



Hospital-Based Quality Improvement in Stroke Prevention for Patients with Non-Valvular Atrial Fibrillation

**A SOCIETY OF HOSPITAL MEDICINE
PROGRAM IMPLEMENTATION GUIDE**

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Society of Hospital Medicine

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VERSION 1.0

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The Society of Hospital Medicine (SHM) is pleased to provide you and your institution this Implementation Guide as a tool intended to improve the care of patients with atrial fibrillation (AF) in the hospital setting.

This Guide will allow you to impact AF care at both the individual patient and the institutional levels, and is intended for hospital leadership such as Chief Medical Officers (CMOs), Vice Presidents of Medical Affairs (VPMAs), Chief Quality Officers (CQOs), quality department personnel, process change leaders and front-line clinicians. In addition, given the interdisciplinary nature of inpatient quality improvement efforts, this Guide will also find an audience with nursing leadership, pharmacists, nurse practitioners (NPs), physician assistants (PAs) and other care providers.

Section I

Introduction

Atrial Fibrillation in Hospitalized Patients: Rationale for Improving Care

Atrial fibrillation (AF) is the most commonly encountered arrhythmia in clinical practice; 2.3 million to 6.1 million Americans had AF in 2010.^{1,2} Since AF is often asymptomatic and frequently goes clinically undetected, experts speculate that these numbers may underestimate the true burden of this disease.^{3,4} AF occurs in 4% of individuals aged 60+ years but increases to 8-10% in those older than 80.⁵ The incidence and prevalence of this condition are expected to climb as the population ages, and as many as 12 million people will have AF by 2050.^{1,2,5}

AF is one of the most common primary and secondary inpatient diagnoses. Index hospitalizations resulting from AF have increased by 60% over the past 20 years⁶ with a concurrent spike in AF-related readmissions.⁷ This growth is due in part to increasing age of the general population⁶ and to the association of AF with stroke and heart failure.²

AF increases the risk of stroke five-fold across all age groups,² and is an underlying cause in up to 20% of all strokes.^{2,8} An individual's likelihood of stroke attributable to AF increases with age; 1.5% of strokes among those 50-59 years and 23.5% of strokes among those 80-89 years are directly linked to AF.^{8,9} AF-related strokes tend to be more severe, disabling and fatal than strokes from other etiologies,¹⁰ placing a heavy burden on patients, families and healthcare services.

Heart failure and AF frequently co-exist since they share several antecedent risk factors. Approximately 40% of individuals with either heart failure or AF will eventually develop the other condition.¹¹ AF prevalence increases in parallel to the severity of heart failure, ranging from 10-50%.¹² AF can also precipitate acute heart failure and may facilitate the progression of cardiomyopathy.⁶

The American College of Cardiology Foundation, American Heart Association and Heart Rhythm Society (ACCF/AHA/HRS) collaborative task force recommends that AF be managed through three non-mutually exclusive methods: rate control, prevention of thromboembolism and correction of abnormal rhythm disturbance.¹³ Antithrombotic therapy has been shown to be a highly efficacious method for the prevention of stroke among AF patients (risk reduction = 61%, 95% CI 47-71%).¹⁴ Patients with AF should receive antiplatelet or anticoagulant treatment. Antiplatelet therapy may be used in low-risk patients or those with contraindications to anticoagulation, while anticoagulant therapy is the most effective stroke prevention treatment for moderate- to high-risk AF patients. Rate and rhythm control may be achieved through either pharmacological treatment or ablation. Pharmacological treatment is typically the first choice for either rhythm or rate control, with left atrial ablation (for rhythm control) or ablation of the atrioventricular conduction system and permanent pacing (for rate control) as second-line choices.¹⁵

Despite the known adverse sequelae of AF, and evidence that at least 25% of AF-related strokes are potentially preventable with adherence to evidence-based care,^{2,15-17} current data indicate that only 50-64% of eligible patients with AF receive antithrombotic therapy.^{17,18}

Given the confluence of epidemiology, cost implications, availability of established guidelines and effective treatments, as well as observed variability in hospital clinical practice, AF represents a high-impact target for inpatient quality improvement (QI) initiatives. Optimizing AF care during and after hospital admission episodes will benefit both patients and healthcare delivery systems.

Atrial flutter carries a stroke risk analogous to that of AF, and similar anticoagulation strategies for stroke prevention in atrial flutter should be employed by care providers in the inpatient and outpatient environments.¹⁹ Although not specifically differentiated in this Guide, both AF and atrial flutter represent significant opportunities for stroke prevention through the practice of evidence-based medicine. For subsequent sections regarding anticoagulation, the "AF" designation refers to both atrial fibrillation and atrial flutter.

Determining the Scope of Hospital-Based Atrial Fibrillation Quality Improvement Initiatives

Numerous care processes related to AF are amenable to inpatient quality improvement. These include:

1. Appropriate recognition of AF and workup of new AF diagnoses
2. Management of patients with known AF
3. Rate versus rhythm control strategies
4. Determining the need for cardiology consultation
5. Appropriate referral for ablation
6. Assessment of stroke risk
7. Use of antithrombotic therapy for stroke prevention when indicated
8. “Handoff” from inpatient to outpatient care providers
9. Patient education
10. Tracking and feedback of performance on AF outcomes

It is important to have a well-defined scope of AF QI work that maps to specific care processes. This Guide will focus on items 6-10, which relate directly to stroke prevention in terms of consistently assessing stroke risk and initiating antithrombotic therapy if indicated. However, your institution may also wish to address some or all of the other AF care processes listed above with separate QI efforts.

We recognize that the inpatient environment represents only one clinical setting in which interventions for AF can occur. AF-related inpatient care should be viewed as part of a care continuum. Since some patients with a history of AF may be followed primarily by their outpatient physicians and may not initially be on anticoagulants prior to admission, it is crucial that the inpatient team communicate their assessment of risks and benefits of an antithrombotic management plan with these primary care providers (PCPs). This is especially important for patients discharged on warfarin who need follow-up laboratory assessments. In addition, the choice of one of the newer oral anticoagulants may be influenced by PCP preference or insurance coverage.

Other groups, such as the American College of Physicians (ACP), American Academy of Family Physicians (AAFP), the American Heart Association (AHA) and the American College of Cardiology (ACC) have previously addressed outpatient AF quality and provided corresponding recommendations (see the ACC/AHA/ESC 2006 Guidelines for the Management of Patients with Atrial Fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the European Society of Cardiology Committee for Practice Guidelines¹⁵ and ACP/AAFP joint clinical practice guideline for the management of newly detected atrial fibrillation²⁰).

The intent of this Guide is to provide strategies that help promote evidence-based management of AF-associated stroke risk when patients are hospitalized, as well as in the post-discharge transitional phase. Accordingly, a stepwise approach for implementing an inpatient AF QI program focused on this area is presented in subsequent sections.

Section II
**How to Implement and Sustain an Atrial Fibrillation
Quality Improvement Project at Your Hospital**

Step 1

Form an Interdisciplinary Team with a Common Goal

When instituting a program to provide evidence-based AF care at your institution, an initial step should be the formation of an interdisciplinary team to measure current processes, analyze baseline data, and design and deploy improvement interventions. To develop or extend an AF QI program, it is critical to have representation from a diverse group of hospital constituents. These members may include, but are not limited to, hospital leadership, front-line practicing hospitalists, cardiologists, PAs, advanced practice nurses (APNs), pharmacists and nurses. The perspectives that different stakeholders bring to the program are unique and will lead to a more robust solution.

1.1 Quality Improvement Team Composition

A formal structure to the QI team will help delineate roles in the improvement process. Responsibilities should be established at the start of the project. An example of team organization is provided below. In many hospital settings there will be overlap between these roles. The important concept is to have the different functions and responsibilities embedded into the team.

1) Executive Sponsor (“The Big Wig”)

The executive sponsor is a member of senior management who provides overall guidance and accountability for the project. For example, this could be the Chairman of Medicine, the VPMA, the CMO or the CQO of your institution. This individual approves the QI team recommendations, ensures timely implementation, secures any necessary financial support, removes organizational barriers to project success and helps ensure that the project has sustained results. This senior leader can provide the leverage necessary to secure the resources essential for success. For example, your project may involve the implementation of an anticoagulation order set for AF patients, but the Information Technology (IT) department may have a backlog of requests to change the electronic medical record (EMR). The executive sponsor, in this situation, can provide the influence to ensure your project receives the necessary priority from the IT department.

2) Project Sponsor (“The High-Level Advocate”)

The project sponsor facilitates the timely and successful implementation of the project. This person has close contact and meets frequently with the project leader. The project sponsor reviews progress, and may be a key decision-maker for approval of final recommendations. This individual could be the hospital medicine practice director, a leader in an academic division or someone with similar oversight responsibility, and would have a detailed understanding of QI strategies and a familiarity with AF clinical workflows and practice standards. Depending on organizational factors (size, governance structure, etc.), the project sponsor function may be encompassed within either the executive sponsor or the project leader roles.

3) Project Leader (“The Main Nuts-and-Bolts Person”)

The project leader is the day-to-day manager of the initiative and completes all deliverables in a timely manner. This person would typically be a front-line practitioner extending his or her scope of activity into the QI area. Key responsibilities include coordinating project team activity (including communication of project status to all levels of the QI team) and ensuring that all project goals are met on time and on budget. From a practical standpoint, the project leader will have the most direct impact on project success, and as such, the role can require a significant investment of time and effort. Accordingly, our recommendation would be that the project leader has some portion of protected time away from his or her other responsibilities to engage the role meaningfully.

4) QI Facilitator (“The Data Guru”)

The QI facilitator has access to the data needed to measure the baseline metrics, as well as to track progress. Often this is a person working in the hospital’s QI department who is trained in data management, basic analysis and supporting process improvement projects. These individuals will generally be comfortable with the use of data storage and statistical software packages.

5) Process Owners (“Those on the Front Lines”)

The process owners are the front-line personnel involved in the process of providing anticoagulation to AF patients in the hospital. Examples include practicing hospitalists not directly leading the project, pharmacists and nursing staff. Their input on existing workflows and ways in which care processes can be redesigned will be a critical component in the improvement process. In addition, “front-line members” on the QI team can help to achieve the necessary “buy-in” from the diverse constituencies present in the hospital.

6) IT Liaison (“The Computer Guy”)

The IT liaison is crucial in electronic medical record (EMR)-based environments to implement the necessary changes in ordering and documentation associated with the QI program. Some examples of the IT liaison’s function include: modifying current order sets, instituting electronic alerts, coding rules within the EMR environment to achieve your project goals, developing IT-based training models and trouble-shooting IT-related issues as they arise. In many systems, this individual will also provide assistance in extracting project-related data from the EMR.

1.2 Create a Shared Need for a Quality Improvement Program






A key phase for performance improvement success centers on creating a common vision of program value. If buy-in to the change effort is low, the program will not be successful. Developing awareness of a shared need forces any resistance or apathy to be addressed up-front, builds momentum to get the performance improvement program launched and validates the program's importance. The need for change can be framed both as a threat (e.g., implications of AF-related readmissions) and an opportunity (e.g., the potential to promote patient-centered care through the reduction of stroke risk).

Stakeholders (considered here to be people or groups who have a vested interest in improving the current processes) can influence program success. Analysis of stakeholder positions will allow formulation of strategies on how to best initiate change.

One stepwise method of performing a stakeholder analysis is presented below (with an accompanying example in Figure 1):

1. List key stakeholders by name and assess their current beliefs regarding the change process.
2. For each individual, plot both the current state of belief regarding the change process ("X" in Figure 1) and the minimum level of support for the change required from the individual for program success ("Y" in Figure 1).
3. Identify gaps between current and desired states.
4. Plan action steps for closing any perceived gaps with influence strategy and coaching.

Figure 1: Example of Stakeholder Analysis Method

Role	Against Change	Moderately Against Change	Neutral to Change	Moderately Supportive of Change	Strongly Supportive of Change
Pharmacy Budget Director	X  Y				
PCP	X  Y				
Hospitalist	X  Y				
VPMA, CMO	X  Y				
Cardiologist	X  Y				

Step 2

Obtain Institutional Support

Institutional support (at multiple levels) is critical to QI project success as it provides access to the resources required to change current hospital culture and practices. QI efforts should align with the hospital's mission and vision while addressing issues identified as care delivery and operational priorities. The clinical rationale for improving hospital-based management of AF was presented in this Guide's Introduction (Section I). A compelling business case likewise exists, based on the increasing prevalence of this condition and the high costs of care associated with its preventable sequelae. Both rationales can be employed to obtain “buy-in” of the hospital's senior leadership. Gaining this high-level endorsement will help garner the core components needed for a successful QI initiative (status as something important to do, personnel, IT assistance, etc.).

2.1 Atrial Fibrillation as a Healthcare Quality Issue That Impacts Hospital Reimbursement

Over the past decade, market forces, healthcare legislation and conceptual shifts regarding the need for systematic approaches to healthcare improvement have spurred healthcare delivery organizations to view the provision of care through a new lens. The Patient Protection and Affordable Care Act (commonly called the Affordable Care Act, or ACA) increased monetary drivers for improved quality by placing more dollars ‘at risk’ according to outcomes, and the movement toward accountable care organizations (with bundled payments) will accelerate the need to manage patients longitudinally across a continuum, rather than in “siloes” episodes of care.

Measures in the Centers for Medicare & Medicaid Services' (CMS's) Hospital Value-Based Purchasing (HVBP) Program pertain to AF as it is a common comorbidity for conditions currently included in the program. More details about HVBP are available at <http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772237361>.

Measures in the Hospital Inpatient Quality Reporting (IQR) Program pertain to AF. Participation in the IQR Program is required to receive annual payment updates from CMS. Details about IQR are available at <https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1138115987129>.

Four specific examples of AF intersecting with current quality reporting, performance and financial incentives are described below.

2.1.1 Outcome Measures: 30-Day All-Cause Mortality and Readmission Rates

Hospital performance metrics have gradually moved from process measures to a heightened emphasis on outcomes measures with two of the most important being 30-day mortality and 30-day all-cause readmissions.

In Fiscal Year (FY) 2014, the HVBP Program includes 30-day all-cause mortality rates for acute myocardial infarction (AMI), heart failure (CHF) and pneumonia (PNA) as components of hospital quality assessments. Performance in these areas will impact receipt of incentive payments or payment reductions.

Under Medicare's Inpatient Prospective Payment System (IPPS), as included in the ACA, adjustments to payments made for excessive readmissions in acute care hospitals during fiscal years began on October 1, 2012. The ACA focuses initially on three conditions: AMI, CHF and PNA. Rehospitalization within 30 days for *any cause* following an index stay for one of these three conditions is attributed as a readmission. In FY 2015, the policy expands to include chronic obstructive pulmonary disease (COPD), coronary artery bypass grafting (CABG), percutaneous transluminal coronary angioplasty (PTCA) and other vascular conditions as index admission diagnoses subject to the 30-day all-cause rehospitalization parameter. It is also anticipated that this list will include additional diagnoses in coming years.

AF is a common comorbidity in patients with AMI, CHF and PNA, giving AF management during an inpatient care episode or at a care transition point the potential to directly impact 30-day all-cause mortality and readmission measures. For example, if a patient hospitalized with a primary diagnosis of pneumonia has AF as a comorbid condition, issues related to anticoagulation (failure to resume anticoagulation, lack of dose adjustment of warfarin in the setting of antibiotics, etc.) can precipitate rehospitalization after discharge from the initial stay, and this would be attributed as a pneumonia readmission. Hospitals performing worse in these areas relative to their peers will suffer financial penalties from CMS.

2.1.2 Structural Measures: Participation in a Systematic Clinical Database Registry

Hospitals must systematically send clinical care data to centralized databases to fully participate in CMS reporting programs. Patients with AF are represented by the requirement for hospitals to send stroke data to a database registry.

The Paul Coverdell National Acute Stroke Registry is one of the Centers for Disease Control and Prevention's (CDC's) national initiatives to reduce the burden of disease, disability and death from stroke. The Coverdell program is designed to monitor, promote and improve the quality of stroke care in U.S. hospitals (http://www.cdc.gov/dhdsp/programs/stroke_registry.htm).

The American Heart Association/American Stroke Association Get With The Guidelines®-Stroke program is an in-hospital program for improving stroke care by promoting consistent adherence to the latest scientific treatment guidelines. Since its initiation in 2003, 1,656 hospitals have entered more than two million patient records into the Get With The Guidelines-Stroke database. Numerous published studies demonstrate the program's success in achieving measurable patient outcome improvements (http://www.heart.org/HEARTORG/HealthcareResearch/GetWithTheGuidelinesHFStroke/GetWithTheGuidelinesStrokeHomePage/Get-With-Guidelines-Stroke-Overview_UCM_308021_Article.jsp).

