Executive Highlights

The diaTribe foundation hosted Musings Under the Moon event at ADA 2016, gathering nearly 250 attendees in an intimate setting to hear perspectives on digital health and diabetes technology. The all-star panel included Bigfoot CEO Jeffrey Brewer, Medtronic Diabetes President Hooman Hakami, Qualcomm Life's Dr. James Mault, IBM Chief Health Officer Dr. Kyu Rhee, Novo Nordisk Executive Vice President Jakob Riis, and Dexcom CEO Kevin Sayer. Close Concerns' Head of Diabetes Technology & Digital Health, Adam Brown, moderated the 75-minute discussion. We thank Novo Nordisk and Qualcomm Life for providing the funds to gather everyone and to expand education, advocacy, and convening programs at The diaTribe Foundation.

"Data" was probably the most frequently used word during this panel, which will be the fuel that drives this entire field: knowing what patients are doing, and equipping them and their providers with better tools and algorithms to make more informed and better decisions. There was no doubt on the panel that the technology already exists to make a serious difference today; what is lacking is a system and reimbursement environment to tie it all together.

Panelists agreed on the importance of the field in terms of driving success for patients and healthcare providers and were mixed on how quickly things will move. Mr. Riis and Mr. Sayer felt it will take several years for the field's business models to be transformed. Most on the panel pointed to payers as a very big challenge, agreeing that incentives have to change and payment for outcomes will be the future - but how will payments based on outcomes be divided? Notably, the FDA wasn't presented as a barrier, a testament to how far the Agency has come on CGM, automated insulin delivery, and mobile apps. Dr. Mault pointed to the pace of progress in miniaturized electronics, noting that the entire field is on the cusp of serious change - "Disruption is painful especially for those disrupted," he warned the room. Several argued that the biggest barrier is training healthcare providers, who are not ready for this revolution. A healthcare provider in the audience agreed, noting that he spends 75% of his days as a documentation specialist!

In terms of opportunity, the dangers of dosing insulin came up often, and most agreed that insulin dose data is still a major missing piece of the ecosystem. Patients routinely underdose basal and prandial insulin and many who should take it don't - it was terrific to hear this discussed as a solvable problem. The panel talked a great deal about the huge potential of giving providers better clinical decision support, particularly in type 2 diabetes where there is so little data on what patients are actually doing.

Below, we enclose some of our favorite quotes from the panel discussion, followed by a more complete review of the discussion. The diaTribe Foundation thanks the sponsors, Novo Nordisk and Qualcomm Life, for making this event possible.

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ON THE BIGGEST OPPORTUNITY

- ▪ **"We don't know how much insulin people are taking.** Investors can't believe that we don't know how much of this dangerous drug is being administered ... If you know how much insulin is being taken and what the blood glucose is doing, you can actually do something." - Mr. Brewer

- ▪ **"With type 2, I think the biggest opportunity is to empower the primary care community** to better manage patients with type 2 diabetes. ...Monitoring plays a big role in that, and I think it's a big opportunity." - Mr. Hakami

- ▪ **"...we could bring a system to the market that tracks how much insulin you are taking and when you are taking it.** It's what is needed to make personalized dosing algorithms work, and we can make insulin safer that way." - Mr. Riis

- ▪ **"I think the low hanging fruit is how we change how we make decisions** via either an activity monitor or glucose monitoring or vital signs. We can make intelligent decisions for these patients rather than just guess ..." - Mr. Sayer

ON THE BIGGEST CHALLENGES

- ▪ **"I think we should aim to have payers genuinely value our products. What's crazy about that?** That's not how we currently have our dialogue with payers. When connectivity will give us proper data on treatment outcomes - payers will realize what's good innovation and what's not." - Mr. Riis

- ▪ **"There's one disease we don't talk about in the diabetes community, and I have it: 25% of the time, I use my license** and do what I'm supposed to do as a doctor. 75% of the time, I'm a documentation specialist ..." - Audience member Dr. Anuj Bhargava (My Diabetes Home)

- ▪ **"What keeps us awake is the fact that healthcare professionals are not prepared for this new world of digital health**...in the future, we're going to be taking care of hundreds and thousands of patients without physically examining them. You've got to retrain providers to practice medicine in ways they haven't practiced medicine before. That's ... what's holding up our transition to a more digital healthcare world ... The biggest hurdle is retraining HCPs and writing guidelines to take advantage of the opportunity we currently have and that other industries have already taken advantage of." - Dr. Mault

- ▪ **"We have a lot of data and we have not necessarily translated it.** In the same way that diabetes is an invisible disease, the data has been invisible. We have to figure out how to get it to the true payer." - Dr. Rhee

- ▪ **"One question I ask myself is: How good do we need to be to make a difference?** ... Sometimes we look at accuracy of systems rather than their impact on the system. You really can create something better for patients even with a level of inaccuracy that people are normally uncomfortable with. We can't let perfect be the enemy of the good." - Mr. Brewer

