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Journal

The Joint Commission Journal on Quality and Patient Safety, 43(7)

ISSN

1553-7250

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Publication Date

2017-07-01

DOI

10.1016/j.jcjq.2017.03.006

Peer reviewed

HHS Public Access

Author manuscript

Jt Comm J Qual Patient Saf. Author manuscript; available in PMC 2018 July 01.

Published in final edited form as:

Jt Comm J Qual Patient Saf. 2017 July ; 43(7): 353–360. doi:10.1016/j.jcjq.2017.03.006.

Designing and Implementing an Electronic Patient Registry to Improve Warfarin Monitoring in the Ambulatory Setting

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Abstract

Background—Warfarin requires individualized dosing and monitoring in the ambulatory setting for protection against thromboembolic disease. Yet in multiple settings, patients spend upwards of 30% of time outside the therapeutic range, subjecting them to an increased risk of adverse events. At an urban, publicly funded clinic, the electronic health record (EHR) would not support integration with extant warfarin management software, which led to the creation and implementation of an electronic patient registry and a complementary team-based work flow to provide real-time health-system level data for warfarin patients.

Methods—Creation of the registry, which began in August 2014, entailed use of an existing platform, which could interface with the outpatient EHR. The registry was designed to help ensure regular testing and monitoring of patients while enabling identification of patients and subpopulations with suboptimal management. The work flow used for the clinic's warfarin patients

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Conflicts of Interest. The authors report no conflicts of interest.

was also redesigned. An assessment indicated that the registry identified 341 (95.6%) of 357 patients actively seen in the clinic.

Results—For the cohort of the 357 patients in the registry, the no-show rate decreased from 31% (preimplementation, August 2014–December 2014) to 21% (postimplementation, January 2015–November 2015). The ratio of visits to no-shows increased from 2.3 to 4.03 visits.

Conclusions—Design and implementation of an electronic registry in conjunction with a complimentary work flow established an active tracking system that improved treatment monitoring for patients on anticoagulation therapy. Registry creation also facilitated assessment of the quality of care and lay the groundwork for ongoing evaluation and quality improvement efforts.

More than 20 million Americans take warfarin, which requires individualized dosing and monitoring in the ambulatory setting for protection against thromboembolic disease.[1] Studies show that in multiple settings, patients spend upwards of 30% of time outside the therapeutic range, subjecting them to an increased risk of adverse events [2]. As one of the most frequent culprits of adverse drug events in outpatient settings, overdosing warfarin can cause serious bleeding complications and under-dosing does not provide adequate protection against thromboembolism [3]. In safety-net clinics caring for uninsured patients, maintaining warfarin in the therapeutic range poses an additional challenge because of limited health literacy and educational attainment [4, 5], cognitive function [6], and various socio-economic challenges [7].

Because inadequate monitoring of the International Normalized Ratio (INR) through periodic blood tests has been implicated in both adverse drug events [8] and failure to meet adequate time in therapeutic range (TTR)[2], it is vital to develop strategies that support outpatient warfarin monitoring. Not only will more active monitoring improve therapeutic efficacy, but recent studies have demonstrated that modest increases in TTR can translate into significant reductions in adverse events and associated costs [9].

While at-home INR monitoring and novel oral anticoagulants, which require no monitoring, have the potential to transform the practice of ambulatory anticoagulation [10], millions of patients will remain on warfarin with provider-dependent dose monitoring for many years to come [2, 8, 11]. One strategy to enhance completeness of monitoring is the use of electronic registries. Electronic registries identify all patients within a pre-specified group that are in need of some treatment, monitoring, or intervention. These software platforms have been widely used for screening, outreach and management of chronic illnesses, including diabetes, asthma, cancer, depression and congestive heart failure [12-17]. Their implementation is cost-effective, associated with better health outcomes [18-20] and serve as a key tool for the provision of team-based care.