2.1.3 The Joint Commission Disease-Specific Care Certification as a Stroke Center

Formal certification as centers of excellence for specific conditions represents a competitive advantage for hospitals to gain market share often by directly advertising to patients. In the area of cerebrovascular disease, The Joint Commission offers a designation of "Primary Stroke Center" for hospitals meeting certain criteria.

These Joint Commission criteria include >80% compliance with a set of eight stroke care process measures. The third measure in this set ("Stroke 3") tracks the percentage of patients with an ischemic stroke attributed to atrial fibrillation/flutter who are prescribed anticoagulation therapy at hospital discharge. More specifically, the numerator of this measure is the number of ischemic stroke patients prescribed anticoagulation therapy at hospital discharge and the denominator is the number of ischemic stroke patients with documented atrial fibrillation/flutter. Additional information can be found at http://www.jointcommission.org/certification/primary_stroke_centers.aspx.

2.1.4 Physician Quality Reporting System

The national Physician Quality Reporting System (PQRS), formerly known as the Physician Quality Reporting Initiative (PQRI) (<http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html?redirect=/PQRI>), has been using incentive payments, and will begin to use payment adjustments in 2015, to encourage healthcare professionals to report on specific quality measures. This CMS-based initiative has appropriate anticoagulation of patients with AF as one of the endorsed measures. This measure evaluates the percentage of patients aged 18 years or older with a diagnosis of non-valvular atrial fibrillation or atrial flutter whose assessment of specified thromboembolic risk factors indicates one or more high-risk factors or more than one moderate risk factor, as determined by CHADS₂ risk stratification, who are prescribed warfarin or another oral anticoagulant drug that is approved by the Food and Drug Administration (FDA) for the prevention of thromboembolism. Currently, physicians may qualify for bonus dollars from CMS if performance targets are met. Beginning in 2015, there will be a downward payment adjustment for eligible professionals who do not satisfactorily report data for covered professional services.

Positioning AF management as an issue that affects hospital reimbursement by highlighting these programs to senior leadership will help prioritize your AF QI project as something warranting institutional support.

Step 3

Assess the Current State of Atrial Fibrillation Management in Your Facility

Understanding the current state of inpatient AF management in your facility will help identify targets for intervention while concurrently defining the scale of your project. This baseline knowledge can also be used to allocate project resources appropriately and to establish realistic performance improvement benchmarks. We suggest conducting this current state evaluation through the series of assessments described in Sections 3.1-3.5.

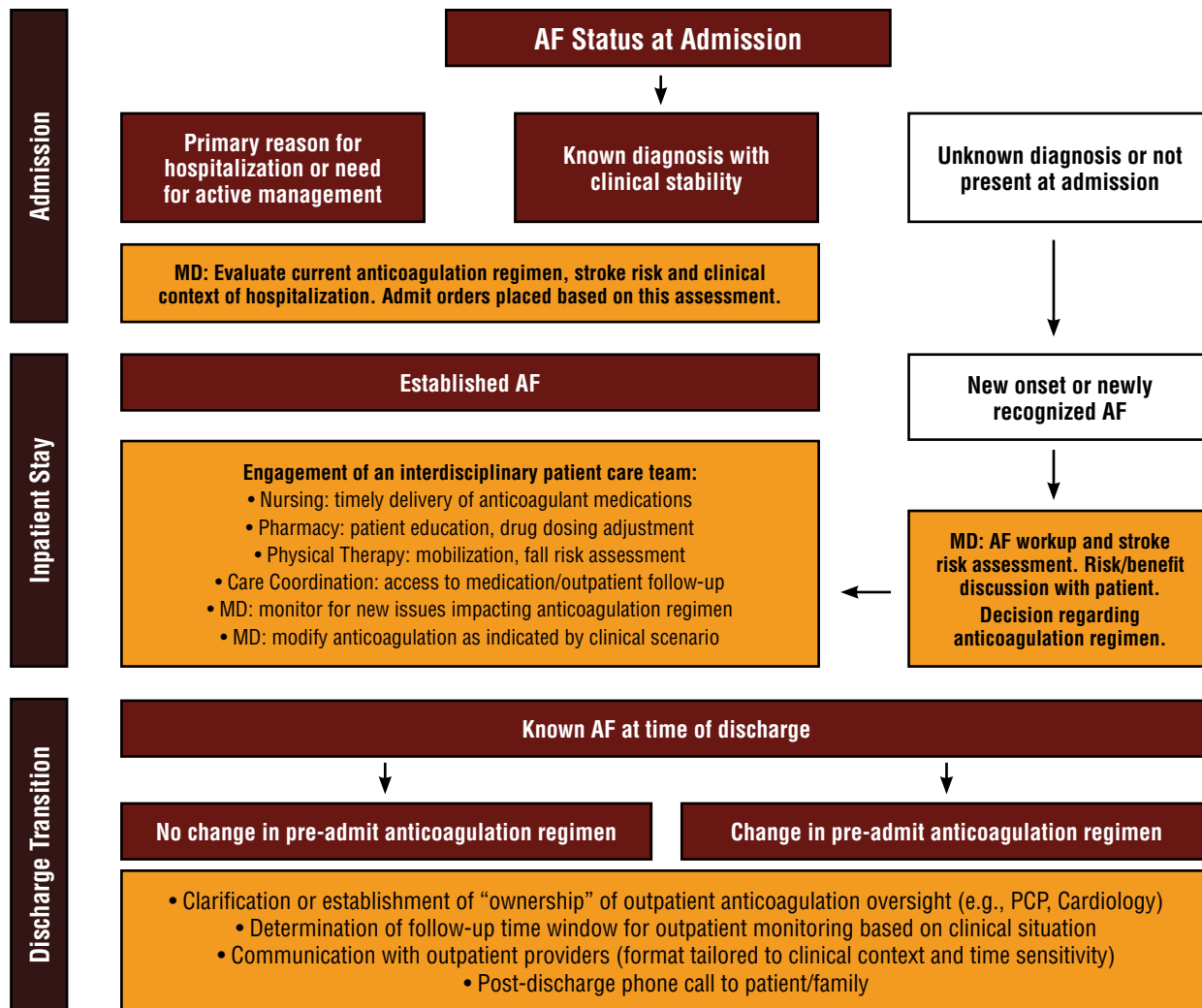
3.1 Create a High-Level Process Map

Summarizing the key steps in a care delivery process is essential to understanding the scope of the QI project and identifying specific targets for improvement. As noted earlier, this Guide is focused on the narrow scope of assessing the need for anticoagulation and initiation of treatment if indicated. However, the process map will allow you to locate specific target areas where the QI intervention may be able to improve anticoagulation rates. Ideally, the collective expertise of the project team is utilized to create these high-level process maps by:

- Defining the major function (output) of the process
- Identifying all participants (e.g., admitting hospitalist, rounding hospitalist, nurses, pharmacists)
- Delineating beginning and ending points
- Brainstorming on critical steps and determining the process sequence
- Validating workflow by “test driving” the process

An example of a process map focusing on anticoagulation in patients with AF is provided in Figure 2. Maroon or white boxes reflect patient status; orange boxes represent provider actions.

Figure 2: Example of AF Anticoagulation Process Map in the Hospital Setting



As indicated in Figure 2, multiple points in the hospital care episode are good substrates for a QI intervention (e.g., optimizing physician's admission orders through decision support; involving pharmacy to review and provide input on anticoagulation orders for patients with AF; enhancing discharge communication mechanisms). Once the individual areas have been selected, our recommendation is that the specific steps be mapped out in a similar, but more granular level. Again, the focus here is facilitation of stroke risk assessment and when appropriate, initiation or maintenance of anticoagulation.

3.2 Determine Atrial Fibrillation Case Volume and Prioritize Hospital Unit Locations

The objective here is to get an estimate of the AF population size within your facility, and determine where these patients receive their care to allow you to focus on a particular geographic area to start your AF QI project. This information will generally be available in administrative datasets. An example of data extraction specifications for this step, as well as the results of applying those specifications to a 900-bed tertiary hospital, is provided in Table 1. From within the medical record, the following data points could be extracted:

- Time Period: January 1, 2011 – December 31, 2011
- Admission Status: Inpatient or 23-hour observation
- AF ICD-9 Codes: 427.3, 427.31 or 427.32 within the first 20 discharge diagnosis fields
- Hospital Unit Location at Time of Discharge (discharge rather than admission unit selected to capture where care transition planning would usually occur)

Table 1: Example of AF Case Volume and Hospital Unit Distribution at Discharge

Discharge Unit	Total # AF Cases	% of Total AF Cases
CARDIO/TELE	527	14.5
TELEMETRY 1	485	13.4
TELEMETRY 2	472	13.0
TELE/SURG	469	12.9
GEN MED 1	202	5.7
ORTHO 1	136	3.7
PULMONARY	112	3.2
NEURO	109	3.0
GEN SURG 1	98	2.7
GEN MED 2	95	2.6
GEN MED 3	95	2.6
OBSERVATION	89	2.5
GEN SURG 2	72	1.9
MED ICU	63	1.7
SURG SPECIALTY	61	1.7
ORTHO 2	58	1.6
GEN MED 4	54	1.5
ORTHO 3	47	1.3
CCU	46	1.3
15 other units	<40 cases each	<1% per unit
Total	3,627	100%

Table 1 indicates that AF cases are found throughout this hospital, but more than 50% are clustered within four telemetry floors. These units would be a logical choice to launch an AF QI program, which could then be disseminated to other floors over time.

Ultimately, the goal would be to have the improvement interventions related to an AF diagnosis alone rather than incorporating geographic location. However, if resources are limited or the hospital is large, starting a project as a localized pilot on a specific unit with high case prevalence represents a useful approach to move past scale-related organizational barriers commonly encountered in enterprise-wide initiatives.

3.3 Conduct Environmental Scan for Existing Hospital Atrial Fibrillation Resources

The aim here is to identify components within your facility that may be readily integrated into the QI project, as well as to avoid duplication of effort. Some examples include:

- Clinical decision support (CDS) tools embedded into paper documents or electronic health records: These could relate to stroke and bleeding risk assessments, anticoagulation order sets, etc. CDS tools that are “hardwired” into hospital workflow (as opposed to external applications available on the Web or individual mobile devices) are particularly helpful.
- Anticoagulation teams: Some hospitals deploy pharmacist-led teams to monitor and optimize patients with active anticoagulation orders, or clinical diagnoses that would warrant consideration of anticoagulation. This model has also been used successfully in the area of venous thromboembolism prophylaxis.²¹
- Active and historical QI projects overlapping with AF: These can be referenced and used in your QI project.

3.4 Determine Data Extraction and Management Capabilities

Most hospital facilities fall somewhere within the spectrum of a fully leveraged EMR and a purely paper-based workflow. For purposes of an AF QI project, some of the key data management issues to examine include:

- Are current data systems able to identify AF cases in real-time and retrospectively?
- Can the data elements be obtained electronically, or is manual review required?
- Can QI team members access and manage project data, or is additional help needed?

Since the project design can be influenced by these factors, answering these questions before any active implementation phase is essential.

3.5 Determine Baseline Performance

Step 5 further details potential outcome measures for an AF QI project, with additional information on suggested data collection strategies. Whatever metrics are chosen, obtaining current performance prior to QI project initiation is essential, as it will both help confirm whether the proposed metrics are appropriate and assist with setting performance targets. For a common condition such as AF, looking at a small random sample of cases over a defined period of time (e.g., 10 cases a month for 12 months) is generally sufficient to establish a baseline for process measures. Baseline outcome measures (e.g., 30-day readmission of patients with an AF diagnosis) can usually be obtained from administrative data.

Three time points during a hospital episode provide a good substrate for an AF QI program: admission, intervening hospital days and discharge transitions. Figure 3 provides an example of how baseline data could be collected in the starting phases of an initiative with a minimal commitment of resources (e.g., 10 minutes a chart).

Figure 3: Example of a Structured Baseline Data Collection Process for AF QI

Source	Data Extracted
Administrative Data	Random sample of cases with discharge diagnosis codes of 427.3, 427.31 or 427.32
Admit	<p>Was AF a pre-existing or new diagnosis? If existing, was anticoagulation part of the home meds? If home med, was anticoagulation continued at admit? If not continued, was there a valid clinical reason? If new diagnosis, was anticoagulation ordered at admit? If not ordered, was there a valid clinical reason?</p>
Admission H&P Admission Orders	
Interim Stay	<p>Was stroke risk documented? Was anticoagulation ordered during the inpatient stay? If not ordered, was there a clinical reason?</p>
Daily Progress Notes Medication Orders	
Discharge Transition	<p>Was stroke risk documented and discussed? Was anticoagulation ordered with discharge meds? If not ordered, was a valid clinical reason indicated? Were there instructions regarding anticoagulation (to either patients or outpatient providers)? Was patient education on anticoagulation provided?</p>
Discharge Summary Discharge Medication List Discharge Instructions	

Step 4

Identify Best Practices in Antithrombotic Therapy for Atrial Fibrillation

National and international guidelines relating to stroke prevention in AF provide a body of evidence-based strategies for the evaluation of stroke risk and the initiation of antithrombotic therapy. This review of current evidence is critical prior to considering any specific improvement approaches (e.g., the content in an AF-related protocol or a decision support tool). Professional society guidelines are good additional sources for this content in a summary format.

The National Guideline Clearinghouse within the Agency for Healthcare Research and Quality provides a comprehensive source for guideline searches (www.guideline.gov). A review on best practices in antithrombotic therapy for AF found the following sources:

- Antithrombotic therapy for atrial fibrillation: antithrombotic therapy and prevention of thrombosis, 9th ed: American College of Chest Physicians evidence-based clinical practice guidelines¹⁹
- Evidence-based management of anticoagulant therapy: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines²²
- Guidelines for the management of atrial fibrillation: the Task Force for the Management of Atrial Fibrillation of the European Society of Cardiology (ESC)²³
- 2011 ACCF/AHA/HRS Focused Updates Incorporated Into the ACC/AHA/ESC 2006 Guidelines for the Management of Patients With Atrial Fibrillation: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines Developed in partnership with the European Society of Cardiology and in collaboration with the European Heart Rhythm Association and the Heart Rhythm Society¹³
- Management of patients with atrial fibrillation (compilation of 2006 ACCF/AHA/ESC and 2011 ACCF/AHA/HRS recommendations): a report of the American College of Cardiology/American Heart Association Task Force on practice guidelines²⁴
- *2011 ACCF/AHA/HRS Focused Update on the Management of Patients With Atrial Fibrillation (Update on Dabigatran): A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines*²⁵
- ACC/AHA/ESC 2006 Guidelines for the Management of Patients with Atrial Fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Revise the 2001 Guidelines for the Management of Patients With Atrial Fibrillation): developed in collaboration with the European Heart Rhythm Association and the Heart Rhythm Society¹⁵
- Antithrombotic and thrombolytic therapy for ischemic stroke: antithrombotic therapy and prevention of thrombosis, 9th ed: American College of Chest Physicians evidence-based clinical practice guidelines²⁶

4.1 Tools to Assess Stroke Risk and Corresponding Treatment Recommendations

4.1.1 CHADS₂ Risk Tool

A review of the literature indicates that the identification of stroke clinical risk factors has led to the publication of various stroke risk schemes, the simplest of which is the CHADS₂ scoring system. Current clinical guidelines incorporate the CHADS₂ scoring system as a well-validated tool for estimating the risk of stroke in patients with non-rheumatic atrial fibrillation.²⁷

The CHADS₂ scoring system is based on a point system in which 2 points are assigned for a history of stroke or transient ischemic attack (TIA) and 1 point each is assigned for age >75 years, a history of hypertension, diabetes or recent cardiac failure. This risk index evolved from the AF investigators and Stroke Prevention in Atrial Fibrillation (SPAF) study. It is used to determine whether or not treatment is required with anticoagulation (full-dose warfarin, or newer oral anticoagulant) or antiplatelet therapy (aspirin).

As shown in Table 2, there is a clear relationship between CHADS₂ score and stroke rate. The original validation of this scheme classified a CHADS₂ score of 0 as low risk, 1-2 as moderate risk and >2 as high risk.

