Electronic physician notifications to improve guideline-based anticoagulation in atrial fibrillation: a randomized controlled trial

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BACKGROUND: Oral anticoagulants reduce the risk of stroke in patients with atrial fibrillation. However, many patients with atrial fibrillation at elevated stroke risk are not treated with oral anticoagulants.
OBJECTIVE: To test whether electronic notifications sent to primary care physicians increase the proportion of ambulatory patients prescribed oral anticoagulants.
DESIGN: Randomized controlled trial conducted from February to May 2017 within 18 practices in an academic primary care network.
PARTICIPANTS: Primary care physicians ($n = 175$) and their patients with atrial fibrillation, at elevated stroke risk, and not prescribed oral anticoagulants.
INTERVENTION: Patients of each physician were randomized to the notification or usual care arm. Physicians received baseline email notifications and up to three reminders with patient information, educational material and primary care guidelines for anticoagulation management, and surveys in the notification arm.
MAIN MEASURES: The primary outcome was the proportion of patients prescribed oral anticoagulants at 3 months in the notification ($n = 972$) vs. usual care ($n = 1364$) arms, compared using logistic regression with clustering by physician. Secondary measures included survey-based physician assessment of reasons why patients were not prescribed oral anticoagulants and how primary care physicians might be influenced by the notification.
KEY RESULTS: Over 3 months, a small proportion of patients were newly prescribed oral anticoagulants with no significant difference in the notification (3.9%, 95% CI 2.8–5.3%) and usual care (3.2%, 95% CI 2.4–4.2%) arms ($p = 0.37$). The most common, non-exclusive reasons why patients were not on oral anticoagulants included atrial fibrillation was transient (30%) or paroxysmal (12%), patient/family declined (22%), high bleeding risk (20%), fall risk (19%), and frailty (10%). For 95% of patients, physicians stated they would not change their management after reviewing the alert.
CONCLUSIONS: Electronic physician notification did not increase anticoagulation in patients with atrial fibrillation at elevated stroke risk. Primary care physicians did not prescribe anticoagulants because they perceived the bleeding risk was too high or stroke risk was too low.
TRIAL REGISTRATION: ClinicalTrials.gov identifier NCT02950285

KEY WORDS: atrial fibrillation; oral anticoagulation; primary care; electronic notifications; randomized controlled trial.

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Atrial fibrillation (AF) is a prevalent arrhythmia and is associated with a fivefold increased risk of ischemic stroke.[1, 2] Oral anticoagulation reduces the risk of stroke by approximately two-thirds.[3] Despite the clear benefits of oral anticoagulation, studies have repeatedly demonstrated that about 40–50% of patients with AF and elevated stroke risk do not receive oral anticoagulants.[4–11] A gap between physician awareness of patient eligibility for anticoagulation and guideline recommendations for stroke prevention has been cited as a potential factor for the apparent underuse of oral anticoagulation in patients with atrial fibrillation.[10, 12–14]

It remains unclear whether addressing provider awareness of patient stroke risk can increase utilization of oral anticoagulants. Furthermore, there is limited understanding of current provider-based reasons for not prescribing oral anticoagulants in a contemporary adult cohort of patients with AF. Structured interventions using electronic medical record (EMR) decision support and electronic alert tools in patients with AF are feasible.[15–17]

We conducted a randomized controlled trial to test whether an electronic notification distributed to primary care physicians (PCPs) would increase the proportion of patients prescribed oral anticoagulants. Within the notification, we

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embedded educational support materials and a survey to assess who was making decisions regarding anticoagulation for each patient, the reasons why patients were not prescribed oral anticoagulants, and how PCPs might be influenced by the notification.

METHODS

Setting and Participants

This study was conducted in 18 primary care practices within Massachusetts General Hospital (MGH), with 180 PCPs (hereafter referred to as physicians) who cared for at least one patient with AF. Physicians were introduced to the study via email and given the choice of opting out. Of 180 physicians invited, five were omitted (two physicians opted-out, two were on extended leave, and one was not contacted due to incorrect contact information).

