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TRANSCRIPT - GR 12 02 22 "Economics and Medicine" Shichun Bao, MD, from Vanderbilt Health

UVA Medicine Grand Rounds

- Well welcome everyone who's here, and then welcome to those on Zoom. Uh. It is today's medicine grand rounds. So today I have the privilege of introducing Dr. Chi Twin bao from the University of Vanderbilt, Uh. Dr. Bao is an associate professor of medicine in the division of endocrinology, and will be speaking to us about the currency
- of affairs for diabetes technology and into the near future as well. Dr. Bao received her medical degree from Shanghai Medical University. She then received a Ph. D. From Indiana University with a special interest in Diabetes path of physiology.
- He subsequently worked as a post doctor, fellow and Clinical associate at M. Usc. Focusing on diabetes, clinical research and clinical trial design
- Uh. Dr. Bob completed her internship and Residency training at the Brodie School of Medicine at East Carolina University, and then completed her endocrine fellowship training at Vanderbilt, where she stayed on as a clinical faculty ever since.
- With this wealth of experience and knowledge she is well suited to her role as the Vanderbilt Diabetes technology program Leader.
- Dr. Bao conducts clinical research and has been the principal investigator of multiple clinical trials with her research focus being on diabetes related clinical pharmaceuticals and clinical research and diabetes technology.
- In fact, we read one of her many excellent clinical trials that she's been a part of in our last year's outpatient Journal Club. It was the effect of continuous glucose monitoring on Glycena control and patients with type two diabetes. This was published just last year, in Jama
- so very excited to have her talk with us today. Please put your hands together for Dr. Xi. Xuan bow.

Shichun Bao

00:20:29

Thank you. Um. Thank you so much for the kind. Introduction. Uh, it is my great uh pleasure and honor to give this a grant round talk on diabetes uh technology. Uh, and we know that Uva is the more leader in um developing that based technology, especially the um

- hybrid, closer system, the automatic instability system. So I'm thrilled to give this locked.
- Give the talk here, and uh, I hope to. I love to hear heat back and learn from expert in your Institute uh that being said, Here's my disclosure. Uh and uh, this is outline of my talk. So I'm gonna quickly go over the evolution of diabetes technology, and we're gonna talk about the current state and future direction of diabetes technology. And I will also incorporate uh some clinical uh cases uh
- kind of uh involved in a diabetes technology.
- So uh, first let's talk about what is diabetes. Technology about it is about glucose sensing, insulin delivery diabetes, data management, and the diabetes device connectivity. So the rest of my talk will be uh focused on specific topics of of those Uh. Why, that be. Technology is imported, as we all know,

which i'll talk more. And then, my uh later uh slides uh diabetes. Technology can help reducing the glucose monitoring burden

- so the current available Cgm can really send the real-time glucose data to patient smartphone or a receiver every five uh one to every five minutes without the need to,
- you know, prick their finger, and also can uh send alert. One patient sugar is a little high. Allow them to share their Cg. Glucose data with their family. With the provider uh technology can certainly help improving uh diabetes care by reducing the hyperglycemia, Hyperbolic female glucose variation, especially uh, with the use use of the aid system, and help improve the timing range of their glucose, which is a better indicator for uh, a guide to control than hemoglobin a one.
- See? I'm sure you're all familiar with, and therefore it can help improve the quality of patients alive and patient satisfaction.
- Uh: so it's quite a big deal. Um. So uh talking about the evolution of diabetes technology. This is a quickslide summary of the those. So back in um fifteen hundred Bc. Uh diabetes. The first recognized uh,
- uh, then around uh six hundred Bc. Uh
- for Egyptian scientists that they realize that the ants seems to be attracted to the urine of a diabetic patient, therefore had the idea of testing tasting the urine glucose for diagnos of a diabetes, which is sounds pretty yucky uh, and then uh, around mid one thousand eight hundred early uh one thousand nine hundred. The effort to um
- quantify the glucose in the urine. Uh started. Um! So the we all know the insulin was first available in one thousand nine hundred and twenty-one, and then the first human being received. The insulin uh treatment is a a type one diabetic patient by the name Count uh
- Leonard Thompson, and he's a Canadian uh type, one diabet patient. At age of thirteen he received the an insulin extracted from cattle pancreas, uh, and he survived for another thirteen years and died at H twenty-six of pneumonia. But prior to that patient was type. One diabetes literally cannot live long at all. Um! So uh that was the landmark, and then in one thousand nine hundred and seventy, the first, the but glucose meter became available uh in one thousand nine hundred and seventy-eight. At first the insulin pump become available, and I'll show you those
- pictures in my later slides in one thousand nine hundred and ninety nine. The first
- glucose sensor was approved by Fda, that is, the metronic sensor, and in two thousand and five the first the real time uh Cgm became available. That's metronic, Scottie and Cgm, which can also send alert to the patient when their sugar is high or low uh the first uh available in held insulin was pfizer's uh zupra uh, it's approved in two thousand and six, but it came off the market in two thousand and seven due to low consumer. Uh, it's not because
- the product um this low cell, and then the second inhaled insulin, which is still currently the only available in health, insulin the Fraser from mankind. Uh it's still available. That's the uh inhaled insulin. And then, uh, in two thousand and sixteen. The first is on pump with um
- aid or hybrid closed, the system became available, and that it approved. Um is available in early two thousand and seventeen. That's metronic, six hundred and seventy g um
- minima, six hundred and seventy-two pump, and of course our future direction is to have fully close the loop uh, and the know your is to this leading that effort of developing a fully closed loop system.
- Um. So move on to the first topic of glucose uh monitoring, As we all know, the current available uh two category device for sale. Patient self, monitor and glucose is the Vdm. Bug, because monitoring, which require finger stick and all the Cgm continuous groups monitoring uh which uh some still require things to calibrate, and some don't. We'll talk a little bit more, detailed it, and this is a picture of the first uh of group glucose meter. It was developed by uh, an twin clement in one thousand nine hundred and seventy.

