

Preventing preventable strokes: A study protocol to push guideline-driven atrial fibrillation patient education via patient portal



Michael Fitzpatrick, DO,^{*†} Hammad Sadiq, BS,^{*} Sanjeev Rampam, BS,^{*} Almaz Araia, BA,[‡] Megan Miller, BS,[§] Kevin Rivera Vargas, BS,[§] Patrick Fry, BS,[¶] Anne Marie Smith, MBA,[‡] Mary Martin Lowe, PhD,^{||} Christina Catalano, MBA,[¶] Charles Harrison, MD,[¶] John Catanzaro, MD,[¶] Sybil Crawford, PhD,^{*} David McManus, MD, MSc,^{*†} Alok Kapoor, MD, MSc^{*†}

From the ^{*}Department of Medicine, University of Massachusetts Medical School, Worcester, Massachusetts, [†]Department of Medicine, University of Massachusetts Memorial Health Care, Worcester, Massachusetts, [‡]Department of Practice Improvement and Policy, Heart Rhythm Society, Washington, District of Columbia, [§]Department of Medicinal Chemistry, University of Florida College of Pharmacy, Jacksonville, Florida, ^{||}Learning Advisors LLC, Chicago, Illinois, and [¶]Department of Medicine, University of Florida College of Medicine, Jacksonville, Florida.

BACKGROUND The main approach to preventing stroke in patients with atrial fibrillation (AF) is anticoagulation (AC), but only about 60% of at-risk individuals are on AC. Patient-facing electronic health record-based interventions have produced mixed results. Little is known about the impact of health portal-based messaging on AC use.

OBJECTIVE The purpose of this study was describe a protocol we will use to measure the association between AC use and patient portal message opening. We also will measure patient attitudes toward education materials housed on a professional society Web site.

METHODS We will send portal messages to patients aged ≥ 18 years with AF 1 week before an office/teleconference visit with a primary care or cardiology provider. The message will be customized for 3 groups of patients: those on AC; those at elevated risk but off AC; and those not currently at risk but may be at risk in the future. Within the message, we will embed a link to UpBeat.org, a Web site of the Heart Rhythm Society containing patient educational

materials. We also will embed a link to a survey. Among other things, the survey will request patients to rate their attitude toward the Heart Rhythm Society Web pages. To measure the effectiveness of the intervention, we will track AC use and its association with message opening, adjusting for potential confounders.

CONCLUSION If we detect an increase in AC use correlates with message opening, we will be well positioned to conduct a future comparative effectiveness trial. If patients rate the UpBeat.org materials highly, patients from other institutions also may benefit from receiving these materials.

KEYWORDS Anticoagulation; Atrial fibrillation; Electronic medical records; Patient portal message

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Background

Atrial fibrillation (AF) is one of the most common cardiac arrhythmias.¹ At least 6 million people in the United States are affected by AF, and that number is estimated to increase to 12 million by 2050.² According to data from the Framingham Heart Study, an estimated 25% of men and women older than 40 years will develop AF at some point in their life.^{3,4} AF carries a 5-fold increased risk of stroke and a 2-fold increased

risk of heart failure.^{5,6} In fact, it has been shown that patients with AF have more severe ischemic strokes or longer-lasting transient ischemic attacks (TIAs) than individuals without AF.⁷

The main approach to preventing stroke is anticoagulation (AC), but only about 60% of at-risk patients are on AC.^{8,9} Patient refusal, lack of education regarding risk of stroke, and provider hesitancy to initiate AC in older individuals because of the concern for bleeding risk are major reasons why AC may not be started in at-risk patients.^{10–13} Interventions to overcome these barriers have produced mixed results. Electronic messaging and clinical decision support in the form of electronic health record (EHR)-based alerts have not consistently raised the level of AC use.^{11,14–19}

Address reprint requests and correspondence: Dr Alok Kapoor, Biotech One, Suite 100, University of Massachusetts Medical School, 365 Plantation St, Worcester, MA 01605. E-mail address: Alok.Kapoor@umassmemorial.org.

KEY FINDINGS

- Patient-facing electronic health record–based interventions offer an alternative approach to improving patient outcomes but have produced mixed results.
- Little is known about the impact of health portal–based messaging on anticoagulation (AC) use.
- We describe a protocol for a before-and-after study for assessing the effectiveness of electronic health portal messaging as a vehicle for educating patients and its association with AC use.