ON BUSINESS MODELS

- ▪ **"Five years from now, I don't want Medtronic Diabetes to be a medical device company that sells hardware.** If we are successful, we will be a diabetes management company that provides outcomes." - Mr. Hakami

- ▪ **"...the model we have doesn't work and it can't continue that way ...We have to change the transaction so it's relative to outcomes ...** you may still have a transaction centered around the physical product, but price has to be relative to the total value you offer. Going forward, regular price increases above CPI [inflation] are not going to happen, unless new clinical data documents that the clinical value is bigger relative to when you started pricing. The future will look different when it comes to pricing - it will be relative to outcomes." - Mr. Riis

- **"...the hardest thing is to serve the payers**. How do we motivate them?" - Mr. Brewer
- **"We're not going to move to a service business overnight.** We have to find ways to break down walls. Outcomes data is critical in this regard. We presented DIaMonD and saw a wonderful outcome. We hope that this is the beginning of ... patients access to CGM more quickly. However, when business models get tough is when you have partners involved." - Mr. Sayer
- **"In the spirit of transparency, I'll give people a sense of what it took for a behemoth like United Healthcare to create an entire healthcare design predicated on wearable digital technology.** This is a program that will allow employees to earn $4 a day and up to ~$1,500 a year and another ~$1,500 for their spouse in return for not just wearing the wearable, but for following a specific directive curriculum of activities. ... United isn't doing this just for fun. They won't do it unless they know they'll make money. It actually took very extensive outcomes data from four million patient records and analytics efforts that took four years and pilot programs over the last two years with 150,000 employees each to get to the right outcomes vs. cost." - Dr. Mault

Introductions

ADAM BROWN: Before I introduce our panelists, I want to tell a story to set the stage for this panel. I was riding to the airport about a month ago, and as the driver and I made small talk ("What do you do?"), there was a long pause. "I'm a diabetic myself," he eventually said. Here's his story.

He takes NPH and fast-acting insulin twice per day using a sliding scale to determine the dose - it doesn't matter what he eats. He only tests his blood glucose twice per day. His A1c "once got down to 8%," but he recently had several weeks of blood sugars over 300 mg/dl. He has already developed some kidney problems, and more recently, issues with his feet. He's only in his 40s!

"I love fried chicken and eat it every single day," the driver shared. He also said he frequently drinks regular soda, snacks on chips, and eats too many sweets. He is overweight and drives 10-14 hours per day, leaving no time for exercise. Perhaps worst of all, he has Kaiser insurance and does see his primary care doctor regularly. A pharmacist mostly helps him with his diabetes and his insulin doses, often by phone. At a recent appointment, his doctor didn't realize he was on insulin - and he has been taking insulin for two years!

This is a true story, and it reveals the challenges before us, and also some windows where digital health can help:

- **Collecting more comprehensive data** on what is actually happening, instead of two fingersticks per day (if that) and zero information about insulin doses. This can happen passively.
- **Giving him some actionable insight** in real-time to make changes, help him navigate the toxic food environment, motivate him when he makes progress, help him learn from mistakes, etc.
- **Tightening the feedback loop**: notifying his doctor he needs to be intensified, helping his doctor choose different therapies, helping him titrate his own insulin.
- **Connecting** his doctor, pharmacist, payer, and other stakeholders so they know exactly what is happening, and we no longer hear comments like, "Wait, you've been on insulin for two years?"

If digital health is successful, it is going to make the biggest difference for people like that driver - not for people like me.

And now, to introduce our panel and share a few things about each company that we've found really impressive.

- **Kevin Sayer is the CEO of Dexcom.** I'll never forget my first summer here when I got on the Dexcom Seven Plus after hearing a panel of patients on CGM. What a transformative technology. Dexcom has seen impressive growth, with 14 (!) straight quarters of ~50%+ YOY growth and improving profitability. They have also blazed a trial at FDA. A few years ago, we thought G5 - a class III medical device on a phone - was impossible. Dexcom Share was a monumental approval last year

too, down-classifying secondary display of CGM data, and opening up faster iteration potential - now, anything that touches CGM data is NOT a class III device, which knocks down a remarkable barrier for software development. Dexcom has done an amazing job of launching many products over the past few years, has a deep pipeline (including the partnership with Verily), and they have pushed to open their data and integrate with platforms like the Apple HealthKit.

- **Hooman Hakami is the President of Medtronic Diabetes.** He came in about two years to lead this Group from GE, and boy does he have big goals. He wants to serve 20 million patients and more than double revenue from $1.8 billion to $4 billion per year in five years. Hooman has created a type 2 business unit, which recently partnered with Qualcomm Life to build a single-use, professional CGM. He has also established a Diabetes Service and Solutions business, including a partnership with IBM Watson, compatibility with Glooko, and acquiring a Nordic diabetes clinic in Diabeter. "We want to be a holistic diabetes management company," says Hooman, a big move away from the business built on primarily serving intensively managed type 1s.

