AHRQ Final Progress Report:

Investigating Failures of Notification and Monitoring in Outpatient Care: the Safety Promotion Action Research and Knowledge Network

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ABSTRACT

Purpose: Patient safety issues are a significant problem in ambulatory care,[1,2] including ambulatory safety-net settings that serve predominantly un- and under-insured, low-income populations. Patient safety disparities remain understudied in part due to fragmentation of care and lack of implementation of standardized definitions and measurements.[3] The overall purpose of the Safety Promotion Action Research and Knowledge Network (SPARKNet) is to measure the extent of patient safety disparities in ambulatory settings and to understand the underlying reasons for the disparities.

Scope: Over a period of 5 years, five publicly funded health systems in California (CA) supported and contributed patient safety metric data for the investigative team's assessment of patient safety disparities. These health systems are Alameda Health System (AHS), Contra Costa Health Services (CCHS), Kern Medical Center (KMC), Los Angeles County Department of Health Services (LACDHS), and the San Francisco Health Network (SFHN).

Methods: We identified specific measures of ambulatory safety through a modified Delphi process and implemented measurement efforts.[3] Measures included laboratory monitoring and follow-up for high-risk persistent medications as well as breast and colon cancer screening and follow-up metrics from our SPARKNet study sites. We conducted an in-depth root-cause analysis demonstrating multiple vulnerabilities in the abnormal cancer screening follow-up process related to system, provider, and patient factors.[4]

Results: We demonstrated suboptimal performance and safety challenges across California safety net institutions.[5] Furthermore, our informal conversations with clinicians revealed myriad challenges involved in measuring performance using outdated electronic health record and data management systems and staffing challenges.

Key Words: Patient Safety, Quality of Healthcare, Ambulatory Care, Medicare, Medically Uninsured, Safety-net Providers, Public Hospitals,

PURPOSE

Ensuring patient safety remains a critical issue for health care systems. In 2016, nearly 884 million outpatient visits were conducted in the United States (US).[6] Patient safety in ambulatory safety-net care settings is not well characterized and remains a critical issue for health systems that serve vulnerable populations. The aims of this project are:

Aim 1: To develop feasible, timely, and accurate electronic measures of patient safety notification and monitoring gaps in an ambulatory care setting for high-risk sub-populations and characterize the extent of disparities in patient safety. Leveraging the Public Healthcare system Evidence Network and Innovation eXchange (PHoENIX) study infrastructure to access public ambulatory care data, we will develop measures in two high-priority areas of patient safety: 1) test results management and 2) outpatient monitoring for patients receiving high-risk treatments (such as anticoagulation or immunosuppression) that lead to adverse events, specifically examining race/ethnicity, language, and health literacy disparities.

Aim 2: To conduct a root cause analysis of patient safety notification/ monitoring gaps in five public ambulatory care settings to identify factors contributing to these disparities. We will use an in-depth, semi-structured qualitative research approach to trace the source(s) of failures in sending notifications about abnormal test results or for outpatient monitoring, using representative cases sampled from those cases identified in Aim 1. This methodology uncovers root causes for adverse events that can in turn inform strategies for future interventions to eliminate disparities in patient safety.

Aim 3: To evaluate the pilot implementation of patient safety monitoring methodologies developed from Aims 1 and 2 across five diverse ambulatory healthcare settings. We will work with five safety net healthcare institutions to evaluate the extent to which patient safety measures and methodologies developed from Aims 1 and 2 can be implemented among hospitals in outpatient settings. We envision that pilot findings from this project will result in a measurement and root cause analysis toolkit of patient safety monitoring methodologies that can be widely disseminated across healthcare systems that care for diverse populations.

The magnitude of missed monitoring and test results notification and timely action remains unclear. Moreover, the underlying causes of these safety gaps are almost completely unknown. The overall goal of this proposal is to improve the care of diverse patients cared for in safety-net settings by using mixed methods to develop and promote detection and investigation strategies.

SCOPE

Background

Overview: Patient safety in ambulatory (outpatient) settings is understudied despite high potential for patient harm. Although ambulatory visits constitute the majority of medical care encounters, relatively little is known about patient safety in the ambulatory setting.[7,8] The Institute of Medicine theorized that adverse events may be more common in ambulatory settings compared to acute care settings.[9] Fragmentation of care in ambulatory health systems constitutes a major barrier to patient safety[10]; in safety-net health systems where patients experience unique barriers to healthcare and which are exacerbated by health systems that have a less robust health information technology (HIT) infrastructure,[7,8] these safety risks are likely to be even greater. Significant medication intensification and high-risk medication use takes place in ambulatory care, with corresponding reports of adverse events in settings ranging from diabetes[11,12] to rheumatoid diseases[13,14] to organ transplant.[15,16] Prior work has demonstrated significant morbidity and mortality from patient safety problems in outpatient care.[1,9,17–20] These studies have largely addressed discrete events, including post-hospital discharge errors[21] and adverse events leading to emergency department visits or risk management[22] and malpractice claims.[23]

The incidence of “dropped balls,” delays, and omissions of needed care[24,25] has been documented, but the magnitude of the problems, or systems to identify and address them in clinical practice, has not been defined.

Context

Safety-net healthcare systems, which provide care for low-income, uninsured, and under-insured patients, may have the most to gain from the development and use of such standards. These health systems operate under resource constraints that can make medical errors and process breakdowns more likely, and their performance on existing quality measures has been worse than in other settings.[26–29]

US health systems are increasingly accountable for measuring and reporting quality metrics. The Public Hospital Redesign Incentives in Medi-Cal (PRIME) Program,[30] California’s Medicaid waiver for safety net hospitals, is a pay-for-performance program that creates funding incentives for safety net healthcare systems to measure ambulatory patient safety. However, patient safety solutions developed in well-resourced, cutting-edge health systems with advantaged patient populations are unlikely to be feasible in the safety net. Challenges faced in safety-net healthcare practices are shared by many small ambulatory practices nationally, particularly in needing practical, feasible safety solutions that can be implemented across multiple technological platforms. Understanding and improving patient safety in ambulatory settings requires a foundation of agreed-upon definitions and measurements to assess the frequency, type, and causes of medical error.

Settings

Summary: Based at Zuckerberg San Francisco General Hospital (ZSFG) and the University of California, San Francisco (UCSF), SPARKNet launched in 2015 with collaborators from five publicly funded health systems (Table 1) in California that provide services for ethnically and linguistically diverse patient populations in both urban and rural settings. We convened these safety-net health systems to participate in this proposal in collaboration with the California Association of Public Hospital’s Safety Net Institute (CAPH-SNI) through our established innovation network, PHoENIX, described below. Our sites were selected because they serve a high proportion of vulnerable populations, meaning predominantly low-income individuals who receive public health insurance through Medicare or Medi-Cal (Medicaid).