Patient-facing interventions offer an alternative approach to improving appropriate AC use. The advent of patient portals makes electronic messaging an attractive, low-cost method to reach patients, but the responsiveness to this methodology for AC use in patients with AF is unknown. In this article, we describe the protocol for a prospective, intervention study in which we will send patients with AF a patient portal message before the appointment with their primary care provider (PCP) or cardiology provider. These messages will include a link to educational materials housed on a professional society Web page (UpBeat.org produced by the Heart Rhythm Society [HRS]), as well as a link to a survey soliciting feedback about the educational materials. Our goal is to assess the effectiveness of health portal messaging as a vehicle for educating patients. We will track opening of messages, reviews of the Web page, and responses to survey questions.

Methods

Setting

Our setting is the primary and cardiology care practices affiliated with a tertiary care academic center in central Massachusetts, all of which utilize the Epic Systems (Verona, WI) EHR.

Population

We will include patients aged ≥ 18 years with AF, an active patient portal, and office/teleconference visits with a cardiology provider or PCP over 3 months beginning November 2021. Furthermore, we will group patients based on their AC status, CHA₂DS₂-VASc score, and patient portal status (approximately 70% of our patients with AF have an active portal account). Specifically, group 1 will include those at elevated risk and currently on AC; group 2 will include those at elevated risk and off AC; and group 3 will include those at low risk and not on AC but who may soon in the future benefit from AC. To identify AF and calculate the CHA₂DS₂-VASc stroke risk score, we will rely on *International Statistical Classification of Diseases, Tenth Revision* (ICD-10) diagnostic codes associated with active problems in the problem list in the electronic chart of each patient,

following the example of our previous work.¹⁷ Figure 1 shows the inclusion criteria. In our previous study, we demonstrated high specificity for electronic capture of AF (98%) and CHA₂DS₂-VASc score ≥ 2 (100%). For the proposed study, we will define elevated stroke risk as ≥ 2 for men and ≥ 3 for women—equivalent to a combined stroke and embolism risk $\geq 2.9\%$ per year—following guidance from the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the HRS.²⁰

Procedures

Intervention

Our intervention will involve research assistants sending patients a health portal message containing HRS-generated educational materials before appointments with their PCP or cardiology provider to increase adherence to AC guidelines.

To identify all eligible patients, we will utilize the Epic Systems EHR-based tools. Most inpatient and outpatient documentation is entered under either Flowsheets or Smartforms modules. The data entered in these fields can be extracted through Epic System's Reporting Workbench module. This module is a highly customizable tool that can extract relevant hospital or clinic notes and demographic data from hundreds of patient records into an organized table. In our case, Reporting Workbench will filter patients based on age, AC status (on vs off) as described later, CHA₂DS₂-VASc score, and provider type.

Using the Reporting Workbench module, we will screen patients through a Health Insurance Portability and Accountability Act (HIPAA) waiver of authorization to access eligibility information. Research assistants will run this module every weekday to capture patients having an appointment the following week with their cardiology provider or PCP. Before the launch of this study, we secured permission from our institutional review board (IRB) to send messages without concurrently notifying providers. However, we did meet with our cardiology and primary care division leaders, presented our project, and addressed any concerns to achieve their support. We also notified administrative staff of the existence of the study and requested they route any questions related to the study to our research staff.

After identifying a list of these patients through the Reporting Workbench module, we will utilize the Bulk Communication tool to send our messages through the MyChart Patient Portal. The latter tool allows for patients to communicate with their providers as well as receive messages from their health care team.

Our research team will compose a message using the SmartText and SmartPhrases tool within the Epic Systems EHR to generate large text blocks or text templates that can easily be inserted by typing a short phrase. This tool will simplify workflow so that research staff do not have to retype or copy and paste the content of messages. Each of the 3

groups will receive a version of the portal message customized for their AC status and risk of stroke.

The general content of each of our SmartPhrases used for the 3 groups will contain an introductory letter, a single-page fact sheet, and a HIPAA authorization form to facilitate informed consent (Supplemental Appendix A). Our message will begin with a 1-page introductory letter that will introduce the purpose of the message and study. In the letter, we will embed a link specific to our institution and screenshots to orient patients to the professional society Web page. The unique link provided to us by HRS will allow us to track interactions with the Web page via a Google Analytics dashboard. Our message will request patients to review the professional society Web page and complete a survey before their visit. Following the introductory letter, our single-page fact sheet will orient patients as to their rights as a study participant, including information on how to opt out of participating. The final section of the message will include a HIPAA authorization form approved by our IRB related to the type of data that will be abstracted from patient charts. In this informed consent process, we are requesting a waiver of documentation of informed consent. Our local IRB approved our protocol based on the rationale we provided, including minimal risk of the study, waiver not adversely affecting the rights and welfare of subjects, and the study could not practicably occur without the opt-out process.

