

AHRQ Grant Final Progress Report

Title: Measuring and Improving Ambulatory Patient Safety with an Electronic Dashboard

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Structured Abstract (250 words max)

PURPOSE: Lack of timely information and fragmentation of care exacerbate safety problems among ambulatory patients. Less robust HIT infrastructure in the safety-net setting compounds risks, and improved strategies to detect high-risk situations are urgently needed.

SCOPE: We set out to provide real-time health-system level data aimed at improving outpatient safety through an electronic dashboard and updated clinical workflow in San Francisco General Hospital's Anticoagulation Clinic.

METHODS: We developed, piloted, and evaluated a safety dashboard using an electronic registry and updated workflows to more efficiently track and identify patients overdue for monitoring and quickly intervene. We implemented the technical and clinical infrastructure needed to reach out to patients overdue for treatment on a weekly basis. To test the efficacy and utility of the intervention, we assessed the rate of no-show patients, number of patients lost to follow-up, improvements in clinical outcomes, integrity of the electronic registry, and usability.

RESULTS: The registry was implemented, and an audit revealed greater than 97% accuracy in patient inclusion status. No-show rates decreased after implementation. We uncovered usability concerns and are working on improving utility of the dashboard and provider satisfaction. Because of inconsistent acquisition of baseline data prior to project inception, we established accurate pre-implementation clinical data and currently collecting post-implementation data. We are expanding upon the dashboard and associated clinical workflows into a related project, the AHRQ- funded Patient Safety Learning Laboratory Ambulatory Safety Center for iNnovaTion, ASCENT (PI Sarkar, P30 HS023558-02).

KEY WORDS: health information technologies (HIT), patient safety, ambulatory, safety-net, quality improvement

Purpose:

Despite the well-documented risks to patient safety in the ambulatory setting, few efforts to improve ambulatory safety through health system-level interventions have been developed or tested, and even fewer have been implemented in safety-net health systems. We set out to identify and mitigate patient outpatient safety risks using health information technologies (HIT) across safety-net health care systems. The objective of our research was to develop an HIT interface that synthesizes data from the electronic health record to create an outpatient-focused ambulatory safety dashboard (visual summary of safety measures) and to pilot-test this tool in a safety-net patient-centered medical home (PCMH) setting. Due to the progress made, we focused on an evidence-based, clinically important, measurable safety problem that can serve as a "test case": inadequate anticoagulation monitoring.

Health care "dashboards" that summarize selected patient data in an electronic interface have been utilized in research and quality improvement to measure provider performance on quality measures and for single diseases. Rather than focusing on visit-based care provided by the primary care physician, our dashboard was designed to allow real-time intervention for individual patients provided by teams and provide health-system level data that will prompt changes to care processes to enhance ambulatory safety. While we focused on the Anticoagulation Clinic (ACC), we developed our dashboard so that it can be utilized in other high-risk safety gaps identified in collaboration with clinical leadership as areas are of high clinical priority,⁽¹⁻³⁾ implicated in health care disparities,^(4, 5) and aligned with the health system's operational goals. These high-risk safety gaps include inadequate monitoring of high-risk conditions, such as abnormal colonoscopy, head and neck cancers, pulmonary nodules,

prostate cancer, and rheumatology, as well as failure to timely and accurately manage subcritical test results such as radiology or laboratory results.

Guided by experience with the dashboard approach and preliminary data indicating significant existing safety problems, we proposed two specific aims:

Aim 1: To develop an ambulatory safety electronic dashboard (visual summary of safety measures) for use in primary care settings. The dashboard is designed to use data stored in the electronic health record and administrative databases to inform panel managers and clinicians about selected, evidence-based, high-priority safety risks in outpatient care settings. The utility of the dashboard is to synthesize available electronic data to more efficiently and quickly detect safety problems, in order to facilitate timely intervention.

Aim 2: To conduct a pilot study to assess the feasibility of incorporating use of the dashboard in a primary care setting. We conducted the pilot study in a primary care clinic at San Francisco General Hospital (SFGH). In addition to enabling us to assess the feasibility of incorporating the dashboard into a busy primary care setting, this pilot study enabled us to collect preliminary data on its “real world” utility in ameliorating selected high-priority safety problems, which will be helpful in calculating sample sizes for later efficacy trials.

Scope:

Background and Context:

Inadequate patient safety has been recognized as a major public health challenge in the United States. According to the Institute of Medicine (IOM), total national costs of preventable adverse events are between \$17 billion and \$29 billion.⁽⁶⁾ A recent IOM report noted that the number of errors in outpatients is likely to far exceed those from the inpatient setting.⁽⁷⁾ The consequences of medical errors in ambulatory settings may be greater than those in the inpatient setting.

Among ambulatory patients, safety problems included missed and delayed diagnosis,⁽⁸⁾ failures of monitoring, miscommunication,⁽⁹⁻¹¹⁾ and adverse drug events.^(12, 13) Lack of timely information available and fragmentation of care in ambulatory health systems exacerbate these problems,⁽¹⁴⁾ and in safety-net health systems where patients experience unique barriers to health care, exacerbated by health systems that have a less robust HIT infrastructure,^(15, 16) these safety risks are likely to be even greater. Proactive and efficient strategies to detect high-risk situations in ambulatory care are urgently needed. Moreover, innovations to improve patient safety will have the greatest impact on public health and disparities if they are successful in the safety-net. With the 2009 HITECH Act's incentives for electronic health record implementation,⁽¹⁷⁾ widespread deployment of HIT creates an opportunity to address safety problems at the health system level, using HIT to detect safety problems in real time.⁽¹⁸⁾ In parallel, the growth of the PCMH movement⁽¹⁹⁾ provides an opportunity to move beyond visit-based care^(20, 21) and to integrate ambulatory patient safety surveillance as part of panel management.⁽²²⁾ PCMH models should address disparities in population health and improve safety if implemented in safety-net settings.⁽²³⁻²⁶⁾

