



# Self-Monitoring of Blood Glucose

## A Web-based Training

Presented by

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## Introduction and History

I am an internal medicine physician by training. I am also a Captain in the United States Public Health Service. I went to the Uniformed Services Medical School and then did my internal medicine residency at the Mayo Clinic here in Scottsdale, Arizona.

From there, I actually went directly to the Phoenix Indian Medical Center and have held a variety of positions there including Staff Internist, Acting Chief of Medicine, Director of their research program. Then up until July of this past year, I spent the past five years as Acting Director for their Centers of Excellence, which includes their Diabetes Center of Excellence. I was also Acting Clinical Director, Ambulatory Care Director there for the past year until transferring to the Phoenix Area Office in July of this past summer where I currently am the Deputy Chief Medical Officer for the Phoenix Area.

What we're going to talk about today is self-monitoring of blood glucose. We're going to go through a little bit of history about where it came from, how we started doing it, and where we are now. Talk a little bit about the use and accuracy of these machines, because knowing how accurate any device is or any test is is imperative to your ability to apply it clinically. A little bit, we'll talk about some of the evidence that's currently out there behind the use of self-monitoring of blood glucose and diabetes. Then we'll review the clinical guidelines that currently exist for the use of self-monitoring, and then we'll have some examples of practical approaches that folks can use every day in their clinical practice.

The learning objective is at the end of the presentation, hopefully, folks will be able to incorporate FDA approved indications for using SMBG in managing patients with diabetes. They'll be able to summarize information regarding the accuracy of the meters and glycemic control. Be able to find and utilize the IHS Standards of Care for Diabetes and hopefully, be able to take away some pearls that will allow you to change and incorporate something into your clinical or public health practice.

Let's start with the definition. What is self-monitoring of blood glucose? So the Joslin organization, which is well known for their work in diabetes, defines self-monitoring of blood glucose as simply the checking of your blood glucose with a blood glucose meter. Egyptians first made the mention of diabetes back around 1500. During medieval times, there were many attempts to identify disease state by examining urine samples for appearance, color, sediment, and even taste. In the 19th century, glucose was identified as being present in the urine. So Elliot Joslin who founded the Joslin Diabetes Center advocated in the late 1800s for the self-management concept that related diet and exercise and urine testing to keep urine sugar-free.

So the initial glucose testing was actually done in urine and it actually required heat early on for the color development that they would see. This product, the Clinitest, was actually the first product to resolve the issue of the heat required by the development of a modified copper reagent tablet which actually heated the urine mixture to a boil and was able to oxidize the glucose, changing the color that you see here – actually, over here. So those were the first tests that were done.

So then in 1957, they also realized that the urine testing with Clinistix could also give approximate results from blood. So, something that was called the Dextrostix was created in the 1960s. This essentially was a paper reagent that used the glucose oxidase/peroxidase reaction, but also allowed a large drop of blood to pass through to react with the dry reagent causing the color change. This was a semi-quantitative visual reading.

So, more interest in self-monitoring and in monitoring glucose continued and then they developed reflectance meters. Reflectance meters allowed for some bedside testing but they were very bulky and heavy and expensive. They went away from the reagent copper and the heating issues to enzyme electrode, and they required less blood and battery operated, but still not too user-friendly.

So then we came to the first generation of the meters that we are getting to know or use today. These were qualitative results instead of quantitative results. They were able to considerably decrease user interference and narrow the hematocrit ranges, but they still took a relatively long result time. There were still enough operator-dependent steps where people really experienced a lot of errors. We're talking result times in these first-generation meters of 40 seconds to two minutes long.

So they continued in their technological development and we developed the second generation of meters which basically required very small amounts of blood, shorter test times, they improve the accuracy, there was less interference, and those are the meters that we are continuing to use today and you'll continue to see further developments on.

## Accuracy and Safety

So, that's a little bit of a history of where the meters came from, but as we look at blood glucose meters, are they regulated? So blood glucose meters are in fact considered by the FDA as in vitro diagnostic monitoring devices. They are considered Class II or to be a moderate risk device. An in vitro diagnostic monitoring device is the reagent instrument or system intended for use in the diagnosis of a disease or other conditions in order to cure or prevent disease or its sequelae.

So the FDA defines the indications for blood glucose monitors, as their intent is for quantitative measurements of glucose by lay users at home or by health care professionals in clinical settings to assist in the evaluation and management of individuals with diabetes.

Keynote: the FDA does not state that they are for diagnosing or even screening for diabetes. This is an important point, as many folks at health fairs will use glucose monitors for screening. We need to remember that if you do in fact use a glucose monitor for screening and you get a higher reading or something that is concerning, that that needs to be followed up then in lab in the typical way that we would diagnose diabetes or prediabetes.

The other important thing to know is that the FDA currently says that there is no distinction between the performance requirements for over-the-counter and professional use glucose meters. So as far as the FDA goes, the systems that we use in our clinics, in our hospitals, follow the same regulations as the systems that we use at home. And really, the self-monitoring of blood glucose really does take a system. So it's not just the meter that we're talking about or that the FDA looks at, it's really looking at the test strips and the quality control solutions, sometimes the lancing devices and alcohol wipes. Each system of all these various components are considered to be a separate system and according to the FDA requires its own performance and is evaluated separately.

So there is an organization that looks at standardization and quality of these meters and that's the International Standards Organization. So, what you need to know is that they have determined that for a blood glucose device, that 95% of individual readings should fall within 15 milligrams of the result of the reference measurement for blood glucoses that are less than 75. So, what that means is that 95% of your blood glucoses that come out at 60 should fall at least 15 milligrams on either side of that. Well, if you think about it, that's a pretty wide variation. If you're at 60, then, well, are you sure that that blood glucose really isn't 45 or 75?

