Robert Eckel:	00:04	Welcome and thank you for joining us on this podcast from the new and informative podcast series on cardiovascular disease and diabetes for healthcare professionals. The goal of this series is to reduce cardiovascular disease death and incidents of heart attacks and strokes in people with diabetes. And is based on the new collaborative initiative between the American Heart Association (AHA) and the American Diabetes Association (ADA) entitled Know Diabetes by Heart™. This series is brought to you by founding sponsors Boehringer Ingelheim and Eli Lilly and Company's Diabetes Alliance and Novo Nordisk. And National Sponsors Sanofi and AstraZeneca.
Robert Eckel:	00:45	I'm Dr. Robert Eckel, an endocrinologist and joining me today are Trish Montesinos, a certified registered nurse practitioner as well as a certified diabetes educator. And Dr. Jay Shubrook, an osteopathic family physician. We're going to discuss the what, the why and the how of shared decision-making in patients with diabetes who are at risk for developing cardiovascular disease. Welcome Jay, welcome Trish.
Jay Shubrook:	01:15	Hello.
Patricia Montesinos:	01:15	Thank you.
Robert Eckel:	01:16	All right, let's begin with this concept of shared decision-making. Both of you I'm sure operationalize this in your practice. So get me some up front information about this shared decision making that I think increasingly is part of patient care. Trish, why don't we start with you?
Patricia Montesinos:	01:33	Sure. So, the American Heart Association defines shared decision-making as the process through which clinicians and patients share information with each other and work towards decisions about treatments chosen from medically reasonable options that are aligned with the patient's values, goals and preferences. It's really a patient centered approach to medical care and a very useful method to engage patients in their care.
Robert Eckel:	02:00	So Jay, does that mean that the patient tells us what to do as healthcare providers?
Jay Shubrook:	02:04	Oh no, not necessarily. So, I think that was a really great description about what shared decision-making is and why it's so important in diabetes is diabetes is largely self-managed. So I think that while we give important information, we facilitate really the best care for our patients with diabetes and cardiovascular disease, ultimately the work is on the patient.

		And so, I think recognizing the patient's contribution to their self-care and their involvement in the decision-making's going to make one, better care for the patient and two, a more engaged patient because they've been part of the answer. So I don't think it's just do what they say. I think give them a voice in the conversation.
Robert Eckel:	02:41	So in this whole space of diabetes and cardiovascular disease, is this joint venture called Know Diabetes by Heart™ by the AHA and the ADA. This whole process of shared decision-making involves potentially many members of the healthcare team. Trish, what are your thoughts about how many players should be part of this game called shared decision-making?
Patricia Montesinos:	03:02	Well we really want to have a multidisciplinary approach to this. We want to involve our primary care providers, our specialists like endocrinologists, cardiologists particularly, nurses, our certified diabetes educators and dieticians can be extremely helpful in this process. They do tend to have more time with their patients, which can be one constraint to us as providers and so it's really great to be able to involve many different players in the game, all of the different clinicians.
Robert Eckel:	03:34	Well you're a certified diabetes educator. What's your role in this whole task?
Patricia Montesinos:	03:39	I think one of the really important parts about shared decision-making is informing patients and educating patients about their different treatment options. And that's one thing that we can really focus on is educating them on many different particularly medication options that we have available now as well as how they might impact their care and really help patients discuss their goals and fine tune a treatment option that's individualized to the patient.
Robert Eckel:	04:09	So Jay, there's some feeling that maybe patients with diabetes are relatively unaware of their risk for cardiovascular disease. As a primary care physician, this is a role you certainly can play. You want to comment on that further?
Jay Shubrook:	04:23	I think it's really important, diabetes is a complex disease and lots of times people will focus on those microvascular conditions. But it's the macrovascular, cardiovascular disease heart disease and stroke that kills most patients. And like all complications with diabetes, they're most commonly silent. So if we're not educating our patients about what to look for, and we're not doing appropriate screening as recommended by the guidelines, then we're really missing an opportunity. So yeah, I