CAPH-SNI: This organization includes 16 county-owned and -operated and three University of California (UC) hospitals, healthcare systems, and academic medical centers that comprise its membership. In addition, though not formal members of CAPH, two additional state university academic hospital systems—UCSF and UCLA—participate in CAPH’s improvement programs and in the Delivery System Reform Incentive Payments (DSRIP), bringing the number of public hospital systems actively engaging in joint innovation work to 21. Although we refer to these institutions as “hospitals,” these systems provide care across the entire care continuum, from preventive, primary, and specialty services to emergency, acute care, palliative care, trauma, and rehabilitation services to a highly socially and medically vulnerable population. These 21 hospitals provide services in 15 counties, where more than 81% of Californians reside. Public hospital systems deliver care to 2.5 million Californians, providing over one third of the hospital care to the state’s 6.7 million uninsured, and over 30% of all hospital-based care to the state’s Medi-Cal population. Public hospital systems also provide over 10 million outpatient visits each year in over 100 outpatient primary care and specialty clinics and operate more than half of the state’s trauma centers and nearly half of its burn centers, and they train 43% of all new doctors in the state. In addition, all the CAPH members are now using both inpatient and ambulatory electronic health record (EHR) systems, with the last four systems going live in 2012-2013.

Public Healthcare system Evidence Network and Innovation eXchange (PHoENIX): Led by Dr. Sarkar and California Association of Public Hospital’s Safety Net Institute executive director Dr. David Lown, MD, the

overall goal of PHoENIX is to transform care delivery in California's public hospital systems by disseminating innovations and evidence-based practices. In 2012, CAPH-SNI awarded UCSF-CVP a grant to complete in-depth interviews with public hospital leadership. These demonstrated interest in collaborative improvement work and peer learning and engagement to enhance timely and actionable data to improve quality.[31] Building on these findings, we obtained a dissemination grant (AHRQ R24HS022047, PI: Sarkar) in order to create an infrastructure to disseminate several innovative, evidence-based practices. By applying implementation science methods to quality improvement, PHoENIX has gained valuable insights into implementation processes generalizable to other safety-net health systems, demonstrating that safety-net health systems can become nimble and flexible learning organizations that rapidly take up, adapt, and implement evidence-based interventions to maximize population health. We established a website in collaboration with CAPH/SNI (https://sites.google.com/site/phoenixthebigaims/home), through which we disseminated not only innovation factsheets and tools but also actual protocols, policies, workflows, and scripts that are relevant to improvement and innovation activities relevant to safety-net health settings.

Participants

We included a subset of five health care sites: (1) San Francisco General Hospital (2) Contra Costa Regional Medical Services, (3) Alameda Health Care Systems, (4) Los Angeles County Department of Health Services (LACDHS), and (5) Kern Medical Center. Table 1 shows that the selected sites serve patient populations and include both urban and rural areas of California.

Table 1: Characteristics of SPARKNet Sites

Characteristic	Total, n	Alameda Health Services**	Contra Costa Health Services**	Kern Medical Center	Los Angeles County Department of Health Services***	San Francisco Health Network
Site Lead		Palav Babaria, MD, MHS	Chris Farnitano, MD	Aaron Plant, MBA	Helen Tran, MD	Urmimala Sarkar, MD
Location (All in California)		Oakland	Martinez	Bakersfield	Los Angeles	San Francisco
Primary care clinics, n	55	4	11	5	23	12
Total Patients	344,238	8,500	100,000	24,162	100,000	111,578
Sex, %						
Female	173,911	55	55	52	47	49
Male	170,327	45	45	48	53	51
Race / Ethnicity*						
White	72,192	16	32	35	7	22
Black	63,983	41	23	10	18	15
Hispanic	132,804	16	21	49	63	32
Asian	55,902	10	17	1	9	26
Insurance, %						
Public	284,493	97	95	91	70	80
None	42,798	1	3	5	25	13

*Other race/ethnicities not shown, totals do not match total number of patients
**Patient population for one clinic
***Total population for LACDHS is 538,215; n shown is the selected number available for recruitment in study

Incidence and Prevalence

The epidemiology of patient safety disparities in ambulatory care is largely unknown, in part due to the lack of standardized definitions and measurements. There are multiple challenges to better characterizing the burden of adverse events in ambulatory settings. Fundamentally, issues of definition and classification remain. First, the traditional definition of an adverse event, from Dr. David Bates in the Harvard Medical Outcomes Study, is "harm to the patient as a result of medical management rather than the natural history of disease."[21] We have broadened this definition to include harm resulting from patient self-management as well as medical management, in order to more accurately reflect the centrality of the patients' role in ambulatory care.[32] This definition of patient harm is beginning to be widely accepted and adopted in the patient safety literature. Second, a key challenge to advancing the science of patient safety is the ascertainment of adverse events, which has been subject to numerous biases in previous research.[23,33,34] Several studies have used incident reporting to identify outpatient adverse events,[35–37] but incident reporting is known to capture only a small, nonrepresentative subset of adverse events.[38,39] Based on data from malpractice claims, Gandhi et al measured diagnostic errors in outpatient settings and found that 59% of claims had involved diagnostic errors causing harm to patients; however, closed claims represent a nonrepresentative sample of adverse events because of bias in who pursues legal action.[40] After reviewing data from three US outpatient clinics, Singh et al estimated the frequency of diagnostic errors to be 5.08% (about 1 in 20 adults); half of these errors were estimated to bring potential harm to patients as a result of missed or delayed diagnosis.[41] In a retrospective medical record review study of 5,434 randomly sampled patients, Casalino et al reported that the incidence of failure to inform patients of abnormal test results is estimated to be 7.1%.[42] However, this study only included selected medical practices that agreed to participate, so failure to inform rates may be limited by selection bias, leading to potentially underestimated rates of failure to inform.

The overall goals of this proposal are to examine the epidemiology of patient safety in ambulatory care settings that care for diverse, low-income populations as follows; (1) to characterize the incidence and prevalence of specific safety gaps, by race/ethnicity and language proficiency; (2) to gather in-depth, qualitative evidence about strategies that can improve safety and characterize disparities in patient safety; (3) to pilot-test patient safety monitoring methodologies in a diverse sample of five safety-net healthcare systems; and (4) to develop a measurement and error investigation toolkit for dissemination amongst safety-net healthcare systems.

METHODS

Study Design

Overview: We sought to develop methodologies for timely and accurate measurement of the burden of critical patient safety problems and the extent of disparities in patient safety in ambulatory care settings. Additionally, we sought employ error investigation methodology to uncover underlying reasons for these patient safety gaps and for disparities in their incidence.

Aim 1: To develop feasible, timely, and accurate electronic measures of patient safety notification and monitoring gaps in an ambulatory care setting for high-risk subpopulations and characterize the extent of disparities in patient safety.

We conducted a formal and validated measurement development process for novel measures to identify delays and gaps in notification of appropriate clinician and of patient/family for abnormal test results that require follow up and monitoring for patients who have high-risk conditions (e.g., cancer, following treatment) or are undergoing high-risk treatments (such as anticoagulation) using EHR and health information technology analytics. After measure development, we described the extent of patient safety gaps and resulting disparities in missed monitoring and test results management among patients in ambulatory settings across diverse safety-net healthcare systems.

Data Sources/ Collection

From January through February 2016, we used a modified Delphi process to obtain expert opinions and reach consensus on a set of patient safety measures to be used with EHR-based data in safety-net health systems.

Table 2: Delphi Participants

Characteristics of Panelists	n=8
Position	
Special Projects Manager	1
Director, Quality/Risk/Patient Safety[2]	1
Ambulatory Care Medical Director	1
Chief Medical Officer	1
Chief Administrative Officer, Ambulatory Services	1
Associate Professor/General Medicine Clinician[1,2]	1
Associate Professor/Rheumatology Clinician[1]	1
Academic degrees obtained	
MBA	1
MPH	2
PhD	1
MD/DO	7

[1]Also co-author of this article.
[2]Practicing primary care clinician.

