A Primary Care Initiative to Improve Equitable Screening and Management Strategies in NVAF

CMEO Podcast Transcript

David S. Kountz:

Hello, I am Dr. David Kountz and on behalf of CME Outfitters I would like to welcome you to tonight's educational activity entitled, "A Primary Care Initiative to Improve Equitable Screening and Management Strategies in Non-Valvular Atrial Fibrillation [NVAF]." Today's educational program is supported by an educational grant from the Bristol Myers Squibb and Pfizer Alliance. This CME activity is certified by CME Outfitters, a jointly accredited provider of continuing education for clinicians worldwide.

Once again, I am David Kountz. I'm Co-Chief Academic Officer and Vice President for Academic Diversity at Hackensack Meridian Health. I'm Professor of Medicine and Senior Associate Dean for Diversity, Equity, and Inclusion at the Hackensack Meridian School of Medicine in Nutley, New Jersey. I'm very pleased to be joined today by a superb panel while asked to introduce themselves, starting with Dr. Cho.

David J. Cho:

Hi, I'm David Cho. I'm an Assistant Clinical Professor and Co-Director of the Quality Program in the Division of Cardiovascular Medicine at UCLA Health. I'm also the current Chair of the Healthcare Innovation Section for the American College of Cardiology.

David S. Kountz:

Thank you, David. Dr. Ko?

Darae Ko:

Hi, I'm Darae Ko. I'm Assistant Scientist II at the Hinda and Arthur Marcus Institute for Aging Research at Hebrew Senior Life, and I'm an attending cardiologist at Boston Medical Center in Boston, Massachusetts, the largest safety net hospital in New England, where 70% of our patients that we treat are on Medicare and Medicaid.

David S. Kountz:

Thank you both. What is superb panel we have tonight.

Let's begin tonight's program by reviewing our learning objectives. After completing this activity, learners should be better able to, one, implement screening and primary care settings to identify patients with non-valvular atrial fibrillation who might benefit from anticoagulant therapy; two, integrate current practice guidelines into the care of patients with non-valvular atrial fibrillation; and, three, collaborate with team members and patients to optimize screening and management strategies for non-valvular atrial fibrillation.

David S. Kountz:

To set the stage for tonight's program, let's take a brief look at the prevalence and impact of AFib in the United States. As you can see from the slide, the epidemiology of atrial fibrillation shows a rising prevalence in all groups, but especially in those over the age of 65. We'll also note that 11% to 14% of patients are undiagnosed atrial fibrillation. The prevalence estimates its 2010 range from 2.7 million to 6.1 million and the prevalence is predicted to increase to 12.1 million by 2030.

Of course, what we all worry about as clinicians is the risk of complications associated with atrial fibrillation, including cardiovascular death, MI, or stroke, and these are significant risks within five years of diagnosis. In fact, mortality was the most frequent major outcome during the first five years after diagnosis. Among non-fatal cardiovascular events, heart failure was the most common.

We want to discuss in tonight's program the significance of social determinants of health and how different patient groups may not all be receiving the same optimal therapy. The determinants of racial inequity can be recognized across the atrial fibrillation care continuum—changes or differences in the prevalence of risk factors, less awareness of atrial fibrillation and lower detection, less treatment for atrial fibrillation, and, as we showed earlier, an increased likelihood of complications.

Interesting there is a well-appreciated atrial fibrillation paradox in African-American patients. Despite increased predominance of traditional risk factors—diabetes, hypertension, obesity—Black individuals have a lower prevalence of atrial fibrillation. We might, when we get into our discussion, hear from our cardiologist about why this might be. However, this should not be meant to say that this is not a significant issue in the African American population, but there is this unique paradox that's been recognized. Next, we're going to hear from Dr. Cho about screening high risk patients for non-valvular atrial fibrillation in the primary care setting. We'll also discuss some of the current and emerging technologies and mobile apps used for detecting atrial fibrillation.

This discussion will address our first learning objective—implement screening and primary care settings to identify patients with non-valvular atrial fibrillation who might benefit from anticoagulant therapy. But first, let's get our audience involved with a quick audience response question. And here's the question. Opportunistic screening for atrial fibrillation is recommended by which of the following guideline committees? Is it the European Society of Cardiology, the U.S. Preventative Services Task Force, Both, or neither, or, E, you're not sure.

Okay. Well, the right answer is, A, the European Society of Cardiology. Thirteen percent of you got that right, so good for you. We'll learn more about this in just a moment.

Okay, Dr. Cho, let me turn it over to you.

