The Heart Rhythm Society/American College of Physicians Atrial Fibrillation Screening and Education Initiative

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BACKGROUND The prevalence of both atrial fibrillation (AF) and stroke is increasing. Stroke is common in AF and can have devastating consequences, especially when AF is unrecognized and anticoagulation is not initiated.

OBJECTIVE The purpose of this study was to demonstrate the feasibility and yield, both in identifying previously undiagnosed AF and in educating patients and caregivers about AF, of systematic screening events in internal medicine practices using a mobile electrocardiogram device (Kardia/AliveCor iECG).

METHODS With support from the Heart Rhythm Society and the American College of Physicians, 5 internal medicine practices performed systematic screening and education of patients at higher risk of AF using the Kardia/AliveCor device and a variety of educational materials. Patients screened as "unclassified" or "possible AF" were referred for further evaluation. Patients and providers (physicians, nurses, and allied professionals) assessed the screening process.

RESULTS A total of 772 patients were screened. The mean age was 65.2 ± 15.4 years, and 281 (28.2%) were 75 years or older. The majority, 521 (67.5%), were female, and 586 (75.7%) had a CHA_2DS_2-VASc score of ≥2. Six hundred seventy patients (86.8%) were screened as "normal," 85 (11.0%) as "unclassified," and 17 (2.2%) as "possible AF." Participants demonstrated a significant knowledge deficit about stroke and AF before the screening events, and the majority felt that their awareness of these issues increased significantly as a result of their participation.

CONCLUSION This collaborative Heart Rhythm Society/American College of Physicians systematic screening effort using the Kardia/AliveCor device was feasible. Although it resulted in a relatively modest yield of "unclassified" or "possible AF" screens, it had significant educational benefit to participants and caregivers. The diagnostic yield of future programs could be enriched by including more elderly patients and those with more risk factors for AF and stroke. A greater duration or frequency of monitoring would likely increase sensitivity but be more complicated and costlier to administer. Future events should include on-site confirmatory testing with a 12-lead electrocardiogram. Devices such as the Kardia/AliveCor monitor may enhance patient engagement in screening programs.

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KEYWORDS Atrial fibrillation; Screening; Stroke (Heart Rhythm 2019;16:e59–e65)

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Background

The health care burden of atrial fibrillation (AF) in the United States is substantial and increasing. More than 3 million individuals are currently affected, and it is estimated that by the year 2050, more than 8 million people in the United States would have been diagnosed with AF.[1,2] The Framingham

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Heart Study[3] found the lifetime risk of developing AF in a 40-year-old to be approximately 1 in 4. In high-income North America, the lifetime risk of stroke of all causes is also about 1 in 4.[4] AF more than quadruples the risk of ischemic stroke, is associated with almost 20% of such events, and results in strokes that tend to be more severe.[5–8] While anticoagulation can significantly reduce the risk of stroke and its associated morbidity, many episodes of AF go unrecognized until patients present with stroke. Even among North American patients with known AF who are at high risk of stroke (CHA_2DS_2-VASc score $\geq$2), as many as one-third are not anticoagulated,[9] despite the availability of newer anticoagulants that are safer and easier to administer than warfarin.

Given the importance of identifying and effectively treating AF, several studies have examined the use of both opportunistic screening (offered as part of a routine medical encounter) and systematic screening (mass screening or targeted screening of a high-risk population). The latter often use handheld devices such as the Kardia/AliveCor application (AliveCor Inc., Mountain View, CA), which can be used with smartphones and tablets, including Apple and Android products, and have found them to be feasible and potentially valuable.[10] In the screening for atrial fibrillation in the elderly (SAFE) Study,[11] both methods of screening performed similarly and identified more cases of AF than did routine care. In a study performed in Halmstad, Sweden, stepwise screening of individuals aged 75–76 years with risk factors for stroke found that screening over a period of 2 weeks with a handheld device that recorded an electrocardiogram (ECG) identified 7.4% of individuals as having paroxysmal AF while 1% were identified by the intake ECG. This study had the added benefit of identifying a number of patients with known AF who were not receiving anticoagulation.[12] These findings were extended in the STROKESTOP study,[13] which demonstrated both a similar yield of newly identified AF and the success of the screening process in initiating anticoagulation in these patients. The Assessment of Remote Heart Rhythm Sampling Using the AliveCor Heart Monitor to Screen for Atrial Fibrillation (REHEARSE-AF) study examined the feasibility, yield, and cost per AF diagnosis of using twice weekly ECG recordings with the Kardia/AliveCor monitor. Overall, this randomized trial identified almost 4 times as many monitored patients (19 vs 5) as having AF as those receiving standard care. No difference, however, was seen in the incidence of stroke, transient ischemic attack, or systemic embolus between the groups, though the study was not powered for these events.[14]