- It has a needle uh that uh! Can indicate intensity of blue light reflected from the paper uh strip that the actual stick which is in in this and uh, I use a cool cause of today's message. We're still the message that current to Google comm to use. So that meter waited uh three pounds, and this sold at uh six hundred fifty dollars. We're talking about nineteen, seventy. So it was super expensive, and nowadays we have these fancy glucose meter
- that much smaller and more accurate, and only require, uh, you know, a five microlit or less blood, and they give you reading uh in one microleader blood, and they give you a reading about five seconds uh, so much better, and uh, also more affordable. And they these are the one I had just the example of the one I have The uh bruise capability allow patients to share their uh fingers. They glucose a reading with their family, with their a provider. Uh so,
- and in terms of the Cgm. These are the currently uh available uh updated uh Cgm. That can give glucose alert. This is the metronic. A guardian connect Cgm. Of, approved in two thousand and eighteen uh it's a seven day where sensor it has a transmitter uh sit on top of the transmitter is rechargeable good for a whole year, and the uh Cgm reading glucose. Reading goes to their app uh every five minutes, and it has a model of nine point six mod, and we all know it's.
- It's called main absolute relative difference it's used to indicate uh, how accurate the uh, you know meter or uh Cdm. Is so mod under ten is considered as very good. Uh this uh Cgm still require fingers that glucose two to four times a day to calibrate. Um, and uh
- Myronic also has a guardian uh three Cgm. Which is an integrated with their Mini Meta, six, seventy, or seven, seventy uh hybrid corners of the system.
- And this is the Uh textcom Gcgm, which has a ten day where sensor uh, and that has a transmitter. That's a good for three months, and it says, Send glucose reading every five minutes to either patient smartphone or to their receiver. For people don't have compatible phone, and that's the one for a press uh applicator, and it's approved in two thousand and eighteen, with a model of nine. Uh. It does not require any fingers to calibration,
- and this is the efforts uh libre Cgm. This is a leap rate. li. This is the three uh libre, two uh is the size of a quarter as the two that quarter. It does uh check sugar every single minute, but patient has to scan. The sensor was either the Libra to reader or the Libra to app uh, and they have to scare at least every eight hours to capture the Cgm data. So if they don't scan the data could get uh a lost um, and then um! It's approved in a June,
- two thousand and twenty. I was a model of around nine point, two to nine, point seven, and of course the newer version of the lead race. Three uh is uh a become available in May of this year. Uh, the sensor is much smaller, the size of a uh a penny, and it can send the glucose reading every single minute to the lead race. Three app without the need to scan the sensor. Uh and the you know, private. The trend is also a fourteen day uh, we're sensor with a model of a seven point nine uh that was from a you know, a study of ninety-five.
- So um, and
- it does not require fingers to calibration as well. And this is the um metronic ever since implantable. Cgm. Uh it's there is a ninety day uh one and a uh one hundred and eighty day or six months one. So this is a sensor that's implanted under the skin, and they have to wear a transmitter on top of the skin uh, and those transmitters also uh reusable. It'll reach out, I mean, it's retrogable good for a year, and this uh Cgm
- does still require fingers to calibration for the three months since, so they have to uh do. Finger stick twice a day for the uh six months one. They have to calibrate once a day with a finger stick, but it is use a different technology. Use the lumin that, and technology is quite uh neat, and it's implantable. Um!
- So uh
- the next I want to talk a few clinical trial uh showing the benefit of a Cdm. So this is the Go trial uh showing the Cdm in type. One pathetic on multiple daily insulin injection is uh published in Gemma

back in two thousand and seventeen. The sensor used to. There is the dexcom a G four uh Cgm. That one is the seven day where census still require finger stick calibration uh at the time. Uh, and it was a uh

