**American Heart Association**

**Moderator: Anastasia Pargulski**

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**3:30 p.m. ET**

Operator: This is Conference #: 87221271.

Ladies and gentlemen, this is the operator. Today’s conference is scheduled to begin momentarily. Until that time, your lines will, again, be placed on hold. Thank you for your patience.

Operator: Good day and welcome to today’s webcast. My name is (Caroline), and I will be your event specialist today.

All lines have been placed on mute to prevent any background noise. Please note that today’s webcast is being recorded. During today’s presentation, we will have a question-and-answer session. You can ask text questions at any time. To do so, click the green Q&A icon on the lower left-hand corner of your screen, type your question in the open area, and click ask to submit.

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It is now my pleasure to turn today’s problem over to Steve Dentel, national consultant and lead for Get with Guidelines AFib with the American Heart Association. Mr. Dentel, the floor is yours.

Steve Dentel: Thank you so much and good afternoon and welcome to the American Heart Association, American Stroke Associations’ Get With The Guidelines National Webinar.

Today’s session, we’ll review 2016 ACC/AHA Clinical Performance and Quality Measures for Adults with Atrial Fibrillation or Atrial Flutter, a report of the American College of Cardiology, American Heart Association Task Force on Performance Measures.

For our call today, we are fortunate to have as our presenter, Dr. Bill Lewis. Dr. Lewis currently serves as the chief of cardiology in the MetroHealth System and he’s also a professor of Medicine at Case Western Reserve University. Dr. Lewis earned his Medical Degree from Ohio State University in 1986, and he received his Internal Medicine training at University Hospitals at Cleveland and Case Western Reserve University. He continued his training there for Cardiology and Clinical Cardiac Electrophysiology.

In 1993, Dr. Lewis became independent physician at MetroHealth Medical Center an affiliate of Case Western Reserve University where he is a professor of Medicine and Chief of Cardiology. He has served as the president of the Ohio Chapter of the American College of Cardiology and President of the Cleveland Division of the American Heart Association. He was a member of the Leadership Cleveland Class of 2012. He’s currently the chief of Cardiology in MetroHealth System and professor at Case Western Reserve. And he is the lead for the Get With The Guidelines AFib Program.

During today’s session, Dr. Lewis will provide detailed information about American Heart Association as careful crosswalk of the current Get With The Guidelines AFib Measures to align with the latest evidence required by the ACC/AHA Task Force on Performance Measures.

As the operator has shared, at the conclusion of today’s presentation, you have an opportunity to ask questions and we will do our best to address all questions during the call. There will also be a short survey at the end of the call and please take a few moments to answer the questions as they will help ensure that these calls remain relevant to you.

Thank you, again, for your participation, and Dr. Lewis, I hand things off to you.

William Lewis: Thanks, Steve, and welcome to everyone on the call. I first want to make sure we thank our sponsors of the – of the program, the Get With The Guidelines AFib Program. Without them, this program would be difficult to run.

I do want to point out in the upper right part of the screen, and since I don’t have a pointer, you’re going to have to move your own personal pointer up to there, and notice that you’ll see three logos up there. The first logo is the American Heart Association logo, the last logo is the Get With The Guidelines AFib logo. But the in middle is a – is the logo of the Heart Rhythm Society and I’m proud to say that we are now partnering the Heart Rhythm Society on the Get With The Guidelines AFib Program. It’s a – it’s a pleasure to be partnering with them in that – and that it brings a lot of things together that really can make this program very robust. So, again, thanks to the American – to the Heart Rhythm Society for the hard work that they did to get to this point and we’ll move on.

So, the title of this talk is the 2016 ACC/AHA Clinical Performance and Quality Measures for Adults with Atrial Fibrillation or Flutter, and this was the report from the – from the ACC/AHA Task Force on Performance Measures.

So, I’m going to move forward on this and say, first of all, to remind you of the patients who can be enrolled in the American Hearth Associations Get With The Guidelines AFib Program and they include patients with the principal diagnosis of atrial fibrillation or atrial flutter admitted to the hospital as an inpatient.

And we also encourage you to enter patients a secondary diagnosis of atrial fibrillation or flutter and optionally for you, you may enroll – hospitals may then choose enroll patients who are in observation status and not admitted as inpatient. We do still exclude patients who are coming in from the emergency department if they are – if they are discharged from the emergency department with no observation or admission status. Although we’re, you know, we do have a plan to include them in the future and also we exclude patients who are less than 18 years of age.