Intervention – Delphi Consensus Process

The Delphi method involves multiple rounds of questionnaires in which expert opinion is first solicited, then aggregated and de-identified for use in subsequent rounds. It is important to emphasize that the Delphi approach does not aim to develop consensus through recruitment of a representative sample. Rather, it focuses on eliciting opinions from a purposive sample of participants with relevant expertise and can be particularly helpful when evidence to support a practice or set of practices is contested or lacking.[43]

The Delphi process (three rounds) began with the selection of 13 patient safety measures by the principal investigator of SPARKNet, in consultation with the Chief Medical Officer at SNI. Our measures were drawn from those proposed by the National Quality Forum (NQF) and by the Public Hospital Redesign and Incentives in Medi-Cal (PRIME) program, which ties federal Medicaid funding to the achievement of metrics associated with improvements in the delivery and cost-effectiveness of care.[30] Representatives from all SPARKNet health systems were invited to participate in the Delphi panel. All individuals invited were responsible for PRIME implementation at their institution and/or had demonstrated expertise in patient safety measure development. Our Delphi panelists were asked to anonymously rate the validity and feasibility of each measure on a nine-point Likert scale, with “1” being definitely not valid/feasible and “9” being definitely valid/feasible. Validity and feasibility were defined through a set of existing questions developed for AHRQ (Center for Health Policy 2011) that were presented to panelists. An open-ended comments section was also included for panelists to qualify their votes and/or add their own measures for discussion. During a break in the meeting, mean, minimum, and maximum scores were calculated for each measure. The results were reported back to panelists to prompt discussion of the rationale for a high or low validity or feasibility score for specific measures.

Measures - Patient Safety Notification and Measurement

Under PRIME, Designated Public Hospitals are required to report measures associated with outpatient-related projects. We collected PRIME measures that address 4 distinct aspects of ambulatory patient safety:

1. eReferrals from one provider to another;
2. Medication safety;
3. Timely follow up of test results;
4. Timely diagnosis

These measures were chosen because they represent a variety of areas in which ambulatory patient safety gaps are likely to occur. Our study sites independently reported metrics to the California Department of Health Care Services for the PRIME Program. Systems reported both the denominator (the number of eligible patients) and the numerator (the number of patients who had the desired outcome) for each measure. We collected data from July 1, 2015–June 30, 2016, and July 1, 2016–June 30, 2017.

We conducted descriptive analyses of data reported for the seven measures and described the systems with suppressed data. Some data we received were suppressed for confidentiality per California Department of Health Care Services guidelines (numerator <11 or denominator <30, including cases in which a system reported 0 for the numerator and denominator). We were not provided with the reasons for these low numerators or denominators. Possibilities include that the system had too few eligible patients (denominator) or too few patients who received the recommended services (numerator) or that, when the system captured the measure as specified, the automated capturing capabilities could not extract the necessary data elements.

Aim 2: To conduct a root cause analysis of patient safety notification/ monitoring gaps in ambulatory care to identify factors contributing to these disparities.

In order to understand the underlying causes of events uncovered in the course of measuring safety gaps, we conducted a rigorous root cause analysis of barriers to timely colonoscopy for our study sites.

Data Sources/Collection

Root cause analysis (RCA) entails semi-structured interviews of all involved parties (patients, staff, providers, leadership) in a safety problem. This method offers a validated means of analyzing patient safety events that may shed light on colonoscopy delays. The goal of an RCA is to apply a close lens to a small number of adverse events to expose a richer number of root causes contributing to the event.[44]

We conducted an RCA of a convenience sample of cases, among which there was a clinically significant (greater than 6-month) delay in obtaining recommended colonoscopy for a positive Fecal Occult Blood Test (FOBT). Cases were identified across the five safety-net healthcare systems in California (see Participants section).

Although root cause analyses often only focus on one or two cases, we sought to capture as many cases that could be identified through the data sharing enabled by our sites. Our team developed inclusion/exclusion criteria, adapted from precedent work on delayed colonoscopy[45] in partnership with participating SPARKNet site leaders. Patients were eligible if they were adults older than 18 years, were English speaking, were cognitively able to consent to an interview, had a positive FOBT test, either had a colonoscopy appointment scheduled or completed a colonoscopy greater than 180 days past the positive FOBT result, and were empaneled to a primary care provider (PCP) with continuity. The 180-day cutoff was chosen based on findings showing increased risk of colorectal cancer (CRC) with delays greater than 6 months,[46] and empaneled patients were chosen so as to focus on root causes of delays among patients with healthcare access. Exclusion criteria included the following: patients institutionalized or residents of a nursing home, as they would not be representative of the general primary care safety-net population; and patients who had been diagnosed with active CRC, as ethically we did not wish to cause emotional harm to patients undergoing cancer treatment. A member of the study team compiled a list of eligible patients from each study site and worked with SPARKNet leads at each site to contact PCPs. Primary care physicians were contacted first to ensure that patients' cases would be relevant for analysis and for permission to contact patients. If a PCP could not be contacted, we did not conduct outreach to patients. We attempted to reach all patients involved up to a maximum of five times. Recruitment occurred from April 2018 to October 2018, and interviews occurred from May to September 2018, with data analysis occurring from December 2018 to February 2019.

Aim 3: To evaluate the pilot implementation of patient safety monitoring methodologies developed from Aims 1 and 2 across five diverse ambulatory healthcare settings.

Our proposed approach to Aim 3 was to use a mixed methods approach[47] to characterize the extent and progress of implementation of two patient safety strategies: measurement and in-depth investigation. Our goals were to critically examine the implementation of the measures developed from Aim 1 and the error investigation methodology developed from Aim 2 sites to determine how they should be more broadly implemented. We also sought to facilitate implementation of these measurement and investigation activities across California's safety-net health systems by developing a toolkit for further dissemination.

Limitations:

Aim 1

Measurement Development/Delphi Consensus Process*:* Our limitations include the small number of participating panelists (n=8), even though our panelists represented five health systems that are broadly representative of California's safety net in terms of patient population, information technology systems, and population density.

Patient Safety Notification and Measurement: At the end of the project, we have collected 2 years of PRIME data with plans to collect data for the 3 remaining PRIME years. First, because we wanted to report on the same systems in both years, we do not present data from district and municipal public hospitals (DMPHs). Smaller and more rural than Designated Public Hospitals, these hospitals did not start reporting data until year 2, to allow time to develop data infrastructure. Second, consistent with most pay-for-performance programs, including Healthcare Effectiveness Data and Information Set (HEDIS),[48] all PRIME Program data were independently collected by health systems, so data collection methods varied. Third, only some systems chose to report data for the optional measures we analyzed. As a result, data from only five healthcare systems are presented for each optional measure. Despite this, for every measure, the systems that reported data collectively represented at least 300,000 outpatients each year. Overall, our collection efforts were unprecedented in scale, and our results establish baseline performance in ambulatory patient safety among California safety-net health systems.