Currently, the European Society of Cardiology recommends opportunistic screening for AF in patients older than 65 years with pulse palpation or an ECG rhythm strip[15] while US guidelines make no recommendation.[16] It is quite clear, however, that primary care physicians (PCPs)/internists, as well as cardiologists and heart rhythm specialists, have unique roles to play in improving the identification and education of patients at risk of AF and optimizing their coordinated and effective treatment. Therefore, the Heart Rhythm Society (HRS) and the American College of Physicians (ACP) partnered in this initiative to gather more information about the feasibility and effectiveness of systematic ambulatory screening of individuals identified by internal medicine practices to be at increased risk of AF.

Methods

The study design was conceived by HRS in partnership with ACP. The study proposal was developed jointly and then submitted to sponsors. Funding was secured from the Bristol-Myers Squibb–Pfizer Alliance. An HRS/ACP advisory panel with expertise in AF and screening was appointed, consisting of 3 cardiac electrophysiologists (D.S.F., J.C.H., and L.E.R.), and 2 internal medicine physicians (A.N.A., and A.O.), and a patient advocate (M.T.H). The goal of the initiative was to develop a systematic screening and educational program aimed at patients from internal medicine practices to identify undiagnosed AF and educate participants about the risk of stroke associated with AF. Additional goals included informing patient caregivers about the risks associated with AF as well as facilitating follow-up and treatment as warranted for those patients with screenings indicating possible AF. Surveys, designed by the advisory panel, were administered to individual participants and to organizers from the sites chosen for the project.

The advisory panel selected 5 centers to participate in the program on the basis of a thorough application process, including the screening method description, governance, and implementation plans.

Institutional review board (IRB) approval was sought and received first by HRS, and IRB reliance documents were approved by the individual sites, as required by their institutions. The selected sites were distributed across the United States: Illinois (Carle Foundation Hospital), Texas (Houston Methodist), Florida (University of South Florida), Pennsylvania (Thomas Jefferson University), and California (University of California at Irvine). One site (Carle Foundation Hospital) performed screening at 3 advertised fairs, one of which was associated with a medical grand rounds designed to educate providers about AF, while the others screened participants before scheduled internal medicine or primary care clinic sessions.

Subjects provided consent for the AF screening and were offered educational materials about AF, whether they chose to participate or not. Data for those with a preexisting diagnosis of AF or atrial flutter were excluded from the site results. Participation in the program also provided an opportunity to complete the HRS risk assessment questionnaire (www.AFibRisk.org), including a CHA_2DS_2-VASc stroke risk scorecard, in conjunction with a provider. Participants were required to have at least one of the following AF risk factors: ischemic heart disease, diabetes, hypertension, congestive heart failure, chronic obstructive pulmonary

disease, obesity, obstructive sleep apnea, age 65 years and older, a history of smoking, thyroid disease, or female sex.

Each participating center was given 4 Kardia/AliveCor iECG devices to perform rapid point-of-care screenings. The Kardia/AliveCor mobile ECG device (iECG) provided a 60-second iECG via a simple fingerprint touch, with the ECG recorded on an iPad using the downloadable application. The iECG identified the rhythm as "normal," "unclassified," or "possible AF."After consent, a reading of "normal" resulted in transmission of a copy of the iECG to the subject's PCP or electrophysiologist/cardiologist, along with information on the initiative. For a reading of "unclassified" or "possible AF," a copy of the iECG and a referral was promptly delivered to a PCP, cardiologist, or electrophysiologist. Information, including "Call to Action" resources from www.myafib.org, www.hrsonline.org, and www.stopafib.org, was given to the patient. Site-specific additional resources on the risks of AF and stroke due to AF were also provided to each patient.