- **Jeffrey Brewer is the CEO of Bigfoot Biomedical, and previously served as** the CEO of JDRF. He has a son with type 1 diabetes. What impresses me about Bigfoot is the team they have assembled: some of the smartest people in diabetes to automate insulin delivery, including Bryan Mazlish, Lane Desborough, and Jen Block. They have deep experience in the DIY community and automation, and plan to pursue subscription diabetes care and a risk-sharing business model with payers.

- **Jakob Riis is Novo Nordisk's Executive Vice President.** Novo Nordisk has an incredible history in protein chemistry, and a few years ago, we never would have thought this $12 billion insulin leader with such deep diabetes experience would be up here helping lead a discussion on digital health! Jakob personally has a big interest in digital health, and he's talked about how there is so much potential for this field to really improve drug delivery - drug selection for prescribing, drug dosing and titration, and collecting real-world adherence data and outcomes. Novo Nordisk is partnered with IBM Watson to bring better insights to providers and patients, and we cannot wait to see where they focus, whether it be clinical decision support, comparative effectiveness research, predictive analytics, or better data for payers.

- **Dr. Kyu Rhee is the Chief Health Officer of IBM,** where he has global responsibilities for Watson Health and assuring a Culture of Health at IBM. IBM Watson now has diabetes partnerships with Medtronic, Novo Nordisk, ADA, and HelpAround, as well as a new project in diabetic retinopathy. IBM CEO Ginny Rometty has referred to healthcare as IBM's "moonshot." IBM also transitioned from a hardware to a service company, and we look forward to seeing what diabetes can learn from that move. I love this quote from IBM Watson Health's Chief Science Officer Dr. Shahram Ebadollahi, shared at ATTD: "Unstructured data is growing exponentially and projected to reach 44 zettabytes by the year 2020 ...." (...Dr. Ebadollahi taught us that if grain of rice is a byte, a zettabyte will fill up the Pacific Ocean - that means 44 zettabytes is 44 pacific oceans.)

- **Dr. James Mault, MD is Qualcomm Life's Chief Medical Officer and came to Qualcomm Life** in 2013 when his remote patient monitoring company Healthy Circles, which he had led since 2009, was purchased. Qualcomm and Qualcomm Life have been important to watch in this field - Qualcomm Life invested in Telcare early on and recently partnered with Medtronic to make a single-use, professional CGM. I love this quote: "Qualcomm is creating the connectivity fabric and chipsets for the Internet of Things (IoT), which link 26 billion objects over the next five years." A very notable example of what they're doing came earlier this year in a partnership with UnitedHealthcare: they have developed special wearables to give to beneficiaries, who can earn up to $4 per day for meeting certain activity goals. That's ~$1,400 per year, and a real testament to UHC's belief that wearables and wellness are worth paying for.

Questions and Answers

ADAM BROWN: If you magically found $150 million and you had to spend it on one thing - one product, one app, one service - what would you invest in building and who would it help? And, what would you *not* spend it on?

KEVIN SAYER: Jeffrey [Brewer] and Bryan [Mazlish] told me to say I'd give it to them. [Laughter] We don't have a problem spending money at Dexcom. We spend a lot. If I found $150 million, I'd speed up what we're doing. We have lots of things on the horizon. We have our Google relationship. We're trying to miniaturize our platforms. We're working on advanced analytics. Also, the type 2 problem that you talked about earlier is something that we've spent a lot of time on. We get feedback from type 2 patients that have worn CGM for a week, and they say that the educational experience is incredible. They say, "I didn't know how badly I ate." The information is incredible. So I'd give my money to type 2, short of giving it to Jeffrey and Bryan.

HOOMAN HAKAMI: Well I think that I'd start with $5 million. Your story at the beginning really highlighted a big need. It's impossible to fill holes of data. We have to do better when physicians don't have enough data. For us, it's about trying to build those data sets. It's about building partnerships with organizations like IBM. We need to get a more complete picture of the patient and run that through algorithms so we can provide meaningful info in real time for both the patient and physician. If you look at the need, it's massive. In type 2 diabetes, for example, we need to provide insights that can help with the basics - what medications is the patient taking - to more sophisticated insights - such as recommendations on how a patient can better control their glucose based on an analysis of their exercise, food, sleep and other biometric data. And doing that on a broader scale around the world is a huge need and opportunity.

JEFFREY BREWER: We actually need about $150 million total …!. I spend a lot of time raising money for Bigfoot. It takes a lot of money to build a business and build our version of a solution. I meet with investors who say, "Can't you do this with an app and cloud solutions?" Yes, we can and then that would be mated with device. The system would connect to a network and capture data. We need pens that can provide connectivity, pumps that can stream to the network, and CGMs that can do the same. We don't know how much insulin people are taking using shots. Investors can't believe that we don't know how much of this dangerous drug is being administered. The ecosystem needs to be developed, and it costs money to do so. We are on a journey to try to offer a solution to this.