Then they say that the standards say that 95% of the individual results for blood glucoses of over 75 should fall within plus or minus 20%. So, that's still a very large degree of error that's allowed for these devices. So again, clinically, when you're looking at this and you're discussing this with

patients, you need to understand and realize what the variations might be and what is actually acceptable.

Why such high variations? Well, as we've talked about with the early meters, a lot of different things can impact how that reading is that you get; user performance, whether you have interference from things like peoples' cholesterol, their hematocrits, from medications that they're taking, from temperature and humidity and altitude. So all of these things need to be considered when you're looking at the validity and consideration of the blood glucose reading.

So obviously, there is some controversy and concern over the wide variation that is accepted in these, and so they are trying to tighten up the standards a little bit. I think that most folks agree that really, we'd at least like to see that 95% of the values that – for values that are greater than 75 are not 20% total error but down to 15, and that readings below 75 aren't 15 milligrams in error but 10. You'll find that most of the modern monitors that we use actually fall well within this range, but you just need to be aware that those are the numbers.

I put this chart in here only just to talk about and to show you the various things that can result in errors in your blood glucose, things such as, "Are the test strips expired?" We all have patients who hoard test strips and they end up grabbing something out of their cupboard that's been there for three or four years and potentially, that may lead to an erroneous result. We have folks that are on peritoneal dialysis, and there are less and less meters that are impacted by interference of maltose, xylose, and galactose, but those meters that do require GDH-PQQ for their reagents are issues and shouldn't be used in those patients. For those meters that still have coding, there are issues of miscoding and that sort of thing. So just be aware that there really are a lot of potentials for variation and error when you're looking at these.

Again, not to kind of drill at home but here is another table and specifically, I wanted to call your attention on the peritoneal dialysis issue. The ACCU-CHEK monitors, specifically, does have issues with regard to folks that are on peritoneal dialysis. They are in the midst and have been in the midst of changing variations, but just be aware of that. Other things like acetaminophen or salicylate also depending upon the type of meter that you're using in your facility may or may not have issues of interference.

The other issue just to be aware is, again, the performance parameters. I find this interesting. So the Bayer Contour meter is good for down to a hematocrit of zero. So I'm not sure how that works because I think if your patient has a hematocrit of zero, they're probably not viable, but just to be aware, that there are different hematocrit ranges for the different meters. There are different operating temperatures. For those of us out in Phoenix where it gets to be 115 in the summer, those are issues that we need to talk about or think about. Other issues with regard to folks that have dyslipidemia with very high triglycerides, how is that affecting it and which meter may or may not be the best for our use in our patients? So, just to be aware of that.

The other thing that the FDA keeps track of, because it is a regulated thing, is the adverse events and the injuries. It was a surprise to me when I attended a blood glucose FDA meeting back in 2010 to find out that actually, glucose meters have one of the highest numbers of device adverse events reported each year.

These are probably generally underreported, actually, but there are thousands of medical device reports sent each year. There are billions of tests, but it's still something to be aware of that there are, it's not as if it is a benign procedure as we all make it out to be.

Some of the injuries, and again, this table just sort of shows what the different reports with injuries were coming from treatment with medications, and that's interpreted to be a blood sugar with a pain and interpreted in a particular way which caused a medication to be given which might have resulted in injury based on an erroneous blood sugar result. You can see the list of various adverse events or injuries.

This is the pie chart that, again, shows the adverse events in death between the periods of time of 1992 to 2009, 100 deaths actually, associated with glucose meters. Again, over a period of time, maybe not so much, but again, we use them so frequently, we prescribe them so much and we think nothing of it, and just to realize that they are an actual medical device that bad things can happen with.

So just to kind of close on, I wanted to go through that fairly quickly just because I wanted to get to the meat of the actual monitoring, but certainly, technology has come a long way. I think we're all very happy and fortunate and appreciate the fact that we're not monitoring people's urine for their blood sugars. I think that we do all need to realize that there's lots of external factors that can influence the accuracy of meters and I'll say this and I'll say it repeatedly throughout the presentation is, if we interpret blood glucose or any lab result or test result, if the result doesn't make sense, then we need to question it. And so knowing something like this, that there are so many things that can impact that, we need to use our clinical acumen and really our relationship with the patient to have that discussion as to whether those readings are making sense or not. You do need to realize that there is controversy over the accuracy of the current meters. You will find that most all the meters that we are currently using well adhere to those accuracy requirements and really exceed them, but do realize that they do exist. Then there are a significant number of adverse events reported each year from the use of these machines.

## **SMBG in Type 2 Diabetes**

So let's get down to some of the meat of it, which is simply, "Is SMBG useful in the treatment of non-insulin treated diabetes?" I say non-insulin treated diabetes because that's where I'm focusing my talk. The DCCT and the UKPDS has really shown that in Type 1 diabetics and for even Type 2 diabetes patients who use insulin, it clearly shows that SMBG is effective for patients. Why is that? Again, as we kind of go through the presentation, a lot of reasons come to the fact that they're utilizing those numbers and those readings to take an action or to realize how they need to adjust something. As we kind of go through and I give you some, hopefully constructive, clinical guidelines on how to do that, you'll realize that that's key.

