

Final Progress Report

TITLE PAGE

Title: Building an Ambulatory Patient Safety Learning Laboratory for Diverse Populations: The San Francisco Ambulatory Safety Center for iNnovaTion (ASCENT)

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STRUCTURED ABSTRACT

Purpose: Despite strides in patient safety, significant gaps remain. Evidence-based practices have not been consistently implemented. These issues are particularly acute in safety-net healthcare settings that disproportionately care for diverse and low-income populations. We created a transdisciplinary patient safety learning laboratory, the San Francisco Ambulatory Safety CEnter for iNnovaTion, to address outpatient safety issues in safety-net settings.

Scope: We focused on three high-priority ambulatory safety issues: (1) test result management: when patients' diagnostic test results are not acted upon in a timely fashion, diagnostic delays and failures often ensue; (2) monitoring for high-risk subpopulations: failures of monitoring for patients receiving high-risk treatments can cause adverse events; and (3) medication comprehension: patient medication self-administration has been implicated in outpatient adverse drug events, and validated methods to enhance comprehension have not been implemented systematically.

Methods: We utilized flexible, systems engineering and design methodologies to conduct problem analysis, design, develop, implement, and evaluate technical and workflow solutions for these issues in an urban, integrated public delivery system.

Results: The epidemiological extent of ambulatory safety gaps is difficult to assess due to fragmented record keeping systems and limited resources. We conducted medical record review, focus groups, and interviews to identify and characterize the most concerning ambulatory situations. We then engaged frontline healthcare workers in co-design and co-development to pilot and implement a technologically enabled workflow solution to these challenges. We demonstrated that implementation science can successfully be applied in response to the constraints of a health care environment.

Key Words: Patient Safety, Implementation Science, Information Systems, Systems Engineering, Safety-Net Health Systems

PURPOSE:

Despite strides, improving patient safety remains a critical issue for healthcare systems.¹ Although most healthcare is delivered in ambulatory settings, with 884 million outpatient visits annually in the United States,² patient safety in these settings remains understudied.^{3–6} Evidence-based practices are not widely implemented in clinical care.^{7,8}

To address the gap between patient safety research and real-world clinical practice, we sought to apply implementation science methodology to ensure that our findings could be translated to effective, sustainable, and scalable solutions.^{9,10} Our long-term goal was to establish and sustain a patient safety learning laboratory that works across the continuum of innovation – from problem analysis through to design, development, implementation, evaluation, and adoption and spread of successful innovations, in order to improve patient safety for vulnerable populations cared for in safety-net healthcare systems. Our specific aims were as follows:

Aim 1: To create a transdisciplinary patient safety learning laboratory, the San Francisco Ambulatory Safety Center for iNnovaTion (ASCENT). This will include patient safety, reliability science, design thinking, and operational leadership and stakeholders to collaborate on creative and effective solutions.

Aim 2: To design and iterate technical and workflow solutions for high-priority ambulatory safety issues in a publicly funded, safety-net health system caring for diverse, vulnerable patients. We believe that patient safety solutions require not only technological innovations but also changes in roles, responsibilities, and organizational culture.¹¹ Design and development will be in the context of the specific health system environment in the San Francisco Health Network (SFHN). We aim to address (a) test results management, (b) outpatient monitoring for high-risk conditions, and (c) enhanced medication comprehension to reduce adverse drug events (ADEs).

Aim 3: To implement and evaluate solutions in the SFHN using implementation sciences methodology. We will implement our solutions iteratively such that quasi-experimental designs can be used to assess outcomes. We will use mixed methods to measure the extent of implementation, fidelity to planned implementation, and barrier and facilitators of implementation in addition to the safety outcomes of interest.

Aim 4: To scale up effective solutions across the health system and disseminate among safety-net health systems. We have strong collaborations with two state-wide dissemination partners: the Public Healthcare Evidence Network and Innovation eXchange (PHoENIX, funded by AHRQ R24 HS022047), and the Safety Net Innovation Network (SNIN), which both foster innovation among California's safety net.

SCOPE:

There are specific and unique challenges to safe outpatient care. First, ambulatory settings have traditionally lacked electronic health records (EHRs) and other technological tools that can be harnessed for safety, although “meaningful use” made it more feasible to employ technology.¹² Second, patients play a central role in self-managing their care in outpatient settings, in contrast to hospitalized patients under observation, for whom a care team is available 24 hours a day.¹³ Third, the traditional visit-based model of outpatient care does not support the activities needed to maintain safety for a population. In contrast, the Patient-Centered Medical Home (PCMH), a transformed model for outpatient care that emphasizes coordination and communication, allows re-envisioning of outpatient safety for a defined population rather than just for patients physically in a clinic visit.¹⁴

We prioritized three specific ambulatory safety problems:

- Missed and delayed diagnoses lead to significant morbidity and mortality and represent the leading cause of successful ambulatory malpractice claims.^{15,16} Though diagnostic problems are multifactorial, it is clear that lack of timely identification of test results contributes to diagnostic failures and delays.¹⁷
- Gaps exist in ongoing monitoring of high-risk conditions, such that delays occur in recognizing and ameliorating known adverse effects of treatment.^{4,18,19}

- There is a significant burden of adverse drug events (ADEs) in outpatient care,^{20–25} and patient error in medication self-administration plays a significant role in such errors.^{26,27}

We coalesced our laboratory around three projects to address these three ambulatory safety problems:

- Project 1: Timely, Accurate, Active Test Result Management
- Project 2: Population Management to Monitor High-Risk Conditions and Treatments
- Project 3: Implementation of Patient-Centered Medication Labels

The challenges that our projects address are exacerbated in safety-net healthcare settings, which lack critical HIT infrastructure and resources to devote to safety programs.²⁸ Marginalized, minoritized, and low-income patients are disproportionately cared for in safety-net settings.^{29,30} These health systems must lead the charge in developing and implementing effective, acceptable, and feasible safety solutions in order to reduce health disparities. Solutions developed in well-resourced, cutting-edge health systems that serve advantaged patient populations are unlikely to be feasible in the safety net. Therefore, we situated our laboratory in the public delivery system of the city and county of San Francisco, the SFHN.