There are several challenges to creating safety measures in the outpatient setting. First, patients are responsible for day-to-day management of their health and medical conditions, and outpatient safety overlaps with patient adherence to recommendations. Second, the relative lack of regulatory scrutiny in ambulatory setting contributes to less emphasis on safety. Third, the structure of brief outpatient visits with multiple transitions and fragmentation of care increases

risk of safety problems.⁽²⁷⁾ For all these reasons, we did not find existing measures that address the known ambulatory safety problems addressed by this research.

More recently within the health care industry, electronic dashboards are beginning to be used to support disease management and pay-for-performance programs by providing feedback to physician leaders and individual physicians on how they are performing on key quality measures. These ‘quality dashboards’ can also be linked to the electronic health record and provide providers feedback on their adherence to local or national guidelines, help them identify patients most in need of attention, and facilitate tasks such as test ordering, letter writing, appointment scheduling, and prescriptions writing.⁽²⁸⁻³¹⁾ In addition, dashboards that compare individual physicians or physician groups against each other may further motivate clinicians into taking action by leveraging the competitive nature of health-care providers.^(32, 33) By providing feedback to physicians and allowing them to act on the feedback directly, electronic dashboards have significant potential to improve the quality of care.^(34, 35) While using a dashboard to manage ambulatory safety problems is novel application, it is a promising approach based on prior applications of dashboards in health care.

Building upon this growing body of research, we proposed to identify and mitigate safety risks in the outpatient setting, by developing and evaluating an electronic tool, the Safe Ambulatory Focused Evidence Dashboard (SAFE-D), in the context of PCMH panel management. The population-based approach to health care delivery embodied by the dashboard requires a multi-tiered evaluation strategy. Our study period coincided with the transition into a certified, comprehensive electronic health record (EHR), eClinical Works (eCW), known locally as CareLinkSF, throughout the ambulatory care settings at the main site for our study, SFGH. This transitional period represented an ideal time for implementation of the dashboard because set up to receive inputs from eCW would result in minimal disruption, although it did not come without its usability and efficacy challenges.

The transition to a new EHR across an entire health network is an intensive process, and we plan to continue to iteratively develop and evaluate the dashboard and workflow as this quality improvement focus advances on through the Ambulatory Safety Center for iNnovaTion (ASCENT),⁽³⁶⁾ a four-year quality improvement study funded by AHRQ that seeks to design and develop workflows and HIT-facilitated interventions that prevent medical errors and improve the safety of care provided in the SFHN. We have developed the dashboard so data streams between SFHN’s previous EHR, in which some clinical care information still lives, current EHR (eCW) and future EHR will be compatible.

Settings:

We developed and piloted SAFE-D within an academic safety-net setting, the Richard H. Fine People’s Clinic at SFGH. This outpatient primary clinic is part of the city-and county-funded SFHN which provides care to uninsured, Medicaid, and Medicare populations in San Francisco. Patients seen at this clinic are low-income and are ethnically and linguistically diverse, with high incidence of limited health literacy^(37, 38) and with established disparities in chronic disease outcomes. As in many academic settings, there are multiple part-time providers, including trainees, necessitating outpatient care transitions. Many clinical studies and demonstration projects have taken place in the Richard H. Fine People’s Clinic, including one of the few studies to show the value of a patient-centered medical home model in a safety-net setting.⁽³⁹⁾

Basing our pilot study at this setting enhanced the potential for generalizability, for several reasons. First, many health systems face challenges of disadvantaged, chronically ill populations with multiple clinicians and resource constraints (AHRQ’s Priority Populations), and

if the dashboard approach proves to be feasible in this clinic, we can infer that it has the potential to be readily transplanted across health systems. Second, the team-based approach to care, in which we deploy medical assistants, nurses, and physicians, to strive to quality for all patients rather than those visiting the clinic only, is rapidly becoming the new standard for outpatient care. Third, our team is well-positioned to foster dissemination of this tool. We work closely on innovation with the California Association for Public Hospitals' quality improvement arm, the Safety Net Institute; if successful, this approach can be readily promoted among other California safety-net settings. Moreover, as part of a Practice-Based Research Network with an extensive track-record of conducting clinically-relevant research, we are well-positioned to scale up this pilot and ultimate approach.

We focused on anticoagulation monitoring for a number of reasons. First, our setting includes a clinical-pharmacist-run ACC in which clinical research projects have been successfully undertaken.^(40, 41) Additionally, the ACC is physically located in the same space and shares many staff with the Richard H. Fine People's Clinic, which will facilitate the clinical actions to bring unmonitored patients back into active oversight. We also selected anticoagulation monitoring because we believed it to serve as a good "test case" for monitoring safety gaps because of not only the presence of safety problems among a high volume of patients but also the lack of a mechanism for identifying patients overdue for monitoring. Over 20 million Americans take warfarin, an anticoagulant, in the ambulatory setting to protect against thromboembolic disease.⁽⁴²⁾ However, dosing warfarin in a therapeutic range is so difficult that warfarin is consistently dosed in range less than 70% of the time⁽⁴³⁾ and is, as a result, culpable for a high frequency of adverse drug events in ambulatory settings.⁽⁴⁴⁾ Under-dosing causes inadequate protection against thromboembolism and over-dosing results in serious bleeding complications. Approximately 475 individuals are currently managed in the Richard H. Fine People's ACC. This high patient volume is made more complex by the fact that many of these patients have primary care providers off-site, making follow-up activities challenging in this setting. Prior to our intervention, no mechanism existed to identify patients overdue for monitoring and proactively encouraging the resumption of care.