As our existing electronic health record (EHR) would not support integration with extant warfarin management software, we implemented an electronic registry at an urban, publicly funded clinic in the San Francisco Bay Area and created a team-based work flow to provide realtime health-system level data aimed at improving the safety and therapeutic benefits for warfarin patients. Given the high-risk of stroke and bleeds on warfarin, particularly in the

safety-net setting, where risk-adjusted model have demonstrated management to be suboptimal,[21] there is arguably no other site or patient population in greater need of such a technology and work flow– based intervention.

Methods

Setting

The 1M Anticoagulation Clinic (1M ACC) is located within the Richard H. Fine People's Clinic, a publicly funded clinic at the Zuckerberg San Francisco General Hospital and Trauma Center (ZSFG). Patients who receive primary care at any of San Francisco's publicly funded San Francisco Health Network clinics may also receive care through 1M ACC. A team of clinical pharmacists and pharmacy interns with oversight by an attending physician provides care to this ethnically diverse, low-income, and publicly insured or uninsured patient population. Drawing on research demonstrating the cost-effectiveness of specialty clinics for anticoagulation [22], by centralizing management of these patients the Anticoagulation Clinic is able to optimize and safely care for patients in accordance to 2016 Management of Venous Thromboembolism published in the Journal of Thrombosis and Thrombolysis and CHEST 2016 guidelines [23, 24].

Every week, pharmacists see an average of 50-60 patients in clinic and manage 20-25 additional patients via telephone. Visits include adjusting medication doses on the basis of the current INR result, ordering coagulation blood tests, providing education, monitoring for adverse effects and adherence, and referring patients for urgent medical evaluation if indicated. An estimated 350 individuals are currently managed by the 1M ACC, many of whom have primary care providers off-site.

Rationale for the Intervention

While a work flow as in place, prior to intervention, there was no standardized process to identify those who are overdue for monitoring and proactively encourage resumption of care, let alone in a targeted, risk-conscious fashion. Because of the high volume of patients and the prevalence of advanced marginality and comorbidities, we implemented a technological solution to monitor the clinic population and help target patients at greater risk of bleed or stroke, assessed in relation to no-show rates, loss to follow-up, and TTR.

During the design phase of the intervention, which extended from August through December 2014, we began collecting data on no-show rates—to find a no-show rate of 31%. Given the importance of monitoring, high rates of no-shows suggest suboptimal TTR and high-risk of adverse events, especially among patients lost to follow-up.

Creating the Registry

To optimize monitoring, in August 2014 we began creating an electronic registry, using an existing platform, i2iTracks (i2i Systems Inc., Santa Rosa, CA), which can interface with our outpatient electronic health record (EHR), eClinicalWorks (eClinicalWorks, Westborough, MA). Patients with warfarin on their active medication list are included in the registry population; this includes some patients who are not cared for in the anticoagulation

clinic, who can be manually deleted by the pharmacy staff. For patients who had three consecutive therapeutic INRs on a stable warfarin regimen and are relatively healthy, have good health literacy, and demonstrated excellent engagement with health care, the follow-up interval is at most 10 to 12 weeks. Otherwise, pending the INR result, patients may require either weekly or monthly follow-up[23]. The electronic patient registry helps clinicians keep track of patient monitoring/visits and avoid loss to follow-up in addition to storing information about factors specific to each patient's warfarin therapy.

Prior to designing the intervention, the clinic population's no-show rates, loss to follow-up, and TTR were unknown. However, drawing from risk-adjusted models of warfarin therapy, we assumed management in our clinic population to be suboptimal [21]. Given the importance of regular monitoring for warfarin therapy, we chose an intervention that would help ensure regular testing and monitoring of patients while at the same time enabling the clinic to identify patients and sub-populations with suboptimal management. Table 1 describes the data elements included in our registry.

In January 2015, we also began revising our existing 1M ACC work flow for warfarin patients, as we now describe.

Work Flow

"Current" and "Proposed" Work Flows—The "current" (preimplemenation) and "proposed" (postimplementation) work flows for patients ("patient work flows") are compared in Figure 1. In the current work flow, patients due for monitoring are managed through visits with the pharmacist. Prior to the pharmacist visit, patients must obtain their INR value from the laboratory.

