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Engaging with quality improvement in anticoagulation management

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Abstract

Anticoagulants are highly effective at preventing thrombosis across a variety of clinical indications. However, their use can also lead to devastating effects, including major bleeding and death. Anticoagulation providers strive to balance the benefits of anticoagulant therapy with the risks of major bleeding. A measure of quality care can be used to assess the strengths and potential weaknesses in any system of coordinated care delivery. Quality measures in anticoagulation include patient-centered outcomes (e.g. major bleeding, time in the therapeutic range) and provider- or process-focused outcomes (e.g. compliance with guideline recommendations and response times to out-of-range laboratory values). Engaging in quality improvement activities allows anticoagulation providers to assess their own performance and identify areas for targeted interventions. This review summarizes the justification for engaging in quality improvement for anticoagulation management and describes a number of example programs. Interventions benefiting the management of both warfarin and the direct oral anticoagulants are included. The review also details potential quality measures and resources for any anticoagulation provider looking to begin a quality improvement process.

Keywords

Anticoagulation; Quality improvement; Warfarin

Introduction

Anticoagulants were prescribed in nearly 2 million US clinic visits in 2011 [1]. Warfarin is highly effective at preventing stroke in patients with atrial fibrillation or a mechanical valve as well as preventing venous thromboembolism (VTE). However, use of warfarin is also associated with an increased risk of major bleeding, which can lead to significant morbidity and mortality. For warfarin, the delicate balance between preventing thrombosis while avoiding major bleeding complications occurs best when the international normalized ratio (INR) is between 2 and 3.5 [2]. However, most patients treated with warfarin spend a large portion of their time with an INR value outside their target range [3]. Numerous studies have demonstrated increased risks of bleeding, thrombosis and death with poor quality warfarin control [4-8].

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Warfarin, a highly effective medication with dangerous potential, makes it an ideal target for quality improvement efforts. In atrial fibrillation patients, improving the quality of warfarin care has been projected for significant cost savings, in addition to reductions in major bleeding, stroke and death [5, 8]. Within the Veterans Administration, an improvement in the time in therapeutic range (TTR) by 2.5 % is estimated to save nearly 100 ischemic strokes, over 350 deaths and over $8 million [5]. Studies have demonstrated a strong association between higher TTR and lower stroke, hemorrhage and mortality rates [5, 8]. Similarly, studies have demonstrated associations between improved quality of warfarin anticoagulation and reductions in long-term complications from VTE [9, 10].

Up to 10 % of all adverse drug events involve anticoagulants, which led to a call to action rom the US Department of Health and Human Services to improve the delivery of anticoagulation care nationally [11]. Specifically, use of anticoagulant management tools and educational materials to optimize care delivery for high-risk patients was requested. They also highlight the National Quality Forum's call to implement practices that will prevent patient harm due to anticoagulant therapy [12].

In this review, we discuss a number of potential measures and targets for quality improvement in anticoagulation management. We highlight the activities from the Michigan Anticoagulation Quality Improvement Initiative (MAQI^2), a six-center quality improvement collaborative of anticoagulation management services in Michigan. We also highlight other reports of quality improvement measures and interventions in anticoagulated patients. Lastly, we provide a number of resources for developing customized quality improvement measures for anticoagulation providers in both large and small practices.

Potential quality improvement measures and targets

Key outcomes for quality improvement initiatives can be categorized as patient-centered and provider- or process-focused (Table 1) [13, 14]. Patient-centered outcomes include hard events that most patients (and providers) value, such as bleeding and thromboembolic events. However, they also include the frequency of emergency department visits and hospitalizations. While critically important to measure and understand, smaller scale quality improvement projects might be limited by the relative infrequency of these hard clinical outcomes to adjudicate a successful intervention. For that reason, a number of intermediate clinical outcomes can also be assessed. These include the TTR, INR variability, percent of in/out of range INR values and the percent of missed INR draws [6, 15]. Because these outcomes can be measured on a more frequent basis, they allow for quicker assessment of a quality improvement intervention's effectiveness.

