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Digital Diabetes Congress 2017

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Abstract

The purpose of developing mobile applications for diabetes is generally to: (1) provide enhanced access to timely information for patients, health care professionals, and researchers; (2) facilitate remote monitoring and diagnosis of patients, often based on information delivered by wearable devices; (3) provide decision support to assist patients in selecting treatment; or (4) deliver timely recommendations for treatment to increase adherence to prescribed therapy. There is a perception that mobile applications can provide meaningful clinical benefits, however, there is only sparse convincing evidence to support this belief at the present time. Compounding this problem is the short life span of digital software, such that if a traditional type of randomized controlled trial is conducted on a product, by the time the study has been designed, approved by an IRB, conducted, and analyzed, the product might have significantly changed to a next generation system. Because of great interest in establishing what are the potential benefits, metrics of success, and appropriate components of mobile applications for diabetes, Diabetes Technology Society and William Sansum Diabetes Center launched the Digital Diabetes Congress, March 7-8, 2017, in San Francisco. This report contains summaries of the meeting's 12 sessions. Each summary was written by the session's moderator who helped develop the session prior to the event and keep it on track during the event. This meeting report presents a summary of how 57 panelists, speakers, and moderators, who are leaders in digital health, see the current and future landscape of digital health tools applied to diabetes.

Keywords

cybersecurity, apps, digital diabetes, privacy, data

Session 1: How to Create a Successful App and Define the Metrics of Success

Moderator: Jenise C. Wong, MD, PhD, University of California, San Francisco, San Francisco, CA
Panelists: Rick Altinger, MS EM, Glooko, Palo Alto, CA
Anand Iyer, PhD, MBA WellDoc, Baltimore, MD
Pierre Leurent, MS Voluntis, Cambridge, MA
Shelagh Mulvaney, PhD, Vanderbilt University, Nashville, TN

Digital health tools have the potential to help improve the lives of people living with diabetes and those who care for them. In the opening session, four leaders in the field of diabetes apps spoke about their digital solutions, key partners and considerations in the development process, how they provided evidence and evaluated the success of their apps, and the importance of aligning financial incentives for users, health care providers, and payers. The panel discussed three barriers to adoption of digital health and provided potential solutions. First, different users have different needs, and apps cannot provide a single solution for multiple situations. In

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designing an app, it is critical to involve users in design and implementation to ensure successful integration with daily lives or workflow. Second, users and payers need clinically relevant outcome data to drive adoption. Fear of loss of ownership of ideas and cultural barriers between academia and industry can stand in the way of generating high quality evidence. The panel encouraged close collaboration between researchers and industry to design evidence-based solutions backed by data from randomized controlled trials or other rigorous study designs. Finally, users need incentives and want to understand the value of digital solutions. Digital health designers should engage users on clinical outcomes, financial rewards, and/or increased quality of care, considering that the ideal app may enable users to spend *less* time on diabetes and using apps, encouraging them to engage only when necessary and appropriate.

Session 2: Pathways to Regulatory Approval

Moderator: Yarmela Pavlovic, J.D., Hogan Lovells US LLP, San Francisco, CA
Panelists**:** Courtney Lias, PhD, US Food and Drug Administration, Silver Spring, MD
Bakul Patel, PhD, US Food and Drug Administration, Silver Spring, MD
Elaine Tseng, JD, King & Spalding, San Francisco, CA

Many types of digital diabetes technology are actively regulated by the Food and Drug Administration as medical devices, while some tools either are not medical devices or are not actively regulated by FDA at this time. Recent changes to the Agency's statute following passage of the 21st Century Cures Act help to clarify regulatory status for certain software tools, but for others further correspondence with the Agency is needed before certainty about regulatory status can be reached. Nonetheless, where FDA does actively regulate diabetes technology, the Agency is aware that product innovation is important to meet the needs of the community, particularly when it comes to therapy delivery tools. FDA believes that innovations, such as using a commercial smartphone as the primary user interface of a system, are important for addressing patient needs. Issues such as delivery of alarms when a phone is in quiet mode and managing operating system updates must be addressed, but are not true obstacles to development. In addition, while therapy delivery tools, such as closed-loop artificial pancreas systems, are designed today with very specific components, the FDA envisions a time when interchangeability and interoperability of components is a reality, though the necessary steps to reach that goal are not yet fully understood. The Agency continues to work with industry to bring new technologies to market.