		think it starts with very base care of day to day how does this disease affect me and how do I reduce my risk of all of these complications?
Robert Eckel:	04:56	There's a theme out there today that the ADA has promoted as has the European Association for the study of diabetes in individualizing the care for the patient with diabetes. Trish, how does individualization of care involve shared decision-making, making sure that the patient's medical needs are met? But in addition, the patient's concerns about their treatment follows?
Patricia Montesinos:	05:19	Well I think this is really not a one size fits all. We need to take into consideration that patient's goals, preferences, needs, values when we are coming up with decisions. And we want to involve our patients in the process of this medical decision. And the other thing is, there are so many medical advances and different options. And there may not always be one best option. There may be multiple. And so we want to present those options to our patients. Make sure that they understand them. And really help guide them through risks and benefits to each option. And make sure that they understand the implications and how one treatment may actually help them several different ways.
Robert Eckel:	06:04	Well for the ADA, the individualization has been mostly directed towards glycemic management. In other words, what is my goal hemoglobin A1C for this patient? Often that becomes problematic because of duration of diabetes, the whole issue of type one versus type two diabetes. Complications present or absent. So Jay, how do you take into consideration all of these factors when you're individualizing glycemic goals? Or in fact, is this too complicated for the average primary care physician either the internist or family practitioner?
Jay Shubrook:	06:41	Yeah, I think that it's not too complicated. I think we do that already with most of the conditions that we treat. We are always triaging like what's the appropriate level of care for that person at the time. I think generally that beautiful list from the ADA that shows all the different factors, one or two of those tend to predominate. So if I have a young person who pays cash for their appointments and let's say they're migratory, I might end up having a very different decision about where their care intensity fits. As opposed to someone that might have insurance and have access to many of the things that we want to utilize. Conversely, if I've got someone that's got a long duration of disease, they are going to be other factors that are less important. But if they've got long duration disease and complications, that's going to be the predominant factor. And I

		think that while there are many, we usually highlight one or two things that help us make our decisions.
Robert Eckel:	07:31	Good, that's very helpful. Trish, turning back to you now, the data seemed to indicate that when the patient's involved in his or her decision-making process, there's greater adherence to the treatment regimen. Has that been your experience and can you comment on that further?
Patricia Montesinos:	07:46	Absolutely. I think when patients are made aware and informed about their options, we can come up with a tailored treatment regimen that they can be excited about. That they feel is reasonable for them. And I think what's exciting for them to see is that when they participate in that decision and they see the outcomes by retesting their A1C in several months, it really helps to keep them on track. We want them to feel like they are moving forward. And in order to do so, we need them to buy in to whatever treatment option we feel might be appropriate for them, and they feel might be appropriate for themselves.
Robert Eckel:	08:29	Jay, your experience in that space.
Jay Shubrook:	08:32	Well certainly yes. If you involve your patient in the decision-making, it's harder for them to feel like they're not going to engage in that. And I will actually call them on it. I'll say, hey we talked last time. I asked what your goals were for the visit, your goals for treatment. These are the things that we decided on. Do you feel good about them? So I think inherently when we buy in, we're much more likely to follow through or at least feel some sense of responsibility. So I don't want there to be a negative thing, but I do think people tend to follow through when they get to have a say in the decision.
Robert Eckel:	09:02	Well part of the reason for this podcast is the fact that the three of us understand quite clearly that diabetes is a substantial risk factor for cardiovascular disease. That risk compared to sex and age match people without diabetes is somewhere between two and three times higher. So in relationship to that, we've really entered into a new arena of the therapy of patients with type two diabetes, particularly in terms of reducing the risk. And that relates to several new classes of medications. But before we turn to how we orchestrate that therapeutic decision-making in the clinic, I'd like to turn to lifestyle. And I'll just kind of volunteer that being part of the lifestyle guidelines of the American Heart Association historically, ultimately I kind of begin with lifestyle in everyone. And I know in practice this can be sometimes quite frustrating because we want people to be more active. We want them to eat a heart healthy and a