JAKOB RIIS: A lot of problems would be solved if we could make a glucose-sensitive insulin. We've started on that, but honestly, we won't get very far with US $150 million [laughter]. For less than that, we could bring a system to the market that tracks how much insulin you are taking and when you are taking it. It's what is needed to make personalized dosing algorithms work, and we can make insulin safer that way. [In a later conversation, Mr. Riis added, "Connectivity has a much more profound meaning to Novo Nordisk than data exchange - it's about being truly patient-centered. Giving interaction designers $150 million to develop digital health solutions would allow us to better connect with our customers, and thereby, better help them in their daily lives.]

DR. KYU RHEE: I think of patients and entrepreneurs, and I'd love to give it to a patient advocacy group. *The* diaTribe Foundation, the ADA …. And I'd decide how to spend it with entrepreneurs and there are lots of innovation opportunities out there. How I wouldn't spend it - I probably wouldn't go to Harrah's and bet on black. But maybe tonight, I'd bet on red.

DR. JAMES MAULT: Raise your hand if you have a credit card or know someone with a credit card. Keep your hand up if you're aware that you can go online and pull up your Starbucks transaction from this morning. [All hands stay up] Keep your hand up if you or someone you know has had their cholesterol taken and received immunizations. Keep your hand up if you can find that online. [Most hands go down] All of you should know that there's not a single state but one - Connecticut - that gives consumers a legal right to a copy of their medical records. When taking care of diabetes, it is absurd that data is not liquid and available to people when they need it. That's just plain and simple and we need to do a better job of enforcing that almost civil right.

MR. BROWN: What is something you believe that other people think is crazy?

MR. BREWER: So I'll give you some real crazy talk. <mark>I believe a PCP can prescribe and support an automated insulin delivery system.</mark>

MR. RIIS: <mark>I think we should aim to have payers genuinely value our products. What's crazy about that? That's not how we currently have our dialogue with payers. When connectivity will give us proper data on treatment outcomes - payers will realize what's good innovation and what's not</mark>. There's a lot we need to rethink within the healthcare sector - there's a lot of wasted energy in the system right now.

MR. BROWN: Data for payers would be a huge win. My payer sends me information on pregnancy tests. They have no idea who I am. It is laughable.

MR. HAKAMI: Something crazy? I get a lot of funny looks when I talk about 20 million patients by 2020. We have to shoot for big goals. <mark>It can't just be Medtronic. I want to see Dexcom be as successful as they can. As well as all the people and organizations on this panel. Twenty million patients is just a fraction of all those out there with the disease. We need to collectively do better</mark>.

MR. SAYER: I'm going to go back to a <mark>conversation I had when I first came to Dexcom with someone else in the industry - they said you'll never see the day when you impact [glucose] strip sales. Really? I wasn't crazy. And we've said for a long time that our goal is to replace fingersticks and we won't back down from that.</mark> The data we provide to this ecosystem is extremely useful across the board in diabetes. We have a lot to figure out how to get your payer to pay for it. I agree with Hooman - everyone should be served by these devices. Everyone will be served in a different way. So, <mark>when we used to say we were going to replace fingersticks we were looked at as insane. Not so much anymore.</mark>

DR. RHEE: The thing I'd speak to is the concept of transparency. In this healthcare ecosystem, transparency is essential to trust which is essential to transformation. Often, we get caught up in a lack of transparency.

MR. BROWN: A question on business models. I love the example of Kodak, who made all its money selling film years ago. The first digital camera was actually invented at Kodak, and when executives saw it, they buried it - they were scared about what it would do to the film business they had built. And then Kodak went bankrupt. What can be learned? Kodak forgot their mission, which was not to sell film; it was to record memories. In diabetes, how should we think about delivering this stuff? Hooman and Jeffrey have been very vocal about how diabetes technology needs to be a service business and not just about selling hardware. How is this all going to change?

MR. HAKAMI: We have been very vocal about it. We've talked about it several times this week. <mark>Five years from now, I don't want Medtronic Diabetes to be a medical device company that sells hardware. If we are successful, we will be a diabetes management company that provides outcomes.</mark> Technology is a part of that, but it's not only about the product. It's about the other things around the product - such as the data about the patient that's relevant to their health and to the management of their disease. You have to turn that data into actionable insights and feed that back into an integrated patient care system and enable the system to provide care in real time in a meaningful way. If you look at what we've been up to, it's about building the puzzle pieces to make the transition to a diabetes company that ultimately provides diabetes management and outcomes, not products.

