher PACIC scores.

We found no substantive changes to any results (data not shown) for alternative time stressor specifications – continuous instead of dichotomous classification, all respondents instead of medical team only.

Table 11. Patient Experience of Care (PACIC) Models

	Patient Assessment of Chronic Illness Care (PACIC) (Mean)							
	Model 1		Model 2		Model 3		Model 4	
Practice-Level Time Pressure (Chaos)	0.719*	(0.104)			0.743**	(0.072)		
Encounter-Level Time Pressure			0.779	(0.178)			0.828	(0.136)
Good English Proficiency (versus poor)					0.930	(0.057)	0.919	(0.057)
18-24					Reference		Reference	
25-44					1.390	(0.433)	1.419	(0.442)
45-64					1.339	(0.405)	1.347	(0.408)
65+					1.309	(0.396)	1.315	(0.398)
Female					0.900***	(0.028)	0.903**	(0.028)
8 grade or less					Reference		Reference	
GED or some high school					0.831**	(0.057)	0.827**	(0.057)
4 year college degree or some college					0.734***	(0.053)	0.727***	(0.053)
More than 4 year college degree					0.749***	(0.061)	0.740***	(0.060)
Social Functioning (1-5)					0.986	(0.022)	0.988	(0.022)
Physical Functioning (1-5)					0.985	(0.025)	0.983	(0.025)
Emotional Functioning (1-4)					1.040	(0.028)	1.039	(0.028)
Patient Activation Measure (PAM)					1.281***	(0.051)	1.280***	(0.051)
Doctor Only					Reference		Reference	
Other Providers Involved					1.102**	(0.036)	1.101**	(0.036)
CollaboRATE (mean)					1.658***	(0.029)	1.655***	(0.029)
Observations	1282		1282		1169		1169	
AIC	3130		3132.5		1890.7		1895.9	
BIC	3150.7		3153.1		1981.9		1987.1	
ICC (Standard Error)	0.012	(0.010)	0.019	(0.012)	0.012	(0.010)	0.026	(0.015)
Exponentiated coefficients; Standard errors in parentheses								
* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$								

Discussion

Time pressure effects for care within an encounter were not correlated with practice-level time pressure (chaos). The two measures used in this study seem to be capturing distinct processes and experiences, or at least different perceptions about the clinic environment and its potential effects on patient care. In this study of 16 primary care practices, we found every combination – one chaotic clinic with considerable encounter-level time pressure effects, several chaotic

clinics without perceived encounter-level time pressure effects, several calm or low practice-level time pressure clinics with perceived encounter-level time pressure effects, and finally relatively calm clinics without perceived encounter-level time pressure effects of overlooking important opportunities to diagnose or treat patients during their visits. These patterns highlight the complexity of managing experiences and perceptions of time pressure for health care systems such as the ACOs we studied.

Individual primary care team members experience encounter and global practice-level time stressors in different ways and we found systematic differences by team member role. Medical assistants were more likely to perceive practice chaos compared to primary care physicians, controlling for other clinic effects. Part of a medical assistant's role is to help the doctor focus on direct patient care work by buffering any rough edges in logistics and communications outside the exam room.(17–19) Some medical assistants may want to protect doctors from the chaotic side of the clinic. Alternatively, because of their lower positional status, they may not feel comfortable sharing information about the chaotic environment with physicians, or have much efficacy in addressing it. We hypothesized no relationship between time pressure effects within the encounter and work group role. However, primary care physicians were significantly more likely to perceive encounter-level time pressure effects on patient care compared to medical assistants and nursing personnel. Physicians may have the best line of sight to detect actual risks from time pressure in an encounter, or they may tend to worry more about adverse effects, relative to the other team members. If the former situation is true, patient safety concerns merit attention to balancing physician loads, adding scribes, exploring delegation arrangements and other efforts to mitigate encounter-level time pressure effects.

As hypothesized, several organizational factors were associated with each time stressor. At the practice site level, more leadership facilitation – including management assuring enough time to discuss changes to improve care – was associated with less chaos. At the encounter level, more patient-centeredness, better availability and use of HIT capabilities, and higher levels of relational coordination were associated with fewer time pressure effects. The protective direction for HIT on encounter-level time pressure was even stronger after controlling for work group and clinic site, suggesting HIT has a potentially pivotal role in alleviating time stress during patient-clinician interactions. Greater solidarity among team members could either increase time pressure effects if time for peers reduced capacity for patient care, or time pressure effects could lessen group-oriented culture meaning that team members backed each other up more, easing workloads. The lack of finding an association between solidarity and time pressure in our study could mean that both mechanisms operate and canceled out effects of each other.

Previous studies have shown that practice-level chaos is associated with adverse physician effects such as lower job satisfaction and more burnout, but results are mixed for patient safety and quality effects.(15,31) We found a significant relationship between chaos and worse patient-reported experience of receiving chronic care support (PACIC-11). The magnitude of the association was consistent after adjusting for demographics, patient engagement, and level of

patient-team partnership (CollaboRATE and importance of non-physician team members). This suggests that a practice characteristic perceivable by the team, especially medical assistants, may be an important lever in effective chronic care management.