Patients with a high CHADS₂ score (and high stroke risk) would benefit from anticoagulation therapy while those with a low score (and low stroke risk) can opt for antiplatelet treatment. More specifically, by adding up exact points, this tool allows clinicians at the bedside to estimate yearly stroke risk based on readily available data from clinical trials.²⁷⁻²⁹

Table 2: CHADS₂ Score and Stroke Rate

CHADS ₂ score	Patients (n = 1733)	Adjusted stroke rate (% / year) ^a (95% confidence interval)
0	120	1.9 (1.2–3.0)
1	463	2.8 (2.0–3.8)
2	523	4.0 (3.1–5.1)
3	337	5.9 (4.6–7.3)
4	220	8.5 (6.3–11.1)
5	65	12.5 (8.2–17.5)
6	5	18.2 (10.5–27.4)

^aThe adjusted stroke rate was derived from the multivariable analysis assuming no aspirin usage; these stroke rates are based on data from a cohort of hospitalized AF patients, published in 2001, with low numbers in those with a **CHADS₂ score** of 5 and 6 to allow an accurate judgement of the risk in these patients. Given that stroke rates are declining overall, actual stroke rates in contemporary non-hospitalized cohorts may also vary from these estimates. Adapted from Gage BF, et al. Validation of clinical classification schemes for predicting stroke: results from the National Registry of Atrial Fibrillation. *JAMA*. 2001;285(22):2864-2870.

AF = atrial fibrillation; CHADS₂ = cardiac failure, hypertension, age, diabetes, stroke (doubled).

Source: Reproduced with permission from Table 7 in Camm AJ, Kirchhof P, Lip GY, et al. Guidelines for the management of atrial fibrillation: the Task Force for the Management of Atrial Fibrillation of the European Society of Cardiology (ESC). *Eur Heart J*. 2010;31(19):2369-2429.

Treatment recommendation based on CHADS₂ score:

- Daily aspirin (81-325 mg) *or* a new oral anticoagulant (i.e., dabigatran, rivaroxaban or apixaban) for patients with no risk factors (CHADS₂ score of 0);
- Daily aspirin *or* warfarin to achieve an international normalized ratio (INR) of 2.0-3.0 for patients with one moderate risk factor (CHADS₂ score of 1);
- Warfarin to achieve an INR of 2.0-3.0 or new oral anticoagulant (i.e., dabigatran, rivaroxaban or apixaban) for patients with multiple moderate risk factors or any high-risk factor (CHADS₂ score of 2).^{13, 23}

4.1.2 CHA₂DS₂-VASc

While the CHADS₂ risk assessment tool offers the important benefits of simplicity and extensive validation in multiple cohorts, room for improvement remains. The majority of non-valvular AF patients are categorized in the moderate risk group (CHADS₂ score of 1), for which the national guidelines give the recommendation of either aspirin or full anticoagulation, leaving discretion for either option. A more comprehensive risk factor-based approach, incorporating other risk factors for thromboembolism, has been proposed.

CHA₂DS₂-VASc is a refinement of the CHADS₂ score, the use of which was advocated in the European Society of Cardiology (ESC) 2010 AF guidelines.²³ CHA₂DS₂-VASc applies a second assessment step to patients falling within the CHADS₂ “moderate risk” group who have a CHADS₂ score of 1. It incorporates additional clinically relevant non-major risk factors such as female gender, age 65-74 years and vascular disease (specifically, myocardial infarction, complex aortic plaque and peripheral arterial disease) (See Table 3.).

Since these additional risk factors are cumulative, the simultaneous presence of two or more of these additional clinically relevant non-major risk factors would justify a stroke risk that is high enough to require anticoagulation. Thus, the incorporation of these new risk factors provides a more detailed stroke risk assessment especially in situations when the initial CHADS₂ scoring is 1. It is important to note that patients who score 2 or more in this second-stage assessment are categorized as higher risk and should receive a strong recommendation for full anticoagulation (See Table 4.).

CHA₂DS₂-VASc also defines the “truly low risk” group of patients (those with a risk of stroke of <0.5% per year) more accurately. It should be kept in mind, however, that CHA₂DS₂-VASc has yet to be prospectively validated. The 2006 ACC/AHA guidelines for AF list the additional factors incorporated in CHA₂DS₂-VASc as minor risk factors for stroke in the setting of AF¹⁵ and the ACCP 2012 guidelines also mentioned them but note that the strength of the evidence is not as strong as for the factors included in the original CHADS₂.¹⁹ The CHA₂DS₂-VASc should not be considered as a replacement for the CHADS₂, but rather as a means to augment stroke risk assessment.

Table 3: CHA₂DS₂-VASc Score and Stroke Rate

(a) Risk factors for stroke and thrombo-embolism in non-valvular AF			
‘Major’ risk factors		‘Clinically relevant non-major’ risk factors	
Previous stroke, TIA, or systemic embolism Age ≥75 years		Heart failure or moderate to severe LV systolic dysfunction (e.g. LV EF ≤40%)	Hypertension Diabetes mellitus Female sex Age 65–74 years Vascular disease ^a
(b) Risk factor-based approach expressed as a point based scoring system, with the acronym CHA₂DS₂-VASc (Note: maximum score is 9 since age may contribute 0, 1, or 2 points)			
Risk factor		Score	
Congestive heart failure/LV dysfunction		1	
Hypertension		1	
Age ≥75		2	
Diabetes mellitus		1	
Stroke/TIA/thrombo-embolism		2	
Vascular disease ^a		1	
Age 65–74		1	
Sex category (i.e. female sex)		1	
Maximum score		9	
(c) Adjusted stroke rate according to CHA₂DS₂-VASc score			
CHA₂DS₂-VASc score	Patients (n = 7329)	Adjusted stroke rate (%/year)^b	
0	1	0%	
1	422	1.3%	
2	1230	2.2%	
3	1730	3.2%	
4	1718	4.0%	
5	1159	6.7%	
6	679	9.8%	
7	294	9.6%	
8	82	6.7%	
9	14	15.2%	
^a Prior myocardial infarction, peripheral artery disease, aortic plaque. Actual rates of stroke in contemporary cohorts may vary from these estimates. ^b Based on Lip GY, et al. Identifying patients at high risk for stroke despite anticoagulation: a comparison of contemporary stroke risk stratification schemes in an anticoagulated atrial fibrillation cohort. <i>Stroke</i> . 2010;41(12):2731-2738. AF = atrial fibrillation; EF = ejection fraction (as documented by echocardiography, radionuclide ventriculography, cardiac catheterization, cardiac magnetic resonance imaging, etc.); LV = left ventricular; TIA = transient ischaemic attack.			

Source: Reproduced with permission from Table 8 in Camm AJ, Kirchhof P, Lip GY, et al. Guidelines for the management of atrial fibrillation: the Task Force for the Management of Atrial Fibrillation of the European Society of Cardiology (ESC). *Eur Heart J*. 2010;31(19):2369-2429.

Treatment recommendations based on CHA₂DS₂-VASc score:

Table 4: Approach to Thromboprophylaxis in Patients with AF

Risk category	CHA ₂ DS ₂ -VASc score	Recommended antithrombotic therapy
One 'major' risk factor or ≥2 'clinically relevant non-major' risk factors	≥2	OAC ^a
One 'clinically relevant non-major' risk factor	1	Either OAC ^a or aspirin 75–325 mg daily. Preferred: OAC rather than aspirin.
No risk factors	0	Either aspirin 75–325 mg daily or no antithrombotic therapy. Preferred: no antithrombotic therapy rather than aspirin.

AF = atrial fibrillation; CHA₂DS₂-VASc = cardiac failure, hypertension, age ≥75 (doubled), diabetes, stroke (doubled), vascular disease, age 65–74 and sex category (female); INR = international normalized ratio; OAC = oral anticoagulation, such as a vitamin K antagonist (VKA), adjusted to an intensity range of INR 2.0–3.0 (target 2.5).

^a OAC, such as a VKA, adjusted to an intensity range of INR 2.0–3.0 (target 2.5). New OAC drugs, which may be viable alternatives to a VKA, may ultimately be considered. For example, should both doses of dabigatran etexilate receive regulatory approval for stroke prevention in AF, the recommendations for thromboprophylaxis could evolve as follows considering stroke and bleeding risk stratification:

- (a) Where oral anticoagulation is appropriate therapy, dabigatran may be considered, as an alternative to adjusted dose VKA therapy.
- (i) If a patient is at low risk of bleeding (e.g. HAS-BLED score of 0–2 [internal reference omitted]), dabigatran 150 mg b.i.d. may be considered, in view of the improved efficacy in the prevention of stroke and systemic embolism (but lower rates of intracranial haemorrhage and similar rates of major bleeding events, when compared with warfarin); and (ii) If a patient has a measurable risk of bleeding (e.g. HAS-BLED score of ≥3), dabigatran etexilate 110 mg b.i.d. may be considered, in view of a similar efficacy in the prevention of stroke and systemic embolism (but lower rates of intracranial haemorrhage and of major bleeding compared with VKA).
- (b) In patients with one 'clinically relevant non-major' stroke risk factor, dabigatran 110 mg b.i.d. may be considered, in view of a similar efficacy with VKA in the prevention of stroke and systemic embolism but lower rates of intracranial haemorrhage and major bleeding compared with the VKA and (probably) aspirin. (c) Patients with no stroke risk factors (e.g. CHA₂DS₂-VASc = 0) are clearly at so low risk, either aspirin 75–325 mg daily or no antithrombotic therapy is recommended. Where possible, no antithrombotic therapy should be considered for such patients, rather than aspirin, given the limited data on the benefits of aspirin in this patient group (i.e., lone AF) and the potential for adverse effects, especially bleeding.

Source: Reproduced with permission from Table 9 in Camm AJ, Kirchhof P, Lip GY, et al. Guidelines for the management of atrial fibrillation: the Task Force for the Management of Atrial Fibrillation of the European Society of Cardiology (ESC). *Eur Heart J.* 2010;31(19):2369-2429.

4.2 Estimating the Risk of Bleeding

An overwhelming dilemma of prescribing anticoagulants to patients at risk for thromboembolic strokes is the risk of bleeding complications. Thus, by considering only the stroke risk in determining therapy, one may overlook the risk of potential bleeding from anticoagulant agents. An objective assessment of bleeding risk should be part of the patient assessment before starting anticoagulation.

More robust methods in the anticoagulation decision weigh the benefit of stroke risk reduction against the risk of anticoagulant bleeding. Such an approach is especially warranted when the patient has a significant risk factor for bleeding with full dose anticoagulation. If this type of evaluation is done, the decision to initiate anticoagulation may be easier when the risk of thromboembolism (based on CHADS₂ or CHA₂DS₂-VASc) clearly exceeds that for anticoagulation-associated bleeding.

Several bleeding risk assessment tools exist. The two most commonly used tools to assess bleeding risk are the HEMORR₂HAGES³⁰ and the HAS-BLED^{31,32} risk scores.

4.2.1 HEMORR₂HAGES Bleeding Risk Assessment Method

The HEMORR₂HAGES methodology³⁰ applies point allocations to the 11 identified risk factors (hepatic or renal disease, ethanol abuse, malignancy, older age, reduced platelet count or function, re-bleeding, hypertension, anemia, genetic factors, excessive fall risk and stroke) that are added to give an overall risk score, which then estimates bleeding per 100 patient-years as noted below in Table 5.

Table 5: Risk of Major Bleeding in NRAF Participants Prescribed Warfarin, Stratified by HEMORR₂HAGES Score

HEMORR ₂ HAGES score*	n	No. of bleeds	Bleeds per 100 patient-years warfarin (95% CI)
0	209	4	1.9 (0.6-4.4)
1	508	11	2.5 (1.3-4.3)
2	454	20	5.3 (3.4-8.1)
3	240	15	8.4 (4.9-13.6)
4	106	9	10.4 (5.1-18.9)
≥5	87	8	12.3 (5.8-23.1)
Any score	1604	67	4.9 (3.9-6.3)

* HEMORR₂HAGES is scored by adding 1 point for each bleeding risk factor: hepatic or renal disease, ethanol abuse, malignancy, older (age >75 years), reduced platelet count or function, rebleeding risk (2 points), hypertension (uncontrolled), anemia, genetic factors (not available in this study), excessive fall risk, and stroke.

Source: Reproduced from Table II in Gage BF, Yan Y, Milligan PE, et al. Clinical classification schemes for predicting hemorrhage: results from the National Registry of Atrial Fibrillation (NRAF). *Am Heart J.* 2006;151(3):713-719.

By combining the HEMORR₂HAGES risk score with a clinical prediction rule for stroke, clinicians can weigh the risks and benefits of prescribing anticoagulant versus antiplatelet therapy in elderly patients with AF. Such a strategy identifies patients with a high risk of bleeding for whom anticoagulants should not be used unless their risk of stroke is high enough to justify the risks. Where the risk of stroke does justify use of anticoagulants, it also serves as an alert that the patient's high risk of bleeding requires vigilant monitoring.

4.2.2 HAS-BLED Bleeding Risk Assessment Method

The 2010 ESC AF guidelines²³ and the ACCP 2012 antithrombotic guidelines¹⁹ recommend a more streamlined and slightly better validated risk assessment tool, known as HAS-BLED.^{31,32}

The HAS-BLED scoring system assigns points to the following risk factors: hypertension, abnormal renal/liver function, stroke, bleeding history or predisposition, labile INRs, elderly (age >65) and the use of drugs/alcohol concomitantly (See Table 6.). The sum of the points in the bleeding score then estimates the percent per year risk of bleeding for a patient on anticoagulant therapy. The score of 0 would indicate a “low” bleeding risk, a score of 1 or 2 would indicate “moderate” risk and a score of 3 or greater would indicate a “high” bleeding risk (See Table 7.).

Table 6: Clinical Characteristics Comprising the HAS-BLED Bleeding Risk Score

Letter	Clinical characteristic ^a	Points awarded
H	Hypertension	1
A	Abnormal renal and liver function (1 point each)	1 or 2
S	Stroke	1
B	Bleeding	1
L	Labile INRs	1
E	Elderly (e.g. age >65 years)	1
D	Drugs or alcohol (1 point each)	1 or 2
		Maximum 9 points

^a‘Hypertension’ is defined as systolic blood pressure >160 mmHg. ‘Abnormal kidney function’ is defined as the presence of chronic dialysis or renal transplantation or serum creatinine ≥200 µmol/L. ‘Abnormal liver function’ is defined as chronic hepatic disease (e.g. cirrhosis) or biochemical evidence of significant hepatic derangement (e.g. bilirubin >2 x upper limit of normal, in association with aspartate aminotransferase/alanine aminotransferase/alkaline phosphatase >3 x upper limit normal, etc.). ‘Bleeding’ refers to previous bleeding history and/or predisposition to bleeding, e.g. bleeding diathesis, anaemia, etc. ‘Labile INRs’ refers to unstable/high INRs or poor time in therapeutic range (e.g., <60%). Drugs/alcohol use refers to concomitant use of drugs, such as antiplatelet agents, non-steroidal anti-inflammatory drugs, or alcohol abuse, etc.

INR = international normalized ratio. Adapted from Pisters R, Lane DA, Nieuwlaat R, de Vos CB, Crijns HJ, Lip GY. A novel user-friendly score (HAS-BLED) to assess one-year risk of major bleeding in atrial fibrillation patients: The Euro Heart Survey. *Chest* 2010; March 18 [Epub ahead of print].

Source: Reproduced with permission from Table 10 in Camm AJ, Kirchhof P, Lip GY, et al. Guidelines for the management of atrial fibrillation: the Task Force for the Management of Atrial Fibrillation of the European Society of Cardiology (ESC). *Eur Heart J.* 2010;31(19):2369-2429.

Table 7: Classification of Stroke Risk Based on HAS-BLED Score

HAS-BLED Score	Major Bleeding Events (%/pt-yr)*	Classification of Risk
0	0.9%	low
1	3.4%	moderate
2	4.1%	moderate
3	5.8%	high
4	8.9%	high
5	9.1%	high
6	>10.4%	high

* for patients taking warfarin

Source: Adapted from Lip GY, Frison L, Halperin JL, Lane DA. Comparative validation of a novel risk score for predicting bleeding risk in anticoagulated patients with atrial fibrillation: the HAS-BLED (Hypertension, Abnormal Renal/Liver Function, Stroke, Bleeding History or Predisposition, Labile INR, Elderly, Drugs/Alcohol Concomitantly) score. *J Am Coll Cardiol.* 2011;57(2):173-180.

As with the HEMORR₂HAGES score, the HAS-BLED risk score can be used in conjunction with a stroke risk score to weigh the individual patient's risks for stroke against those for bleeding complications of anticoagulation to identify the optimal treatment strategy.

For example, in a patient with a CHADS₂ score of 1 (2.8% risk of stroke in one year) and a HAS-BLED score of 2 (4.1% risk of major bleeding with anticoagulant therapy in one year), one might decide to use antiplatelet therapy to reduce the potential of a bleeding complication. Thus, the use of bleeding and stroke risk scores also provide "hard numbers" summarizing the benefits of stroke prevention versus risk of anticoagulation-related bleeding that can be readily communicated to patients, enabling them to more readily participate in the decision-making process and provide informed consent to treatment.