Among participating physicians, we identified 2336 patients in their care as of the study start date (February 7, 2017)[18, 19] who had a diagnosis of AF, elevated stroke risk and were not currently prescribed oral anticoagulants. We identified patients with AF by implementing a validated algorithm, using a population health management informatics system (TopCare, SRG Technology),[20] based on billing codes, procedure codes, electrocardiograms, and medication prescriptions.[21] We defined elevated stroke risk as a CHA_2DS_2-VASc score ≥ 2,[22] which was calculated by summing one point each for age 65–75 years, the presence of congestive heart failure, hypertension, diabetes, vascular disease, and female sex, and two points for age $\geq$ 75 years, or a prior stroke, transient ischemic attack, or systemic embolism. Covariates and use of oral anticoagulation were ascertained from the EMR as previously described.[23] We have observed similar rates of oral anticoagulation use in this sample as compared to prior studies.[23]

Study Design and Randomization

We conducted a randomized, controlled trial to alert physicians of their patients with electronically ascertained AF and elevated stroke risk that were not currently prescribed oral anticoagulants (Fig. 1). Patients of each physician were randomized using a computerized random number generator to the intervention of physician notification at baseline or to the usual care control group without physician notification (all physicians were also offered the option to receive notifications for control patients after the trial period). To minimize physician burden, we limited the number of notifications to 10 per physician. For example, for physicians with 20 or fewer eligible patients, randomization was 1:1 to the intervention or usual care arms. For physicians with ≥ 21 eligible patients, the intervention was randomly allocated for 10 patients and usual care for the remainder (Fig. 2).

We sent physician email alerts without regard to clinic visits for patients since we assumed that physicians would prescribe anticoagulation or modify treatment if the alert information was considered actionable and since physicians are often burdened with multiple alerts during clinic visits.[24] We assumed the likelihood of contamination in the usual care arm from the alerts was low since physicians were unaware of the patients in their panels randomized to usual care, alerts were distributed irrespective of a scheduled visit, and the trial period

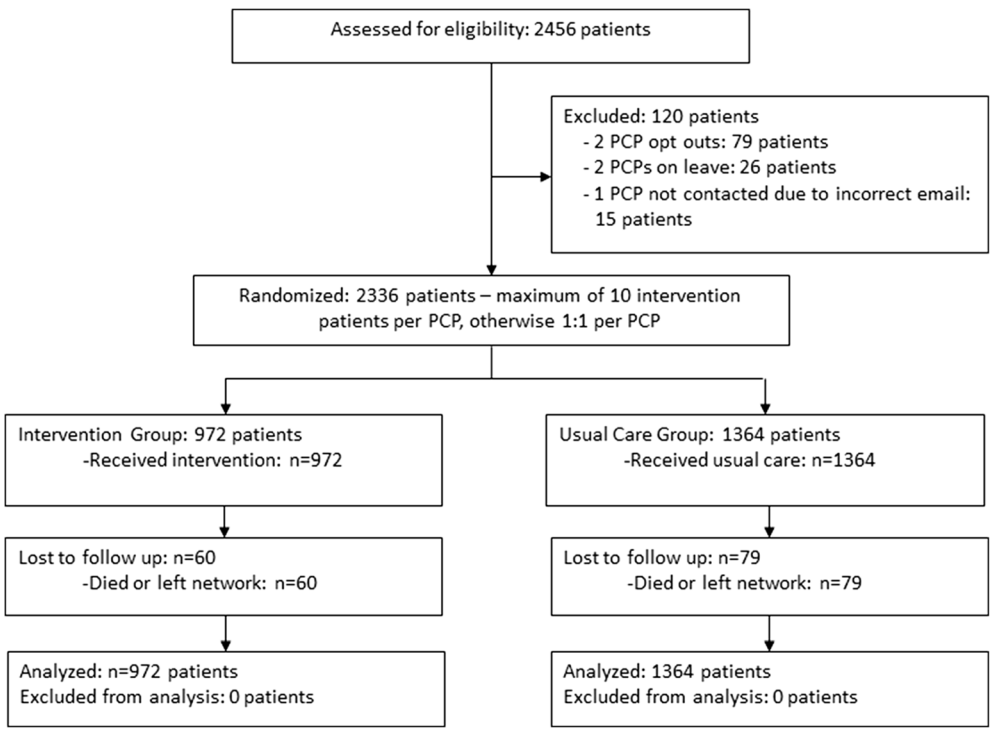

Figure 1 CONSORT diagram depicting flow of patients through randomization, intervention, and outcome analysis.

