Executive Highlights

This document contains our coverage of digital health at ADA 2016. Immediately below, we enclose our themes on the category, followed by detailed discussion and commentary. Talk titles highlighted in yellow were among our favorites from ADA 2016; those highlighted in blue are new full report additions from our daily coverage.

For comprehensiveness, we have included some talks in this report that also overlap with our ADA 2016 Glucose Monitoring and Insulin Delivery Full Reports.

Themes

- **The International Diabetes Center signed agreements to license its one-page, standardized Ambulatory Glucose Profile (AGP) report to Roche, Abbott, Diasend, and Glooko.** This news marks a very important step towards device-agnostic BGM/CGM download report standardization, which should improve clinical efficiency, hopefully drive less overwhelm and greater therapeutic change, and perhaps even expand adoption of CGM. Dr. Rich Bergenstal told us three other device companies and aggregators are expected to sign similar agreements in "the next month" - the big glucose monitoring players that have not signed on yet include Ascensia, Dexcom, J&J/LifeScan, and Medtronic. Ultimately, the vision for AGP is to become the EKG report of glucose data - something every clinician understands how to interpret and use - and we hope this creates momentum and pressure for every device company to sign on. Not every company is going to get what they want with a standardized report, but the field will benefit significantly from consensus, and companies can obviously innovate on top of AGP. This has been a long time in the making, as the IDC/Helmsley Charitable Trust expert panel on this topic convened in 2012, and the follow-up joint publication appeared in *DT&T/JDST* in 2013. Kudos to IDC, the Helmsley Charitable Trust, and so many advocates for pushing this forward, and we cannot to see how AGP is implemented and what impact it has on the field.
    - **The partnerships give the companies the right to use the AGP in *all* their diabetes devices and existing software**; the agreement with Abbott extends the groups' existing partnership to other devices, since AGP is already used to visualize downloaded FreeStyle Libre glucose data. The Glooko agreement to use AGP will presumably allow Medtronic and Dexcom CGM data to be displayed in the one-page standardized format, though we wonder if both players will formally sign on. Presumably this expansion also means Roche's CGM may use AGP when it launches.
- **Medtronic was extremely active on the diabetes data front at ADA, announcing summer updates to CareLink to help optimize pump settings, summer launches of the Glooko and IBM Watson partnerships, and a new food app partnership with Nutrino.** It's such a far cry from the siloed, proprietary Medtronic of three years ago, who simply did not partner and share data, and did not have a pipeline of mobile apps.
    - **Next-gen CareLink Pro reports to optimize basal and bolus settings:** These will launch this summer and identify optimal insulin:carb ratio, insulin sensitivity factor, and basal rate change. CareLink will suggest which time of day and direction pump settings should change (Increase basal rate from 8am - 12pm). These are step short of the exact recommendations DreaMed will provide with Glooko ("change basal rate to 0.75 u/hr from 8am-12 pm"), but a clear improvement over the status quo!

- **Glooko compatibility:** Medtronic pump/CGM devices will (finally!) be compatible with Glooko's web-based software, kiosk, and mobile app in July. This integration has been more than a year in the making (Medtronic invested in Glooko last March) and we give HUGE kudos to Glooko (and particularly Holly McGarraugh) for breaking open the Medtronic CareLink data silo.
- **Medtronic/IBM Watson Health app, SugarWise:** The app is officially named "SugarWise (bringing insight to blood sugars) and is still expected to launch this summer. The first generation app will analyze *retrospective* data and provide insights based on past CGM, insulin, and nutrition data. The retrospective example from the pre-ADA Analyst Meeting said, *"In the last 30 days, high glucose pattern found usually after glazed donut for breakfast."* A future-generation version will add the hypoglycemia prediction feature that we first saw at CES in January - unfortunate this won't be in gen one.
- **Nutrino food app:** The beta app launched during ADA for customers who use MiniMed Connect, providing an individualized picture of how daily food intake and other measures impact glucose levels - see the video here and download the app here. The app reads from Apple's HealthKit, meaning it should work with Dexcom CGM and Bluetooth meters too (we have not fully tested it yet).

- **Abbott also had several key digital health announcements related to FreeStyle Libre at ADA, continuing the entire field's move into connectivity, apps, and cloud-based software:** (i) its LibreLink Android app for scanning FreeStyle Libre sensors has officially launched in Sweden and the Netherlands on Google Play and more countries are coming by end of month; (ii) a new integration agreement with Diasend enables data from the LibreLink app to automatically populate a patient's diasend account wirelessly and passively ; and (iii) LibreView was unveiled in the exhibit hall, Abbott's cloud-based data management software. It is excellent to see Abbott, Dexcom (G5), and Medtronic (MiniMed Connect) all offering mobile app data viewing and passive download to the cloud - now, we hope the magic of really driving therapeutic change with smart algorithms can begin! Abbott's LibreLink is the only one of the three apps to offer direct Android compatibility for the patient, as both MiniMed Connect and G5 only work with a patient's Apple iOS device. (Both allow followers to use Android, and both plan to launch Android patient apps this year).
- **In addition to the Medtronic progress, IBM Watson announced three more (!) diabetes partnerships with:** (i) ADA to create a sophisticated diabetes advisor to help inform treatment decisions; (ii) HelpAround to provide crowd-sourced, on-demand help to people with diabetes who need it; and (iii) a predictive model to predict retinopathy risk with Israeli HMO Maccabi Healthcare. These augment the Medtronic Diabetes work (see above) and the Novo Nordisk partnership signed last December. With all these partnerships, Watson brings tremendous potential to improve prescribing, to personalize therapy, to improve prediction, and to make sense of all the data that already exists.
    - **ADA:** ADA CEO Mr. Kevin Hagan announced an exciting long-term partnership with IBM Watson to create a sophisticated diabetes advisor to help inform treatment decisions, plus potential apps for patients and researchers. Clinical decision support and more personalized therapy are clear goals - we can imagine a "Dr. Watson Advisor" that tells clinicians at the point-of-care what therapy to prescribe for a given patient at a given time, similar to its compelling work in cancer - leveraging the entire history of diabetes clinical trials, a patient's entire case history, and perhaps genomic and other data to give evidence-based, confidence-ranked recommendations. What clinician wouldn't love that? A new Watson-based innovation program, "Challenge Diabetes," is also pushing developers to propose apps that will improve the lives of people with diabetes or prediabetes; submissions begin this summer and finalists will be announced this fall. We are elated to see this partnership and wonder if something would be ready by ADA 2017!

- **HelpAround:** HelpAround is a fascinating "mobile safety net for people with diabetes," an app that allows patients and caregivers to ask questions and even find supplies from local patients in moments of need. The IBM Watson partnership will "analyze every help request in real-time, assess its sentiment and tone, and identify frustrations, dissatisfaction and expressions of urgency," helping further optimize the network of assistance. For example, recognizing in real-time that an individual is in distress in regards to their insulin or glucose levels will allow HelpAround to connect the patient with other insulin users, a nearby retailer, or even a chat with the insulin manufacturer.
- **Retinopathy:** This Watson partnership with Israeli HMO Maccabi Healthcare will use machine learning to retrospectively sift through 20 years of data on two million patients to identify who is at risk of retinal damage. The information will be used to design personalized eye examination plans. Theoretically, this same paradigm could be applied to any number of diabetes complications in the future, so that they are caught and treated earlier in development. Nice!