4.2.3 Which Bleeding Risk Assessment is Most Accurate?

The HAS-BLED score was originally derived from the Euro Heart Survey and the c-statistic measuring its ability to predict major bleeding was 0.72. However, the 25% missing data regarding the occurrence of major bleeding during the study's follow-up period indicated possible selection bias. Patients who were lost to follow-up were more likely to have had more comorbidities and to have transferred to nursing homes or died, which might have led to underestimation of the overall bleeding rate.³¹

Subsequently, the HAS-BLED risk score was compared to three other risk assessment tools (including HEMORR₂HAGES) using the SPORTIF III and V database, and was found to estimate the risk of bleeding more accurately.³² This greater accuracy was particularly apparent in patients allocated to the low-risk group. Patients classified as "low risk" by the HAS-BLED score had an incidence rate of major bleeding events of <1%/patient-year, while those identified as "low risk" by the other risk assessment tools had an incidence rate of >1.9%/patient-year.³² In the future, the HAS-BLED tool will likely be adjusted to incorporate a range of ages rather than the current dichotomous designation of risk before versus after the age of 65. Thus, the HAS-BLED score may be the more attractive method for the estimation of oral anticoagulant-related bleeding risk for use in clinical practice, supporting recommendations in national and international guidelines.

4.3 Other Contraindications to Anticoagulation

As useful as the bleeding risk assessment tools described above are, they do not cover all the factors that should be considered in determining whether it would be appropriate to withhold anticoagulation in a particular patient's case. Contextual factors, such as a planned surgery in which full anticoagulation would create hemostasis-related bleeding risk post-operatively, must also be taken into account.

Some examples of contextual factors, which would be contraindications to anticoagulation that may not be captured in bleeding risk indices, are shown in the following list. An expert panel at your institution should determine other common contraindications to anticoagulation that you may wish to include in your algorithms.

- Risk of or active hemorrhage
- Anticipated procedure in the next 24 hours
- Post-operative bleeding concerns
- Risk of intracranial hemorrhage
- Hemophilia
- Coagulopathy (INR >2 or PT >18)
- Low platelets or platelet dysfunction
- History of heparin-induced thrombocytopenia or heparin allergy
- Creatinine clearance <30 mL/min

4.3.1 Cautionary Information About Estimating Fall Risk

Current evidence suggests that elderly patients with AF are frequently under-prescribed anticoagulation therapy due to the perceived risk for falls and subsequent bleeding complications, particularly the much-feared adverse event of intracranial hemorrhage (ICH).³³

The mortality for fall-related ICH is approximately 33% overall, and >50% in the context of patients taking warfarin.³⁴ Although the high mortality rates appear to warrant clinicians' reluctance to prescribe anticoagulation, results of a Markov decision analytic model (using input data from a systematic review of the literature reporting probabilities, risk factors and/or outcomes for stroke, major bleeding, subdural hematoma, ICH and falls published between 1966 and 1996) concluded that for elderly patients with AF, their propensity to fall was not an important factor in determining optimal antithrombotic therapy as the benefits of anticoagulation often outweigh the risks of fall-related bleeding by a wide margin.³⁵

It was estimated that a patient with a 5% per year risk of a stroke from AF would have to fall approximately 300 times for the bleeding risk associated with antithrombotic therapy to supersede the benefits of stroke prevention.³⁵ A similar conclusion was reached by a study conducted in Medicare beneficiaries with AF and a documented high risk of falls, which found that in patients with CHADS₂ scores ≥2, the benefits of stroke prevention still outweighed the risks of ICH.³⁴

Most recently, a prospective trial conducted in 515 consecutive patients discharged on oral anticoagulation from a single Swiss hospital demonstrated that patients at "high risk" for falls did not have a statistically elevated risk for major bleeding complications compared to those at "low risk."³⁶ In this patient cohort, only three major bleeds (all of which were non-fatal subdural hematomas) occurred directly after a fall, and only one of these occurred in a patient classified as having a "high risk" for falls.³⁶

While the majority of the data on fall-related bleeding complications in the setting of anticoagulation is retrospective and potentially biased, the results of the three studies described above can perhaps increase our comfort in prescribing full anticoagulation for patients with AF, particularly for those with a high risk for thromboembolic strokes.

4.3.2 Determining Patient Preferences

The views of the individual patients should be considered when decisions are being made about antithrombotic treatment for AF. Patient preferences and expert-generated clinical practice guidelines regarding treatment decisions may differ.

The anticoagulation decision involves making trade-offs between desirable and undesirable consequences (stroke prevention versus bleeding) that need to be discussed carefully with each patient as a particular patient's thresholds for how much reduction in risk of stroke is necessary relative to how much risk of excess bleeding is acceptable with antithrombotic treatment may vary significantly from person to person. In fact, many studies indicate that patient values and preferences regarding anticoagulation treatment appear to be highly variable and unpredictable. Participant responses may depend on their prior experience with the treatments as well as social factors.

Most often, however, patients at high risk for AF placed more value on the avoidance of stroke and less value on the avoidance of bleeding. Since patient preferences can have a substantial impact on the clinical decision-making process, acknowledgment of their importance should be incorporated into clinical practice guidelines. Practicing physicians need to balance the patient preferences with the treatment recommendations from clinical practice guidelines.

The risks and benefits associated with each treatment option should be discussed so that the patient can make an informed decision. Most importantly, the patient needs to understand the relative benefits and risks and must be involved whenever possible in the net value decision.

By using the risk tools, CHADS₂ and HAS-BLED, one can provide to the patient an estimate of the yearly stroke risk and bleeding risk to allow for more informed decision-making. Along with discussing yearly stroke risk based on CHADS₂, a discussion of relative risk reduction (RRR) for thromboembolic stroke of various antithrombotic agents may be of some value in deciding to use warfarin versus a newer oral anticoagulant. This should be clearly reviewed with the patient. Randomized trials indicate the following RRR:

- Aspirin – 22% RRR compared with placebo
- Warfarin – 66% RRR compared with placebo
- Dabigatran (150 mg b.i.d.) – superior to warfarin
- Dabigatran (110 mg b.i.d.) – equivalent to warfarin
- Rivaroxaban – equivalent to warfarin
- Apixaban – superior to warfarin

Along with the HAS-BLED bleeding risk estimate, the following data regarding the risk of bleeding with the use of warfarin versus that of the new oral anticoagulant may be helpful in your discussion with the patient. As compared to warfarin, the new oral anticoagulants have the following relative bleed risk:

1. Dabigatran (110 mg b.i.d.) less than warfarin
2. Dabigatran (150 mg b.i.d.) slightly greater than warfarin
3. Rivaroxaban equal to warfarin
4. Apixaban better than warfarin

4.4 Developing a Course of Action: How to Incorporate Stroke and Bleeding Risk into a Final Decision

The following critical points should be considered when weighing choices of antithrombotic strategy:

- 1) Assess risk of thromboembolic strokes.
 - Use CHADS₂.
 - If a CHADS₂ score of 0-1 is obtained, apply CHA₂DS₂-VASc for better discrimination of risk.
- 2) Assess risk of major bleeding complications.
 - Use HAS-BLED (or HEMORR₂HAGES) risk tool.
 - For patients who have a high bleeding risk, opportunities to reduce this risk should be sought. Some examples include addressing uncontrolled hypertension, correcting anemia, correcting labile INRs and reducing fall risks.
- 3) Assess risk for falls.
 - Most clinicians overestimate the morbidity of fall risk as noted earlier. For additional references, please review the following:
 - Choosing antithrombotic therapy for elderly patients with atrial fibrillation who are at risk for falls. *Arch Int Med.* (1999);159(7):677-685.³⁵
 - Incidence of intracranial hemorrhage in patients with atrial fibrillation who are prone to fall. *Am J Med.* (2005);118(6):612-617.³⁴
 - Remember that *overall* risk of stroke usually outweighs risk of major bleeding complications if CHADS₂ score \geq 2.
- 4) Ascertain patient preference on outcome priority.
 - Keep in mind that some patients will have a mindset to:
 - Prioritize stroke risk reduction more heavily than risk of complications.
 - Minimize iatrogenic complications (i.e., bleeding).
 - Minimize inconvenience of frequent monitoring.
- 5) Assess other considerations.
 - Risk of noncompliance
 - Adequacy of access to healthcare
 - Affordability of medications and monitoring
 - Example: Cost of new oral anticoagulant or warfarin monitoring-related cost of PT/INR is ~\$ 44–\$72 per lab check.
- 6) Based on steps 1-5 above, make a decision regarding the use of antithrombotic or antiplatelet medication to decrease stroke risk.

4.4.1 Clinical Scenarios and Case Studies: Examples of How Anticoagulation-Related Decisions May Be Made

4.4.1.1 Scenario 1: Clear Need for Anticoagulation

A 65-year-old male with history of persistent AF, systolic congestive heart failure with an ejection fraction of 35%, coronary artery disease, hypertension, hyperlipidemia, diabetes mellitus (type 2) and CKD stage 4 presents to the hospital medicine unit with his first TIA.

- Taking the steps listed in Section 4.4, his CHADS₂ score is 5, giving a corresponding risk for a thromboembolic stroke of >12% per year, indicating a strong recommendation for full anticoagulation if only stroke risk is considered.
- It is essential that the patient be made aware of this high risk for stroke, after which his willingness to undergo full anticoagulation must be ascertained based on his preferences and personal values.
- Using the HAS-BLED tool, the patient in this scenario has a risk score for major bleeding complications of 4, with a corresponding high bleed risk per year noted to be 8.9%.
- However, the risk for stroke does outweigh the risk for major bleeding complications and the patient has indicated that his desire to reduce his stroke risk is greater than his reluctance in facing a bleeding complication.
- The discussion regarding full anticoagulation should always include educating the patient about anticoagulation-related monitoring.
- Decision: Full-dose anticoagulation with warfarin or a new oral anticoagulant is agreed upon based on risk and benefit data and patient preference.

4.4.1.2 Scenario 2: Ambiguous Conclusion

A 75-year-old female with a past history of paroxysmal AF, spinal stenosis, hypertension, cerebrovascular accident (CVA), prior bleeding peptic ulcer disease and CKD stage 3, who ambulates with the aid of a rolling-walker and has a history of falls averaging approximately twice a year, presents to the hospital medicine unit for altered mental status strictly related to narcotic side effects. A review of her medications on admission reveals she is on no antithrombotic treatment for stroke prevention.

- Assessing her CHADS₂ score for stroke risk, she scores 4 points, which has an estimated 10.9% per year risk for stroke.
- Her risk score for major bleeding complications as assessed by the HAS-BLED is 5, giving an estimated bleeding risk of approximately 9.1% per year. The combination of this bleeding risk and her history of falls would possibly equalize the risk of anticoagulation with the benefit of stroke prevention, regardless of which agent is chosen.
- In such a scenario, it is crucial to assess the patient's preference. As noted in the ACCP 2012 AF guidelines,¹⁹ where patients are in clinical equipoise, their desires to maximally reduce the risk for a stroke (or in this case recurrent stroke) may outweigh their concerns for bleeding complications (or vice versa), and thus become the final determining factor in the decision of whether to pursue anticoagulation. In this case, the patient is willing to pursue full anticoagulation as she places a high priority on maintaining her level of cognition and avoiding stroke.
- Given the patient's high risk for major bleeding complications, initiation of full anticoagulation would necessitate timely outpatient follow-up and preferably a referral to a dedicated warfarin clinic with documented time in therapeutic range (TTR) approximating 66%-70%.
- Decision: Based on patient consultation and joint decision-making with a provider, the decision may be to the use full-dose anticoagulation with warfarin or a new oral anticoagulant.

4.4.1.3 Scenario 3: Clear Contraindication to Anticoagulation

A 75-year-old male retired engineer with persistent AF and recurrent falls related to Parkinson's disease presents to the Hospital Medicine unit after another fall. A review of his stroke risk factors is negative for congestive heart failure, diabetes mellitus, prior TIA or CVA, hypertension or peripheral vascular disease. A review of his medications on admission reveals the use of once daily aspirin at 81 mg. Comorbidities include chronic kidney disease with a serum creatinine level of 2.5 mg/dL, a history of chronic hepatitis C with cirrhosis and a current history of alcohol abuse.

- His CHADS₂ score is 1, but his CHA₂DS₂-VASc score is 2, which indicates a higher risk (estimated 2.2% per year) for thromboembolic events.
- His HAS-BLED risk score is 4 with an estimated risk for major bleeding complications of 8.7% per year.
- Based on these factors, the bleeding risk from full anticoagulation is significantly greater than the benefit of stroke risk reduction.
- In discussing the benefit versus risk of anticoagulation with the patient, he agrees that although he values stroke risk reduction, the risk of bleeding is too high for his preference.
- Decision: Based on an asymmetry of risk versus benefit and incorporating patient preferences, no anticoagulation is chosen.

4.4.1.4 Scenario 4: Fall Risk

A 76-year-old male with a history of persistent AF, hypertension, diabetes mellitus and chronic lower extremity weakness with atrophy due to neuromuscular disorder presents with benzodiazepine withdrawal symptoms to a local hospital. Upon discussing the case with family, it is noted that he has had trouble ambulating, with multiple falls in the past year, and intermittently is noted to have mental status changes due to benzodiazepine dependence.

- His CHADS₂ score is 3, giving an estimated stroke risk of 8.6% per year.
- His HAS-BLED risk score is 2, giving an estimated risk for major bleeding complications at 4.1% per year.
- Based purely on the risk and benefit evaluation, it would appear that the bleeding risk from full anticoagulation is much less than the benefit of stroke risk reduction. However, there is a significant fall risk due to lower extremity weakness and frequent drug-induced cognitive impairment.
- Discussing the above issues with the patient and family, they concur that the fall risk is a large factor in the anticoagulation decision and too high to consider full treatment.
- Decision: The decision is made to defer full anticoagulation and to use only low-dose antiplatelet therapy.

4.5 Selecting an Anticoagulant

When the decision is made to initiate full-dose anticoagulation for stroke prevention in AF, there are a number of therapeutic options available. These include warfarin, IV unfractionated heparin while hospitalized, low molecular weight heparins (LMWHs) and now several new novel oral anticoagulants (NOACs). Currently, three NOACs have been FDA approved to prevent stroke in AF.

As most clinicians are familiar with and experienced in the use of warfarin, and IV and LMWHs, the properties of these agents and the current guidelines on their use are not included here. The three new oral anticoagulant agents for stroke prevention in patients with non-valvular AF that have been approved by the FDA are reviewed below.

4.5.1 A New Era for Anticoagulation: Oral Direct Thrombin Inhibitors and Oral Factor Xa Inhibitors

For 50 years, warfarin was the only oral anticoagulant approved to treat venous thromboembolisms and prevent systemic thromboembolisms. However, a new era for treatment has arrived with the recent FDA approval of a direct thrombin inhibitor (dabigatran) and two new factor Xa inhibitors (rivaroxaban and apixaban), drugs that require no therapeutic-level monitoring.

Warfarin has demonstrated utility as a preventive and therapeutic intervention, decreasing incidence of strokes by 68% in patients with AF compared to the 21% reduction with aspirin.³⁷ Warfarin, however, has significant issues in the form of frequent drug-drug interaction, metabolism issues and the need to check therapeutic levels. Thus an important aspect of developing better alternatives to warfarin is to reduce or eliminate warfarin's key negative attributes, while achieving comparable preventive and therapeutic results. The new NOACs represent a drug class that demonstrates comparable efficacy and safety and also minimizes the above-mentioned negative attributes of warfarin. The clinical trials evaluating the newly approved oral anticoagulants published to date have been randomized, double-blind trials evaluating these new agents against warfarin. There are, however, no head-to-head comparisons between the new agents.