- perform in Sweden, uh one hundred and forty-two patient was in enrolled randomized one to one to either Cgm or bgm, and then uh, after six months there's a seventy week uh wash out, and then it's a cross over to alternate intervention. Uh, so the original Cgm uh patient will come off. The Cgm. Use Bgm: and the original Bgm. Patient will use the Cgm for another six months, and uh, the primary outcome is compared to difference in a one, c.
- So that's the study Result: The go trial show that uh
- a Cdm. Use can definitely improve the care of diabetes by reducing the A one, c. By zero point, four, three, Ah! There are less time in hypoglycemia and less glucose variability, and a study approved that the patient can, and where will, where? The Cgm are a daily basis, so that we're talking about the old, The Cgm. Require fingers. They get only seven days. Still compliance with pretty good eighty, eight percent of the time they were using it and improve the patient's satisfaction. Patients have less fear for hypothesis.
- And, uh interestingly, you know, when the Cgm. Was removed from them, the initial Cgm. Back to the Bgm. For another six months the A. One C. Uh. Is worse back to the baseline, and there are more uh hypoglycemia so truly showing the benefit of a Cgm. This is another trial. Um!
- The one that you were talking about earlier mobile trial. It's a you a in a type two patient uh with the Dex County, sixty jet on base or insulin uh, along with all the premier insulin. It's a Us. Study. And Venice, one of the participants, and one hundred and seventy-five patient, were in row, and they are managed by primary care doctors. So we uh the study Side investigator only provide the A. Cgm report and the recommendation once a month to the Pcp. And is still up to Pcp. How they manage it.
- So we're just the consultant. So the it was patient was initially two to one randomized the Cgm and the beach or Bgm, and the end of the eight months uh
- the Cgm group was randomly reassigned to one, to one to either continue the Cgm or switch to the Bgm for another six months. Uh, and the primary outcome is the a one, c. A secondary allcom is timing range and the main glucose, and you probably already know the results. Yeah, it did show the Cgm. Uh improve the control by reducing the a one, C like around Point Five. Improve the timing range and decrease the severe hypervis email hypoglycemia. And the most interesting finding is that
- the glycemic benefit may be primary, actually due to the patient. Factor. Maybe they're more compliant with the regiment. Maybe they're more uh. I've spent more effort in lifestyle modification, because the amount of an insulin used in two group are really not significant, different, and also the amount of the type of uh medication adjusted by Pcp. For that Iv. Is not much different. So it's really not. You know. Uh, it's more than
- the patient where a device, seeing their data and kind of act on it. That's the main reason for their diabetes uh control improvement, and that this continue the Cgm result in the loss of about fifty percent of the initial uh gay in the timing range that being achieved during the Cgm. Uh, and the other uh interesting finding is, this is really the study applied to. Uh, you know, everyone uh, including those uh rich,
- different gender, a different ethnicity, and a different uh socioeconomic diverse group. So the majority of the patients actually are non-wide and less than college degree education and without private insurance. So this kind of advocate for broader coverage of the Uh Cgm. And that help the Medicare uh relax their Cgm criteria last year uh in July. They no longer require that patient have to be on at least three shots a day uh for six months, or have to be on doing fingerprick
- four times a day for at least two months to qualify Cgm. Now a Medicare patient, as long as they are insulin even just the one shot they can get the Cgm covered by Medicare part B for pretty much no charge. So uh that's really a excite uh exciting change. Uh this will probably all familiar. This is the

standard Cgi Metrics for clinical care, originally published in diabetes care in two thousand and twenty-one. So this is a standard agp uh report and very glucose profile which include the

- um. The number of Cgm is one we typically use fourteen day. All you can choose thirty day uh it include the uh,
- the percentage of a Cgm that is active. And uh, we really aim for at least seventy percent active. Otherwise means patient is really not utilizing them well, and include the main glucose. Uh, what is the include? The Google's Man management indicator, which i'll talk a little bit more later, and it can close variability, and the percent in range, and the percentage in um level one hypoglycemia, which is below seventy but uh over fifty-five or level two hypoglycemia, which is below fifty-five
- level, one hyperglycemia uh over uh one hundred and eighty, but below two hundred and fifty and the level two hyperglycemia that is over to uh fifty, and that's the curve. So for provider like myself, who want to bill for Cgm data interpretation, which is C Pd. Code of a nine, five, two, five, One uh, we do have to include all these uh matrix in your uh, to qualify for Cgm. Uh billing for a data interpretation. Uh,
- and this is the two most uh commonly used the uh glucose variation matrix. I'm sure you're all familiar. The one is the standard deviation, which is sort of a mean uh average glucose, the other coefficient of variation. You'll see those on the Cgm report uh the go for uh standard deviation is less than a third of the average group, and the goal for uh creation of variation is less than uh thirty-six for eighty eight uh recommendation. And this this
- portion of the variation is preferred
- in one metric, because it give a single uh, you know, a a goal of thirty six versus the standard deviation. You have a set of go based on different glucose readings. But you will see both um certain reports. Yeah.
- And uh, uh, so earlier, Cgm: report, you might notice. They use this E. A one, C, which is a estimated, a one, C. Um, but it calls some confusion, you know. Patient will say, why this one says this and my measure the uh blood a one, c. Or the point of care it once it's different. Uh, because the you know, estimate a one, c. We only include the time of the uh sensor, where you choose, where the fourteen day or thirty day, whereas the after a one, c. Is estimated of a glucose over the past three months. So, after the feedback from Fda, from
- the expert in the area, from the patient, from the you know. Uh the lab uh expert, and especially after this landmark article published Um uh
- in a
- two thousand and eighteen uh by Dr. Perk install uh it was consensus agreement that we should use the glucose management Indicator: a new terminology for estimating a one, c. For a Cgm uh monitoring. And this is a different formula, but for one patient the glucose is the lower, the estimate a one, c. The E. A. One, c. Is lower than the Gmi, and when the patients every sugar is higher, the E one, C is a little uh uh higher. So the Gmi is a better
- uh indicator for the estimated a one, C uh this. Probably you're all familiar uh the clinical targets for Cgm: Um. Data. I was uh first published in uh two thousand and nineteen diabetes care. So for majority type, one and type two patient. We really aim for timing range. It'd be greater than seventy level. One hypoglycemia, less than four percent level, two hypoglycem, a less than one percent, and the level one hyperglassing you less than one percent and the level one hyperglassing you less than one percent and the level one hyperglassing you less than one percent and the level one hyperglassing you less than one percent and the level one hyperglassing you less than one percent, and the level one hyperglassing a less than twenty five percent for patients who are elderly, who
- more prone to have hypoglycemia. We aim for Tom and targeting branch greater than fifty percent, a hypoglycemic to the less than one percent and for a pregnant type one patient we uh uh aim for a little

narrower target range, or between sixty, three to one hundred and forty, rather than seventy to one hundred and eighty, and for a Gdm. And a type. Two patient is still undefined at this point.