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Thomas Pieber, MD (Medical University of Graz, Austria)

Symposium: Inpatient Management of Diabetes and Hyperglycemia - Novel Insights and Effective Approaches

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Posters

GLUCOMMANDER OUTPATIENT, A CLOUD-BASED INSULIN MANAGEMENT SOLUTION ADJUSTED INSULIN DOSES AND ACHIEVED 2.7% DROP IN A1C PERCENTAGE POINTS (84-LB)

John G. Clarke, Bruce W. Bode

A Glytec poster (84-LB) showcased very impressive results from a 41-patient, uncontrolled, 3-month, outpatient study testing its Glucommander insulin dosing clinical decision support software - from a high baseline A1c of 10.3%, patients ended three months with an estimated average A1c of 7.6% (p<0.000001). The study enrolled 41 type 1 and type 2 patients (mean age: 38 years, BMI: 32 kg/m²) at Dr. Bruce Bode's clinic in Atlanta, who were treated for 12 weeks with Glucommander Outpatient. The cloud-based software provided periodic insulin dose titration recommendations to a provider based on analysis of a patient's SMBG glucose data, communicated wirelessly via the cellular-enabled Telcare meter. The provider then communicated the new insulin doses to patients via text message or email. The topline findings from this small study are very impressive - patients using Glucommander saw a 2.7% reduction in A1c (baseline: 10.3%) at three months, and only 1.6% of blood glucose values were <70 mg/dl. Strikingly, no values were <40 mg/dl and, on the human factors side, patients satisfaction results indicated that 96% of patients would recommend the service to family and friends. The poster hinted at Glytec's strong long-term data as well, citing a smaller cohort of patients that have continued on Glucommander for six (n=14) and nine (n=5) months and have maintained this 2.7% reductions. Small cohorts, but still, this is a whopping improvement. The outcomes are encouraging given the challenges of titrating insulin and the potential for this software to scale expertise, though larger prospective randomized clinical trials are needed to confirm these positive early findings from an uncontrolled study. The company does plan to begin a larger study that includes cost-related metrics such as readmissions, emergency room visits, medication adherence, and healthcare provider productivity, and we're hopeful that data will show this kind of clinical decision support is very warranted (a "no-brainer" many say). We're not sure what the business model looks like going forward, but

assume Glytec's in-hospital experience will be very valuable as it thinks about going outpatient. As a reminder, Glucommander Outpatient is already FDA-cleared and is in the process of being deployed across the US. See our previous in-depth coverage here.

- **How could the Glucommander software be scaled? Could it be packaged with existing devices or even drugs?** We've long thought that insulin-dose titration is a missing piece in the diabetes data ecosystem, and this early data shows how much can be done (and parallels what Hygieia has shown in Europe). We wonder how this Clinical Decision Support software could be packaged with existing devices or even drugs on the market to enhance their effectiveness in the hands of providers. We also have to assume this product saved tremendous provider time, and we look forward to seeing larger studies showing cost-effectiveness. This is where we see digital health really driving better outcomes: collecting data seamlessly and making valuable recommendations that drive seriously better outcomes with less effort.

EHEALTH-ASSISTED LAY HEALTH COACHING FOR DIABETES SELF MANAGEMENT SUPPORT (725-P)

P Tang, M Peeples, J Duni, S Peskin, J MacLeod, S Kowitt, and E Fisher

This small demonstration project evaluated telephone-based lay health coaching combined with WellDoc's BlueStar software in 43 people with type 2 diabetes. Patients received bi-weekly phone calls from two community-based, nonprofessional health coaches, and used the BlueStar app on their smartphone/ computer ad libitum for a six-month period. A preliminary analysis showed a strong 1.7% reduction in A1c from a high baseline of 9.7%. The patient-engagement figures for BlueStar were also solid: 86% of enrollees used the BlueStar app (plugging in an average of 6.5 entries per week), 78% of patients sent providers reports from BlueStar, and 70% of patients sustained engagement with the program (not defined). "Most" participants expressed that they would highly recommend the program and could articulate at least one behavioral change it induced. What was interesting about this model was that it used only two health coaches for 43 patients, and the coaches were not medical professionals (receiving just 16 hours of initial training and periodic follow-up training) - we assume that is pretty scalable. What is hard to piece out from these results, of course, is the relative efficacy: how much did lay coaching and BlueStar individually contribute to improved A1c and self-management in this evaluation? We assume they worked synergistically in this study, and the combo of low-touch phone calls plus 24/7 BlueStar is exciting. Dr. Steven Peskin from Horizon Blue Cross Blue Shield of NJ was a co-author, suggesting this may have been a payer pilot. WellDoc is certainly making moves to scale up, having just hired three new executives and fresh off a $29.5 million round of financing.

- **It was notable that patients only averaged one entry into BlueStar per day,** though we assume there were some power users and some that barely used it at all. Presumably the barrier of having to open the app and enter data prevented more input, and these were high A1c patients that probably weren't collecting a lot of diabetes data anyways (e.g., blood glucose values). We assume the data input will improve markedly when this software is embedded into a LifeScan meter itself, per the partnership announced in March.
- **This small study brings to mind other questions too:** Did patients who used BlueStar more frequently experience a greater improvement in A1c? What separated power users from low users? Which demographic groups were most likely to take advantage of and benefit from the program? Is it possible to now a priori who is more likely to benefit from calls vs. BlueStar alone vs. both?
- **We are intrigued by the model of e-health-supported lay health coaching**, which does seem quite scalable and high ROI. We wonder how payers evaluate these demonstration projects and weigh them with WellDoc's strong published clinical trial data.

Oral Presentations: Management of Hyperglycemia in the Hospitalized Patient (with State-of-the-Art Lecture)

EFFICACY, SAFETY, AND USABILITY OF A CLINICAL DECISION SUPPORT SYSTEM FOR BASAL-BOLUS INSULIN THERAPY IN HOSPITAL ROUTINE CARE

Katharina Neubauer, BSc, MSc (Medical University of Graz, Austria)

Ms. Katharina Neubauer presented data demonstrating the efficacy, safety, and usability of GlucoTab - a mobile decision support system that provides suggestions for insulin dosing - in non-critically ill type 2 patients (n=92). The software aids nurses by providing a starting basal dose based on a patient's age, weight, renal function, and insulin sensitivity and recommending subsequent bolus dosing depending on the patient's food consumption and blood glucose levels throughout the day. Results were solid, especially given the typically inadequate care inpatients with diabetes receive - patients on GlucoTab achieved a mean glucose of 159 mg/dl (baseline: ~220 mg/dl) with 69% of blood glucose measurements in-range (70-180 mg/dl). Notably, the software completely eliminated episodes in which blood glucose dropped below 40 mg/dl and only 2.3% measurements came in <70 mg/dl. Equally importantly, findings suggested that provider's adherence with advised insulin doses exceeded 91%, implying that there was a relatively high level of trust in the automated system (this is always a key question when talking about handing over decision-making to technology). This confirms the huge potential of meaningful clinical decision support in the hospital setting, which could shorten hospital stays and make healthcare professionals' jobs easier. This was not a randomized controlled study, so there could be some study effect, but it's clear that digital insulin titration is a heck of a lot better than what's happening in hospitals right now. We hope to see more work on hospital insulin management, particularly in automating insulin delivery with the technology that is already available.

- **GlucoTab aids nurses by providing a starting basal dose based on a patient's age, weight, renal function, and insulin sensitivity and recommending subsequent bolus dosing depending on the patient's food consumption and blood glucose levels throughout the day.** The process is repeated the following morning, with the new basal dose informed by the objective experience of the patient the previous day - i.e., if there were many hypoglycemic episodes, then the basal dose of insulin would be decreased. This study enrolled 92 hospitalized patients (40 female, mean age = 70 yrs), most of whom were already on insulin.
- **We noticed one unexpected result - pre-lunch blood glucose values were elevated compared with other pre-meal blood glucose levels**. We wonder whether the algorithm could be tweaked to address this concern or whether this was an artifact of the study design in some way.

Questions and Answers

Q: Does GlucoTab account for the number of carbohydrates that the patient eats?

A: No, it only considers if the patient is eating or not.

Q: Do you make adjustments for steroids?

A: Not many patients in our studies were on steroids. It was not in the exclusion criteria, but we have an ongoing clinical trial for patients treated with steroids.