But there's a lot of debate on the effectiveness of whether SMBG as a tool in self-management of patients with Type 2 Diabetes who are not using insulin is useful. So, what I'd like to do is just review some of the information that we have on that. In 2010, the Cochrane Group had done a review and there were six randomized controlled trials. We have an additional six randomized controlled trials that have come out. So, what the Cochrane Group does is they have various requirements to determine whether a study is valid enough to be included in their review with the very rigorous design that they look at in terms of their protocol, but they identified these twelve studies, which included 3,259 patients. The intervention duration for these studies ranged anywhere from 6 months to 12 months. So again, these are randomized controlled trials. So these are actually proactive trials where people were randomized to particular groups.

So of the twelve, nine compared SMBG with the usual care without monitoring at all. One compared SMBG to self-monitoring of urine glucose. One had three arms comparing SMBG to SMUG and then to usual care, and one had three arms where they actually did a more intensive monitoring to a less intensive monitoring to usual care.

So this is a forest plot of comparison of a few or most of the studies that were included. The thing that I want to draw your attention to is that this is actually looking at people who were followed or were randomized to either self-monitoring of blood glucose or to control, and this is at six months of follow-up. If you stay on the forest plot, the left where my arrow is, it's favoring SMBG and the right is favoring the control. So if you'll look at this, you'll notice that almost all of the studies actually showed that for six months, it actually did have usefulness in hemoglobin up to 1% or 2% in some aspects for the monitoring of those patients.

What they went on to say in the review was that in newly diagnosed Type 2 patients who are not using insulin, that they found that during the first year, there was some benefit in the lowering of the hemoglobin A1C and the use of the SMBG. What they also found was that once you got over a year in newly diagnosed diabetics that they no longer found a lot of benefit or use to the monitoring, to the use of SMBG. What they also showed was that for folks who had had diabetes for greater than one year's duration, in folks that are non-insulin treated again, that really the glycemic control benefit of the use of SMBG was small up to 6 months and again, subsided after 12 months.

So they really made the differentiation that, well, what they found was using it in newly diagnosed was useful up until a year. Using it in people that had had diabetes for longer than a year, you may get some initial benefit during the first six months of intent or using it but that benefit subsided in terms of glycemic control after a year.

The other things that they noted in some of these randomized controlled trials was that even despite possible beneficial glycemic effect, that the monitoring had no relevant effect on general well-being and health-related quality of life. So various ones of these studies looked at various health-related questionnaires and other things, and whether patients felt secure or not so secure in using the monitoring system and they really didn't see that it had any effect on that.

They also saw in these controlled trials that people who use SMBG were just as satisfied with their treatments as those people not using SMBG. As one would expect, they actually did find that you had increased reporting of hypoglycemic episodes with folks who were using SMBG on a regular basis. You can have hypoglycemia without being symptomatic. So if you're not checking, you may be hypoglycemic and not know about it. So of course, you're going to find more episodes of hypoglycemia if you're checking on a regular basis.

## **Morbidity, Mortality, and Cost**

So I just wanted to cover a couple of other studies that were not randomized controlled trials that kind of continued to show the controversy and the inability of a lot of evidence to tell us whether there's real usefulness to SMBG or not. The ROSSO study looked at the relationship with SMBG with disease-related morbidity and mortality. The study followed 3000 patients roughly with the diagnosis of Type 2 Diabetes between 1995 and 1999 until the end of 2003. They had a mean follow-up of about six and a half years. This was actually a retrospective review from medical records.

So, what they found, they were looking at endpoints, all-cause mortality, blindness, dialysis, MI, stroke, and amputation. And that was their endpoint. You'll see that the red lines are actually the SMBG cohort. The blue lines are non-SMBG cohort. You'll notice that the SMBG cohort started at a much higher A and fasting blood glucose than the non-SMBG cohort.

What they saw was that the SMBG was associated with a decreased related severe morbidity and all-cause mortality, and that both groups, initially, had some effect and were able to maintain that with the use of self-monitoring of blood glucose. These are the survival curves, which again showed

that the red is the self-monitoring group; the blue, the non-self-monitoring group, and again, this study did show that they had decreased related morbidity and all-cause mortality by folks that utilized self-monitoring.

The Fremantle study assessed whether SMBG was an independent predictor of approved outcomes in a community-based cohort. This was a cross-sectional design and it actually also looked at folks on diet alone, oral medicines, and then multiple insulin injections. They actually saw that SMBG was related with a 48% decreased risk of cardiovascular mortality in insulin-treated diabetics, but they found the actual 79% increased risk in non-insulin treated diabetes. So, what they found was that, again, very useful for folks that were treated with insulin but actually found increased risk of the use of SMBG with those that were non-insulin treated. Then they did find that actually, SMBG was independently associated with a 48% reduced risk of retinopathy in the entire cohort.

This study just shows again – it's a little bit difficult to read because they're kind of right next to each other and it's mainly looking at the A1C impact of whether you're monitoring or not monitoring. You can see that they're relatively – and these were not specifically different in most of these cases for folks that monitored or not monitored with regard to the hemoglobin A1C benefit.

So the DiGem study looked at three arms and it was to determine whether SMBG alone or with instructions in incorporating results into self-care would be more effective than standardized usual care in people who were non-insulin treated. They followed 453 non-insulin treated Type 2 diabetics with the average A1C initially start at 7.5. What they saw was that there was no statistical difference at 12 months in the A1C levels. So again, DiGem looked at non-insulin treated folks over time randomizing them to more intense versus less intense versus normal care, and what they found was that there was no improvement in hemoglobin A1C.

What they did find was that in both groups, but certainly greater in the more intensive blood glucose, was that the adherence waned over time. So again, when you're asking people to prick themselves and check their blood sugars multiple times a day, many of our patients perceive that as interrupting their quality of life or really get tired of doing it, and so their compliance with it wanes over time.