And I’ll remind you, the original achievement measure is very quickly because we’re going to go through them in much more detail. The original (ACE) in six achievement measures were ACE or ARB for LV dysfunction, assessment of thromboembolic risk factors, beta-blocker and on discharge for patients with LV systolic dysfunction, discharged on FDA approved anticoagulation therapy, a PT and INR plan for warfarin therapy patients, and statin on discharge for patients with atrial fibrillation and coronary disease, stroke or TIA, or peripheral vascular disease.

So, you know, on June 27th of this year, the ACC Task Force on Performance Measures published a new set of performance and quality measures. This measure set included a total of six performance measures, three inpatient and three outpatient and 18 quality measures 10 inpatient and eight outpatient measures. This therefore was 21 new measures and revisions to the three existing 2008 outpatient measures.

The Get With The Guidelines Clinical Workgroup formed a small working group with started working in March of 2016 to carefully crosswalk the current Get With The Guidelines AFib Measures to align with the latest performance measures that were recently published.

And again, I want to be – I want to thank the group of very hardworking people who put this together. It was a – it was a monumental task to only crosswalk the performance measures but also to cleanup a few things that we’ve had – that we’ve been working on for a while and sort of put it all together and get the Get With The Guidelines Program really well aligned.

As we mentioned before, we have to focus on inpatient measures. So, I will briefly go through each of these performance measures and quality measures and then we will go through them in detail. First of all, one of the performance – performance measure one was (CHA2DS2-VASc) risk score documented prior to discharge and this replaced a current Get With The Guidelines Achievement Measure which was documentation of thromboembolic risk factors.

So, we’ve often talked about this in our committee meetings about the fact that sometimes, you know, you just go one, two, three, “OK, you need an anticoagulant.” You don’t even actually do the (CHA2DS2-VASc) score but the bottom-line is that the risk increases as the number of risk factors increases as well. And so it’s important to document that you know the actual (CHA2DS2-VASc) risks score as your – and you know, in an inpatient chart. And so the – we decided to align ourselves with the performance measure group and to – and to actually replace the current measure which was just documenting the thromboembolic risk factors. Now, we want you to actually document the (CHA2DS2-VASc) risks score.

Performance measure two is anticoagulation prescribed prior to discharge and, again, that was a prior performance measure with Get With The Guidelines and we aligned it with the current performance measures and PT INR planned to follow-up documented discharge for warfarin treatment, again, this was a prior achievement award measure in the Get With The Guidelines Performance Program and we aligned it to be consistent with the performance measures.

There were a lot of quality measures. As we mentioned, there were 18, 10 of which were inpatient measures. I will go through those, again, very briefly.

Quality measure one was beta-blocker prescribed prior to discharge when ejection fraction is less than 40 percent. Again, we were – we aligned this but it remains an achievement measure in Get With The Guidelines Program. So, it’s a quality measure with the performance – in the performance document. It is an achievement measure in Get With The Guidelines.

Quality measure two is ACE inhibitor, angiotensin-receptor blocker prescribed prior to discharge when ejection fraction is less than 40 percent. Again, we were – we aligned this but, again, it remains an achievement measure.

Quality measure three was inappropriate prescription of anti-arrhythmic drugs prior to discharge in patients with permanent AFib for rhythm control and, again, this was new and it was new and it was adopted. Many of these are measures that you have probably never seen before, but they make logical sense and we’ll go through them each individually in a little bit.

Quality measure four was inappropriate prescription of dofetilide or sotalol prior to discharge in patients with atrial fibrillation and end-stage chronic kidney disease or on dialysis prior to discharge. And again, this was a new quality measure for the Get With The Guidelines AFib and we adopted it.

Quality measure five was inappropriate prescription of a direct thrombin or factor X inhibitor prior to discharge in atrial fibrillation patients with a mechanical heart valve. And again, this was a new performance – sorry, new quality measure and was adopted by the Get With The Guidelines Program.

Quality measure six was inappropriate prescription of a direct thrombin and factor X inhibitor rivaroxaban or edoxaban prior to discharge in patients with atrial fibrillation and end-stage chronic kidney disease on dialysis. And again, this was a new and was adopted in the Get With The Guidelines Program as quality measure.