Limitations

Although this study benefits from multilevel data collected directly from patients and the clinical teams that serve them at a randomly selected set of primary care clinics in two regions, it has several limitations. First, encounter-level time pressure effects on patient care are based on perception about likelihood of missing important care needs, and are not verified by medical record review. Social desirability would suggest that we are underestimating the likelihood of adverse effects for patients, but it is also conceivable that clinicians, particularly physicians, worry about missing opportunities to provide necessary care and therefore overestimate the chance compared to other primary care team members. Second, in the organizational factors analysis, but not the patient experience analysis, independent and dependent measures come from the same survey, resulting in potential for common method variance bias inflating correlations among the same individuals responding to all the questions, and increasing the chance of spurious associations.⁽³⁹⁾ Because we analyze two separate dependent variables in a full model of all organizational dependent variables with null results as predicted, this concern is not as strong. Third, the cross-sectional nature of the study precludes conclusions about cause and effect in the associations detected. Finally, the study is limited to primary care practices of ACOs, and therefore is not necessarily generalizable to other practice environments. Given the transformational goals of ACOs and their increasing role in health care delivery, however, our findings provide relevant insight into time pressures faced by primary care team members with considerable incentives to simultaneously improve quality of care and patient experiences, while also reducing total costs of patient care.^(40,41)

Conclusions

Our study builds on the limited base of organizational research about time-related stress among health care professionals, the work they do, and the consequences for patients. This study provides initial support for the notion that there are two distinct time stress constructs (patient encounter-level and global practice-level), with distinct potential organization design and culture contributors, as well as different possible consequences to patient care—missed clinical care opportunities and less patient experience of chronic care support.

Organizations control time allotments to workers, and in turn, the potential stress experienced by those doing the organization's work if there are inadequate allocations. For face-to-face clinic visits, patients are typically scheduled for a particular time allotment (e.g., 10 minutes)

based on the work anticipated (based on minimal information from patients who call in), the reimbursement environment, and the organization's financial circumstances (e.g., limited resources for safety net providers, production pressure in for profit operations).(2) Patients often do not know the time allotment, though cues such as a doctor's movement toward the door or a full waiting room may convey a sense of time pressure, while empathetic listening has the opposite perceptual effect.(42) Some physicians ignore appointment time limits in order to enhance their job satisfaction, even if they anticipate adverse financial consequences.(43)

Practices that are more patient-centered may provide more time to the clinical team to carry out their patient-facing work. Based on our study results, primary care practices need to consider the potential effect of malleable organizational factors such as HIT capability and patient-centered culture on the level of time stress that could be associated with poor patient outcomes. For longitudinal chronic care management within the context of an adaptive sociotechnical systems approach, time pressure both within and outside encounters is relevant to optimal patient care.(44,45) Given high burnout levels of primary care clinicians and staff,(46) identifying the determinants and consequences of different forms of time stress in primary care is key to developing mitigating strategies.

Given the increase in consolidations in ambulatory care with the emergence of ACOs, the finding about an ACO level effect on chaos underscores the utility of data collection and analysis at multiple levels – patient, team, clinic, and parent organization. With ACOs, the practicality of such data collection has improved. Some ACOs may be motivated to monitor practice-level (chaos) and encounter-level time pressure as early warning signals for their workers and patients, who together are co-producing health outcomes.(47) ACOs are also in a good position to work closely with their frontline teams to identify the specific time stressors that are most concerning, and whether interventions tied to our findings merit testing. For example, HIT is often implicated as increasing clinician burden, (48,49) yet specific features of HIT assessed in this study are associated with perceptions of lower likelihood of missing diagnoses and treatment opportunities. Interventions that aim to make accessible some of these capabilities such as ease of assessing basic data, integrating data, and communication with other providers and patients could reduce time stress at the encounter level, and in turn, potential adverse consequences to patients. Likewise, the focus for team work (i.e., patient-centeredness) and how work is organized and coordinated (i.e. capabilities for relational coordination among the different roles) may be particularly important for buffering physicians from missing opportunities to diagnosis and treat patients in the exam room.(50) In terms of reducing practice-level time pressure, recent research on chaotic practices suggests that clinic leaders might focus first on specific office bottleneck challenges such as availability of interpreter services and phone access.(31)

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CHAPTER 6

Final Conclusions and Contributions

The three research papers together aimed to contribute to the emerging area of diagnostic safety and quality research with a particular focus on organizational factors. By focusing on different but complementary settings in ambulatory care, taking qualitative and quantitative methodological tactics, working within the NAM framework, (1) and drawing from organizational science, this work contributes insights about ways for ambulatory care organizations to improve diagnosis. The three projects also collectively provide examples of interrogating key aspects of the NAM framework for improving diagnosis, demonstrating how this conceptual framework is useful for patient-centered, organizationally sensible research. Therefore, the contributions from this set of papers are expected to be practical, methodological and theoretical, while also informing further research.

Insights for Ambulatory Care Organizations

As a qualitative field study, the first project started with a problem faced by five specialty clinics operating under challenging circumstances familiar to those who care for economically disadvantaged populations within safety net settings. The clinic teams expressed worry about patients falling through metaphoric cracks in a system of care primarily designed to handle patients one encounter at a time, as opposed to across time and place. When patients have potentially sinister but inconclusive findings, they need longitudinal follow-up and testing. If the clinics are unable to track, communicate and see these patients at intervals determined by their unique clinical situations, they may experience a delayed or missed diagnosis of cancer and other life-threatening conditions. Coordination of care challenges across settings and time are pervasive and considered a national priority, but previous studies have not recognized such challenges for this population of high-risk patients.(2,3)

The first paper addressed that gap in practical terms. The research set up the ability to design interventions for rapid prototyping and testing in the safety net environment, with an eye to problems in workflow and clinician needs surfaced from the research. In particular, the product of the research—potential remedies in the form of design seeds – are prioritized and assessed for their anticipated effects on clinician time and patient safety. Common vulnerabilities included shortcomings in HIT, limited organizational attention to population management of high-risk patients, and extremely time-crunched personnel. All three of these vulnerabilities are likely present at numerous other specialty clinics. The design seed approach to developing key attributes for robust population-level monitoring solutions enables customization to other contexts (i.e., other specialty or multi-specialty clinics), followed by testing and implementation.