Aim 2

Root Cause Analysis of Barriers to Timely Colonoscopy: We focused on individuals who actually completed the FOBT screen to obtain a positive FOBT result. Patients who cannot complete the FOBT itself may have different needs in the primary care safety net. Second, this analysis focused on 12 cases to enable a "deep dive" of each case applying an RCA framework (see Table 3). Although this is a larger sample than most RCAs, our sample was small, and our findings emphasize prevalent root causes within these cases rather than qualitative findings that arrived at thematic saturation. We were not able to interview all patients involved in the included cases, most often because we were not able to reach them. Just as there are unmeasured barriers that impeded patients from participating in this study, these barriers may prevent them from completing a needed colonoscopy. Risks of bias include selection bias related to cases that may not have been identified within participating SPARKNet sites, selection bias related to patients we could not interview, and recall bias on behalf of participating interviewees. Our sample was limited to English-speaking patients and focused on California and may not be generalizable to other language groups and geographic regions. However, our study also has strengths: we obtained a geographic spread of sites serving Medicaid-eligible populations, and the individual- and system-level barriers described here are likely shared at other sites serving vulnerable populations.

Aim 3

Evaluate Pilot implementation of Patient Safety Monitoring Methodologies: At the end of the fifth project year, our team collected two years of patient safety data from safety-net health systems. Our attempt to capture patient safety metrics allowed us the unique opportunity to assess the feasibility of wide-scale measurement and acquire population-level data from safety net health systems. At the same time, we encountered challenges with fragmented EHR systems and inadequate adoption and implementation of robust data infrastructure. In order to facilitate a toolkit of measurement implementation strategies as described in Aim 3, we believe that 3 additional years of data (5 years total) are necessary to develop comprehensive tools and strategies.

RESULTS

Summary of Key Findings: All Aims

SPARKNet has enabled us to identify specific measures of ambulatory safety through a modified Delphi process and implemented measurement efforts. We collected data and demonstrated both suboptimal performance and safety challenges across California safety net institutions. We conducted an in-depth root-cause analysis demonstrating multiple vulnerabilities in the abnormal cancer screening follow-up process related to system, provider, and patient factors. Furthermore, our informal conversations with clinicians revealed myriad challenges involved in measuring performance using outdated EHR and data management systems and staffing challenges.

Outcomes

Aim 1

Measurement Development/Delphi Consensus Process: The Delphi process included eight panelists. Consensus was reached to adopt nine of 13 proposed measures (Table 1). All nine measures were unanimously considered valid, but concern was expressed about the feasibility of implementing several of the measures.

Table 3: Demographic Characteristics of Patient Cases

	Patient Cases (n=12)	PCPs (n=11)
Sex, %		
Female	4	3
Male	8	3
Not disclosed		5
Age, y		
50-59	5	Not disclosed.
60-69	4	
70+	3	
Race / Ethnicity (>1 may be selected)		
White	5	
Black	1	
Asian	1	
American Indian / Alaskan Native	1	
Native Hawaiian / Pacific Islander	1	
Other	3	
Hispanic / Latinx	3	
Latinx		2
Unavailable		7
Employment		
Full time	1	
Unemployed	1	
Disabled/on disability	1	
Retired	2	
Educational Attainment		
<High school	1	
High school	2	
Some college	1	
Graduate school	1	
Family medicine		6
Internal medicine (includes MD, PA, and FNP)		5
Time to colonoscopy, median (IQR), month	7.10–38.07 (median, 10.98;IQR, 6.28)	
Colonoscopy results		
Normal / negative	2	
Findings polyps, diverticulosis,tubulovillous adenomas;“11 benign polyps”;“tubular adenoma, 1 with high grade dys-plasia”;“tubular adenoma andhyperplastic polyp"		

Demographic provided for all patient cases; not all patients were interviewed. One PCP was interviewed for two cases. FNP, family nurse practioner; IQR, interquartile range; PA, physician assistant.

Table 4: Patient Safety Measures Considered

Measure Description	Validity Score Round 1 (1 9 scale)		Validity Score Round 2 (1 9 scale)		Final vote on inclusion
1. Monthly INR Monitoring for individuals on warfarin (NQF measure)	8.30	8.43	7.63	7.86	YES
2. Proportion of patients who were on warfarin and received an abnormal INR test result	No vote. Measure considered redundant.				
3. Proportion of those who were on warfarin and received an abnormal INR test result and received appropriate follow up in the appropriate time period	8.13	8.57	6.80	7.23	YES
4. Percentage of patients 18 years of age and older who received a least 180 treatment days of ambulatory medication therapy for a select therapeutic agent (ACE inhibitors) during the measurement year and at least one serum potassium and a serum creatinine therapeutic monitoring test in the measurement year (NQF measure)	7.38	7.86	7.13	7.57	YES
5. Percentage of patients 18 years of age and older who received a least 180 treatment days of ambulatory medication therapy for a select therapeutic agent (ACE inhibitors) during the measurement year and had at least one abnormal test result (serum potassium and a serum creatinine therapeutic monitoring test in the measurement year)	No vote. Measure considered redundant.				
6. Percentage of patients 18 years of age and older who received a least 180 treatment days of ambulatory medication therapy for a select therapeutic agent (ACE inhibitors) during the measurement year, received at least one abnormal test result (serum potassium and a serum creatinine therapeutic monitoring test in the measurement year) and received appropriate follow up (repeated test)	7.63	7.86	6.13	7.43	YES
7. Percentage of patients age 18 years and older diagnosed with chronic pain with functional outcome goals documented in the medical record (NQF measure)	4.50	4.00	2.75	2.57	NO
8. Proportion of Patients with chronic pain is on long term opioid therapy who are checked in Prescription Drug Monitoring Programs (PDMP)	8.30	7.86	4.38	4.57	NO
9. Closing the referral loop: receipt of specialist report: Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred	8.80	8.86	7.00	7.71	YES
10. The percentage of members 50-75 years of age who had appropriate screening for colorectal cancer.*	8.38	8.86	7.50	8.29	YES
11. Medication reconciliation - Percentage of patients aged 65 years and older discharged from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) and seen within 30 days following discharge in the office by the physician providing on-going care who had a reconciliation of the discharge medications with the current medication list in the medical record documented	7.63	7.43	6.38	4.86	NO
12. Proportion of women 21-64 years of age received one or more Pap tests to screen for cervical cancer AND received an abnormal result (any type of abnormal result – ASCUS, HSIL, ASIL) AND evidence of appropriate follow-up (Have either a colposcopy or repeat PAP within 6 months) - (adapted from NQF 0032)	8.13	8.23	5.38	5.79	NO
13. BIRADS = 4 or 5 – Percent who received the recommended breast biopsy within 14 days	8.25	8.29	5.38	5.57	YES