For the proposed work flow, we appointed a pharmacist volunteer as the panel manager (medical clerk), who queried the registry database weekly to identify patients overdue for monitoring. If the visit was planned, the panel manager would make a telephone call reminding the patient of the upcoming appointment. If the patient was overdue for monitoring but had no visit or INR test scheduled, the panel manager would request an appointment and order an INR test through eCW. The panel manager also conducted outreach to the patient about the upcoming appointments using a telephone script.

The proposed work flow offers several advantages over the current patient flow for 1M ACC patients and health care teams. Prior to implementation, the only means to keep track of patients was through reviewing individual patient charts prior to and during the clinic visit itself; while this allowed for assessment of monitoring in real-time, it did not allow for prospective planning or targeted intervention. The patient registry enables the 1M ACC health care team to more efficiently identify patients who are overdue for monitoring and then quickly intervene to avoid loss to follow-up and decrease risk of potential adverse events when there is no regular INR monitoring. A panel manager adds an additional level of oversight and care coordination. Also, in the proposed patient flow, the health care team can better track if INR tests have resulted and use the aggregated INR data to assess TTR in the 1M ACC.

Work Flows for Initial Versus Follow-Up Missed Appointments—The work flow differs slightly for initial versus follow-up missed appointments. For initial visits, patients are automatically rescheduled twice. If they fail to attend any of these appointments, the clinic notified their primary care provider, who must place another electronic referral in order for them to be seen in anticoagulation clinic. Patients who have initiated care in the 1M ACC are lost to follow-up after three missed follow-up appointments, and referred back to their primary care provider.

Data Collection

From January 2015 through November 2015, we collected real-time data to evaluate the performance of the registry. By tracking the patients seen in the ACC, we were able to manually add these patients' data from eCW to a registry of patients being actively treated, while some data about the patients automatically populated into 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.

Before the registry, the clinic had no way to identify patients who were about to be lost to follow-up and prioritize outreach. To develop a list of patients requiring follow-up for outreach, we manually tracked patients who had reached the missed-appointment threshold established in the ACC prior to our intervention. We also identified patients through the registry who were actively receiving anticoagulation treatment, but had not had an INR test completed within the last 90 days and did not have an appointment scheduled in the coming 30 days. We manually tracked patients who completed or discontinued treatment, left the SFHN, stopped treatment due to poor adherence, or deceased by changing their status to “inactive” in the registry. For those who discontinued treatment, we manually checked if they had reinitiated therapy on a monthly basis.

Measures

Measures of the reach, efficacy, adoption, and implementation of this registry and clinical work flow include assessing the no-show rate, number of patients lost to follow-up, improvements in clinical outcomes, and the integrity of the electronic registry.

No-Show Rate—The proposed work flow was designed to better identify patients overdue for monitoring and those patients who would typically be lost to follow-up in the existing work flow. To determine whether or not the intervention reduced the average of no-show rates over time, we compared monthly averages of no-show rates before and during the intervention. We measured no-show rates by referencing the ACC schedule to determine how many patients arrived to their scheduled appointment. We calculated daily no-show rates and averaged these for each month, as clinic days varied from month-to-month due to holidays.

Patients Lost to Follow-Up—The registry and work flow intervention were also designed to limit the possibility of patients being lost to follow-up by enabling 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 logged all patients that had missed an appointment and were therefore classified as a no-show on a given day. Since notification that patients were discharged from the clinic due to missed appointments is not obvious, we performed a chart review to confirm loss to follow-up and, if so, determine whether adverse events occurred.

Clinical Outcomes—TTR is a measure of the length of time that a patient's INR is maintained within the therapeutic range and is regarded as an ideal measure to assess quality of and gauge improvement in anticoagulation therapy [21]. Inadequate INR monitoring has been implicated in the failure to meet adequate TTR. Therefore, to optimize TTR and get the full effects of warfarin therapy, INR monitoring must be frequent and consistent [25]. We were not able to conduct pre-post analysis because TTR had not been systematically calculated in the ACC prior to our intervention and the duration of the study was only long enough to establish baseline measures. For baseline assessment, we calculated TTR for all of the active patients currently in the registry (as of December 11, 2015) who 1) received warfarin therapy and INR testing for at least one year ($N = 290$) and 2) had no more than 90 days between tests using the Rosendaal method [26]; we excluded the first six weeks of INR results during which appropriate dosing is established in our calculations.