David J. Cho:

Thank you, Dr. Kountz. It's a pleasure to be here tonight. So atrial fibrillation presents with a wide range of symptoms, from no symptoms or very subtle symptoms such as generalized fatigue or mild shortness of breath. Severe symptoms can include rapid heart rate, chest pain, palpitations, and heart failure. Regardless of symptom burden, however, untreated atrial fibrillation can lead to significant morbidity and mortality. Currently, our best estimator for stroke risk related to AFib is the CHA_2DS_2-VASc score model. On the right, you can see the annual risk of ischemic stroke or an AFib patient without anticoagulation on an annualized basis. Current guidelines recommend that males with a score of two or greater should start anticoagulation in the absence of significant contraindications. And for women, a score of three or greater would warrant initiation of an anticoagulant.

There is an ever expanding number of ways that AFib can be detected in today's world. This slide demonstrates the whole gamut of options from the lowest tech, which is the typical and traditional physical examination through palpation and auscultation. More traditional options such as Holter monitors, [electrocardiograms] ECGs, implantable cardiac monitors, and the newer technology modalities, including [photoplethysmography] PPG sensors from a camera light, wearables such as smartwatches or other devices, and point of care ECG devices that are sold directly to consumers. However, despite our increased capabilities to detect and diagnose atrial fibrillation, there is still uncertainty about whether we should be screening patients for atrial fibrillation. Guidelines from the European Society of Cardiology, or ESC, and the US Preventative Services Task Force, or USPSTF, are shown here.

While the ESC recommends opportunistic screening for patients greater or equal to the age of 65 and systematic screening to be considered for patients greater than or equal to 75 years old or those at high risk for strokes, such as those with valvular heart disease, the United States Preventative Services Task Force actually states that the evidence to recommend universal screening or opportunistic screening for atrial fibrillation is insufficient at this time to make a formal recommendation. The ESC does provide certain situations where screening can be considered, such as those with implantable devices such as pacemakers who have high atrial rate episodes, which can be a potential precursor to atrial fibrillation, or those with a history of cryptogenic stroke in whom ambulatory monitoring is inconclusive.

But let's take a step back and actually talk about what is opportunistic screening as a definition. In short, it means you're screening a patient without symptoms at an opportune time, such as during a routine office visit or other healthcare encounter.

Contrast this method with systemic screening recommends that anyone meeting certain criteria are invited to be screened. There is a trade off as well to increasing the sensitivity of AFib detection. AFib is currently defined as a standard 12 lead ECG diagnosis or a 30-second ambulatory Holter monitor episode, yet we know that the duration of AFib episodes correlates strongly with the increased risk of stroke. Is a single 30-second episode of AFib detected on a 7-day Zio patch monitor really the same risk as someone diagnosed 20 years ago through the traditional ECG? How much AFib is clinically meaningful? We don't quite yet know the answers to this question, among many others, which is in line with what the US Preventative Task Services has recommended at this time.

David J. Cho:

This demonstrates a list of the current diagnostic tools available to consumers to purchase over-the-counter that can detect and diagnose AFib. These devices have been FDA cleared through software algorithms to detect AFib through abnormalities in heart rate variation as well as single lead ECG rhythm analysis. Some of these devices are quite expensive, and they all require a smartphone with some form of data plan or Wi-Fi. Disparities in access to these tools and population level decisions on screenings based on bias study populations have the very real risk of worsening health equity and making recommendations on limited data.

There are a few large studies underway to study the impact of these modern tools in the care pathway of AFib. The Heartline study is studying whether patients greater than or equal to 65 years old with an Apple Watch will have improved detection and outcomes for AFib in the real world.

Northwestern is studying the impact of an intermittent anticoagulation strategy dependent upon the Apple Watch's ability to detect AFib burden in low AFib burden risk patients. However, perhaps most appropriate to this webinar is the National Health Services [NHS] in England. They are running a large randomized trial called SAFER, which will screen more than 120,000 patients greater than or equal to 75 years old across over 300 practices in England and Australia. The results of this study will help guide the NHS's decision on whether or not to institute the national AFib screening program.

David S. Kountz:

Thank you, Dr. Cho. I wonder if I could ask you two questions that are in the chat since they're timely to your presentation. The first is if you know if and when the Preventative Services Task Force will reexamine their statement regarding wearable devices with regards to screening for atrial fibrillation.

