# Impact of a Quality Improvement And Education Initiative on 'Appropriate' Use of Anticoagulant Therapy in Women with Atrial Fibrillation

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## I. OVERALL AIM AND OBJECTIVES

Atrial fibrillation (AF) is the most common significant cardiac rhythm disorder and is also the most powerful common risk factor for stroke: about 15% of all strokes in the U.S. are attributable to AF. Its frequency increases with age, reaching a prevalence of 10% in persons over age 80. With the aging of the U.S. population, the prevalence of AF will increase substantially from over 2.2 million to more than 3 million by the year 2020. In particular, the risk of stroke in women with AF is underappreciated.[1] A recent study by Conen and colleagues showed middle-aged women to be at significantly increased risk of death from AF.[2] Furthermore, studies have shown that populations of women at equivalent risk of stroke are less likely to receive anticoagulant therapy than men.[3] Over the past decade, numerous randomized trials have established that anticoagulation can significantly reduce the stroke risk posed by AF. However, studies have documented widespread underutilization of this therapy, or, at times, inappropriate use. As a result the recognition of stroke risk from AF and its prevention have become a high profile issue for many organizations. The American College of Physicians recently has moved ahead with an initiative on atrial fibrillation and stroke prevention. Similar initiatives have been promulgated by the American Heart Association, and treatment guidelines continue to be publicized by the American College of Chest Physicians (ACCP) and the American College of Cardiology. **The goal of this project is to reduce the risk of stroke in women by using a computerized decision support tool for individual patient-level decision-making about oral anticoagulant therapy (OAT) in ambulatory patients with non-valvular AF.**

We propose to study the impact of adding a quality-improvement (QI) intervention to an educational activity (for practice staff and clinicians) using a computerized decision support tool for individual patient-level decision-making about OAT in patients with non-valvular AF. The QI tool will incorporate individual patients' risk factor profiles for ischemic stroke and bleeding. We will accomplish this by performing a cluster randomized clinical trial of an educational activity, with and without the addition of the QI intervention.

**Specifically, this project aims to:**

1. *Improve clinician and staff knowledge and ability to assess stroke and bleeding risk in the treatment of patients with AF.*
2. *Improve appropriate prescribing of OAT in patients with AF; and answer the question:*
3. *Does addition of a QI intervention utilizing an AF decision support tool result in larger improvements in "appropriate" antithrombotic therapy and provider knowledge about stroke and bleeding risk than an educational intervention alone as an adjunct to ordinary care?*

The UCHealth Primary Care Network (PCN) consists of 15 primary care practices (general internal medicine, internal medicine/pediatrics, and family medicine) in the Greater Cincinnati area. These practices include two urban residency training sites (University Hospital Internal Medicine and Medicine-Pediatrics), the University Hospital Internal Medicine Faculty Practice, and 12 urban and suburban community sites, including several practices that provide services to Medicaid and underserved populations. All practices in the PCN use a common electronic health record (EHR). A centralized data warehouse containing clinical information for the entire

PCN is housed in the University's Center for Health Informatics (CHI). There are 69,000 unique patients with at least one primary care visits in the last 12 month period.

Although appreciation of stroke risk and appropriate preventive treatment with anticoagulation therapy is a significant issue for women, interventions of the type we are proposing are not practical unless applied to all at-risk patients in a primary care practice. Therefore our ***target patient audience*** will include female and male patients with non-valvular AF. We recognize that a patient's clinical course is a dynamic process over time. Factors that influence the risk of stroke or bleeding may change; therefore we will continually reexamine the anticoagulation decision in light of new and changing clinical information. We will focus our intervention on prevalent (rather than incident) AF in the **ambulatory setting**. In order to be respectful of clinicians' and patients' time, our implementation strategy will focus on a reexamination of the decision on patients for whom the current anticoagulation decision **may not** be optimal.

Our ***target audience for the educational intervention*** will include clinicians and clinical staff at the 15 UCHealth PCN practice sites to be involved in the study (more than 50 primary care physicians and their clinical staff). The intervention arm deploying the QI initiative will address some of the recognized physician barriers to the appropriate prescribing of warfarin by providing timely and patient-specific information regarding the patient's risk for thromboembolic stroke and major hemorrhage, along with a decision analytic projection of gain or loss in quality-adjusted life expectancy resulting from the use of OAT compared with aspirin or no treatment.