Session 3: Defining the Population of Target Users Within the Diabetes Global Village

Moderator: Suneil Koliwad, MD, PhD, University of California, San Francisco, San Francisco, CA
Panelists: Cynthia Castro Sweet, PhD, Omada Health, San Francisco, CA
Christopher Glibert, MBA, Insulet Corporation, Billerica, MA
Courtney Lyles, PhD, University of California San Francisco, San Francisco, CA
Jennifer Schneider, MD, MS, Livongo Health, Mountain View, CA

Panelists from the diabetes technology industry, as well as academia, discussed three challenges to the development and use of technological approaches to prevent and treat diabetes. The first focused on addressing diabetes in vulnerable populations while competing successfully in the marketplace. Solutions focused on conducting clinical studies, including those involving academic collaborators, and targeting digital tools toward specific populations, including underserved, low-income, elderly, and those with multiple chronic medical problems. There was agreement that more successful studies are needed to produce tailored, personalized, and durable diabetes tech solutions.

Another challenge focused on targeting personalized tech solutions specifically to people taking insulin. Solutions centered on gaining a detailed understanding of how users live their lives, and tailoring products accordingly. Another solution focused on optimizing partnerships between makers of meters, pumps, CGM devices, and other insulin delivery systems to benefit specific patients. It was also deemed critical to make sure that these improved solutions are accessible, affordable, and fit in within the current climate of health care reimbursement.

A final challenge had to do with the importance of culture and language when developing tech solutions for diabetes and its prevention. Language-specific phone systems, meters and devices, and culture- and language-sensitive coaching platforms were discussed as responsive solutions.

Session 4: User Interface/User Experience Including the Place of Gamification

Moderator: Julia Hu, MBA, LARK, Mountain View, CA
Panelists: Dennis Boyle, MS, IDEO, Palo Alto, CA
Joel Goldsmith, Abbott Diabetes Care, Alameda, CA
Pek Pongpaet, Impekable, San Francisco, CA
Patricia Salber, MD, MBA Health Tech Hatch & The Doctor Weighs In, Larkspur, CA

We were joined by experts in hardware design, software design, and health care systems in discussing the importance of UI and UX in the treatment and management of diabetes. There is a promising, growing trend of creating health care devices, apps, and services that are as delightful to the end-user as consumer products are.

The top goals of good UI and UX for medical devices, apps, and services are

(1) to lower the barriers to use
(2) to "design delight" into an experience that is highly intimate and personal
(3) to create long-term engagement such that the health outcome goals are achieved
(4) to design the engagement to be short and just enough without spending too much of the users' time, quite unlike most consumer offerings.

However, the major barriers of designing delightful health care services and devices are the sometimes competing critical needs to fulfill regulatory and safety standards, the extremely long design cycles, and the need to service multiple masters (not just the patient but the health system and the providers).

The panel found that the best ways to address this multivariate problem for better hardware design is to provide "sacrificial prototypes"—create a lot of prototypes so that people don't fall in love with one solution too early. For better software design, a great tactic is to "build mass customization"—to think of software as a platform to build semicustomized solutions for different cohorts of individuals.

Session 5: Social Media and How to Harness Their Potential

Moderator: Patricia Salber, MD, MBA, Health Tech Hatch & The Doctor Weighs In, Larkspur, CA
Panelists: Anna Baker, American Diabetes Association, Alexandria, VA
Deborah Greenwood, PhD, RN, BC-ADM, CDE, FAADE, American Association of Diabetes Educators, Chicago, II
Scott Johnson, mySugr GmbH, San Diego, CA
Joyce Lee, MD, MPH, University of Michigan, Ann Arbor, MI
Amy Tenderich, MA, DiabetesMine, San Francisco, CA

This panel of active social media users discussed a range of topics related to the use of social media in diabetes management, including:

Breaking down isolation

Connecting people to peers

Diabetes management challenges

Diabetes education

Recruiting for clinical trials

Three of the barriers identified by the panel were as follows:

(1) How do you engage people who are unfamiliar or intimidated by the technology or social process? One solution, used by American Association of Diabetes Educators, was to convene a Tweet Chat at their Annual Meeting. This allowed users to see a Tweet Chat in action, become familiar with the rapid fire, somewhat disjointed conversation, and gain confidence to jump in as a participant.
(2) Another problem that was identified was sorting out reliable from unreliable information, a problem that is magnified in this age of fake news and use of paid social media influencers. The panelists felt that one way to sort this out is to encourage use of reliable sites that have influencers who are already active in the community, people who are known for their knowledge and passion about the topic. The panel felt that people in these active online diabetes communities will call out bad information, a form of self-policing that they felt obviates the need for more formal policing of content.
(3) Many doctors view social media as a nuisance and, so far, there are few formal outcome studies related to the value of online peer support. This may be changing as digital diabetes companies publish their own outcome studies. There is still a need for more rigorous, independent studies to make their way into high quality peer-reviewed journals, but to date funding for such studies has been limited.

Other issues that were raised included how to make social media work for people who are not social, how to help people understand whether they should trust a site or not, and how to use social media to communicate about digital health solutions and still comply with FDA and other regulatory requirements. We are still in the early stages of understanding how to harness the power of social media for the benefit of the diabetes community.

Session 6: Promoting Adherence to Digital Health Devices and Interventions

Moderator: Adrian Aguilera, PhD, University of California, Berkeley, Berkeley, CA
Panelists: Korey Hood, PhD, Stanford School of Medicine, Stanford, CA

Julia Hu, MBA, LARK, Mountain View, CA
Neal Kaufman, MD, Canary Health, Los Angeles, CA
Chandra Osborn, PhD, MPH, One Drop, Informed Data System, Inc, Nashville, TN

Addressing Barriers to Engagement

Personalization. A major theme when discussing the barriers to engagement in technology-based interventions for diabetes was the need to personalize interventions to users. One panelist recommended segmenting the population of interest to better target groups. Another suggested building a behavioral model of each person to intervene at the right times by looking for deviations and opportunities. Specific segments that were discussed were individuals with low health literacy, people who needed human support (real or perceived), and individuals with generally low motivation to engage in behavior change.

Narratives and Storytelling. An overarching theme of the session was low levels of getting engaged and staying engaged with digital health tools. A possible solution that continued to arise was the idea of storytelling and building a narrative to elicit emotions that motivate positive behavior change. Part of that was the idea of "emergence," which was described as emerging someone in an experience and not breaking that experience.

Financial Incentives. The panelists discussed the use of financial incentives and provided an example of an 84% response rate to a text messaging intervention for diabetes when paid a modest amount to respond compared to around 50% in nonpaid interventions. However, financial incentives may not work for everyone as there are different motivations to achieve improved health. In addition, the panelists questioned how long the effect of payments might last.

Session 7: Good Idea, Now Find an Investor!

Moderator: William Long, B.A., Stonepine Advisors, Menlo Park, CA
Panelists: Leslie Bottorff, GE Ventures, Menlo Park, CA
Wende Hutton, MBA, Canaan Partners, Menlo Park, CA
John Ryan, Onset Ventures, Menlo Park, CA

The panel discussion highlighted investments made by panelists and the characteristics that made these investments attractive and financially successful. The venture capitalists also outlined a number of issues that make it challenging to select investments in the diabetes technology sector. For this summary of the discussion, we will focus on the following topics:

(1) The healthy start-up financing ecosystem, entrepreneurial energy, and desire to help people with diabetes and other medical conditions have resulted in the creation of hundreds of companies. Traditional venture capitalists find it overwhelming and challenging in the current environment to identify attractive investment opportunities.
(2) Many of the companies developed in this healthy start-up ecosystem are led by entrepreneurs with little health care experience and in many cases the companies have not addressed a series of issues that are critical for complying with regulatory requirements, demonstrating efficacy, and integrating into clinical and IT environments.
(3) The panelists believe that in addition to proof of efficacy, that making the patient engagement simpler and less time consuming is one of the most important elements to developing a successful diabetes technology company.
(4) Developing apps, products, and services in diabetes technology sector is but one of the first steps building a successful company. The panelists explained that as hard as it is to work though the technical and regulatory processes toward market introduction, distributing and selling products into a crowded and complicated ecosystem is often even more challenging and capital intensive.
(5) Early stage financing is the first step in a venture capital investment that in successful situations leads to the return of capital to investors through a sale of the company or initial public offering. The panelists believe it is important for the company and investors to have future financing and exit hypotheses at the time of initial investment.

1. Many early stage companies in diabetes technologies make it challenging for VC's to currently identify attractive investment opportunities.

The healthy start-up financing ecosystem, entrepreneurial energy and desire to help people with diabetes and other medical conditions, has resulted in the creation of hundreds of companies. Some of these companies are as simple as a mobile phone app and others as comprehensive as integrated solutions that connect the patient with blood glucose monitors and insulin pumps and medical professionals. The VC panelists' view was that with so many relatively young companies, they believe that successful companies will emerge, but in the current environment, they could not easily identify the eventual winners. With this assessment, the panelists said that they would prefer to selectively engage companies and wait for signals of success to become evident before making an investment. The VC's were also concerned with significant competition from within the start-up ecosystem and from more established, sophisticated incumbent companies,

many of which have more experience in the sector. The venture capitalists stated that one of their key selection criteria was that the product and company were developed with a strong understanding of patient needs, which they felt many current generation diabetes technology companies did not understand well enough.

2. Knowledge of the complex health care ecosystem is critical from inception of a company.

Diabetes technology companies started and developed by entrepreneurs and executives without life science experience may not be aware of the clinical, regulatory, and commercial complexities of developing and commercializing products and services. Unlike many technology products and services developed for consumer and business enterprise markets, life science companies face a series of complex requirements that must be addressed to successfully develop, commercialize and scale their offerings. The highest standard in developing a life science technology company that is involved in the patient care pathway is deciding on the clinical endpoints you are seeking to impact and establishing clinical goals to prove effectiveness. There are a range of accepted standards for proving clinical efficacy from small proof of concept trials to large randomized controlled trials. From inception, entrepreneurs should have a framework of when and how they wish to demonstrate clinical efficacy to patients, caregivers, payers and regulatory agencies. When thinking about setting the company standard for proof of clinical efficacy, it's important to understand the patient care ecosystem in which the product or service will be used. With diabetes technology, companies should carefully consider the clinical proof standards set by incumbent technology. Clinicians, especially physicians, health insurance payers, employers and other customers will want to see proof of efficacy before supporting a product. The panelists thought this proof of efficacy was often not taken seriously enough in direct to consumer products.

3. Making the patient engagement simpler and less time consuming is one of the most important elements to developing a successful diabetes technology company.

One of the venture capitalists stated that "I think anything that reduces the amount of time people need to spend managing diabetes is a pretty good bet". The other panelists agreed with this statement. The VC's highlighted two issues that do not reduce time needed to manage diabetes. The first issue is that many diabetes technology solutions add steps and interfaces that are not thoroughly integrated with existing devices and workflows. Innovations in many cases make care more complicated and time consuming. The second issue is that many diabetes management products and services require extensive patient and caregiver interaction to achieve intended clinical outcomes. This more demanding interaction can create significant hurdles to adoption and compliance.

4. Scaling a diabetes technology company is complicated and expensive.

The venture capital panelists presented examples of companies that successfully developed and launched products. In one example the venture investor discussed an insulin pump that was successfully brought to market and then was not able to break through with revenue growth. In this example the simple inexpensive insulin pump was targeting patients with type 2 diabetes. The product was easy to use and the company had produced large amounts of clinical data to support clinical efficacy. The company and investors miscalculated the expense it would take to break into a well-established market and demonstrate their product differentiation. The company has struggled for some time to build revenue.