Oral Presentations: Diversifying our Portfolio of Self-Management Intervention Approaches

HYPOAWARE, A BRIEF AND PARTLY WEB-BASED PSYCHOEDUCATIONAL INTERVENTION FOR ADULTS WITH TYPE 1 AND INSULIN-TREATED TYPE 2 DIABETES AND PROBLEMATIC HYPOGLYCEMIA: A RANDOMIZED, CONTROLLED TRIAL

Frank Snoek, PhD (VUMC, Amsterdam, Netherlands)

Dr. Frank Snoek detailed results from a randomized control trial (n=124) investigating the efficacy of HypoAware, a glucose awareness training, in adults with type 1 diabetes or insulin-treated type 2 diabetes.

The four-week training included three moderated workshop group sessions of 2.5 hours each and two online modules; patients using HypoAware were compared against the standard of care at eight clinics in the Netherlands, with measurements taken at baseline, two, four, and six months follow-up. Results showed that HypoAware participants experienced 35% less episodes of severe hypoglycemia compared to control. Further, the HypoAware arm saw a 62% reduction of impaired hypoglycemia awareness, and a 20-30% reduction in "hypoglycemia worries." Notably, 90% of participants completed all three sessions and mean A1c did not change. Dr. Snoek noted that an unexpected 24% of patients in the control group used real-time CGM vs. 8% in the HypoAware group, which may have skewed results (presumably in favor of the intervention). This study shows what a difference education can make, and we wonder if it can be scaled up, reimbursed, and long-lasting; this is extremely high ROI for patients and the healthcare system.

Symposium: Digital Health in Diabetes - Hope or Hype?

LESSONS LEARNED - A CLINICIAN'S PERSPECTIVE ON DIGITAL DIABETES CARE

Howard Wolpert, MD (Joslin Diabetes Center, Boston, MA)

Dr. Howard Wolpert's masterful presentation on the state of digital health shared his belief that technology is going to shift us away from traditional, prescriptive approaches to diabetes care and towards more interactive coaching that targets individual problem areas. The presentation revealed his great enthusiasm for digital health and neatly boiled down the key elements of clinical success in diabetes management into two factors: (i) improving the mechanics of glucose control [e.g., data analytics, insulin/medication optimization]; and (ii) promoting patient behavior change [e.g., identifying problem areas, triggering engagement in self-care]. We're very excited by this sense and hope that HCPs will be able to get enough funding to make this worthwhile. Digital health solutions are particularly promising in Dr. Wolpert's view because they target both these niches, whereas the majority of clinical contact focuses on the former (e.g., prescribing an insulin dose, telling patients what to do). Dr. Wolpert acknowledged that he himself only began to appreciate the promise of digital health when he came to terms with the value of enhancing self-management - "What I began to appreciate is that the biggest change in glucose control in my patients came not when I adjusted their insulin dose but when THEY began identifying their own glycemic trouble spots ... yet we rarely assess this." He suggested that technology creates uniquely teachable moments and allows patients to engage in their own care, thereby creating tighter feedback loops between real-world choices and outcomes (or as Dr. Bill Polonsky likes to say, "Makes something click"). Ultimately, Dr. Wolpert asserted that current therapeutic approaches rely far too heavily on providing data to patients without telling them what it means and teaching them to use it effectively - and what good is that, he asked? Dr. Wolpert's concluding remarks stressed that connecting the dots is where digital health solutions can turn the tide in diabetes care, making patients the ultimate managers of their day-to-day care.

DIGITAL HEALTH AND DIABETES

Chris Bergstrom (Associate Director, Digital Health, Boston Consulting Group)

Mr. Chris Bergstrom's discussion of the past, present, and future of digital health described how the field is poised to make a very real impact on healthcare in the near future. He opened by impressing upon the audience the potential of digital health solutions, noting with examples from Uber to Airbnb how "digital disruption has proven powerful ... the potential is HUGE!" He characterized the previous half-decade as a time of successful idea generation in diabetes that has resulted in dramatic technological progress, suggesting that such progress has and continues to build an infrastructure that will be critical to the success of the field. He drew an analogy to how the proliferation of computers and reliability of the postal service served as lynchpins of the growth of home delivery services (e.g., Amazon, eBay), noting that digital health is similarly at the cusp of having the infrastructure in place to grow exponentially. He stressed, too, the way that various stakeholders in medicine (FDA, entrepreneurs, providers, patients) have become increasingly comfortable with digital health in recent years, citing a number of factors - (i) President Obama recognizing Tidepool's Mr. Howard Look as a Champion for Change; (ii) five-fold growth in EMR adoption between 2009 and 2015; (iii) FDA mobile app guidance documents; (iv) Abbott launching FreeStyle Libre ("an exciting new technology"); and much more - as evidence that the foundation for digital health success is

actively being built. He also predicted that digital health solutions are going to be particularly instrumental to clinical trials, helping the community recruit more efficiently and amass expanded, continuous data sets. Ultimately, he concluded that there is no "silver bullet" for the field and that digital health solutions of the future will instead provide clinicians a diverse toolbox from which to individualize therapy.

- **Among many emerging technology he identified, Mr. Bergstorm shared great praise for Emminens' chronic disease data management platform.** We had never previously heard of this company, who has apparently partnered with Roche to bring a diabetes downloading/ analysis software to Spain. Indeed, slides specifically alluded to glucose analysis though we did not get any details on the platform structure - Is it wireless? What devices and data streams does it support? According to Mr. Bergstrom, additional EU launches and a US launch are planned for the future though he did not share timing. All in all, it is fantastic to see Roche pushing forward on data and connectivity, and we'll hope to get an update from the company when the ADA Exhibit Hall opens tomorrow.
- **As he did in our interview last fall, Mr. Bergstrom noted that the next five years will be all about "acquisitions and roll-ups and partnerships and IPOs."** He stressed that industry is finally comfortable with the concept of digital health, which will allow companies in the near future to focus on collaboration and consolidations between large and small organizations. He identified the big entrants in the digital health space (Google, Qualcomm, Samsung, Apple) along with the large healthcare companies (biopharma, medtech), forecasting that the diversity of players is going to bring fantastic perspective to the field in the coming years.
- **Mr. Bergstorm also spoke during his presentation about the potential of digital health solutions to "offload administrative burden."** In his ideal future, he suggested that digital heath solutions would allow clinicians to practice at the pinnacle of their abilities rather than getting "bogged down in things they are overqualified to be doing [e.g., paperwork, etc.]." He suggested that this is already done in other industries, noting that it isn't a stretch to expect the diabetes field to catch up.

IS TRANSFORMING DIABETES POSSIBLE? LESSONS FROM PARTICIPATORY DESIGN OF DIGITAL HEALTH SOLUTIONS

Joyce Lee, MD (University of Michigan, Ann Arbor, MI)

Dr. Joyce Lee provided an overview of her team's fascinating Nightscout user survey, highlighting the value of lead-user innovation for driving progress in patient-centered technology - "People in the community will not wait for healthcare providers to come up with technology. They won't wait for regulators to regulate, or companies to innovate. They need solutions now." She referenced the strong traction the Nightscout movement has gained over the past few years, noting that since launch in 2013, over 25,000 patients from around the world have reported using the system. According to Dr. Lee, the private Facebook group for CGM in the Cloud now has 18,000 members, making it one of the largest groups representing diabetes on Facebook. Dr. Lee summarized findings from a University of Michigan-led survey of a subset of the Facebook group (n=1,276) - we first saw these results at the 2015 DiabetesMine Innovation Summit and D-Date Exchange, where we were impressed by Nightscout's positive impact on CGM adoption, improved quality of life, and reduction in self-reported A1c. Notably, a striking ~20% of CGM in the Cloud members started CGM as a result of Nightscout and ~9% restarted CGM as a result of Nightscout. Survey respondents reported a significant improvement in quality of life metrics, and a majority stated that they found the technology "extremely empowering" and "not at all prying." Self-reported A1c also indicated that glycemic control improved meaningfully (0.7%-1.2%) pre- vs. post-Nightscout. In addition, survey results suggested that users largely replaced their BGMs with CGM data for insulin dosing; respondents reported taking fewer blood sugar checks per day and giving a greater number of insulin boluses without a meter blood sugar on Nightscout. This reinforces our impression that many patients use CGM for insulin dosing regularly, a fact that has become increasingly pertinent given the upcoming FDA Advisory Committee meeting to vote on a replacement label claim for Dexcom's G5 CGM.