Other important measures of high-quality anticoagulation care center on provider practices (Table 1) [5, 13]. Understanding how care is delivered, especially through the application of guidelines and polices, can greatly impact patients' anticoagulation effectiveness. Potential measures include the number of INR draws in the first 2 weeks of warfarin initiation, the time from warfarin initiation to the first therapeutic INR and the time required to contact a patient once an out-of-range INR value is identified. Assessing compliance with guideline

therapy can also be an effective quality measure, including the proportions of patients with appropriate medications, target INR ranges and receiving high-quality warfarin education.

Michigan anticoagulation quality improvement initiative

MAQI^2 was created to design, implement and report on results of anticoagulation quality improvement efforts. The initiative began in 2008 and includes regular face-to-face meetings with medical directors, managers, and staff to review both aggregate and individual site metric data. These meetings promote discussion on variations in practice, comparison of protocols/algorithms, and the sharing of best practices among the participating anticoagulation services. MAQI^2 includes an inception cohort of patients treated with warfarin for any indication at six diverse anticoagulation management services in Michigan.

Several quality metrics were developed among the different sites within the consortium to facilitate quality improvement efforts. These include both patient-centered targets in addition to provider and process-centered targets. Some of the provider measures include well-established metrics, such as clinic TTR, prevalence of major bleeding and clotting event rates and INR overcorrection rates. Population-focused measures consist of percent of patients receiving appropriate anticoagulation based on available guidelines, appropriate length of anticoagulation, and appropriate INR testing intervals. The list of metrics is periodically modified as new measures are identified. Below are some example quality improvement projects that MAQI^2 is currently engaged in.

Low risk atrial fibrillation

Patients with atrial fibrillation are known to be at risk of stroke and thromboembolism. However, patients in the lowest-risk category may not warrant warfarin therapy due to the risk of major bleeding. In our initial analysis, 3.4 % of all atrial fibrillation patients were in the lowest-risk stroke group (CHA_2DS_2 – VASc = 0) without another indication for anticoagulation (e.g. cardioversion) but were still receiving anticoagulation [16]. We have initiated a program where an anticoagulation staff member regularly reviews all patients for appropriate indications for anticoagulation. If a patient is found to have a low-risk CHA_2-DS_2 – VASc score and no other indication for anticoagulation, the referring provider is contacted and asked if they wish the patient to continue or discontinue anticoagulation therapy.

Provoked deep venous thrombosis anticoagulation

Warfarin has traditionally been used for treatment of VTE; however, guidelines vary as to the recommended length of treatment for various types of VTE [17-19]. A few clinical scenarios have widespread agreement regarding the appropriate length of treatment, including patients with first VTE provoked by surgery and patients who develop a VTE provoked by a fracture with immobilization or recent pregnancy [20-24].

Within MAQI^2, a quality improvement initiative designed to decrease inappropriately prolonged therapy in patients with a provoked VTE has resulted in systems changes that engage referring providers in discussions about the risks and benefits of extended therapy in patients with a very low risk of VTE recurrence. If the patient is felt to have a provoked VTE

with a strong guideline-based recommendation for only three-months of therapy, a staff member from the anticoagulation service contacts the referring provider to discuss therapy options. A standardized e-mail notification is available for all sites to use when contacting referring providers. This e-mail provides a reminder along with references to primary VTE recurrence data, national guideline recommendations, and a thrombosis expert at the individual center who can be contacted with any questions or more information. Preliminary results have been positive with 80 % of providers agreeing to stop warfarin after being contacted. Several sites have embedded a notification in the electronic medical record to indicate when the length of treatment has been achieved.

Extended INR testing interval

Different guideline recommendations exist on the optimal interval necessary for INR testing in patients prescribed warfarin. The ACCP now suggests (Grade 2B recommendation) that testing frequency can be extended up to 12 weeks for patients with stable INRs, defined as 12 weeks of INR in therapeutic range and no warfarin dose adjustments [25]. When 226 patients with stable warfarin doses were randomized to INR checks every 4 weeks versus every 12 weeks, the TTR was similar between the two groups [26]. As an additional benefit, fewer patients in the 12-week testing group required warfarin dose changes compared to the 4-week group.

In response to the new ACCP guidelines, warfarin patients at each MAQI^2 site are now offered extended INR testing intervals if they meet that site's specific requirements for a stable INR without any warfarin dose change or change in clinical status. During the first 6 months of the initiative, 222/889 patients (25 %) with stable INRs had the testing interval extended to 12 weeks, resulting in significant reduction in INR testing. Safety analyses of patients undergoing the extended testing interval are on-going and preliminary results suggest no differences between patients who are extended beyond 4 weeks and patients with an INR scheduled within the standard 4 week window.