The second paper started with a much broader group of clinics, both primary care and specialty clinics from every region of the U.S., that opted into a government-run database about patient safety culture at medical offices (clinics). Practices completing the survey responded to

questions about the frequency of office quality and safety issues related to the diagnostic process such as incorrect patient information, not having results available when needed, untimely follow-up of abnormal test results, and problems exchanging accurate, complete, and timely information with other provider types. The clinic offices also provided information about their level of implementation of HIT system tools.

Using multivariable regression methods, the second project estimated the association between office-reported HIT implementation levels and perceived frequency of 8 office problems that could lead to diagnostic errors, with and without including stratified patient safety culture scores at the clinic office level. Separate analyses of the subscales of the culture survey included one on work pressure and pace, a time-related variable of interest, that demonstrated an association with the office problem of tests not available when needed. The findings also offer partial support for the paper's three main hypotheses relevant to ambulatory care clinics: 1) a higher frequency of office problems that could lead to diagnostic error were associated with partial levels of HIT implementation compared to no implementation, 2) lower frequency of office problems was associated with full HIT implementation compared to no implementation, and 3) worse office safety culture was associated with more frequent office problems.

The third paper was motivated by a major gap in the literature about effects of time pressure on teamwork in the clinic setting, including the possibility of missing consequential diagnoses. Based on this observation, the third project incorporated measures of time pressure into an ongoing study of primary care practices in order to learn about potential organizational determinants and patient consequences of time pressure for team-based care.

The third project's cross-sectional observational approach found associations between time pressure and organizational factors, such as HIT capabilities, patient-centered culture, relational coordination among practice teams and leadership facilitation of change, and in turn, associations with adverse consequences for patients. But these associations do not confirm what comes first – the organizational factors reducing time pressure effects in the theorized direction, or less time pressure galvanizing organizations to become more patient-centered and use HIT capabilities more frequently. While either explanation is possible, the project's measures of two types of time pressure experienced by practice team members (i.e., encounter-level and practice-level) allowed testing associations related to hypothesized significant directional effects and null effects. The analyses provided some support for the distinction of effects theorized, whereby changes in the organizational factors would be expected to cause changes in time pressure effects, and in turn have adverse consequences to patients. In the future, the study could be extended with the encounter-level and practice-level time pressure questions incorporated in a subsequent survey of these same primary care practices to allow longitudinal analysis that more directly explores cause and effect relationships. Additionally, examination of interview data collected from the primary care team members at these 16 practice sites from concurrent field work could provide further insights into the time pressure findings.

Theoretical and Methodological Contributions

The first paper articulates both textually and visually how intervention development can be informed by complex adaptable socio-technical systems theory. The study also links the research findings of more than 40 vulnerabilities elicited from the clinics directly to the NAM conceptual framework, demonstrating its utility as a conceptual map in this domain.(1) Finally, the first project demonstrates a novel integration of industrial and human factors methods (journey mapping, process tracing, design seeds) for organizational analysis and intervention design within the safety net setting.

A key contribution from the second paper is its focus on office problems that could lead to diagnostic error. Because diagnostic safety is an emerging area of concern in health care, researchers are somewhat stymied by a lack of measures of diagnostic performance.(1,4,5) In the meantime, proxy measures are useful. The paper demonstrates that office problems, as assessed in this national survey may provide one reasonable signal for concerns about diagnostic safety gaps because they are sensitive to HIT and office culture in ways that have face validity. In addition, the findings contribute to the existing literature on the importance of safety culture. Those in the diagnostic safety arena of research have asked whether a diagnostic safety culture measure is needed, apart from general safety culture measures.(1) This study shows that the MO-SOPS is sensitive to a proxy measure of diagnostic safety. Further research on the domains covered by MO-SOPS and other diagnostic safety-related measures would help determine whether this general safety culture measure for ambulatory care settings is adequately sensitive to ambulatory care diagnostic safety concerns.

Since the research literature on time pressure effects in actual practice is scant, the third paper's observational methodology complements what is known from experimental studies about these effects. In addition, the adaptation of the Linzer et al metric on missed opportunities (i.e., encounter-level time pressure effects) as a metric of perceived time pressure patient safety effects, including diagnostic errors, was proven feasible in a survey of practice teams. As a potential new measure, the encounter-level time pressure measure gains initial evidence of construct validity based on the demonstrated association with hypothesized organizationally-shaped factors.

All three studies set out to explore theoretically and empirically relationships between key components of the NAM Framework (i.e., work system, diagnostic process, diagnostic team, tools such as HIT, patient outcomes, etc.). For example, each study explored some aspect of HIT's role in exacerbating or reducing time pressure stress and its effects on diagnostic quality and safety. With major HIT investments underway and ubiquitous awareness of the burden of medical documentation,(6,7) findings from this theoretically-informed research has the potential to inform decisions by policy makers, innovators, and delivery systems about changing the HIT landscape in a way that is responsive to the needs of diagnosis in the ambulatory care setting. More importantly, the combined study of HIT, time pressure, diagnostic teamwork and

ambulatory care organizations undertaken for the three papers⁵ holds promise for improving diagnosis for patients.