		diabetes healthy and a cancer healthy diet, which would in my opinion the evidence suggests a dietary pattern such as DASH or Mediterranean style diet.
Robert Eckel:	10:06	And we also many times in type two diabetes we want the patient to lose weight. So we need to be realistic here, how much time do we have as practitioners, and back to more of a team approach to these patients at risk for cardiovascular disease with diabetes, how do we go about emphasizing and implementing the importance of a healthy lifestyle to reduce that risk for cardiovascular disease? Jay, I'll start with you on that one.
Jay Shubrook:	10:31	Sure. So I think the first thing you need to do is make sure you know where the patient is right now and what they do currently. I think too often, at least I have in the past kind of went with the ideal, and if the ideal's far from where they're at, it's going to be very hard to meet in the middle. So I think I try to assess where they're at in terms of dietary, lifestyle, sleep, exercise, all of those things up front. It takes a long time, so this is another reason to reinforce the team. So it might be that I initiate them to do some kind of logging of their foods.
Jay Shubrook:	11:02	But then they see the diabetes educator or the dietician who then gives me further feedback. I think if we tried to do it all by ourselves we'd have to have a whole lot of visits or have to have a whole lot of time for one visit, which is probably not reasonable. So I think start where they're at, make small goals for them. And make sure you use a team based approach so that you can have multiple touch points and get the information you need to give them small steps to achieving a healthier lifestyle.
Robert Eckel:	11:27	So Trish, can you complement that?
Patricia Montesinos:	11:30	Absolutely, yeah. I think Dr. Shubrook brings up a good point, is setting goals. And I think setting overarching goals and then further delineating how can we make smaller time sensitive or more specific goals so that say they're walking the dog five minutes twice a day, several days a week. We slowly incrementally bring that number up to work towards ultimately 30 minutes a day, five days a week. Or up to 150 minutes per week, and say do you think it would be realistic within the next week that you pick it up to 10 minutes twice a day? And work your way up slowly. So really having defined short term and long-term goals with regard to being specific in what's realistic for the patient.

Robert Eckel:	12:16	I routinely employ a dietary quality assessment in all of my patients. And I go through questions like how many servings of fruits and vegetables do you eat a day? And how many servings of whole grains do you eat a day? And sometimes you have to pause there and describe what a whole grain is because many people may not be able to adequately define whole grains. And then I ask them how many fish servings per week? Do you read food labels? And questions like that to get some sense of the quality of the diet. And one response I typically kind of get is that well, I read food labels, but I'm reading the carbohydrate content of the label.
Robert Eckel:	12:53	And of course, being someone who kind of cross dresses as a preventative cardiologist having my clinic in cardiology, I'm more concerned about the saturated fat content than I am the carbohydrate content. Of course we know that the carbohydrate content of the diet does reflect on the glycemic excursion after a meal. We certainly understand that. But the complex carbohydrate, which we find that whole grains contain is an important part of a heart healthy diet. And I think when many times weight reduction is our goal, I think we don't need to spend a whole lot of time assessing the quantity of food intake because often we're not given the kind of information we can adequately utilize in that menu and prescription to follow. So I'd like your comment Jay.
Robert Eckel:	13:35	We take small steps, Trish, you emphasized that too. In terms of modifying the overall diet, in terms of the diet that we would consider in best interest for their cardiovascular disease risk and of course their glycemic management. But moreover, I think in terms of weight reduction, we need to go slowly and probably get others involved in that paradigm. So Trish, when you as a certified diabetes educator have a goal both in terms of the dietary quality and ultimately weight reduction, do you refer these patients to a dietician or do you in fact feel adequately engaged and experienced in that area to work with the patient directly?
Patricia Montesinos:	14:14	I think it really depends. It depends on the patient's needs. If they're extremely motivated and they feel it would be helpful to them to get more into the specifics of nutritional values and reading food labels, then I would absolutely recommend them meeting with a dietician for a full medical nutritional therapy visit or two. But some of the patients, sometimes keeping it more simple, keeping it simpler can be an easier method for them. A more realistic method for them. So just focusing on portion sizes and maybe not taking the approach of all or nothing, but really moderation and portion control is something

		that I really endorse with my patients with regard to most foods in the diet.
Robert Eckel:	15:04	Great. Well Jay turning to you, just in my own experience I have the pleasure of working with a certified diabetes educator who also is a ... she's a certified nutritionist. And so she brings that back around to the clinic with her. And I ultimately then feel that the primary care physician or the specialist, whichever, and the nutritionist need to be on the same page. Has that been your experience Jay, when you refer a patient to a nutritionist, is she or he potentially on the same page as you are in terms of what the recommendations might be?
Jay Shubrook:	15:37	I think that's a really important point. We do need a team. And I think that as a primary care provider, I can have a lot of influence whether we're on the same page. So I think part of my referral is to ask for some specific things. I find that when I work with my diabetes educators and I work with dieticians, they often can do some of the problem solving. And maybe I've identified the problem and they can help with solutions. So for example, if we're trying to limit fat in the diet, or we're trying to reduce carbohydrates, it's one thing to do less, to cut something out. It's much harder to find the long-term solution of what you can do ongoing. And so, I think that's where the team-based approach is so important because they can really help with those long-term solutions like what is a carb substitute or a fat substitute that's one, going to meet my cultural and my nutrition needs? And two, still help me advance in health?
Robert Eckel:	16:27	Good comments. And I think taking in the considerations of those other factors that you just mentioned is so very important. And we can't forget about physical activity. And I think it's important for us to assess routine patterns of physical activity, whether there are limitations to exercise or more physical activity. And again, go slowly because many of our patients may be at risk or in fact have cardiovascular disease that's unaware to them. And if we start in a rigorous matter, we may have outcomes that are unfavorable to follow. So let's turn now to a rapidly advancing area of management of diabetes patients and their risk for cardiovascular disease, and that's the many outcome trials that have been done with the new classes of medications that since 2008 have required safety assessments initially, followed by efficacy for primary outcome benefit to follow.
Robert Eckel:	17:18	So Trish, in your interactions with patients in terms of decision making beyond lifestyle, which again I think we all agree is important, how do you help the patient or work with the