Patient survey

At the bottom of the introductory letter, we will ask participants to click on a link that will take them to a survey housed on our institution's REDCap Web site. This survey will consist of multiple-choice and free-text fields that will cover several domains. Patients can complete the survey at any time, although we request and anticipate completion before the visit with their provider (Table 1 and Supplemental Appendix B).

Outcomes

Anticoagulation

We will track AC use through medication and laboratory records from our EHR. Specifically, our Reporting Workbench module will search the current medication list for AC medications closest to the day the report was run. We will consider a patient "on AC" if they have an active prescription for an AC at a therapeutic dose to prevent stroke associated with AF. AC agents that we will include are enoxaparin with total

daily dosage (TDD) >40 mg, apixaban TDD \geq 5 mg, edoxaban TDD \geq 30 mg, dabigatran TDD \geq 150 mg, rivaroxaban TDD \geq 15 mg, dalteparin with TDD >5000 international units, or any dose of warfarin (the most common vitamin K antagonist). We will label patients as warfarin users if their most recent international normalized ratio is \geq 1.5 and will be recorded within 60 days of when the report was run. Given the possibility that some patients will have inaccurate medication reconciliation (eg, a provider does not update the list because the patient received a paper prescription or received a prescription from a non-UMass provider), we will perform a chart review of a fraction of the cases to verify electronic capture of change in AC status.

Survey

We will compare survey data for each of our 3 groups, particularly patients' opinions of HRS materials, their history of AC use, and their discussions with providers regarding personal stroke risk.

For group 1 (at risk, on AC), the survey will cover domains of discussions of personal stroke risk, history of AC use, and persistence. For group 2 (at risk, off AC), the survey will cover discussions of personal stroke risk, report by patient of receiving provider suggestion to take AC, and reason for stopping AC for those with previous use. For group 3 (low risk, not on AC), the survey will cover likelihood of learning more about personal stroke risk, willingness to start AC, and reasons for AC hesitancy.

Although the surveys vary slightly so as to provide accurate context, each patient will have the same materials on rating the professional society using the same 3 questions, with 5-point Likert response scale ranging from strongly disagree to strongly agree.

Independent variable

Independent variable for AC outcome

We will track message opening as a categorical variable (eg, opened at least 1 message in the event of multiple visits for a single patient).

Independent variable for survey outcomes

The independent variables for the survey outcomes will be the group assigned as well as demographic variables including age, gender, and race/ethnicity.

Covariates

We will include stroke risk based on the CHA₂DS₂-VASc score, comprising congestive heart failure, hypertension, age, diabetes, previous stroke, vascular disease, and gender. To adjust further for potential confounders of the association between AC use and message opening, we will include demographics omitted in that score (race, ethnicity, language preference, zip code-based income, primary insurance). Finally, we will include bleeding risk factors and other comorbidities (chronic kidney disease, chronic liver disease, low platelet count, anemia, hemophilia, other bleeding

Inclusion Criteria
• Atrial fibrillation or flutter
• Age \geq 18
• Elevated CHA ₂ DS ₂ -VASc (\geq 2 for men or \geq 3 for women)
Exclusion Criteria
• Left atrial appendage closure
• Hospice status

Figure 1 Summary of the study population.

Table 1 Patient survey domains

Group 1
Discussed risk of personal stroke risk with provider
AC use (length of time taken, numbers of missed days, and reasons why dose was missed)
Attitudes toward patient education materials
Group 2
Discussed risk of personal stroke risk with provider
Provider recommended use of AC
Reasons for stopping AC
Attitudes toward patient education materials
Group 3
Likelihood of learning about personal stroke risk
Willingness to start AC
Reasons for AC hesitancy
Attitudes toward patient education materials

AC = anticoagulation.

diathesis). In general, we will rely on ICD-10 codes for presence of a comorbid condition. For chronic kidney disease, low platelet count, and anemia, we will rely on laboratory data.

Analysis

Association of AC with message opening

We will construct a generalized logistic mixed model with AC status (on/off) as the dependent variable and message opening as the independent variable. To assess for the difference in effect of intervention in group 1 (ie, already on AC) vs group 2 (not on AC), we will test the interaction between message opening and baseline AC status. To adjust for potential confounding and clustering by provider, we will include in our model covariates mentioned earlier and a random effect for provider. Given the potential for bias from other efforts at our institution to increase AC use (ie, secular trends), we will explore methods that account for confounding by indication, including inverse probability of treatment weighting.

Views of professional society Web site

Unlike message opening, we will not have information on which exact patients viewed materials on the professional society Web site. Nevertheless, we will gather number of views, number of views by the same user, and the pages/content within the Web site reviewed by patients through a custom Google Analytics dashboard.

Survey responses

We will calculate the mean response on each of the 3 items of attitude toward the Web site materials. Later, we will combine these items to calculate a composite mean if a patient responded to a minimum of 2 of the 3 items.