Measure seven was inappropriate prescription of an anti-platelet or and/or anticoagulation prior to discharge – excuse me, for patients who do not have coronary artery disease or vascular disease. And again, that was new and was adopted.

Quality measure eight was inappropriate prescription of a nondihydropyridine calcium channel antagonist prior to discharge in patients with a reduced ejection fraction or decompensated heart failure. And again, that was a new and adopted quality measure.

Quality measure nine was patients who underwent atrial fibrillation catheter ablation who are not treated with anticoagulation therapy during or after the procedure. That one was – that one was submitted by (Captain Obvious) and it was a new – a new quality measure for us and we adopted it.

Quality measure 10 was shared decision-making between physician and patient an anticoagulation prescription prior to discharge. We did not adopt this because we felt that the documentation characteristics would be too difficult for a hospital to assure that shared decision-making it actually occurred. So, we were unable to put ourselves in a position to make sure that we were able to achieve that and that there was a lack of definition of what achieving that really is. So, we – so, we actually decided not to adopt that one.

So, the major changes in summary were the following. First of all, transient reversible atrial fibrillation which is referred to in both the guideline and the new performance measure that is atrial fibrillation that is precipitated by an event such as sepsis, the patient is admitted with sepsis, is now recognized as a new data element as not requiring anticoagulation or (CHA2DS2-VASc 2) calculation.

Another major change was the Get With The Guidelines differs with the performance measure on valvular atrial fibrillation. The performance measure focused on non-valvular atrial fibrillation and Get With The Guidelines includes patients with mitral stenosis, bioprosthetic or mechanical valves that actually – and requires warfarin anticoagulation in those patients who has felt that those patients could not be excluded because they were still at risk of stroke in patient and atrial fibrillation.

Patients with left atrial occlusion devices were excluded from (CHA2DS2-VASc) calculation or anticoagulation. And an exclusion for patients who have purely cardioembolic strokes for statin requirement was also put in place. That is if you don’t have another indication for a statin and the physician determines that this was a cardioembolic stroke, you did not – you do not – you’re not required to place the patient on a statin. This was an issue that was brought up by multiple people who were participating in Get With The Guidelines AFib and we thought that it was an appropriate time to adopt it.

So, there needs to be a transition, and upon initiation of the modified achievement measures, the hospitals will have until the start of January 1, 2018 discharges to make changes in their processes before they old measures would not be an option any longer. So, new measure and old measure will be accepted until January of 2018. Beyond that, we will need to be aligned.

So, again, in summary on the nomenclature changes, you can see that the nomenclatures on the right, which are the new nomenclatures are actually more specific than the ones they were in the original – in the original achievement measures that are on the left. So, it’s much more specific.

So, let’s go through a couple of these that were – that I felt kind of needed to be further discussed. So, quality measure three was the inappropriate prescription of anti-arrhythmic drugs prior to discharges – discharge in patients with permanent atrial fibrillation for rhythm control. The logic that came from the performance measure task force was that the transition from frequent AFib to infrequent tolerated recurrences of atrial fibrillation is reasonable and does not indicate that the therapy should be discontinued. However, if attempts at rhythm control are abandoned that is the AF has now been declared permanent, the anti-arrhythmic drug should be discontinued.

And I think that we’ve all dealt with this kind of situation before where we’re – where we’re watching a patient and there may be an AFibs 50 percent of the time and we’re saying, “Well, we think that the anti-arrhythmic drug is doing them some good.” But at some point when the patient is in AFib all the time, you’ve cardioverted them basically, you were not going to be able to keep them in sinus rhythm and you’ve elected to not ablate them, they’re now in permanent atrial fibrillation, the anti-arrhythmic drug should be discontinued.

Thus, in risk benefit analysis, if the drug is not being used to convert or maintain normal sinus rhythm, there is no benefit and there could be harm. So, these are data from the original SCD-HeFT Trial where patients were randomized to an ICD or a placebo or they were randomized to amiodarone then you can see that if they had Class III heart failure, the amiodarone itself placed them at higher risk of mortality over time and that was statistically significant.