David J. Cho:

So I believe that the most recent recommendation came out in 2020 of inconclusive. I believe probably in the next couple of years we may have an updated recommendation. A lot of these preventative guidelines are made in conjunction and with advisement from our professional society, such as the [American College of Cardiology] ACC or American Heart Association, Heart Rhythm Society… The guidelines that were most recently updated by these professional societies was last updated in 2019. And updates come out every few years, so we'll have to wait a little bit longer before we get an updated assessment on the inconclusive and a little bit more data as well in the real world.

David S. Kountz:

Great. And another question asked, the audience member asked if the wearables you described can measure blood pressure as well as a heart rhythm. Are they focused just on rate and rhythm?

David J. Cho:

So currently by FDA cleared and de novo pathways, so far it is only for the detection and diagnosis of AFib either by the actual EKG that's a single lead or through an abnormal heart rhythm, their own proprietary algorithm. There are some companies in Europe and Korea actually that are approved over there for the detection of blood pressure through wearable PPG signals, but at this time the studies are still investigational. And any devices that are claiming otherwise should be taken with a grain of salt.

David S. Kountz:

Thank you, Dr. Cho. Next up is Dr. Darae Ko, who's going to talk about current guidelines for the equitable management of patients with non-valvular atrial fibrillation. This question will address our second learning objective, to implement current practice guidelines into the care of patients with non-valvular atrial fibrillation.

But first we have another audience response question, so please get ready to respond to this question. Which of the following direct oral anticoagulants, or DOACs, reduces the risk of major bleeding versus warfarin? A, apixaban, B, dabigatran, C, edoxaban, D, rivaroxaban, or, E, you're not sure.

A, great job, 55% of you. The correct answer is, a, apixaban. Terrific. Dr. Ko, over to you.

Darae Ko:

Thank you and it's certainly a pleasure to be here and talk about anticoagulation management in patients with atrial fibrillation. As many of you know, anticoagulation is the cornerstone treatment in AFib and that's because, without anticoagulation, AFib increases the risk of ischemic stroke about by fivefold. And cardioembolic stroke from AFib is more fatal and causes greater disability compared to a non-AFib stroke. It carries a 30-day mortality of 24% and an additional 35% are rendered unable to live independently after AFib-related stroke. And we know that compared to placebo and from the data from the warfarin era the anticoagulation reduces the risk of stroke by at least 64% compared to placebo.

So how do you select patients for anticoagulation? You've heard already about CHA_2DS_2-VASc score and, according to the American guidelines, we use for men two points or greater and for women three points or greater to select patients for anticoagulation. The current guidelines or most updated guideline for American Heart Association in 2019 states that the DOACs should be the first-line therapy. And we have four options in America. We have a apixaban, dabigatran, edoxaban, and rivaroxaban. Warfarin is no longer on the equal level with the DOACs, and it's now considered the second-line therapy. And finally, I want to emphasize that aspirin should never be used as an alternative for stroke prophylaxis in atrial fibrillation. I sometimes see how among patients who are referred to me they are on aspirin because of the concern for bleeding risk instead of on anticoagulation, but that is no longer recommended. The decision should be either anticoagulation or no aspirin and that's because we now have definitive data from clinical trial that aspirin carries a bleeding risk that is similar to apixaban.

Darae Ko:

So why are the DOACs now the first-line therapy according to the guidelines? That's because as a group they have superior efficacy in prevention of thromboembolic complications compared to warfarin. According to the meta-analysis that was published in 2014, as a group, the DOACs reduce the risk of thromboembolic complications compared to warfarin. And after about a decade of using these drugs, we are now confident the DOACs are probably superior to warfarin in terms of prevention of ischemic events.

Really, the benefit of using DOACs come from their superior safety profile. All four DOACs reduce the risk of hemorrhagic stroke by 50%, the most devastating complication of anticoagulation therapy. Apixaban is the only drug that's been shown to reduce the risk of major bleeding compared to warfarin and that's by about 30%. And the apixaban was also tested against aspirin, 81 to 325 milligrams, and that's been shown not to increase the risk of bleeding, but not all DOACs are the same. Rivaroxaban was shown to increase the risk of [gastrointestinal] GI bleeding versus warfarin in the pivotal trial. Only apixaban, as I stated before, reduces the risk of major bleeding versus warfarin and currently apixaban is the only FDA-approved DOAC to be used in patients on dialysis. There is currently a substantial underutilization of oral anticoagulants in patients with atrial fibrillation.

This is a study that we recently published using study cohorts of patients who are beneficiaries of Medicare Advantage Plan. And so we looked at people with new diagnosis atrial fibrillation and investigated whether or not they were starting on an anticoagulation therapy within 12 months of the diagnosis. And in year 2020 that rate is about 33%. The availability of DOACs has improved that percentage by about 12% to 13% in a decade, but still a substantial number of patients with AFib remain untreated with anticoagulation therapy.