SFHN is San Francisco's health system and has locations throughout the city, including San Francisco General Hospital (SFGH), Laguna Honda Hospital and Rehabilitation Center (LHH), and over 15 primary care health centers.

SFGH is a level one trauma center in the SFHN. SFGH is a licensed general acute care hospital, which is owned and operated by the City and County of San Francisco Department of Public Health (SFDPH). SFGH provides a full complement of inpatient, outpatient, emergency, skilled nursing, diagnostic, mental health, and rehabilitation services for adults and children. The hospital treats approximately 100,000 inpatients and 80,000 outpatients annually, more than one third of whom are uninsured. There were nearly 340,000 outpatient visits in fiscal year 2019-2020.³¹ Outpatient services are provided through over 100 primary care, specialty care, and subspecialty care clinics.

The majority of patients cared for in the SFHN are insured by public sources, with only 3% of outpatient visits covered by commercial insurance. Patients are also racially and ethnically diverse. Thirty-seven percent of patients are Hispanic, 21% are Asian/Pacific Islander, 18% are White, 15% are African American, and 9% are another race/ethnicity.³¹

METHODS:

As in other areas of healthcare, a significant gap exists between patient safety research and day-to-day clinical practice.^{32,33} Despite the long-standing awareness of ambulatory safety concerns, comprehensive efforts to achieve solutions are still lacking.^{1,34} Traditional health services research methods do not provide the tools to move from problem identification to implementation of effective, sustainable, scalable solutions.¹⁰ Therefore, we drew on design thinking, systems engineering, health communication, and implementation sciences methodology^{9,35} to ensure that our laboratory developed context-sensitive and patient-centered solutions.

Project 1: Timely, Accurate, Active Test Result Management: Our aims for this project were as follows:

Aim 1: To engage stakeholders across an integrated safety-net healthcare system to identify the most concerning set of subcritical abnormal laboratory and radiology results, current gaps in communication of these results to responsible clinicians, and current gaps in tracking clinical actions to follow-up these results.

Aim 2: To design and develop a health information technology (HIT) solution to allow for timely, trackable, subcritical test result management.

Aim 3: To pilot the technical solution at two sites and iterate upon it based on feasibility, usability, and workflow considerations.

Aim 4: To implement the iterated, workflow-integrated technical solution at an evaluation site and conduct qualitative and quantitative evaluation to determine effectiveness in reducing delays in clinical action for two selected radiographic and two sample laboratory subcritical results using an implementation science framework.

Problem Analysis: The extent of gaps in communication and missed follow-up of abnormal test results is often unknown or underestimated due to incomplete data capture and fragmented information technology. As mentioned in the preceding section, these challenges are heightened in safety-net health systems that suffer from limited resources, staffing, and technology. It is particularly crucial to understand the extent of this problem in safety-net settings that treat vulnerable populations that often face additional barriers to follow-up of abnormal test results, such as language barriers or difficulty getting to clinic for follow-up appointments.

We engaged in a robust problem analysis across the SFHN to identify the most concerning set of subcritical abnormal laboratory and radiology results, current gaps in communication of those results to responsible clinicians, and current gaps in tracking clinical actions to follow-up these results (Aim 1). This problem analysis enhanced the fit of our intervention and allowed us to build a business case for its uptake with network leaders.

First, we conducted a series of five semi-structured focus groups with purposefully sampled clinicians from radiology, hospital medicine, emergency medicine, risk management, and ambulatory care in the SFHN.³⁶ We used thematic analysis with an inductive framework to identify emergent themes from the associated transcripts as well as applied the Systems Engineering Initiative for Patient Safety (SEIPS) model to transcript excerpts. The SEIPS model identifies the inter-relationships of structural domains, and leverages human factors and systems approaches to patient safety improvements.

The findings from these focus groups, described in the results section, helped target our efforts in querying the clinical administrative database used in the SFHN to investigate the volume of subcritical abnormal test results and whether follow-up is adherent to evidence-based recommendations, patient outcomes, and associated patient and provider characteristics. We performed comprehensive chart reviews in two different high-risk scenarios to identify the points at which management of subcritical abnormal test results typically breaks down, assess the extent to which tests have been documented and acted upon by clinicians, share abnormal critical results with appropriate leadership to ensure gaps in care are addressed, and report the frequency and severity of subcritical results in order to best target an intervention.

One of the medical record reviews entailed a retrospective cohort study of patients aged 50-75 who received an abnormal fecal immunochemical test (FIT) between April 2012 and February 2015 to evaluate if those patients received the recommended follow-up colonoscopy.³⁷ Completion of a colonoscopy after an abnormal FIT test is integral to effective stool-based colorectal cancer screening. Members of the study team independently reviewed records, also abstracting details on patient homelessness, polysubstance abuse, and comorbidities.