In addition, data from the AFFIRM Trial that were presented by Steinberg. As you can see are displayed here and these are data that I’ve modified from the – from Steinberg’s Study, but you can see that the major findings are these is that if you have heart failure, you are at increased risk of death. If you’re on warfarin, you’re at lower risk of death. The keys are these if you were on anti-arrhythmic drug in the AFFIRM Trial, you were at increased risk of death but comparatively, if were normal sinus rhythm, you were at lower risk of death. So, the drug itself even if it’s not being used to convert the patient to sinus rhythm, places the patient at increased risk of death.

Quality measure four, inappropriate prescription of dofetilide or sotalol prior to discharge in patients with atrial fibrillation and end-stage chronic kidney disease or dialysis prior to discharge. As you can see here, the manufacturer and the FDA suggests that these drugs are contraindicated due to increased toxicity in patients with severely reduced renal function.

So, I thought I would take a moment to talk a little bit about triggered arrhythmias and the – and early afterdepolarizations that occurred in patients who are on excessive amounts of potassium channel blockers. As you can see these drugs are reverse use dependent, that is the slower the heart rate, the more blockade of potassium channels that there are.

They contribute to the development of prolonged QT-related arrhythmias and they are caused by entering the drugs which interfere with repolarization such as potassium channel blockers. And in this slide you can see, the A panel is a normal action potential, the B panel is an action potential with an early afterdepolarization after the QT or action potential duration are increase in duration and that is occurring because of potassium channel blockade.

In panel C, you can see that eventually those can produce action potential, so you can see the triggered – (really) afterdepolarization in B now becomes a triggered after – a triggered beat which occurs as a result of potassium channel blockade. And in the lower panel, you can see what I mentioned before and that these rhythms tend to be pause dependent, that is they tend to be – to occur more when there’s a long pause. The QT interval and the blockade of potassium channel is increased when the pause is long and you can see in the bottom panel, the pause produces a triggered short run of a – of ventricular tachycardia.

And thus, when we’re looking at class III agents, both the dofetilide and sotalol are cleared by – are cleared renally. And dofetilide itself is actually initiated as an inpatient by FDA requirement and sotalol in the guideline should be initiated in patients only with abnormal QT and normal heart structure and that the QT interval and the risk of torsades are dose dependent and need to be monitored. Amiodarone, as you know, has mixed effects and can be initiated as an outpatient when the risk of bradycardia is low.

This is an example that – that is obviously very old and as much as it’s on a black and white slide. But, you can see a patient who has – who comes in with an atrial tachycardia which results in a pause and that the QT interval prior to the pause is 400 milliseconds but goes to 500 milliseconds when the pause occurs, resulting in a triggered beat that you can see, that’s the last beat on that – on that screen, and that this can become runs of polymorphic VT. You can see the tremendous QT prolongation of the first beat followed by a run of nonsustained ventricular arrhythmia, another pause and another run of nonsustained ventricular arrhythmia until this actually produces sustained torsades. By the way, this is on a 12-lead machine and you should never see sustained torsades on a 12-lead, it will necessitate quick action.

Quality measure number five is the inappropriate prescription of direct thrombin or factor X in inhibitors prior to discharge in patients with atrial fibrillation with a mechanical heart valve. The logic that the – that the committee used was that patients with mechanical heart valves or hemodynamically significant mitral stenosis, were all excluded from the three major trials of these drugs including RE-LY, ROCKET AF and ARISTOTLE.

And that there was actually a trial that looked at dabigatran and that was the RE-ALIGN trial and the RE-ALIGN trial was a Phase 2 dose-ranging study on the use of dabigatran compared with warfarin in patients with mechanical valves which was stopped due to dabigatran users were more likely to experience strokes, myocardial infarction and thrombus on the mechanical valve than were warfarin users.

This study was in patients who had an aortic or mitral valve replacement within the past seven days and who had undergone such a replacement at least three months earlier. They were randomized in a 2 to 1 ratio to receive either dabigatran or warfarin. The doses of dabigatran were actually adjusted to obtain a trough plasma level of 50 nanograms per milliliter.

And warfarin was adjusted to normal INRs of 2 to 3 or 2.5 to 3.5, depending on thromboembolic risks and the type of valve. And as I mentioned, the study was terminated prematurely after enrollment of 252 patients because of excess thromboembolic and bleeding risk in the dabigatran – in the dabigatran group.