And it's been very well documented that there are substantial disparities in the way that we treat AFib patients with anticoagulation. Black and Hispanic individuals are less likely to receive an oral anticoagulant. And among those patients who do receive an oral anticoagulant, Black and Hispanic individuals are less likely to receive a DOAC. And the reality is that even though the DOACs are first-line therapy for Medicare beneficiaries, they can increase substantial out-of-pocket costs. So a classic story that I observe in my clinic is that our patients who have been doing pretty well on warfarin and I want to switch them to DOAC just because of the safety profile of apixaban, for example, but I can't because their out-of-pocket costs can be like $400 a month.

And related to that is also a disparity in access to specialty care. We have data now to that shows that the likelihood of starting a patient on an anticoagulant increases with the physician's specialty. So electrophysiologists [EPs] are most likely to start patients with AFib with guideline eligibility for [oral anticoagulant] OAC on anticoagulation, but they only have 2,200 of electrophysiology in the United States, so their access to EP doctors is limited. And then general cardiologists are more likely to start patients on anticoagulation compared to aspirin. If there is any hesitancy about starting a patient on an anticoagulant due to their bleeding risk, the patient should be referred to cardiologists as soon as possible. And in this era, in year 2023, we should not have any patients unprotected for this devastating complication, yet highly preventable, complication from AFib.

David S. Kountz:

Thank you Dr. Ko. I'd like to ask you a few questions that have come in during your presentation. And I agree with you, no patient should be left unprotected today. And sadly, I do see a number of patients admitted to my hospital with known atrial fibrillation on aspirin, and it's a frustrating situation I'm sure all of us see, we hear that.

Do you encourage patients who have been stable on warfarin for years to switch to a DOAC?

Darae Ko:

I have for multiple reasons because of the safety profile of the DOACs. You know, in the past there was a hesitancy about switching these patients in part because there's a question of the DOACs have a reversal agent, the data about the rivaroxaban increasing GI bleeding risk… But at this point, it's been about 12 years after we've been using these drugs, and they really improve the quality of life for these patients. My patients don't have to take [international normalized ratio] INR checks anymore. They don't have to worry about the interaction with other medications with warfarin. They don't have to worry about the food interaction between warfarin and different types of food that they can eat and not eat. I really think that it improves their quality of a life at minimum.

David S. Kountz:

Great. And Dr. Cho, if there are some questions you'd like to respond to, please jump in.

The next question has to do with you mentioned never using aspirin for stroke prophylaxis. What about the role for clopidogrel?

Darae Ko:

No, I don't do that either because really the hypothesized benefit of using antiplatelet as opposed to anticoagulation is because you think that the bleeding risk is less, but with aspirin, it's not. That was shown in AVERROES trial that was published with Aristotle, which was a trial that led to the approval of apixaban. And I do not think the clopidogrel reduces bleeding risk compared to apixaban, but I think it's inferior to apixaban or another DOAC in terms of prevention of thromboembolic complications. And I keep saying apixaban because, as you saw in that figure that I presented, the vast majority of patients in the United States now with new AFib diagnosis, they're being started on apixaban.

David S. Kountz:

Great. I think you just answered the question for the individual—the aspirin comparison with regard to bleeding with other agents.

David S. Kountz:

Dr. Cho, I wonder if I could bring you back in. There are a couple of questions related, one question related to the wearable devices and how they make the diagnosis of AFib, and I'll put this in quotes, specifically "if a patient comes in showing an ECG that shows AFib, are you rechecking that in the office? If so, and the patient is not an AFib, what would your next step be? Would you order a Holter monitor? Is there any kind of either guideline or approach that you would take in that situation?"

David J. Cho:

Certainly. So this is a great question. I think just before I answer that, just the current devices, they do have the ability to do a single lead EKG, just like single lead Holter. And that software analysis, just like our traditional ECG softwares, can detect or have been shown with high accuracy to detect atrial fibrillation or normal rhythm.

Now, there are some limitations. I believe that there's an upper heart rate above I think 150 or so. It will classify it as inconclusive, so typically the less rapid AFib will be diagnosed. Then there's these in addition to just the Apple Watch, Fitbit, Galaxy, as I showed in the document, there's all these other hosted ones that can also detect AFib through heart rhythm. And the way that one works is that these monitors have the ability to detect heart rate throughout the day. If it starts noticing more irregularity, it notes that and then starts sampling more frequently. And then based on that proprietary algorithm, that has actually been what the Apple heart study, the Fitbit study, that's what they were actually using to diagnose atrial fibrillation.