Power analysis

Using estimates from our EHR, we predict 1600 patients with elevated CHA₂DS₂-VASc score will have visits over 3

months. The number of patients on AC will be approximately 70% type. Assuming an error rate of 5%, we will have 80% power to detect a $\geq 7\%$ increase in AC use as long as $\geq 50\%$ of patients open our message.

Discussion

Several published studies have demonstrated the efficacy of direct patient communication. One study looked at the relationship between blood glucose control and the use of a mobile application and patient/provider Web portals to create a more personalized behavior intervention. The investigators found that the intervention group had a higher rate of decline in glycosylated hemoglobin (a laboratory test measuring average glucose over 90 days) compared to usual care.²¹ Another group looked to improve bowel preparation before colonoscopy by sending messages to patients regarding their adherence to diet and prescribed laxative starting 4 days before colonoscopy. The study found that individuals in the intervention group had a lower likelihood of insufficient preparation, a higher rate of adenoma detection, and less discomfort during the procedure.²² Maduka and Tobin-West²³ reported success of delivery of educational materials through text messages in improving adherence to retroviral therapies. Similarly, Szilagyi et al²⁴ demonstrated improved adherence to influenza vaccination through patient portal messages.

In contrast, several other studies did not find direct patient communication to be effective. A controlled before-and-after study by Riippa et al²⁵ implemented patient portal informational messaging and communication with a chronically ill patient cohort (ie, diabetes, hypercholesterolemia, and hypertension). They found no significant improvement in patient activation or short-term self-reported health status. Another group looked at a text messaging intervention on hemoglobin A_{1c} levels in diabetic patients admitted to an emergency department. The group developed a 1-way messaging app that delivered text messages related to exercising, medication adherence, and patient education but found no statistically significant improvement in hemoglobin A_{1c} levels.²⁶

A quality improvement study looking at an EHR-based reminder messaged by Roseland et al²⁷ found no improvement in adherence to first-time or rescheduled magnetic resonance imaging or computed tomography scan appointments within 2 months. Similarly, Turakhia et al²⁸ found no significant improvement in AC with an intervention consisting of messaging and transmission of educational materials delivered through a smartphone application.

Study limitations

Our setting is a single academic center and associated outpatient practices, which will limit the generalizability of our findings. Analyzing AC use in patients receiving messages could ignore other trends/efforts to get patients on AC. We will mitigate the effect of this potential bias by looking at AC starts within the first 3 months of the encounter. In

addition, in sensitivity analysis, we will explore other methods for addressing bias from secular trends.

We may encounter a number of limitations that result from using and deploying messages through the EHR. Our findings may not be generalizable to the public because users of patient portals tend to have higher motivation, self-determination, and income; have greater access to technology; and are more involved in their health care.^{27,28} Our survey also may suffer from bias for items related to recall of discussions that patients had with their providers. Additionally, we will not be able to ascertain whether patients read our message, only that our MyChart message was opened. In many cases, a family member will be opening the message. Engagement and interaction with professional society educational materials have similar challenges. Although education by proxy through a family member may lead to decisions to take AC or stay on it, we will not be able to distinguish the discrete effect of direct vs proxy communication in the current study. Finally, our portal messaging intervention does not have a provider component. Educational interventions that target only patients or only providers in isolation may be less effective than multifaceted interventions such as the IMPACT-AF (International Multi-center Clustered Randomized Controlled Trial to improve Treatment With AntiCoagulantS in Patients With Atrial Fibrillation.) trial.²⁹ In future work, we hope to expand our digital intervention to include provider-facing decision support.

Conclusion

In this article, we described a protocol for a study examining the impact of sending health portal messages to patients with AF. Outcomes will include AC use, attitude toward educational materials housed on a professional society Web site, and several domains relating to history and knowledge of AC. We described a protocol to analyze the impact of patient portal messages and an associated professional society educational Web site on AC use. Previous investigators have demonstrated mixed results on how the EHR can be leveraged through patient-facing interventions to improve health outcomes. Through patient surveys, we will measure patient attitudes toward our educational material as well their understanding of AC use across multiple domains.

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Authorship

All authors attest they meet the current ICMJE criteria for authorship.

Disclaimer

Given his role as Editor-in-Chief, Dr David McManus had no involvement in the peer review of this article and has no access to information regarding its peer review. Full responsibility for the editorial process for this article was delegated to Dr David J. Slotwiner.

Appendix Supplementary data

Supplementary data associated with this article can be found in the online version at [10.1016/j.cvdhj.2022.07.068](https://doi.org/10.1016/j.cvdhj.2022.07.068).

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