The venture investor then provided an example of how the Glooko diabetes management system addressed the market break through challenge from the inception of product design. The first step that Glooko took was to specify and build the foundational technology. They started the product design process with the regulatory, clinical outcomes and compliance milestones in mind. From company inception, the executive team embraced the likely FDA regulatory pathway for an insulin dosing application and its interfaces with blood glucose monitors and insulin pumps. Glooko integrated with approximately 90 blood glucose monitors and insulin pumps devices to collect data and provide a consistent mobile-phone app user interface for patients and clinicians. When clinicians learned and became comfortable with the user interface, they only had to learn it once, even though they were reviewing data from dozens of devices. The product fit into the physician work flow and streamlined it. The consistent patient user interface and integration with existing devices, enables Glooko to focus development efforts on a consistent, evolving user interface.

Glooko's partnering and integration approach enabled them to benefit from the substantial installed bases, education and marketing resources of their diabetes ecosystem partners. This approach led to the company having wide product adoption without having to go direct to consumers and spending substantial capital on market development. The panelists contrasted this integrated platform approach to the many siloed, niche products and services available, especially mobile phone apps.

5. When considering investments, venture investors consider how much additional financing is needed and the likely path to have their capital returned through a sale of the company or IPO.

As previously noted by the panelists, diabetes technology companies should consider regulatory and compliance requirements from inception. When raising capital at more developed stages of the company, seasoned life sciences investors will carefully consider the company's compliance

with regulatory standards, including methods for developing software that will impact patient care and be integrated with existing devices and applications. When evaluating these areas, investors will develop a sense for the investment and timeframes needed to come into line with their own standards before investing. Some of the key areas investors will evaluate include: documentation and compliance with FDA regulations, HIPAA compliance, and robustness of security elements. These issues are best addressed from inception and they are complicated and expensive to address later in the product and company development processes.

Many diabetes technology companies will likely be M&A candidates for large franchise players. Without a strong regulatory and compliance provenance, large acquirers will not consider an M&A purchase. The investors discussed how many of the current generation of diabetes technology companies do not easily fit within the ecosystems of large franchise medical device, pharma and health care IT players. This has two implications; first, it will likely cause the companies to have to raise more capital on their own to finance commercialization and growth and, second, the probability of an M&A exit at an attractive valuation is likely lower.

Session 8: Business Modeling—Scale and Sustainability

Moderator: Giles Hamilton, FRSA, Orbital Diagnostics, San Francisco, CA
Panelists: Casper de Clercq, Norwest Venture Partners, Palo Alto, CA
David Goodman, MD, MSE Sunday Medical Clinic, Greenbrae, CA
William Long, Stonepine Advisors, Menlo Park, CA

The principal barrier to digital health adoption the session identified was the lack of financial reimbursement for physicians and companies developing digital health products and services.

For wide-scale adoption, clinicians require payment incentives to use of digital tools in their practice. Digital health investors and technology companies are unlikely to achieve scale based on business models which rely on patient self-pay. Reimbursement is required to make a return on their investment and support digital health products in the field.

At least three randomized control trials showing meaningful clinical benefit and evidence of positive financial returns for payers are required to secure reimbursement. In practice, multiple further studies over several years to secure engagement with payers are often required to gain national coverage.

The second barrier identified was many digital health tools require patients and clinicians to undertake additional steps in their daily lives and practice.

The solution identified were minimally invasive apps and technologies that are ideally seamless with current clinician and patient behaviors. Interfaces with digital health which improve and sit within existing workflow for clinicians was seen as a way of increasing adoption.

The final barrier to adoption was seen as reliance on conventional business models to develop digital health. These can be overcome by using innovative business models that focus on unlocking economic drivers for adoption at all points in a digital health deployment. In addition to conventional parameters for success in medical products, inclusion of net promotor scores can help make the case to payers to show quality of engagement.

Designing a business model based on taking a holistic view of the requirements of all stakeholders and incorporating use of success models in nonmedical technology roll outs when developing digital health solutions may significantly reduce time to reimbursement, clinical, and patient adoption and subsequent benefits.