- Uh. So we move on from uh glucose uh sensing to in some delivery as Well, no insulin can be delivered. Strong shots uh using a vial, all using the pen, or can be uh given through continuous infusion, which is the pump. So this is the picture of the glass orange and the metal uh needle used by uh bending the best to inject the dialog. Uh and um, they? Uh, it's kind of cool. And then, of course, nowadays we have. These syringes are much safer disposal
- with a smaller needle, a safety cap. Um. So make the injection a little easier, and certainly with the availability of the insulin pen that was uh started available in uh uh, two thousand a short acting, and both the long acting analog at the in insulin pen is even better, because they are good in room temperature uh, and uh easy dial, and uh easy to carry, and the later on we have the smart ins on Pan uh, this is the um
- Now it's under metronic, now uh companion, initial companion, Medical uh in Penn. So it is. Each pen is good for a year. Uh, and they have a uh insulin codes loaded in. So the two thing about these pens. They can automatically record the time and amount of the insulin and mystered, and the app will show those data. And you can also set. You know, the carb ratio, and it's incentive. They factor the target almost like a insulin pump version for short acting insulin.
- Yeah. So this uh approved insulin for use the in pen or the novel lock, human log, and the fias, and it's also integrated with the dexcom and the many uh metronic Cgm: So you can see the impact report uh incorporate into the uh
- clarity uh for the text on Cgm. Or the care link. Cdm report. So that's the smart insulin pen,
- and then move on to the pop. This is the first, the pomp uh, uh, first developing one thousand nine hundred and sixty-three by Dr. Honor, the cottage in Uh. Uh L. A. And it's the size of a big backpack, and it became available in one thousand nine hundred and seventy-eight. Uh, and nowadays we have these uh aid systems. So these are the current available aid system. Um the metronic mini-made uh six hundred and seventy g and tendons T. Uh
- t, one, x, two uh pomp uh contra qaed that integrate with Dexcount G. Six, and Cgm. And also the omnipot from insulin on the part of five uh that integrate with the dexcom uh. This was a recently approved in January, and the tandem approved in two thousand and nineteen.
- So a little bit more detail about those system. Uh, many matters. Six hundred and seventy was first approved in one thousand nine hundred and sixteen for age, fourteen above later, was approved for a younger age seven. Above it aimed for a one
- target glucose of one hundred and twenty uh, and it a use uh a guardian, three Cg. Which still require finger stick calibration, and has the integrated uh, the meter which integrated to the palm. And uh, and this is the newer version, the seven hundred and seventy G uh. Which has a group.
- It's use the same algorithm as a six hundred and seventyg pomp, but it has a bluetooth uh connectivity. Um! So it's a little better, and of course the uh next one is the seven hundred and eighty G uh which Hasn't been proved by us, yet currently under review, for it has been under review for quite some time, hopefully will be approval, but it's available in Europe. So that's the uh minimum uh aid system, which is the first available uh hybrid closed loop. And this is the pivotal trial of the six hundred and seventy G. System, publishing gamma in two thousand and sixteen
- ten sites uh ninety-four adopt patient uh thirty uh the other lesson patient. There's initial two week of open loop or manual mode, followed by three months of uh auto mode, all uh hybrid closed loop, and here's the study. Result: uh the aid or auto mode uh improved uh timing ranch, you know, from sixty-six to seventy, two decrease the for glucose variability, and also reduce the a one c. Um from seven point four to six point nine,
- and uh move on to the tendon contrary to system. And your Institute is certainly and help developing this system. It was uh approved uh, in December, two thousand and nineteen, initially for age,

fourteen above and later was for six year above uh. It has a touch screen uh feature uh bluetooth connectivity. Uh, it has software uh update will feature. So if the company has a new uh pop, the current user just need to hope their pump to the computer uh do a little software update and a

- You enjoy the latest version where it's the mettronic six hundred and seventy G, seven hundred and seventy. It does not have software uh update for feature. Uh, it also has this hourly automatic correction bolus, which is another, a very nice feature. Uh, when the sugar is a high, it has adjustable glucose target between one hundred and twelve to one hundred and sixty. It has a sleep mode uh in. During that sleep mode the target could be between one hundred and twelve to one hundred and sixty,
- and no fingerstick library is required because they integrate with Dexcon, G. Sixc. Gm. That does not require finger stick.
- And uh, this is the contrary queue treatment value. So we pay when patients school coast is between one hundred and twelve to one hundred and sixty uh, they'll use the the uh set basal rate when their group goes to below one hundred and twelve uh every five minutes. The system will uh adjust it. If it's less than one hundred and twelve, it reduced the basal delivery when it sugars over one hundred and sixty, it will increase the basal delivery, and when she was over one hundred and eighty, then that hourly uh
- uh Bolus correction bowlers will kick in, and during the sleep mode. Um, there's no automatic correction bolus hourly. But when the sugar is over one hundred and twenty, the basal in something really will already increase, and during exercise mode when it's below eighty, it will suspend in some delivery. So uh reduce the you know, uh risk of hypoglycemia. And this is the uh the t connector app uh for not only serve as a second display for the
- I don't. I don't. I don't. I don't think I can use it for uh in some delivery uh bolus in some delivery, so they don't have to pull that pop the punching the car, and uh take a uh a correction bowl as they can just do all those uh from their mobile app. Uh, and also the apple will send it the data to the cloud. So we can uh see patients to pump data uh remotely through that um
- very cool system. And this is the six months randomized motor center trial of the contrary Queue and and your Institute the lead at the Studied, and that was published in New England Journal. Uh in two thousand and nineteen, one hundred and sixty eight patients were enrolled. Uh and uh it were randomized into closed loop group. Uh, and also the since augment the pump group with all the aid. And uh, you can see the results from here. Uh the patient in close. The loop has improved
- time in range from sixty one percent to seventy, one percent, whereas the control group they remain at
- the timing range uh state unchanged at uh fifty-nine uh and uh, uh, the closer loop group overnight uh really improved the timing range significantly compared to the to the control group. Uh and uh a one C uh in control uh in close loop group in have reduced the A one, C uh compared to the control group by uh Point three, three, and also the closed loop group uh has uh less uh hypocalizedemia compared to control group
- um.
- So kind of reinforced. And this is the third aid system which is the omnipot aid um system. It's approved by Fda in January for two thousand and twenty-two for type, one age six above. So it has these uh pods which hold a two hundred units of insulin a change every three days, and the top every pod itself uh is enhanced with smart, that just technology that communicate with Dexcount G. Six uh Cgm. That can adjust the basal instant delivery
- every five minutes, based on the glucose and the predicted glucose over the next sixty minutes, and patient can use the uh
- Controller to uh deliver the bolus insulin a meal bowl of correction, Bolus. And if a patient doesn't have their uh controller with them. They They're still getting the basal rate adjustment. Uh, so it's directly