## II. CURRENT ASSESSMENT OF NEED IN TARGET AREA

The recognition of stroke risk from AF and its prevention have become a high profile issue for many organizations. The ACP recently has moved ahead with an initiative on atrial fibrillation and stroke prevention. Similar initiatives have been promulgated by the AHA, and treatment guidelines continue to be publicized by the ACCP and the ACC. Despite steady improvements over the past two decades[4, 5], studies continue to document substantial underutilization and at times inappropriate utilization of OAT.[6-9]

**Preliminary Data:**

Our own data on the use of anticoagulation therapy in an Ohio Medicaid population show that only 9.7% of all patients and 11.9% of those without apparent contraindications filled prescriptions for warfarin in the period from 7 days proceeding, to 30 days after, the development of AF.[10, 11] We assembled a retrospective, observational cohort of Ohio Medicaid patients from January 1, 1997 through May 31, 2002 analyzing 6,123 Ohio Medicaid recipients with two or more claims containing an International Classification of Diseases, Ninth Revision, Clinical Modification code (ICD-9-CM) for AF (427.31) during the study period. We used pharmacy claims data to verify use of warfarin. We utilized a decision analytic tool that incorporates patient-specific risks for ischemic stroke and major bleeding events and calculates expected outcomes for patients with atrial fibrillation with and without warfarin treatment.[12, 13] This decision support tool (DST) explicitly accounts for the risk of bleeding and formally addresses the balance of risk of bleeding with the benefit of stroke prevention. It is designed to

individualize treatment recommendations based upon a patient's age, gender, and different degrees of risk for thromboembolism and hemorrhage by predicting quality-adjusted life years (QALYs).

The mean (SD) age of the study population was 76.2 (13.4) years. The majority of patients were women and were white. The population had numerous comorbidities known to increase the risk of stroke in AF, particularly hypertension, congestive heart failure, diabetes mellitus, and prior myocardial infarction. The DST recommended warfarin for 3,008 patients (49%); however, only 298 (9.9%) of these were prescribed warfarin. In particular, of 2,278 women for whom the DST suggested oral anticoagulant treatment, only 209 (9%) were receiving such therapy. In contrast, 89 of 432 (21%) men for whom oral anticoagulant was suggested were receiving such therapy. Women were almost 2.5 times less likely to be prescribed warfarin in a population typical of that seen in many of the PCN practices.

Regarding the consequences of underutilization or inappropriate oral anticoagulation therapy, we calculated hazard ratios for strokes and bleeding events among the two groups with treatment that was either concordant or discordant with the recommendations of the DST. In the first group - patients recommended for anticoagulation by the DST and receiving warfarin (compared to those recommended for anticoagulation, but not actually receiving warfarin), there was a trend towards a decreased risk for stroke (0.9, 95% CI: 0.58 – 1.41) with warfarin treatment. The lack of a statistically significant difference in stroke risk may be secondary to the low overall use of warfarin in this cohort. In patients for whom withholding anticoagulation was recommended by the decision support tool (compared to those NOT recommended for anticoagulation and not receiving warfarin) there was a statistically significant increased risk of gastrointestinal bleeding. In the final adjusted Cox proportional hazards model using the covariate of propensity for warfarin prescribing, the relative hazard for gastrointestinal bleeding was 1.54 (p=0.031). Thus, for this group of patients OAT may actually result in more harm than benefit.

A recent systematic review comparing current treatment practices for stroke prevention in AF with published guidelines showed underuse of oral anticoagulants in high risk patients in the majority of 54 studies reviewed.[9] Among patients in 29 studies with a history of prior stroke or transient ischemic attack (TIA) who should be receiving anticoagulant therapy, treatment levels averaged less than 60% (range 19% - 81.3%). Among high risk patients with a $CHADS_2$ score[1] ≥ 2 treatment levels averaged less than 70% (range 39% - 92.3%). While there has been a trend towards improvement in utilization of anticoagulant therapy over the past decade[5], a study of community-based practices in the Christiana Care Health System in northern Delaware published in 2012, continued to show substantial underutilization with almost one-third of high risk patients ($CHADS_2$ score ≥ 2) never receiving anticoagulant therapy despite the absence of identified barriers to such treatment.[7] Interestingly, in an analysis of predictors of warfarin use among the 1,141 patients studied there was a trend among men to be more likely to receive treatment. In an analysis of predictors of warfarin interruptions, there was a trend towards an increased risk in women.