This, I just wanted to kind of put in here. This was a study that was done looking at meal-related structured self-monitoring of blood glucose. This is a randomized controlled trial that basically compared an education intervention combined with monitoring. What I wanted to show there is that there was improvement, actually, with blood glucose tied to an intervention, that being this lower curve versus regular or no testing. I think that that will become clear and more important as we kind of talk about, "Well, what is the utility of testing?" Again, going back to insulin treated patients, they're testing for a purpose. They're looking to do something with those results. They're not just sort of gathering data that may or may not be reviewed by someone.

One last study, again, this looks at a huge registry of Kaiser patients, looked at for strip use and basically, this actually also shows that for those folks that tested on a more regular basis, that there was improvement in hemoglobin A1C.

In one last trial, which was the ESMON trial, and the reason why we put this in was to talk about – basically, this looked at the impact on psychological and disease in patients with newly diagnosed Type 2 Diabetes who were asked to monitor or not monitor with self-monitoring of blood glucose. They evaluated 184 non-insulin treated patients who had no prior experience with monitoring. What they actually found, they found no difference in the hemoglobin A1C between the groups over the 12-month period and they also noted that the group that was required or asked to do self-monitoring had a 6% higher score in the depression subscale of the well-being questionnaire.

So again, the Cochrane Review said that in their 12 trials, randomized controlled trials, they didn't really find that it impacted the well-being or not. It suspects all of us have had instances in conversations with our patient who say, "It kind of bums me out to have to check my blood sugar multiple times a day" or I had patients tell me, "It's just a constant reminder and I don't know what to do with the information" or "I'm not sure why I'm doing it, so I just choose not to do it."

Then lastly, we need to talk cost. Now, these are some old numbers. They've been unable to come up with the new numbers, but the cost of monitoring is huge. It is estimated that – this was ten years ago; \$6 billion is spent worldwide on monitoring. When you think about the monitoring and the components and the strips and everything, it's a huge money business and it cost our facilities and limited resources a lot of money.

When I was preparing for this talk, I was talking to some of the pharmacists at the Phoenix Indian Medical Center and they shared with me something that I had not heard, which was, evidently, strips are a big hot ticket item at the flea market. So there are patients who are taking their strips and selling them at flea markets because they can get \$20 a bottle or \$30 a bottle for the strips. So we need to make sure that if we're dispensing these, again, it's for a medical device and that we're doing it appropriately and that we're utilizing the limited resources that we have and are doing it in an evidence-based way.

So in summary of the research part, there's conflicting data to support the benefit of standardized, and I'll say "standardized" because it's going to be another key point. Self-monitoring for people who are not insulin treated. The most recent review really has shown that if you're going to do it and do it intensively, doing it newly diagnosed patients during the first six months certainly up to the first year, is going to get your biggest bang for your buck. Even in folks who have been diagnosed for longer than a year, probably you're not going to get necessarily a lot of benefit in glycemic control by intensive monitoring after about six months.

There's so much controversy. I try to choose some studies that showed, "Yes, it is beneficial," "No, it's not beneficial," and I think that what you'll find is the clinical guidelines are saying, "We still need more data. We still need more randomized controlled trials to determine the best way to do this and how we're going to get the best results and be able to take care of the best we can for our patients." Then lastly, it's really an expensive prospect. Phoenix Indian Medical Center spends about \$350,000 a year on strips and that's a substantial portion of their pharmaceutical budget as well as I'm sure each one of your facilities is spending as well.

## **Official Recommendations**

So let's shift gears to what the official recommendations are. So the International Diabetes Federation back in 2008 had recognized that there was a lot of controversy and concern over the use of self-monitoring. So they developed a task force to address the issues, specifically of self-monitoring of blood glucose in people with Type 2 Diabetes that were not treated with insulin.

Basically, they looked at a lot of the studies that were looked at in the Cochrane Review as well as the studies that I reviewed with you today, and they said, "They're inconsistent due to differences and designs and populations and interventions used." Part of a result of their investigation and recommendation was that we really do need further studies to better assess the benefits and the optimal use and cost-effectiveness of the monitoring.

Really, where they came down on after looking at all the studies was that it's likely to be effective only when the results are reviewed and acted upon by individuals or health care providers to actively modify behavior and/or adjust treatment.

So again, if we're just sending our patients out and we're saying, "You've got to meter. You've got to meter," and we're not telling them what to do with those results or we're not reviewing those results with them, then that's probably not useful. So they have a list of six or so guidelines that they've put in their plan. A link to their plan is on the button of the slide. Basically, they said, "You need to use self-monitoring in a health care team that has the knowledge and willingness to work with the patient and have a care plan established to attain agreed treatment goals," okay? So those goals may be different for each individual. In fact, they probably are going to be different for each individual. So as goals are different for each individual then so would the monitoring plan that you may be discussing with that patient.

They again did agree that you should consider at time of diagnosis that there was benefit as part of an individual's education, so they can start understanding how food impacts what they do, how exercise impacts what they do, and all that. Then it could be considered again as an educational tool for ongoing diabetes self-management.

Again, stressing the individualization. Even glycemic target needs to be individualized at this point. One size doesn't fit all for self-monitoring either. We need to look at whether people, where they are in their spectrum of disease, where they are in their spectrum of ability to change their behaviors. We want to use it as a tool that helps patients be empowered not as punitive measure or something that they feel like is just a chore that just reminds them or brings them down or anything like that.