These are data from the study and you can see that the time to first thromboembolic event was higher in the dabigatran group compared to the warfarin group. And you can see that almost a 30 percent thromboembolic rate at one year in patients on dabigatran compared to a much lower incidence in patients with warfarin on board.

In addition, there was a higher bleeding rate in patients with dabigatran on board. Again, same – similar graph structure. This is time to first bleeding event on the – and on the X axis is time. Bleeding risk is on the – on the Y axis.

You can see that again the risk of a first bleeding episode with dabigatran on board was almost 30 percent and with significantly higher than that on the warfarin group. Thus, based on these data and other – and the fact that the data don’t exist for the use of these drugs in patients with mechanical valves or mitral stenosis, the committee made this quality measure to prevent the use of these drugs in patients with mechanical valves.

Quality measure number six was inappropriate prescription of a direct thrombin and factor Xa inhibitor rivaroxaban or edoxaban prior to discharge in patients with atrial fibrillation and end-stage chronic kidney disease or on dialysis. And you can see the creatinine clearances in all the – all of the drugs that we talked a bout with rivaroxaban, dabigatran, apixaban and edoxaban.

Notice that the quality measure does not include apixaban and when you read the package insert, there it says that the drug should be used carefully in patients with end-stage renal disease. Therefore, the committee only recommended that the drugs that should be not used are the ones where the package insert is clear, that rivaroxaban, dabigatran and edoxaban should not be used in patients with end-stage renal disease or on dialysis. And again, those creatinine clearances are listed above the – basically if the creatinine clearance is less than 50 milligrams per day then the drug is not recommended.

Quality measure number seven, inappropriate prescription of antiplatelet and oral anticoagulation prior to discharge in patients who do not have coronary artery disease or vascular disease. And again, I want to – this was one that I thought was very interesting in that there’s a number of us who – when we treat a patient with atrial fibrillation with an anticoagulant, the patient comes to us, often being started on aspirin because the primary care physician did not feel comfortable doing that or another physician did not, or an emergency room physician did not feel comfortable starting an anticoagulant.

So, they start aspirin and there is no indication for aspirin once the warfarin is begun and the data on this are that combining oral anticoagulants and anti-platelets agent is associated with a higher risk of fatal and non-fatal bleeding. This is a meta-analysis by Dentali that showed patients who are treated with both aspirin and warfarin versus warfarin alone. And they reviewed the 10 studies looking at 4,000 patients and the risk of thromboembolism was no different. So, aspirin did not confer an additional benefit but the risk of bleeding was significantly higher in patients receiving oral aspirin or oral anticoagulants compared with oral anticoagulants alone. And you can see that, I should say, when I said significantly it really is on the borderline would be the 95 percent confidence intervals being 1.0 to 2.02 but the risk ratio is 1.43.

Here is the Forest Plot for that study. You can see that nearly everyone of those studies demonstrates an increased risk to the – of aspirin in addition to warfarin compared to warfarin alone in those patients, although none of them were large enough to reach statistical significance.

Another study looked at patients with bleeding events in atrial fibrillation in the Medicare database. So, this is a larger study looking at 10,000 patients in the Medicare database with atrial fibrillation discharged from the hospital on warfarin alone versus warfarin plus an antiplatelet, most of the time this was aspirin.

In the absolute risk of bleeding at 90 degrees, was 1.3 percent of the warfarin-alone group and 1.9 percent in the combined therapy group. And 180 days after this, it was – their bleeding rate was 2 percent in the warfarin-alone group and 2.8 percent in the warfarin plus antiplatelet.

And at both times, the intracranial hemorrhage risk was three times that in patients when they were on combined therapy. Thus, the risk of bleeding is significantly higher in patients with warfarin and aspirin on board. And if there is no indication for the aspirin, then it probably warrants elimination of that.

Now, this is not with just the warfarin alone. This is a study, again the meta-analysis looking at patients with atrial fibrillation treated with aspirin plus warfarin or dabigatran or rivaroxaban. Thirty-nine percent of those patients were on monotherapy and 61 percent were on a combination therapy with aspirin.

In this study, the addition of aspirin did not reduce the stroke rate as well. However, you’ll notice on the graph on the right, the risk of bleeding is higher – major bleeding is higher in patients with dabigatran plus aspirin versus dabigatran alone, rivaroxaban plus aspirin versus rivaroxaban alone and warfarin plus aspirin versus warfarin alone. So therefore, we don’t get any – we’re not (at) any additional benefit by using a novel anticoagulant.