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⁵ The creative basis for this Dissertation’s logo, displayed on the dedication page and after this chapter.



Appendices

Appendix 1: Script for Data Collection on Design Seeds

Script:

Thank you for taking the time to meet with me today. We have the opportunity to improve patient monitoring in your clinic. In order to meet your needs for improved monitoring, we'd like to validate our findings and get your feedback.

Specifically, we would like to follow-up on the discussion you had with George Su regarding vulnerabilities of monitoring patients with high-risk conditions/ receiving high-risk treatment in your clinic. We've found that many other subspecialty clinics are facing similar challenges.

We'd like to get your feedback on potential technology and organizational solutions that may alleviate the problems experienced in managing high-risk populations. Did we appropriately capture the problems you experience in your clinic? Do you think our suggested solutions will improve patient monitoring and efficiency?

As we go through the exercise, I'd like to remind you that there is no correct or incorrect answer. Your responses allow us to get a better sense of your experiences monitoring high-risk situations in clinic.

We expect this feedback collection exercise will take about 30 minutes. Thank you for your input!

Instructions:

Part I

First, we'll look at a list of the problems we heard about from each clinic. **As you look at these problems, make a check next to those that you experience. You can circle problems that are even more relevant and make notes on these cards.**

Part II

We'll now look at a set of cards that list 13 suggestions to improve patient monitoring. The solutions respond to issues raised by at least one of the clinics we visited.

From your vantage point at your clinic, think about patients who are at high-risk of being lost to follow-up and/ or require multiple steps or high effort to track/ monitor.

We'll also ask you to prioritize the cards according to importance. If you think a solution characteristic is particularly important, you can mark it with an asterisk so it is easier to rank them at the end of the exercise. We also encourage you to take notes or talk aloud if any other ideas come to mind. This will allow us to both refine our findings and better understand the differences between clinics.

Here is the first solution card. All 13 look like this. This (*pointing*) is a statement from a specialty clinic's viewpoint that motivates the solution attribute. The summarized solution attribute is in bold (*pointing*), followed by details related to the solution attribute (*pointing*). After you read the quoted statement and information in each box, please respond to the statements at the bottom. You can do this after I tell you one more thing. As you go through all the cards, please order them so that you end up with the most important solution card on the top and least important one on the bottom. It is fine to move them around as you go, or to go back through at the end. I will mark the cards 1-13 according to your final order. If we have time after the exercise, I'll ask you to explain why you ranked in the order that you did.

Ask for:

Additional comments – reasons for ratings, choices, and thoughts about any of the potential solutions

What clinic is participant representing?

Appendix 2: Feedback Form for Data Collection on Design Seeds (examples)

PART I: Vulnerabilities Experienced

- 8 slides: 40 vulnerabilities
- Check any that you believe apply to your clinic

Check any that apply

- Don't have a system to put patients into subgroups for more efficient monitoring
- Hard to stratify patients into subgroups for monitoring due to many individual patient differences
- Creating list of patients requiring monitoring takes time
- Maintaining list of patients requiring monitoring takes time
- Manually monitoring patients is error-prone
- Manually monitoring patients is time intensive

PART II: Solutions to Vulnerabilities

- 13 Slides: 13 solution attributes
- Read and then respond to statements at bottom
- Sort as you go to prioritize most important to least important

"Our clinic needs an accurate list of all patients that need monitoring."

RANK IN ORDER OF IMPORTANCE (1-13)

SOLUTION ATTRIBUTE

Population registry functionality for high-risk patients

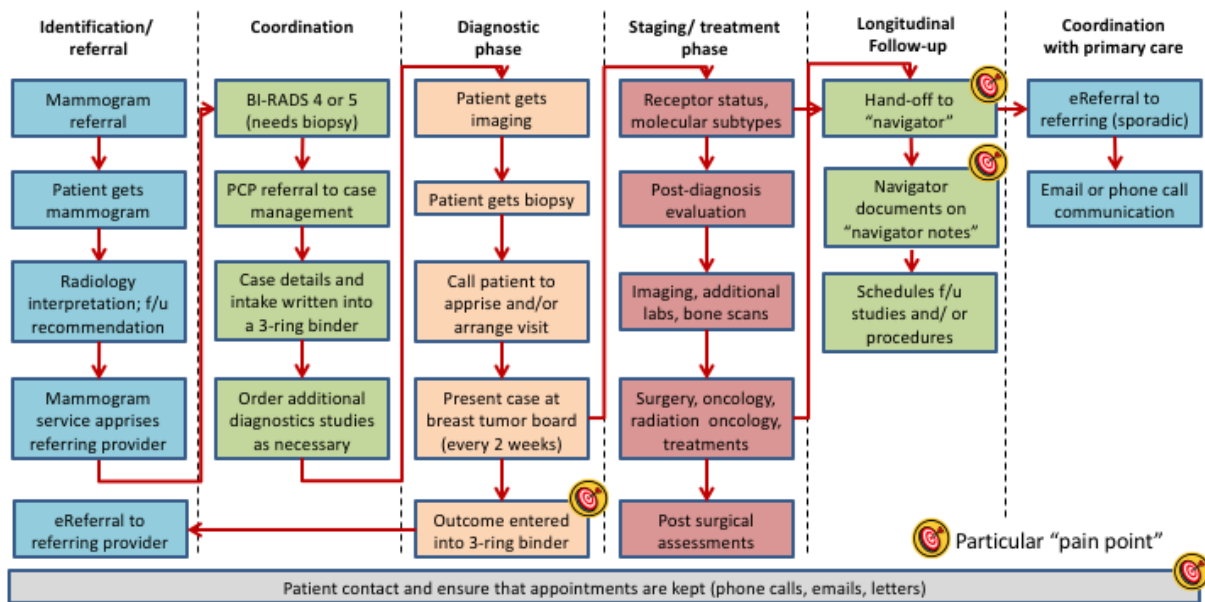
- Serves as a functional list of patients for population management
- Uses visualization/ sorting to quickly identify patients in need of follow-up
- Uses prioritization to identify highest risk patients first
- Merges different sources of information needed for case identification and referral tracking
- Groups patients by PCP (or lack of PCP)