connected, and the app uh can be a download to patients uh phone are currently only available for Android uh, certain Android phone. But the company is working on the uh iphone version with the Tai pool. Um and uh, also uh

- the study, showing that the um the time, you know, patiently using it. It's actually they stay uh you know ninety-five of the time uh ninety, six percent in, and it has a adjustable to it, range between one hundred and ten to one hundred and fifty, and it can set different time of the day to be a different target. Um, and uh,
- so that's a um uh the uh,
- you know, without any chord to uh aid, and this is the only part. Five pivotal trial at your Institute also participate. Lead to the uh uh effort of the study. Two hundred and forty patient enrolled. Uh, and it was uh randomized to the there's initial fourteen day study, and then followed by three months of the aid phase, so similar results a one, C Uh. Improved by zero point, seven, one in children and improved by point, three, eight percent in adults.
- Timing range improved by fifteen point, six percent in children nine point three in doubt, less hypoglycemia when they were in the Id and the less hypoglycemia, and the spending auto mode was very good ninety-six uh, and with the control uh trial Also, the time in the automotive is like ninety percent. So most of the time they're in the auto mode.
- Um. So next i'm going to talk a few case uh these are all my patient um uh their evolution over that. They're diabetes care with the using of the technology. So this is a forty-nine year old type. One diabet patient uh was diagnosed at twenty-three, uh, and he was initially on animus in some pump, and the later switched the metronic pump. And when animus pompex is the pump of market in two thousand and seventeen, and he was initially using the Bgm. Monitoring his sugar later switch to the Cgm. And the pump, he later switched to the
- so and the next slides. It's kind of cool to watch at the different uh face of his diabetes care. So this guy always want the perfect control. He really doesn't care that much about the low. He just want his uh, you know sugar to be. Uh, you know he wants to be good. Uh. So this is the one he was still wearing the animus palm, using the Bgm. Uh at the visit in January, two thousand and nineteen. He was checking sugar a lot, you know, six times a day. He's pricking his finger, and he's a one. Z. Pretty good six point eight, and timing range pretty good, but
- he has a lot of hypoglycemia seven, and he said, Why, the variation of his sugar between forty-eight to three hundred and thirty-five um, And when he's next to visit with me in August, twenty, nineteen he was on the dexcom. He was still wearing the animos pump, his point of care A. Once he was six. It was kind of a very, very uh tied control. And then he did have a more timing range. But then I saw that he still had eight percent low. So with a little puzzle the why, and it shouldn't be the case. But that.
- And I realized by looking at his report, he not only, said he's low, alert to be sixty, which is kind of a low, but he insist they don't want to be sixty, and he turn his a low alert off, so he's not getting those alert, so really to be the purpose. So, um! So we had a long discussion that you know you really have to utilize your device correctly, to enjoy the maximum benefit of it. So during his next visit he it did turn on his uh alert, but he still capital or not to be uh sixty, but at least the Lord is on. So you can see His hypothesemia is less.
- See this four uh, and a one, c. Still six point two, all good. And then the next the visit with me. Uh, uh, He switched the phone. The metronic uh six hundred and thirty G with did not have a Id to the attendant, contrary to a Id system. So see the big difference. His timing range for the improved the eighty-four, and he's low only one, and he's a once. He kept it about the same. So that's another and a strong uh example, showing that you can't just look at the A. One, c. You really look how to look at
- the present timing range and the percent low, and all those parameters to decide whether this patient is really in and perfect control or or not.