Adverse events reviews

Avoiding serious adverse events associated with warfarin therapy is the primary purpose of anticoagulation services. Within the MAQI^2 consortium, the serious adverse event rate varied between 2.4 and 10 per 100 patient-years in the first years of the consortium. Multidisciplinary teams were created at several high volume sites to review serious adverse events (major bleed, embolic stroke, VTE) in patients prescribed warfarin. Members of these teams include front line anticoagulation service practitioners (RN and/or PharmD), chart abstractors, and physician directors. Detailed case reviews are discussed to determine if any avoidable errors were made, and to determine if protocols or algorithms should be created or changed to decrease the likelihood of these events in the future.

Initially, three of the anticoagulation management services participated in the detailed review of all serious adverse events recorded. A root cause analysis was completed in 48 serious event cases with the primary cause identified in 42/48 (88 %) of these. The majority of the events (31/48, 65 %) were due to patient-specific factors, such as comorbidities, taking the wrong dose, not following diet guidelines, and not notifying the service of

medication changes. Nearly all of the remaining adverse events were due to ineffective communication among providers. As a result, several institutional changes were made with the intention of preventing future adverse events; these were shared among all participating MAQI^2 centers [27]. Based on the success at the initial three centers, all MAQI^2 anticoagulation clinics are now undergoing regular adverse event root cause analysis with a multidisciplinary team.

Other anticoagulation quality improvement efforts

Targeting high-risk patients

A number of metrics have been described to identify patients at highest risk for adverse events associated with warfarin therapy. Recently, the SAMe-TTR score was developed to predict a patient's subsequent TTR on warfarin therapy [28]. It is well known that patients with low TTR scores are at increased risk of hemorrhagic and thromboembolic complications while on warfarin [4]. The SAMe-TTR score may help to identify patients who require extra attention or a focused intervention to assure high quality and safe warfarin therapy. Others have suggested that patients who repeatedly miss INR draws are at increased risk for thromboembolic complications [15]. Similarly, patients with a highly variable INR have been described as having an increased risk of mortality, bleeding, stroke and hospitalization [7, 29]. Developing a simple tool to screen "at risk" patients and provide focused, patient-oriented interventions can be an important way to improve the overall quality of anticoagulation care provided and avoid important complications.

Concurrent medication use

Interventions targeted to reduce the risk of bleeding can be potentially life saving for patients taking warfarin. The American College of Cardiology, American Heart Association and the American College of Gastroenterology have produced an expert consensus document with recommendations to reduce the risk of gastrointestinal bleeding for patients on warfarin therapy [30]. Specifically, they recommend the use of proton pump inhibitors in patients taking anticoagulants along with one or more antiplatelet medications. Additionally, recent data has suggested that patients who require long-term anticoagulation along with antiplatelet agents may be able to safely discontinue one antiplatelet agent [31-33]. Assessing patients who are at risk for gastrointestinal bleeding and may benefit from either removal of an antiplatelet agent or addition of a proton pump inhibitor warrants consideration. Importantly, concurrent use of non-steroidal anti-inflammatory (NSAID) medications and warfarin is common and dangerous [34,35]. Efforts to reduce concurrent use of NSAIDs and warfarin can help to avoid gastrointestinal ulcers and bleeding complications. Lastly, the use of low-dose aspirin is not beneficial (and potentially harmful) in patients with stable coronary artery disease who are concurrently treated with oral anticoagulant therapy for atrial fibrillation [32, 36].

Direct oral anticoagulation management

The direct oral anticoagulants (dabigatran, rivaroxaban, apixaban and edoxaban) were designed to provide high-quality anticoagulation therapy without the need for frequent monitoring, dose adjustment or interactions with other medications and foods. For this

reason, they are increasingly being prescribed by a variety of clinicians [1, 37-40]. However, inappropriate use of these agents is associated with significant risk of bleeding [41]. Some centers have found the frequency of inappropriate dabigatran and rivaroxaban use to be as high as 25 % [42]. Of particular concern is the interplay between renal function and dosing of the direct oral anticoagulants [39].