- **Dr. Lee also discussed the "maker movement" mentality, stressing its role in unleashing a cascade of creativity and innovation.** For Nightscout, this has resulted in a plethora of devices, codes, and functionality, providing opportunities for customizing the glucose monitoring experience. [The same is true of the DIY OpenAPS community, which has a lot of overlap with the Nightscout developers.] Dr. Lee noted that patients are also "tinkering" with the system's hardware, creating solutions such as xDrip, a tiny alternate CGM receiver that can be used to receive data from the Dexcom G4 transmitter and send it to other devices.
- **According to Dr. Lee, the current issue is whether or not Nightscout will disappear now that the FDA has approved commercial solutions that display CGM data on personal devices (Dexcom G4/G5, MiniMed Connect).** She believes that Nightscout's popularity will persist, given the high rate of new members entering the community. We believe the influx speaks to the community that Nightscout has created; the wider device compatibility and more "glanceable" and customizable displays on smartwatches; and to the overall message that Nightscout brings to the diabetes community: an empowering solution to help patients and caregivers monitor glucose with increased safety and more peace of mind.
- **Dr. Lee's presentation echoed a valuable JAMA viewpoint she recently coauthored,** which details Nightscout's patient-driven founding, the system's rapid growth, and its impact on changing the current definitions of health production and patient engagement.

Symposium: Technology and Diabetes Care - Your Patients Are Moving Forward. Are You Observing or Moving?

MAKE THE DATA WORK FOR YOU—INCREASING ACCESSIBILITY, INTEGRATION, AND USABILITY OF AMBULATORY GLUCOSE PROFILES

Deborah Mullen, PhD (Park Nicollet Health Services, Minneapolis, MN)

Dr. Deborah Mullen opened her presentation with a simple message: "Diabetes is complicated. Your data shouldn't be." With that context, she took attendees through an overview of the International Diabetes Center's Ambulatory Glucose Profile (AGP) with a specific focus on how the one-page glucose data download report can facilitate personalized medicine. She stressed that one of the biggest gating factors to improved diabetes management is lack of feedback, arguing that AGP software both helps patients understand their own data at home and helps providers provide more individualized feedback in clinic. We've heard lots of enthusiasm for AGP over the past year and Dr. Mullen's commentary echoed much of what we've heard before - however, she did remark on new news that the IDC has signed two agreements in the past week to license its AGP to two diabetes device makers (Roche and Abbott) and two diabetes data management companies (Diasend and Glooko), calling the partnerships a huge step in the right direction. We would agree! (See our coverage of the announcement here for more.) Ultimately, she pushed for even more consensus on this front, emphasizing perfect should not be the enemy of the good - an agreed-upon one-pager will go a long way for clinicians, and she urged industry not to be dissuaded by "not-invented-here" syndrome (plus, as she noted, it would not be too difficult for industry to provide proprietary reports on top of the standardized one-pager).

Questions and Answers

Q: Can you provide a comparison of your product vs. Glooko?

A: Glooko is a licensed AGP partner now. Their newest mobile app actually has the AGP graph on it. We are doing work together. We have partnerships, too, with Roche and Abbott and diasend who all have plans to come to market with AGP soon. That too, we have other partners coming.

IS THERE A NEED AND WHAT CAN BE LEARNED FROM ONLINE DIABETES COMMUNITIES?

Anna Floreen (Glu, T1D Exchange, Boston, MA)

Ms. Anna Floreen provided a comprehensive overview of Glu, an online community for patients with type 1 diabetes and their families. She noted that the Glu community currently totals ~16,000 participants (~11,000 people diagnosed with type 1 diabetes and ~5,000 family members), while its associated clinical program has 74 leading centers and 26,000+ patients in the registry. The Exchange has also collected bio-samples from 2,000 unique patients, offering potential for biological research studies (e.g., C-peptide). Aside from offering a way to collect data, Ms. Floreen stressed that the Glu platform can help study how communities offer support and education through peer networks. She shared results from a 1,000-person survey conducted by Glu, in which a majority of patients reported joining the online community to either receive emotional support, foster learning, give or receive help, and compensate for not knowing others living with type 1 diabetes. Ms. Floreen stressed that such communities of like-minded individuals and families serve an important role in driving better and faster research for improved care, offering a fresh perspective to complement traditional methods of coping with and thinking about diabetes.

Questions and Answers

Q: Is there any concern in the context of insurance coverage when giving medical advice to those who are not specifically patients?

A: We do not offer medical advice, but the community is self-policed by the "report abuse" button. We can take down harmful, misleading, or irrelevant posts.

TELEMEDICINE - AN ENGINE FOR TEAM ACTIVATION

Jodi Krall, PhD (University of Pittsburgh, Pittsburgh, PA)

Dr. Jodi Krall presented encouraging results from the TREAT (Telemedicine for Reach, Education, Access and Treatment) model for rural diabetes care. Dr. Krall first reviewed the rationale for telemedicine, emphasizing that it is a way to reach underserved communities that struggle with high rates of diabetes and a shortage of endocrinologists and healthcare resources. The TEACH model combines team-based care with technology to create a delivery model that enhances care in rural communities. In this model, primary care providers in rural communities connect patients with diabetes to the service, which partners the patient with a local diabetes educator and an endocrinologist located in an urban center. The glycemic management consultation occurs through a virtual video consult. Dr. Krall highlighted statistically significant outcomes, including an impressive 2.1% reduction in A1c (adjusted baseline: 8%) vs. 0.7% with usual care (adjusted baseline: 8.2%) - see the outcomes in Diabetes Care (Toledo et al., 2014). A separate study reported lower diabetes distress and an increase in patient empowerment (Simenerio et al., Diabetes Educator 2014). In a follow-up study, shared decision making aids were incorporated into the model such that the patient was able to be an active participant in developing goals. It's great to see that telemedicine can enable better outcomes in a more efficient care delivery model; of course, this was a trial setting that didn't have to deal with reimbursement, meaning some real-world translation work will be needed.

Questions and Answers

Q: Why couldn't you use a nurse practitioner specialist instead of an endocrinologist? Also, how do you charge for this service?

A: In our model, we had the availability of endocrinologists, so that is why we used them. We did not collect for the TREAT model. Our healthcare system offered the service free of charge. We need to think about how to provide this as a reimbursable service.

Q: The data from your efficacy study is impressive. After the initial consultation, how were decisions made? Who contributed to helping make those decisions?

A: All the patients came back for a 3-month telemedicine visit. In the meantime, between visits, we were working with a diabetes educator in the local community who managed the communication structure and followed up with the patient. But they only received recommendations from an endocrinologist every 3 months.

Q: Do you interact with other specialties? Is that in the plan?

A: We haven't had a discussion about how to expand the model to include additional service lines, but if we can, it would be great and we could provide more holistic care.

Q: As you reached out and made this intervention available in the community, what was the initial response from the primary care sites and how quick was the uptake?

A: We were working with a great diabetes educator who had good relationships with local primary care offices and she was able to encourage them. We were booking patients months in advance and now we simply don't have room in the template to bring in new patients.