And then they'll usually get a notification saying, "Hey, you might be in atrial fibrillation. You should see a physician." They then have the ability to do a single EKG to confirm that, and the Apple Watch just got FDA cleared to detect in people who have known AFib how much of burden of AFib that one is happening. Something I just learned as well recently is that doesn't quantify 0%. It'll just say 2% or less, so it could be 0% or it could be somewhere in between. That was something that was new to me. And then an actual number is given the more AFib you have. Anecdotally, if a patient comes in and the ECG says atrial fibrillation, I do go through the pictures where they're able to export a PDF for me in an office visit.

And I typically am ordering a confirmatory Holter monitor of some form, but for the most part, if they've had a whole bunch of them and it looks like AFib in the ECG monitor and they have a high CHA_2DS_2 score, I actually feel comfortable starting them on an anticoagulation because the data and the fidelity and accuracy of their ability to diagnose against cardiology trained human people is actually quite accurate. But for the most part, I will sometimes want to get a monitor also to detect burden of atrial fibrillation a little bit more specifically.

David S. Kountz:

Great. I'm going to take a couple of more questions now and then we'll do the third part of our program and then we'll have time if there are other questions that come in for our speakers.

There's a question about why the rate prevalence is rising and I'm going to think that part of that is because the risk factors are increasing. The obesity epidemic, the rates of diabetes. We've already heard that many underrepresented populations perhaps have under recognized or untreated AFib, but I wonder either Dr. Cho or Dr. Ko, if there are other thoughts that you have about why the prevalence is increasing that we haven't already touched on.

Darae Ko:

I think it's probably at least in part due to aging, the aging population. If you look at the studies from CHARGE-AF cohorts, so we have a lot of epidemiology we know about atrial fibrillation comes from population-based studies such as Framingham University, where I did my training. And if you look at CHARGE-AF cohort and that study looked at a combination of multiple cohorts and looked at risk factors from AFib, one of the most important risk factors for AFib is actually aging. And so I think the reason that we will expect to find greater number of patients with AFib is because people are aging successfully. They're living longer and therefore they're going to accrue more comorbidities that are associated with AFib, not just with aging. And I think that's probably why that the prevalence is projected to rise to that at least 12 million as that study that you cited.

David S. Kountz:

Thank you both. I'm going to get started on the third learning objective and, again, we should have a few minutes at the end for any unanswered questions or for some dialogue.

This section of the program, this learning objective, is to collaborate with team members and patients to optimize screening and management strategies for non-valvular atrial fibrillation. And so this is our final audience response question. Patient focused interviewing and care is an example of which of the following—cultural humility, health equity, implicit bias, social determinants of health, or you're not sure?

Hey, everybody, thank you as always for answering this question. The answer is actually, A, cultural humility. Cultural humility is really defined as both self-reflection from the provider and then really having that open ended, if you will, non-paternalistic collaborative relationship with patients, which is part of the definition of patient-focused interviewing.

And really has been shown to better engage patients, to be part of their care, to be more activated and proactive in terms of positively addressing health outcomes. So, we wanted to start this section with a definition, but we'll touch on the others as we continue through this section of the webinar.

David S. Kountz:

So, I think we all appreciate, and we saw a slide earlier that the optimal care of a patient with atrial fibrillation is truly a team approach, like most conditions that we treat. The patient is in the center. The idea, again, of that, really a focus on the patient and ideally they're going to have their primary care provider, their cardiologist, perhaps their electrophysiologist, and, as Dr. Ko mentioned, perhaps if there's a anticoagulation clinic there may be a nurse specialist who's helping them with management. And then beyond that are another group of healthcare professionals. They might have comorbid conditions such as sleep apnea, diabetes, where those specialists who work in those areas are part of the broader care team. They may need have other [cardiovascular] CV risk factors, so having an exercise physiologist, a psychologist if there are issues such as depression that are limiting or interfering with their interest in exercising, taking medications, following up, and of course a pharmacist. So really important to think about this broader interprofessional model to provide optimal care.