- So the power of a technology. This is another case. A patient of my twenty-eight year old female uh was type, one diabetiagnosed age a uh! She was initially on Mdi, and then uh put on only part uh you's pop, which is the uh older pump, and did not have a a bluetooth or uh aid, and then switch to the only part dash which has bluetooth, but not aid that most recently, just a few months ago to the omni part of five uh uh, which is the aid system.
- So here's the results. Um, and this is only like two weeks after we started only part of five aid. So uh this dexcom a report. Her average sugar improved, her timing ran to improved her hypoglycemia, reduced again another example of the power of diabetes technology. And that being said again, one patient Don't, use their device properly, and they're not showing us, you know, enjoying all the benefits. So this example of the patient using leapy to Ctf. But you can see she's not scanning it, you know,
- and you have to scan at least eighty hours every eight hours to grab the data. So we're missing uh, most of the Cgm Uh data. And this is another patient, also using lead rate. She was wearing most of the time, you know, seventy-six percent data were captured. But you can see her average group is three hundred and ninety-four. So she, basically ignoring all those numbers, and there's still non comply with the in the regimen, did not miss the appointment, and did not communicate with us for the hyperglycem. So even she is using the nice device. But she is not enjoying the benefit of device,
- because, you know, she's not taking care of her diabetes. And This is another example. A patient is on control, iqaid. But the glucose is still a sub operate controlled uh with every google's two hundred and twenty-nine, and if you look at her report here, she's really not taking her bolus insulin at all. She's not taking her and not punching the car, not taking the meal, but it's not taking the fraction. Both she's totally rely on the pump itself. So the pump is really working very hard at delivering these hourly Uh, you know, uh correction bullets, but
- you know for safety reason. These cannot be uh, you know, used to replace your um your meal, Bolus. Um. And so certainly talking about the future direction. We want to have a forty um
- calls a loop where patient do not have to uh put in the carb, and they will get their um sugar under control. And that's certainly under a going uh research. So move on to the diabetes data management. Uh, So each Device Company have their a platform. Uh so for the Cgm metronic use care, link platform. That's kind of used to connect
- omnipotence glucose. Uh, and also uh, we have these commercial platform. Uh, like a good code. That's what our clinic to use. Uh, we use Google for download the uh majority of our uh meter, and also some pump and uh Cgm: So uh for the groupco patient can connect their device listed uh these uh through broutuse, either uh through the group or app, or Google Web uh to connect to the glucose, and they can link their personal Google account to our clinical
- account. Uh: so a sharing call. So we can see their Uh device data remotely, which is very helpful during the Uh pandemic. You know where we do a lot of telemedicine. Um, and then there are also a non-commercial platform. Uh, uh, this is a pool. We also use uh injunction with the gluco in our clinic. So type pool is, is originally founded. Uh, in two thousand and thirteen. It's a nonprofit by a nonprofit organization, with the goal of making diabetes data
- more accessible, more meaningful, more actionable, so patient can. It's pretty easy to use, and it's totally free uh no charge uh, and the patient can upload their data to a type pool uh using the uploader, and everybody can download it. I have all that in my computer. So when I need I can download it. Yeah, and it's totally free, and it cover majority of the meter. I'm not gonna read those, but really majority of the currently available meter, including the Walmart, Rely on, You know Walmart is a meters only sell for nine dollars
- uh for a patient doesn't have insurance. They can pay cash by the meter without the uh prescription, and it can be used to dial a majority of the pump uh like a Mini mad, except for the seven hundred and seventy G. But the early version can use that uh omnipot the e as a dash pom, but not the only part

five yet, because you know all the new device. They take time to add on. It can be used for download tendon, palm, uh, and the decks can see jam that we bracey Gm: So uh it's a very nice uh platform uh without any cost. Um!

- And uh, of course, we always encourage our patient to use the app, if all possible, and that way they can stay connected because the app can send their data through the call to the uh, you know, uh the platform. So we can see the data remotely. That's a dexcom app for them to see their data on their smart device phone device, and the clarity app is for them to generate a report and share with a healthc provider uh follower. App is for them to share the desk, count data with their family of friends. Uh, and the liberate to liberate three app
- uh It's also used to for them to, you know. Send it the data through the call to the Lib Review uh used to connect with uh, our clinic and Libri link up is for them to share their data with their family friends, and that this the meant many met mobile app for the seven hundred and seventy G. Pump, and of course t connect the app we already talked about, and then omnipot uh app five app. They can use their only part of data to the glucose through the part central uh
- account, to be connected. And so talking about the future direction. Uh, we really want the device wise. We want it to be smaller uh faster. No paying. We don't want to prick uh and easy to use. We want it to be more accurate with fully integration. We want a full closed loop, and the most important. We want to be affordable with better insurance coverage. So just a few example. Uh, this is a deeper three, you probably already familiar. It's a very easy to use just to open the
- device, the one push and this one scan and start, and then after that, you know, you just got all your data and minute by minute data uh on the on, the on the app, and this is a desk, Count G seven uh which Lorry proved in Europe, and that's supposed to be approved in us anytime. Soon, maybe later this month, maybe, or the next year, so it will be all in one uh device. Uh improved from the previous version. The current at G six, and the application will be a smaller, and it' be a little more accurate.
- So uh, anyway, it's getting better and better in terms of the aid. This is the beta Bionic uh by Homon all um aid system currently uh and run clinical trial. It has both a group of chamber and insulin chamber, and uh, uh, we do not have to set the basal rate. We do not have a set, a cover ratio. It's more uh, you know, based on the uh weight, and the algorithm will automatically uh adjust it. A patient does not have to, uh, you know, announce their
- uh did not have to put in a meal car, and I know your Institute uh also meeting developing uh a new aid uh uh, algorithm you know, a doctor, a Boris Uh. K. Show attack and Dr. Super. I I think they received the multi million hour. One grant to the to develop a new algorithm um called uh adaptive motif, based control as supposed to be superior than the um current available aid system, and of course, other than device. We also want the Ehr integration,
- you know. Right now we have to go to all those platform, either individual company platform or a a commercial or non-commercial platform to grab the data, and then they have to, you know, put in a chart and hopefully someday you know it. Go to the epic we use at picking our our inst to you to click. You know the paid patient is on the lead. R: Just click, deliberate, and then the Cgm data will be right in front of you automatically safe to the chart. So uh the company. They're different company working on that. And of course we want a population health, you know. Imagine. Maybe you can choose every two weeks or every month
- the platform would generate a set of data for you. Say, among your patient. You know these patients are still have timing range the very suboptimal. I have a lot of hypoglycemia all for the patient, you know. Say, hey, you know that automatic reminder that your next appointment, You better upload your pump, or you're having too many low, so all those are uh will be a nice feature for the future. Um!
- So last few minutes I'm going to quickly talk about inpatient use of diabetes technology, Uh: so currently the Cgm. Is not approved by Fda for hospital setting. Uh, and in March two thousand and twenty Fda granted temporary exemption of Cgm. Using hospital in to minimize the health care and

the staff exposure to Covid and save the Uh Ppe and march two thousand and twenty-two Fda granted the break through device, Vaccination for dexterity gaming hospital uh, so make the this uh device hopefully uh get to the hospital market faster. And