We conducted another retrospective chart review of adults at SFGH with incidentally discovered pulmonary nodules requiring follow-up per the Fleischner Society guidelines.³⁸ This was a novel investigation because few studies examine rates of follow-up among patients with incidentally discovered pulmonary nodules, and even fewer look at rates among an urban, integrated, public health system; it is particularly innovative in its use of natural language processing algorithms to identify computerized tomography (CT) scans incidentally finding pulmonary nodules. The study team reviewed charts for patients who had nodules between 5 and 8 millimeters discovered on a CT scan between 2008 and 2014 to identify if follow-up adhered to evidence-based recommendations released by the Fleischner Society and identify associated patient outcomes and patient and provider characteristics.

Design and Development: In our design and development phases (Aim 2), we leveraged systems engineering methodologies to create journey maps of test result management, described in more depth in the Project 2 description that follows. Journey mapping and key informant interviews helped us understand changes in clinical workflows over time, identify similarities and differences across pilot sites, and align the technology development with existing clinical workflows.

Pilot and Evaluation: The aforementioned co-design and co-development processes illuminated synergies between Projects 1 and 2, allowing us to introduce a single technology solution that could be adapted to both test results management and population management. Pilot and implementation (Aims 3 and 4) are described in more depth in the Project 2 section.

Evaluation: We developed a study protocol to evaluate the feasibility, acceptability, and safety outcomes of the health information technology (HIT) intervention. Specifically, we sought to evaluate the delays of follow-up testing and proportion of patients lost to follow-up before and after the intervention.^{39–41}

Project 2: Population Management to Monitor High-Risk Conditions and Treatments: Our aims were as follows:

Aim 1: To conduct robust problem analysis to optimize monitoring for high-risk conditions across primary and subspecialty outpatient care settings in the SFHN.

Aim 2: To design and develop technical and workflow solutions to ensure that populations with high-risk conditions or receiving high-risk treatments are appropriately undergoing monitoring, which includes not only observation but also needed periodic diagnostic testing.

Aim 3: To implement a high-risk monitoring safety solution and assess its feasibility in outpatient primary care and specialty care settings in the SFHN.

Aim 4: To evaluate the effectiveness of a high-risk monitoring safety solution in providing real-time intervention in high-risk ambulatory conditions.

Problem Analysis and Design: During problem analysis and design phases (Aims 1 and 2), we conducted interviews with frontline staff in five specialty clinics (otolaryngology, pulmonary, urology, breast, and gastroenterology) in the SFHN.³⁵ We applied a systems engineering method, journey mapping, to co-design visual representations of real-world workflows for monitoring patients with high-risk conditions and receiving high-risk treatments. We identified systems vulnerabilities shared across clinics and developed “design seeds” for potential solutions. These design seeds serve as preliminary concepts for improving the robustness for outpatient monitoring. Finally, we conducted a face validity and prioritization assessment of the design seeds with the original participants.

Development and Implementation: In development and implementation phases, we established contracts with a third-party software company, CipherHealth, and with SFDPH and UCSF. To operationalize this multi-stakeholder partnership, we established a payment mechanism to CipherHealth and SFDPH, engaging in weekly meetings with informational technology analysts from both groups; set up a secure environment to send SFDPH protected health information to CipherHealth; developed an audit process to ensure that all users are authorized to view SFDPH protected health information (PHI) in CipherHealth; and, finally, tested and validated interfaced output from SFDPH clinical systems to CipherHealth’s platform. Concurrently, we collaborated with future clinical users to customize the technical platform so that it meets their test result management needs and clinical workflows. We frequently collaborated with stakeholders, such as clinical, ambulatory care, and primary care leadership, for continuous feedback and iterative improvements.

The SFHN, like many safety-net health systems, struggled with the challenges of multiple record-keeping systems. The ASCENT technical solution integrated data from multiple sources to ameliorate some of the previously identified safety and communications gaps.

Evaluation: We developed protocols to pragmatically evaluate the health information technology (HIT) platform using systems engineering methodologies.^{39–41} We sought to evaluate feasibility, acceptability, and the time it takes for patients to progress through key treatment milestones prior to and after implementation. We proposed to use models controlling for secular trend to estimate the effect of the intervention on improving timely and successful completion of recommended treatment.

Project 3: Universal Medication Schedule Implementation: Our aims were as follows:

Aim 1: Conduct problem analysis with the goal of Universal Medication Schedule (UMS)/Concordant Rx prescribing becoming the standard of care for patients care for within the SFHN.

Aim 2: Design and develop an HIT platform and a provider workflow that will support an effort to make UMS/ConcordantRx instructions the new standard across all the electronic prescribing platforms in the SFHN.

Aim 3: Implement the UMS/ConcordantRx via electronic prescribing throughout the SFHN and evaluate from patient, provider, and pharmacy perspectives.

Problem Analysis: In partnership with members of our advisory board and pharmacy directors, we held meetings with pharmacists at each site to secure buy-in and determine which medications would be appropriate for UMS instructions.

Design and Development: After reaching consensus on which medications were eligible for UMS implementation, the pharmacy software was modified to automatically dispense eligible medications with UMS instructions, reaching full compliance.

One site, the outpatient pharmacy at SFGH, was unable to modify their dispensing software and relied on manual implementation of eligible medications, which placed a significant burden on the pharmacy staff and led to suboptimal implementation. To promote buy-in, ASCENT investigators presented the data supporting UMS implementation to the pharmacy staff and engaged the SFGH Chief Medical Officer to send a network-wide memo to providers describing the implementation effort and encouraging providers to prescribe using UMS language whenever possible to ease the burden of implementation on pharmacists.