Participants:

The team of investigators includes Principal Investigator Dr. Urmimala Sarkar, MD, MPH, Associate Professor at UCSF and primary care physician at SFGH, Dr. Shin-Yu Lee, PharmD, clinical ambulatory care pharmacist at SFGH, Dr. Liz Goldman, MD, Associate Professor at UCSF, primary care physician at SFGH, and CareLinkSF Quality and Reporting Liaison for the SFHN, Dr. Courtney Lyles, PhD, Assistant Professor at UCSF, Dr. George Su, MD, Associate Professor at UCSF and Lead of the SFDPH Innovation Hub, and Dr. Emily Patterson, PhD, Assistant Professor at Ohio State University.

Additionally, we established a clinical advisory board that met bi-monthly to review the design and protocols embedded in the dashboard. Participating providers include Dr. Alice Chen, Chief Medical Officer of the SFHN, Dr. Claire Horton, director of the Richard H. Fine People's Clinic, Dr. Mary Gray from Cardiology and Dr. Justin Sewell from Gastroenterology clinics at San Francisco General Hospital; clinic leadership from Rheumatology clinic and the Family Health Center (Drs. Jon Graf and Hali Hammer, respectively), Dr. Fred Strauss, who practices primary care within the Community Health Network of San Francisco and served as the physician lead for implementation of eClinical Works, Dr. Lisa Golden, Quality Improvement Medical Director of the SFDPH, and Dr. Ellen Chen, Quality Improvement Primary Care Director with the SFDPH.

Beyond the clinician advisory board, we also collaborated with frontline staff and programmers during this study to ensure that we can access the correct electronic data fields, make any needed changes in clinic workflows, and design an electronic dashboard interface that is usable and effective.

Through the process of identifying stakeholders in the SFHN, we established additional clinical and non-clinical partnerships including Dr. Jeanette Cavano, PharmD, Ambulatory Care Clinical Pharmacy Supervisor of the SFHN who will be able to provide guidance and aid implementation.

Prevalence:

To support our proposed metric of missed monitoring for warfarin, we presented data on adverse drug events resulting from warfarin use among patients followed at SFGH's Richard H. Fine People's Clinic. Over a 12-month period, we found 46 adverse drug events related to warfarin, with international normalized ration (INR)>5 in each case. Chart review revealed inadequate monitoring as the underlying cause for 100% of these cases.⁽⁴⁵⁾ These data reveal that there are significant safety gaps associated with inadequate monitoring of warfarin, and that we can detect and track the adequacy of monitoring use laboratory and visit data.

Methods:

Study Design:

The EHR in the SFHN, eCW, includes visit data, laboratory and imaging test results, and all primary care provider documentation for patients seen at the Richard H. Fine People's Clinic. SFGH also utilizes an electronic registry, i2i Tracks, for selected conditions such as diabetes. These data are regularly queried and reported for operational purposes. Moreover, the database can be queried for purposes of research as well. Uses include identifying populations for inclusion in intervention studies, describing population health and risk data, and characterizing health care utilization. The reporting database used to construct the dashboard includes data from the SFHN's prior EHR (Invision/LCR) server and enhanced data warehouse, from the disease registries in i2iTracks, to data from free-standing applications. The design and development of the dashboard was performed by an experienced database expert and programmer based at the Center for Innovation in Access and Quality (CIAQ), supervised by Dr. Sarkar. The clinician advisory board reviewed the design and protocols embedded in the dashboard throughout development.

We conceptualized the on-going evaluation plan for our electronic dashboard using the RE-AIM framework, assessing the 5 dimensions of reach, efficacy, adoption, implementation, and maintenance.⁽⁴⁶⁾ Because this was an early-phase study, we did not expect to proceed through each phase of the RE-AIM framework but plan on continuing this assessment of the dashboard as it evolves with ASCENT. We explain in detail in the results section (Table 2) how these concepts apply to our dashboard development and evaluation as this research progressed. Briefly, we believe the *reach* of the approach is to encompass the entire population at risk, in contrast to visit-based patient safety strategies. Our pilot-testing allowed us to estimate *efficacy* in that we could report the extent of mitigation of safety risks and number of interventions needed to mitigate risks, although a larger implementation will produce more precise effect sizes. Using one pilot site allowed us to identify barriers to *adoption* of the dashboard, and we observed the extent of *implementation* that occurred within the scope of this 2-year grant mechanism. We plan for this to lead to longer-term implementation and

maintenance of this HIT innovation through ASCENT due to the success of the pilot demonstration.

Data Sources/Collection:

We used data from eCW to create the registry. By tracking the patients seen in the ACC, we were able to manually add these patients to a registry of patients being actively treated, while some data about the patients automatically fed into the electronic registry, i2i Tracks, such as INR values and dates. We regularly reviewed the ACC's schedule to determine the patients who missed scheduled appointments and conducted chart reviews to assess whether or not patients had been lost to follow up.

To develop a list of patients requiring follow-up for outreach, we manually tracked patients who had missed three or more rescheduled appointments (or their first two appointments in the ACC), as this would be the situation in which the patient would no longer be followed-up upon in the ACC per the clinic's pre-intervention workflow. We also would see if patients who were actively receiving anticoagulation treatment had not had an INR value read within the last 90 days and did not have an appointment scheduled in the coming 30 days were in need of follow-up by running a query in i2i Tracks.