So SDOH, or social determinants of health, is an increasingly recognized important issue for us to think about as clinicians. I think I certainly trained in an era where the focus was on pharmacotherapy devices, and we've heard terrific discussion tonight of devices to help identify atrial fibrillation, but we've also heard that underrepresented patients have a greater burden of complications associated with atrial fibrillation. So important for us when we're interacting with patients—when we see them in our hospitals, our health systems—to think about this broader context of social determinants. Are there issues with their engagement with specialists, with clinicians? Are there financial resources, something we've already touched on? Do they have access to those appropriate specialists? Do they have easy access for follow-up care? Are we thinking about health literacy? All of us on this call likely deal with very literate colleagues and family members, and we need to remember that the average reading level in this country is probably at the fifth to sixth grade level, so certainly no higher than the eighth or ninth grade. So is the information that we're making available really appreciated by that large percentage of people who are low health literacy patients? And then what is that patient's social network? Are they hearing messages from friends or family members that is discouraging them from accessing continuous care? Are we making that effort to create those relationships with patients that will connect them with caregivers? This can be very scary for patients to be told or recommended to see a cardiologist, to see an electrophysiologist, to go for testing in a laboratory. Just the nature of that language to many patients is very scary, even terrifying.

So how do we approach patients about social determinants of health? And it's having that very patient-centered discussion with them. It's almost rather than the frustrated physician with arms crossed, it's palms up and arms open. Sample questions—what challenges do you have getting appointments? Do you have access to a pharmacy? Do you have access to care in your preferred language, et cetera? You see all of those questions here. And by moving a little bit away, sometimes, from our traditional focus on the nuts and bolts of the prescription and other things and showing the patient that we acknowledge that there may be barriers I think can go a long way and can help with problem solving that you or members of your office and the patient can address together.

David S. Kountz:

This is a busy slide, but it also reminds us of the importance of health equity. That is providing the right care to the right patient. Not every patient needs the same type of support. There are going to be patients, such as the low health literacy patient, for whom, if you identify that, you're going to with their permission perhaps call a family member to ensure that the information that was discussed in that visit is conveyed, or you're going to use the teach-back method. Now, perhaps that's something we should be using with all patients, but especially for that patient who needs that to ensure that they understand recommendations. So this just reminds us of a lot of inputs to address health literacy, leadership of your organization or your practice, spending time every month talking about what you as a practice can do, as a member of the department can do, to address literacy, intersocietal collaboration, working with patient groups, support groups to help address health equity, finding other resources such as grants, et cetera. So a lot of things that perhaps we need to think a little bit out of the box to address health equity.

And then a very important issue… I think in the last several years, something that has really come to fore, I'm going to say around COVID, and the recognition that in many pivotal trials and many disease states we don't have equal representation of patients to know whether they would benefit from specific treatments. Well, this is certainly the case in AFib studies, and this is a slide going from the late 2000s until current day looking at a number of AFib studies. These are the acronyms of many different studies and showing overwhelmingly the participation of White patients compared to racial and ethnic underrepresented groups. And so not all of us on this call are involved in research, but hopefully we can all be advocates. We also need to appreciate when we read studies and make decisions about treatments—were the patients that are in front of me and I'm treating studied in that particular clinical trial? And so I think we can, if you will, keep the pressure on to ensure that whoever's funding the study ensures that it is as equitable in terms of ensuring that all patient groups are participating. A really important role that we can play to address this inequity.

And then just a definition of implicit bias, this is something that we all have. It's an automated response. It conserves brain energy, and in many instances we're right. So when I speak on this topic to our trainees, I tell them that we're all biased and we need to get over that. It's an automated reaction, but they can negatively impact our understanding actions and decision making and it's sometimes difficult to potentially acknowledge that. There have been famous studies about pain management in emergency departments and how members of underrepresented groups received less pain management. There have been studies looking at attitudes and scenarios where individuals who score highly on a test such as the implicit association test that that can actually be picked up by patients. And they literally feel that those clinicians spend less time with them, the veracity of their recommendations are not as strong, the level of connectivity is not as great. So I will just tell you in the education world today we're teaching about the potential impact of bias. It's hard to know exactly what to do about it, admittedly, but it is part of I think a growing conversation when we look at unequal health outcomes to consider the role of implicit bias.

So when we think about the discussion tonight and what we can do as clinicians, how we can move forward, it's important to think about smart goals. SMART stands for Specific, Measurable, Attainable, Relevant, and Timely.

David S. Kountz:

So examples using the CHA_2DS_2-VASc score and other evidence-based tools to identify non-valvular AFib appropriate patients to assess digital tools that Dr. Cho talked about as well as others he may not have had a chance to mention that may facilitate screening and monitoring of patients at risk of atrial fibrillation… To implement current evidence-based management strategies for anticoagulation in AFib, to engage in shared decision making with patients while considering the impact of social determinants of health, and to be willing to shine that mirror on ourselves and reflect on our own practice and the possibility of implicit bias and provide equitable care to all patients regardless of race, ethnicity, or socioeconomic status.