Quality measure number eight is the inappropriate prescription of nondihydropyridine calcium channel antagonist prior to discharge in patients with reduced ejection fraction or decompensated heart failure. As we know, diltiazem and verapamil are negative inotropic agents. They enhanced the neuroendocrine activation, thereby accelerating left ventricular decompensation.

And this is a relatively old idea, right? You know, it’s old when you looked at the citation at the bottom and the citation is a 1991 circa article. And I think in 1991, circulation was actually being published in – on onion skin. So, the Multicenter Diltiazem Postinfarction trial was a randomized, double-blind, placebo control of diltiazem at 240 milligrams daily in the 2,466 patients, 3 to 15 days postinfarction.

The mean follow-up was 25 months. The patients with an ejection fraction of 40 percent or less at baseline that they noticed heart failure recurring late after the myocardial infarction and 12 percent of those receiving placebo and 21 percent receiving diltiazem. In addition, the diltiazem-associated rise in the frequency rate of congestive heart failure was progressively greater, an increased – an increasingly severe decrements with baseline EF.

So the lower your EF, the more likely – or the worse your heart failure was, the higher the frequency of heart failure when diltiazem was used, and these are data from that trial. You can see that at 1,200 days into the study, the risks of – and this is onset of heart failure, you can see that almost 25 percent of patients with diltiazem on board versus 15 percent of those people are patients with placebo on board, developed heart failure at 1,200 days into the study.

Quality measure number nine, we’re getting close to the end folks, patients who underwent atrial fibrillation catheter ablation who were not treated with anticoagulation therapy during or after a procedure. When our group talked about this, we basically said that we didn’t think anyone ever get one of these without having anticoagulation on board. But the performance measure group felt it was important to put this in place.

And their logic was basically this, that atrial fibrillation patients are at increased risk of thromboembolism during immediate – during immediately following in for several weeks to months after an ablation. The recommendation of the task force was that heparin should be administered prior to or immediately following transseptal puncture and adjusted to achieve our target ACT of 300 to 400 seconds.

And this recommendation reflects the well-established observation of thromboembolic (in form) on the sheath through the electrode catheter almost immediately after crossing the septum and that early heparinization is substantially decreases this risk. I just wanted to show you a picture of thrombus on the tip of a – of a catheter.

You can see at the top of the A is where – is the probe is in the right atrium looking into the left atrium. On the left side of the dark area is the sheath and the – entering the left atrium and the white line you see is the catheter and at the tip of that is a mobile fuzzy looking thing which is a thrombus that is actually in the left atrium. At this point, the objective is to try to get that thrombus out but the better thing is to actually not – is to anticoagulate patients before and during the procedure to minimize that risk.

So, in conclusion and we want to leave enough time for questions regarding these, these are a lot of changes that we made that Get With The Guidelines AFib Achievement, Quality and Reporting Measures were aligned with the 2016 task force performance and quality measures for atrial fibrillation including the measures and coding instructions. Generally, the changes were minor.

One major important change was the achievement measure change to replace assessment of thromboembolic risk factors with (CHADS2-VASc 2) risk documented prior to discharge and then hospitals will have until the start of January 1st, 2018 to make changes to their processes.

The next steps for this include the changes in the – in the – in the PMT which will have to occur this winter and we will keep you apprised as to when the system is going to change. Need to fill the – we need to change the data fields and reports. We have internal testing in user acceptance testing from customers to make sure that these changes are going to work. We will have another customer webinar at the time and the release date will be sent via email and also posted in the PMT Community page.

So, I guess at this point, we'll open this up to questions. I appreciate your – your attention – as I mentioned, this is – I try to make this less – at least dry as I possibly could but I'm sure that I did not achieve that as well as I would have liked. Good to see that 240 people are still on the line, however.

So, let me know if there are any questions and we'll go from there.

Operator: Thank you and at this time, we would like to take any questions that you have for us. To ask a question, please click on the Q&A button on the lower left-hand corner of your screen, type your question in the open area and click Ask To Submit. Please also note that there is a copy of today's presentation available for download and to access the file you'll click on the blue files button next to the Q&A button on the lower left-hand corner of your screen.