Surveys exploring barriers to optimal anticoagulation have identified numerous issues. In our own analysis of Ohio Medicaid recipients with AF, we identified several factors including

[1] Stroke risk score based on **C**ongestive heart failure, **H**ypertension, **A**ge ≥ 75, **D**iabetes, and previous **S**troke.

alcohol or other drug abuse or dependence, psychiatric disease, homelessness or inadequate housing and lack of a caregiver as significant predictors of warfarin non-prescribing.[10] Clinician awareness of the benefit of anticoagulation therapy in stroke prevention has been identified as a barrier in a study by Cohen and collegues.[14] Beyth and colleagues noted that physicians were less likely to prescribe warfarin for older patients.[15] Others have shown that advanced age, female sex, and rural residency predicted underuse of OAT.[16] The pivotal physician-related factor seems to be an insufficiently balanced evaluation of the risk versus benefit of OAT.[17]

Several studies have shown that women, particularly older women, are less likely to receive OAT for AF.[18-20] Fang and colleagues explored this issue in the large community-based AnTicoagulation and Risk factors In Atrial fibrillation (ATRIA) cohort of 13,559 AF patients in the Kaiser Permanente system of northern California. They found that women not taking oral anticoagulants were at higher risk for stroke than men at both younger and older ages, with an adjusted relative risk of 1.6 (95% CI – 1.0 – 2.3) and 1.8 (95% CI – 1.4 – 2.3) respectively among patients ≤ 75 years of age and > 75 years of age.[21] Several mechanisms have been proposed for this observed difference in AF-related stroke, including observations that women with AF may have higher levels of von Willebrand factor, prothrombin factor F1.2, and tissue plasminogen activator antigen. Addressing this issue, the more contemporary stroke risk prediction tool $CHA_2DS_2VASc$[2], provides additional discrimination in risk score calculation on the basis of female gender.[22]

Regarding the inappropriate use of OAT, in low risk patients for whom current practice guidelines would not recommend anticoagulation (ie., age < 65 years, without a history of diabetes, hypertension, congestive heart failure, or previous TIA or ischemic stroke), upwards of 30% have been identified as receiving anticoagulant therapy.[5] In summary, both underutilization and inappropriate use of OAT occur in substantial numbers of patients. Furthermore, patients differ in their underlying risk for ischemic stroke, and their risk of major bleeding from anticoagulants. Thus, the decision to treat AF patients with antithrombotic therapy is ideally suited to a patient-centered decision analytic approach.[23]

## III. TECHNICAL APPROACH, INTERVENTION DESIGN AND METHODS

Utilizing a cluster randomization approach, we will randomize practice sites to either a control or intervention arm. This project will be reviewed by the University of Cincinnati Institutional Review Board.

**Overview:**

*Identification of Patients –* All eligible patients with non-valvular AF in each of the participating practices will be identified using appropriate ICD-9-CM codes (427.3x for any ambulatory visit or inpatient hospitalization over the past 1-year period).

*Collection of Clinical Information Needed to Run the Decision Support Tool –* Predictions of stroke risk and risk of major hemorrhage will be calculated for each patient using the $CHA_2DS_2VASc$, which provides additional discrimination for age (65 to 75), **female gender**, and

[2] Adds **V**ascular disease, **A**ge 65-74 years, **S**ex category to $CHADS_2$ score.

the presence of concomitant vascular disease[22]; and HAS-BLED[3] score. The necessary clinical information will be extracted from the University of Cincinnati's clinical data warehouse, housed in our Center for Health Informatics (CHI).