4.5.1.1 Oral Direct Thrombin Inhibitor: Dabigatran

The first new oral anticoagulant to receive FDA approval for stroke prevention in non-valvular AF was dabigatran. The RE-LY trial³⁸ compared two dosages (110 mg or 150 mg twice daily) of dabigatran to warfarin. The lower dose (110 mg p.o. b.i.d.) demonstrated an equivalent rate of stroke or systemic embolism as warfarin (~1.5-1.7% per year), but a significantly lower rate of major bleeding (2.71% per year vs. 3.36% per year with warfarin).³⁸ The higher dose (150 mg p.o. b.i.d.) was found to reduce the risk for strokes by 33% compared with warfarin, but had an equivalent rate of major bleeding complications (~3% per year).³⁸ Looking at the specific outcome of hemorrhagic stroke, both dosages showed a significantly decreased risk compared to warfarin (incidence rates of 0.12% per year and 0.10% per year with the 110 mg and 150 mg dosages of dabigatran, respectively, compared to 0.38% per year with warfarin, $p < 0.001$). This is an obvious advantage as the mortality rate with ICH in the setting of anticoagulation approaches 50%.³⁹

Reviewing this evidence, the FDA approved the use only of the higher dose (150 mg) of dabigatran. Due to the demonstrated benefits over the long-established gold standard for antithrombotic therapy in AF, the ACCP Evidence-Based Clinical Guidelines 9th edition (published in 2012), states that when the CHADS₂ score is ≥ 1 and oral anticoagulation is implemented, dabigatran is favored over warfarin.¹⁹

The lack of a true reversal agent represents a concern for all NOACs in situations of a brisk bleed. Currently, two interventions are available to counteract the bleeding but have not been studied in published clinical trials: transfusion of prothrombin complex concentrate (PCC) or transfusion of recombinant factor VII concentrate.

Caution must be used with dabigatran in patients with poor renal function. The pharmacokinetics show dabigatran to be excreted renally with a longer half-life in the renally impaired. The RE-LY trial excluded patients with end-stage renal disease (ESRD) or creatinine clearance of < 30 mL/min (chronic kidney disease [CKD] stage 4 & 5). The estimated half-life is 12-17 hours but longer if renal function is reduced.

Approximately 11% of patients in the RE-LY trial reported reflux symptoms, related to the tartaric acid coating used to enhance absorption. As dabigatran needs an acidic environment to enhance bioavailability, concomitant administration of a proton pump inhibitor will reduce its absorption.

Other concerns may be that dabigatran is dosed twice a day, which may reduce compliance, and that it has not been studied in patients with significant liver dysfunction. Although this medication isn't metabolized via the cytochrome P450 system, it is a substrate for P-glycoproteins and has the potential to interact with medications such as amiodarone, digoxin, quinidine, verapamil, nicardipine, ketoconazole and clarithromycin. A subgroup analysis of patients on these medications from the RE-LY trial did demonstrate a trend toward increased complications, but this was not statistically significant.³⁸ Post-marketing monitoring of bleeding complications will need to be scrutinized.

4.5.1.2 The New Oral Factor Xa Inhibitors: Rivaroxaban and Apixaban

Two additional new oral anticoagulants (both factor Xa inhibitors) have emerged as alternatives to warfarin for stroke prevention patients with AF. Rivaroxaban has received FDA approval for this use and most recently, so did apixaban.

Rivaroxaban

Rivaroxaban received FDA approval for anticoagulation in patients with non-valvular AF following demonstration of non-inferiority to warfarin in preventing strokes or systemic embolisms in the ROCKET-AF trial (in the intention-to-treat analysis, the rate of stroke or systemic embolism was 2.1% per year in the rivaroxaban group compared to 2.4% per year in the warfarin group [hazard ratio, 0.88; 95% CI, 0.74 to 1.03; P<0.001 for non-inferiority]).⁴⁰ Unique to the newer anticoagulants, rivaroxaban is dosed once daily, which is expected to increase patient compliance.

The ROCKET-AF trial specifically investigated rivaroxaban in patients with a moderate-to-high risk of stroke, requiring a CHADS₂ score of at least 2 among its inclusion criteria. Thus, while the other two new oral anticoagulants (dabigatran and apixaban) have been studied in high-risk populations, the ROCKET-AF trial exceeded them in this risk severity arena, as the mean CHADS₂ score was 3.5, relative to 2.1 in both RE-LY and ARISTOTLE. In ROCKET-AF, >50% of the study participants had previously suffered a stroke or systemic embolism.⁴⁰

Similar to the RE-LY results for dabigatran, the ROCKET-AF trial showed rivaroxaban to have an equivalent rate of major bleeding complications to warfarin, a significantly increased risk of gastrointestinal bleeding (3.2% compared to 2.2%, P<0.001) and a significantly reduced risk of ICH (0.5% per year vs. 0.7% per year; hazard ratio, 0.67; 95% CI, 0.47 to 0.93; P=0.02).⁴⁰ "Critical bleeding" (i.e., bleeding events that were intraspinal, intraocular, pericardial, intra-articular, intramuscular with development of compartment syndrome or retroperitoneal) and "fatal bleeding" were also significantly reduced compared to warfarin.

The patients in the rivaroxaban arm of the ROCKET-AF trial were compared to those on warfarin that were within time in therapeutic range (TTR) for a mean duration of 55% of the time (median: 58%, interquartile range: 43-71%).⁴⁰ This was the lowest TTR among the clinical trials testing the new oral anticoagulants but one can certainly argue that this 55% mark better reflects real-world TTR for warfarin outside the context of clinical trials and thus was an effective comparison.

Apixaban

The second factor Xa inhibitor showing promise as an oral anticoagulant alternative to warfarin, apixaban, received FDA approval for the prevention of strokes in patients with AF in late 2012. Apixaban showed superiority relative to warfarin in the primary outcome of stroke prevention compared to warfarin in AF patients.

Apixaban was studied in a moderate-to-high-risk patient population with an average CHADS₂ score of 2.1, and substantial proportions of patients who were elderly (>30% were over the age of 75) or had previously suffered CVA (almost 20% of participants).⁴¹ The ARISTOTLE trial compared apixaban with warfarin in this population, and demonstrated both non-inferiority and superiority for the composite outcome of ischemic or hemorrhagic stroke or systemic embolism (hazard ratio with apixaban, 0.79; 95% confidence interval, 0.66–0.95; P<0.001 for non-inferiority; P = 0.01 for superiority).⁴¹ Rates of major bleeding (hazard ratio, 0.69; 95% CI, 0.60–0.80; P<0.001) and all-cause mortality (hazard ratio, 0.89; 95% CI, 0.80–0.99; P = 0.047) were also significantly lower with apixaban.

Apixaban is partially cleared renally, so patients with a creatinine clearance less than 25 mL/min or serum creatinine >2.5 mg/dL were excluded from the ARISTOTLE trial, and only 15% of the enrolled patient population had a CrCl <50 mL/min. Thus, similar to dabigatran, there are questions about use in patients with poor renal function.

4.5.1.3 Bleeding Complications with New Oral Anticoagulants

Post-market monitoring of dabigatran resulted in reports of major bleeding complications that exceeded the rates expected based on the results of the RE-LY trial. Thus, dosing and monitoring recommendations and warnings about bleeding were updated in 2011.⁴² The reported bleeding events appear to occur more frequently in the elderly who are underweight and have diminished renal function.⁴³ Although routine monitoring of coagulation labs is not required with dabigatran, its effect on the coagulation system can be estimated via PTT, PT, ECT (ecarin clotting time) or Thrombin Time but not with INR.⁴⁴

For the factor Xa inhibitors, there is some evidence that the anticoagulation effects can be reversed by the administration of PCC.²⁷ In general, supportive measures such as withdrawal of the anticoagulant, fluid resuscitation and blood transfusions are the mainstay of management of major bleeding complications. Infusion of PCC or recombinant factor VII, or repeated doses of either or both, are potential means by which an anticoagulant's effects may be overwhelmed and hemostasis generated but these methods have not been extensively studied in clinical trials.

In acute bleeding with patients on dabigatran, since only one-third of the circulating dose is protein bound, a burdensome but possible alternative in the context of a life-threatening bleed would be to dialyze dabigatran from the serum.⁴⁵ In contrast, rivaroxaban and apixaban are protein bound, and therefore dialysis is not an option for their anticoagulation reversal.⁴⁶

4.5.2 Conclusion

Certainly the new oral anticoagulants are groundbreaking therapeutics with important favorable characteristics, such as decreased risk of ICH (intracranial hemorrhage). We will need to closely monitor the rates of major bleeding complications as the new oral anticoagulants are administered beyond the closely screened patient populations in the RE-LY, ARISTOTLE and ROCKET-AF trials. The hemorrhagic risk in the elderly, who are often underweight and have reduced renal function, which is frequently overlooked, will need to be particularly closely monitored. Although the published trials enrolled significant percentages of patients older than 75, their inclusion of the very elderly (80+), who may often be at very high risk for AF and stroke, is unclear at this time.

Patients who have been on warfarin and have demonstrated an adequate TTR (time in therapeutic range), minimal bleeding complications and good compliance should perhaps be maintained on their current anticoagulation therapy. A head-to-head comparison of the new oral anticoagulants would be useful in addressing the question of which one anticoagulant provides superior stroke prevention with the least risk of major bleeding complications. In the absence of such direct comparative data, Table 8 provides a side-by-side comparison of the key attributes of the NOACs.

Table 8: Side-by-Side Comparison of Dabigatran, Rivaroxaban and Apixaban, Based on the RE-LY, ROCKET-AF and ARISTOTLE Randomized Controlled Trials (RCTs) Comparing Each of These Agents to Warfarin^{38,40,41,47}

	Dabigatran (150 mg) vs. Warfarin	Rivaroxaban vs. Warfarin	Apixaban vs. Warfarin
Stroke or systemic embolism	RR (95% CI) = 0.65 (0.52–0.81) p < 0.001 for non-inferiority	HR (95% CI) = 0.88 (0.75–1.03) p < 0.001 for non-inferiority p = 0.12 for superiority	HR (95% CI) = 0.79 (0.66–0.95) p = 0.01
Major hemorrhage	RR (95% CI) = 0.93 (0.81–1.07) p = 0.32	HR (95% CI) = 1.04 (0.90–1.20) p = 0.58	HR (95% CI) = 0.69 (0.60–0.80) p < 0.001
All-cause mortality	RR (95% CI) = 0.88 (0.77–1.00) p = 0.051	HR (95% CI) = 0.85 (0.70–1.02) p = 0.073	HR (95% CI) = 0.89 (0.80–1.00) p = 0.047
% TTR for the warfarin comparison group in the RCT	<u>mean:</u> 64.4% (s.d. not reported)	<u>median (IQR):</u> 58% (43–71%)	<u>mean:</u> 62.2% (s.d. not reported)
Age of RCT study population	<u>mean±s.d.:</u> Dabigatran (150 mg): 71.5±8.8 yrs Warfarin: 71.6±8.6 yrs	<u>median (IQR):</u> Rivaroxaban: 73 (65–78) yrs Warfarin: 73 (65–78) yrs	<u>median (IQR):</u> Apixaban: 70 (63–76) yrs Warfarin: 70 (63–76) yrs
Mean±s.d. CHADS₂ score in the RCT study population	2.1 (s.d. not reported)	Rivaroxaban: 3.48±0.94 Warfarin: 3.46±0.95	Apixaban: 2.1±1.1 Warfarin: 2.1±1.1
Dosing	b.i.d.	daily	b.i.d.
FDA approval for stroke/systemic embolism prevention in AF	October 2010	November 2011	December 2012
Half-life	12–17 hours	5–9 hours 11–13 hours (elderly)	12 hours
Route of elimination	80% urine	66% urine, 28% feces	25% urine, 55% feces
Potential anticoagulation reversal means*	1. recombinant factor VII 2. prothrombin complex concentrate 3. dialysis removes 66%	1. prothrombin complex concentrate 2. recombinant factor VII	1. prothrombin complex concentrate 2. recombinant factor VII

CI = confidence interval; HR = hazard ratio; IQR = interquartile range; RCT = randomized controlled trial; RR = relative risk; s.d. = standard deviation; TTR = time in therapeutic range

*not extensively studied in human clinical trials

4.5.3 Transitioning from Standard Anticoagulants to a New Oral Anticoagulant

With the new availability of alternative oral anticoagulants, there may be situations in which it would be appropriate to transition a patient from an existing warfarin regimen to dabigatran, rivaroxaban or apixaban. Below are some suggestions to consider.

4.5.3.1 Dabigatran and Standard Anticoagulant Transitions

I. Switching from warfarin to dabigatran

A. Note that dabigatran is 100% renally cleared.

1. Stop warfarin and wait until INR ≤ 2 .
2. Then start dabigatran based on renal function.

- If creatinine clearance >30 mL/min, start dabigatran at 150 mg p.o. b.i.d.
- If creatinine clearance 15-30 mL/min, start dabigatran at 75 mg p.o. b.i.d.
- If creatinine clearance <15 mL/min on dialysis = dabigatran is NOT recommended.

II. Switching from dabigatran to warfarin

A. Dosing is based on renal function.

1. If creatinine clearance >50 mL/min, start warfarin three days before stopping dabigatran.
2. If creatinine clearance 31-50 mL/min, start two days before stopping dabigatran.
3. If creatinine clearance 15-30 mL/min, start one day before stopping dabigatran.
4. If creatinine clearance <15 mL/min, dabigatran should not have been used.

III. Transitioning from parenteral anticoagulant (enoxaparin, heparin) to dabigatran

- A. Start dabigatran at the time the heparin drip is to be stopped; or
- B. In the case of enoxaparin, start dabigatran 0-2 hours before next dose of enoxaparin was to be given.

IV. Transitioning from dabigatran to parenteral anticoagulant (enoxaparin, heparin)

A. Dose is based on renal function.

1. If creatinine clearance >30 mL/min, then start 12 hours after last dose of dabigatran.
2. If creatinine clearance <30 mL/min, then start 24 hours after last dose of dabigatran.

4.5.3.2 Rivaroxaban and Standard Anticoagulant Transitions

I. Switching from warfarin to rivaroxaban

- A. Stop warfarin and when INR <3, start rivaroxaban.

II. Switching from rivaroxaban to warfarin

- A. There are no clinical trial data to guide converting from rivaroxaban to warfarin. Rivaroxaban affects INR, so INR measurements made during co-administration of rivaroxaban with warfarin may not be useful. One approach is to discontinue rivaroxaban and begin both a parenteral anticoagulant and warfarin simultaneously when the next dose of rivaroxaban would have been taken.

* Rivaroxaban will increase the INR levels, so monitoring warfarin therapeutic range during this time is difficult.

III. Transitioning from parenteral anticoagulant (enoxaparin, heparin) to rivaroxaban

- A. Start rivaroxaban at the time the heparin infusion is stopped.
- B. Start rivaroxaban within 0-2 hours of the time the next dose of parenteral anticoagulant (i.e., enoxaparin) was to be given.

IV. Transitioning from rivaroxaban to parenteral anticoagulant (enoxaparin, heparin)

- A. Start parenteral anticoagulant when the next dose of rivaroxaban was to be due (24 hours).

4.5.4 Reversal of the New Anticoagulants

Due to the novelty of direct thrombin and factor Xa inhibitor anticoagulants, the quality of the research data on reversing the effects are lacking. Most of the data available are from research conducted in animals (mice, rats, baboons), with only two small trials in humans.^{44,48} Numerous organizations (Thrombosis and Hemostasis Summit of North America, American Society of Hematology, Italian Federation of Thrombosis Centers, PHARMAC of New Zealand Government) have compiled the available data and summarized recommendations to help guide clinicians when they encounter bleeding complications. Their recommendations include:

1. Provide supportive care: fluid resuscitation, inotropes if needed.
2. Optimize renal function (novel anticoagulants are to a certain extent renally cleared).
3. Transfuse blood (packed RBCs).
4. Stop further doses of the anticoagulant (novel anticoagulants have short half-lives).
5. Use local or surgical hemostatic measures: topical measures include use of aminocaproic acid, tranexamic acid.
6. Consider a reversal agent.

4.5.4.1 Recommendations Specific to the Context of Dabigatran-Induced Major Bleeding

1. If recent ingestion (~2 hours), perform gastric lavage and/or give activated charcoal.
 - A. Check activated partial thromboplastin time (aPTT)⁴⁹ or ecarin clotting time (ECT).⁵⁰
 - If aPTT or ECT is normal, it is unlikely that dabigatran is contributing to the bleeding.
 - If aPTT or ECT is elevated, implement the general measures described previously.
 - B. Maintain renal function as dabigatran is cleared renally.
 - C. Consider infusion of PCC, or activated PCC (factor eight inhibitor bypass activity [FEIBA]), or recombinant activated clotting factor VII (rFVIIa)**, or dialysis.***⁴⁹
2. If patient is on an anti-platelet agent or thrombocytopenic (<70,000), consider platelet transfusion.⁵⁰
3. Consult Hematology service.