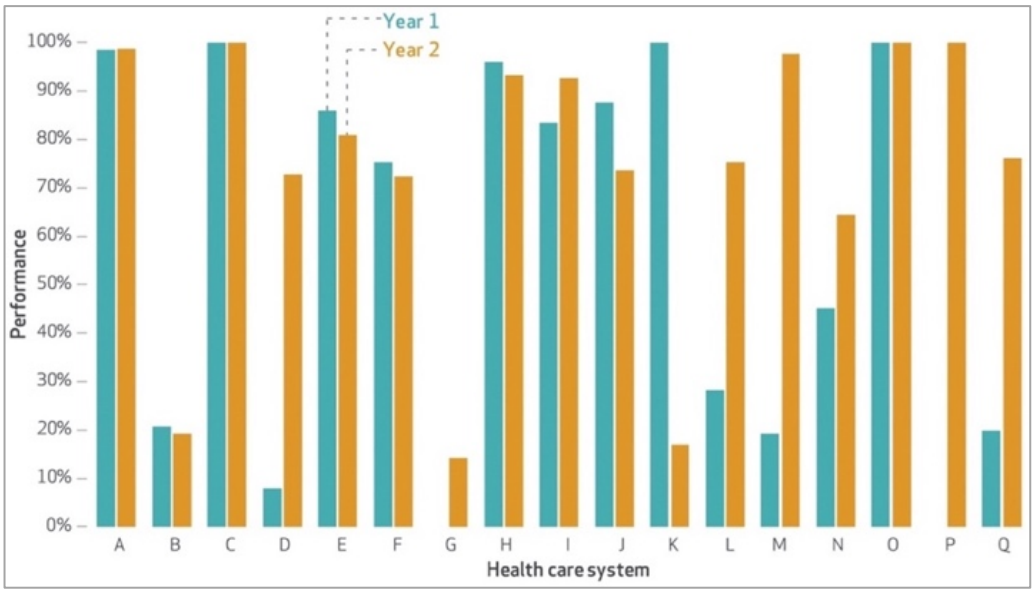
Patient safety measures considered during Delphi process. (INR) Abnormal international normalized ratio; (ACE) Angiotensin Converting Enzyme; (CRC) Colorectal Cancer Screening; (BIRADS) Breast Imaging Reporting and Data System

Patient Safety Notification and Measurement

eReferrals from one provider to another: We collected performance data from 17 safety-net public healthcare systems on closing the referral loop in years 1 and 2 of their participation in the California Public Hospital Redesign and Incentives in Medi-Cal (PRIME) Program.

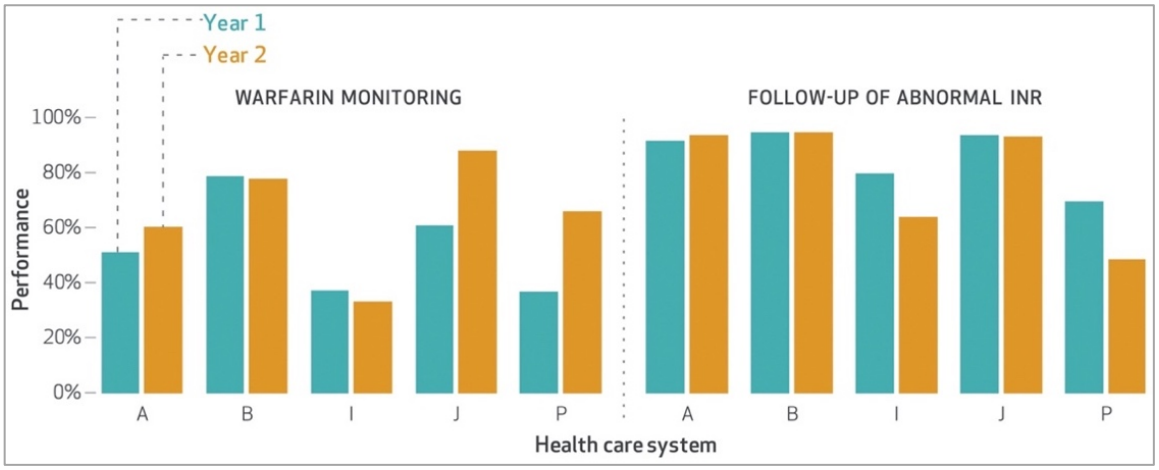
The median performance for closing the referral loop (a required measure that assesses whether referring providers receive information from consulting providers) was 83% in year 1 and 76% in year 2 (Figure 1).

Figure 1: Performance on Closing the Referral Loop



Medication safety and high-acuity abnormal test follow up: The median performance was >80% in both years for annual monitoring of persistent medications, follow up of abnormal international normalized ratio (INR), and follow up of abnormal potassium. (The INR measures how well a blood thinner is working; blood that is too thin or not thin enough can be dangerous. Similarly, potassium levels that are low or high can be immediately life threatening by affecting heart and nerve function.) Warfarin is a blood thinner medication, and guidelines advise assessing its efficacy by measuring the patient's INR every 8 weeks. Performance on the measure of warfarin monitoring was lower than that on the other three measures: 51% in year 1 and 66% in year 2 (See Figure 2).

Figure 2: Warfarin Monitoring and Follow Up of Abnormal INR



INR Monitoring Adherence: In a manuscript in preparation, we describe the relationship between sociodemographic factors and INR monitoring adherence among English-preferring and Non-English-preferring patients. Monitoring compliance is having at least one INR test performed during each 56-day interval with active warfarin therapy. The outcome of interest, monitoring adherence, is defined as having at least 80% monitoring compliance. We use multivariable log-binomial regression models to estimate the adjusted relative risks of being monitoring adherent.

Among English-preferring patients, age and gender factors are more likely to be monitoring adherent, but patients with private insurance, with other insurance, or those who are Black are less likely to be monitoring adherent (Figure 3).

For non-English-preferring patients, female patients, Medicaid patients, and Hispanic patients are more likely to be monitoring adherent, but Black patients are less likely to be adherent (Figure 4).

Timely diagnosis: For follow up of an abnormal fecal immunochemical test (FIT, a stool-based test used to screen for colon cancer), the median performance was 49% in year 1 and 36% in year 2 (data not shown). Similarly, the median performance for a timely biopsy after a high-risk mammogram was 52% in year 1 and 48% in year 2. System O reported divergent performance changes for both measures.

Timely follow up after an abnormal fecal immunochemical test (FIT): In an additional analysis for a manuscript in preparation, we conducted a multivariable logistic regression analysis than included the following predictor variables: age [reference category: 51-54 years], gender [reference category: male], race/ethnicity [reference category: non-Hispanic White], language [reference category: English],