*AF Decision Support Tool Treatment Recommendation –* Once the annual stroke and major hemorrhage rates have been calculated in both the intervention and control practices, we will run each case through a decision analytic model that estimates the gain (or loss) in quality-adjusted life expectancy resulting from the use of anticoagulant therapy (warfarin in the base case) for each individual patient.[24] Using a decision analytic model allows us to incorporate patient values (utilities) into the decision making process. Life spent in less-than-perfect states of health, such as life following a non-fatal stroke, can be valued through multi-attribute metrics, such as quality-adjusted life expectancy, to facilitate explicit tradeoffs between the risks and benefits of therapies. Current antithrombotic therapy will be classified as either concordant or discordant with model recommendations as above.

*Description of Intervention –* For patients in the intervention group, a practice-level and physician-level summary report will be generated for all patients with treatment recommendations that are discordant with current therapy, along with an explanation for the recommendation, the gain or loss in QALYs predicted by the decision model and the current 2012 ACCP guidelines. Practices will be encouraged to revisit the anticoagulation decision in these patients, and processes to accomplish this will be developed in collaboration with the UCHealth Quality Manager and local practice leadership. All practices (intervention and control groups) will receive an educational activity focused on physicians, and clinical and non-clinical staff who would be involved in this QI process. This educational activity will consist of a didactic noon conference series on atrial fibrillation with a review of up-to-date anticoagulation guidelines for stroke prevention, and distribution of educational materials (e.g., pocket cards with $CHA_2DS_2VASc$ stroke risk assessment and HAS BLED risk factors). This activity will also review much of the data previously described in this proposal and will provide the opportunity for an open dialog among learners and faculty about potential strategies for improvement. These activities will all be certified for AMA Category 1 PRA credit and/or AAFP Prescribed Credit.

We will achieve our 3 objectives through the following activities:

*At ALL UCHealth PCN practices*:

1. Work with practice managers and QI physician leads to develop an informative and useful education activity along with a feasible approach to implementation.
    a. Work with the UCHealth PCN Quality Manager to meet with practice managers and QI physician leads to –
        i. design an educational activity that addresses the needs and perceived knowledge gaps in the practices; and
        ii. develop a convenient format for delivering this educational activity once developed.

[3] **H**ypertension, **A**bnormal renal/liver function, **S**troke, **B**leeding history or predisposition, **L**abile INR, **E**lderly (>65), **D**rugs/alcohol concomitantly).

2. Deliver the educational activity to all practice sites.
3. Working with staff and investigators in the CHI, we will use our EHR data warehouse to -
    a. identify all eligible patients with non-valvular AF in each of the participating practices;
    b. develop and implement computerized queries to extract the clinical and demographic information needed to calculate stroke and bleeding risk and to run the AF DST;
    c. develop a computer program to calculate for all identified patients in the control and intervention groups:
        i. the annual stroke rate using $CHA_2DS_2VASc$, and
        ii. the annual rate of major hemorrhage using the HAS-BLED score;
    d. develop a computerized routine to automate and batch process the application of the AF DST on all patients using demographic and clinical information from the EHR along with the calculated stroke and bleeding rates (above).
        i. Note: due to ethical considerations, the AF DST will not be used to make treatment recommendations for patients in the control group until the end of the study, at which time that information will be calculated and shared with the clinicians responsible for the care of those patients.

*At UCHealth PCN practices in the Intervention Group*:

4. Work with UCHealth PCN Quality Manager along with practice site managers and QI physician leads to –
    a. optimize the content, format, and delivery method for patient-specific information regarding individual patient level AF-related stroke risk, bleeding risk on anticoagulant therapy, treatment recommendation and projected gain/loss associated with OAT; and to
    b. develop QI processes and approaches best suited to each of the individual practices.
5. Generate anticoagulation treatment recommendations and expected gains/losses in quality-adjusted life expectancy (QALYs) for each patient in the intervention group, using the AF DST.
6. Deliver practice-level and physician-level reports for all patients with treatment recommendations that are discordant with current therapy, along with an explanation for the recommendation, the gain or loss in QALYs predicted by the decision model and the current 2012 ACCP guidelines.
7. Conduct academic detailing visits to the practices to implement QI processes to address this information. When possible (and reasonable), we will design QI to match the requirements for PI CME so that physicians can earn credit for their improvements.
8. Assess the impact of adding a patient-specific QI intervention to the educational activity through outcomes described in the following section (Evaluation Design).