MR. BREWER: My particular journey in this business has given me a certain perspective. When I started the artificial pancreas project, I had a lot to learn about healthcare from reimbursement to regulatory. It took me a decade to come up with some minimal level of competency, at which point I could have an opinion about the various constituents that needed to be served. I think one group that needs to be served better is patients. This is not a small ask, and I wish it were different because my son has type 1 - we need to increase the safety of devices and make them fit more seamlessly into lives. The second group I would identify is providers. From a business model perspective, you have to create something that's easy to digest and easy to use. <mark>You have to make devices as easy to understand as a shot of Lantus</mark> or three shots of insulin. <mark>Then, thinking about business models, the hardest thing is to serve the payers. How do we motivate them?</mark>

DR. MAULT: This goes back to our [big announcement with UnitedHealthcare](#). In the spirit of transparency, I'll give people a sense of what it took for a behemoth like United Healthcare to create an entire healthcare design predicated on wearable digital technology. This is a program that will allow employees to earn $4 a day and up to ~$1,500 a year and another ~$1,500 for their spouse in return for not just wearing the wearable, but for following a specific directive curriculum of activities. Coming back to the whole point, United isn't doing this just for fun. They won't do it unless they know they'll make money. It actually took very extensive outcomes data from four million patient records and analytics efforts that took four years and pilot programs over the last two years with 150,000 employees each to get to the right outcomes vs. cost ...

DR. RHEE: And I love how innovative that is in the partnership with Qualcomm and United Healthcare. Who is the payer? Raise your hand if you're a payer. There are trillions of dollars, and half the money goes to Medicare, Medicaid, and military. Another half goes to employer-based insurance. What's happening is clearly a movement toward expecting value in healthcare. We have a lot of data and we have not necessarily translated it. In the same way that diabetes is an invisible disease, the data has been invisible. We have to figure out how to get it to the true payer.

MR. SAYER: These business models are still hard. It needs to be easier to get these devices into patient hands. We're not going to move to a service business overnight. We have to find ways to break down walls. Outcomes data is critical in this regard. We presented DIaMonD and saw a wonderful outcome. We hope that this is the beginning of us breaking down some walls and getting patients access to CGM more quickly. However, when business models get tough is when you have partners involved. For example, when Glooko partners with us on the data side and someone else adds the insulin component, how do you split the pie? It's nice to be able to offer the whole service but we don't and it's not easy. It leads to a lot of great days with thoughtful exercises and over time, it's going to evolve. It's going to take a while.

MR. RIIS: I think the business model is going to continue to rely on the physical products when we discuss digital solutions within insulin treatment. But that doesn't mean we can't provide value beyond the product. We recognize it's difficult to integrate the digital products into the current business model - but a few can do it. There just has to be a link.

MR. BROWN: Where is this field going to make the biggest difference in the next 5 years? What's the lowest hanging fruit?

MR. BREWER: Knowing how much insulin is taken is the fundamental data point. We are big fans of data, but also of solving small, targeted problems that will have amazing returns. If you know how much insulin is being taken, what the blood glucose is doing, you can actually do something. If you don't know that reliably, then you don't know anything. Right now, we won't be focusing on diabetes at large, but on type 1 specifically. There's a problem right in front of us and we think it's very solvable and we're going to go after it.

MR. HAKAMI: I would break this question up between type 1 and type 2 patients. I think if you look at type 1, it is closing the loop. We are on a path to that with hybrid closed loop. We are in a position where we are close to eliminating adverse events with a systems-based approach. That system is our goal. With type 2, I think the biggest opportunity is to empower the primary care community to better manage patients with type 2 diabetes. I think monitoring plays a big role in that, and I think it's a big opportunity.

MR. SAYER: I think the low hanging fruit is how we change how we make decisions via either an activity monitor or glucose monitoring or vital signs. We can make intelligent decisions ...rather than just guess. We ask patients, "Why are you on Victoza?" And they say, "because that's the commercial my wife and I see the most." And that's it. I think we'll have much more intelligent decisions and patients and payers will all benefit.

DR. MAULT: So what I'm holding here is a chip that's actually smaller than my pinky fingernail that has Bluetooth, a motion sensor, heart rate, body temperature, etc. It has a battery with a two-year shelf life and it's disposable for less than 10 dollars. This is already going on every patient admitted preoperatively, postoperatively, and they get a new one when they get home. We talk about how proud we are of our modern medicine, but we are still living in the dark ages. We practice medicine by trial and error - it's haphazard and uninformed. We are about to enter the age of intelligent care, where we are going to have real information for the first time. And real data, not just snapshots in time. We'll have data and predictive analytics like we've

never had before. In five years, we will be able to see data and know things that clinical practice has not been able to do manually.

DR. RHEE: As a primary care provider, I often reflect on how the patient is the most important member of my focus. But to be honest, you've also got nurses and educators and psychologists and nutritionists and physical trainers - health and healthcare is a team sport. In the next five years, I see an opportunity to bridge what has been siloed and to push for ways in which diversity can breed creativity. There are important partnerships that need to be developed at global and multinational levels. This is what we were thinking in our partnerships with Novo Nordisk, Medtronic, and ADA. What we've learned is that transformation requires a team effort.