To maintain the accuracy of the registry, we manually tracked patients who completed or discontinued treatment, left the SFHN, stopped treatment due to poor compliance, or deceased by removing them from the active patient registry and adding them to an inactive patient registry. We manually checked patients on a monthly basis to see if any discontinued patients had restarted anticoagulation treatment. Table 1 describes the fields that are included in the registry. While we did not utilize all fields for this study period during which we were establishing a baseline for the effectiveness of the dashboard solution, we will use demographic fields in the future to determine if there is a variation in regards to demographic factors of patients such as age, gender, language spoken, race/ethnicity, insurance status, etc.

Table 1: Fields Populated in Registry

Name of Data Element	Field Codes
Patient Characteristics	Medical Record Number Name Location Provider DOB Gender Race Language Phone Number
Patient Type	New (first visit) Established (last visit within 1 year) Re-established (last visit > 1 year)
Reason for Therapy	Atrial fibrillation/Atrial flutter Stroke Deep vein thrombosis Mitral/aortic valve replacement Hypercoagulation Pulmonary arterial hypertension Orthopedic prophylaxis

Length of Therapy	3 months 6 months Lifetime To be determined Other
Start of Therapy	Date
Goal INR	1.5-2.5 2.0-3.0 2.5-3.5 Other
INR Values	Last 3 INR dates and values
Significant Bleeding History	Yes No

To assess usability, we used questionnaires, direct observation, and informal interviews with clinical pharmacists and staff. Members of our research team documented feedback and we used it to inform the development of the dashboard and changes to the ACC's workflow.

Intervention:

This final progress report focuses specifically on dashboard efficacy and usability in the ACC at SFGH. There is clear evidence that suboptimal management of Coumadin/warfarin leads to significant harm without appropriate action. During this pilot period, we tracked the follow-up activities in the ACC occurring as a result of dashboard data to track the appropriate actions needed to mitigate the safety risk at the individual level. To accomplish this task, we worked with Clinical Ambulatory Care Pharmacy staff and volunteers within the ACC Clinic at SFGH to modify their workflow with the goal of reducing loss to follow-up and ensuring that patients who were due for INR readings were contacted to schedule appointments. .

In the initial workflow, an e-Referral referral form is printed out at each clinic, which tracks which patients are due for monitoring and have scheduled appointments. If the patient attends the visit, a pharmacy student enters their information into an excel sheet, codes the patient as "showed" and no further action is required. However, if the patient does not attend, then the pharmacist follows up with their primary care physician (PCP). If the patient does not have a PCP, a pharmacy student fills out an appointment form and schedules an appointment within the next two weeks. If the patient attends the rescheduled appointment, the information is logged into an excel sheet. If not, the same process for the first missed appointment is followed and a third appointment is scheduled. If the patient does not attend this appointment, they are dropped from the follow-up list. If the patient attends, the information is recorded in an excel file as aforementioned. In this workflow, tracking the patients due for monitoring involves piecing together disparate data across systems; it is a time-intensive and complex process that does not produce a concise and frequently updated list of patients due for monitoring.

The workflow we developed seeks to provide real-time health data for accurate monitoring of all patients being seeing in the ACC. It operates through a registry of patients, whose information a volunteer or pharmacy student manually enters into the SFHN's registry system, i2i Tracks. Using this registry, a panel manager (medical clerk) queries the registry database weekly to identify patients overdue for monitoring. If the visit/monitoring is scheduled, the panel manager will place a telephone call to the patient using a standardized script to remind the patient of the monitoring need and upcoming appointment. The patient will then attend the visit with the pharmacist and be scheduled for a follow-up visit. If there is no

visit/monitoring scheduled, then the panel manager requests an appointment and a test order for the INR through the EHR. Next, the pharmacist will contact the patient regarding the upcoming appointment using the telephone script. In contrast to the prior workflow, our new model seeks to eliminate loss to follow-up except in extreme cases, such as mortality.

Through the new workflow, we have added an additional level of oversight through the role of the panel manager. Moreover, the registry system seeks to more efficiently identify patients who are overdue for monitoring, thereby providing an opportunity for intervention and prevent loss to follow-up. With the new workflow, assigning clear responsibilities to the care panel was integral to ensuring quality of care. The updated clinic workflow delineates roles for the care team while also providing flexibility to see urgent walk-ins, demonstrating panel management aligned with the goals of the PCMH. With the new workflow, we sought to develop ongoing training guides to ease transition. As this workflow has iteratively developed, a volunteer in the pharmacy department compiled a comprehensive manual detailing how the future panel manager can input data into the registry, follow-up with patients, schedule appointments, and effectively monitor warfarin regimens.

We initiated other key changes to the ACC to support the adoption, implementation, and efficacy of the new workflow. First, we reorganized and amended the old appointment template used in eCW to pre-populate with forms integral to patient safety. Added elements include a form that prompts pharmacists to check for additional symptoms of adverse drug effects, such as signs of stroke or swelling rather than just bleeding or bruising, as well as questions to ask the patient that may indicate the cause or onset of ADEs (missed/extra doses of warfarin, changes in medications, changes in diet). There also now exists a form within the appointment template that tracks all historical INR results, dates, and regimens, making them easier to view for the pharmacist and therefore improving both efficiency and potentially limiting mistakes. Last, there is also a form in the template that prompts pharmacists to educate new warfarin patients on the importance of compliance, managing missed doses, communicating with the ACC, etc. The updated appointment template provides a consistent rubric for visits across the panel.