Steve Dentel: Thank you, operator. And there are a couple of questions that have come in already. The first one is can you provide data for rationale for quality measure six, the statin for requiring patient with diabetes but no history of CAD, C – stroke or PVD be prescribed statin regardless of LDL levels?

William Lewis: So, we can provide the data that the – so, as you know, in this data come directly the – sorry, this position comes directly from the – from the new performance – I'm sorry from the new lipid guideline that was released in 2013 that that guideline was very controversial and I don’t disagree with people who would argue the position. However, that’s we – we gauge what we did based on that – based on that that guideline. So, the guideline directly and specifically relates to that, I'm trying to get to that place, it's six, am I correct, Steve? Because I did …

Steve Dentel: Yes, I think it was …

William Lewis: No, it's not six.

Steve Dentel: … numbers, yes. Hold on.

William Lewis: Early on in that presentation. That the key – one of the keys is that that we – one of the things that we changed was that we were – because of the way it was setup, we were requiring statin therapy in everybody who had a stroke or TIA and what was pointed out to us is that we were now dealing with a new set of patients that were completely different than what we had been taken cared of before. We were taking care of patients who had purely thromboembolic strokes that they had no risk factors, they had nothing and so we felt it was important for us to change that and I'm trying to find the spot so that I can let you know what that is.

But it was important for us to make that adjustment and so, you know, we – and we did make that adjustment. So, what it says is this, it says and I'm now on it is that in the – so prior to this, we were – that the – one of the achievement measures was that if you had a stroke or a TIA you needed to be on statin and that was taken directly out of the Get With The Guideline Stroke Module.

In our patients and Get With The Guidelines AFib, there is a significant population of them which probably is not as significant but is – but is still probably a significant population and Get With The Guidelines Stroke may want to look at this, but in our population there was a significant group of patients who'd had a stroke solely because they had atrial fibrillation.

They had no atherosclerosis. They had no risk of – they had no – they had very little risk of embolic stroke from atheroma and so therefore the risk of giving them a statin routinely was higher than what it should have been. And so therefore, we went directly with what the guidelines said the 2013 Lipid Guideline which said patients with coronary disease, diabetes, who have an LDL less than 180 and are greater than 40 or less than 75 or patients between 75, 40 and 70 who have an LDL less than 70, those patients were able to be excluded from the – from the group. So, if it's purely a cardio-embolic stroke we wanted to give our members the ability to code that directly and know that they didn’t have to give a statin.

Steve Dentel: Next question, quality measure eight is reduce the (EF) equal to less than 40 percent as with other measures?

William Lewis: Quality measure number eight, yes, it is. I'm sorry, with reduce ejection fraction or decompensated heart failure, yes. So, reduced ejection fraction in this case is less than or equal – is less than 40 percent not less than or equal to 40 percent. It is less than 40 percent.

Steve Dentel: OK. Our patient is not receiving heparin but receiving other anticoagulants, are they excluded from the recommendations? Angiomax does not correlate with ACP readings for patients testing positive for HIT.

William Lewis: So, I'm going to – I'm going to address the question solely from the standpoint of ablation because I think that’s where the question is going and if you – if you put this question in and I'm missing the boat on this please go ahead and update your question because obviously Angiomax is not a great – it would not be a drug that we would send somebody home on even if that had – if they had HIT.

So, the answer to the question is that the – I don’t know and I don’t think that the performance measure task force addressed Angiomax in this – in this performance measure. The recommendations about the ACT are only related to those patients who and whom heparin was given.

The last point to make about this is that I've – I am nearly positive that we place an exception for the use of this – of Angio, no, I'm positive, Angiomax is in the – is in the ablation registry as being an acceptable alternative to heparin during an ablation therapy – during ablation therapy.

Steve Dentel: OK. Next question, the anticoagulation during ablation procedure is in expectation regardless of whether or not it is RFA versus cryoablation?

William Lewis: That’s correct. We should mention that this is a quality measure, OK? And the quality measures are different than achievement measures and that quality measures are measures reported back to you that this is of what's going on. Now, when – you know, when we develop a plus program, you will have the ability to use, you know, to have certain quality measures become measures for the plus program. But again, these are – these are quality measures but the answer is yes.