Implementation and Evaluation: The ASCENT Scientific Core and Advisory Board met regularly with pharmacy leadership across the SFHN to implement UMS via electronic prescribing across the network's major prescribing sites.

To assess provider buy-in, we conducted a network-wide survey that revealed overwhelming support for implementation. However, the burden of implementation remained on pharmacists. We conducted focus groups with SFGH pharmacists to characterize concerns regarding provider buy-in and patient safety.⁴² To address patient safety concerns, we conducted phone interviews with patients (n=49; response rate 42%) to determine if UMS was improving medication adherence from April 2017-April 2018.

Limitations: Two external challenges limited the impact of ASCENT overall: (1) Implementation of an EHR (EPIC, Verona WI) occurred during the study and led to suspension of study activities for several months. Moreover, the implementation process was work intensive and created significant change fatigue among both leaders and frontline healthcare workers and providers. (2) The processes to enable an outside technology vendor to access patient data required a lengthy ethics approval, university contracting, and separate agreements with the health systems. It took significant effort and many months of delays to secure approvals. Both of these issues are generalizable to innovation work across many health systems, and broader approaches are needed to address them.

RESULTS:

Project 1: Timely, Accurate, Active Test Result Management Principal Findings and Outcomes

The extent of gaps in communication and missed follow-up of abnormal test results is often unknown or underestimated due to incomplete data capture and fragmented health records. Due to ASCENT's applied nature, much of our work in this aim focused on solidifying the evidence base of abnormal test result management, which is lacking.

We conducted a series of five semi-structured focus groups with purposefully sampled clinicians from radiology, hospital medicine, emergency medicine, risk management, and ambulatory care in the SFHN (N=43).³⁶ Exemplar quotes are shown in Table 1. Common challenges to the management of abnormal subcritical tests discussed in focus groups included:

- Lack of health information technology system integration
- Challenges tracking tests and results (particularly in the context of rotating providers)
- Opaque paths of communication among providers
- Disagreements about who is responsible for follow-up
- Inadequate staffing for a reliable point of contact
- Lack of clarity about the acuity of a result
- Challenges serving vulnerable populations (such as missing or frequently changing contact information).

Participants also suggested solution characteristics, such as protocols to support assigning responsibility, improved paths of communication, and systems to track test status. Focus group participants also felt strongly that technology and workflow solutions should be integrated into existing structures.

Table 1. Facilitators and Barriers to Safe Management of Abnormal Subcritical Tests in Safety-Net System³⁶	
Theme	Exemplar Quote(s)
Multiple nonintegrated EHR systems cause change fatigue.	"I think adding another system when people are reaching a breaking point with managing multiple systems . . . I think it would not be well received." – Inpatient
Lack of reliable tracking test and results impeded trust in the system	"So it's a handoff, but there is not a . . . population-based tracking process." – Primary care
Beliefs about who is responsible for test results differ by department	" . . . I think if someone orders a study they're responsible for the findings. . . " – Radiology "So they want to work with us in how to make it better but our philosophy is that this is not really an ED problem." – ED "I always feel like there's a little bit of debate; even if I put something in there [discharge summary], like what is actually appropriate for the outpatient provider to work with. The minute I put it in there, I mean it's their responsibility. . . It's like, well, they may not get seen for two to four weeks. Why is that all of a sudden is that your responsibility? . . ." – IP
Clear paths of communication critical	"The problem is when you spend hours to try to track who to call." – Radiology
Adequate staffing necessary to allow for a reliable point of contact	"Our issue is personnel. We don't have a staff who are dedicated (to test management), people to access that registry and then people to act upon it. . ." – Primary care
Rotating providers increase risk of poor outcomes.	"There is no continuity with physicians." – Radiology
Populations without reliable contact information and without primary care high risk	" . . . there are patients that we serve in the specialty care clinics that don't have primary care. . . I think those processes and making sure that those patients get the care they need is another population to focus on." – Primary care "We do get a lot of the patients that are brought back quickly where there is no update, there is zero information in their contact information, so that makes it really challenging."
Care transition	"Some of these. . . are tests pending, right? So there's no result at all. . . it isn't until you actually get somebody who's interpreted the result to determine if its critical or subcritical" – Risk management
Time/acuity of result	"I think you could make a pretty clear line that if it needs to be followed up within days, it's on the inpatient person. If it needs to be followed within weeks, then it's reasonable to expect the PCP to do it." – Inpatient

IT, information technology; ED, emergency department; PCP, primary care provider.

The focus groups helped direct our efforts to investigate the volume of subcritical abnormal test results, if follow-up is adherent to evidence-based recommendations, and the impact of incomplete follow-up on patient outcomes.

Our deep dive into utilization of diagnostic colonoscopy found that colonoscopy completion is suboptimal in our safety-net health system, with only 55.6% of all patients (N=2,238) completing a colonoscopy within 1 year of an abnormal FIT test (Figure 1).³⁷ Systems issues identified included lack of clear documentation addressing abnormal results and of systematic workflow for follow-up.

We also investigated follow-up of incidental pulmonary nodules among patients seen at SFGH.³⁸ We found that, of 551 patients with incidental 5-8 millimeter pulmonary nodules, 156 (28%) received complete, 87 (16%) received partial, 93 (17%) received late, and 215 (39%) received no documented surveillance.