**rFVIIa infusion is associated with a high risk for arterial thrombosis ~5-10%.⁴⁹

***Dialysis is effective as dabigatran is not highly protein bound (~35%). Dialysis should be strongly considered in the context of a life-threatening bleed (intracranial), hemorrhagic shock, reduction in Hb >5, of transfusion requirements >4 units PRBCs. Dialysis removes approximately 62% to 68% of dabigatran in two hours and four hours, respectively.⁴⁸

4.5.4.2 Recommendations Specific to the Context of Rivaroxaban-Induced Major Bleeding

1. Check prothrombin level.⁵⁰
 - A. Administer activated oral charcoal if ingestion <2 hours.
 - B. Stop further doses of rivaroxaban.
 - C. Maintain renal function as 33% of rivaroxaban is renally cleared (**note:** dialysis not recommended as 92-95% is protein bound).
 - D. Infuse non-activated four-factor PCC as single dose (50 UI/kg).****

****One small trial involving 12 healthy subjects demonstrated that the elevated PT is reversed; however, effect on actual bleeding is unknown.⁴⁴ Four-factor PCC consists of factor II, VII, IX and X and minimal concentrations of protein C and S.

Step 5

Choose Metrics and Develop a Data Collection Plan

5.1 Existing Atrial Fibrillation Performance Metrics

Current standardized performance metrics in AF are primarily process measures limited to the areas of stroke risk assessment and anticoagulation. Many of the current performance measures were originally designed for ambulatory settings, and do not account for the spectrum of conditions encountered in hospital practice (incident versus prevalent disease, management of AF in periprocedural scenarios, bleeding complications, etc.).

Table 9 displays current AF performance metrics formally endorsed by professional societies or accrediting agencies. More recently, the American Heart Association has also launched a new Get With The Guidelines®-AFib program also emphasizing stroke prevention, with a similar set of performance measures: http://www.heart.org/HEARTORG/HealthcareResearch/GetWithTheGuidelines-AFib/Get-With-The-Guidelines-AFib_UCM_448881_SubHomePage.jsp.

Given the heightened focus on preventable readmissions, the shift toward patient-centered outcomes in clinical trials and comparative effectiveness research, as well as the availability of new treatment options (e.g., anticoagulants other than warfarin), there is a need to augment the current process-based AF metrics with additional care domains. Further expanding the range of performance metrics to include outcomes-based measures would also facilitate management of AF from a population health perspective. For example, tracking annual risk-adjusted stroke rates among patients with an established diagnosis of AF might be one way to compare the performance of one accountable care organization versus another for effective care of this condition.

Table 9. Non-Valvular Atrial Fibrillation and Atrial Flutter Performance Measures

Performance Metric	Description^a
ACC/AHA/AMA Physician Consortium Performance Measurement Set⁵¹	
1. Assessment of thromboembolic risk factors	Percentage of patients aged 18 years and older with a diagnosis of non-valvular AF or atrial flutter with an assessment of all of the specified thromboembolic risk factors documented
2. Chronic anticoagulation therapy	Percentage of patients aged 18 years and older with a diagnosis of non-valvular AF or atrial flutter at high risk for thromboembolism who were prescribed warfarin during the 12-month reporting period
3. Monthly INR measurement ^a	Percentage of calendar months during the reporting period during which patients aged 18 years and older with a diagnosis of non-valvular AF or atrial flutter, receiving warfarin therapy, have at least one INR measurement made
The Joint Commission Disease-Specific Care Certification Program	
1. Patients with Atrial Fibrillation/ Flutter Receiving Anticoagulation Therapy (DSC/Stroke-03)	Patients with a principal discharge diagnosis of ischemic stroke with atrial fibrillation/flutter discharged on anticoagulation therapy
National Voluntary Consensus Standards for Clinically Enriched Administrative Data^b	
1. New Atrial Fibrillation: Thyroid Function Test (EC-083-08)	Identifies patients with new-onset atrial fibrillation during the measurement year who have had a thyroid function test six weeks before or after the diagnosis of atrial fibrillation
2. Atrial Fibrillation: Warfarin Therapy (EC-244-08)	Percentage of adult patients with AF and major stroke risk factors on warfarin

Source: Adapted from Estes NA, 3rd, et al. ACC/AHA/Physician Consortium 2008 clinical performance measures for adults with nonvalvular atrial fibrillation or atrial flutter: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures and the Physician Consortium for Performance Improvement (Writing Committee to Develop Clinical Performance Measures for Atrial Fibrillation): developed in collaboration with the Heart Rhythm Society. *Circulation*. 2008;117(8):1101-1120.

^a International normalized ratio (INR) of prothrombin time ($[\text{patient}/\text{control}]/\text{ISI}$), where ISI refers to the international sensitivity index of the thromboplastin reagent utilized during the test.

^b These performance measures are based primarily on ambulatory administrative data.

5.2 Suggested Initial Metrics for Hospital-Based Atrial Fibrillation Quality Improvement Projects

Good performance measures share attributes of being correlated to patient outcomes, validity and feasibility (particularly in terms of time and effort required for data collection).⁵¹ Based on these principles, the existing metrics in Table 9 and the areas prioritized in the AHA Get With The Guidelines®-Atrial Fibrillation campaign (http://www.heart.org/HEARTORG/HealthcareResearch/GetWithTheGuidelines-AFib/Get-With-The-Guidelines-AFib_UCM_448881_SubHomePage.jsp), we recommend tracking one or more of the following performance measures as part of an AF QI project.

- Assessment of thromboembolic risk factors with the CHADS₂ score in the inpatient care record for patients with AF
Numerator: # of patients with AF (ICD-9 Codes 427.3, 427.31, 427.32) having a CHADS₂ score recorded in physician clinical documentation at any point during hospitalization
Denominator: Total # of patients with AF diagnosis documented during inpatient stay
- Ischemic stroke patients (principal diagnosis) with AF discharged on anticoagulation:
Full specifications for this metric can be found at:
<http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPPage%2FQnetTier4&cid=1228773564870>.
- Documentation of a risk/benefit discussion with patient/family regarding anticoagulation in the inpatient care record for patients newly diagnosed with AF or requiring a change in their pre-hospital anticoagulation management
Numerator: # of patients with newly diagnosed AF (based on physician clinical documentation) plus # of patients requiring a change in pre-hospitalization anticoagulation management (based on clinical documentation) with risk/benefit discussion recorded in physician notes at any point during hospitalization
Denominator: Total # of patients with new AF diagnosis or change in pre-hospital anticoagulation regimen during inpatient stay
- 30-day all-cause unplanned readmission rate, measured in patients with principal or secondary AF diagnosis (ICD-9 Codes 427.3, 427.31, 427.32)
Specifications for the all-cause readmission metric can be found at:
<http://www.qualityforum.org/QPS/MeasureDetails.aspx?standardID=1789&print=1&entityTypeID=1>.

The metrics above are intended to be example starting points and can be adapted or revised according to hospital needs, regulatory requirements and the ongoing work of external groups (NQF, professional societies such as the AHA) aimed at development of better performance metrics for AF.

5.3 Define Data Collection Strategies

The main decision point regarding data extraction for AF QI relates to the availability of EMRs within your facility and the extent to which these systems contain data elements of interest that can be collected without manual chart review. Even if AF populations and use of associated anticoagulation treatments can be identified using EMR data, unless a structured note has been created to record stroke risk assessment, some manual extraction will be required.

For data elements that can be extracted electronically, a 100% case sampling approach should be used. For data requiring manual extraction, a random sampling approach (10 charts a month is typically adequate for a given unit or hospital) is a cost-conscious and well-accepted approach for process performance measurement.

Suggested guidelines to be established regarding the manual extraction process include:

- What is the sampling plan (what, where, when and how much data)?
- Who will record the data and what will be measured?
- What instrument(s) will be used to classify performance of the measure(s)?
- Is there a standardized data collection form?
- What sort of training will be required for those performing the data extraction?
- How will the data be logged and collated?
- How will a truly random patient sample be secured?

Data can be extracted from electronic sources more efficiently, but generates many of the same issues listed above, along with some new issues, such as:

- Where can the electronic data elements be found in an accessible format?
- Does the electronic data need to be transformed to be useful?
- Is the electronic data valid? How will this be checked?
- Are structured notes available?

5.4 Evolution in Data Collection

Initially, most hospitals will have to collect data using a hybrid approach of electronic and manual data extraction, as indicated in Table 10.

Table 10: Initial Data Collection Matrix for AF QI

Data Element	Source	Metric Supported
ICD-9 Codes	Administrative data	Population identification
CHADS ₂ score	Physician notes	Documented performance of stroke risk assessment
Anticoagulation at discharge; ICD-9 Codes	Medication records; administrative data	% of patients with ischemic stroke from AF discharged on anticoagulation
Risk/benefit assessment	Physician notes	Documentation of anticoagulation risk/benefit discussion with patient/family
ICD-9 Codes Relationship of AF to readmission	Administrative data Determining causality would require chart review	30-day all-cause readmission rate in patients with a discharge diagnosis of AF

Over time, as each hospital's EMR evolves, an increasing percentage of these data elements will be amenable to electronic extraction. Building infrastructure (in the form of note templates, interactive risk assessment tools embedded into the EMR, medication records, etc.) to support this type of streamlined data collection (and minimize reliance on manual chart review and multiple data sources) can be a very useful specific tactic in the QI program itself. Time invested early on in the project with IT collaborators to create discrete, readily extractable data elements for performance measurement and reporting will yield major returns. Ultimately, a functional "inpatient AF registry" containing clinical and administrative data would be a desirable future state, and could be used to generate customized reports.

Step 6

Deploy Interventions and Monitor Impacts

6.1 Implementing Your Protocol

After you have identified your AF performance metrics and determined your baseline performance on those metrics, your QI team will need to develop solutions and intervention strategies at various points of the patient encounter.

This section will provide possible strategies to improve the documented assessment of thromboembolic and bleeding risk factors with the CHADS₂ and HAS-BLED scores, respectively, in the inpatient care record, and documentation that patients with AF are prescribed warfarin or other anticoagulation for the prevention of cerebral thromboembolism if indicated based on risk and benefit as well as patient preference.

We recommend the following three-step approach to anticoagulation decision-making in patients with AF. Thus, the QI tactics outlined here are designed to facilitate such a process.

- 1) First, assess a patient's stroke risk using an established scoring tool as outlined in the earlier sections of this Guide during every hospital admission and record it in the chart or EMR to ensure that changes in stroke risk are updated every time.
- 2) Second, determine the patient's bleeding risk using the scoring tools as outlined in the earlier sections of this Guide.
- 3) Third, discuss the net benefit of stroke prevention and the bleeding risk with the patient and consider other factors such as patient preference and values, cost and patient compliance.

As you evaluate opportunities for systems change, consider incorporating key patient safety principles in your efforts:

- Reduce reliance on memory. Systems that combine clinician education with additional strategies that do not depend primarily on clinician memory to do all the necessary QI steps will provide the most comprehensive results.
- Use fail-safe systems and forcing functions. By using methods that integrate into provider workflow with fail-safe systems and forcing functions, your initiative will have a greater likelihood of success. Thus, provider-based point-of-care alerts within the EMR that require completion will ensure that the appropriate assessments will be done. Of course, electronic alerts will need to be well integrated into workflow so the requirements are easy to complete.
- Standardize and simplify processes. Assessments need to be standard across the care continuum so the same risk stratification tools are used every time. Clinicians will more likely accept processes that are simple and well designed and also not redundant. Assessments done on admission should not need to be completed again on discharge if clinical risk does not change.
- Enhance access to complete and timely information. To assist clinicians in completing assessments, access to a fully updated medical record will ensure that the information that is being entered is correct. For example, pop-up alerts, if within the EMR, should allow clinicians to close the alert, access clinical information and then return to the content of the reminder rather than forcing the clinician to complete the information with no opportunity to re-access the patient chart.
- Improve quality and cycle time. The goal of any QI project will be to obtain the desired results to improve the outcome of interest in a timely manner. Thus, your systems changes should lead to an increase in the percent of patients who receive stroke prophylaxis based on risk assessment over a defined period.

Once you have determined your baseline rates of anticoagulation in the AF population at risk for stroke, you can develop specific intervention strategies to ensure that stroke and bleed risk assessments are completed.

Layering multiple interventions to allow for process change rather than focusing on one particular intervention will improve the effectiveness of any QI initiative. The relative efforts placed on each intervention will depend on the infrastructure, the barriers to change and the resources at your institution.

One approach to structuring your project with the layering of multiple interventions is to consider the points in the patient encounter that are opportunities for intervention. Table 11 notes multiple interventions that will be discussed in more detail in this section and sorts their impact at various points in the patient encounter.

Table 11: Achieving Systems Changes — Timing Relative to Patient Encounter

	Admission	During Hospital Stay	Time of Discharge	Post-Discharge
Provider education	X	X	X	
AF protocol with risk and bleed tools	X			
Real-time decision support if anticoagulant dropped		X		
Discharge-based alerts to use risk and bleed tools			X	
Audit and real-time feedback		X	X	X
Patient education			X	X
Organization and operational change	X	X	X	X
Policy and incentives				X

6.1.1 Electronic Medical Record-Based Triggers in the Computer Physician Order Entry Environment

In hospitals that have an EMR and CPOE (Computer Physician Order Entry), systems change can occur by leveraging the technological capabilities of your IT systems. As you consider how the EMR can trigger the stroke and bleed risk assessment to appear for completion, one start point would be to use the admission order entry process that is completed by the physician to incorporate AF-related risk assessments. Your QI team will need to have an understanding of the capabilities of your individual hospital's IT systems and how the admission order entry is structured. For example, how you incorporate the AF risk assessment will partly depend on the scope of the admission order sets that are being used at your institution. Some hospitals use disease-specific order sets while others use generic admission order sets. This is an important distinction as you consider how to trigger assessments.

If your institution has disease-specific admission order sets for certain primary diagnoses, then the stroke and bleed risk assessment can be written into the AF-specific order set, which should be used for all admissions that have a primary diagnosis of AF. This process change can be effected through direct discussion with your IT department about incorporating the risk assessments but you may also need approval of this addition by various committees as is common in most hospitals. However, when a patient does not have a primary diagnosis of AF but a secondary or other diagnosis, then your process will not capture the AF patient, and the AF risk assessments will not appear. For example, if a patient is being admitted with pneumonia but happens to have chronic but known AF, the pneumonia admission order set is likely to be used to place admission orders, and the AF stroke and bleed risk assessment would not be embedded into such an order set. In those cases when AF is not a primary diagnosis, your QI team will need to utilize a different methodology to capture this type of patient such that the stroke and bleed risk assessment is done. The EMR will need to recognize that the patient has a secondary or other diagnosis of AF. See the section below on how the EMR can identify these situations.

If your institution has service-specific order sets that are not clinical diagnosis based, your QI team will need to consider if the AF risk assessments will be embedded into all of those order sets. For example, some hospitals have generic admission order sets such as those used for hospitalist general medicine, hospitalist telemetry, surgery or ICU admissions. The provider will still need to remember the patient has AF, either as a primary or other diagnosis, and to complete the AF risk assessment. If you chose not to embed the AF risk assessment into the generic order sets, then the AF stroke and bleed risk assessments will not be completed unless they are triggered to appear using another mechanism. In those situations, the EMR will need to recognize in real time that a patient has AF to allow for the stroke and bleed risk assessments to trigger.

Thus, in situations when the AF risk assessment is not written into the initial order set, your QI team will need to develop methods to trigger the AF risk assessments, a process that will greatly depend on the capabilities of your EMR. One strategy employed in many EMRs is to use the concept of problem lists at time of order entry to assist in triggering the assessments for AF patients. Although the notion of a problem list has typically been associated with a list that is written by the physician as part of his or her clinical note, problem lists can be developed in EMRs that are entered by the physician at time of admission order entry. Some EMR systems have a list of the most common medical diagnoses appearing at time of admission order entry and require the physician to place a checkmark next to all applicable diagnoses a patient may have. If AF is checked as a diagnosis (either primary, secondary or any), then the EMR can recognize this discrete data point. EMR-based code language can then be written such that if AF is in this list, it will trigger an AF-specific risk assessment. This process, however, will rely on the physician accurately completing the problem list. Another approach is to use ICD-9 diagnosis codes from prior admissions and link them to all future patient encounters. Thus, if the patient had AF at any time in the past, this discrete level of information will be associated with the patient during all future hospitalizations. EMR-based codes can then be written such that this diagnosis of AF can be used to trigger AF risk assessments.

Thus, the approach of how to trigger the AF risk assessment will differ based on your EMR and will require you to partner with your IT department in writing EMR code language to assist you in this process. In fact, many hospitals currently trigger reminders for a variety of quality metrics. The process used for deep venous thrombosis (DVT) prophylaxis is one example of such a reminder triggered in many EMRs. However, unlike this metric that requires risk assessment on all admitted patients, the AF risk assessment would only trigger if the EMR recognizes that the patient in question has a diagnosis of AF. You will need to individualize your approach based on your specific institution's EMR. The strategies noted below on alerts during the hospitalization and on discharge will also depend on your EMR recognizing that the particular patient in question has AF.