Again, as we work within the agency and health care to work on a team-based approach, we really need to have that discussion with the patient. So, you know what? If you tell a patient, "I want you to check five times a day," and that patient has no intention of checking five times a day, you now have sort of violated that patient relationship that you may have. Have the dialogue, spend the time with the patient to try to figure out what it is that you are trying to achieve by monitoring these blood sugars and really what the patient is willing to do.

Then you need to also realize – one of the recommendations is that you need to regularly monitor the performance and accuracy of their glucose meter. I suspect we've all had issues of patients coming in. "My battery died. This doesn't make sense. I forgot how to do it." So if you're going to be utilizing SMBG, you need to make sure that on a regular basis, you're reviewing that with the patient. So that was, the International Diabetes Federation guidelines. It's a very nice white paper. It's probably about 30 pages long. It's an easy read. I highly recommend all of you taking a look at that.

The American Diabetes Association does have a statement on the use of SMBG. So certainly, they give it a Level A evidence. Again, the DCCT, UKPDS, all say, patients who are on multi-daily dosing of insulin, or using a pump, blood glucose monitoring is very much evidence-supported and useful. They again have looked at the evidence and said, "Well, we're not sure what to tell you about people that aren't on insulin." So it may be a guide to the success of therapy, but we're not quite sure. Then basically, it could be used to achieve postprandial glucose targets and it may be appropriate, but the evidence is still out there or still lacking.

I put this in there only for completeness. A lot of it has to do with continuous glucose monitoring which I didn't cover today, but they do have indications and usefulness with regard to that. A lot of that is really for folks that are on insulin pumps and various things like that. But again, the ADA also emphasizes that if you're going to be using it, you need to really teach people how to do it, how to prick your finger, do it right, and make sure that the techniques are being used.

So this is what the IHS Division of Diabetes and Treatment and Prevention has on their recommendations. Again, the DDTP site is an excellent site. It is a tremendous source of information for all of us. I've put the links specifically to this page on the slide, but would highly recommend you

guys reviewing this. So again, they are on board. They say, "All insulin treated patients." So, that's not the question. But really, for those non-insulin treated patients, again, it should be an individualized plan. You're encouraged to consider when it's appropriate, when it's useful, what you're doing with it versus just sort of blanketly telling people, "You have to meter," okay?

Then, again, looking at the schedule based on an action and I'm going to give you some examples shortly of how you can do that. Then we still should encourage, especially if you're having your patient monitor, encourage them to bring the meter to the visit with you. I would also encourage you if they're going to meter, they should be doing a log. Sometimes the meters are supposed to have their time set well, but they don't and then you're trying to figure out. You've got 30 readings and you can't really tell whether it was done pre-meal, post-meal, fasting, or not fasting. So the use of a meter also allows the patient or the use of a log also allows the patient to write down things that were happening around the time or make sure that we have the time right.

### **Shift from Monitoring to Manage**

So one of the key points, I think, that I want to emphasize is that; really, it's a shift from self-monitoring of blood glucose to self-management of blood glucose. So it's not enough just to monitor it, right? So getting a lot of data that we don't do anything with is not a very useful excursion for our patients or for our care team. What we want to do is manage our blood glucose, right? We want to set goals that are realistic, based on the individual patient. Whether they're elderly, whether they're newly diagnosed, we want to make sure that the goals that we set for the patient make sense for that patient. They don't necessarily make sense to meet GPRA or to meet whatever your facility may arbitrarily has defined, but we're taking care of patients and at this point, we're taking care of the individual patient, and you need to make sure that what we're doing is for the self-management of that patient.

So, what can you do and how can we do it? Well, you can give clear and consistent messages about when to test, and I'm going to show you some examples shortly. Those goals need to be agreed upon by the patient. Again, arbitrarily saying, "Well, somebody says you should be testing five times a day." If that patient has no intention of doing that, then we shouldn't even be talking about it. We need to talk to our patients with that relationship that we're building through the care team to identify, "Well, what are their goals and how are we going to meet that?"

You need to teach patients how to respond to highs and lows. I will tell you, I do believe that every patient who has diabetes, whether they're on insulin or on oral medications, should have a meter and should know how to use it. It always is appropriate to check your blood sugar if you're feeling symptomatic, flat out, period, no question. So you need to make sure that patients know what to do if they go low or if they go really high.

Then it's all about looking for glucose patterns, right? I mean, you should teach your patients especially in between the times that they're coming to you and not. "How do you look for patterns? How are you going to act on those patterns? What is the difference between an individual reading and a pattern?" So I think a lot of you have heard me say before and I'll say it again, checking random blood sugars in the clinic is a useless endeavor. It's not tied to anything. You have no idea what to do with it. It's an individual reading. You're not going to do anything with that reading necessarily. If you check the blood sugar in the clinic and it's 350 or 400, the patient probably lives there. You're not going to actively chase that, especially if the patient is not symptomatic. So, what you want to do is just make sure that people understand the difference between individual reading and then pattern.

I would also say that – and again, this is from the DDTTP website, which is making sure that you and your patients are all very familiar with what the estimated average glucose and the A1C is. I put that in there because it is always confusing the patient. When we talk about the A1C and then we talk about individual readings, which – obviously, the estimated average glucose is just sort of an interpretation portion of link. So we say, to what patients are familiar with from that random blood glucose or that single point in time to the average? But make sure the patients are aware of it. So if they know that they're consistently getting readings that are 300, oh my gosh, that means that oh, I must be, over time, having an average A1C of 12. So again, this is on the website, I highly recommend. People are using this. Most of our labs are recording this at the same time they record the hemoglobin A1C.

This is from the International Diabetes Federation and again, the thing I like about this is it's very similar to the chronic care model, right? It's that we're not checking blood sugars in a vacuum.