Figure 3: INR Monitoring Adherence Among English-Preferring Patients

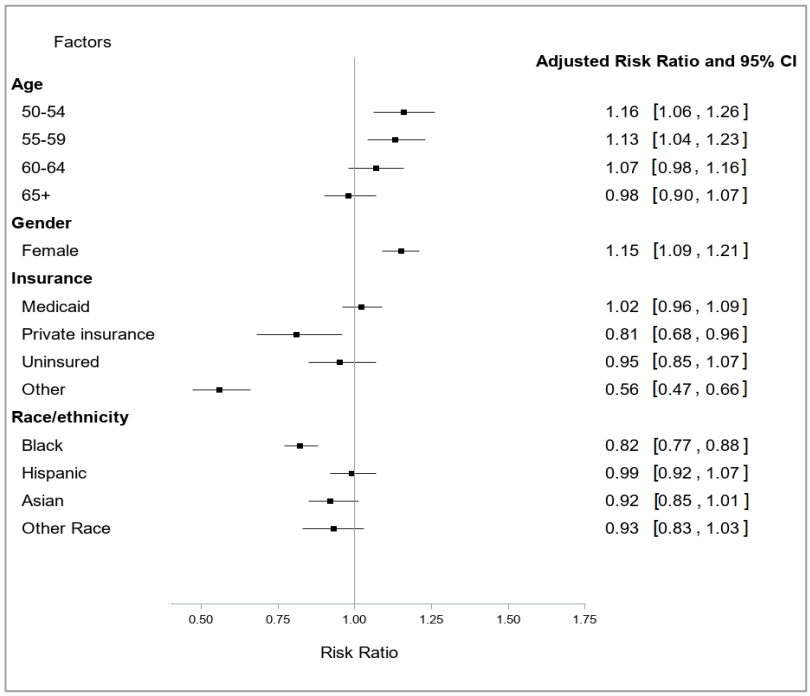
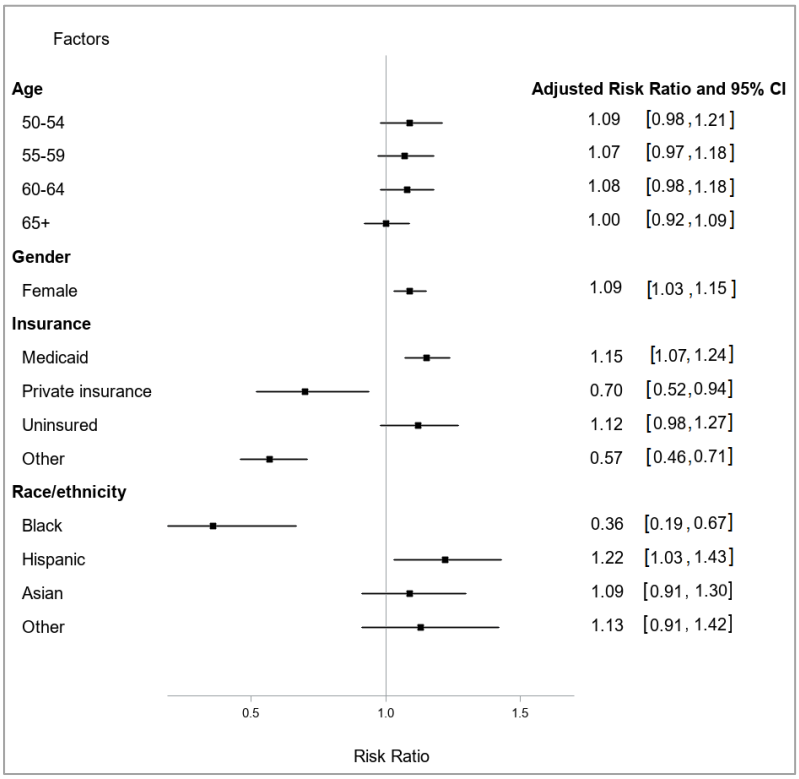


Figure 4: INR Monitoring Adherence Among Non-English-Preferring Patients



insurance coverage/type [reference category: private insurance], and site [reference category: site A]) . Language, insurance type/status, and site were significantly associated with follow up (see Figure 5).

Timely biopsy after a high-risk abnormal mammogram: In an additional analysis for a manuscript in preparation, we conducted a multivariable logistic regression analysis than included the following predictor variables: age [reference category: 50-54 years], race/ethnicity [reference category: non-Hispanic White], language [reference category: English], insurance coverage/type [reference category: private insurance], and site [reference category: site A]). After adjusting for other variables, system-level factors for sites B, D, and E were significantly associated with follow up (Figure 6).

Timely follow up to incomplete mammogram: We conducted a multivariable logistic regression analysis than included the following predictor variables: age [reference category: 50-54 years], race/ethnicity [reference category: non-Hispanic White], language [reference category: English], insurance coverage/type [reference category: private insurance], and site [reference category: site A]). After adjusting for other variables, system-level factors for all sites were significantly associated with follow up (Figure 7).

Aim 2

Root Cause Analysis of Barriers to Timely Colonoscopy: We identified 12 unique cases, comprising five patient and 11 PCP interviews. Eight patients completed colonoscopy; median time to colonoscopy was 11.0 months (interquartile range, 6.3 months). In our analysis, three patients had advanced adenomatous findings. Primary care providers highlighted system-level root causes, including inability to track referrals

Figure 5: Performance on timely follow-up after an abnormal fecal immunochemical test (FIT)

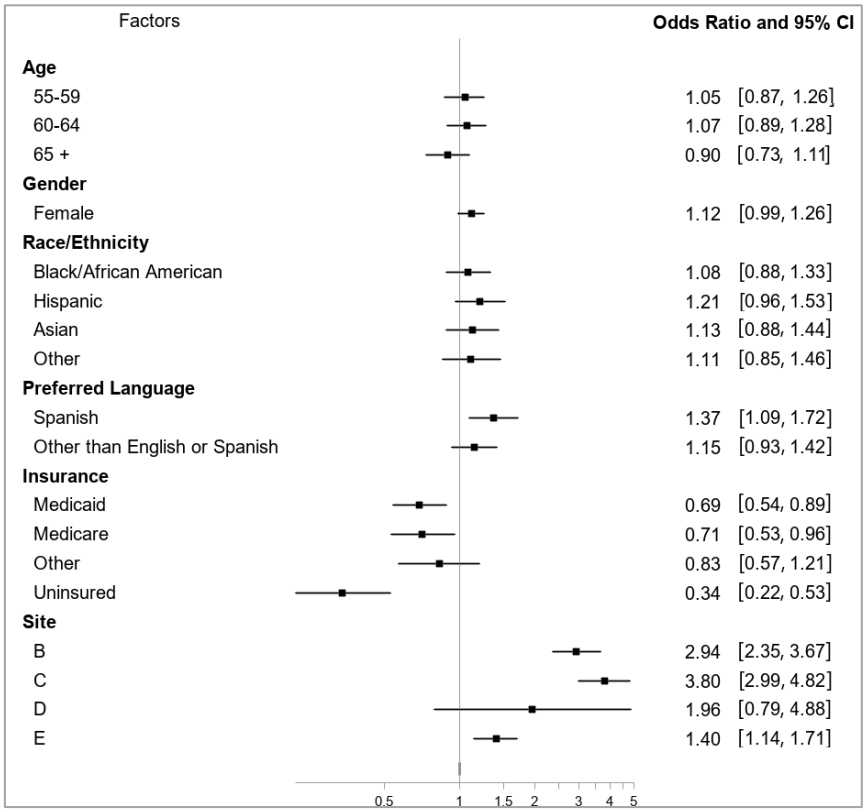
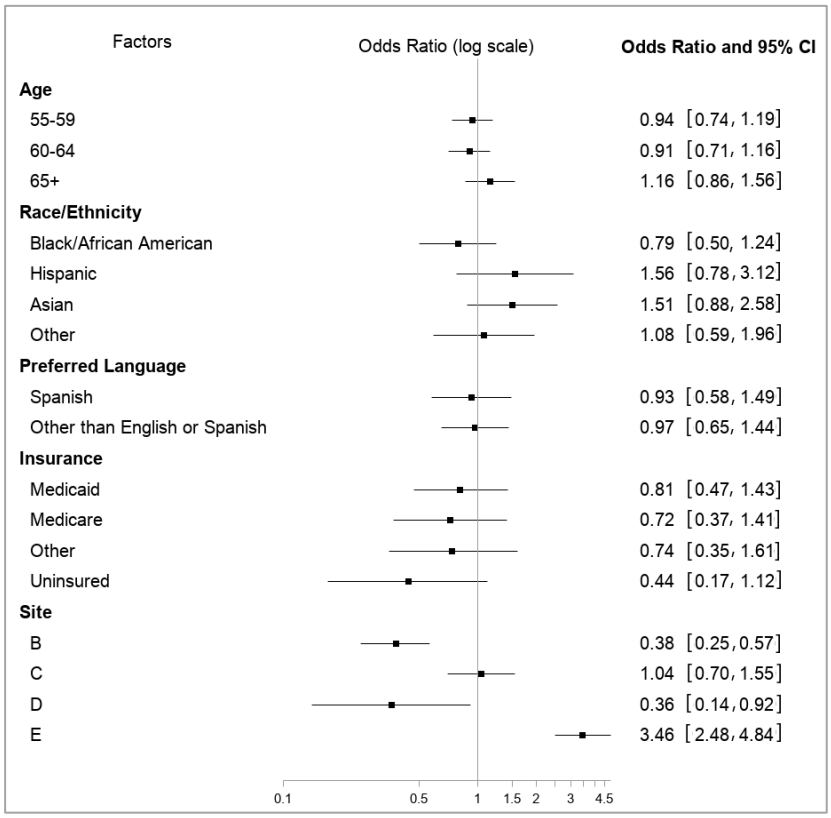