DON'T LET TECHNOLOGY SLOW YOU DOWN - WHAT YOU NEED TO KNOW WHEN YOUR PATIENTS USE APPS

Jennifer Smith (Integrated Diabetes Services, Wynnewood, PA)

Addressing an audience of physicians and providers, Jennifer Smith sought to alleviate concerns regarding the use of diabetes self-management apps. She spoke in glowing terms about their potential, noting that apps that provide glucose and trend information have the ability to empower patients in extremely positive ways. That too, she spoke about the burden and stigma of diabetes, noting that digital tools can play an important role in enabling discretion - e.g., smartwatches that are able to sync data, provide vibration alerts, and eliminate the "chore" of removing a device from one's pocket. Ms. Smith also provided examples of some of her favorite web-based and app-based platforms, which ranged from Medtronic's Carelink/ MiniMed Connect and Dexcom's Clarity/G5 to data management offerings from Glooko and Diasend. A unified theme across all her "favorites" was the ability to track data relatively seamlessly, provide accurate information to aid in insulin dosing, and connect to a social network. With these benefits in mind, Ms. Smith stressed that it's providers' responsibility to learn about these digital solutions and encourage patients to explore available apps to find solutions that work best for them. Again, we loved her notion that one size does not fit all and came away with the clear message that apps and digital tools should be individualized in the same way that various drug class should be. In this case, perhaps the risk-benefit tradeoff changes to a burden-benefit tradeoff, which should improve over time as data collection becomes more seamless and results are more automatically analyzed.

Symposium: Inpatient Management of Diabetes and Hyperglycemia - Novel Insights and Effective Approaches

AUTOMATING INSULIN DOSING DECISIONS - BENEFITS, LIMITATIONS, AND COST EFFECTIVENESS

Thomas Pieber, MD (Medical University of Graz, Austria)

Dr. Thomas Pieber shared results of a study that evaluated the clinical usefulness and cost-effectiveness of GlucoTab, a tablet-based workflow management software that provides suggestions for inpatient insulin dosing. The system provides glucose management advise directly at the point of care, by documenting blood glucose levels over time and recommending changes in insulin delivery based on a patient's age, weight, renal function, insulin sensitivity, and food consumption. In a non-randomized study of the device in four clinical wards, results indicated that patients using GlucoTab experienced substantial improvements in glycemic management - the odds of a patient experiencing a hypoglycemic event was 3.1 times lower among patients managed with GlucoTab vs. those not managed with the software (95% CI: 1.4-6.8) while the odds of hyperglycemic events was 2.2 times lower (95% CI: 1.1-4.6). Notably, Dr. Pieber shared that these benefits could theoretically result in cost savings of as much as 26 million euros (~$30 million) per year in direct costs (excluding indirect costs and costs due to medication errors) if GlucoTab were implemented in

all hospitals in his home country of Austria - this would more than cover the projected cost of implementing the program (six million euros). Dr. Pieber admitted that the software's greatest shortcoming is that there is not yet RCT outcome data to support it. However, his team hopes to conduct a larger trial across Switzerland, Austria, and Germany in the near future that will strengthen the body of evidence supporting the software. He did not share any timing and it sounded like financial resources are the gating factor. We wonder if such a trial is even needed, given how grim and difficult some inpatient management is - software really can do this better.

Questions and Answers

Q: How accepting was the nursing staff to this degree of digitalization?

A: This is an important question because it's subjective. We measured acceptance with a questionnaire and they liked it overall because it was organized. However, there is a threshold you have to overcome when introducing a new system, but they grew to like it.

Q: How many different medical or surgical departments and countries has this been evaluated in?

A: We want to get the funding to do a large randomized controlled trial in Switzerland, Austria, and Germany. Currently, our studies are in regional hospitals. Non-university hospitals are our next step.

Q: Was there one tablet per floor? Does the tablet provide other functions, or is the tablet solely dedicated to the practice of insulin management?

A: There would be one in a nursing group, which would take care of between 8-12 patients. The software is also web-based so they would not be limited by the single tablet.

Symposium: Inpatient Management of Diabetes and Hyperglycemia - Novel Insights and Effective Approaches

REMOTE MONITORING OF AND SUPPORT FOR INPATIENT DIABETES MANAGEMENT THROUGH THE INPATIENT EMR

Robert Rushakoff, MD (UCSF, San Francisco, CA)

Dr. Robert Rushakoff provided a comprehensive overview of UCSF's outpatient telemedicine model for patients with diabetes. The program co-opts EPIC's electronic medical record system to allow patients to upload diabetes data from home (e.g., blood glucose, insulin, carb counting, etc.). It automatically flags significant highs or lows to alert providers that certain patients may need additional care and leverages portable videoconferencing hardware to actually allow providers to check in with patients at home. Dr. Rushakoff shared that mean glucose in patients enrolled in the telemedicine program for three years decreased from 171 mg/dl to 166 mg/dl. This difference was statistically significant ($p<0.001$, $n=336$), though Dr. Rushakoff noted "not clinically significant." Instead, Dr. Rushakoff suggested that a more promising finding might have been the reduction in overall workflow time, from 45-90 minutes per patient consultation to 20-40 minutes following the implementation of the program. Put differently, glucose control (as measured by average glucose) has remained roughly the same, while providers are more efficient - that is a huge win in our book. He stressed that the improvements in workflow efficiency have translated to a higher volume of patient consultations and, importantly, more time allocated toward higher-risk patients. Enabling providers to focus their time on patients who need it most is a critical benefit of remote monitoring and digital health, and we hope these programs aren't held to a superiority standard - if they can provide the same outcomes as face-to-face care, but with more convenience and more efficiency, that is a win for the system. The downside, as Dr. Rushakoff noted in Q&A, is that reimbursement for this model doesn't exist.

Questions and Answers

Q: Do you bill for these telemedicine encounters? Can you bill for these encounters?

A: As of now, this process doesn't get billed for anyone. Payment is administered via administrative costs. However, we expect to be paid in the future. As payment systems for inpatient care changes to a bundled

system, this outpatient system should be a huge cost saver. Currently, every time you see a patient using a telemedicine program, that encounter is a loss of money.

Q: How do you preempt acute events, such as a patient having a future procedure?

A: If a patient has a procedure the next day and we don't know about it, then we may still put in a recommendation for an insulin order but the physicians don't have to follow it. Part of the disclosure about e-consultations is that they are recommendations and not binding.

Industry Updates

VICTORY FOR DATA STANDARDIZATION: ROCHE, ABBOTT, DIASEND, GLOOKO SAY YES TO AGP

In a win for data standardization, we learned at ADA that the International Diabetes Center has signed two agreements to license its one-page, standardized Ambulatory Glucose Profile (AGP) to two diabetes device makers (Roche and Abbott) and two diabetes data management companies (Diasend and Glooko). This was terrific news to hear - we're eager to see greater standardization of data and use of that data to drive therapeutic change. The partnerships give the companies the right to use the AGP in all their diabetes devices and existing software; the agreement with Abbott extends the groups' existing partnership to other devices since Abbott already uses the AGP report to visualize downloaded FreeStyle Libre glucose data. Clinicians have for a long time told us how much they like this standardized report and it's fantastic to see that companies are beginning to sign on, especially after hearing for years the laundry list of reasons why industry was hesitant: (i) a desire to maintain control of data due to liability concerns; (ii) a desire to protect against competition by building their own proprietary software; (ii) a desire to preserve their direct relationship with patients; and (iv) the antiquated view that patients do not need access to their data (though we'd note that this is almost gone now.) Indeed, on all these levels, the willingness of Abbott, Roche, Diasend, and Glooko to license the report is a real win for patients and providers alike - after all, not every company is going to get what they want with a standardized report, but the field will benefit significantly from consensus. We're hopeful this creates momentum and these partnerships set the stage for this standardization movement to reach a critical mass - will Dexcom and Medtronic sign on? Along these lines, we learned that AGP partnerships with three additional device companies and aggregators are slated for "the next month," and we'll be watching closely for updates on the IDC team's recently launched website: AGPreport.org.

MEDTRONIC ANNOUNCES NEXT-GEN CARELINK REPORTS TO OPTIMIZE PUMP SETTINGS, GLOOKO COMPATIBILITY, IBM WATSON APP NAMED SUGARWISE, FOOD APP PARTNER: NUTRINO

Medtronic had a number of diabetes data announcements at ADA: (i) next-gen CareLink Pro reports will help optimize basal and bolus pump settings and launch this summer; (ii) Glooko pump/CGM compatibility is finally done and will be out in July; (iii) the name of the IBM Watson app is "SugarWise," the first-gen will launch this summer, and it will only do retrospective pump/CGM data analysis at launch; (iii); and (iv) a new beta app with Nutrino has launched to incorporate food and CGM data via MiniMed Connect.