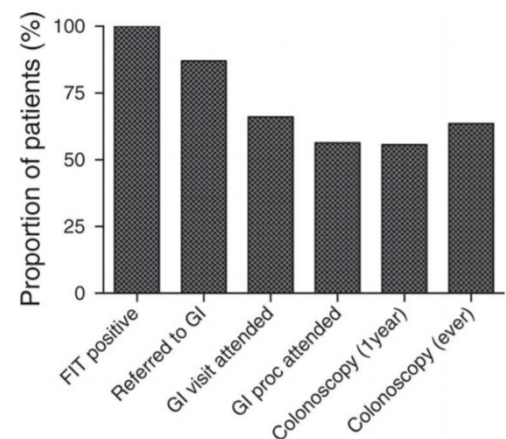


Figure 1. Proportion of patients remaining after each step in the process of care from positive FIT to colonoscopy completion.

Follow-up completion was higher among patients who saw a primary care provider during the follow-up period. We did not find a statistically significant association between nodule surveillance and mortality (individuals with late surveillance experienced an increase of 0.45 deaths per 100 person-years [95% CI, -1.10 to 2.01] and individuals with no surveillance experienced an increase of 1.05 [95% CI, -0.35 to 2.45]).

Frontline stakeholders engaged in journey mapping exercises and iterative feedback to prepare the technology for pilot. Figure 2 illustrates a “swim lane diagram,” co-developed in partnership with staff and leaders in the Pulmonary clinic, which served as a visualization of journey mapping.

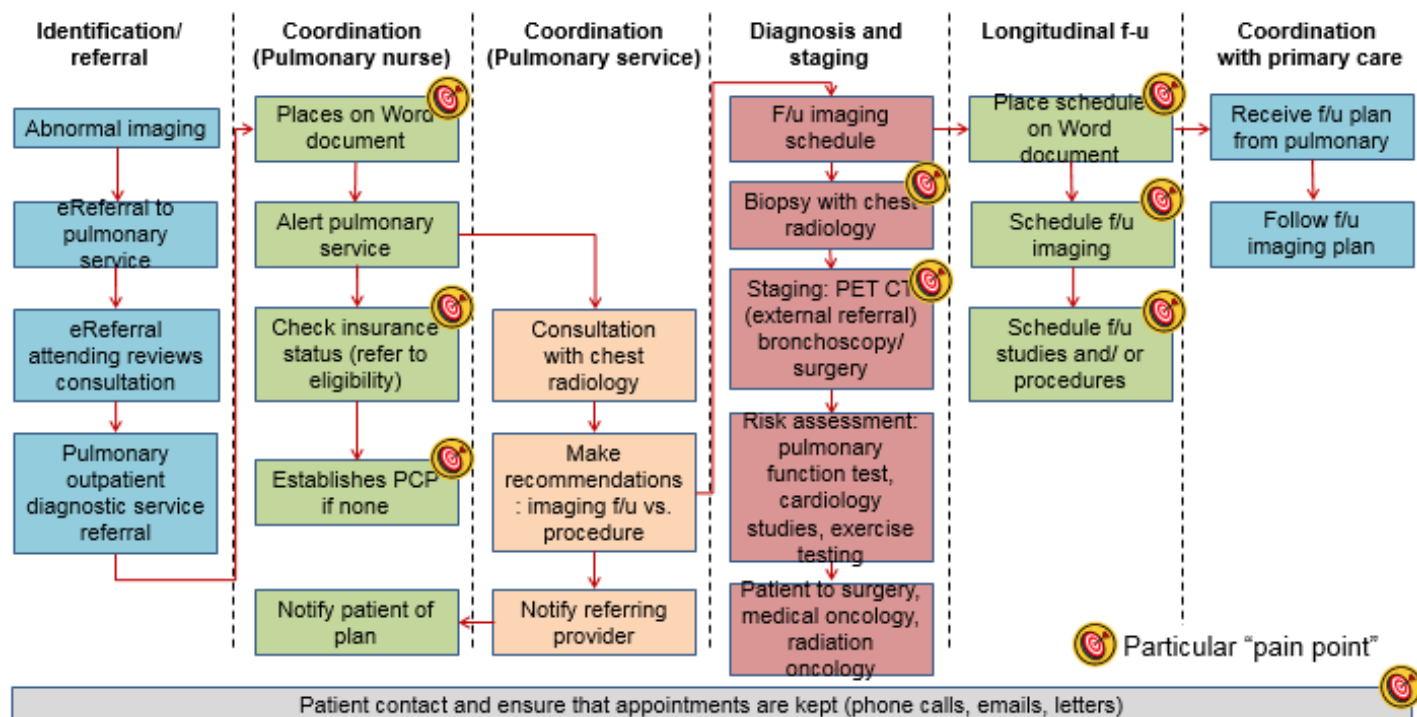


Figure 2. Pulmonary nodule journey map

Due to synergies between projects 1 and 2, the ASCENT team integrated key findings from the problem analysis, design, and development phases of project 1 into the implementation and ongoing iteration of project 2.