Measures:

Measures of the reach, efficacy, adoption, and implementation of this dashboard and clinical workflow include assessing the (1) no-show rate, (2) number of patients lost to follow-up (3) improvements in clinical outcomes, (4) integrity of the electronic registry, and (5) usability and provider satisfaction. Table 2 includes a summary of these measures in the context of the RE-AIM framework and their rationale.

Table 2: Summary of Measures

Dimension definition ⁽⁴⁷⁾	Application to safety dashboard	Study Measurement	Measure
Reach: Proportion of the target population the participated in the intervention	<i>Accuracy of the dashboard</i> (Aim 1) in capturing the population at risk for safety intervention	Chart audit on a random sample of patients identified in the EHR to see if they are correctly captured on dashboard	Accuracy of registry in identifying patients in and out of care
Efficacy: Success rate if implemented as planned	<i>Extent of mitigation of patient harm</i> (Aim 2)	Rates of safety risks per population/test reviewed	Tracking no-shows
Efficacy: Success rate if implemented as planned	<i>Extent of mitigation of patient harm</i> (Aim 2)	Extent of harm to patients per event	Time in therapeutic range (TTR) can reflect adverse health effects due to

			monitoring failures
Adoption: Proportion of settings, practices, and plans that will adopt this intervention	<i>Extent of dashboard use (Aim 2) at the pilot site within panel management</i>	- Direct observation of panel manager's dashboard use - Electronic audit to track viewing of dashboard	Usability and provider satisfaction
Implementation: Extent to which intervention is implemented as intended in the real world	- <i>Timely and appropriate follow-up actions (Aim 2) to mitigate individual risks</i> - Health system changes in response to aggregate patterns of risk (Clinician Advisory Board)	- Tracking of follow-up actions from dashboard review - Tracking of changes in health care processes affecting dashboard metrics	Measure mitigations of individual risks by timely and appropriate follow-up by tracking number of patients lost to follow-up and implications
Maintenance: Extent to which program is sustained over time	Future work: Multi-site implementation and evaluation	Future work: Examine extent of dashboard use after the conclusion of the pilot study	Future work: Examine changes in safety risks after the conclusion of the pilot study

No-show Rate

The proposed workflow was designed to better identify patients overdue for monitoring and those patients who would typically be lost to follow-up in the existing workflow (when the patient misses the third rescheduled appointment, or when a new patient misses their first two appointments). When a patient misses a scheduled appointment the patient will be classified as a “no-show.” The electronic registry and updated workflow prompt panel managers to call and remind patients about upcoming appointments with the goal of reducing no-show events. Therefore, to determine whether or not this strategy is effective we sought to determine whether or not the dashboard and workflow intervention reduced the average of no-show rates over time. We compared monthly averages of no-show rates before and during the intervention. In order to track the patients seen in the ACC, we added them to the anticoagulation registry in i2i Tracks. We measured no-show rates by running monthly reports in i2i Tracks and cross-referencing the ACC schedule to determine whether or not a patient arrived to the scheduled appointment. We then tracked the number of unique no-show cases to calculate the average monthly no-show rate.

Patients lost to follow-up

The dashboard and workflow intervention were also designed to eliminate the possibility of patients being lost to follow-up after missing three consecutive appointments (or the first two appointments for patients new to the ACC) by allowing a panel manager to perform a weekly query of the registry and determine which patients are due for monitoring so the clinic can perform outreach to those patients. To measure the efficacy of this aspect of the HIT innovation, we measured the number of patients lost to follow-up prior to and during the intervention. We logged all patients that had missed an appointment and were therefore classified as a no-show and then performed a chart review of all patients that had missed three or more consecutive appointments in the ACC. Prior to the intervention, these patients would be lost to follow-up. During the intervention, the updated workflow and dashboard allow panel managers to continue to contact these patients to schedule appointments so patients are not lost to follow-up.

Clinical Outcomes

TTR is a measure of the length of time that a patient's INR is maintained within the therapeutic range and has a direct impact on the efficacy and safety of anticoagulation treatment.⁽⁴³⁾ Inadequate INR monitoring has been implicated in the failure to meet adequate TTR. We could not conduct pre-post analysis since TTR had not been systematically calculated in the ACC for over thirty years. However, to establish a baseline we calculated TTR for a cross-

section of 30 patients who received INR testing between April-June 2015 using the Rosendaal method.⁽⁴⁸⁾

Dashboard Integrity

We assessed the integrity of the anticoagulation tracking registry by logging the number of patients who, due to manual entry or auto-population errors, did not appear in the registry despite being active patients who had recent visits (phone or in-person) at the ACC. We performed random audits on the registry to assess accuracy and detect errors as a result of human error. We tracked patients who were actively being seen in the ACC but for one of three reasons were deactivated in the i2i Tracks registry and therefore unable to be added to the registry. Patients can be deactivated in i2i Tracks if (1) they have not seen a PCP in the SFHN in over 24 months, (2) they have not been assigned a PCP within the SFHN, or (3) they have deceased. These i2i Tracks rules negatively impacted the integrity of the data in the registry because they force exclusion of patients that are within the inclusion criteria (actively being treated at the ACC within a certain time frame).

Usability

As prior studies have shown, busy clinicians and staff are concerned about the speed of HIT applications.⁽⁴⁹⁾ In addition, the usability of the application was an important focal point throughout the design process.⁽⁵⁰⁾ We engaged end users early in the design process to help the design team understand how the application will be used, as well as allow users to validate the user interface and underlying data through iterative reviews of prototypes. Users were also observed using early versions of the application to uncover unanticipated usability issues. Additionally, we conducted an informal interview with the Clinical Ambulatory Care Pharmacist towards the end of the pilot to discern remaining pain points and general usability. It should be noted that while we conducted non-participant observation, what we observed may be different without the presence of surveillance. We plan on continuing usability studies and receiving feedback from users as we integrate the dashboard into ASCENT's software platform.