- **Next-gen CareLink Pro reports to optimize basal and bolus settings:** These will launch this summer and identify optimal insulin:carb ratio, insulin sensitivity factor, and basal rate change. CareLink will suggest which time of day and direction pump settings should change (Increase basal rate from 8am - 12pm). These are step short of the exact recommendations DreaMed will provide with Glooko ("change basal rate to 0.75 u/hr from 8am-12 pm"), but a clear improvement over the status quo!
- **Glooko compatibility:** See screenshots elsewhere in this report, which will officially launch in July. The user interface looks great and adds Glooko's new "Personal Advisor," bringing new pattern recognition features in the patient-facing app (high and low trends by time of day, best day, fun emoji faces, etc.). This integration has been more than a year in the making (Medtronic invested in

Glooko last March) and we give HUGE kudos to Glooko (and particularly Holly McGarraugh) for breaking open the Medtronic CareLink data silo.

- **Medtronic/IBM Watson Health app, SugarWise:** The app is officially named "SugarWise (bringing insight to blood sugars) and is still expected to launch this summer. The first generation app will analyze *retrospective* data and provide insights based on past CGM, insulin, and nutrition data: "William, the last few times you did this, then this happened." The example from last week's Analyst Meeting said, *"In the last 30 days, high glucose pattern found usually after glazed donut for breakfast."* A future-generation version will add the hypoglycemia prediction feature that Medtronic we first saw at CES in January *("In the next two hours, there is a high likelihood that you will go low")*. It's a shame the latter isn't included in this first-gen version, as it seems fairly low risk. On the other hand, getting the accuracy of future hypoglycemia prediction is only one piece of the puzzle - alarm fatigue and data entry burden are both important questions with this feature. Medtronic and IBM have now worked on the hypoglycemia prediction feature with a dataset of 10,000 anonymous patients, showing preliminary prediction accuracy of 75%-86% within a two-to-four hour window.
- **Nutrino food app partnership**: Medtronic and Nutrino launched a beta food app today for customers who use MiniMed Connect, providing an individualized picture of how daily food intake and other measures impact glucose levels - see the video here and download the app here. Nutrino imports the CGM and insulin data seamlessly from MiniMed Connect (from a Medtronic pump) and identifies how different foods affect blood glucose levels, allows patients to take meal pictures, scan bar codes, carb count, and more. Nutrino also gives a FoodPrint that shows how daily food intake, activity, sleep and other parameters affect glucose levels - whoa! From what we can tell, it's a more built out version of Meal Memory, and it can read data from Apple's HealthKit (which presumably means it works with Dexcom CGM and Bluetooth-enabled meters - we're confirming).

GLOOKO SHOWS OFF MOBILE INSULIN DOSING SOFTWARE, NEW PUMP/CGM PERSONAL ADVISOR

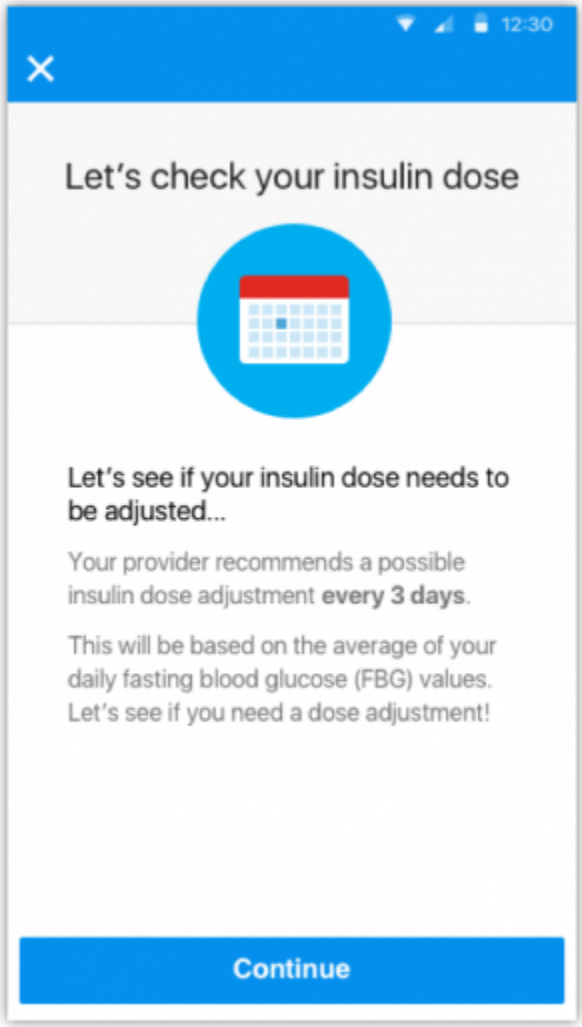
Glooko had its largest exhibit hall presence at ADA ever, flanked by computers highlighting its next-gen work to optimize insulin dosing: the DreaMed partnership to develop a pump settings advisor (clinical trial starting later this year) and its own Mobile Insulin Dosing System (MIDS) to optimize long-acting insulin for type 2s (studies in 2H16, commercial launch in 2017). Both were first announced at ATTD, though we appreciated another look at MIDS in particular, which allows a clinician to select an insulin plan, and then allows patients to confirm fasting blood glucose values and receive constantly updated insulin doses in the app. See the screenshots below. Glooko and Medtronic also announced their integration work is complete and will officially launch in July. The user interface for displaying pump and CGM data looks great and adds Glooko's new "Personal Advisor," bringing new pattern recognition features in the patient-facing app (high and low trends by time of day, best day, fun emoji faces, etc.). This integration has been more than a year in the making (Medtronic invested in Glooko last March) and we give HUGE kudos to Glooko (and particularly Holly McGarraugh) for breaking open the Medtronic CareLink data silo. A massive win for diabetes data! Glooko is riding impressive momentum after its partnership with Insulet was announced in January, and management told us it is in more than 1,000 US clinics now. We love seeing all the new work on optimizing insulin dose titration and have very high hopes it will save the system massive costs, save providers time, and help patients more safely dose this very dangerous drug.

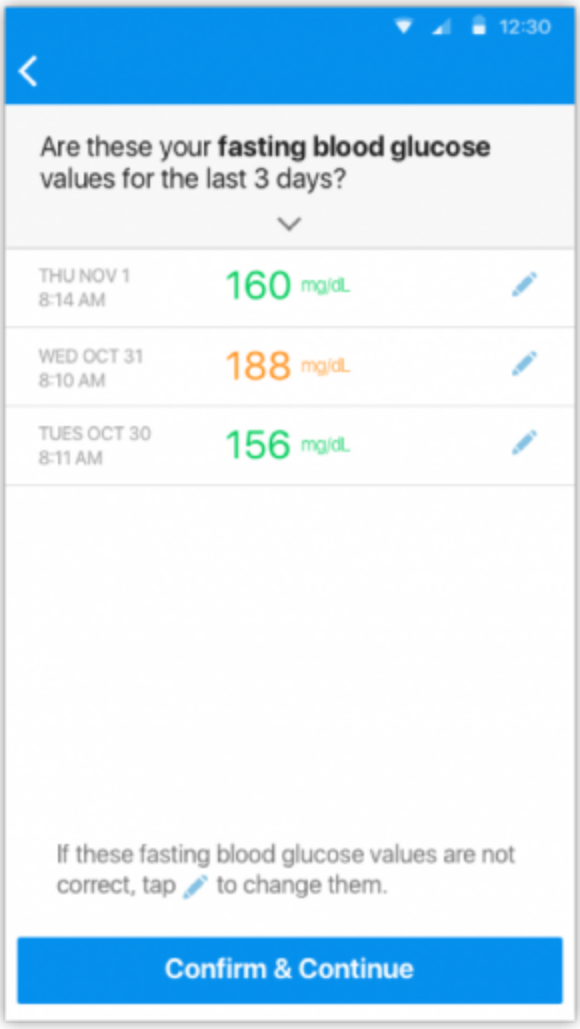
- **Glooko's mobile insulin dosing system (MIDS) for type 2 patients on long-acting insulin will help clinicians and patients continuously titrate insulin based on observed glucose readings (pictures below).** A clinician will select and/or configure insulin-dosing titration instructions, with the option of selecting standard titration schemes (e.g., AACE geriatric dosing template). Clinicians enter a patient's basic information, type of insulin, glucose range, and time periods. A patient's mobile device then receives the personalized dosing configuration, with reminders to check glucose and to take insulin doses. Titration happens on a regular basis based on the glucose readings collected (e.g., from a Bluetooth-enabled meter) and the clinician's