		primary care provider or the endocrinologist and cardiologist make decisions related to medications?
Patricia Montesinos:	17:36	So we want to look at both patient factors and medication factors. And really using the American Diabetes Association new treatment algorithm is really helpful because it takes these things into consideration. So it's looking at both patient comorbidities such as atherosclerotic cardiovascular disease, heart failure, chronic kidney disease, also looking at these different medications and their risks for hypoglycemia, their impact on weight, cost, which is a huge concern. Risk for side effects and patient preferences. And so using all of those different factors and then coming up with a tailored treatment approach along with the patient. And so, we know in the leader trial that Liraglutide has been shown to reduce cardiovascular events as well as the SGLT2 class now in the EMPA-REG outcome clinical trial.
Patricia Montesinos:	18:31	So we have these new medications and these new classes of medications, the GLP1 receptor agonists and the SGLT2 inhibitors, which give us a two for one deal. They give us A1C lowering and they give us cardiovascular risk prevention.
Robert Eckel:	18:48	So Jay, turning to you and your prescribing patterns, is your belief up front that metformin remains the primary treatment for type two diabetes?
Jay Shubrook:	18:56	Boy, that's a million dollar question. I would say because the data so far with these new classes of drugs really are looking at people with established cardiovascular disease, when we go back to the bigger population of all people with type two diabetes, I think as of today, metformin still should be our first medication based on its risk benefit profile. It's cost and patient factors.
Robert Eckel:	19:18	I would tend to agree with that. I think it's consistent with the guidelines that's put forth by the ADA and the AHA I'm sure is on the same page in terms of their recommendations. However, the metformin data is showing benefit in at least people with metformin as the primary therapy for type two diabetes is not overly convincing. So we do need to think beyond that in higher risk people. And as you mentioned very, very nicely is that the people in these trials typically have disease or at very high risk. So, in terms of implementing the algorithm Jay, beyond metformin what are your considerations? And I think the thiazolidines can't be dismissed entirely because we do have some supportive evidence of their benefit too in terms of cardiovascular disease risk. Jay, your thoughts here.

Jay Shubrook:	20:06	Yeah, so as I approach a patient, again, we talk about all the different factors. One of the things at least for type two diabetes is the great majority of my patients would gain great benefit from weight loss. And that's not just from diabetes and cardiovascular disease, that's from many conditions. So when I look at that, if all of the things are equal, I'm looking at glucose lowering and weight loss is one of my primary factors, and I think it's up to us to again educate our patients about the risk of cardiovascular disease. Because I don't know in shared decision-making that they would be picking that as one of their topics. But if I'd share with them that hey indeed not only do we worry about all these other things, we worry about cardiovascular disease, that might also raise to their awareness too and their desire to involve one of the new medications. So I mentioned the twofer Trish, if I can get something that improves glucose, lowers weight and reduces cardiovascular risk, well that sounds like a threefer for me.
Robert Eckel:	20:58	Well that's the benefit certainly of the GLP1 receptor agonist and the SGLT2 inhibitors. They not only modify the outcomes that relate to cardiovascular disease risk, but they also have a benefit in terms of modifying glycemic control and also weight in many, many patients. So Trish, how do these trials influence your interaction with the patient in terms of which direction you might head? And keeping in mind up front that the individual with diabetes who's not had an event yet, a stroke or a heart attack, he or she may not be adequately informed. So how would you allow that information to be provided so the shared decision-making might follow for best therapy?
Patricia Montesinos:	21:39	So when they put it in terms of weight loss as far as both of these classes of medications not only lower A1C, they assist with weight loss, and then oh by the way, they also have been shown to reduce risk of cardiovascular events like heart attacks and strokes. So really putting it in terms of all those added benefits for one additional medication as long as cost is not a prohibitive factor there. The other thing is these medications really do minimize hypoglycemic risk. And that's a really important quality of life factor for a lot of our patients. So, we can add a medication that may be able to minimize insulin or sulfonylurea use, or even just adding this onto metformin. Even the combined use of these medications. There's a very extremely low risk of hypoglycemia and that's a nice benefit for our patients.
Robert Eckel:	22:33	So Jay in the patient that we describe, the person with type two diabetes, let's say for eight to 10 years who's not had a cardiovascular disease event, on metformin, what features of