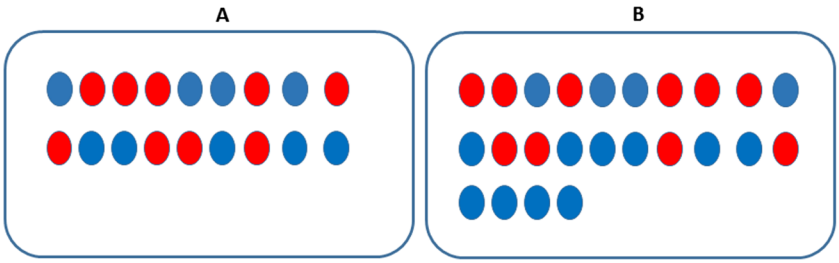

Figure 2 Schematic overview of patient-level randomization within physician panels. Panel A represents a hypothetical scenario in which a physician has ≤20 eligible patients (circles). Each patient is randomized 1:1 to intervention (red) or usual care (blue). Panel B represents a hypothetical scenario in which a physician has ≥21 eligible patients. 10 patients are randomly allocated to intervention (red), with the remainder to usual care (blue).

was brief in duration. We therefore performed randomization at the patient level to minimize the number of alerts and surveys per physician and maximize the number of physicians eligible for survey participation.

Intervention Details

We developed a physician notification alert and survey and utilized REDCap (Research Electronic Data Capture) to email the alerts to each provider and to collect survey responses.[25] The alert displayed individualized patient clinical information, including CHA_2DS_2-VASc stroke risk score and bleeding risk factors. In addition, we embedded a link to curated educational content and primary care guidelines relating to anticoagulation management developed and reviewed by a group of MGH physicians and specialists that is available as standard of care (eFigure 1). The survey asked the physician to confirm the AF diagnosis and anticoagulation status, provide input on who makes the anticoagulation decision, document reasons for not prescribing oral anticoagulants, and indicate what the next step in the management of this patient will be after receiving the alert (eFigure 2). The survey component of the physician alert was developed with input from a focus group of representative physicians within MGH. As an incentive, all physicians who completed surveys were provided with a $10 café gift card and eligible to win one of three $250 cash prizes. Physicians received email notifications on February 7, 2017, and up to three subsequent reminders over the 3-month follow-up period.

Outcome Measures

Patient characteristics, comorbidities, and prescriptions were obtained from a central data repository at Partners HealthCare.[26] We calculated the ATRIA bleeding risk score for each patient by assigning three points for a diagnosis of anemia, three for renal disease, two for age ≥75 years, one for prior hemorrhage, and one for hypertension.[27] Physician characteristics were obtained from the hospital registrar.

The primary outcome was the proportion of patients prescribed oral anticoagulants at 3 months in the notification arm compared to the usual care arm. Secondary outcomes were survey-based reasons for not prescribing oral anticoagulants and planned next steps by physicians in response to the alert. Survey responses for reasons for not prescribing oral anticoagulants were pre-defined, with a free-text option. Two investigators independently reviewed all free-text responses provided by physicians for this question. Each investigator reclassified free-text responses into existing categories if possible, created new categories based on common free-text responses, and met to review any discordances in reclassification. Two investigators independently performed manual chart reviews of patients where a physician indicated the patient did not have AF to assess for any history of AF. A third investigator reviewed patient charts if there was discordance.

Statistical Analyses

Analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC). For the primary outcome, we compared oral anticoagulant status at 3 months between the two arms using a logistic regression model accounting for clustering by physician using a generalized estimating equations approach (PROC GENMOD) in intention-to-treat analyses. We assessed the intervention effect in different subgroups based on whether patients had an office visit during the study period, patient age (≥75 years and <75 years), gender, stroke risk (CHA_2DS_2-VASc scores 2 or 3 and ≥4), bleeding risk (ATRIA scores 0–3 and ≥4), and whether patients had prior history of oral anticoagulant use in the EMR. In separate models, we included an interaction term of treatment group (notification arm or usual care arm) with each subgroup to assess whether the effect of the alert was modified by visits, patient age, gender, stroke risk, bleeding risk, and prior oral anticoagulant use. Descriptive statistics to summarize survey data used mean or median for continuous variables and frequency with percentage for categorical variables. For the primary outcome, we considered a clinically meaningful difference in proportion of individuals adopting anticoagulation to be 4%. Assuming up to 6% of patients in the usual care group were newly anticoagulated, the sample provided over 90% power to detect this difference. The Partners Institutional Review Board approved this study with a waiver of written informed consent. The study was registered with ClinicalsTrials.gov (identifier NCT02950285).