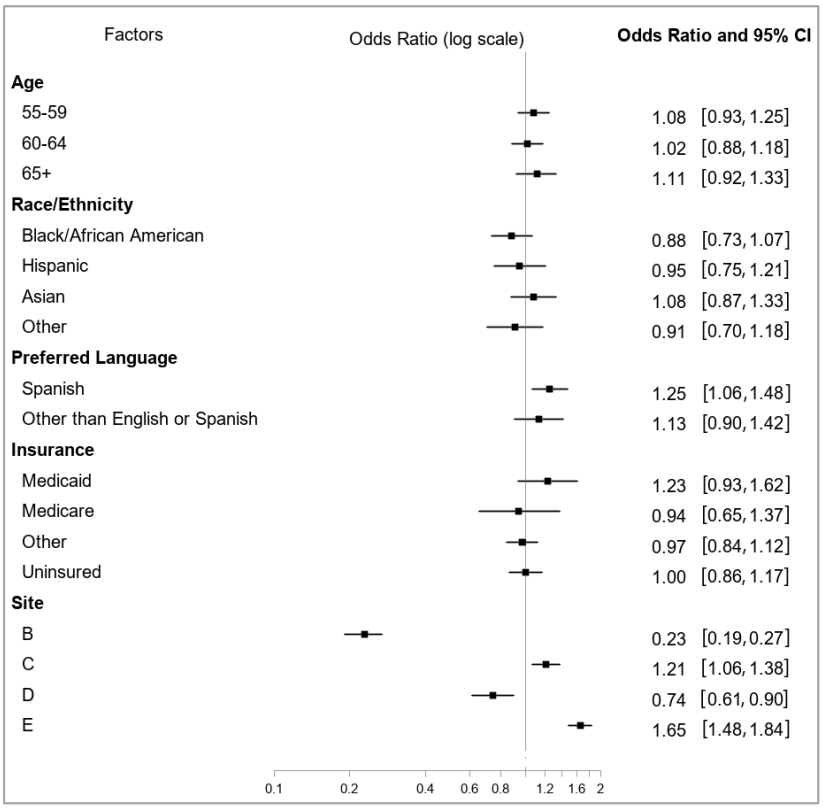
Figure 6: Predictors of tissue biopsy after abnormal high-risk mammogram (BIRADS 4/5)



between primary care and gastroenterology, lack of protocols to follow up with patients, lack of EHR interoperability, and lack of time or staffing resources compelling tremendous additional effort by staff (see Figure 8).

In contrast, patients highlighted individual-level root causes, including comorbidities, social needs, and misunderstanding the importance of the FOBT. There was a little overlap between PCP- and patient-elicited root causes.

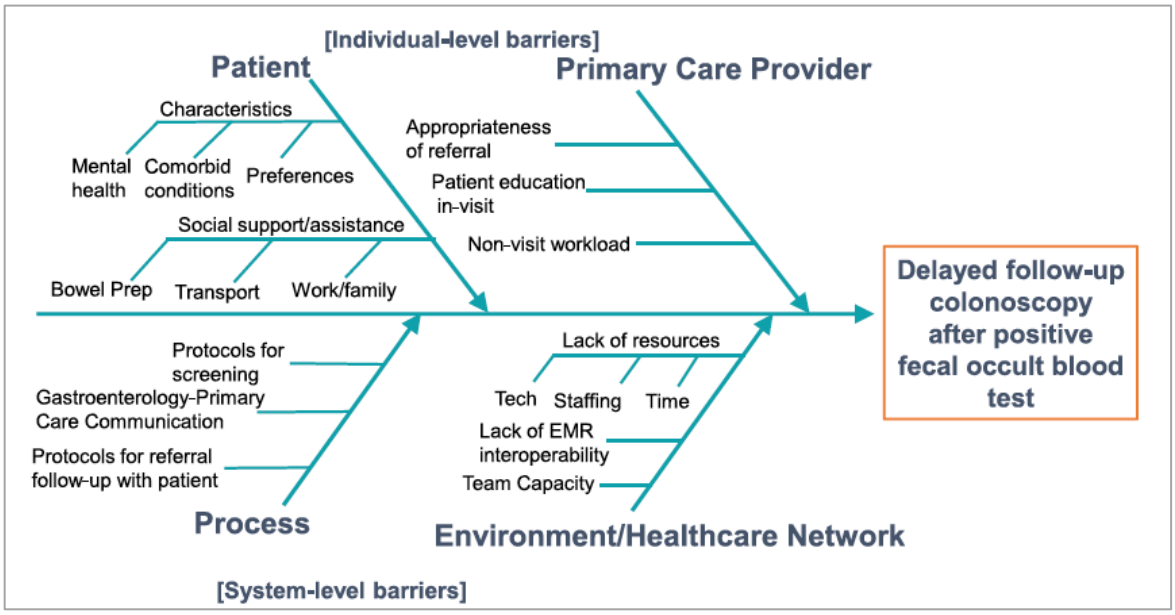
Figure 7: Predictors of diagnostic mammogram after incomplete screening mammogram (BIRADS 0)



Aim 3

Evaluate Pilot Implementation of Patient Safety Monitoring Methodologies: Our findings from Aim 1 and 2 set the groundwork for our aim to study the implementation of patient safety measurement strategies. Although we did not collect sufficient data to develop a measurement and root cause analysis toolkit of patient safety monitoring methodologies that can be widely shared across safety-net systems, we now have a better understanding of what measurement efforts are needed to yield improved safety measurement in the future. Specifically, we collected 2 years of data from our study sites and documented challenges in data collection that included complex measures that require the integration of different types of data and lack of robust EHR infrastructure in low-resource settings.

Figure 8: Fishbone Diagram of Root Causes of Delayed Colonoscopy in the Safety Net



Discussion

Aim 1

Measurement Development/Delphi Consensus Process: The consensus measures reported here represent one step toward improving ambulatory patient safety in safety-net health systems. Our modified Delphi process evaluated standardized measures that could be used to track patient safety gaps in two ambulatory care processes: 1) notifying patients of actionable test results and 2) monitoring patients with high-risk conditions. Several rounds revealed broad consensus about the importance of nearly all proposed measures, and some disagreement about the feasibility of at least half the measures—with concerns focused on (a) the challenges of translating an important patient safety concern into a standardizable measure and (b) IT and human resources-related barriers to producing, obtaining and sharing required data. By the final round, the panel unanimously agreed to adopt nine measures (see Table 4).