We've got people with diabetes. We've got the health care team. We have the overall glycemic assessment. We're talking about how we want to optimize therapy. What's their understanding and education about diabetes? How can we use SMBG as a tool to help that? How can we use SMBG for behavioral changes? Because in folks that are non-insulin treated, that's really what we're talking about, and then what's the impact? We've talked a little bit about the economic impact, the safety impact, whether it could help glycemic control or not glycemic control and then the quality of life. Again, where is that patient in their continuum of what they're willing to do, how it's going to impact them, and how we're going to utilize that.

So a couple of years ago at PIMC, we had the opportunity to switch out meters. So, what we did was we said, "Okay. We're going to really hit this home with our patients and we're going to meter with a purpose," right? No longer are we just going to blanketly say to people, "Okay. This test, five times a day, five days a week." We're going to meter with a purpose and we're going to educate patients as to why we're doing this.

So we took from Staged Diabetes Management – and I'll briefly go through these because I want to leave a couple of minutes for questions, but we said, from Staged Diabetes Management, let's look at folks that are diet and exercise only, right? Then we say there's a start phase, there's an adjust phase, and there's a maintenance phase. So again, similar to the information that we've learned today was, when you're starting something, when you're newly diagnosed, doing it a little bit more frequently is very useful. When you're adjusting things, that's probably useful too, but when you get to that maintenance phase, when you've been a diabetic for a long time and you're doing the same thing, checking your blood sugar three times a day is probably not useful if you're not on insulin.

Then we said, "Remember, if you're doing this and you're checking your blood sugar, let's tie it to something, right? We want it to be fasting. We want it to be pre- and post-meal. We want you to be able to say, "Oh, yes. So I had a snack last night and this is my blood sugar this morning" or "This was my blood sugar. It was 150 before I ate this meal and then I ate all these things and now, two hours after, it's 350." So, what was it within that meal that impacted that? So you'll want to make sure that you're tying it to somebody, to something.

So here is one for oral medications. So these are people that are on oral pills only. Maybe it's a little bit more testing in the beginning and in the adjustment phase, but I believe it's the same as the diet and exercise, but again, once you get to that maintenance phase, if you're on metformin alone, checking your blood sugar three times a day is not going to be helpful to you, but if you're going to check it, let's make it useful. Let's tie it to something. Let's have more information for it.

Folks that are on oral medication and bedtime insulin. Again, maybe there you want to focus more on the fasting because you really want to see what that insulin is going to do and how you need to adjust that insulin. Then again, tie it to something; teach them how to react to highs and lows, but it needs to be tied to something. Then I put the insulin one in there only just for an example of how many times a day and when you should be testing, but it's something that you guys can hopefully use in your everyday practice.

This is from the International Diabetes Federation again, just some different regimens that you could use. Note that even in the staggered regimen, it's pre-breakfast, post-breakfast. Again, you're tying two readings together. If you just test something two hours after you ate and you didn't know what it was when you started? That's kind of a useless piece of information. So if you're going to be having your patients checking their blood sugars, make sure that you're doing it with a purpose, an agreement, and that it's going to be able to be acted on. Meal-based testing, again, this is a little bit less intensive than the one above, but again, tie it to something.

I just want to bring up, as I come to the close, again, the DDTP website and all the resources that are there. They've recently come out with the mobile app that you can download to your phone. It has the algorithms on it. If you're sitting there in the clinic and you have a question or the patient has a question and you're not sure, you can bring out if you have a smartphone and take a look at it. It's really awesome and I highly recommend it. But there are also all the provider resources, the algorithms, the standards of care. Take a look at those because those are things that can be used in everyday practice for us. This is, again, from the website, just a simple guide from the DDTP on the self-monitoring of blood glucose that goes a little bit more into what their recommendations are.

I only put in exams and test use to monitor because again, we want to make sure that we're meeting standards of care and that we're doing what we can for the patients. Again, the estimated average glucose, only because I still – even though I have a really pat way of how I try to explain hemoglobin A1C, it is a hard thing for patients to grasp and the more the education that we can give, the more tools and similarities we can give them to understand what we're doing on a regular basis, the better off they're going to be able to participate in their care and understand what they're doing and help to set their own goals.

## Case Study

So, we're just going to go through a case study now that sort of sees the application of the protocols for monitoring of blood sugars when folks are on no medications, oral medications, oral medications with insulin and with insulin. So, we're just going to follow one individual through a period of time as she progresses through the various phases.

So, Ms. A is a 31-year-old female, to start, with three children. She actually had normal glycemia in her first pregnancy, but after that pregnancy, she got an additional 10 pounds of weight compared to her pre-pregnancy weight. So, during the next two pregnancies, she actually was diagnosed with gestational diabetes. During those pregnancies, she was able to follow a meal pattern that was prescribed to her. She was instructed and was able to do some self-monitoring of blood glucose and she actually did use insulin successfully to manage her gestational diabetes. However, with each pregnancy, she kept on an additional 10 pounds. So, by the third pregnancy after she delivered, she was 30 pounds over where she had started prior to having any children at all.

So, when she comes in, shortly, about a year or so after her third pregnancy, her weight, as you can see, was 175 pounds. BMI was calculated at 32, which puts her in obese category. She was eating three meals a day, which was good, but she was not doing any exercise at all. This was post-pregnancy; again, not really diagnosed with diabetes at this time other than gestational diabetes, so

she was not monitoring her blood sugars at this time. Her glycemic status on the visit revealed an A1C of 7.6%. So, the patient was diagnosed at that time with diabetes.