Session 9: Value Added Opportunities for Pharma and Device Companies and the New Players in Health Care

Moderator: David Kerr, MD, FRCPE, William Sansum Diabetes Center, Santa Barbara, CA
Panelists: Giles Hamilton, Orbital Diagnostics, San Francisco, CA
Michael Kloss, Ascensia Diabetes Care, Basel, Switzerland
James Malone, MD, Eli Lilly, Cambridge, MA
George Savage, MD, MBA, Proteus Digital Health, Redwood City, CA

Questions

What does value look like for people with diabetes, clinicians and payers?
Do we need better devices and drugs or a more holistic management approach, and where can digital health help?
How should the world of diabetes be segmented beyond type 1 and type 2 diabetes?
Will we eventually see clinical trials of a digital health product versus traditional pharma products and what will the design of a trial of a digital health product look like?

Summary of Discussion

Value can mean different things to different stakeholders (people with diabetes, clinicians and payers). Beyond HBA1c, metrics gaining importance are (a) quality of life, (b) more cost-effective use of existing resources including sustained adherence to therapies, (c) positive benefits on clinician productivity and the use of technology to create "anticipation" of future events. Digital technologies were also viewed as more than just tools to improve on existing pharmaceutical products by

offering a more holistic approach to diabetes care. For this there need to be outcomes that are meaningful and not just the use of surrogate measures or engagement. Consumer innovation has occurred as a consequence of redefined business models rather than directly through technological development. One concern is the perception that digital health is offering earlier access to clinicians but not always to the same clinician—negatively affecting continuity of care.

Should diabetes be segmented beyond simply type 1 versus type 2. Suggestions included "down to the individual (ie, n = 1 personalized care)" to "it's impossible to tell a priori so let's make all data available to everyone." Others could be duration of diabetes or hypoglycemia risk as segmenting variables or targeting "high-cost" individuals with digital health such as smart insulin pens. Payers also need to consider new models of reimbursement to reverse the existing perception that products requiring more cognitive inputs are reimbursed at a higher rate than more simple technologies. All panelists felt that in the future and in addition to supporting pharmaceutical products, digital health technologies may also compete directly with medicines.

Barriers and Solutions to the Adoption of Digital Health

Lack of clinician and payer engagement is that these stakeholders do not consider engagement as an important metric of success. They need evidence from clinical trials and real-world experiences the latter by creating postmarket introduction registers with a priori defined metrics of success that matter to people with diabetes.

Many existing products lack a target audience. The solution is to create segmentation of the market and for this early clinical input during the development phase is crucial as is focusing on the user interface and experience.

The burden of diabetes falls unfairly on minorities in the United States, yet they are invariably not major participants in development and clinical trial phases. More effort should be applied to enhance minority engagement.

Session 10: Data Streams From Multiple Sensors—Volume, Velocity, Veracity, Variability, and Variety

Moderator: Kong Y. Chen, PhD, MSCI National Institutes of Health, Bethesda, MD
Panelists: David Delaney, MD, SAP, Boston, MA
Howard Look, Tidepool, Palo Alto, CA
Daniel McCaffrey, Dexcom, San Diego, CA
Huzefa Neemuchwala, PhD, MBA, Medtronic Diabetes, Northridge, CA

Diabetes is a chronic disease that requires self-management. Advancements in sensor technology and wireless communication present wide-open opportunities for advancements of personalized diabetes care solutions. The real-time signals streaming from on-body wearable sensors, together with contextual data from diet to behavior and environments, are important yet challenging for the people living with diabetes, their families, caretakers, and clinicians (the care continuum). To make sense to each of these audiences, data needs to be and be presented in simple, meaningful, and actionable ways. To achieve this goal, various advancements in medical device connectivity, processing, patient engagement, and machine-learning analytics are required. Since diabetes management is dependent on the context of the individual, such advancements also need to consider collecting other sensor data such as those from wearables and food logs. Data security and patient privacy are paramount considerations in any such endeavor. Some believe that the industry should adopt open data protocols to make such data available and accessible to everyone, while making it secure. If device makers and app developers make data protocols transparent, it could help foster a vibrant ecosystem for digital diabetes management. Machine learning and big-data analytics can help uncover and model potential connections and modifiers previously unknown, such as glucose correlations and predictions that can drive behavior change. Large datasets will yield generalized predictions, and advanced machine learning and artificial intelligence techniques will optimize precise solutions for individual users with their own historical data and models from similar cohorts. There are still significant gaps to overcome for the future, such as measuring diet, sleep, stress, and physical activities, and accessing primary data for some devices and interoperability are still challenging.