Sites were responsible for data collection, including the number of individuals screened along with the following information for each individual: age, sex, risk factors, CHA_2DS_2-VASc score, screening results, and survey responses. Each participating site submitted data to HRS for tabulation and analysis. Qualitative data such as the assessment surveys, as well as information on the overall experience, were also provided to HRS in the final reports from the sites. Each section of the document was written by a writing group member. All sections were then compiled and edited by the working group chair.

Statistics

Continuous variables are expressed as means ± standard deviations. Differences in continuous variables between the 3 groups were assessed using the analysis of variance test. Categorical variables are expressed as numbers (percentages).

Results

Overall, 772 individuals participated at the 5 screening sites. The most significant challenge to implementation of the screening events was obtaining local IRB approval. The mean age of the participants was 65.2 ± 15.4 years, and 218 (28.2%) were 75 years or older. The majority (551 [71.4%]) were caucasian, and 521 (67.5%) of those evaluated were female (Table 1). Associated risk factors for stroke and AF are also presented in Table 1. By design, these risk factors were prevalent in the screened population. About 466 (60%) of participants had hypertension, and about three-quarters had a CHA_2DS_2-VASc score of $\geq$2 (Table 2).

The majority of those screened, 670 (86.8%), were found to be "normal." Overall, 85 (11.0%) had findings that were "unclassified" and 17 (2.2%) had "possible AF." There was a progressive increase in age from those screened as "normal" to "unclassified" and to "possible AF" (mean age 64.5 ± 15.0 years vs 68.0 ± 17.8 years vs 78.0 ± 12.2 years, respectively; P = .002) (Table 1). The mean CHA_2DS_2-VASc score similarly increased from those with readings of "normal" to "unclassified" to "possible AF" (2.5 ± 1.3 vs 2.8 ± 1.5 vs 3.4 ± 1.6, respectively; P = .02) (Table 2). Unfortunately, follow-up information on the ultimate diagnosis of these patients is not available because of IRB constraints.

Participants were quite satisfied with the screenings as indicated by qualitative statements solicited as part of the exit surveys. Most notable, however, was their perception of the educational value of these screenings, as evidenced by their responses to the questionnaires provided. An assessment of 8 key facts about AF and the risk of stroke indicated a significant knowledge deficit before the events (Table 3), and more than 90% of respondents felt that their awareness of the association between AF and the risk of stroke was increased after screening (Figure 1).

Discussion

In internal medicine practices, we detected "possible AF" in 2% of participants and "unclassified" rhythm in an additional 11%. While data are not available on the ultimate diagnosis of these patients, the positive predictive value of systematic AF screening in higher-risk individuals identified with findings of "possible AF" by the Kardia/AliveCor device has been reported to exceed 90% in a population of patients with known AF by using a 12-lead ECG as the criterion standard. The positive predictive value of "unclassified" rhythm was reported to be 34% in that study.[17] Certainly, in a population without known AF where the true prevalence of disease is lower, the positive predictive value would be expected to be lower as well. Nevertheless, using these reported values, our screening program could have identified as many as 44 cases of AF in the total screened population of 772. As a comparison, a randomized trial of population-based colonoscopy screening, a widely accepted screening procedure, identified colorectal cancer in 0.5% of participants and high-risk adenomas in 10.4%.[18]

As with any screening diagnostic test, the positive predictive value increases with the true prevalence of disease in the population screened. To enrich the prevalence of AF, we required participants to have at least 1 risk factor for AF. The prevalence of AF increases steadily with age. For example, in the Framingham Heart Study, AF was present in 5% of participants aged 60–70 years compared with 22% of participants older than 90 years,[3] and our results are certainly consistent with this finding. In order to increase the diagnostic yield of future screening programs, more elderly populations or those with more than 1 risk factor for AF or stroke could be targeted in locations such as nursing homes, community centers, and casinos. In contrast, settings enriched with young people, such as schools, would be expected to result in even lower diagnostic yields and higher false-positive rates and likely should be avoided in future screening programs.