## IV. EVALUATION DESIGN

**OVERVIEW:** Major outcomes will include before and after measures in both control and intervention groups, stratified by gender (as well as comparison of control and intervention groups at baseline and at project month 20) of:

- Percentage of AF population in each practice with treatment being discordant with decision model recommendations;
- Improvement in "appropriate treatment" following the intervention (or control), as defined by both the 2012 ACCP AF treatment guidelines[25] and the AF DST.
- Physician and clinical staff knowledge about AF, current treatment guidelines, the problems of underutilization as well as inappropriate use of anticoagulant therapy, and current stroke and bleeding risk prediction tools. This will be assessed using an AF knowledge assessment that will be developed by the research team.

We will expect to see a statistically significant improvement in both "appropriate" treatment and knowledge scores in the intervention practices compared with the control practices.

### *Baseline Measures –*

| Patient-level Measures | |
|---|---|
| | Age |
| | Gender |
| | $CHA_2DS_2VASc$ |
| | HAS-BLED |
| | Insurance Status and Type |
| | Treatment Recommendation – AF DST<br>ACCP AF guidelines |
| | AF DST projection of expected gain/loss (QALYs) with OAT |
| | Hormone Replacement Therapy or Oral Contraceptive Pills (current use) |
| Physician-level Measures | |
| | Specialty (Internal Medicine, Med-Peds, Family Medicine) |
| | Years in Practice |
| Practice-level Measures | |
| | Clinician FTEs |
| | Clinical Staff FTEs (RN, PA, NP) |
| | Non-clinical Staff FTEs |
| | Culture Survey[4] |
| | Location (urban vs. suburban) |

### *Outcome Measures (in control and intervention arms) –*

| Group being Evaluated | At baseline | At project month 20 |
|---|---|---|
| Physicians and Staff involved in performance improvement | | |
| | Atrial Fibrillation Knowledge Assessment | Atrial Fibrillation Knowledge Assessment |
| Practice sites | | |

[4] Culture Survey developed for the Greater Cincinnati Health Collaborative; contains information on organizational readiness for change.

| | | |
|---|---|---|
| | Patients with "appropriate" prescribing of OAT‡ | Patients with "appropriate" prescribing of OAT‡ |
| ‡ Determined by application of a) ACCP treatment guidelines and b) AF DST. Measured as absolute number and as percentage of AF patients. | | |

### *Estimate of Patient Numbers –*

Using data from UC's CHI, roughly 69,000 patients had at least 1 visit in the UCHealth PCN over a recent 12 month period. Of these, 1,378 had an active diagnosis of AF. 15% of these may have contraindications to anticoagulant therapy[9], leaving 1,171. In the largest community-based AF cohort, ATRIA, 55% of patients were at high stroke risk ($CHADS_2$ score ≥ 2)[4], suggesting, in our case, 644 high risk patients. The most recent literature-based estimates suggest that 35% of high risk patients are not receiving OAT.[6, 9] Thus, we estimate 419 patients receiving OAT and 225 not receiving it, among likely appropriate patients. Conversely, roughly 15% of patients with AF have no additional risk factors for stroke (ie, $CHADS_2$ score of zero),[4] in our case suggesting 176 low risk patients. In another study, 45% of such low risk patients were receiving anticoagulant therapy.[5] Based on these figures, we would expect that as many as 79 low-risk patients in the UCHealth PCN are inappropriately receiving OAT (97 appropriately not receiving OAT). Thus, we expect that as many as 304 UCHealth PCN patients could benefit immediately from this QI intervention. Rounding, we estimate there will be 150 patients with current therapy that is discordant from recommended therapy in the practices randomized to the control group, and a similar number in the practices randomized to the QI intervention group, while each group would have approximately 260 appropriately treated patients.

### *Data Analysis and Management –*

Data will be stored on our secure server at our Center for Health Informatics as spreadsheets, or in Oracle™ or Microsoft SQL™ as appropriate. SAS data files will be created as necessary for statistical analyses using unique coded patient identifiers.