So we're going to move now into some additional questions and answers. We're going to take a look at some of the questions that were added and there are a lot, which is terrific.

So I'm going to open this up to Dr. Cho and Dr. Ko. And so let me start with the first one on my screen is a [primary care physician] PCP. I'm not sure when to refer to a specialist. Can we as PCPs start DOACs without sending the patient to a specialist, presumably a cardiologist?

Darae Ko:

Definitely, yes. And that will minimize the gap, from the time that someone is diagnosed with AFib and the time that the patient has done anticoagulation. The reason I think it's worthwhile to refer all patients with AFib to cardiology at least once is not so much because of anticoagulation management. I certainly think that that can be managed by primary care doctors. It's because of how to treat that AFib for the rhythm control because earlier that you treat the AFib for rhythm control, for example, with catheter ablation, much more likely that the patient will stay in sinus rhythm. And what you don't want is that there's a delay. Someone has paroxysmal atrial fibrillation or essentially AFib occurring intermittently. That patient doesn't get to see a cardiologist for a year or longer and then that paroxysmal atrial fibrillation turns into persistent AFib. At which point that it becomes the success of catheter ablation, for example, is much more reduced.

David S. Kountz:

Thank you. Dr. Cho, a question for you. It has to do with how does a smart stethoscope work? And a related question, do wearable watches continuously look for arrhythmias or only when the user activates that function?

David J. Cho:

Sure. For the first part of that question, the smart stethoscope, that's the one I think you're referring to, is the Eko device. That doesn't detect it based on heart rhythm alone. There's a specific device where they have a single lead EKG. It basically looks like a stick and creates a single lead EKG while you're listening. And then from that single lead EKG can determine whether or not you're in AFib. So it's a tool that's useful for potential screening for primary care physicians. It's kind of like an advanced stethoscope that has a single lead EKG capability for the opportunistic screening, but, again, that evidence is inconclusive based on USPTF at this time. For the question about the wearable watches and the ability to detect AFib, that is a function usually you need to set up through the app itself, whether it's the Fitbit app or the Apple Health app or whatever device you're using. And the way that it looks for it is it's not continuously. It's basically triggered when it's periodically checking your heart rate throughout the day. If it's noting more irregularity in that, then it starts sampling more frequently and then you'll enter the algorithm.

It's been trained to potentially under detect AFib because it didn't necessarily want to create a tool that was overly sensitive and having people be notified for potential short duration of AFib in an attempt to try to make it less sensitive and perhaps a little bit more clinically relevant.

David S. Kountz:

Thank you. There are a couple questions related to representation of racial ethnic groups in AFib trials. The first is why is this happening? And I would volunteer that it's similar to underrepresentation in lots of clinical trials. There is a historic distrust issue of underrepresented patients in research and this is a bigger topic for another evening. There are barriers in terms of perhaps getting to the research center. The investigators or others part of the research may not people look like the subjects and there may be a lack of confidence. There is a question for our two panelists, if either of you know if there are AFib anticoagulation trials that are enrolling that the audience could recommend to potential patients. And I know that there are lots of trials, but do any trials come to mind that are big trials still enrolling that we could make the audience aware of?

Darae Ko:

Yeah, so I just want to go back to that question of about underrepresentation of racial and ethnic minority patients in the cardiovascular trials, really. And I think there are a couple issues and, number one, for these trials that are trying to test a new drug with the hope of getting FDA approved, really the focus is making sure that they enroll enough patients. And it's been just really hard to enroll patients in America. A lot of patient enrollments comes outside of the United States, particularly in Europe. So you can imagine in that situation it's going to be really hard to have diverse representation in these trials. And secondly, I try to enroll patients for clinical trial at Boston Medical Center, which I've mentioned before is a very large safety net hospital. I think the challenge is with a lot of safety net hospitals there's a lack of infrastructure to enroll patients efficiently into clinical trials.

Darae Ko:

Not all trials come with a startup package for investigators to efficiently run this of to hire an RA, for example. Hospitals are able to enroll a lot of patients, already have established infrastructure and those hospitals are not safety net hospitals. In terms of current trials that are for anticoagulation, yes, actually phase three trials for Factor XIa inhibitors, I believe, have literally just started. I'm not involved with the trials at all, but I've been following the science. As you can tell from the data that I showed you, despite availability of these DOACs, which are considered safer alternatives to warfarin, there's a substantial underutilization of anticoagulation. So the idea is that with the Factor XIa inhibitors, which haven't shown to reduce risk of bleeding compared to DOAC, particularly apixaban and rivaroxaban, we would be able to anticoagulate more of these patients, especially high risk patients, patients who are at high risk of bleeding.