	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
This solution will contribute to improved monitoring in my clinic	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
This solution will reduce time spent monitoring high-risk patients	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

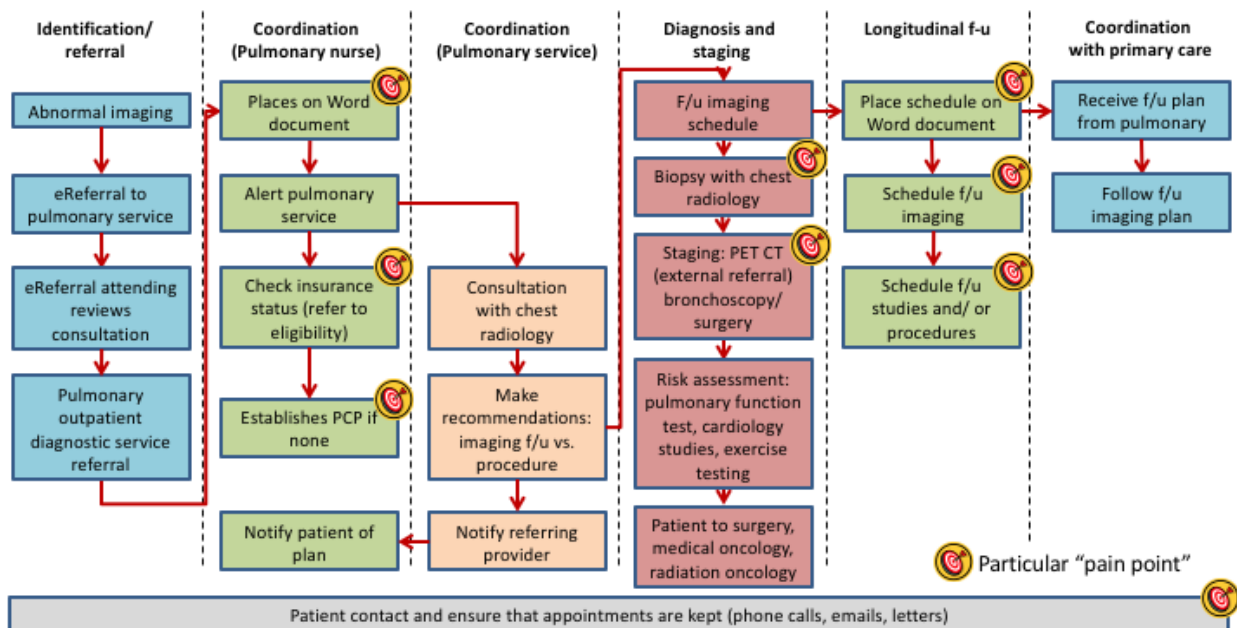
11

Appendix 3: Additional Workflows (breast, gastroenterology, urology) with Targets

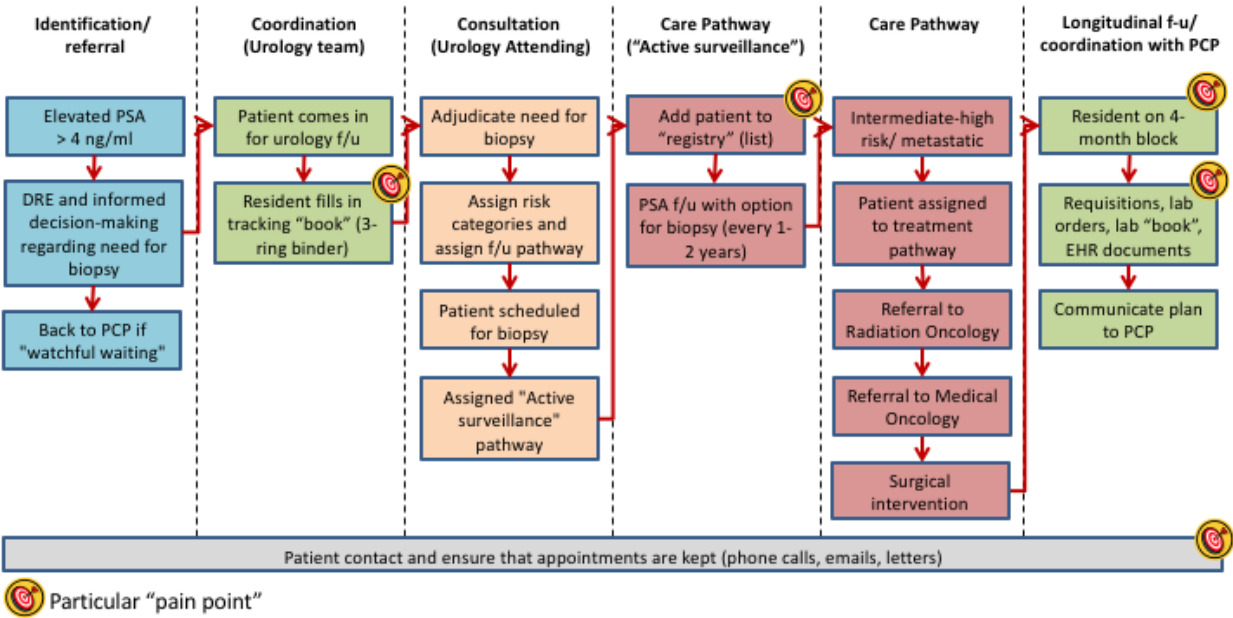
BREAST CANCER ONCOLOGY NAVIGATION SERVICE