Registry Integrity—We assessed the integrity of the anticoagulation tracking registry by comparing the registry list to a manually assembled list of patients seen in the ACC during the study period derived from the clinic schedule. We determined the number of patients who did not appear in the registry despite being active patients who had recent visits (phone or in-person) at the ACC. The registry identified 341 of 357 patients (95.6%) actively seen in anticoagulation clinic. Our investigation of the 16 missing patients found a problem with automated rules in i2i Tracks software. Specifically, patients who were actively being seen in the ACC but were deactivated in the i2i Tracks registry (1) had not seen a PCP in the SFHN in over 24 months, or (2) had not been assigned a PCP within the SFHN, or (3) were deceased. These i2i Tracks rules negatively affected the integrity of the data in the registry because they force exclusion of patients that are within the inclusion criteria.

Results

Demographics

Within the cohort of the 357 patients in the 1M ACC registry, the average age of patients was 62 years of age (range, 21–92 years of age; median, 63 years of age). The majority of patients were males (62.7%; n=224), non-Hispanic/Latino (78.4%; n=280) and identified English as their primary language (68.9%; n=246). Aside from English, patients identified Arabic, Cantonese, Mandarin, Russian, Spanish, Tagalog and Vietnamese as primary languages. Thirty percent of the patients (n=107) identified as Asian, 25% as White (n=89), 22% as Black or African American (n=78), 21% as Other (n=75), 1% as Native Hawaiian/ Pacific Islander (n=3) and 1% as American Indian/Alaskan Native (n=3).

No-Show Rates

Tracking of no-show rates in the ACC for the August 2014–December 2015 period revealed found a reduction in no-shows after the implementation of our proposed work flow 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%. As clinic volume varies by day and month, the ratio of visits to no-shows is perhaps a more useful measure. Prior to the intervention, there was an average of 2.3 visits for every no-show; by the end of the study period, this became 4.03 visits for every no-show, indicating a 75% improvement. These findings are portrayed in Figure 2.

Patients Lost to Follow-Up

Between January 1, 2015 and December 31, 2015, 85 patients were lost to follow-up in the ACC. Of these 85 patients, 31 (36%) were new patients referred from the inpatient setting who never initiated care in the ACC. Of those lost to follow up, medical record review revealed that 19 patients (22%) experienced adverse events related to anticoagulation, including deep vein thrombosis and pulmonary embolism; 2 additional patients experienced adverse events that may have been related to anticoagulation.

Compared to the 1M ACC population, patients lost to follow-up were younger (57 years old vs. 62 years old) and a greater proportion was male (76% vs. 63%). Patients who identified as black, white and other race were over-represented in the group of patients lost to follow-up by 9%, 6% and 4%, respectively. Patients who identified as Asian were dramatically under-represented (-21%) among patients lost to follow-up. There were also a greater proportion of English-speakers in the group lost to follow-up (84% vs. 69%).

As we did not know the characteristics of patients lost to follow-up prior to intervention, we are unable to say how our registry mitigated disparities in monitoring and outcomes along the lines of age, race, gender, ethnicity and language. However, a registry like ours hold potential to identify the population-level factors that place patients at greater risk of negative outcomes and allows for targeted efforts to produce equitable outcomes.

Clinical Outcomes

The overall distribution of TTRs is displayed in Figure 3 as the proportion in patients in each quintile. In 1M ACC, the average TTR was 67.8%, with a range of 14.8%-100% and a median of 71.2%. However, the effect of survivorship bias is an inherent limitation in using TTR as a quality indicator as the requirements to accurately calculate TTR excludes patients who were lost to follow-up and do not have sufficient INR data; arguably, these patients are at the greatest risk of adverse events. Nevertheless, our TTR calculations capture the management of patients insofar as the clinic is able to facilitate and promote active monitoring. Our site reflected previously demonstrated [(7)] racial disparities exist in warfarin management, with average TTR for patient identified as Asian (N=100), White (N=69), Other (N=61) and Black (N=53) being 71.9%, 69.1%, 65.8% and 60.1%, respectively. Drawing from Rose et al, the estimated costs of a disparity of 10% can be as much as 29 million dollars and 1,606 quality-adjusted life years over a two year period[(9)].