Furthermore, as AF often occurs intermittently, it is well established that the greater the frequency and duration of monitoring, the more cases will be detected. For example, in patients with cryptogenic stroke or transient ischemic

Table 1 Demographic characteristics and medical comorbidities of the participants

Variable	Total	Normal	Unclassified	Possible AF
No. of patients	772 (100)	670 (86.8)	85 (11.0)	17 (2.2)
Age (y)				
19–29	34 (4.4)	28 (4.2)	6 (7.1)	0 (0.0)
30–39	26 (3.4)	24 (3.6)	2 (2.4)	0 (0.0)
40–49	57 (7.4)	51 (7.6)	5 (5.9)	1 (5.9)
50–59	95 (12.3)	87 (13.0)	8 (9.4)	0 (0.0)
60–69	218 (28.2)	200 (29.9)	16 (18.8)	2 (11.8)
70–79	223 (28.9)	195 (29.1)	22 (25.9)	6 (35.3)
80–89	96 (12.4)	70 (10.4)	20 (23.5)	6 (35.3)
≥90	23 (3.0)	15 (2.2)	6 (7.1)	2 (11.8)
Mean ± SD	65.2 ± 15.4	64.5 ± 15.0	68.0 ± 17.8	78.0 ± 12.2
Female sex	521 (67.5)	465 (69.4)	48 (56.5)	8 (47.1)
Race/ethnicity				
White/Caucasian	551 (71.4)	465 (69.4)	70 (82.4)	16 (94.1)
Hispanic/Latino	72 (9.3)	64 (9.6)	8 (9.4)	0 (0.0)
Black/African American	85 (11.0)	80 (11.9)	4 (4.7)	1 (5.9)
Asian	54 (7.0)	52 (7.8)	2 (2.4)	0 (0.0)
American Indian/Alaska Native	6 (0.8)	5 (0.7)	1 (1.2)	0 (0.0)
Race not provided	4 (0.5)	4 (0.6)	0 (0.0)	0 (0.0)
Risk factors				
CHF	26 (3.4)	14 (2.0)	7 (8.2)	5 (29.4)
Hypertension	466 (60.4)	406 (60.6)	50 (58.8)	10 (58.8)
Age 65–74 y	256 (33.2)	228 (34.0)	24 (28.2)	4 (23.5)
Age >75 y	218 (28.2)	172 (25.7)	35 (41.2)	11 (64.7)
Diabetes	150 (19.4)	129 (19.3)	18 (21.2)	3 (17.6)
Previous stroke/TIA	60 (7.8)	45 (6.7)	12 (14.1)	3 (17.6)
Vascular disease	118 (15.3)	92 (13.7)	19 (22.4)	7 (41.2)
Female sex	521 (67.5)	465 (69.4)	48 (56.5)	8 (47.1)
COPD	27 (3.5)	21 (3.1)	4 (4.7)	2 (11.8)
OSA	106 (13.7)	90 (13.4)	14 (16.5)	2 (11.8)
Obesity	180 (23.3)	164 (24.5)	14 (16.5)	2 (11.8)
Thyroid disease	140 (18.1)	123 (18.4)	13 (15.3)	4 (23.5)
Smoker	41 (5.3)	34 (5.1)	6 (7.1)	1 (5.9)
Family history	97 (12.6)	83 (12.4)	14 (16.5)	0 (0.0)
Ischemic heart disease	8 (1.0)	5 (0.7)	2 (2.4)	1 (5.9)

Values are presented as n (%) unless specified otherwise.

AF = atrial fibrillation; CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; OSA = obstructive sleep apnea; TIA = transient ischemic attack.

attack, use of a continuous, 30-day monitor increased the diagnostic yield more than 6-fold compared to a 24-hour Holter monitor.[19] Still greater increases in diagnostic yield have been reported with use of insertable cardiac monitors over a 3-year period.[20] Even when using an intermittent monitor such as Kardia/AliveCor, repeated testing over time increases diagnostic yield. For example, as noted in the Swedish studies, the yield of AF diagnoses increased with 2 weeks of twice daily 30-second recordings.[12,13] Similarly, in the Assessment of Remote Heart Rhythm Sampling Using the