MR. RIIS: I'm not so sure that there is a low hanging fruit. This is going to be difficult. We need to tell the world that we're up for it, and that we're going to stick together in our various partnerships, until we have delivered. To ask about a low hanging fruit is a great panel question. But it might create some misperceptions that there are quick wins in this area. And if expectations get ahead of us, we may get too many disappointments, which in turn could dampen the pace of innovation. We are very ambitious in Novo Nordisk within this area, and are prepared to work hard at it - while expecting it to be difficult.

MR. BREWER: We are not waiting. Technologies exist, but they need to move faster into the lives of people with this disease. It is unacceptable to not have basic connectivity and information on how to give it. When my son was diagnosed, I was given a hand drawn sliding scale for how to dose insulin. Then later I was at a diabetes technology conference and met people in the field trying to build solutions. We've been on a journey, and now it's really time. There is some real focus and energy. It just shouldn't be acceptable any more; people shouldn't die because the data saying they're in trouble isn't being shared and seen by others.

MR. BROWN: One of my biggest takeaways from ADA 2016 is how dangerous insulin therapy is. This concept that patients are asked to dose insulin based on a given A1c, which could mean an 80 mg/dl spread in average blood glucose - for a 7% A1c, that could mean your average blood glucose is anywhere from 120 mg/dl to 200 mg/dl - that's crazy! So with that mind, what single question keeps you up at night about this field?

DR. MAULT: Disruption is painful especially for those disrupted. What keeps us awake is the fact that healthcare professionals are not prepared for this new world of digital health. You've got to retrain providers to practice medicine in ways they haven't practiced medicine before. That's ... what's holding up our transition to a more digital healthcare world ... The biggest hurdle is retraining HCPs and writing guidelines to take advantage of the opportunity we currently have and that other industries have already taken advantage of.

MR. BREWER: I agree that there are challenges around training. But we need tools in technology to support the jobs that people do. We shouldn't have to retrain people. That's the biggest takeaway for me. We have no tools in the medical device industry that people can self-assemble. I think we can do a lot better in supporting clinicians and not requiring them to change to leverage tools. And same for patients. Also, the FDA has given us an open field running to do what we want to do. They're not a reason to stop.

DR. RHEE: IBM is a B2B company. I'm always struggling with how this relationship works for patients - how does the B2B translate to B2C. That is often what I focus on.

MR. SAYER: What keeps me up at night? We have life-saving technologies. Are we going fast enough?

MR. HAKAMI: The exact same thing. You all heard the passion tonight that Jeffrey showed when he was answering this question. We need every person in our organization feeling that way. "Because it's hard" is not a reason we shouldn't move ahead. It's about our people and our mindset.

MR. BROWN: As we open it up to audience questions, I just wanted to recognize Mr. Kevin Hagan, CEO of ADA, who is in the house - he and his team have created an absolutely incredible Scientific Sessions. [Applause]

RICK ALTINGER (Glooko, Palo Alto, CA): Digital health is a big topic. What I'd like to ask is one thing, a rhetorical question: how has Dr. Howard Wolpert helped you in digital health? Howard is about to transition

from Joslin, where he has had an incredibly impactful career, to Lilly. I would just like to take my moment here to thank Howard for what he's done and the impact he's going to make in the future. [Applause]

DR. AARON KOWALSKI (JDRF, New York, NY): This is an amazing time in the diabetes technology revolution and we know so much is possible. I've been fortunate to spend a lot of time with all of you in the panel. We have potential, but we have FDA in the middle. I'm a scientist at JDRF, but now I work on policy. Kevin, think about it - we had G4 and then G4AP, but it took many months for you to get just a new algorithm with more accuracy through the Agency. How do we drive some radical acceleration of the speed and pace of technology in an FDA regulated world?

MR. HAKAMI: Look, I'll give you a contrarian view. We have been working closely with FDA for the last three years - incredibly closely. Because of the work we're doing with them, we've put ourselves in a position to launch our hybrid closed-loop platform first in the US and then in the EU. This is totally the opposite of the way every other product launch has gone. What I've found about the FDA - in working with Courtney Lias and Stayce Beck - is that the organization is much more open and willing to partner with industry. If you look at the historical charter of FDA, the description focuses on promoting public health. That will, of course, continue to be the charter and the focus. Historically though, this focus on promoting the public health has resulted in a singular focus on ensuring products are safe and effective. However, if you look at mindset today within the FDA under Dr. Shuren's leadership, they are realizing that in addition to safe and effective products, innovation and technology also help promote the public health, and you have to encourage both - safe and effective products and innovation. As a result, we have been seeing greater collaboration with respect to innovation. This doesn't mean we always agree with each other or we move as fast as everyone wants, but there has been big progress and I really commend the FDA for this.