Discussion

By designing and implementing an electronic registry in conjunction with a complimentary work flow, we were able to establish an active tracking system that improved treatment monitoring for patients on anticoagulation therapy. Registry creation also allowed us to assess the quality of care in the clinic and lay the groundwork for ongoing evaluation and quality improvement efforts. Moving forward, maintenance and continued improvement will rely on more integrated automation and a dedicated panel manager staff member.

We found that our IT–work flow solution reduced the average monthly no-show rates with limited errors in regards to both manual entry and automated registry management. We observed a decline in the no-show rate immediately upon initiation of the intervention. 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. Improving appointment adherence is an important precursor to maintaining clinical control in anticoagulation, given the association between consistency of care and improved outcomes[18].We were unable to gauge for improvement in TTR during the study period, but plan to continue to track this over time to determine whether registry use improves TTR.

We learned significant implementation lessons. 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 registries and new work flows into other subspecialty clinics. To further address this, we aim to eventually eliminate the need for manual entry of new patients into the registry by enhancing the software's automated capacity. This difficulty should be anticipated and accepted as part of the process of registry creation. Moreover, during optimal implementation, we saw significant reductions in no-show rate. Due to the importance of regular INR monitoring and testing, a decrease in no-show rates can be considered a proxy for improved clinical outcomes [25].

Therefore, one of the most important keys to future success will include the permanent assignment of panel managers to ensure that any required maintenance and monitoring occurs actively, thereby at least maintaining if not further reducing no-show rates and loss to follow-up. Chart review revealed a significant complication rate among patients lost to follow-up, suggesting that having dedicated personnel responsible for panel management is critical to preventing clinical complications and improving patient safety.

We believe that creating an in-registry method to calculate TTRs for patients in the registry will promote safer anticoagulation monitoring and treatment. Active TTR calculations will allow clinicians to identify patients with suboptimal therapeutic efficacy and thereby help elucidate and mitigate the disparity in clinical outcomes. We are looking into adding this component into the integrated online registry as we continue developing it.

Limitations

This was a single-site study in a safety-net health system; our results may not generalize to settings caring for privately ensured patients. [28]The technical feasibility of the registry approach was challenging because this health care setting, as in many other safety-net health systems [27], lacks a single comprehensive EHR, which created a need for manual entry into the registry.

Consequently, the patient safety registry proved to be most effective when a volunteer in the ACC was dedicated to the registry's development and maintenance. After the volunteer departed from the clinic, data integrity and outreach 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.

Finally, because our health system is not completely integrated, selected patients may receive INR readings or refill a medication within other health care systems, resulting in incomplete data capture in our registry. 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 registry tool in identifying patient safety problems. We do not expect clinical harm with loss of specificity, so we would prefer to err on the side of higher sensitivity.

Challenges and Implications

Registry development is an ideally suited approach to ambulatory monitoring because of the need for standardization, time sensitivity, and predictability. Registries have been successful for diabetes management and mammography screening and they can be successfully replicated in the ambulatory setting to manage an array of high-risk conditions and treatments requiring monitoring. Our registry and panel-based approach provides a straightforward way to leverage health care personnel and newly instituted HIT infrastructure to address intractable safety issues inherent with warfarin-based anticoagulation monitoring.

The challenges we experienced in our research reflect the general challenges and roadblocks experienced by practitioners, patients, and health system innovators in implementing registries for chronic disease management [13-15]. 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.