So, you have a discussion with the patient, which really initially is centered around diet and exercise. If you look at the start phase of that, we know where she started. So, what we want to do is really encourage her to work on diet and exercise and then just start checking her blood sugars so she can have an idea of where they are. And again, every time we check her blood sugar, it's going to be tied to an event. So, in this case, for her start phase, we're going to instruct her to check her blood sugar daily before and after two meals.

She did agree and we would want her to try to do some carb counting, and so her meal plan could include something like 45 grams of carbohydrates at breakfast and lunch and 60 grams at dinner. And start maybe encouraging her to use the measuring equipment to learn about portion size. And again, we give her a chart or a record where she can record her food intake and blood sugars.

So at this point, newly diagnosed diabetic, we're really focusing on that diet and exercise and any self-monitoring of the blood sugars that we're going to do are really tied to those events. Initially, in this case, really ties to understanding what her diet is and how that affects her blood sugars.

So, she comes in at two weeks. She's actually lost four pounds. Her BMI had gone down a little bit. She's able to present to us her food diary and her blood sugars that are associated with the meals. And we talk a little bit more about carb counting.

So, we focused the first two weeks on the diet and now we're going to encourage her to start to exercise. So, we've talked about what kind of exercise regimen might work for her, what would be – and again, it's useful at this point to find out what is available to her and what kind of exercise that she is interested in.

In this case, Ms. A was agreeable to add a 15-minute walk to her schedule each day. She's agreed to continue with the carbohydrate counting, the self-monitoring of blood sugars and the record keeping and we'll add exercise. Again, for this time, while we're looking at things, she will still be testing her blood sugar pre and post an event at least twice a week. So, again, whether that is a dietary event or an exercise event, she will be testing pre and post. She was very pleased at this time that she would not have to be started on oral medications or insulin. Again, you really want to congratulate her on her four-pound weight loss at this time as well as her commitment to doing the carb counting and really sort of starting to understand what will affect her blood sugars.

So, we send her off to start her walking program and probably have her come back in about one month.

So, at that time, she's now come back; this is her third clinic visit after her new diagnosis of diabetes. We're six weeks in. We'd really focus to this point on diet and exercise in a sequential manner, tying whatever blood sugar monitoring that we're doing, not overly so, but to the events and only doing two events per week.

So, at this point, she's lost another four pounds, down to 163 or 167 and she really has been doing well. At this point, she's been six weeks out. It would be reasonable to check another A1C on her and we did so in this patient. Her A1C is down to 6.5%. So, she has really made good progress in understanding sort of what will impact her blood sugars, how she can affect them, how diet will affect her A1C as well as changing her diet and exercise will affect it.

So, at this point, we will say, "Well, you're doing really well. You've been very successful in what you tried to do." We would, at this point say; we want her to continue to do carb counting. It's a good idea to continue the food diary, continue the walking and try to increase that walking or whatever exercise program that she does. At this point, she's very well controlled. You could tell her to really test once a week and then maybe tie it to an event. So, really, two tests per week, but they're tied to a particular event. At this point, you say, "Let's come back in three months and see where we're going."

So, time goes on, you continue to see her every three months over the years and her blood sugar stays stable, but she now has three kids and life is getting away from her. After a couple of years, it's starting to develop where she's not being able to control things perhaps so well with the diet and exercise. Her A1C, four or five years later, has crept up from the 6.7% after the initial intervention to 7.8%. She has continued for the most part to do what she can with the carb counting and the exercise. Then after discussion with her, she really said, "I don't know that there's much else I can do with my diet and/or exercise."

So, at this point with the goal A1C in this patient of 7%, she's at 7.8%. You've talked about oral medications and you start her on metformin. You instruct her on the signs of hypoglycemia, which of course, you wouldn't expect to see with metformin, but always a good thing to cover. Basically, we now review with her the protocol for self-management of blood glucose when oral medications are used.

So, this is her first visit back at the four to five years. Again, her weight has crept up from that low of 167 to 180 pounds. She does still eat three meals a day. She's doing the carb counting. She was able to increase the duration of her walking; however, she's only walking three days a week. She had continued to test on a weekly basis. But as we've said, her A1C had crept up to 7.8%.

So, we're starting her on metformin. We've talked to her again about the carb counting and the use of the food diary and time and monitoring that she's going to do with meals. We encourage her to continue walking and if she could walk more than three days a week that would be great. We say, "Well, after we started you on the metformin, what we really want you to do is, for the next two weeks, we want you to check your blood sugar two to four times daily and we wanted to do before and after events." So, really what we're asking her to do is to monitor one to two events daily pre and post and to do that for two weeks after starting on the metformin.

So, she comes back in two weeks. She's lost four pounds and she again continued the three meals a day, does the carb counting. She's not been able to increase her walking, but she says that her blood sugars fasting are now between 120 to 150. Her two-hour post-prandials are less than 200.

Then we say, "Well, let's think about this. Let's go ahead and increase the metformin to maximize that." So, probably if you started at something on either 500 milligrams at nighttime or 500 milligrams b.i.d., you can increase that appropriately and to what she would tolerate based on her symptoms. And then you say, "Well, okay, so you tolerated the Metformin. We're going to increase it. We don't really expect you to be hypoglycemic, but let's just reduce our monitoring now to two to three days a week for the next one to three months." Again, we always want to tie it into an event.

So, now, you see her back at six weeks. She's lost an additional six pounds, and her A1C has reduced from 7.8% down to 7%, and so she's doing a good job. She's at goal. She's probably at this point on metformin a thousand twice a day. Really, what we say, "Well, we're just going to maintain you. So, really what we want you to do is continue the carb counting, continue the food diary, continue and try to increase that exercise." Again, just like the maintenance phase with diet and exercise, she's well controlled. "Test before and after an event, but otherwise, you're doing really

good.” At this point you probably also do just want to review with her again the events of the meal or the snack or the exercise or hypoglycemia and talk about when we would see her again.