Table 2 CHA_2DS_2-VASc scores of the participants

Variable	Total	Normal	Unclassified	Possible AF
No. of patients	772 (100.0)	670 (100.0)	85 (100.0)	17 (100.0)
CHA_2DS_2-VASc score				
0	9 (1.2)	9 (1.3)	0 (0.0)	0 (0.0)
1	177 (22.9)	157 (23.4)	18 (21.2)	2 (11.8)
2	188 (24.4)	166 (24.8)	20 (23.5)	2 (11.8)
3	185 (24.0)	167 (24.9)	15 (17.6)	3 (17.6)
4	126 (16.3)	108 (16.1)	13 (15.3)	5 (29.4)
5	54 (7.0)	41 (6.1)	11 (12.9)	2 (11.8)
6	22 (2.8)	15 (2.2)	6 (7.1)	1 (5.9)
7	10 (1.3)	6 (0.9)	2 (2.4)	2 (11.8)
8	1 (0.1)	1 (0.1)	0 (0.0)	0 (0.0)
CHA_2DS_2-VASc score ≥2	586 (75.7)	504 (75.2)	67 (78.8)	15 (88.2)

Values are presented as n (%).

AF = atrial fibrillation.

Table 3 Respondents' prescreening knowledge of facts about AF

Evaluation: Internal medicine AF screening	Yes, I knew	n	No, I did not know	n	Total
Women with AF have a higher risk of stroke than do men.	33.10%	188	66.90%	380	568
AF strokes are much more dangerous than other types of strokes.	21.14%	119	78.86%	444	563
The risk of stroke is much higher if you have AF that is not treated.	54.23%	308	45.77%	260	568
People living with AF are at risk of stroke even if they have irregular heartbeats only once in a while.	42.53%	242	57.47%	327	569
Most AF strokes are caused by a blood clot in the brain.	36.33%	206	63.67%	361	567
Physicians think about AF stroke risk when suggesting choices about treatment.	38.38%	218	61.62%	350	568
Blood thinners can greatly reduce the risk of AF stroke.	59.36%	336	40.64%	230	566
Even those with occasional AF are at risk of AF stroke.	42.50%	241	57.50%	326	567
Some patients with AF may not have any noticeable symptoms.	46.02%	260	53.98%	305	565

AF = atrial fibrillation.

Kardia/AliveCor Heart Monitor to Screen for Atrial Fibrillation (REHEARSE-AF) study,[14] during which participants used the Kardia/AliveCor monitor twice weekly, diagnoses of AF continued to accrue over the entire 52-week study period. Thus, it is clear that the single 60-second screening interval that we used lacks the sensitivity of more prolonged or more frequent monitoring strategies. However, this must be weighed against the simplicity and economy of this methodology.

Regardless of the true diagnostic yield of our screening program, it did provide important collateral benefit in the form of patient and caregiver education. Increased patient knowledge is likely to translate into improved care and, ultimately, prevented strokes. More than 90% of participants stated that the education provided increased their awareness of stroke risk associated with AF and suggests that the educational benefit would be generalizable to most internal medicine settings. During a screening event such as this, participants may be uniquely eager for and receptive to education and the attraction of the Kardia/AliveCor monitor may be the "hook" that gets them engaged. Extensive educational resources have already been developed and are available for use as part of these efforts, such as those available at www.HRSonline.org, www.ACPonline.org, www.myafib.org, and www.stopafib.org.

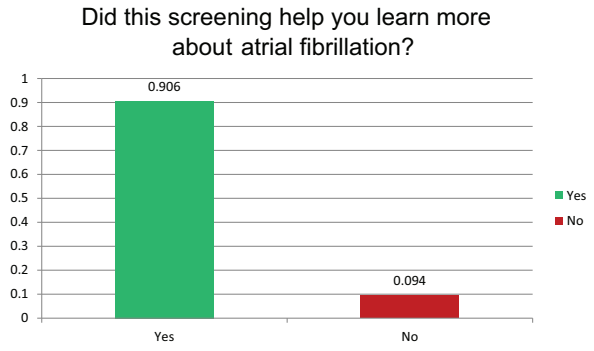

Figure 1 Summary results of the questionnaires completed by participants, indicating their perception of the significant educational value of the Heart Rhythm Society/American College of Physicians Atrial Fibrillation screening events.