Data Availability. The datasets generated and/or analyzed during the current study are not publicly available due to protocol protections to minimize loss of patient confidentiality.

RESULTS

Among 175 participating physicians, the mean age was 50.4 years, 58.3% were female, with a mean of 22.6 years since medical school graduation and 15.7 years practicing at MGH. Among 6412 patients in the network with electronically ascertained AF and CHA_2DS_2-VASc score ≥ 2, 57% were receiving anticoagulation as of the study start date. At baseline, demographics and clinical characteristics were similar between 972 patients randomized to the physician notification arm and 1364 patients in the usual care arm. The mean patient age was 76.0 years, 51.9% were female, and the mean CHA_2DS_2-VASc score was 4.2. Seventy-five percent of patients were being treated with antiplatelet therapy, most of whom (69%) received aspirin alone (Table 1). The proportion of patients who died or left the primary care network before the end of the 3-month study period was similar in both the notification ($n = 60$, 6.2%) and usual care ($n = 79$, 5.8%) arms.

Proportion of Patients Prescribed Oral Anticoagulants

Over the 3-month study period, the percentage of patients newly prescribed anticoagulants during follow-up was very small and not significantly different between the notification (3.9%, 95% CI 2.8–5.3%, $n = 38$) and usual care (3.2%, 95% CI 2.4–4.2%, $n = 44$) arms ($p = 0.37$) (Fig. 3). The effect of the intervention was not statistically significant in any subgroup, although the intervention effect was larger in magnitude among those with visits during the study period compared to those with no visit and among those with prior anticoagulation compared to those without prior anticoagulation. There was no difference in the (null) effect of the intervention by CHA_2DS_2-VASc or ATRIA bleeding risk score (interaction $p = 0.51$ and 0.57, respectively) (Fig. 4).

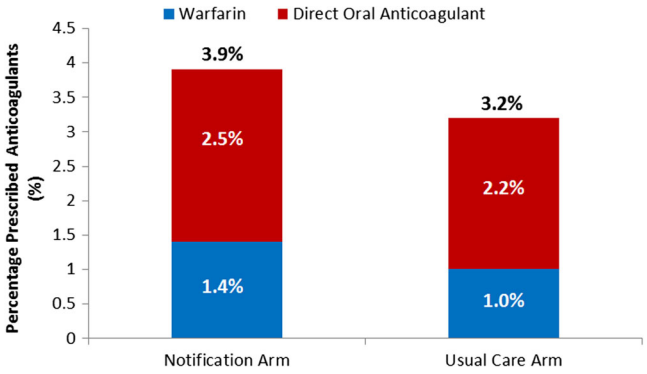

Figure 3 Percentage of patients prescribed oral anticoagulants at 3 months in intervention and usual care groups.

Physician Survey Responses and Reasons for Not Prescribing Oral Anticoagulants

Among 175 physicians, 101 (57.7%) completed at least one survey corresponding to 454 of 972 (46.7%) intervention patients. Physicians indicated that 422 (93.0%) of 454 patients were properly attributed to them, 22 (4.8%) were properly attributed but deceased, and 10 (2.2%) were not their patient.

Physicians confirmed the diagnosis of AF in 180 (42.8%) of 421 properly attributed patients ($n = 1$ missing), indicated that 139 (33.0%) had transient (resolved) or treated AF in the past, did not know the AF status for 3 (0.7%), and did not think that 99 (23.5%) had AF. Based on manual chart review, a diagnosis

Table 1 Baseline Patient Characteristics in Physician Notification and Usual Care Arms