So, she does really well again on the metformin twice a day, kind of hanging in there, doing what she does. By now, she’s got the three kids and they’re all teenagers and she’s running around a lot, and being really, really busy and so she comes back five years later and her A1C has continued to creep up. So, she presents to you, and her A1C is at 9.5%. You’ve maxed her out of the metformin and you talk about whether you really want to start sulfonylurea or whether you really want to go to keeping her on the metformin or really starting a bedtime insulin. Honestly, starting that bedtime insulin is probably the best choice in this patient.

Her weight’s crept up. She’s at 183 and so what we say is, “Well, what we’re going to do is we’re going to start you at five to ten units of NPH at bedtime and that really what we want you to do is check your fasting daily for a week and return to the clinic for adjustment at that point.” Again, reviewing with her the signs and symptoms of hypoglycemia and how to treat that.

So, she comes back in at that one-week visit. She’s actually gained two pounds. So, one of the things when you start insulin that you do need to warn folks about is that they will most likely gain weight. Very, very frustrating for patients, but it’s something to address upfront and just encourage them to increase their exercise, watch their diet; but unfortunately, frequently, people will gain weight once they started insulin.

Again, talking about diet, talking about exercise. Her fastings are back down to 120 to 150 where they were when we first started metformin. Her two-hour post-prandials are all below 200. So, overall, she’s doing pretty well. So, depending upon what dose of insulin you started, you could adjust it a little bit if you want a little bit of tighter control by increasing a few units. Now, we’ve kind of want to see not only whether her fastings are doing, but also let’s try to look at events. So, the question that you’re really trying to answer at this point is, is bedtime insulin enough or do you need to look at multi daily dosing of insulin or changing the insulin regimen.

So, she comes back at four weeks. She’s gained a little bit more weight, but her A1C at this point has decreased from the 9.5% to 8%. So, she’s a little bit frustrated, but she’s happy that her blood sugars are improving.

So, what we say is, “You know what? We’re going to hold you up for now, potentially, and sort of see where it falls out. Continue to work on the diet and the exercise.” At this point, I would probably bring her back in another three months, hoping that she creeps down closer to seven. At this point, we know that she’s not being hypoglycemic so you could probably get away with just the fasting once a week and then pairing some blood sugar test around an event once a week. So, again, just sort of where we’re going to go for the start, adjust, and maintenance phase for oral meds and bedtime insulin.

So, then what happens is she comes back at that month and she really checked in that four to six weeks and she’s really hanging around 8%. Maybe she’s crept up to 8.5% and so at that point you really need to talk about, “We need to add an additional insulin.”

So, once you get past bedtime insulin there’s many, many different ways to do insulin, whether you’re just doing twice a day insulin, basal insulin, whether you’re doing multi daily dosing or whether you’re using long-acting analogs. But once you start past that nighttime dose of insulin you really are talking now about a whole different protocol for how you’re going to monitor your blood sugars. So, specifically, more than likely, you are going to be doing corrective dosing if you’re doing multi daily dosing, and so then you’re going to be requiring patients to test their blood sugars pre-

meal and post-meal. So, potentially, depending upon how the insulin regimen goes, past just the bedtime insulin. I mean, you could be having folks check their blood sugars anywhere from really two to six times per day.

So, that's a whole other discussion that hopefully we'll be able to have another call. But hopefully, what we've done is sort of walk you through how blood sugar monitoring should be doing as the patient may progress through that diet and exercise phase, to that oral medication phase alone, and then maybe to the oral medication phase with bedtime insulin.

One of the things I just throw up there because as you have that discussion with people about events, just to remind people that a snack is not a meal. A snack is really considered to be that 100 calories or less, and so you really want to think about what you're taking in, how many calories. Again, going back to that initial discussion and really focus about measuring what they're eating, portion sizes, and understanding what meals are and what snacks are. Certainly, as we go into further discussion on insulin and snacks potentially involving that is a more complex discussion.

Again, just a reminder when we talk about exercise, you know, blood sugars can do wonky things when people start to exercise. They actually may see their blood sugar increase initially and then they may see them decrease. But that's one of the reasons why, again, we consider it an event and we consider it something that we want to test pre and post so we can understand how that event actually impacts what our blood sugars are.

Always, always, always have the conversation about how to recognize the signs and symptoms of hypoglycemia and then how to treat it, right? So, if your blood sugar is low, and various people will feel that low blood sugar at various levels. Many of us have had patients who are convinced they feel hypoglycemic at a blood sugar of 110 and other people can go down to 50 and not feel anything. But the key is just do make sure that you talk about how to treat it and that it doesn't require eating a entire box of candy to treat it or entire jug of juice that, really, in order to treat hypoglycemia you're talking four ounces of juice or eight ounces of milk or a couple of graham crackers but we're not talking about necessarily needing huge amounts.

Again, once they've started that bedtime insulin dose, they should have easy access to their meter. If they wake up in the middle of the night and they're feeling shaky or hungry or just feeling weird, they should be encouraged to go ahead and check it just so they can make that they're understanding what's happening to their body and they can take the appropriate steps.

So, hopefully, that has sort of walked you through the protocols for self-management of blood glucose on diet and exercise, oral medications, and oral medications with bedtime insulin, focusing on start phases, adjust phases, and maintenance phases for all three of those regimens.

Thank you very much.