Steve Dentel: So, our hospital has pharmacist doing – dosing warfarin, Get With The Guidelinesdoes not accept (CHA2DS2-VASc) from pharmacist, can this be changed?

William Lewis: Sure, you know, I think that it needs to be documented in the chart – I have to look and see what we wrote. Yes, I think that pharmacist would – I think we had nurse practitioners and physicians documenting it in the chart. I agree with you that pharmacist should be in that list and if we didn’t have it in there, we'll have – we should put it in.

Steve Dentel: In the clarification about the statin question was she wanted – my statin points specifically around the diabetes.

William Lewis: So, in the – in the guideline, patients – in the original lipid guideline, if you read the guideline carefully, there are only four groups that require – that require high dose statins and those groups include patients with a prior history of coronary artery disease, but it also include – and patients with an LDL greater than 180, but it also included patients with diabetes with an elevated LDL as well.

So, the – so, I would go back to the, you know, so this is – I don’t know whether – I'm, you know I would go back to the original American Heart Association ACC Guideline on lipid – on the management of patients with hyperlipidemia that was published in 2013 where we took this – we took this completely – directly out of that guideline.

Steve Dentel: Another question, is there a way to sample patients for this registry?

William Lewis: So, we've done this with other – with other – the answer to the question, is that sampling is something that has been used in Get With The Guidelines. I think that if you have a large number of patients that are in – that you enter then the answer is that sampling would be an acceptable process. I don’t know that we've made – we've made arrangements to do that now but we've – but we've done it before and Get With The Guidelines, we've always done it and if your volume is large enough then the answer is yes, you should be allowed to do that.

But, you know, I'm just a speaker, you know, I'm just the talking head and, you know, we have to – I've got to – I've got to get through all of the, you know, the people who work with Get With The Guidelines a lot more than I've – than I do in terms of that. So, but I think the answer is we've done it – we did it coronary artery disease. We do it in heart failure and so therefore sampling is a method that we've used before and we should use going forward.

Steve Dentel: That’s all the questions I have coming in right now. Any last comments, Dr. Lewis?

William Lewis: No, again, I want to – like I said I want to thank I mean this was – this group of people who did this were amazing. They, you know, it takes a lot of effort to align measures with your own program, I mean it requires, you know, changes in the measure name, the numerators, denominators, the coding instructions and everything and that we really put a lot of great thought into it from people from all across the country doing this on multiple conference calls a month, so I want to thank them.

I'm really proud of the fact that this has been the first time this has been done and Get With The Guidelines Program; and moving forward, I think the idea is to do this every time there's a new performance measure that comes out.

Keep in mind that that really the – for achievement the program really did not change very much. The only thing that really changes was the issue over documenting risk factors versus actually putting the score, the (CHA2DS2-VASc) score on the chart.

And beyond that the rest of the stuff you're going to see is stuff to help you not to, you know, not for achievement, you know, not for the – not to develop – get an achievement award, so hope to see everybody in November at the American Heart Association meeting for the awards that will go out to hospitals that have had – that have done very well in this program. And if you're thinking about getting involved in this program, I again want to mention that we've – that the partnership with the Heart Rhythm Society is an amazing partnership that we are – that we're exploring.

And I mean it is a true partnership where members of the – of the Heart Rhythm Society are in equal numbers on the – on the committee and we will work together and try to get tremendous penetration of the program throughout the country. I think being in a – in an ablation registry – an ablation registry right now is preparing you for what is going to happen in the future. So, looking at your data now is really important so that you can be prepared when Uncle Sam starts telling you that you need to do this if you want to actually – if you want to do ablations in the United States.

So, again, thank you very much for everyone attending. If you have any other questions, these guys can feed those questions to me and we can respond via email. It's been a pleasure talking with all of you today. I'm usually a little bit more used to people talking back at me, but that’s OK. Anyway, thank you very much.

Steve Dentel: So, on behalf of the American Heart Association, I would like to thank Dr. Lewis for your wonderful presentation and we want to thank our attendees for your valuable time and participation on today's call.

Again, there'll be a short survey at the end of the call, please take a few minutes to answer those questions as it will help to ensure that these call will remain relevant to you. Thank you again and have a great day.

Operator: Thank you to all of our participants for joining today. This does conclude the webcast and you may now disconnect. Have a good day.

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