Ensuring AF risk assessment protocols are used in hospitals with paper-based medical records faces similar hurdles to those hospitals in the EMR world. If paper-based disease-specific order sets are being used, then the AF risk assessments can be incorporated into those order sets and will capture patients with a primary diagnosis of AF. There will need to be an additional strategy to capture those who have AF but for whom it is not a primary diagnosis and thus are not admitted with completion of the AF admission order set. In addition, there will need to be other approaches to ensure the risk assessment is done during hospitalization if anticoagulation is dropped. Similarly, strategies will need to be developed at time of discharge if an AF risk assessment has not been done and if anticoagulation is not being given for stroke prophylaxis, if indicated.

One additional consideration is to determine if your QI team wants to have an AF stroke and bleed risk assessment completed if the patient is already on anticoagulation for stroke prophylaxis for AF. For example, if a patient has known AF and is already on aspirin or warfarin, does your QI team require that a risk and bleed assessment still be completed and documented? One reason to require that this type of AF risk assessment still be completed is for situations when there is "under anticoagulation." "Under anticoagulation" occurs when aspirin is ordered but warfarin is more appropriate. Studies indicate that the under-prophylaxis rates may represent a significant problem and addressing these situations may substantially decrease the quality gap in evidence-based AF care.

If a patient has AF and is already on warfarin, EMR-based triggers will need to incorporate this information. Thus, your QI team may choose that AF stroke risk assessments do not need to be completed in these situations. The EMR codes will then need to be written such that the EMR does not trigger the assessments if it also recognizes an active order for warfarin. It is, however, suggested that risk assessments still be completed to ensure that there is full documentation of stroke and bleed risk even though anticoagulation for stroke prophylaxis is still in place.

6.1.2 Intervention 1: Focus on Provider Education

Current evidence indicates numerous reasons why almost 50% of patients do not receive evidence-based stroke prophylaxis when indicated. A significant contribution to this quality gap is a clinician knowledge gap in assessing benefit and risk of anticoagulation prophylaxis.

The first step in a successful AF initiative is to ensure that you have educated all providers at your institution on the tools for stroke and bleed risk assessment as well as current anticoagulation options based on these assessments. Your QI team should engage providers in educational seminars and lectures and increase visibility on the need for evidence-based assessments. Some approaches to address this knowledge gap include:

- Development of educational programs on stroke prevention in AF for providers at events such as grand rounds, noon conferences or division meetings. The focus of these sessions should be to review current anticoagulation guidelines for stroke prevention as well as scoring methodologies for assessment of bleeding risk.

- Distribution of educational materials (e.g., pocket cards with CHADS₂ and HAS-BLED risk scoring systems, handouts and clinical guideline reprints).
- Links to educational materials within order sets in the EMR environment. At the time of completion of an admission order set, links to the literature would be an excellent opportunity to provide valuable references that would assist in education of stroke and bleed risk for patients who have AF.
- Creation of visibility of AF initiative on patient floors. Posters, signs and project boards at your institution provide visible reminders of the key concepts of your QI project to all constituents in the hospital.
- Development of RN education campaign that could involve all members of the interdisciplinary team. By focusing education efforts on all members of the healthcare team, your stroke prevention efforts would be potentiated, as team members could work in conjunction with providers.
- Use of Web-based education tools that can be incorporated into the credentialing and re-credentialing process. Requirements to complete a Web-based program on common QI metrics could include anticoagulation efforts in the area of AF.
- Development of a continuing medical education (CME) program led by physician leaders with expertise in AF. Front-line hospitalists, academic leaders and cardiologists can provide education in structured CME formats.
- Identification of a physician champion to lead hospital-wide education efforts. An individual with visibility and respect within your institution can be used to effectively communicate the quality gap and discuss tools available to assist in provider decision-making.
- Development, promotion or dissemination of mobile applications that could be used by providers. Many medical-based calculators incorporate the stroke and bleed risk assessments that can be used in the decision-making process.
- Dissemination of information about quality initiatives at medical staff meetings. Incorporating data on the AF quality initiative at faculty meetings amongst other topics most often discussed such as value-based purchasing, patient satisfaction, readmission rates and adverse events will assist in the staff education process.

By educating providers about the importance of the use of stroke and bleed risk tools and guidelines on anticoagulant use, outcomes will be positively impacted as providers become self-compliant. However, other interventions will need to be layered into your QI project to reach optimal anticoagulant rates.

6.1.3 Intervention 2: Development of a Protocol on Admission

This intervention uses point-of-care decision-making by incorporating reminder systems in admission order sets. Provider reminder systems could link an AF stroke and bleed risk assessment to current order sets to ensure that all patients have these assessments performed upon every admission to the hospital. A survey of the capabilities of your EMR will allow you to understand how to ensure that the risk assessments appear on admission as they will need to be triggered only for patients who have a primary, secondary or other diagnosis of AF.

Please see the discussion above regarding how to develop EMR-based triggers for strategies on how to incorporate AF risk assessments. As noted above, some EMRs require providers to enter an admitting diagnosis or problem as part of the admission order set, which would allow you to develop a mechanism within the EMR system that would trigger AF-related content if AF has been entered as a diagnosis. If such a process does not exist, one approach would be to develop a list of common diagnoses and to require providers to click each diagnosis that applies from a list at the start of the admission order sets. By clicking AF within the problem list on admission, an AF-specific order set would be triggered.

If a diagnosis is not entered as a discrete EMR abstractable field as part of the admission process, a proxy method will need to be used for AF so these patients are identified. For example, some EMRs have within a patient encounter prior-billed ICD-9 diagnoses that are linked to the patient and carry forward with each new admission or encounter. EMR-based codes could then be written that would trigger AF-related risk assessments if a prior ICD-9 diagnosis included AF. In order to develop any of these EMR-based solutions, discussions with your Chief Information Officer or IT leaders will need to be undertaken to leverage important functions in your electronic environment. Regardless of the method used to trigger AF-related assessments, success in the implementation of EMR-based reminder systems will greatly depend on ensuring that physician workflow is not adversely altered.

Within the paper-based environment, the challenge will similarly be to ensure that all AF patients have within their admission order sets, or in their charts, appropriate stroke and bleed risk assessments. A simple first strategy would be to have AF-based assessment sheets on units with a high prevalence of AF. However, the clinician would still need to remember to obtain and complete a risk assessment sheet. One approach may be to have a nurse or unit director place the AF-specific order sets on all patients admitted with AF. This would be a human resource-intensive process. A broader strategy may be to have the AF order set as a preprinted attachment for all patients, which would ensure that all AF patients are included.

Other considerations in the paper-based hospital could be to include daily AF patient identification rounds within current interdisciplinary rounds to ensure the assessments are completed during some point in the hospitalization. A dedicated AF czar could be developed for this process who could possibly be a member of the AF QI team or a nurse champion in the hospital. Lessons learned from a floor-wide initiative undertaken on units that have a large proportion of AF patients can be evaluated and strategies can be expanded across other units.

One example of a paper-based assessment is that developed by the American College of Physicians as part of its Initiative on Atrial Fibrillation and Stroke Prevention. This assessment, which was focused on the outpatient setting, was disseminated to primary care providers (see Figure 4). This sheet includes guidance on appropriate anticoagulation options based on stroke and bleed risk. Once again, a challenge is to develop a system where all AF patients have this sheet completed in a way that does not rely on the memory of the clinician to access this form.

Figure 4: An Example of a Paper-Based Stroke and Bleed Risk Assessment on Patients on Admission

Step 1: Assess Stroke Risk	Step 2: Calculate Outpatient Bleed Risk Index																																																															
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td rowspan="7" style="text-align: center; vertical-align: middle;">CHADS₂</td> <td colspan="2">Record 1 point per condition when present, except previous stroke which gets 2 points</td> </tr> <tr> <td>Congestive Heart Failure</td> <td style="text-align: right;">_____</td> </tr> <tr> <td>Hypertension</td> <td style="text-align: right;">_____</td> </tr> <tr> <td>Age > 75 years</td> <td style="text-align: right;">_____</td> </tr> <tr> <td>Diabetes mellitus</td> <td style="text-align: right;">_____</td> </tr> <tr> <td>Stroke (2 points)</td> <td style="text-align: right;">_____</td> </tr> <tr> <td>TOTAL POINTS</td> <td style="text-align: right;">[]</td> </tr> <tr> <td colspan="3">Estimated risk of Stroke/Year w/o anticoagulants</td> </tr> <tr> <td><input type="checkbox"/> 0 = 1.9%</td> <td><input type="checkbox"/> 4 = 8.5%</td> <td></td> </tr> <tr> <td><input type="checkbox"/> 1 = 2.8%</td> <td><input type="checkbox"/> 5 = 12.5%</td> <td></td> </tr> <tr> <td><input type="checkbox"/> 2 = 4.0%</td> <td><input type="checkbox"/> 6 = 18.2%</td> <td></td> </tr> <tr> <td><input type="checkbox"/> 3 = 5.9%</td> <td></td> <td></td> </tr> </table>	CHADS₂	Record 1 point per condition when present, except previous stroke which gets 2 points		Congestive Heart Failure	_____	Hypertension	_____	Age > 75 years	_____	Diabetes mellitus	_____	Stroke (2 points)	_____	TOTAL POINTS	[]	Estimated risk of Stroke/Year w/o anticoagulants			<input type="checkbox"/> 0 = 1.9%	<input type="checkbox"/> 4 = 8.5%		<input type="checkbox"/> 1 = 2.8%	<input type="checkbox"/> 5 = 12.5%		<input type="checkbox"/> 2 = 4.0%	<input type="checkbox"/> 6 = 18.2%		<input type="checkbox"/> 3 = 5.9%			<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td rowspan="10" style="text-align: center; vertical-align: middle;">OBRI</td> <td colspan="2">Record 1 point per condition when present</td> </tr> <tr> <td>Age > 65 years</td> <td style="text-align: right;">_____</td> </tr> <tr> <td>History of Stroke</td> <td style="text-align: right;">_____</td> </tr> <tr> <td>History of GI bleed</td> <td style="text-align: right;">_____</td> </tr> <tr> <td>Co-morbid conditions ≥ 1</td> <td style="text-align: right;">_____</td> </tr> <tr> <td>Recent myocardial infarction</td> <td></td> </tr> <tr> <td>Hematocrit < 30%</td> <td></td> </tr> <tr> <td>Serum creatinine > 1.5 mg/dl</td> <td></td> </tr> <tr> <td>Diabetes mellitus</td> <td style="text-align: right;">[]</td> </tr> <tr> <td>TOTAL POINTS</td> <td style="text-align: right;">[]</td> </tr> <tr> <td colspan="3">Estimated risk of Major Bleed/Year w/anticoagulants</td> </tr> <tr> <td><input type="checkbox"/> 0 points: Low</td> <td>=</td> <td>0.8%</td> </tr> <tr> <td><input type="checkbox"/> 1-2 points: Intermediate</td> <td>=</td> <td>2.5%</td> </tr> <tr> <td><input type="checkbox"/> 1-2 points: High</td> <td>=</td> <td>10.6%</td> </tr> </table>	OBRI	Record 1 point per condition when present		Age > 65 years	_____	History of Stroke	_____	History of GI bleed	_____	Co-morbid conditions ≥ 1	_____	Recent myocardial infarction		Hematocrit < 30%		Serum creatinine > 1.5 mg/dl		Diabetes mellitus	[]	TOTAL POINTS	[]	Estimated risk of Major Bleed/Year w/anticoagulants			<input type="checkbox"/> 0 points: Low	=	0.8%	<input type="checkbox"/> 1-2 points: Intermediate	=	2.5%	<input type="checkbox"/> 1-2 points: High	=	10.6%
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Step 3: Put Fall Risk into Perspective

A stroke is usually worse for a patient than a major bleed.

The patient with a few falls, who is at 'average falls risk', and has a yearly stroke risk ≥ 2% (CHADS₂ score ≥ 1) would have to fall more than 300 times per year for the harm from falls to exceed the benefits of anticoagulation.

Step 4: Determine therapy given your assessment of potential benefit from anticoagulation

Therapy Guidelines: Benefits of anticoagulation almost always outweigh the risk.
Bleed risk is most relevant for patients with lower CHADS₂ scores.

CHADS₂ "0" = Aspirin "1" = Aspirin or blood thinners "≥2" = Blood thinners

Source: ACP Foundation, <http://www.acpfoundation.org/afib/briefing/afib-worksheet.pdf>.

Hospital-based VTE prevention through the use of anticoagulation prophylaxis is an example of where robust systems reminders have been developed within EMRs as well as paper-based admission order sets at most institutions. Of course, a key difference is that VTE risk is assessed on every patient and does not depend on the EMR or paper system to identify a clinical condition and to trigger only for that condition, as in the case of AF. Thus, as outlined above, the greatest barrier to implementing this intervention is in identifying that the patient has AF and requiring a risk assessment.

6.1.4 Intervention 3: Real-Time Decision Support for Anticoagulation Prophylaxis

There may be a proportion of patients who are captured appropriately on admission for stroke and bleed risk assessment and are started or continued on anticoagulation but may have had it discontinued due to procedures or temporary bleeding contraindications. In these situations, additional strategies should be sought to re-capture these patients for assessment during their hospital stay. This segment of patients, whose anticoagulation was dropped for acceptable reasons, represents a patient population that, if re-captured for anticoagulation, would contribute positively to your outcomes measures.

Similar to the issues noted in Intervention 2, identifying AF patients within the EMR will remain the most difficult challenge. However, if they are appropriately identified through problem lists or another method noted in Intervention 2, the EMR can be leveraged to scan patients who meet the requirement of a diagnosis of AF and the lack of the presence of an anticoagulation order. IT-based codes for alerts can then be written such that CPOE-based reminders trigger when a patient has been tied to a diagnosis of AF and is not on anticoagulation. These alerts could be scheduled to run every 24 hours for patients who meet the appropriate criteria. In those instances, anticoagulation can be restarted at the appropriate time during their hospital stay when procedures are complete or when temporary contraindications to anticoagulation no longer apply.

The approach addressed in this intervention can lead to an increased rate of evidence-driven stroke prophylaxis during the hospital stay and subsequently at discharge. Re-initiation of anticoagulation will need to ensure that post-procedure bleeding risk is low enough for the benefit of anticoagulation and that it does not exceed the risk. In addition, patients admitted on anticoagulation to the hospital who are admitted for procedures may knowingly have anticoagulation held during the admission until they are post procedure. Thus, these alerts would remind providers within the CPOE environment to re-initiate anticoagulation in AF patients if it was held during any point in the hospitalization for procedures.

An important consideration for your QI project may be the notion that repeated alerts for risk assessment may lead to the phenomenon of “alert fatigue” where the frequency of alerts would be a barrier to effective clinician workflow. Thus, involving an interdisciplinary team in QI strategy development will be essential to ensure that there is health system and provider buy-in to your process changes and that there is judicious use of CPOE-based alerts.

6.1.5 Intervention 4: Discharge-Based Alerts

Similar to alerts on admission at the time of initial order entry and during hospitalization in situations when anticoagulation is temporarily dropped, EMR-based alerts at the time of discharge within the CPOE environment represents another opportunity to do the appropriate risk assessments and to start stroke prophylaxis in AF patients. Thus, your QI team may choose the discharge as the point in the patient encounter to initiate risk assessment instead of at the time of admission or during hospitalization. Alternatively, you may choose to use this point in the patient encounter as another opportunity for assessment in addition to those other points in time. Thus, if systems failed to capture the patient earlier, the patient would be captured at the time of discharge. Once again, AF would have to be a discrete field within the EMR for it to recognize the need to trigger the alert, and there would need to be a cross-reference to ensure the lack of an anticoagulant order. Your IT department can provide guidance on the capabilities of your individual IT systems.

The discharge process is often compromised due to time limitations faced by hospitalists. Prioritization must occur such that less time-intensive interventions are acted upon, with those that are more time-intensive passed off in a safe transition to the primary care providers. Thus, in some cases, the benefit of anticoagulation may clearly exceed the bleeding risk, and the decision to initiate prophylaxis may be quite overwhelming. In these cases, the clinician should advocate for the use of anticoagulants to the patient at time of discharge. Of

course, the patient's values in considering their propensity to prevent stroke relative to the risk of facing a bleeding event should still be considered and discussed. In other situations, there may be instances when the stroke prevention benefit may approach or equalize bleed risk. In those difficult situations, although it would be most ideal to make the anticoagulation decision involving the patient at the time of discharge, it would be acceptable to discuss the results of your risk and bleed assessment with the outpatient physician who can continue the conversation with the patient to discuss these risks and benefits on outpatient follow-up.