MR. SAYER: With the algorithm example you gave, from the time we filed to the time we launched was six months. When we commit to the FDA, things go very well. We manage the process and it isn't without conflict and without issues, but by and large when we honor our commitments and deliver the outcome we promised, we get through. It's up to companies to exercise due diligence to what they promise and what they commit. When we say we are going to submit something that's perfect and then it's not, we can't blame the FDA. There's been a lot of progress and they're pretty open. These trials for insulin dosing will be much bigger and much more complicated than anything else we've ever done, but if we get through it we'll bring these devices to people who need them.

MR. RIIS: Well-characterized and documented solutions with clear patient benefits would not always be upheld by the FDA. But we need to acknowledge the huge responsibility that FDA has, and that mistakes will cost lives.

MR. BROWN: I have a question for Jakob. For me, the low hanging fruit is insulin dose titration software for clinicians. What's the missing piece here? The FDA? Why isn't this moving faster?

MR. RIIS: If the technology comes together, we can make it happen. In Novo Nordisk we are currently uncertain about how to construct the solution, or the end product. When we talk about it in broad terms, it all sounds great. But when we discuss the concrete design of the solution, it gets difficult. We can't make things complicated. We need to make the difficult decisions on what we're aiming for. How far do we stretch ourselves towards the 'perfect' solution and how quickly do we want to move? If we get it wrong, we may get something fast, but it won't solve any problems.

MR. BREWER: One question I ask myself is: How good do we need to be to make a difference? We spoke earlier about keeping track of insulin injections, potentially with a cap on disposable pens. As an example, maybe we just have to know that we took between eight and ten units. Maybe being able to identify smaller increments isn't as important as just getting that technology to patients. Sometimes we look at accuracy of systems rather than their impact on the system. You really can create something better for patients even with a level of inaccuracy that people are normally uncomfortable with. We can't let perfect be the enemy of the good.

MR. BROWN: We heard from **Abbott's IMPACT study** of FreeStyle Libre in type 1 here at this meeting that people with an A1c of 6.7% were spending three hours a day below 70 mg/dL [editor's note - below 3.9 mmol]! To what degree could the software and monitoring help us with that?

DR. MAULT: The FDA has been amazingly pragmatic over the last three years, particularly in the area of digital health. Smartphones came out of nowhere and suddenly there are 30,000 health apps. At the FDA, these all started at class III then they downgraded some to class II, then class I [for wellness]. It's a huge boon to entrepreneurs and innovation. Now the FDA is just about to render the guidance we've been all waiting for related to clinical decision support tools. That's where all of this software is going to help manage the insulin.

MR. BROWN: I'd love to hear from a prescriber. What is it like prescribing these technologies?

DR. ANUJ BHARGAVA (My Diabetes Home): There's one disease we don't talk about in the diabetes community, and I have it: 25% of the time, I use my license and do what I'm supposed to do as a doctor. 75% of the time, I'm a documentation specialist. That's what we're doing now. We simply are unhappy ... what is there to get us out of there?

MR. BREWER: The responsibility to live with type 1 is crushing a lot of people. It's an unreasonable responsibility for adults and children and parents. I didn't see it until my son was diagnosed. It's a hard, hard job and it wears people out. The fact that you need twelve different systems and have to figure out copays and do inventory management and record data and upload it - every one of those things erodes quality of life. Any small piece you can get back - like a pre-filled insulin cartridge saving 15 minutes of time - is huge.

MR. HAKAMI: From a Medtronic perspective, when we think about digital health and decision support it's not just decision support for the patient - even though they are obviously a huge stakeholder. The decision support capabilities that we are driving are intended to equally support the physician. An example is in the type 2 business. When you think about diabetes from the physician's perspective, they are maybe seeing their patients every three months. That's tons of meals and BG readings and exercise data, and they are presented with this and have 15 minutes to figure out what to do with it in order to optimize care for their patients - it's next to impossible. We are looking at decision support tools to make the analysis of this data not only possible, but in a way that is easy, personalized and provides the best care for patients.

MR. BROWN: One of the favorite things that I've heard in the past year was from Sonny Vu, a founder at AgaMatrix. It's called the turnaround test. For patients, a device should be so good that you're halfway to work and you realize you forget it, and you actually go back home and get it. It's that essential - you cannot live without it. It would be terrific to see more tools that could pass the turnaround test for providers - what tools can we build that are so useful, they cannot live without them?

HOWARD LOOK (CEO, Tidepool): We have heard so much about the DIY community - there's a clear message from all of us that empowered, engaged patients can do big things. We can't count on big companies to do everything. My question for all of you is what are you doing to not just liberate data so your devices and your software can take advantage, but also so your ecosystem can grow to both read and control devices?

MR. SAYER: I think controlling devices is a different story. With respect to APIs we've recently started building a much bigger stream of data science. We are doing a lot to build that platform with multiple different interfaces depending on goals and objectives. We are laying out data strategy and we've talked to different developers. We don't yet have resources for every problem.