	All patients ($n = 2336$)	Physician notification ($n = 972$)	Usual care ($n = 1364$)
Age, mean (SD)	76.0 (11.3)	75.7 (11.1)	76.3 (11.5)
Gender, female	1121 (48.0%)	482 (49.6%)	639 (46.9%)
Language, English	2081 (89.1%)	869 (89.4%)	1212 (88.9%)
Race, white	1985 (85.0%)	819 (84.3%)	1166 (85.5%)
Heart failure	590 (25.3%)	254 (26.1%)	336 (24.6%)
Hypertension	1867 (79.9%)	783 (80.6%)	1084 (79.5%)
Diabetes mellitus	568 (24.3%)	231 (23.8%)	337 (24.7%)
Vascular disease	816 (34.9%)	335 (34.5%)	481 (35.3%)
Prior stroke or transient ischemic attack	717 (30.7%)	307 (31.6%)	410 (30.1%)
CHA_2DS_2-VASc, mean (SD)	4.2 (1.6)	4.2 (1.7)	4.2 (1.6)
ATRIA bleeding risk score, mean (SD)	3.9 (2.4)	4.0 (2.5)	3.9 (2.3)
History of anemia	787 (33.7%)	337 (34.7%)	450 (33.0%)
Renal disease	209 (9.0%)	99 (10.2%)	110 (8.1%)
Liver disease	536 (23.0%)	234 (24.1%)	302 (22.1%)
Dementia	231 (9.9%)	94 (9.7%)	137 (10.0%)
No prior oral anticoagulation use	1220 (52.2%)	501 (51.5%)	719 (52.7%)
Current antiplatelet therapy			
Aspirin	1603 (68.6%)	671 (69.0%)	932 (68.3%)
Thienopyridine	23 (1.0%)	7 (0.7%)	16 (1.2%)
Dual antiplatelet therapy	129 (5.5%)	55 (5.7%)	74 (5.4%)
No antiplatelet therapy	581 (24.9%)	239 (24.6%)	342 (25.1%)

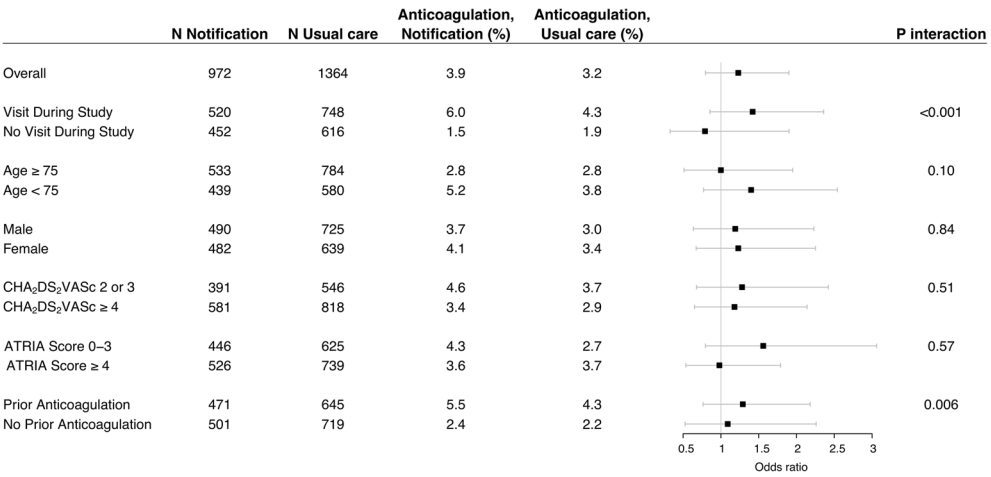

Figure 4 Odds ratios for the primary outcome (prescription of oral anticoagulants during follow-up) among subgroups of patient visits during the study period, patient age, gender, stroke risk, bleeding risk, and prior anticoagulation history.

of AF existed for 51% (50/99) of patients who the physician indicated did not have AF (most recent evidence documented in the medical record a median of 392.5 days [q1, 198 days; q3, 857.25 days] before study start date). Therefore, 11.6% of patients electronically ascertained as having AF did not have clinically evident AF.

Of the 319 patients that physicians characterized as having AF ($n = 180$) or transient/treated AF in the past ($n = 139$), physicians reported that 89.0% (284/319) were properly classified as not currently taking an anticoagulant. Physicians stated they made the anticoagulation decision for approximately one-third of patients, cardiologists for one-third, and both the physician and cardiologist for one-third (eFigure 3). After omitting individuals with transient precipitants or resolved AF, the proportion of patients in the intervention arm who were prescribed anticoagulation at 3 months was 8.3%.