6.1.6 Intervention 5: Feedback of Performance to Providers

Feedback to providers regarding the progress in achieving your AF QI project outcomes can be an effective method to support the change process. Reports detailing outcomes results can be hospital, unit or provider specific. In addition, the results can be in real time or upon audit after discharge. To obtain real-time reports, your EMR would have to abstract patients with a primary or any diagnosis of AF and report if a stroke and bleed risk assessment was completed. In addition, the report could also outline if anticoagulation was started or if the clinician deferred stroke prophylaxis based on risk/benefit or due to patient preference.

Real-time outcomes information is actionable and can improve your desired outcomes metrics. For example, a real-time report generated based on a particular physician's census would allow that physician to see a list of his or her AF patients while in the hospital with corresponding completion or pending status of their AF stroke and bleed risk assessments along with the choice of anticoagulant if any. Real-time reports can also be generated per unit that would allow one to see the same information for the entire unit rather than only for one physician. Interdisciplinary rounds with members of the care team could incorporate a discussion on the stroke and bleed risk scores and the prophylaxis decision by viewing this type of report during rounds. A unit medical director, AF czar or other AF QI team member could also use the real-time report to encourage the completion of tasks to better adhere to your process and outcomes measures. The generation of this type of real-time data is more difficult for hospitals that are not EMR based but could be completed with chart reviews if focused on a high AF area such as telemetry floors. The process chosen and methods to extract such data would need to be individualized to the resources available at your particular institution.

Similar to real-time data evaluating whether a patient with AF had stroke and bleed risk assessments completed, post-discharge data could be obtained looking at the same metrics. Thus, reports could be generated monthly or for any specified time range within your chosen AF QI measures. The results can then be conveyed to a particular unit and its leadership or a particular physician group such as hospitalists or cardiologists. Furthermore, the results could be further stratified at the physician level and made available to individual providers. Recognition can then be given to the highest performers, either at the unit, group or individual provider level. In addition, transparency in the outcomes results can further motivate those groups or individual physicians with the lowest percentage of patients with stroke and bleed risk assessments completed to improve their results. Benchmarking the top performers can lead to a very positive modeling effect for other lower-performing providers. It is critical that your QI team determine the best approach in providing feedback based on your institution's norms and culture.

6.1.7 Intervention 6: Patient Education

Ensuring patient compliance with the plan to care for anticoagulation in AF is critical for your QI project to succeed. Although anticoagulants will be provided while in the hospital, the likelihood of patient compliance is much greater if education is started while patients are in the hospital. In addition, focused education to patients at increased risk for stroke from AF can be a motivator for patient involvement in their care. This type of patient involvement may also encourage them to be an advocate for themselves in obtaining evidence-based stroke

prophylaxis by starting the discussion with their physician. Stroke prevention education can be initially targeted at high AF burden floors such as cardiac telemetry units. Patient education can take the form of pamphlets, educational handouts or even media-based education such as a closed-circuit television program in patient rooms.

To ensure that all patients with AF have education regarding stroke risk, a task requirement could be sent directly to an RN through the EMR based on a physician order or could automatically be triggered within the EMR if AF is a recognized patient problem. Many hospitals do a mandatory patient assessment for quality metrics such as influenza or pneumovax administration to which AF stroke risk education could be added if applicable. Anticoagulation specialized pharmacists may be an important resource for your QI project and can be used in patient education. In addition, visibility of the tenets of your QI project on hospital floors and common areas where patients may ambulate will reinforce the other patient educational strategies that your QI team uses.

6.1.8 Intervention 7: Organizational and Operational Change

As noted in an earlier section of this Guide, creating a shared need for your QI project with important constituencies in the hospital and obtaining institutional support from hospital administration will be critical to your QI group's success. Your team will need to procure resources and infrastructure to allow you to operationalize your project. In addition, you will need to develop new roles to support the functions necessary for AF stroke and bleed risks to be completed. In hospitals that are paper based, new administrative support personnel may be needed to ensure continuous placement of AF protocol order sets in the records of patients with AF, either in high AF burden floors or hospital wide. For hospitals that are EMR based, additional hospital-wide AF QI teams will ensure that this project gets the necessary human resource rich attention that may be required to ensure that the IT-based steps outlined in this Guide are developed and operating as planned. Frequent overview and fine-tuning of the processes developed for AF patient identification will be an ongoing task that can be continually addressed by AF QI teams. Physician, nurse and pharmacy leaders currently dedicated to ensuring other QI metrics are met can incorporate AF QI goals within their job responsibilities and take accountability for the results of your project. In settings where they are available and charged with this responsibility, clinical documentation specialists used by hospitals to assist in coding and billing can be used to enter AF into active EMR-based problem and diagnosis lists so appropriate AF risk assessments can be triggered. Similarly, for medical groups whose physicians code their own charts for billing, additional documentation specialists can provide assistance at various phases of your project.

6.1.9 Intervention 8: Hospital-Based Policy and Incentives

An important aspect of change management is the formation of hospital policy that supports the processes developed within your AF QI project. For example, to ensure that all patients have stroke and bleed risk assessments completed, a hospital may develop policies that require completion of this process through the use of IT-based prompts with “hard stops” such that the clinician cannot move through the ordering process without completion or the documentation of contraindications to appropriate anticoagulation. In addition, the hospital may have external financial incentives based on the achievement of AF anticoagulation performance goals and could in turn reward the highest performing groups or individual physicians based on achievement rates of their AF QI metrics. This reward may be recognition or an actual financial incentive based on performance goals.

6.2 Monitoring the Effect of Your Interventions

Tracking and trending data over time will be important to monitor the progress of your QI project. Robust data collection strategies will be needed to track your performance over time through the EMR or by random sample abstraction of paper charts.

Your QI team may choose to track a variety of different outcomes, such as the percentage of patients who have stroke and bleed risk assessment completed or the percentage of patients on evidence appropriate anticoagulation. The point in time for this outcomes check may be on admission, during hospitalization or upon discharge. You may track your percentages per hospital floor, service or providers. The duration of examination will need to be determined by your work group. Visual methodologies, such as graphs or run charts, may enhance your ability to understand and communicate your results. You will need to analyze any possible variation from your protocol to determine methods to improve your outcomes rates.

In addition, you will need to develop a control phase of your project. The control phase ensures the solution is sustained and the process will not revert to the original state. It also shares the lessons learned across the organization and helps accelerate similar improvements in other areas. The key components of a control plan include a strategy of maintaining the improved process performance over time and definition of specific actions and tools required for sustaining the process improvement or gains.

Step 7

Improve Transitions of Care for Patients with Atrial Fibrillation

7.1 Initiating Anticoagulants Using “Teach Back”

Patients who are newly prescribed anticoagulants must be educated about multiple aspects of medication management such as drug-related interactions, new dietary restrictions or the need for monitoring of drug therapeutic levels through blood draws. Studies indicate that up to 40-80% of medical information that patients receive is forgotten immediately and that nearly half of the information retained is incorrect. The “Teach Back” method is one effective way to ensure that the information you have explained to the patient is transmitted in a manner that the patient understands. Thus, clinicians have the duty to provide information in simple, clear and plain language and to check that patients have understood the information.

“Teach Back” begins with the clinician educating the patient and then asking the patient to repeat, in his or her own words, what the patient needs to know or do. Teach Back is not a test of the patient but of how well the clinician has explained the information. It is also a chance to check for understanding and, if necessary, to re-teach the information. Finally, Teach Back creates an opportunity for dialogue in which the provider gives information, and then asks the patient to respond and confirm understanding before adding any new information.

Despite recent research showing the many benefits of Teach Back, surprisingly few providers actually use it every day. It is likely that clinicians may not be familiar with the Teach Back method or may find it difficult to change their communication style. Teach Back is not time consuming and, at most, only takes a minute or two, but this technique may require a little practice to master. It is suggested that clinicians begin by using Teach Back with only the last patient of the day, just once or twice a week. Once clinicians are more confident of their skills, then the Teach Back method can be used more often. It is important to remember the Teach Back process can be used any time health information is provided to patients including providing instructions, teaching a technique for medication administration or even explaining a diagnosis. In the instance of anticoagulation use, proper understanding of the concepts of medication management will lead to better medication adherence.

7.2 Post-Discharge Phone Call

Studies indicate that the first 48 hours after discharge from the hospital represent a vulnerable time for patients to re-present back to the emergency room or hospital setting due to factors such as lack of understanding of medication management, symptom onset without having an action plan or anxiety relating to their illness. Although it is suggested that patients follow up with their primary care doctor after discharge, there may be a time lag between hospital discharge and outpatient follow-up. The discharge phone call is an effective method to communicate with patients during this gap in time to further discuss their medical concerns, reinforce the discharge plan or help with problem solving. Many of the areas of vulnerability for the AF patient revolve around medication management and often lead to medication errors after discharge.

The post-discharge phone call may be done by the nurse who managed the patient or by a staff member from the unit from which the patient was discharged. The caller should review a copy of the discharge summary and instructions prior to speaking with the patient. Typically the phone call is done the next day after discharge.

Important questions to ask the patient with AF during the post-discharge phone call include:

1. Were you able to obtain all of the medications that were prescribed to you?
2. Are you documenting when you are taking the medications to ensure that you are not unintentionally missing any doses?
3. Do you have any questions about the information provided to you in your discharge instructions?
4. Do you have any confusion regarding the brand and generic names of the medications given to you?
5. Are you having any side effects from your medications?

6. If you develop symptoms, do you know which are severe enough to call 911 or which can be addressed by a phone call with your doctor?

7. Do you know when your follow-up appointment is scheduled with your doctor?

If on warfarin:

8. Do you know when your next INR check is scheduled?

9. Do you know who or which doctor will follow up with the INR result?

10. Does your doctor have a way to reach you promptly to discuss any dose changes?

11. Do you have any questions regarding dietary instructions?

7.3 Elements of a "Quality" Discharge

It is imperative that there is a safe evidence-based care transition from the inpatient to the outpatient setting for the patient with AF. Some components of the discharge process include careful medication reconciliation, completion of a discharge summary with forwarding to the primary care doctor within 24 hours, education of the patient on a symptom management plan, and the placement of a call to the primary care doctor to discuss the hospital course and all follow-up issues. It is very important to assist the patient in the scheduling of a timely follow-up appointment with the primary care doctor. The discharge process should also include a review of the medication profile to reduce polypharmacy and thus possibly reduce bleeding risk. If the risk of bleeding is significant, referral to a dedicated anticoagulation clinic should be a strong consideration.

Communicating with the primary care physician and/or primary cardiologist is crucial for transitioning the patient from the hospital setting to the outpatient arena. In addition to a discussion of the medical issues from the inpatient encounter, clear communication with the follow-up physician should be used to delineate the possible need for rapid follow-up and details of what should be monitored. If warfarin is utilized, it should be discussed whether the patient will have a warfarin clinic referral, what the appropriate doses are and the date of all follow-up appointments. If the patient is prescribed a novel anticoagulant, the discharging physician should communicate the importance of monitoring renal function.

7.3.1 Assess Risk for Noncompliance

At the time of discharge, it is also important to consider the direct and indirect costs for the anticoagulant options for stroke prophylaxis in AF. Insurance coverage should be checked by calling the patient's outpatient pharmacy. Pre-authorization should be completed if needed. An estimate of the out-of-pocket costs should be available and presented to the patient at time of discharge to ensure that there are no financial barriers to anticoagulant adherence.

Assessment of the adequacy of healthcare access should be made at time of discharge. Patients with proximity to a warfarin clinic (preferably one with time in therapeutic range (TTR) ~ 66% or better) are more likely to have better outcomes if warfarin is the anticoagulant that is chosen. It should be made clear to the patient whether a primary care provider or cardiologist will assume responsibility of anticoagulation management.

7.3.2 Ensure Adequate Patient Education

If warfarin is used at time of discharge, warfarin teaching by the treating physician and, if available, the inpatient clinical pharmacist and nutritionist, should be completed. Reliable attention to patient education at the point of discharge from an acute care hospitalization will increase the likelihood of patient compliance and decrease the likelihood of readmission.

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Appendix
Additional Atrial Fibrillation Resources

General Resources

- [American Heart Association-Atrial Fibrillation Information](http://www.heart.org)
www.heart.org
- [American Stroke Association](http://www.strokeassociation.org)
www.strokeassociation.org
- [AntiCoagulation Europe](http://www.anticoagulationeurope.org)
www.anticoagulationeurope.org
- [Atrial Fibrillation Association UK](http://www.atrialfibrillationassociation.org.uk)
www.atrialfibrillationassociation.org.uk
- [Cleveland Clinic AF Center](http://www.my.clevelandclinic.org)
www.my.clevelandclinic.org
- [Heart Rhythm Society-Atrial Fibrillation Patient Site](http://www.hrsonline.org)
www.hrsonline.org
- [Journal of Atrial Fibrillation](http://www.jafib.com)
www.jafib.com
- [Mayo Clinic: Atrial Fibrillation Information Site](http://www.mayoclinic.org)
www.mayoclinic.org
- [MedicineNet.com Atrial Fibrillation Index](http://www.medicinenet.com)
www.medicinenet.com
- [Medline Plus-Interactive Atrial Fibrillation Tutorial](http://www.nlm.nih.gov)
www.nlm.nih.gov
- [Medscape: Atrial Fibrillation Resource Center](http://www.medscape.com)
www.medscape.com
- [National Blood Clot Alliance](http://www.stoptheclot.org)
www.stoptheclot.org
- [National Stroke Association: Atrial Fibrillation Information](http://www.nsa.convio.net)
www.nsa.convio.net
- [The AFIB Report](http://www.afibbers.org)
www.afibbers.org
- [TheHeart.org - Arrhythmia/EP Site](http://www.heart.org)
www.heart.org
- [WebMD: Atrial Fibrillation Health Center](http://www.webmd.com)
www.webmd.com

Atrial Fibrillation Reports and Coalitions

- [Action for Stroke Prevention](http://www.stopafib.org) — *How Can We Avoid a Stroke Crisis* (a report issued by the European Parliament)
www.stopafib.org
- [Alliance for Aging Research](http://www.silverbok.org) — *The Silver Book: Thrombosis*
www.silverbok.org
- [Facing AFib](http://www.15everyhour.com) — Includes a book, *AFib and Stroke: The Heart Head Connection*
www.15everyhour.com

Physician Resources

- [2006 Guidelines for the Management of Patients with Atrial Fibrillation](#) — ACC/AHA/ESC, *Circulation*. 2006;114:e257-e354
www.circ.ahajournals.org
- HRS/EHRA/ECAS, Heart Rhythm Society [Internet], Copyright, 2007
www.hrsonline.org
- [Guidelines for the Management of Atrial Fibrillation 2010](#) — European Society of Cardiology (ESC)
www.escardio.org
- [The Canadian Cardiovascular Society Atrial Fibrillation Guidelines 2010](#)
www.ccsguidelineprograms.ca
- [2011 Focused Updates Incorporated Into the ACC/AHA/ESC 2006 Guidelines for the Management of Patients with Atrial Fibrillation](#) — ACCF/AHA/HRS
www.circ.ahajournals.org
- [2011 Focused Update on the Management of Patients with Atrial Fibrillation \(Update on Dabigatran\)](#) — ACCF/AHA/HRS
www.circ.ahajournals.org
- [Simplified AHA Atrial Fibrillation Treatment Guidelines](#)
www.heart.org
- [Drug Digest](#)
www.drugdigest.org
- [Drug Information Online](#)
www.drugs.com
- [Medline Plus Drug and Supplements](#)
www.nlm.nih.gov
- [PTINR.com](#) — focused on warfarin
www.ptinr.com
- [WebMD Drugs & Interactions](#)
www.webmd.com

Patient-Centered Resources

- AF-ideas.com
- AfibTreatment.com
- [My Atrial Fibrillation Story- 1 year post Wolf MiniMaze 8/3/2006- Russell David Ward](#)
www.weststreetconsulting.com
- [Young Afibbers Blog](#)
www.youngafibbers.blogspot.com

Other Resources with AF-Related Content

- [Health Power for Minorities](#)
www.healthpowerforminorities.com
- [National Forum for Heart Disease and Stroke Prevention](#)
www.hearthealthystrokefree.org
- [Nurse Practitioner Healthcare Foundation](#)
www.nphealthcarefoundation.org
- [Preventive Cardiovascular Nurses Association](#)
www.pcna.net
- [Spirit of Women Hospital Network](#)
www.spiritofwomen.org
- [World Heart Foundation](#)
www.world-heart.org