Limitations:

Sample size

We included the entire patient population seen in the ACC at SFGH from 2014-2015 to evaluate each safety metric rather than taking a sample. We found the scope of SAFE-D in this setting to be large enough to assess feasibility but small enough to complete the pilot with the time and budget of the grant period. We will utilize this data from the pilot study to help determine the appropriate sample size for a larger trial (ASCENT) including the variance of clinical outcomes to help determine effect size, the number of safety risk situations per month, and the time required to address the identified safety problems.

System Synchronization

The SFHN uses many different software platforms to manage the care of its patients. Servers, data warehouses, registries, and health records are designed to communicate to each other, but often data flow is restricted intentionally for security reasons or unintentionally due to data flow incompatibility. By evaluating the dashboard integrity, we uncovered that i2i Tracks registry data was not synchronized with ACC data due to a set of rules established for i2i Tracks that deems patients "inactive" regardless of whether or not they are being seen or have been seen in specialty clinics such as the ACC, diminishing the accuracy of the registry. Similarly, i2i Tracks serves as a "snapshot" of the registry on the date it is run, rather than a historical record

of the registry over time. This vastly reduces the accessibility of historical data within the tool; our team downloaded registries on a recurring basis as a workaround.

Specificity

A potential problem with the dashboard is that our health system is not completely integrated. It is possible, for example, that selected patients may receive INR readings or refill a medication within other health care systems, resulting in incorrect data in eCW. Given that most patients lack health insurance that would allow them to seek care outside the SFHN we do not anticipate this to be an issue for the majority of cases. Moreover, this potential concern would affect the *specificity*, but not the *sensitivity*, of the SAFE-D tool in identifying patient safety problems. We received feedback from panel managers that reviewing patient records identified by the dashboard would not increase their workload when partnered with the efficiency gains of a population management tool such as a registry. We also expect that primary care providers would be aware of outside testing and document results electronically, such that it would be feasible to identify patients who completed screening elsewhere using the EHR. More importantly, we do not expect clinical harm with loss of specificity, so we would prefer to err on the side of higher sensitivity

Emerging and undetected safety gaps

As this research continues to inform our work through the ASCENT project, we expect that we may need to refine the metrics during continued dashboard development. Despite our intimate knowledge of the relevant clinical site, we may not be aware of informal methods of mitigating these safety risks that have arisen in clinical practice. Because we chose these metrics after extensive discussions with clinical leadership, we think they will continue to reflect true safety gaps in our practice setting. Recent studies have also highlighted the need to examine unintended consequences after HIT has been deployed. Unintended consequences may include unexpected changes in workflow, new demands on staff, disruption in communication, over-reliance on technology, shifts in power,⁽⁵¹⁻⁵³⁾ and creation of new errors.⁽⁵⁴⁾ We will monitor for unintended consequences, and, equally importantly, report and disseminate any that we observe.

Results:

Principal Findings/Descriptive Analyses:

We found that our IT-workflow solution reduced the average monthly no-show rates with limited errors in regards to both manual entry and automated registry management. We cannot yet say at this time if we have improved clinical outcomes, as TTR was not being calculated prior to this intervention, but are confident that if we are able to maintain low no-show rates, clinicians can actively advocate for medication adherence as well as monitor patients' TTR in order to optimize clinical outcomes. Synchronizing real-time patient-level data across systems and into the registry proved to involve significant manual entry and was most effective when an ACC volunteer was dedicated to the project. Data integrity and patient outreach declined after the ACC volunteer left the clinic, suggesting that additional project support will be needed to fully integrate dashboards and new workflows into other subspecialty clinics.

Outcomes:

No-show Rates

We tracked no-show rates in the ACC at SFGH from August 2014 through November 2015 and we found a reduction in no-shows after the implementation of our proposed workflow and the development of the anticoagulation tracking registry. The pre-implementation no-show rate (August 2014-December 2014) averaged at 31% whereas the post-implementation rate (January 2015-November 2015) was found to be 21% (Figure 1). This reduction was seen almost immediately upon the implementation of the new workflow and IT solution and leveled off until September, when it began to rise, ultimately back to 30% by the end

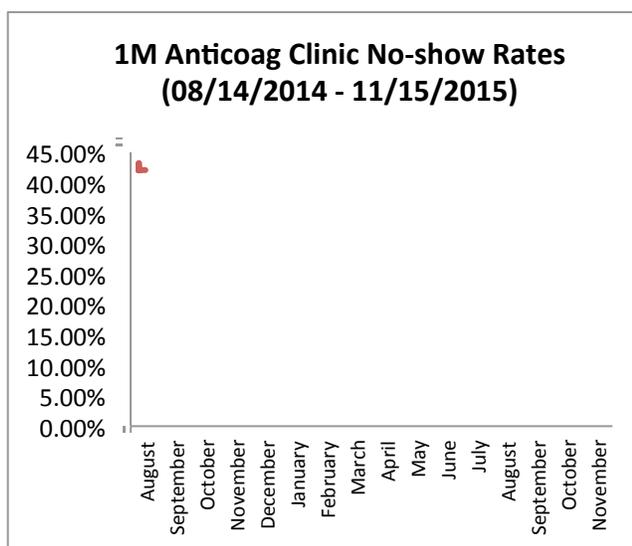


Figure 1

of October. This could be due to the volunteer in charge of the registry leaving at the end of June and the responsibility not being completely passed on. We plan on continuing to monitor no-show rates to better understand the extent to which they are impacted by the intervention.