Among patients confirmed by their physician to not be taking an anticoagulant ($n = 284$), physicians documented reasons why (Table 2) and selected an average of 1.8 reasons per patient (median 1.0; eFigure 4). The most commonly selected reasons for a patient not receiving oral anticoagulants were that the patient (1) had transient AF in the setting of a reversible cause (30%), (2) declined anticoagulation (22%), (3) had a high risk of bleeding (20%), (4) had a high risk of falls (19%), (5) had other health issues (18%), (6) had paroxysmal AF (12%), and (7) was too frail (10%). For 94.8% (253/267, $n =$ 17 missing) of patients, physicians indicated that nothing would change in their management in response to the notification. After the study period, 44 of 175 (25.1%) participating physicians opted-in to receive a list of their control patients.

DISCUSSION

In our study of primary care patients with AF at elevated stroke risk who were not prescribed oral anticoagulants, electronic notifications sent to primary care physicians did not increase guideline-based prescription of oral anticoagulants at 3 months following the notification. In surveys, most physicians indicated that the current management of patients was appropriate, and, in over 95% of patients, physicians stated

Table 2 Primary Care Physician Documented Reasons for a Patient Not Being on an Oral Anticoagulant

Reason	Frequency ($n = 284$)	Percent
Stroke risk related		
Patient had transient AF in the setting of a reversible cause and risk of embolism is lower than suggested	84	29.6%
Patient has paroxysmal AF and the risk of embolism is lower than suggested	35	12.3%
Patient has had an ablation	19	6.7%
Patient's embolic risk is lower than the CHA_2DS_2-VASc score suggests	17	6.0%
Alternative to oral anticoagulation chosen (e.g., left atrial appendage exclusion procedure)	2	0.7%
Bleeding risk related		
Patient's bleeding risk is too high	56	19.7%
Patient is at high risk of falls	55	19.4%
Patient is too frail	29	10.2%
Patient had a bleed on anticoagulants in the past	23	8.1%
Other patient-related factors		
Patient (or their family) has declined	61	21.5%
Patient has too many comorbidities/ this is not the most important of their problems	51	18.0%
Patient is unlikely to be compliant	21	7.4%
Patient has poor mental status/ dementia	21	7.4%
Patient's quality of life would be impaired if they took an anticoagulant	8	2.8%
Patient is too old	5	1.8%
Patient had poor INR control in the past	3	1.1%
Physician or system-related factors		
Primary care physician defers to cardiology	22	7.8%
Limited infrastructure to support education and management of anticoagulant	2	0.7%
Costs of anticoagulation are prohibitive	1	0.4%
Physician not comfortable with novel anticoagulants	0	0.0%

they would not change their management. Reasons for not prescribing oral anticoagulants included concerns that bleeding risk was too high or stroke risk was too low.

Despite guideline recommendations and efforts to increase the use of oral anticoagulants for patients with AF, the proportion not treated with oral anticoagulants has remained between 40 and 50% even among patients at high risk of stroke.[4–9] Many patients with AF at high risk of stroke are treated with aspirin alone, without oral anticoagulation.[28] A multifaceted and multilevel educational intervention directed at both physicians and patients, with regular monitoring and feedback, was associated with a 9.1% absolute difference in change over 1 year compared to usual care in a prior study.[29] Systematic reviews of studies involving physician alerts to improve delivery of preventive services have demonstrated modest impacts.[30, 31] There has been limited research on electronic alerts targeting physicians for their AF patients not on oral anticoagulants. A prior randomized trial of an electronic alert for improving oral anticoagulant use among hospitalized oral anticoagulant-naïve AF patients demonstrated modest improvements in the proportion receiving anticoagulation at hospital discharge.[17] A nonrandomized cohort study of a clinical alert for newly diagnosed hospitalized AF patients did not result in an increase in oral anticoagulant prescribing.[15]

In contrast, our study evaluated the impact of implementing an electronic alert for ambulatory primary care patients in a pragmatic randomized fashion. This trial was conducted outside of the context of a face-to-face clinic visit and represents an intervention that targets all AF patients at elevated stroke risk who are not anticoagulated. Our study was also distinctive in that we collected physician survey-based responses indicating why a patient was not on an oral anticoagulant.

Although the results of the intervention were null, we submit that our findings have three major clinical implications. First, physician notifications that include stroke and bleeding risk information are unlikely to decrease the 40–50% gap in oral anticoagulant use among patients with AF at increased risk of stroke. In this large randomized trial, few patients were newly prescribed oral anticoagulants over 3 months, with no difference between intervention and control groups. Though the notification included educational content and patient-specific information, physicians who completed a survey indicated they were aware of the patient's AF, stroke risk, and oral anticoagulant status and overwhelmingly reported that the alert would not change anticoagulation management.