The harms of any screening diagnostic test must also be considered. In the present study, a false-positive interpretation of "possible AF" may have led to unnecessary patient anxiety. Furthermore, confirmatory 12-lead ECGs were not immediately available at all sites, but rather patients were directed to their physicians for follow-up. This increases the time to definitive diagnosis and treatment. Furthermore, it is possible that the participant was truly in AF at the time of screening, but by the time a 12-lead ECG was recorded, AF was no longer present, reducing the opportunity to diagnose true AF. For future screening programs, we recommend on-site confirmatory testing with a 12-lead ECG and a streamlined process to initiate treatment once the diagnosis of AF is confirmed. An alternative strategy of offering Kardia/AliveCor screening in physician waiting rooms would seem especially effective. As patients check in on an electronic device such as an iPad, they could be offered the opportunity to be screened for AF. If "unclassified" rhythm or "possible AF" is detected, a confirmatory 12-lead ECG could be recorded during that visit and treatment promptly initiated. Regardless of the results, education about AF and stroke prevention could be provided via the same electronic device while patients await their appointments.

Currently the US Preventive Services Task Force[19] concludes that there is insufficient evidence to assess the net benefit or harms of ECG screening for AF. On the basis of this collaboration between HRS and ACP, we call for further

research on this important topic and strongly believe that the added value of patient and caregiver education should factor into the assessment of such screening.

Limitations

We cannot report performance characteristics of Kardia/AliveCor screening given that simultaneous 12-lead ECGs were not performed and our access to the adjudication of "unclassified" and "possible AF" readings was limited by local IRB constraints. Thus, the true diagnostic yield of our screening program is unknown. Nevertheless, it is clear that the educational benefit of the program was of significant value to participants. Whether screening with the Kardia/AliveCor device is more accurate than a pulse check or cardiac auscultation was not assessed by our study. The latter screening modalities, while indeed simple and inexpensive, may be less engaging for patients.

Conclusion

During these internal medicine practice–based systematic screening programs using the Kardia/AliveCor iECG, a moderate number of possible AF cases were identified. Several important lessons were learned, including the following:

1. The diagnostic yield of screening programs can be enriched by targeting populations with a high prevalence of AF, particularly the elderly and those with more than 1 risk factor for AF.
2. The greater the duration and frequency of monitoring, the greater its sensitivity.
3. On-site confirmatory testing with a 12-lead ECG for "possible AF" and "unclassified" rhythm can decrease patient anxiety, facilitate prompt treatment, and perhaps increase yield.
4. For patients with newly diagnosed AF, minimizing the time to physician evaluation and treatment is essential.
5. Devices such as the Kardia/AliveCor monitor may enhance patient engagement in screening programs.
6. Screening programs should take advantage of the opportunity to provide education on AF and stroke prevention, thereby increasing their benefit to all participants.

Appendix 1

See Table A1.

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Table A1 Author disclosure table

Writing group member	Employment	Honoraria/speaking fees/ consulting fees	Speakers' bureau	Supported Research*	Fellowship support*	Ownership/ partnership/ principal/ majority stockholder	Stock or stock options	Intellectual property/ royalties	Other
Alpesh Navin Amin, MD, MBA, MACP	University of California, Irvine, California	3: Bristol- Meyers Squibb; 3: Pfizer; 3: Portola Pharmaceuticals	None	None	None	None	None	None	None
David S. Frankel, MD, FHRS	University of Pennsylvania, Philadelphia, Pennsylvania	1: Boston Scientific; 1: Abbott Laboratories; 1: Strykers	None	None	None	None	None	None	None
Jonathan C. Hsu, MD, MAS, FHRS	University of California, San Diego, California	1: Abbott Laboratories; 1: Medtronic; 1: Boston Scientific; 1: Biotronik; 1: Janssen Pharmaceuticals	None	1: Biosense Webster; 1: Biotronik	None	None	None	None	None
Mellanie True Hills, CSP	StopAfib.org, Decatur, Texas	None	None	None	None	True Hills	None	None	Officer, trustee, director, committee chair, or any other fiduciary role—American Foundation for Women's Health
Lynda E. Rosenfeld, MD, FHRS	Yale University School of Medicine, New Haven, Connecticut	None	None	None	1: Abbott Laboratories; 3: Boston Scientific; 3: Medtronic	None	4: Procter & Gamble; 4: Abbott Laboratories	None	None
Asa Oxner, MD	University of South Florida Morsani College of Medicine, Tampa, Florida	None	None	None	None	None	None	None	None

Number value: 0 = $0; 1 = ≤$10,000; 2 = >$10,000 to ≤$25,000; 3 = >$25,000 to ≤$50,000; 4 = >$50,000 to ≤$100,000; 5 = >$100,000.

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