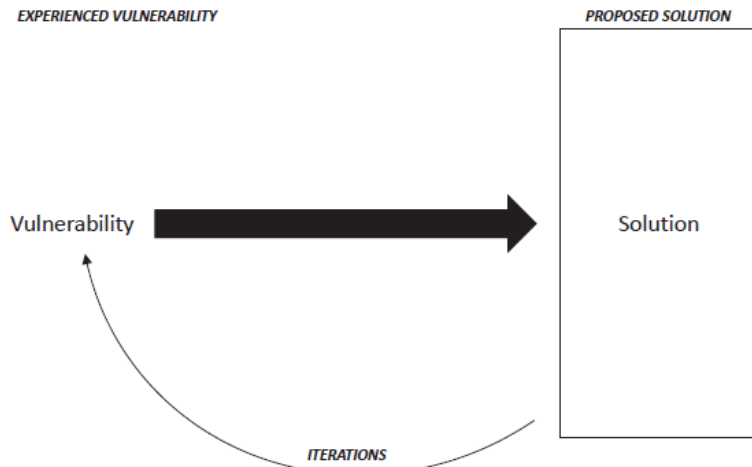
Project 2: Population Management to Monitor High-Risk Conditions and Treatments Principal Findings and Outcomes

Problem analysis activities generated five priority high-risk conditions and treatments for focus in our learning laboratory. We vetted these areas, such as head and neck cancer management, prostate cancer management, and anticoagulation therapy management, with frontline clinicians, staff, and patients at SFGH. Using a National Academies of Medicine framework and context-sensitivity theory, we identified common systems vulnerabilities and validated and prioritized our findings with frontline clinicians.³⁵ Vulnerabilities experienced across at least four of five subspecialty clinics include:

- Have to track some patients in own mind or side system
- Creating list of patients requiring monitoring takes time
- Looking up each patient's information takes time
- Maintaining list of patients requiring monitoring takes time
- Outside of visit-based care, don't always know when patients need follow-up monitoring
- Manually monitoring patients is time intensive
- Analyzing data in ad hoc manner is time intensive
- Inefficient system to create personal, siloed reminders for follow-up

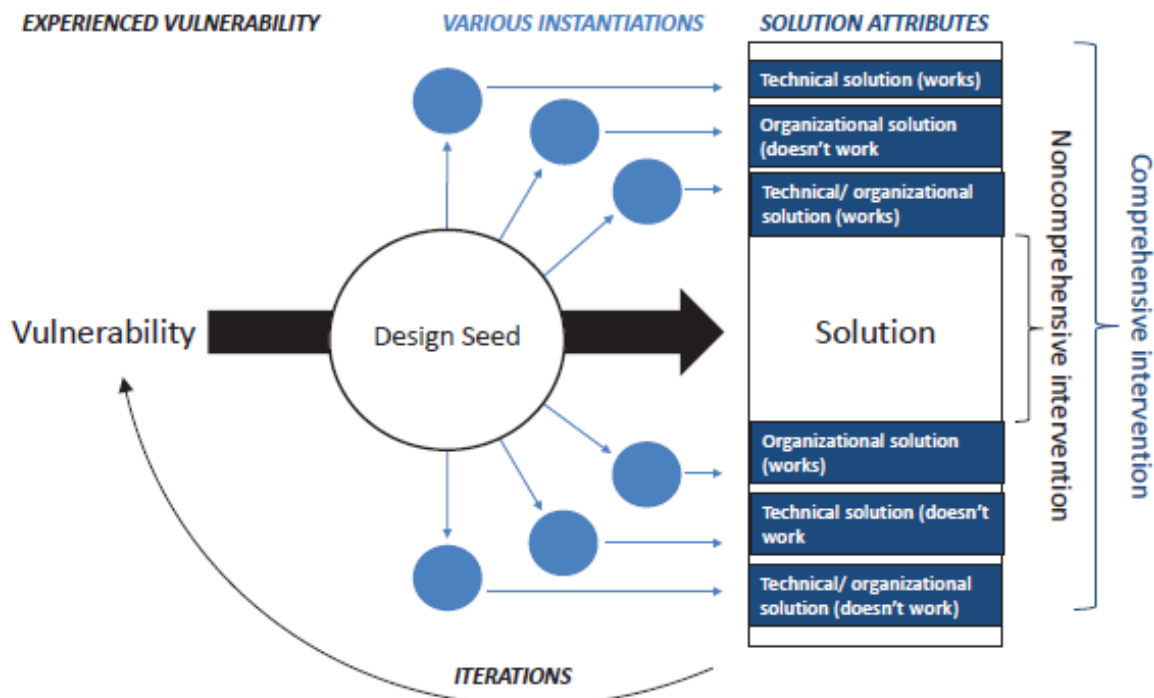
- Systems don't talk to each other
- Don't have a system that puts patients into subgroups for more efficient monitoring
- Overlapping efforts
- Don't know when patient misses appointment
- Don't always know when patient doesn't have PCP

Figure 3. Typical technical development cycle



During the design and development phase, we translated experienced vulnerabilities into leverage points, or design seeds, which are solution attributes that separate the goal of an intervention from the means of achieving it. Specifically, design seeds add an intermediate step that translates these vulnerabilities into a wide range of solution possibilities and provides implementers with various options to consider in different implementation environments. Distinct from the typical technical approach used in software development cycles (Figure 3), design seeds are advantageous because they generate multiple solutions to the same problem in order to uncover unknown vulnerabilities and user preferences (Figure 4).

Figure 4. Sociotechnical Intervention Development Cycle: Design Seed Theory.



For example, stakeholders from the urology clinic informed us that they had a registry for population management, but it was not used. This type of situation can result from the typical development cycle shown in Figure 3.