their presentation and/or their own goals for therapeutic intervention would influence your decision as to whether a GLP1 receptor agonist might be added or an SGLT2 inhibitor added?

Jay Shubrook: 22:57 Yeah. I think that's probably a pretty common scenario, right? You're a decade into the disease, it's unlikely the metformin's going to do the job alone, or metformin plus lifestyle. So in terms of making a decision, hopefully along the way I've been talking with the patient about what sort of things that they feel most good about in terms of their management of their diabetes and which things are their struggles. Many of our patients struggle with weight gain as part of their management of type two diabetes.

Jay Shubrook: 23:23 Many of our medications can cause weight gain. And as they get better controlled, they gain weight. So typically if I say well here are some of our choices, one of the choices is an injection, that is anywhere from twice a day to once a week, but it contributes to weight loss as part of its treatment plan, that may be enough for many patients for them to kind of want to be involved with that. I think the harder question is, how do we truly delineate who's at greatest cardiovascular risk? And I guess I would say that my default has been that 10 years of diabetes, you're at pretty high cardiovascular risk already no matter what your background is because the disease goes on for a long period of time. So, if I'm looking at decision-making, I think the weight loss with help. Injections are not hard at my practice. I think that we introduce them in such a way that it's just part of the treatment. And so we don't find much pushback for injections.

Robert Eckel: 24:13 It's interesting. I saw a patient at the clinic on Friday, a man I've seen for several years now who's wheelchair bound and has type two diabetes. And has an A1C that's climbing. I believe in Friday's visit his A1C was 8.4. And his wife was with him who kind of backed his decision not to be on anything injectable for many reasons because of his partial paralysis ultimately an SGLT2 inhibitor was not the likely therapy. So, for the first time in many, many years, to try to reduce his hemoglobin A1C, and likely but uncertainly reduce his risk for cardiovascular disease I added acarbose. And I almost never go there but this man really did not want to be injected with anything.

Robert Eckel: 24:53 Basal insulin, a GLP1 receptor agonist. And again the SGLT2's in this individual would have been relatively contraindicated. But nevertheless, I think we can work with our patients and really share our decision-making with them in terms of what their goals are versus ours. But I don't think we should be bashful

about setting goals for A1C. Setting goals for blood pressure, and setting goals for lipid management that relate to the current guidelines. So finally, and we'll wrap up here, some final parting words of wisdom. Trish, I'll begin with you.

Patricia Montesinos: 25:26 Shared decision-making is really important. It's patient centered care. It's individualizing care for our patients. It's getting their buy in and making them excited about treatment options and ones that they feel they can adhere to. And really looking at all the factors with regard to weight, A1C lowering effect, cardiovascular benefits, hypoglycemia risk. And sharing all this information about risks and benefits of different options with our patients to come to an option that we feel will be appropriate medically as well as effective. And one that the patient's feel that they can be excited about.

Robert Eckel: 26:06 Jay, summarize for us please.

Jay Shubrook: 26:08 Sure. I think it's important to remember that diabetes is largely self-managed. And because of that, and the work that goes into self-managing, we've got to have the person doing the work have a voice at the table. And when we do that, when we give them a voice, they have ownership. And when they have ownership, it's much easier to follow. I think where we can really be very important is as facilitators and sources of valuable information so people can really make a choice that's best for them. And I still haven't met a patient who doesn't want to live a long, healthy life. So you give them good information, they typically will migrate to things that make a lot of sense and also make sense within the kind of framework of their reality. So I think we're informers, we're facilitators, and we can help them manage this condition.

Robert Eckel: 26:55 I want to thank both Patricia Montesinos and also Dr. Jay Shubrook for joining me in this dialogue that relates to Know Diabetes by Heart™, this joint venture between the American Heart Association and the American Diabetes Association and the many sponsors who have sponsored this podcast. Thanks so much for listening and stay tuned for upcoming podcasts to come.