- they're ongoing trial. Study the accuracy of the safety of Cgm in Dexter Gaming Hospital, and we are actually participating in that trial right now. And so they're already published study uh showing the benefit of Cdm. Use inpatient setting by uh, detecting, preventing the hypoglycemia and reducing the hype
- Hope, like uh reducing the hyp for glycaemia. So this is a recent study publishing diabetes care by Daka's neck is group uh in a just few months ago they enrolled one hundred and eighty-five patient uh general medicine surgery, a patient with type, one type two diabetes. Um uh mdi uh! It randomized into a standard care group where the insulin adjustment is based on the Dex County six Um, uh
- uh data and the primary outcome. They look at the difference in common range and the difference in hypoglycemia. So the study show. There's no significant difference in timing range between the two group uh for this particular study, but it showed that the Cgm group definitely have reduced overall hypoglycemia and also reduce the nocturnal uh hypoglycemia.
- And uh, so it it show that in-patient use of real time is cgm is safe effective guiding, insulin therapy resulting in similar improvement. Guys you may control, but reducing the significant, you know. Reduce the severe hypoglycemia, and there there is no difference in hospitals day, no difference in hospitality in the Cgm group versus the A. Vgm. Group. And this is You probably saw this before. It's a old study, just a a little trial, five patient type, two
- uh, also by Dr. Spenakis group, where the Uh. Dexcon G. Four data was sent to a nurse station. Uh. So for closer monitoring uh and uh, the none of those five patients had hypoglycemia. So I put it here just the you know, for us to imagine in the future uh where the patient uh monitor in a room not only have the uh, eg. E. E. E. Ekg. A blood pressure. It will be nice to have a Cgm traced on a monitor that can, you know, be visible in the nurse station, or by the provider remotely on their device.
- Um! The telemet group was telemetry uh idea. There'll be really nice. Um. So for aid. Obviously it's not approved uh very limited information available. But uh per ada recommendation for patients who are comfortable to use and able to use, we should allow them to continue using aid in a hospital, of course, have to based on individual hospital policy Uh, with good supervision, considering dieting, fraction medication, the other factor that may affect insulin sensitivity.
- And this is a diabet. Technology consensus guideline, two thousand and twenty will be very similar to the eightya recommendation, basically saying the same, if they're a patient comfortable, can use it. We should allow them to use. But considering the the those other factors. Um. And hopefully, there are more study down the road that the you know advocate uh more benefit of aid in a in a hospital setting. So yeah, our uh diabetes technology program was uh, I spotted in January of uh, two thousand and seventeen uh our goal is to educate our patient
- and provider on a new device, and uh, how patient to choose the best device for them and help in trend and follow. And, uh, we have that technology focused the clinic uh with collaboration on team effort of Mdm. Pcd. Rd. Uh. With I'm: Sure. Your center have that all Also Always personalize the uh care. And uh, we also participate in in a in a trial. Uh so uh i'm Sorry I kind of uh really run fast, because I have a lot of slides, and but I did. I think I
- finished on time, and so now the rest. Um Thank you for attending this, and I'm ready to answer any question you have for me.

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01:04:18

Yeah, thank you.

- I was. I was worried for a little bit. You might pass out. You were speaking very fast. You got No, no, we could hear it just fine. But um, I can hear the slides with you that you can distribute later. Oh, perfect. Yeah, that'd be great. Um! You can only hear my voice. There's this uh Some of the residents might have some questions, too, that you might be able to see them on the screen. Um! But one of my first questions was just uh
- for
- accessing the patient data remotely. You know you mentioned in the mobile trial. There was maybe this kind of Hawthorne effect where people were aware they are being monitored, and we're part, maybe keep making healthier eating choices
- as a provider cannot. If someone is hooked up to one of these devices, can I at any time

Shichun Bao

01:05:11

go on to the platform and see what their last glucose was. Absolutely. Yeah, I mean, there's a few hour delay, but you can really see there, uh, you know, real time data. And I do that all the time, you know. Certainly we're busy. We right now, not at the stage where we can actually, you know, like the we have the report available, you know, if we want to, but we really can't do a whole lot in between visit. But if I patients send me a message, You know we have this epic. Ah, patient that can send me a message anytime. Say, hey, doctor, but my sugar is high, and I just uh

- at that point. I just go to say a text on clarity, and then I, you know, downloaded the data, and then now either schedule telemed I'll call patient, hey? You know. Look at this is your Cgm data. It looks like you should be still high after dinner. Let's, you know, Change your Yeah. So yeah, I do have access to all their device uh remotely as long as they uh initial, you know, set up to be connected, which is a very easy if they use the mobile device. It's just the one time set and connected with us. You can see the data anytime. Yes,

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01:06:09

yeah, did. Does anyone? Is anyone hesitant to do that. I don't know why they necessarily would be but just to have access to

- like

Shichun Bao

01:06:18

they're Pr. In some sense it's like private data. I don't know if people feel like their blood sugar to any given time is special to them. But has anyone ever given Push back on that? No, I'll say almost not once a while, maybe all the brutal. You'll see a patients say this patient no longer share with your clinic uh,

but majority patient. Have no problem because they yeah, and they want us to have a and some that are aggressive. They keep telling me. Look, look at my data, look at my answer. You know

- we just talked about a week ago. You're doing fine. I really can't look at it every single day, so it's usually the opposite. Not be uh uh the. They don't want us to look at it. They want us to look at all the time. Usually that's what I

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01:06:59

okay. Very good. We got a couple of questions here in the audience, too, if you want to take it away. Thanks for the record Fire presentation. Um! Two very

- quick questions. First one for patients who like to work out and stuff, or maybe like cycling. How do they adjust the closed loop systems to account for that.