Session 11: Cybersecurity and Privacy

Moderator: David C. Klonoff, MD, FACP, FRCP (Edin), Fellow AIMBE, Mills-Peninsula Medical Center, San Mateo, CA
Panelists: David Kleidermacher, BlackBerry Limited, Santa Barbara, CA
Billy Rios, WhiteScope, Half Moon Bay, CA
Christine Sublett, Sublett Consulting, LLC, San Mateo, CA

Four topics were the emphasized during this session. The first was the definitions of security and privacy, the second was the significance of the recently released DTS cybersecurity standard for connected diabetes devices (known as DTSec), the third was the importance of balancing the advantages and disadvantages of regulating cybersecurity in diabetes devices, and the fourth was the need for a standard for mobile phones controlling medical devices.

(1) Security is the protection of resources or assets against threats. Almost everything we can consider as a

security capability is to protect resources against threats. Privacy is a subset of security which is just a different set of resources and perhaps a different set of threats and ultimately a different set of controls that are there are being used to counter those threats. But in the end privacy is just is just a subset of security.

(2) DTSec is a cybersecurity standard intended to provide the device stakeholder confidence in the security of that product. The biggest problem in the medical cybersecurity world is that we do not have confidence in the security of our medical devices. The only way to know a product is secure is to put it through an evaluation against requirements that were developed by the broad stakeholder community performed by an accredited lab. Security risk cannot be completely eradicated, but the level of attack potential that can be protected against can be raised to be adequate for a defined threat potential.

(3) Cybersecurity regulation must be evaluated in light of the fact that there has not been a publicly reported hack of a patient using a medical device. On the other hand, representatives of FDA and Department of Homeland Security are closely monitoring this field and support development of technologies that can help defend medical devices from cyber-attacks. There must also be a balance between the potential benefits of FDA approving a medically beneficial product against its risks if it were to have poor cybersecurity. In such a case, FDA might look at what are the risks and benefits to postponing some of the steps needed to assure security to the postmarket phase if that were to make sense.

(4) Mobile devices are being used as remote control devices to run critical algorithms. There is no pathway currently for an off the shelf mobile device to be used in life critical control, such as an artificial pancreas. It would be exciting to leverage a smartphone for life critical use. A consensus standard is needed so all the stakeholders can have confidence in using these types of mobile devices. This is a needed project in the field of digital health.

Session 12: Integration Into the Electronic Medical Record—It Has to Happen

Moderator: Saleh Adi, MD, University of California, San Francisco, San Francisco, CA

Panelists: Bernard Harris, Jr., MD, MBA, FACP Vesalius Ventures, Houston, TX

Aaron Neinstein, MD, University of California, San Francisco, San Francisco, CA

Linda Sanches, AB, MPH, US Department of Health and Human Services, Washington, DC

Devin Soelberg, Redox Engine, Madison, WI

The general consensus is that at least some diabetes data must be documented in the patient's EHR. Today, diabetes devices (such as pumps and CGMs) can generate and store a massive amount of data. Much of these data are geared toward aiding the patients in their self-management of diabetes. However, when a portion of the data is reviewed to make clinical decisions such as a change in insulin regimen and/or medications, these data must be integrated into the electronic charts to support the rationale for the changes, and to provide basic documentations for coding and billing purposes. To keep electronic patient charts clean and nimble, the remaining portions of the data would ideally be aggregated to live on a separate HIPAA compliant and secure platform, which can be linked directly to a patient's EHR, both for clinical use as well as research purposes to extract clinical information to be linked to research projects analyzing the big data repositories that live on the data platforms. However, there was significant skepticism about the possibility of connecting various data platforms to different EHR systems, especially if individual institutions or medical centers should undertake such initiatives, which may not be considered to be a high priority.

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