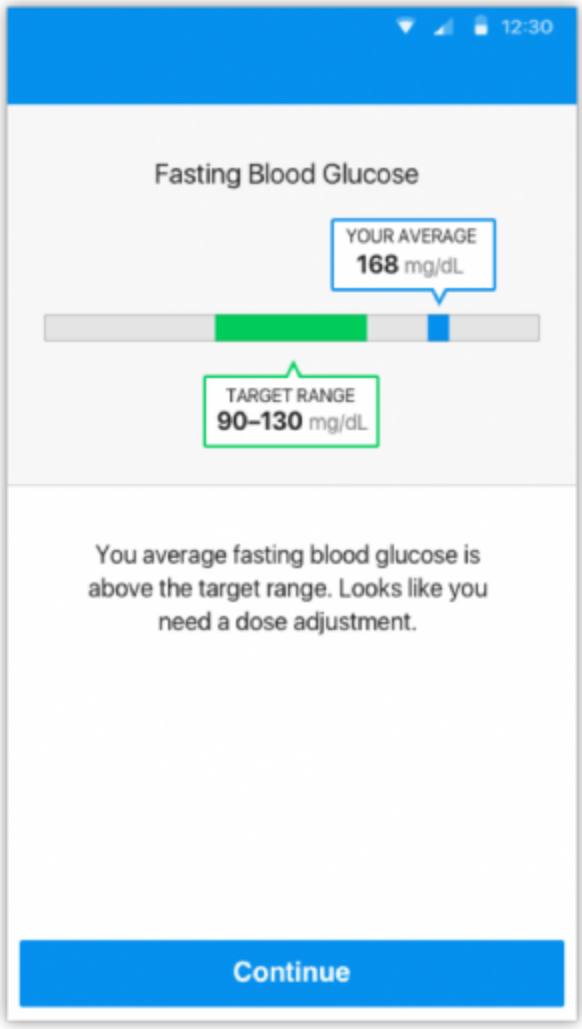
configuration of MIDS. Clinicians can monitor remotely, with everything integrated into EHRs. Glooko is naturally receiving lots of interest from the pharmaceutical industry, medical device companies, and health systems in making this part of their standard of care for new insulin starts.

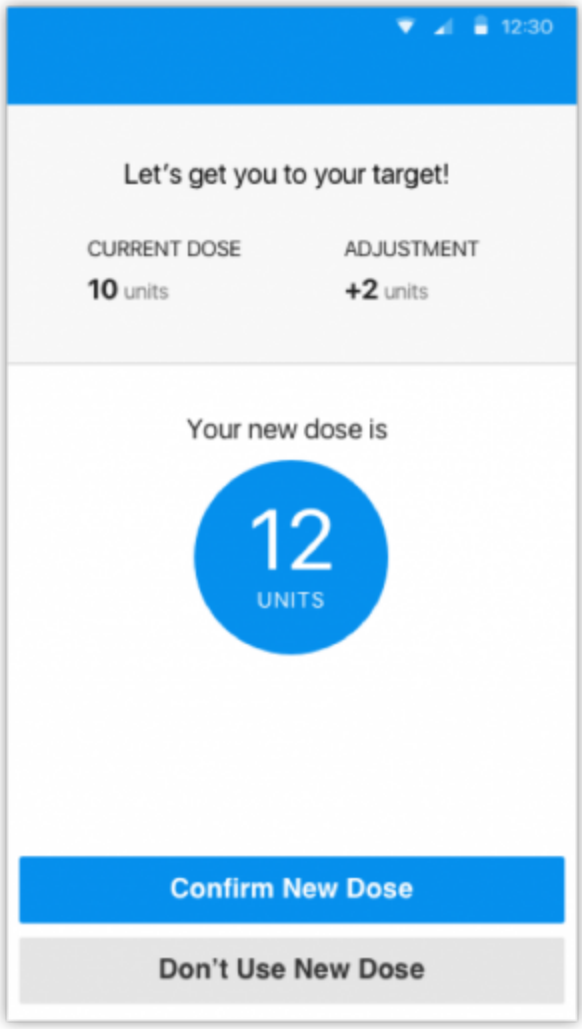
- **Patients will receive notifications such as,** "It's checkup time! Let's see if your insulin dose needs to be adjusted," "Your new dose is 12 units," and "Here's what to do next: take 12 units of Lantus at 9pm every day for the next three days. Check your fasting blood glucose at 7am every day. Your next insulin adjustment will be on Sunday, May 1."