The major outcomes of interest are "appropriate" prescribing of OAT and AF knowledge assessment scores. Two effects will be tested for each outcome: (1) Relative improvements or deteriorations in the two groups. The post intervention scores will be dependent variables, with group and outcome baseline scores as covariates – in other words, predicting Time 2 scores adjusted for Time 1. (2) Absolute improvement or deterioration in the intervention group scores, using a paired t-test or appropriate substitute. Note that although our primary outcome is concordance between the decision model recommendation and actual anticoagulant treatment, whether treatment is recommended or not, we also will examine results differentiating between patients recommended for treatment and those not.

For the above tests and in all models, practice-level covariates will be added when they are useful predictors and/or clinically meaningful. When supported by sufficient sample sizes, secondary analyses on subgroups based on physician factors, and patient-factors, such as gender, age, hormone replacement therapy, $CHA_2DS_2VASc$ and HAS-BLED scores, will be conducted. Patients and/or physicians will be treated as random effects in mixed models or as clusters using a GEE approach, in appropriate generalized linear models. We anticipate that

these analyses will be conducted using SAS Procedures GLM, GENMOD, MIXED, and GLIMMIX. Alpha for each test will be a two-tailed 0.05, unadjusted for multiple tests.

### *Power Estimates –*

Power estimates below assume a two-tailed alpha = 0.05. For our primary outcome measure, "appropriate" prescribing of OAT following the QI intervention, for 410 patients per group, 63% with appropriate treatment pre-intervention (see above), and **without** controlling for pre- vs. post-intervention correlations, we would have 80% power to detect a 9.4 percentage-point difference between the two groups. We expect a high pre-post consistency in "appropriate" prescribing within patients (.8 to .9). After adjusting for "appropriate" prescribing prior to the intervention, we would have 80% power to detect a difference of approximately **4.7 percentage-points** between groups. For comparing concordance rates at baseline to those post-intervention within the intervention group, would have 80% power to detect a change of 3 to 4 percentage-points in "appropriate" prescribing.

### *Evaluation of Educational Program and Qualitative Analysis of QI Intervention Processes –*

We recognize that the behavior of the clinicians and practice staff in response to the educational activity and the academic detailing visits is critical to assessing the outcome of this project. Each clinical practice has its own culture through which our interventions will be filtered prior to any changes in practice. Two team members will make an initial assessment of each practice's culture through a combination of observation, interviews with clinicians and practice staff, and standardized instruments. They will also assess the implementation of practice changes as an adaptation to the practice culture after the project educational interventions. This will also be accomplished via interviews with key practice personnel and observations by the two team members. Interview transcripts will be analyzed via standardized qualitative analyses methods.

### *Impact and Generalizability –*

At the completion of this project we will have accomplished several important goals: 1) the development and dissemination of a valuable educational activity through our local health care system's primary care network; 2) development, dissemination, and testing of a quality improvement intervention to improve decision making about oral anticoagulation therapy for patients with AF. Given the broadening use of electronic health records, if this intervention proves effective, it should be scalable and generalizable to other sites and health care systems in the United States. This project necessarily requires a retrospective chart review to identify AF patients to which the DST is applied. However, the real impact of this tool is at the point of care when patients are diagnosed with AF and physicians are discussing treatment plans with patients. This tool is an adjunct to patient education and engagement and should have a direct impact on patient adherence as well as other barriers to optimal care.

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## Detailed Work Plan and Deliverable Schedule

This is a two-year project with integrated deliverables that fall into three fundamental areas: 1) Practice Engagement and Tool Development, 2) Systems and Practice Changes, and 3) Outcomes Assessment/Research. The first 6 months will focus on meeting with the intervention practices to collaboratively develop content and templates for communication of patient-level information about stroke and bleeding risk, treatment recommendations, AF DST projected gain/loss from OAT, etc., and plan QI processes. During this time we also will meet with practices in both intervention and control arms to plan and develop the educational activity content, format, and mode(s) of delivery, and to collect baseline measures describing the practices and the physicians in those practices. This will include administration of the practice culture survey for readiness for organizational change. During months 7-20 we will implement the educational activity in practices in both control and intervention arms, and implement the QI interventions. At the 20$^{th}$ month we will perform follow-up AF knowledge assessments for physicians and other involved practice staff, and re-assess most current prescribing of OAT among study patients to determine the practice-level "appropriate" prescribing of anticoagulant therapy. During months 21-24 we will perform our intervention and impact analysis, write the final report, prepare professional manuscript(s), and plan for implementing best practices in the control arm practices.