PULMONARY NODULE JOURNEY MAP

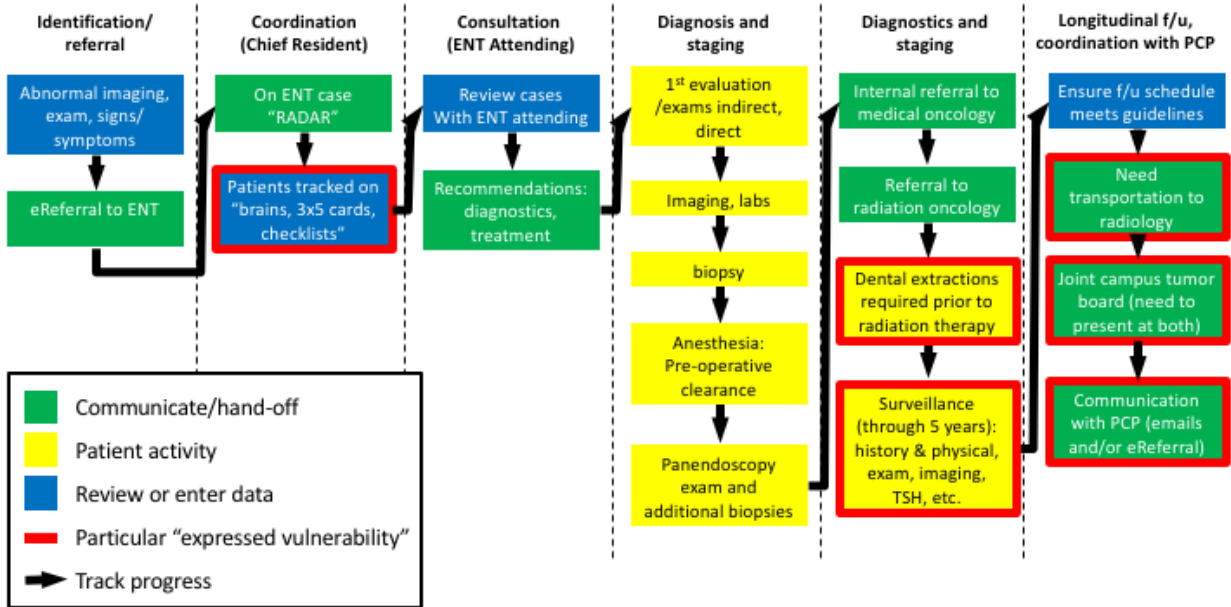


PROSTATE CANCER JOURNEY MAP

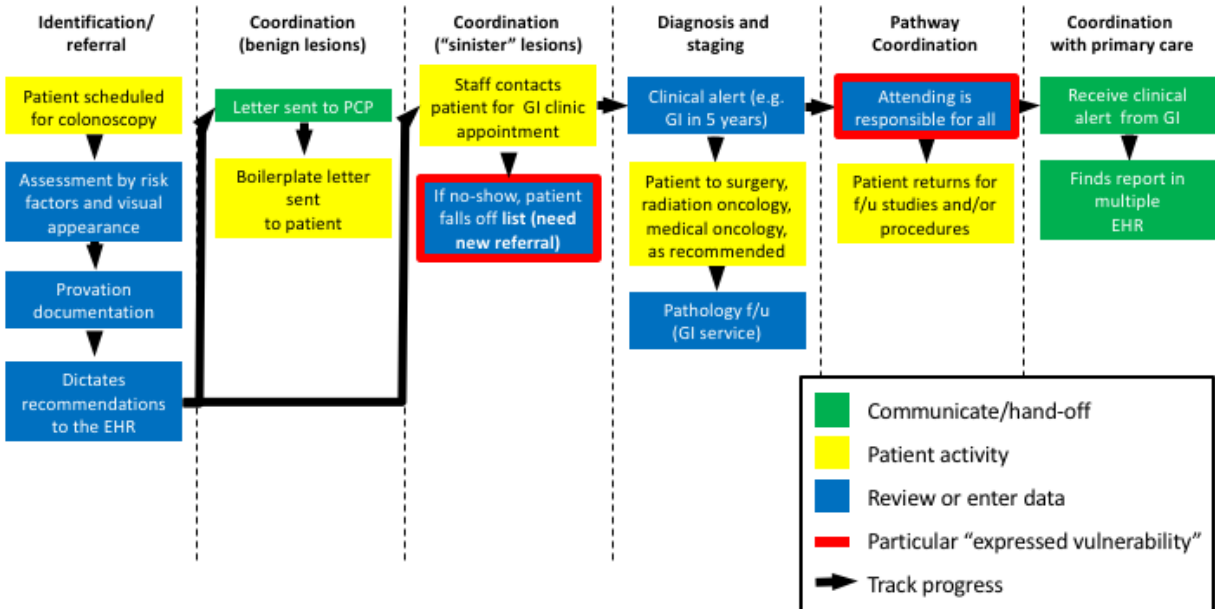


Appendix 4: All Workflows Color-coded as Foundation for Process Trace Sequences

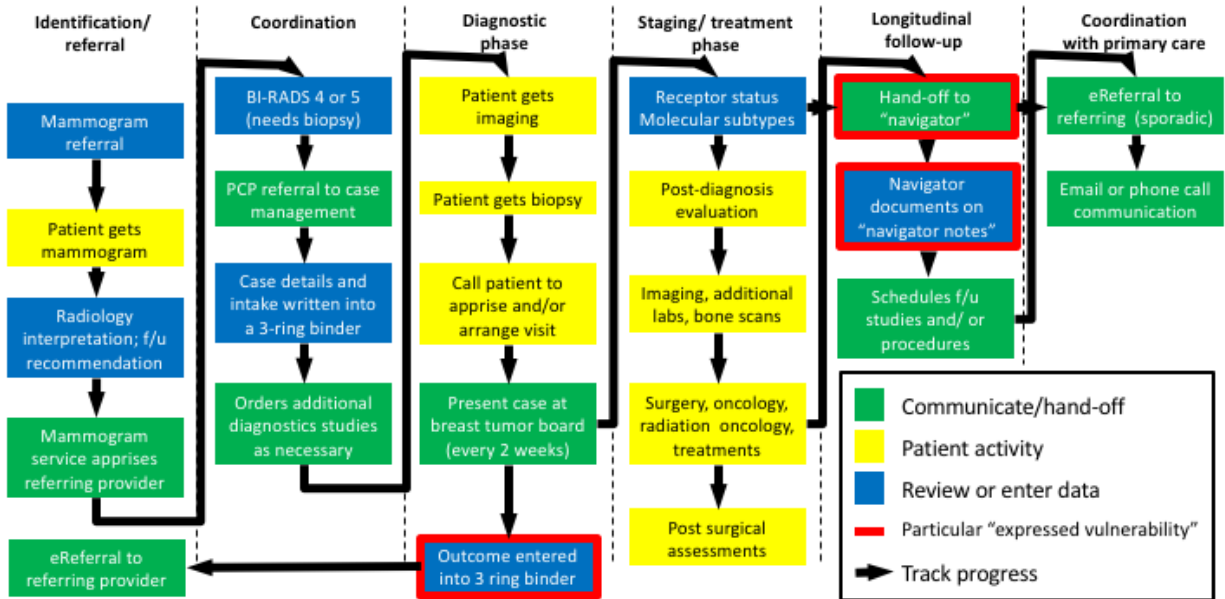
EAR NOSE AND THROAT (ENT) CANCER JOURNEY MAP