MR. RIIS: We're working on connected devices and we're looking at making the insulin injection data available for all solutions. The business model is a new one to Novo Nordisk and is therefore evolving. But it's what the ecosystem needs so that's what we're doing.

DR. RHEE: Watson has a lot of open APIs. So we've got a lot of interest there and we want to continue to open data to people who can be innovative

DR. MAULT: At Qualcomm, open data is our modus operandi. We've got an open ecosystem of over 1,000 medical devices. People often think of Qualcomm and biometrics, but we're now enabling the connectivity, too.

MR. BROWN: As an aside, it's funny to me that you go to CES and see a connected fridge, but few things in diabetes are connected.

DR. RHEE: We wanted to highlight the developer challenge that the [ADA and Watson Health have announced](). We want developers to take advantage of APIs and create new things.

MR. BROWN: What is the role of small companies in all of this? How can they propel innovation?

FREDERIK DEBONG (mySugr, Vienna, Austria): I thought about this opportunity five years ago. And after five years, we're finally hearing, "let's play." There's been amazing momentum in this field, where data is opening up and patients have started organizations like Tidepool and OpenAPS. If we all get along, then we can solve this trend of fewer endocrinologists and diabetologists ...

MR. HAKAMI: I think you alluded to it at the beginning, Adam. Historically, the group would agree that from a data perspective, we had not been open. However, I think what you're seeing with us - especially with our partnerships with Glooko and IBM - is that we're beginning to appreciate the power of data exchange. We're more and more open. It has to happen. We just want to make sure we're doing it with the right partners in the right way. We're proceeding forward but doing it cautiously.

MR. BREWER: There are different roles for different kinds of enterprises. Small startups and big established businesses all play on the same playing field. When you are protecting existing business it's a different kind of approach. They have an advantage that's unfair. That's just the way it works. You literally have less to risk. It's a dream come true to me to see this happening today and I'm happy to be a part of it.

DR. BRUCE BODE (Atlanta Diabetes Associates): One of the issues people have is cost. As you know, the cost of medical care continues to rise, and people with diabetes obviously have a lot of cost. The price of drugs is going up, the price of sensors is going up, etc. How do you plan to get this to the masses to help everyone with diabetes?

MR. BREWER: My experience is the opposite: prices go down. There's a lot of opportunity to use technology to do things cheaper and take cost out. My sense of the payer system is that we've got all these tech opportunities to bring the cost down. That's what payers demand.

MR. HAKAMI: What I would say is the following - and this goes slightly against what one of the panel members said earlier. If you find that you are in a position where you are extracting value from the healthcare system today, but the system doesn't realize value from what you provide until much later, eventually you're going to find yourself in a position where you will be marginalized or commoditized. How you change this is to be on the same side of the healthcare system so that you extract value at the same time and in the same fashion as the system. This is why we support a world where we get paid for outcomes. As we move there, the focus will shift to where technologies and solutions can offer better outcomes that lower the cost of care..

DR. RHEE: Transparency, competition, and value - those are three important things.

MR. RIIS: I agree with you, the model we have doesn't work and it can't continue that way. I agree with the panel. We have to change the transaction so it's relative to outcomes. You may still have a transaction centered around the physical product, but price has to be relative to the total value you offer. Going forward, regular price increases above CPI [inflation] are not going to happen, unless new clinical data documents that the clinical value is bigger relative to when you started pricing. The future will look different when it comes to pricing - it will be relative to outcomes."

DR. FRAN KAUFMAN (Medtronic Diabetes, Northridge, CA): The one word I didn't hear anybody say is "global." Everybody knows that I do a lot of work in Haiti and we need a solution for the 20,000 children with type 1 diabetes that are not making it. We have to think about global solutions.

MS. KELLY CLOSE (The diaTribe Foundation, San Francisco, CA): There are hundreds of millions of people that need help globally - thank you Fran for helping us close on such an important note - I think "global" was in the minds of all the panelists in all the answers that they gave. This discussion has been so

valuable for me - thank you so much! We only had this "Musings" idea a few weeks ago and we're so grateful to Novo Nordisk for saying "yes" and providing opportunity for us to have it - Qualcomm Life also stepped up with a valuable contribution and without these contributions that will help drive our advocacy initiative at The diaTribe Foundation, we can't bring all of you together. So please, a round of applause to all those who really drove this event - this will help enable patient advocacy, and without that, we can't move ahead at our Foundation.

My big thanks, too, to Adam Brown, for leading this conversation. I'm sure you can imagine how happy I was in 2010 when Adam walked into our lives at Close Concerns as a summer associate! What an excellent job he did tonight in helping drive thinking about this field

Finally, please take a look around at everyone in the room that is here and that is interested in making a change: patient advocates, researchers, clinicians. We absolutely need to get more policymakers and government as part of these conversations. So let's toast to making that happen, and to these brilliant panelists who helped make all this happen tonight.

-- by Melissa An, Adam Brown, Varun Iyengar, Ava Runge, and Kelly Close