We see potential gains in all aspects of the triple aim to align and optimize care, health and cost [28] by 1) improving quality of care by enhancing the proportion of patients in therapeutic anticoagulation range and reducing complications, 2) improving patient satisfaction through lowering barriers to monitoring, and 3) reducing costs by de-coupling monitoring and visits where safe. So far, it is evident that our work flow/IT solution is

capable of reducing no-show rates and thereby the loss to follow-up. We anticipate that integrating these positive outcomes with more comprehensive automation will improve clinical outcomes and, thereby, patient/provider satisfaction.

Acknowledgments

Funding and Disclaimer. The information contained in this article note is supported through two grants from the Agency for Healthcare Research and Quality (R21HS021322 and P30HS023558). AHRQ had no role in the design, data collection, analysis, or presentation of results.

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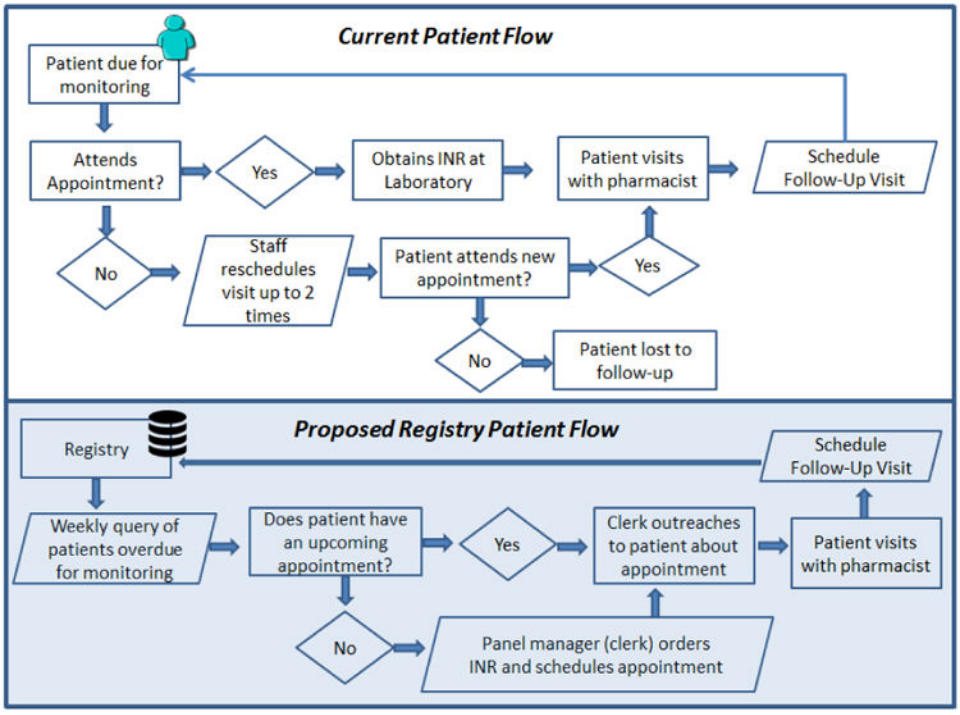

Figure 1. Anticoagulation Clinic Work Flow Comparison

This diagram illustrates the “current” (preimplementation) work flow for patients and the “proposed” (preimplementation) registry patient flow for in-person visits and telephone follow-up. The proposed work flow, unlike the current patient flow, among other advantages, enables the health care team to identify patients who are overdue for monitoring more efficiently. Previously, the only means to keep track of patients was through reviewing individual patient charts prior to and during the clinic visit itself.