The anticoagulation clinic can be an excellent resource for patients taking direct oral anticoagulants. Specifically, the clinic can assess the appropriateness of each patient for the prescribed agent (indication and dose), ensure that baseline laboratory testing was performed (renal function and blood count), and provide much needed education about anticoagulant therapy [43]. For patients using a single-drug regiment to treat VTE, the anticoagulation clinic can also provide support around the time of the dose change (at 7 days with apixaban or 21 days with rivaroxaban). For patients who are started on a parenteral agent (e.g. low-molecular weight heparin) with plans to transition to a direct oral anticoagulant (dabigatran or edoxaban), the anticoagulation clinic can help to ensure that patients have the correct medications available and make the transition on the specified day. The anticoagulation clinic can also help provide further education and ensure that patients are not accidentally taking two medications concurrently.

Quality improvement resources

Any practice looking to engage in anticoagulation quality improvement has a number of resources at their disposal (Table 2). The American College of Chest Physicians (ACCP) guidelines provide a foundation for high-quality anticoagulation care management [25]. Additionally, the Anticoagulation Forum has a Centers of Excellence website (excellence.acforum.org) with a number of high quality, vetted resources for management of warfarin and other anticoagulants. One such example from the Anticoagulation Forum Centers of Excellent website is the Anticoagulation Toolkit (www.anticoagulationtoolkit.org). This resource offers a number of tools for delivering high-quality anticoagulation care and numerous patient educations resources. Practitioners can use these resources to identify targets for quality improvement in their own anticoagulation practices.

Conclusions

Warfarin continues to be an important medication for treatment of nonvalvular atrial fibrillation and VTE. Determining how best to manage patients on warfarin remains an important goal. Incorporating measures to increase TTR and reduce serious bleeding and thromboembolic events should be the central goal of a high-functioning anticoagulation management service.

Identifying key patient-centered and provider/process-centered targets for quality improvement efforts is a critical first step towards establishing an anticoagulation quality improvement program. While some interventions are best implemented in large, formal anticoagulation management clinics, others can be implemented by small anticoagulation management services or by individual practitioners. Resources are available to help identify

an appropriate quality improvement target and to begin establishing interventions aimed to improve the quality of anticoagulation care.

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Table 1

Quality Improvement Measures

Patient-centered
Clinical events
Bleeding
Stroke/thromboembolism
Emergency department visits
Hospitalizations
Death
Surrogate measures
Time in therapeutic range (TTR)
INR variability
Percent of in/out of range INRs
Percent of missed or late INR draws
Adherence to medications (warfarin and direct oral anticoagulants)
Provider-centered
Process of care
Number of INR draws in the first two weeks
Time from warfarin initiation to the first therapeutic INR
Time from an out-of-range INR value to patient contact
Population-focused
Percent of patients receiving guideline-based appropriate care
Drug choice
Length of treatment
Appropriate INR target
Percent of patients receiving appropriate education
Patient with drug–drug interactions at risk for gastrointestinal bleeding

Table 2

Quality improvement resources

Quality improvement resources		
QI resource	**Website**	**Available resources**
American College of Chest Physicians	http://journal.publications.chestnet.org/issue.aspx?journalid=99&issueid=23443	- Evidence-based guidelines
Anticoagulation Forum Centers of Excellence	http://excellence.acforum.org/	- Evidence-based guidelines - Quality of care assessment tool - Provider toolkit
Michigan Anticoagulation Quality Improvement Initiative Toolkit	http://anticoagulationtoolkit.org/	- Risk evaluation tools - Warfarin/TSOAC initiation and management guides - Patient education resources (warfarin/TSOACs)
Cardiosource	http://www.cardiosource.org/Science-And-Quality/Clinical-Tools/Atrial-Fibrillation-Toolkit.aspx	- Risk evaluation tools - Warfarin/TSOAC initiation and management guides - Patient education resources (cardiovascular conditions/warfarin/TSOACs)
Cardiosmart	https://www.cardiosmart.org/	- Provider mobile application - Patient education resources (warfarin/TSOACs)
Combocalculator Heart Rhythm Society	http://sparctool.com/ http://www.hrsonline.org/Practice-Guidance/Clinical-Guidelines-Documents (Guidelines) http://www.hrsonline.org/Patient-Resources (Resources)	- Risk evaluation tools - Evidence-based guidelines - Patient education resources (cardiovascular conditions/warfarin/TSOACs)