| Activity | Project Month | Responsible Person(s) | Anticipated Outcomes |
|---|---|---|---|
| Create and submit IRB protocol | 1-2 | | IRB approval |
| Develop UCHealth PCN practice sites following randomization | 1-2 | | Half of the 16 UCHealth PCN practices (including the Division of GIM's hospital-based practices) will be randomized to intervention and control groups |
| Develop Educational Activity in collaboration with practice site leadership | 1-4 | | Successful development of content and format for noon conference series/educational activity |
| Develop AF knowledge assessment | 3-4 | | AF Knowledge Assessment tool developed |
| Meet with practice leadership to develop and refine QI communication tools; Collect baseline measures and pre-intervention "outcomes" measures | 3-6 | | Collaboratively developed QI communication tools/template;<br>Baseline measures collected |
| Identify overall patient population with AF fulfilling inclusion/exclusion criteria | 3-4 | | Establishment of electronic data for AF cohort (controls and intervention arms) |
| Develop data warehouse queries to extract clinical/demographic data needed to calculate $CHA_2DS_2VASc$ and HAS-BLED scores and run AF DST | 3-5 | | Completed data queries |
| Develop program to automate calculation of $CHA_2DS_2VASc$ and HAS-BLED scores from extracted clinical data; program to automate performance of AF DST in order to generate patient-specific projection of gain/loss associated with OAT and treatment recommendation | 4-6 | | Successful computer program development |

| | | | |
|---|---|---|---|
| Implement data warehouse queries (described above) | 7-8 | | Successful collection of patient-level clinical and demographic data needed to calculate $CHA_2DS_2VASc$ and HAS-BLED |
| Implement patient-level calculation of annual stroke and major hemorrhage rates | 9-10 | | $CHA_2DS_2VASc$ and HAS-BLED calculated for all AF patients in cohort |
| Implement automated performance of AF DST | 11-14 | | Treatment recommendation and projection of QALYs gained/lost with OAT |
| Identify AF population with current therapy discordant with recommended therapy per AF DST | 15 | | Successful identification of patients with current treatment discordant from AF DST recommendations |
| Identify AF population with current therapy discordant with recommended therapy per ACCP treatment guidelines | 15-16 | | Successful identification of patients with current treatment discordant from ACCP AF treatment guidelines |
| Generate QI Reports | 16 | | Completed QI reports for physicians and practices |
| Visit practice sites in both control and intervention arms to disseminate information through the educational activity developed above (noon conference series, etc.) | 5-15 | | Complete noon conference series and distribution of other educational materials at all UCHealth PCN practice sites |
| Initiate QI intervention by communicating patient-level information to physicians and practices regarding patients for whom we recommend a reconsideration of current anticoagulant therapy for AF, using templates developed collaboratively with practice leadership | 16 | | QI summary reports successfully delivered to practice site managers in intervention arm |
| Ongoing communication with practices regarding successes, failures, and barriers to implementing QI processes | 16-24 | | Email and telephone communication with practice site managers in intervention arm |
| Follow-up administration of AF knowledge assessment tool | 20-22 | | Outcome data on post-intervention AF knowledge assessment collected |
| Perform evaluation of educational intervention and other QI program evaluations | 20-22 | | Completed program evaluation |
| Reassess status of OAT prescribing for patients in both control and intervention practice arms | 20-22 | | Updated assessment of current treatment regimen for AF |
| Perform statistical analyses of results | 22-24 | | Study results, statistical analyses, and associated regression analyses |
| Interpret results, generate manuscript(s) and final project report | 20-24 | | Interpretation of study results;<br>Completed manuscript(s) and final report to Pfizer completed and submitted |
| Communicate patient-level AF DST recommendations to practices in the control arm via implementation of best practices discovered through the study | 24 | | QI report submitted to control arm practices |