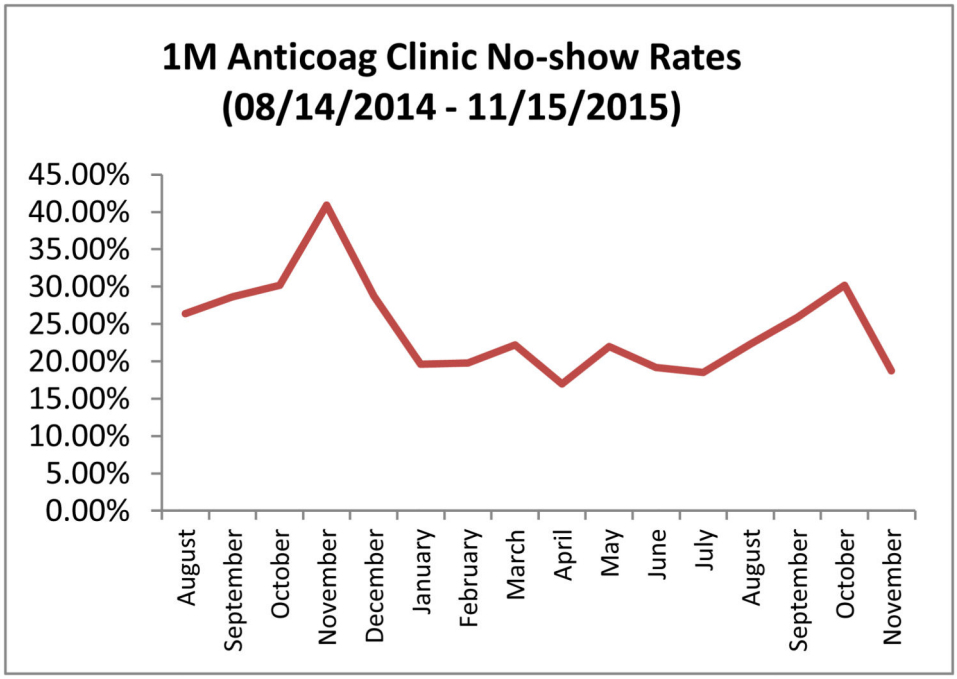

Figure 2. No-Show Rates, Anticoagulation Clinic, August 2014–December 2015

The no-show rate of 31% for the preimplementation period (August 2014-December 2014) decreased to 21% for the postimplementation period (January 2015-November 2015).

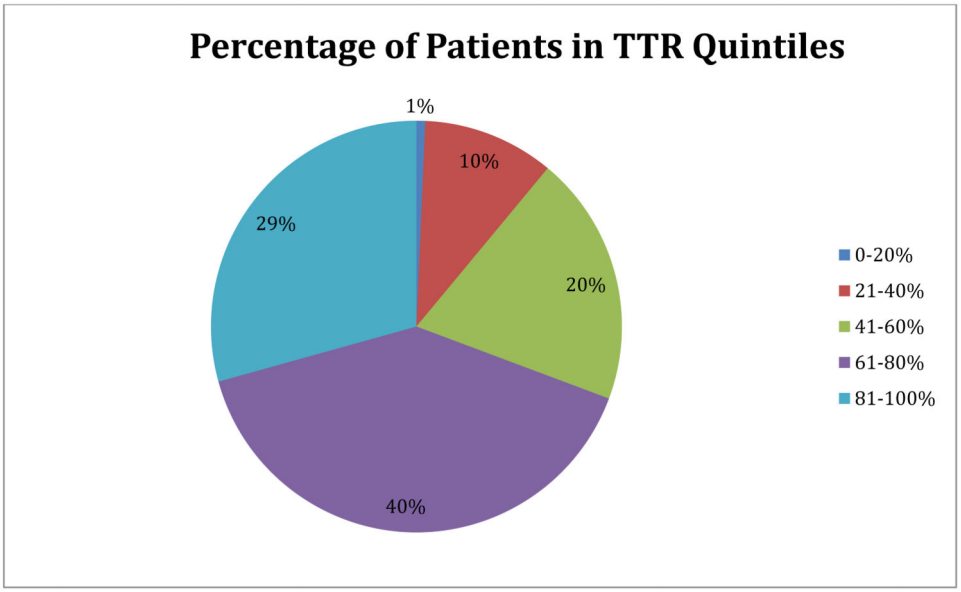

Figure 3. Time in Therapeutic Range (TTR) Distribution, Anticoagulation Clinic, March 1, 2015– February 28, 2016

The percentage of anticoagulation clinic patients who fall into each of the five TTR quintiles are shown from the period. The mean TTR was 67.8% (range, 14.8%–100%; median, 71.2%).

Table 1
Fields Populated in the Anticoagulation Clinic 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