So three Factor XIa trials were probably going into phase three trial. And I believe one of them already started, it was all over the media. Asundexian is one of them. It's conducted by Bayer, so if you just go to ClinicalTrial.gov or go to just type in asundexian and Bayer or Factor Xia Bayer, it'll be all over the media and I think there is a way to enroll these patients. I think the value of enrolling those patients in my personal opinion is really if you have a patient who's not on any anticoagulation therapy for some reason because someone thought that the patient can't be an anticoagulation. I think there may be value to enrolling those patients, but if a patient is doing already well on apixaban then there's an issue with equipoise.

David S. Kountz:

Great, thank you. I think I'm going to get the hook in about a minute, so I'm going to ask some real quick questions and ask you guys to give us some quick answers. Dr. Cho, do you know if there are any enrolling Apple Watch trials?

David J. Cho:

In terms of clinical, I'm sure there are small studies that investigators are doing at their sites. The biggest one is the one that I mentioned, the one that's going live I think at Northwestern and in association or partnership with John Hopkins, which I think they're going to enroll 5,000 or 6,000 patients who have low Afib burden to determine whether a smart device guided anticoagulation strategy may be potentially a new paradigm of care down the line. Meaning let's say I have Afib once every couple of months and it lasts for a couple of hours. I get notified, I start on an anticoagulation for a predetermined amount of time and then I stop. Will that be any different than the current standard of care in terms of outcomes? That study's going to take probably more like seven years before we get any results from it. I'm not sure how to enroll patients into that trial currently, but I do know that they will start enrolling soon. So I don't know if we have any Midwesterners or mid-Atlantic providers on this call.

David S. Kountz:

Thank you.

Dr. Cho, briefly can you discuss, maybe you mentioned this earlier, the future of reversal agents for DOAC? How close are we to have something that's practical?

David J. Cho:

Well, I mean, some of the DOACs do have reversal agents. And, Dr. Ko, I know that you're probably aware of this as well in terms of the reversal agents. I believe apixaban does have a reversal agent, as well, right?

Darae Ko:

Yeah, they've been approved for a while. So for dabigatran it's called idarucizumab. For Factor XI and that's an alpha. Yeah, they're just really expensive. Yeah, the current guidelines recommend that. Not every hospital has it. They are used in certain situations in certain hospitals, let's put it that way, for severe bleeding.

David S. Kountz:

Dr. Ko, there's a question about can a patient receive a DOAC who has an indwelling Foley catheter?

Darae Ko:

Yeah, as long as the creatinine is fine. It's important to know that. And you can quickly look this up on UpToDate if you have any questions. Both we rivaroxaban and apixaban come with directions about reducing your dose, when to reduce the dose. That's the most important thing. Rivaroxaban was 20 milligrams a day is something we'd use at 15. Same with apixaban is you reduce at two and a half to BID. And the indication for dose reduction is clearly it's any website or really UpToDate will have that. It's important to just follow that direction.

David S. Kountz:

There's a question about the challenge of shared decision making when patients aren't interested. I would say it's you just have to try to stick with it. And at one of the visits, if you have that open, interested approach, hopefully patients will come around, but I will be the first to admit that it can feel frustrating. And many times patients are in that more paternal mode, where they just want you as the provider to tell them what to do. But I think we have to try to keep pushing back to find the right place to probe and get that patient engaged. I think the data's pretty clear that, if we can get that patient engaged and activated, they will do a lot better long term.

David S. Kountz:

With regard to asking about social determinants or using a questionnaire, I think depending on the setting both could be done. I don’t think you want to pick and choose. So the advantage of a questionnaire is you get a baseline for all of your patients, but I think it really does benefit from a face-to-face, eye level discussion with patients, making sure they understand how important you know these issues are to their health. And I think that's a very powerful conversation that you can have with patients, in my experience.

I'm almost done. I think I probably need to move on. We didn't get all the questions answered, so I apologize for that. We did the best we could.

To receive CME or CE credit for this activity, participants must complete the post-test and evaluation online. And there is a request credit tab to complete the process and print your certificate. We also want to encourage you to visit the Cardiology Hub at CMEOutfitters.com for more free resources and education for healthcare professionals and patients.

On behalf of Dr. Cho and Dr. Ko and the team at CME Outfitters, thank you for joining us tonight for this discussion. Have a great evening.