Patients Lost to Follow-Up

Since January 2015, 50 patients had been lost to follow-up in the ACC. Of these 50 patients, the majority (n=31) were new patients in the 1M ACC who never initiated care. Additionally, 15 patients lost to follow-up experienced adverse events (30% complication rate), including deep vein thrombosis (DTV) and (pulmonary) embolism after loss to follow-up. Of these 15, 13 patients had events that are definitively associated with inadequate monitoring and treatment and 2 others had events that could maybe be associated with poor warfarin administration; therefore, a more generous complication rate of 26% emerges.

Integrity of the Registry

Rules in i2i Tracks, determined by either the software company or the administrators at SFDPH, cause deactivation of certain patients in the system therefore prohibiting patient addition to a registry, even if the patient is actively being treated and monitored at the ACC. We found 20 patients excluded from i2i Tracks for this reason from January 1, 2015, to November 30, 2015, representing approximately 4% of our registry.

Clinical Outcomes

From our registry, we calculated TTR for a cross-section of 30 patients being seen in the ACC between April-June 2015. On average, the TTR was 65%, with a range of 0%-100% and a median of 52%. It should be noted that we discovered two significant outliers, with INR readings far beyond the therapeutic range (> 7). Both of these patients had missed multiple appointments prior to monitoring, suggesting that their management of warfarin and the clinic's ability to intervene was limited. Additionally, both experienced confusion with regards to warfarin

administration even after educational materials and guidance was provided. As both patients did not speak English, language likely contributed to this lack of comprehension and disengagement with care. Lastly, one of these patients is now deceased and the other no longer visits the SFGH People's Clinic. After excluding these patients, the average TTR of this cross-section rose to 69.6%.

As only the last three recorded INR values appear in the registry, we could not do a more thorough analysis of TTR beyond this cross-section without intensive chart review. However, we have set a protocol in place to calculate TTR going forward and modifications to our dashboard to pull all historical INR results for productive benchmarking.

Usability

The efficacy and utility of the patient safety dashboard proved to be most effective when a volunteer in the ACC was dedicated to the registry's development and maintenance, based on the integrity of the registry and an informal evaluation of its adoption. After the volunteer departed from the clinic, data integrity and outreach performed declined. The personnel infrastructure that would allow panel managers to be dedicated to registry upkeep and outreach was a difficult change to implement on a project-basis and may require system-level change to ensure they have the resources and support necessary. Informal interviews with clinicians at ACC revealed that there is still an urgent need for real-time patient-level health data, but the additional work needed to cross-check registry data with their current system for monitoring patients was difficult to perform without dedicated support, suggesting that patient safety dashboards in both ACC and other clinics will be more successful with additional personnel aiding implementation and maintenance.

Development of the Ambulatory Safety Center for iNnovaTion (ASCENT)

The development and pilot of this dashboard has been foundational in the design and implementation of the Ambulatory Safety Center for iNnovaTion (ASCENT), a four-year quality improvement study funded by AHRQ that seeks to design and develop workflows and HIT-facilitated interventions that prevent medical errors and improve the safety of care provided in the SFHN. One of the primary goals of ASCENT includes targeting and mitigating risk through integrated dashboards accompanied by process change. ASCENT will serve as a medium through which the goals of our ambulatory safety dashboard can continue to develop and expand into a variety of different care settings. The ASCENT software platform will serve as a technology tool that both monitors patients with high-risk conditions to ensure appropriate follow-up of care as well as performs timely and accurate tracking and management of abnormal subcritical test results across EHRs in the SFHN.

The ambulatory patient safety electronic dashboard activities helped inform the development of ASCENT significantly. Under ASCENT, researchers and clinicians have begun developing workflow and IT solutions focused on further automation/alerting for selected high-risk abnormal tests with incomplete follow-up. The most work has been done in the area of anticoagulation treatment due to the progress made during this study period. We plan on continuing to iterate the HIT innovation implemented in the ACC based on measured outcomes and expand our evaluation of its impact both in the ACC and in other sites in which we pilot ASCENT. The ASCENT team will monitor a number of high-risk conditions/subcritical tests results to optimize clinical outcomes through integrating modified workflows with IT solutions, including monitoring of pulmonary nodules, colorectal cancer, head and neck cancer, prostate cancer and rheumatology. The nature of these conditions and treatment lends itself to dashboard-style monitoring. In short, the dashboard developed in this pilot project is a key piece

in realizing the goals of the ASCENT project as we continue communicating with these subspecialties to develop the specifications of a software platform that will serve as an extension of the dashboard into a variety of ambulatory settings and eventually the entire outpatient setting within the SFHN through ASCENT.

Discussion:

We observed a decline in the no-show rate immediately upon initiation of the intervention, which then leveled off. This finding has two implications. First, it demonstrates that our intervention is effective in identifying patients at risk for loss to follow-up. Second, and perhaps more importantly, this modest effect persisted, but did not fully address monitoring gaps. Therefore, we plan to expand upon this approach by enhancing outreach efforts through our successor project, ASCENT. We aim to eventually eliminate the need for manual entry of new patients into the registry, which will free staff time from registry upkeep to patient-facing outreach calls. ASCENT also designs clinical workflows to include the permanent assignment of panel managers to ensure that any required maintenance and monitoring can occur actively, thereby at least maintaining if not further reducing no-show rates and loss to follow-up.