Although measurement is broadly assumed to be a necessary step toward higher quality medical care, reductions in medical errors and process breakdowns will not be achieved simply through standardized measurement. Indeed, the consensus measures reported here will not lead to improved patient safety without the engagement of all stakeholders: patients, clinicians, staff, data system professionals, and health system leaders. Establishing and communicating shared expectations, and identifying mismatched expectations, will be as essential as accurate measurement for understanding the reasons for safety gaps and devising strategies to mitigate them.

Patient Safety Measure Notification: Public health systems have difficulty accurately collecting data for PRIME measures. Differences in site EHR systems and data streams and analytic resources resulted in varying quality and ability of site data acquisition. Performance was better in areas that required limited coordination or patient engagement—for example, annual medication monitoring versus follow up after high-risk mammograms. Healthcare systems that lack seamlessly integrated EHRs and patient registries encountered barriers to reporting reliable ambulatory safety data, particularly for measures that integrated multiple data elements. These data challenges precluded accurate performance measurement in many areas.

Efforts to transform the delivery of healthcare through the PRIME program point to both potential strengths and weaknesses of the performance targets developed here. The proposed targets overlap considerably with those required by PRIME, and feasibility was accounted for. Therefore, safety-net health systems are likely to have built-in incentives and capacity to track their efforts to reach these targets. On the other hand, resource-limited safety-net health systems may be reluctant to pursue new performance targets in an era of increasing measurement burden. Other study limitations include the small number of participating panelists, although participants represented five health systems that are broadly representative of California's safety net in terms of patient population, information technology systems, and population density.

Cancer screening follow up: We are currently working on describing patterns of performance in the five public systems on follow up for abnormal breast cancer and colon cancer screening tests and explore disparity patterns in these outcomes. Preliminary results show factors in health system play important role in follow up on tests, with disparities in insurance status and coverage seen at the patient level.

INR Monitoring: We are currently exploring disparities patterns in anticoagulation management using data on INR monitoring compliance. Preliminary results show differences in compliance by insurance, gender, and race/ethnicity. Further analyses will include identification of health disparities using different definitions of monitoring compliance and describing differences in time to follow up for abnormal INR results by sociodemographic factors.

Aim 2

Root Cause Analysis of Barriers to Timely Colonoscopy

We identified a sample of clinically significant colonoscopy delays, with median time to colonoscopy of 11.0 months. A retrospective analysis of patients with a positive fecal immunohistochemical test result found an increased risk of advanced-stage disease if colonoscopy is obtained 10 to 12 months after the positive test result.[46] For this reason, most networks recommend a goal of colonoscopy completion within 6 months after positive screen. In our sample, four of the eight patients who completed a colonoscopy had clinically concerning adenomatous findings.

Aim 3

Evaluate Pilot implementation of Patient Safety Monitoring Methodologies: We attempted to capture patient safety measures from safety-net systems at an unprecedented scale. We captured patient safety measurement for 2 of 5 years from five study sites and noted challenges with fragmented EHR systems. To prevent harm to patients in ambulatory care settings, hospital systems need research and policies that incentivize the adoption of robust data infrastructure as well as the development of measures and measurement in all areas of ambulatory patient safety (especially test follow-up, diagnostic error, and care coordination). In the future, we plan to collect the remaining years of patient safety measurement data and evaluate a pilot implementation study of patient safety monitoring methodologies.

Significance

As result of SPARKNet, we begun the process of identifying and measuring the extent of patient safety measure disparities. We found found barriers to patient safety measurement. Healthcare systems that lack seamlessly integrated electronic health records and patient registries encountered barriers to reporting reliable ambulatory safety data, particularly for measures that integrated multiple data elements. Our findings support concerns that accurate performance measurement is difficult without a fully integrated data infrastructure. These barriers must be addressed to meaningfully improve patient safety and reduce health inequities.

Additionally, our results established baseline performance in ambulatory patient safety among California safety-net health systems. Although there was variation in performance, the median performance on each measure was stable from year 1 to year 2. Significant performance changes in 1 year are unlikely, so this stability suggests that these data are reasonable estimates of baseline performance, particularly for innovative measures that have not been previously widely measured (abnormal INR or potassium follow up, and timely diagnostic tests after abnormal FIT or high-risk mammogram). However, these results also suggest significant barriers to the wide-scale measurement of ambulatory patient safety measures. In particular, systems without robust health data infrastructure, such as comprehensive EHR systems, might not be able to access data to accurately ascertain quality in multiple areas of ambulatory patient safety.

To prevent harm to patients in ambulatory care settings, hospital systems need research and policies that incentivize the adoption of robust data infrastructure as well as the development of measures and measurement in all areas of ambulatory patient safety (especially test follow up, diagnostic error, and care coordination). These data from the PRIME Program in California hold lessons for future measurement efforts and should inform local improvement initiatives in ambulatory patient safety.

Implications

Our attempt to capture patient safety metrics allowed us the unique opportunity to assess the feasibility of wide-scale measurement and acquire population-level data from safety-net health systems. Through this project, we report that public healthcare systems have difficulty accurately collecting patient safety data. There are differences in site EHR systems and data streams and analytic resources that resulted in varying quality and ability of site data acquisition. Performance was better in areas that required limited coordination or patient

engagement—for example, annual medication monitoring versus follow up after high-risk mammograms. Healthcare systems that lack seamlessly integrated EHRs and patient registries encountered barriers to reporting reliable ambulatory safety data, particularly for measures that integrated multiple data elements.

Ultimately, this project has helped shape the transformation of care delivery in the safety net. We have strengthened relationships with safety-net system administrators and look to the future to continue our progress evaluating patient safety metrics. Advocates of ambulatory patient safety need to consider how to support all health systems in acquiring the data and information system tools and personnel needed to support accurate performance reporting. Use of a certified EHR alone does not ensure ease of extracting accurate, complex data. Policymakers can regulate EHR vendors to create low-cost products that enable easy data collection for performance reporting instead of requiring highly trained expensive analysts and local customization to support reporting. Performance reporting agencies must guarantee that less well-resourced health systems have access to technical support on how to capture accurate data. We look forward to building on SPARKNet, and have submitted an application to renew funding to continue our progress toward our goals.

LIST OF PUBLICATIONS AND PRODUCTS

Ackerman SL, Gourley G, Le G, Williams P, Yazdany J, Sarkar U. Improving Patient Safety in Public Hospitals: Developing Standard Measures to Track Medical Errors and Process Breakdowns. J Patient Saf 2018 Mar 14. PMCID: PMC6138593.

Khoong EC, Cherian R, Rivadeneira NA, Gourley G, Yazdany J, Amarnath A, et al. Accurate Measurement In California's Safety-Net Health Systems Has Gaps And Barriers. Health Affairs. 2018 Nov 1;37(11):1760–9. PMID: 0395496. PMCID: 7491428

Sharma AE, Lyson H, Cherian R, Somsouk M, Schillinger D, Sarkar U. A Root Cause Analysis of Barriers to Timely Colonoscopy in California Safety-Net Health Systems. J Patient Saf. 2020 May 26. PMID: 32467445. NIHMSID: 1606682

Manuscripts in Preparation:

Patterns in Performance and Disparities in Follow-Up of Abnormal Colorectal and Breast Cancer Screening in California Public Hospital Systems
Authors: Khoong Elaine, Rivadeneira Natalie, Lown David, Pramanik Rajiv, Babaria Palav, Tran Helen, Whitezell Tyler, Somsouk Ma, Schillinger Dean, Sarkar Urmimala

Title for INR monitoring adherence paper is in development.

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