In contrast, sociotechnical theory and the design seeds process itself (Figure 4) can draw out the components of population management that are required for patient safety but may not necessarily take the ultimate form of a patient registry. These components may include activities such as the ability to communicate with colleagues about a patient’s care or to track patient progress, for example. The ability to assign roles and responsibilities and figure out which patients require follow-up may emerge as design seeds to these activities (Figure 5). This approach takes the organizational context and all of its variations into account.

We also developed a prototype for the final product by implementing an electronic dashboard using an existing technology and an Excel sheet to track no-show rates and loss to follow-up. After implementation, we observed a 30% drop in no-show rates.⁴³

Findings from this pilot study informed the development of the CipherHealth dashboard, which integrates visit, lab, and radiology data to help clinicians perform critical activities.

In preparation of implementation of the CipherHealth dashboard, we established an agreement with the software company, SFDPH, and UCSF. This agreement describes the roles and responsibilities of all stakeholders involved to establish a secure and sustainable partnership for the development and implementation of a technology application integrated into the health network’s EHR systems and used by UCSF investigators and healthcare providers. This required buy-in from the SFDPH Director of Health along with other executives, reflecting the widespread support of our program and alignment with organizational goals for improving patient safety. Additionally, the approval was the first of its kind in the health network and continues to serve as a model for the public delivery system to partner with agile software companies. This model scaled to other innovations in the SFHN that utilize patient health information to improve patient safety. Specifically, our process has already helped inform the development of an agreement for a quality improvement project focused on reducing readmission rates in the emergency department with automated post-discharge follow-up phone calls as well as a project that facilitates text-message outreach to patients in multiple languages in the gastroenterology clinic to improve colonoscopy completion rates among patients with abnormal fecal immunochemical tests. We documented our process in multiple protocols in order to inform implementation efforts in a myriad of other settings as well, particularly those limited by resources.^{39–41}

During implementation, we closely collaborated with frontline clinical staff, trainees, and leaders. At baseline, the health information technology solution, hosted by CipherHealth, included many of the design seeds described above. However, our collaborators designed and tested CipherHealth in a real-world setting, providing crucial recommendations that CipherHealth has since incorporated into their product to make it more feasible and usable in a safety-net health system.

The platform went live in the Anticoagulation, Otolaryngology - Head and Neck Surgery, Urology, and Palliative Care Clinics and actively monitored 600 patients. Stakeholders from each clinic co-designed and co-developed specific workflows for their unique management scenarios, such as the ability to track lab values in relation to specific goal ranges or push reminders for follow-up after recommended time periods. These workflows were responsive to the design seeds, and provided the ability to control data access, complete patient information, and performance data, for example. Some design seeds were not integrated into this iteration of the HIT tool due to technological limitations, such as the ability to schedule follow-up visits from within the platform itself. A screenshot of the HIT platform is shown in Figure 6.

In August 2019, the SFHN implemented an EHR across the entire network. All downstream applications, including CipherHealth, were disabled as a result of the network deciding to focus on a single, enterprise-level system.

Critical activity category	Design seed
Communicate/coordinate	Ability to control data access
	Scheduling functionality
	Assign roles and responsibilities
	Triggered notifications
Patient activity	Patient support
	Complete patient information
Review or enter data	Keeps list up-to-date
	Standardized data entry
	Complete data capture
	Performance data
Track progress	Population registry functionality for high-risk patients
	Figure out what patients are “on the list”
	Customize the patient list

Figure 5. Design seeds correspond to the critical activities clinics perform

Although the ASCENT Projects 1 and 2 technology platform itself was discontinued – a common challenge encountered by safety-net health systems – the workflows developed through our human-centered design and iterative processes were adopted by the SFHN during their design phases, allowing us to scale this work and enabling the network to leverage existing processes developed by our team and stakeholders.

Figure 6. Screenshot of CipherHealth (patient names are fictitious)

Patient	Team Members	Workflows	Last Intervention	Overdue
Bruce Wolf 71, Male, MRN291922, 8/16/46	SL KM	Active Surveillance Registry	Never	1
Maurine Nicolas 63, Male, MRN166070, 3/15/55	SL KM DH NM DS SY SB	BCG Treatment (High Risk)	6/20/2018	1
Thaddeus Nicolas 77, Male, MRN247982, 5/21/41	SL KM	Stent Registry	6/14/2018	✓

Project 3: Universal Medication Schedule Implementation Principal Findings and Outcomes

We successfully implemented standardized UMS in three major pharmacies within the SFHN: Laguna Honda Hospital, Behavioral Health Services, and Jail Health. Due to an inability to modify the pharmacy software at our largest site, SFGH, implementation at this site was suboptimal. In addition, there were also concerns among pharmacists that UMS might confuse patients and cause further harm. Subsequently, we conducted phone interviews with patients, interviewing a total of 49 patients and observing a slight positive effect on comprehension and adherence among patients who received UMS vs. patients who received standard instructions. However, despite these positive findings and overwhelming support (97%) among surveyed clinicians (n=212) clinicians, implementation remained low due to the difficulty of prescribing in UMS language using the current software. Ultimately, the inability to modify the software to facilitate prescribing in UMS proved to be an insurmountable barrier.

Given the positive results of our study, part of the SFHN's transition to Epic will involve programming UMS instructions into the prescribing component of the software. The entire network will be able to automate and default to UMS instructions, thus optimizing implementation as well as improving comprehension and adherence across the network.