We also anticipate that the fully-integrated and automated registry will address concerns with regards to integrity of the data. Specifically, through complete integration we hope to remove the possibility of patients not being entered into the registry and therefore not monitored as a result of being marked “inactive” in i2i Tracks due to a set of predetermined rules. We believe that creating an in-dashboard method to calculate TTRs for patients in the registry will promote safer anticoagulation monitoring and treatment. We are looking into adding this component into the integrated online dashboard as we continue developing it through the ASCENT project to further enhance workflows and optimize care.

Conclusions:

The progress achieved through this grant allowed for both the implementation of a patient safety dashboard and workflow innovation in the SFGH ACC as well as fundamental steps forward for the development of a quality improvement project, ASCENT. The continuation through ASCENT extends across multiple subspecialties in the SFHN and adds depth to population management to monitor high-risk conditions and treatments in outpatient care with timely, accurate, active test result management and improving medication comprehension through plain-language instructions.

The challenges we experienced in our research reflect the general challenges and roadblocks experienced by practitioners, patients, and health system innovators. Personnel shortages and changes as well as the dynamic nature of the clinic environment resulted in difficulties for our study and reflected some of the challenges of visit-based care, further evidencing the value of panel management in the PCMH. The loss of an ACC volunteer that spearheaded much of the patient outreach in the ACC during the evolution of the panel manager role resulted in a gap in outreach, thus impacting the workflow and the patients requiring follow-up. Additionally, synchronization between the EHR and registry tool proved to be imperfect; the data integration between both servers and systems had to be manual when auto-population was not possible. This demonstrates the need for a future population management tool to be completely integrated with the EHR to accurately track all patients. Beyond qualifying these challenges, our research sought to develop solutions where feasible and set the groundwork for solutions where not.

The successes and shortcomings of the patient safety dashboard in the ACC further demonstrate the necessity of accurate monitoring of high-priority safety areas in outpatient medical care and should encourage future work in this area. For that reason, the findings of this pilot study have been submitted to the Joint Commission Journal on Quality and Patient Safety for publication.

Significance:

There is now abundant research highlighting the risks to patient safety in the ambulatory setting. Studies have demonstrated that lack of timely, synthesized information plays a role in successful ambulatory malpractice claims,⁽⁵⁵⁾ is often cited by physicians as a patient safety concern,⁽⁵⁶⁻⁵⁸⁾ and can lead to delays in diagnosis.⁽⁵⁹⁾ Even systems with comprehensive electronic health records in place are subject to safety problems that could be ameliorated if detected.^(55, 60, 61) Despite these well-documented risks, few efforts to improve ambulatory safety through health system-level interventions have been developed or tested, and even fewer have been implemented in safety-net health systems.

Patient safety dashboards can have a significant impact on ambulatory patient safety across a health network by providing 4 key elements in the critical gap in ambulatory health care: (1) real-time, prioritized information that is actionable, (2) timely review compatible with clinical workflow, (3) appropriate actions to address the individual's safety issue such as patient notifications and appointment scheduling, and (4) structured review of care processes to improve safety at the health system level to allow for changes in care processes. Optimal performance for each of these measures should have a significant public health benefit.

Implications:

The dashboard approach is both patient-centered, thereby promoting timely corrective action for detected safety problems among individuals, and population-based, allowing for clinician-level and system-level measurement of the selected safety metrics. An ambulatory safety dashboard can be readily expanded to include more ambulatory safety metrics and the feasibility of an implementation strategy for use of dashboards in panel management, especially within a safety-net health system with significant access constraints, will inform efforts to design and test HIT innovations more broadly in under-resourced settings. It is known that safety-net health systems have overall less robust HIT infrastructure compared to other health systems, and yet use of HIT innovations has potential to deliver appropriate care more efficiently to under-resourced settings.⁽¹⁵⁾

The dashboard aligns perfectly with the large and growing movement towards transforming primary care into the PCMH.^(62, 63) The dashboard allows for systematic review of the entire clinic population by an interdisciplinary primary care team, similar to reports provided in disease registry programs. As ambulatory health systems implement comprehensive EHRs, which is happening at a rapid pace,⁽⁶⁴⁾ HIT-enabled tools such as this dashboard will be in even greater demand. The safety metrics and the integration into clinical workflow by teams rather than primary care physicians will both be broadly applicable. Multiple integrated health systems, academic and community health systems, both within and beyond safety net systems could take up this innovation immediately, and as PCMH and ambulatory HIT expand, so will the demand for validated and tested HIT innovations such as the dashboard.

Iterations and Expansion into More Monitoring Areas

We plan to continue to iteratively develop and evaluate this dashboard/workflow as this research continues on through ASCENT by expanding into more monitoring areas, including abnormal mammographies/pap tests, rheumatology, urology, head and neck cancer, pulmonary nodules, and abnormal colonoscopies. We'll conduct qualitative research into the feasibility and satisfaction regarding these modified workflows and dashboard by discerning provider and patient satisfaction through structured interviews and satisfaction scales. Going forward, we also plan to develop additional protocols and strategies that focus on prompt discontinuation of treatment and complication rate as well as the planned assignment of panel managers, and referrals for visits/screenings. The learnings from the electronic patient safety dashboard in the ACC at SFGH have informed and will continue to influence the development of innovative HITs, partnered with updated workflows, in ambulatory safety settings across the SFHN to make health care more safe and reliable in a safety-net care setting.

Bibliography of Outputs:

This research resulted in the creation of a new center grant and research project, as well as a manuscript submitted to the Joint Commission Journal for Quality and Patient Safety (under review).

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