Second, physicians believe their decisions not to use oral anticoagulants are appropriate. In this study, regardless of information provided in the electronic alert, physicians cited lower stroke and higher bleeding risk as chief concerns. Concerns about stroke and bleeding risk highlight the complexity of oral anticoagulant management in routine clinical practice. In the survey component of the current study, physicians documented an average of nearly two reasons for why a patient was not currently using an oral anticoagulant. The difficulty of increasing oral anticoagulant use may reflect the challenge physicians face when considering the potential harms and benefits of treating older patients with multiple comorbidities and bleeding risk factors.

Third, algorithm-based automated AF ascertainment schemes using EMR data may identify patients in whom the benefits and risks of anticoagulation for thromboembolism prophylaxis are controversial. For example, physicians identified patients with transient AF in the setting of a reversible cause as the most commonly selected reason for a patient not being on an anticoagulant in this study. Recent data has suggested that there may be increased risk of recurrent AF associated with prior episodes attributed to a secondary or reversible event, and substantial long-term risk of AF-related strokes may exist in such patients.[32, 33] Even after excluding patients with transient AF in the current study, only 8.3% of patients in the intervention arm were started on anticoagulants.

Prior consensus guidelines have suggested that AF may resolve with treatment of the reversible precipitant and therefore obviate the need for long-term anticoagulation,[34] though more recent guidelines have highlighted a lack of randomized data to guide such decisions.[35] Similarly, data increasingly suggest that the burden (amount of time spent in AF) of AF may be associated with stroke risk,[36, 37] a factor which is not currently implemented in clinical guidelines and which electronic AF ascertainment algorithms do not generally take into account. The results of this study highlight the heterogeneity of what clinicians consider actionable AF for which long-term oral anticoagulation is indicated. Future studies should evaluate longitudinal outcomes among patients with reversible AF precipitants and assess whether oral anticoagulation is appropriate among these patients.

Our study should be interpreted in the context of the study design. Since it was conducted within a single primary care network, our findings may not be generalizable to other centers or care providers such as cardiologists. Randomization was at the patient level, so it is possible that the care of control patients may have been impacted by the intervention. We submit this is unlikely to have influenced the results given the infrequent use of anticoagulation in both arms. The electronic alert was conducted outside of a clinical encounter, which may have created an added burden for physicians to contact patients and modify treatment. Future point-of-care alerts may have a different impact on outcomes. It is possible that physicians may have ignored the email alert, whereas mandatory alerts with a hard-stop requirement may have yielded different results. Our AF algorithm misclassified approximately 12% of patients as having AF. Without misclassification, the percentage of patients anticoagulated after 3 months would be expected to be higher in both the intervention and control arms. While our alert included

educational materials for providers, a more multifaceted approach that includes both provider and patient education, as well as regular monitoring and feedback, may be impactful.[29] Only 58% of physicians completed a survey, however, this level of response is typical among physicians and we did not observe a significant difference in anticoagulation rates associated with survey response ($p = 0.28$).[38, 39] The survey element was directed to providers only and not to patients. There appears to be wide variability in patient and physician values related to risks and benefits of oral anticoagulation, and these values and preferences may often be discordant.[40, 41] Future efforts should explore the value of engaging the patients in AF anticoagulation interventions.

In conclusion, a very small percentage of patients were newly prescribed anticoagulants during the 3-month study period and electronic physician notifications did not increase anticoagulant prescriptions compared to usual care. Most physicians were aware of the patient's oral anticoagulation status and did not prescribe oral anticoagulants because they perceived bleed risk was too high or stroke risk was too low, the latter predominantly due to a history of transient AF. Despite the notifications, most physicians felt their decisions not to use oral anticoagulants were appropriate. In the current environment, where there is much clinical and public attention to anticoagulation for AF, electronic alerts and physician education are unlikely to substantially increase oral anticoagulant utilization in patients with AF.

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Contributors *None*

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Compliance with Ethical Standards:

Prior Presentations: *Dr. Ashburner presented this study as a finalist during the Samuel A. Levine Young Clinical Investigator Award Competition at the American Heart Association Scientific Sessions on November 11, 2017.*

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