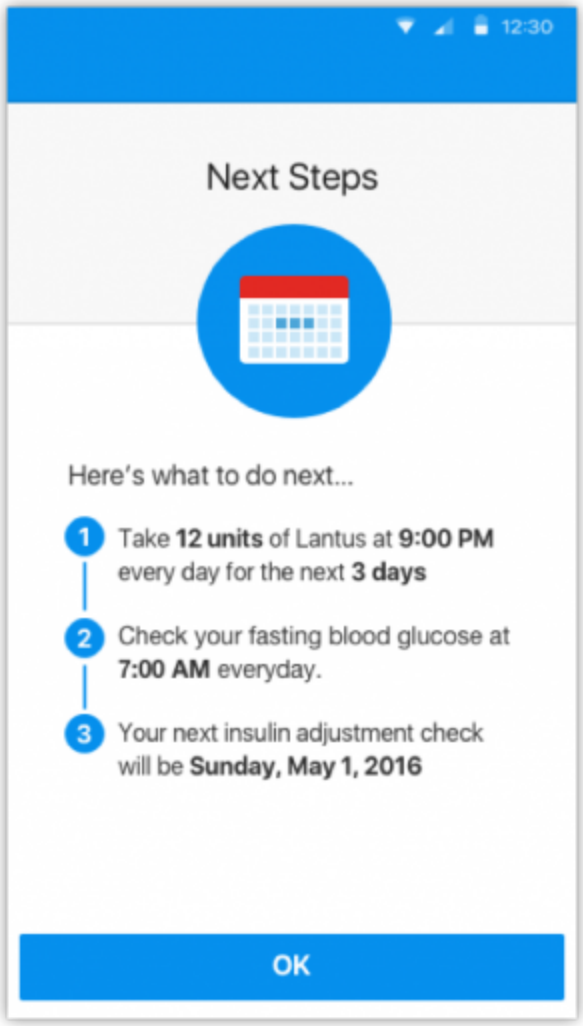
Mobile Insulin Dosing Screenshots



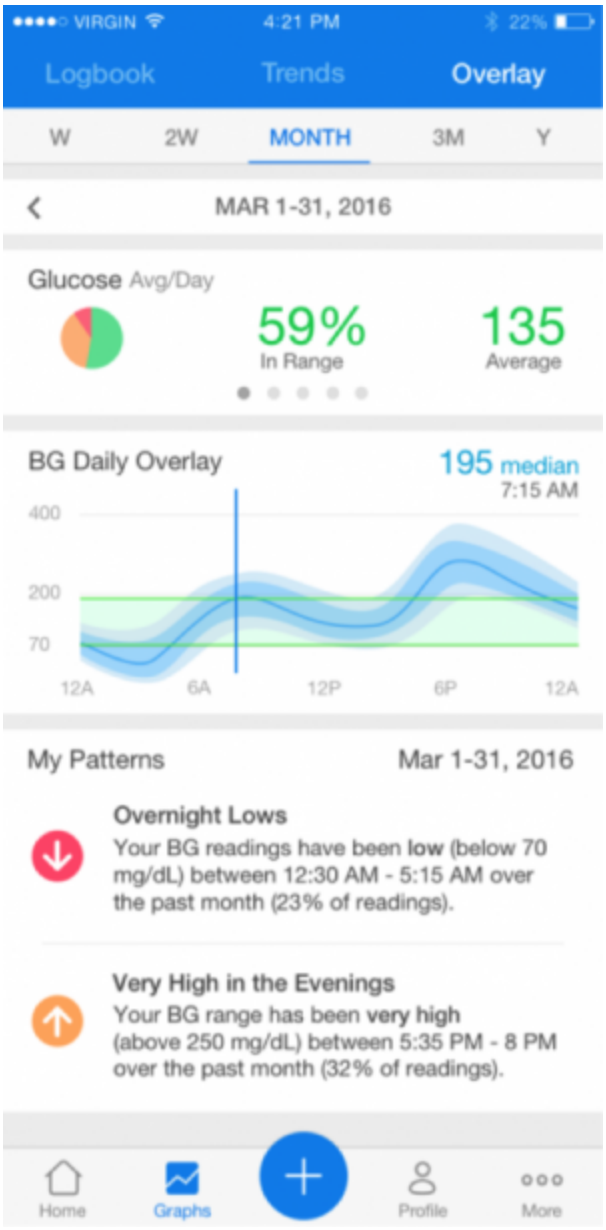

12:30
Are these your fasting blood glucose values for the last 3 days?
THU NOV 1
8:14 AM
160 mg/dL
WED OCT 31
8:10 AM
188 mg/dL
TUES OCT 30
8:11 AM
156 mg/dL
If these fasting blood glucose values are not correct, tap to change them.
Confirm & Continue

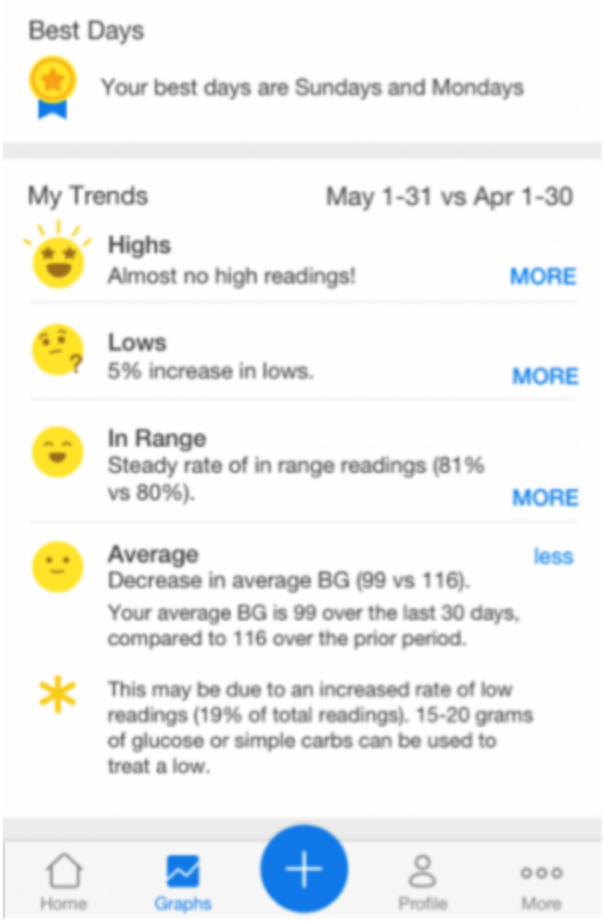

12:30
Fasting Blood Glucose
YOUR AVERAGE
168 mg/dL
TARGET RANGE
90–130 mg/dL
You average fasting blood glucose is above the target range. Looks like you need a dose adjustment.
Continue

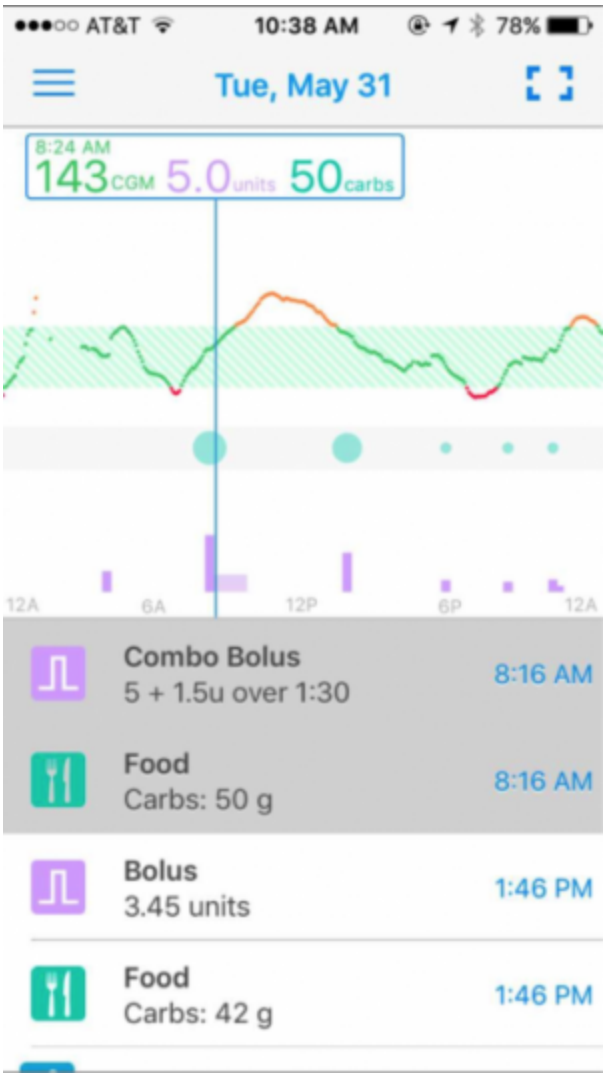

12:30
Let's get you to your target!
CURRENT DOSE
10 units
ADJUSTMENT
+2 units
Your new dose is
12
UNITS
Confirm New Dose
Don't Use New Dose



Glooko Personal Advisor (Pump + CGM Data)


VIRGIN
4:21 PM
22%
Logbook
Trends
Overlay
W
2W
MONTH
3M
Y
MAR 1-31, 2016
Glucose Avg/Day
59%
In Range
135
Average
BG Daily Overlay
195 median
7:15 AM
400
200
70
12A
6A
12P
6P
12A
My Patterns
Mar 1-31, 2016
Overnight Lows
Your BG readings have been low (below 70 mg/dL) between 12:30 AM - 5:15 AM over the past month (23% of readings).
Very High in the Evenings
Your BG range has been very high (above 250 mg/dL) between 5:35 PM - 8 PM over the past month (32% of readings).
Home
Graphs
Profile
More


Best Days
Your best days are Sundays and Mondays
My Trends
May 1-31 vs Apr 1-30
Highs
Almost no high readings!
MORE
Lows
5% increase in lows.
MORE
In Range
Steady rate of in range readings (81% vs 80%).
MORE
Average
less
Decrease in average BG (99 vs 116).
Your average BG is 99 over the last 30 days, compared to 116 over the prior period.
This may be due to an increased rate of low readings (19% of total readings). 15-20 grams of glucose or simple carbs can be used to treat a low.
Home
Graphs
Profile
More



-- by Adam Brown, Samiul Haque, Varun Iyengar, Stephanie Kahn, Brian Levine, Ava Runge, Tony Thaweethai, and Kelly Close