We interviewed 49 patients who were prescribed medicines that were intended to be converted to UMS instructions. Of these, 24 received their instructions with UMS and 25 received standard instructions, because the SFGH Outpatient Pharmacy did not convert them to UMS at the dispensing stage. Patients who appropriately received UMS instructions were more likely to be taking the medications according to the instructions (75%, 18/24, compared to 72%, 18/25, for standard instructions.) Similarly, patients who received UMS instructions were more likely to have adequate medication adherence (defined as taking medicines five or more days in the prior week) compared to standard instructions (65%, 16/24, versus 60%, 15/25).

Implementation scope as well as success varied across sites (Table 2).

Overall, UMS implementation required significant coordination between pharmacy directors and frontline staff as well as external support from network leaders and the ASCENT's research team.

Successful pharmacies were found to have (1) adaptable software, (2) agile teams and tighter communication networks, and (3) an automated implementation strategy.

Discussion

We found that implementation science is a valuable approach to respond to the constraints of a healthcare environment. We began our investigation asking ourselves, “how can the co-design of health information technology interventions influence uptake?” However, we found that the unique context of healthcare delivery plays a major role in uptake, and other implementation outcomes, across settings serving diverse patients. We learned that workflow analysis and journey mapping with frontline staff can help reduce implementation challenges and improve the sustainability of an intervention.

Additionally, we learned that there is limited epidemiological data on the extent of safety gaps, particularly in safety-net settings that struggle with fragmented record keeping systems. We sought to address ambulatory safety issues, such as delayed and missed monitoring of subcritical test results. Many of the concerns that clinicians said kept them up at night - such as incomplete follow-up of incidental pulmonary nodules - lack data describing the extent of the problem. Therefore, we needed to invest in studying the epidemiology behind these safety gaps to better understand the impact of delayed and missed monitoring on patient outcomes.

Conclusions

In outpatient healthcare settings like physicians’ offices, there are significant risks to patients’ safety, including delays in diagnosis and treatment that result in disease progression, preventable complications of treatment, and adverse drug events. Few systems exist to recognize and ameliorate such patient safety problems, and the overall aim is to design, develop, test, and evaluate innovative solutions to improve patient safety.

ASCENT developed, piloted, and implemented a needs-driven technical and culture-based solution for subcritical test results, management of high-risk conditions and treatments, and patient-centered medication language with rich involvement from frontline clinicians and leadership in the health system. Our learnings can help to shape future initiatives in the SFHN and in other complex health systems.

Significance

ASCENT represents one of the largest scale patient safety learning laboratories completely situated in a safety-net setting that serves racially and ethnically diverse, publicly insured, low-income patients. Our experience demonstrates that data collection in these settings still relies on manual methods, such as medical record review, and even then is still limited by fragmented record keeping systems and staffing constraints. Despite these limitations, implementation science is a valuable approach for identifying problem areas and developing context-appropriate solutions. Because we uncovered implementation barriers unique to safety-net settings, in order to truly achieve safe and equitable care, we must continue to conduct safety-related implementation research in safety-net settings.

Implications

Health systems continue to face barriers to optimal patient safety in the outpatient setting. New approaches are needed to address these gaps. One of our key findings was that current EHR functionality does not close safety gaps in complex care processes. Abnormal test management and monitoring of high-risk conditions are highly amenable to tracking using electronic systems, but existing systems do not meeting these needs. This is a massive missed opportunity. Moreover, safety-net health systems are uniquely challenged by resource constraints and technology limitations that persist, even in 2020. Approaches like those undertaken by ASCENT, that iteratively incorporate the unique context of a specific setting using design and systems engineering methodologies, can help health systems address these challenges and improve patient safety.

Table 2. Pre- and Post- UMS Conversion Rates by SFHN Implementation Site		
Implementation Site⁴⁴	Pre	Post
	UMS (% eligible/%total)	UMS (% eligible/%total)
Outpatient Pharmacy	991 (22.9%/12.7%)	835 (23.4%/12.7%)
Laguna Honda	54 (34.2%/34.2%)	541 (88.2%/42.6%)
Jail Health	1070 (82.8%/78.7%)	1296 (98.1%/95.6%)
Behavioral Health	0 (0%/0%)	30 (93.7%/40%)

Our findings suggest that approaches developed in better-resourced health settings are unlikely to be directly translated into safety-net settings. Instead, we advocate for conducting safety research in safety-net settings among diverse populations and with resource constraints that can then be shared across a wide range of settings.

LIST OF PUBLICATIONS and PRODUCTS

Publications

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Products

Our investigative team presented the findings of this work at multiple local, regional, and national conferences.

1. Kith G and Lisker S, Sarkar U, Barr-Walker J, Breyer BN, Palmer NR. A systematic review of observational studies assessing outcomes of prostate cancer patients on active surveillance: an examination of adherence to protocols. UCSF Prostate Cancer Program Annual Retreat. Nov 6 2018. San Francisco, CA.
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We developed a website (<https://ascent.ucsf.edu/>) and Twitter account (https://twitter.com/SF_ASCENT) to share our progress and findings with the general public.

Finally, we were recognized in our institutional and external networks. The SFGH highlighted the work of ASCENT in the 2016-2017 annual report and Stanford University wrote an article describing our “journey mapping” approach (<https://healthpolicy.fsi.stanford.edu/news/team-uses-journey-mapping-design-seeds-help-low-income-network-clinics>). Notably, the Editorial Board of the 2020 IMIA Yearbook of Medical Informatics selected our recent article in *Applied Ergonomics* for listing in the 2020 edition of the Yearbook as one of the best articles published in 2019 in the Human Factors and Organizational Issues subfield of the IMIA Yearbook.⁴⁵

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