Shichun Bao

01:07:21

Yes, what aid, you know uh the uh T Slam. You can really just set exercise mode which they will already reduce the sugar base with Basel insulin when they blow one hundred and forty, and when it's below eighty it will suspend uh so, and metronic also has a a target, you know a for one hundred and fifty, and for the uh omnipot five you can really set, you know. Uh all this time i'm exercising.

- You can, uh really, you know, set a target that is hired, and you can just that all the time. And if, as long as patient using correctly, they really shouldn't run into the trouble, because, you know, like, for on your pop they look at your next hours sugar trend to make that adjustment. The time that patients, still running to low, is there or not using Pre correctly like they do they? You can always override it. You can always just say, i'm gonna just give myself ten units that you know the system cannot prevent you. So if they already take too much in,
- even the pump gets suspended. But they cannot take all the instantly already give to yourself. So then they will have low. But if they just use the device correctly, those Id really should avoid. Uh, you know the severe, low or high, even the exercise, or all, or doing different things.

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01:08:36

Okay, A second question, The um. So all of these algorithms, it seems like they're targeted to optimize minimizations and variability and bug glucose. And this might be obvious. But I don't know.

- Can you help explain why variability and glucose even within a
- even within a target range, is not physiologically optimal. Or do we know that? Or is that attached to like outcomes data at some point.

Shichun Bao

01:09:06

Yes, so you're saying even we have a set target. But they are still patient. All of the target is that

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01:09:11

I think I think I think Griffin's question was about um. We have good data to suggest a one, C as over three months of time. Um correlates with patient outcomes, but is do. We also have data to suggest that that variability um is also important even in patients with the same, a one, C value right? So that's the all the those pivotal trial that I showed you, you know, and also my the example that my patient that is, um, you know.

Shichun Bao

01:09:41

Uh. So yeah, even though he has all this beautiful a one, c. But you can see, with all the technology, he was having a lot of low and you know less timing range. So the a one is really not the best indicator these days. We have to not think about the A one C uh as the uh. Only, you know, target for discuss where your page, patient and a once you can be affected by many other factors, you know, can be underestimating, overestimating uh your No, you know, renal disease anemia that they can all be different.

- So really, you should use the timing range, and you know, percentage of low th that uh metrics that we talked about, for, uh decide that whether the patient is good control or not, but not using the A. One, c. We still do they want to see? But really, that's not the best indicator.

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01:10:26

Okay,

- Shawn Shawn's up next. Hi, Dr. Bao: Thank you for a great talk on some very exciting technology,
- as you all, I'm sure doing, Nashville. We care for a lot of vulnerable patients to those who are under resourced here in Charlottesville. Um if you could speak to the patient demographics and these clinical trials you showed, and specifically, if we know anything about socioeconomic stats and health care literacy, I just

Shichun Bao

01:10:51

I. I worry a little bit about the patient who maybe doesn't even have a smartphone navigating this technology, and how you see this uh fitting into that patient population. True. So that's still the reality. You know the Cgm are uh all the pomp. They're all very expensive, so patient with a so sick, not a disadvantage. It may not have access to it, but that being said, you know the company do have those uh program so especially for, like a Libra. You know anybody should pay more than seventy-five dollars for two sensors a month supply but that's

- it's still seventy-five dollars, and they are uh like we then a bill we have, like indigenous clinic run by students. They got Grant to support from a company uh that can give the Cgm to the patient for free, uh, and you know certain we all know they're going to benefit from these. But how we can get That's why some of the study is to get more medicare coverage, more medicaid coverage for those you know, and that there are some patient, even Don't have any insurance; that how we make those more affordable. But that is a real
- challenging, because, you know, these technology is expensive. Uh, Ted Islam. Pom, you know, cost like eight nine thousand dollars, and that that's just the palm. Be talking about all this infusion set, and all these part, you know. Uh, so it is challenging, but that's why we want to raise the you know the awareness of what all those people they need it, and they will benefit from it so hopefully. Uh, you know more support uh grand can be punched in, or government program can be help them. The coverage is a Medicare already made law
- of changes. Now, to have much, you know, broader coverage for the patient. Uh, because of these studies, you know, they submit to the mandate little bit little loosening that coverage criteria, but still a big challenging. Yeah,
- I hope I answer some of your questions, Some you did. You did. Thank you. I'm. I'm glad to hear that Medicare is making it more accessible for these patients, and even, you know the Medicaid, and they start covering more and more also. Yeah.
- And then, like, say, in our indigent clinic, we really just give them those for free um. There is a you know, Support Grant from the company. We purchase it um for a lower cost, and then we give the patient free. Yeah,

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01:13:02

Great

- um, I think that's that. Does it for the questions here in the audience. Um. And I think, Yeah, I think that's about it for us. Um, this is a great talk, Dr. Bell. Thank you so much for taking the time to do it.

Shichun Bao

01:13:16

I know, maybe a little bit of pressure speaking to some of the people at Uva here are doing some of this as well. But we really appreciate you. You're doing it for us. Yeah. Well, thanks for the opportunity. Yeah, I really enjoyed it and apologize. I talk too fast, and uh like to share my slides with you afterwards. And I'm not really excited to learn from your group, because your group is really the

pioneer in the in the diabetes technology development. Yeah, Great? Well, thank you so much. You have a good rest of your day.

- Thank you. You, too. Bye, bye.