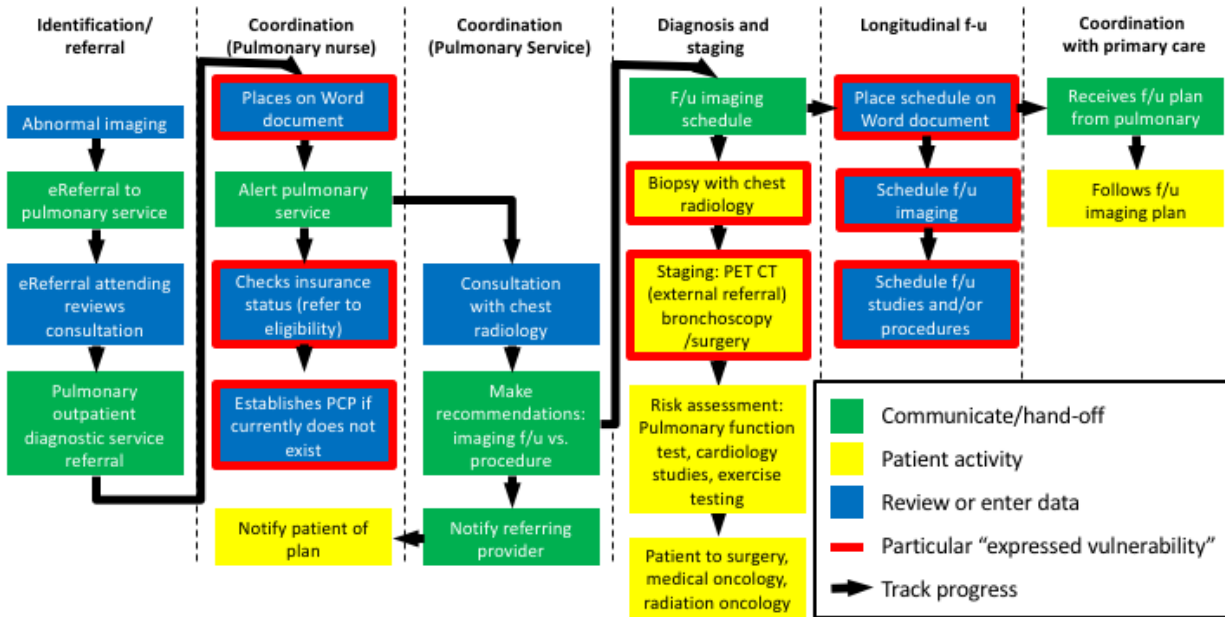
ABNORMAL COLONOSCOPY JOURNEY MAP



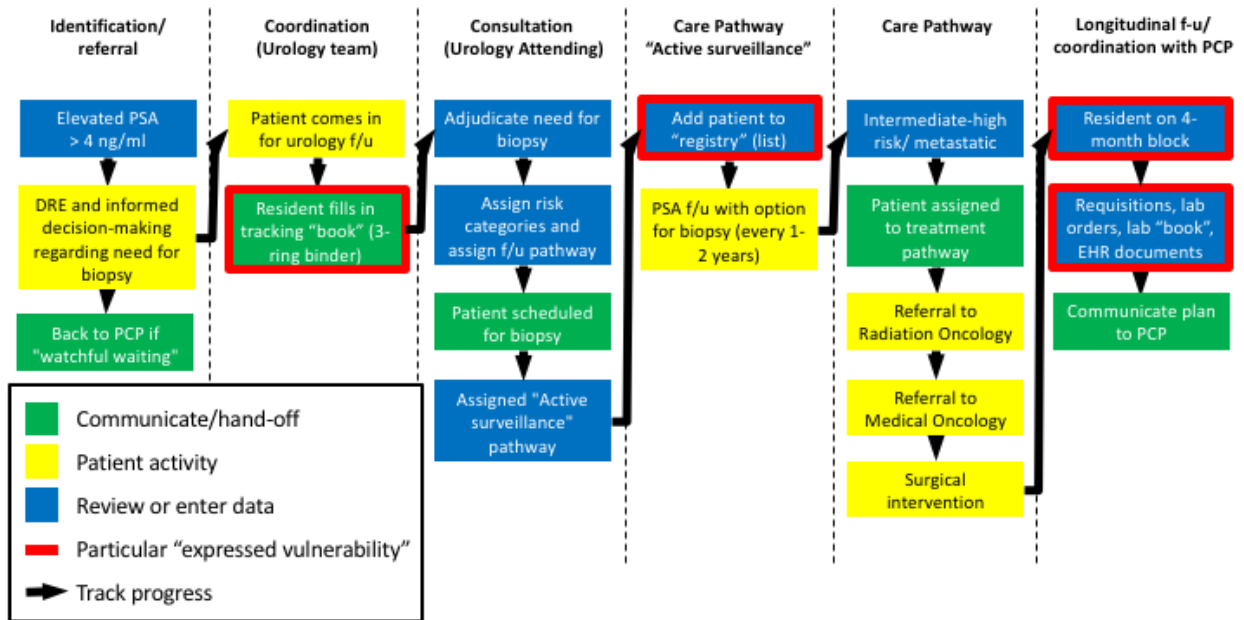
BREAST CANCER ONCOLOGY NAVIGATION SERVICE



PULMONARY NODULE JOURNEY MAP



PROSTATE CANCER JOURNEY MAP



Appendix 5. Excerpts from ACTIVATE Team Survey: HIT and Time Pressure/ Stressor Questions

12. HIT Use

How **easy/difficult** is it for you to use the **electronic health record** to do the following for your **patients with diabetes and/or cardiovascular disease**? Check N/A if “not applicable” because you do not use the electronic health record for the activity assessed.

	Very Easy	Somewhat Easy	Somewhat Difficult	Very Difficult	N/A
Accessing basic data					
a. Review lab results	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Update medication list & drug allergies for patients	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Integrating data					
c. Review information from hospital discharge summaries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Communication with other providers					
d. Review notes about patients (e.g., progress notes, nursing notes, consult notes)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Order new lab tests/medications	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Communicate electronically with other providers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Communication with patients					
g. Send or print after-visit summaries, instructions, educational information for patients	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h. Send or receive messages from patients	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

From Shortell, Rodriguez and CHOIR Team Survey (questions adapted from work by Ina Sebastian)

13. Practice Atmosphere:

Which number below best describes the atmosphere in your practice?

1 Calm	2	3 Busy, but reasonable	4	5 Hectic, chaotic
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

14. Time Pressure:

Given the increasing complexity and time pressure required to care for patients, the care team may not always be able to provide ideal care. Please help us understand how likely you think your care team is to miss the following opportunities in your practice:



How likely is it that <i>over the next month</i> in your practice your care team will...	Very unlikely	Moderately unlikely	Somewhat unlikely	Somewhat likely	Moderately likely	Very likely
a. Overlook a diagnosis of hypertension for a patient with 2-3 elevated BPs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Forget to screen for depression in a patient with other problems who seems a bit down?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Not start an ACE inhibitor in a diabetic patient for whom it is indicated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Neglect to offer aspirin to a diabetic patient with CAD?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Fail to notice an important drug-drug interaction in a patient with multiple medical problems?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Not refer a diabetic patient for an overdue annual ophthalmology exam?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. Not screen a new hypertensive patient for an alcohol use disorder?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

From Shortell, Rodriguez, and CHOIR Team Survey; Questions are adapted from PWS (Physician Work-life Study), MEMO (Minimizing Error Maximizing Outcome) and HWP (Healthy Work Place) studies, projects directed by Mark Linzer, MD.