Journal of Diabetes Science and Technology
2019, Vol. 13(5) 979–989

DOI: 10.1177/1932296819872107
journals.sagepub.com/home/dst
SAGE

Digital Diabetes Congress 2019

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Abstract

New applications of digital health software and sensors for diabetes are rapidly becoming available. The link between healthcare, wearable or carryable devices, and the use of smartphones is increasingly being used by patients for timely information and by healthcare professionals to deliver information and personalized advice and to encourage healthy behavior. To assemble stakeholders from academia, industry, and government, Diabetes Technology Society and Sansum Diabetes Research Institute hosted the 3rd Annual Digital Diabetes Congress on May 14-15, 2019 in San Francisco. Physicians, entrepreneurs, attorneys, psychologists, and other leaders in the diabetes technology field came together to discuss current and future trends and applications of digital tools in diabetes. The meeting focused on eight topics: 1) User Interface/User Experience (UI/UX) for Digital Health, 2) clinical aspects, 3) marketing, 4) investment, 5) regulation, 6) who owns the data, 7) engagement, and 8) the future of digital health. This meeting report contains summaries of the meeting's eight plenary sessions and eight panel discussions, which were all focused on an important aspect of the development, use, and regulation of diabetes digital tools.

Keywords

diabetes, digital health, data, privacy, risk

Session 1: Technical

Plenary: Dennis Boyle

User Interface/User Experience (UI/UX) for Digital Health. The creation of a new product is a human centered process and involves 3 phases: inspiration phase, ideation phase, and implementation phase. The inspiration phase is crucial, resulting from fundamental understanding what (product, service) people need. In order to "think like a designer", the following steps need to be accomplished:

> #1: Immersing oneself in the problem first: surveys and focus groups come later as validation steps. For instance, "secret – medical mystery shoppers" can provide valuable insights into patient experiences at medical facilities.
> #2: Cultivating an awareness of what is good design, and what is not: Classic examples of good design include creation of upside-down ketchup bottle and arrow on the car dashboard indicating the location of gas tank.

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#3: Making notes about workarounds: The value of immersing oneself in the end users' life is of essence before setting out to design or improve a product.
#4: Watching for signs users create to clarify processes. Sometimes symbols are not enough to communicate a message. Instant manuals created as a response provide a design opportunity for the product/process.

Illustrations of products created following above recommended approach to innovation include: (i) Lilly's Trulicity^{R} autoinjector (ii) Ascensia's Contour Next One Bluetooth

BGM and paired app with color LED light to indicate if the blood glucose level is above-, below-, or in-range and (iii) PillPack^{R} – that pre-sorts medications by dose and time of day.

Panel Moderator: Keesha M Crosby MS

Panelists:

1. Brittany Bradrick, MBA
2. Kripa Gaonkar
3. Bryan Mazlish
4. Ashutosh Sabharwal, PhD

This panel covered a variety of technical topics including cybersecurity, UI/UX, interoperability, and future of technology.

The following questions were discussed:

1) How can cybersecurity of devices or apps be improved?

Many of the panelists have experience with cybersecurity. Bryan Mazlish founded Bigfoot Biomedical after hacking an insulin pump to leverage device capabilities and improve their security. He emphasized that many devices are vulnerable because of insecure software. Keesha Crosby explained that software security of devices is needed from a consumer product safety standpoint. Manufacturers are currently deploying software-driven devices to market with known vulnerabilities. Addressing software security is paramount to the safe function of the device. Cybersecurity is a responsibility that should be shared by device manufacturers, government, health care providers, insurance plans, and patients.

2) How do companies leverage this new data to drive personalized care and improve UI/UX?

To address the industry's role in UI/UX, Kripa Gaonkar recommended keeping products simple with sound UI and UX design. Product designs should provide the patient with actionable insights and appropriate timings. Hourly alerts or alarms need to be kept in the market if they are beneficial to patient wellbeing.

3) What are the new methods and models for behavioral interventions being investigated? (Beyond Fitbit)

Ashutosh Sabharwal is working on biomarker measurements from the body via FitBit and other wearables. Using these large datasets could drive future machine learning algorithms. There is also potential for new technology solutions which can create new uses for sensor information.

4) How are data files becoming interoperable across systems (claims, EMRs, device records)? Is Fast Healthcare Interoperability Resources (FHIR) the new standard?

Brittany Bradrick led a discussion on interoperability. Regulatory agencies have been very supportive of interoperability. The focus must be on reconciling patients across these components. Data transfer across different platforms need to be established to allow physicians to obtain and interpret data.

Session 2: Clinical

Plenary: Thomas N. Robinson, MD, MPH

Designing Digital Tools for Behavior Change. Designing and developing effective digital tools for behavior change is challenging. The IDEAS framework (Integrate, Design, Assess, and Share) provides a strategy to integrate behavioral science, design thinking, user-centered design, rigorous evaluation, and dissemination into technology interventions. To date, effective use of behavioral science to guide digital interventions has often been limited. Bandura's Social Cognitive Theory suggests four key processes to maximize learning: attention, retention, production and motivation. Two types of motivations can promote behavior change, including 1) "outcome motivation," to achieve an anticipated outcome (e.g., weight loss, blood glucose control), and 2) "process motivation," to participate in the intervention itself (i.e., the process of change). Research in psychology has identified intrinsically motivating design factors that can act as process motivators. These include perceived choice and control, curiosity, goals and challenge with feedback, competence, fantasy and contextualization, perceived individualization, cooperation and competition, community and belonging, and social interaction. Interventions that incorporate these strategies can be considered as "stealth interventions," not because they are deceptive but because from the perspective of the patient or participant, the health-related target behaviors become the side-effects of participating. Target behaviors that are designed to be motivating in themselves may be even more effective (e.g., dance classes for young girls as a form of physical activity). To produce greater magnitude and sustained effects, stealth interventions can piggyback onto social and ideological movements that share goals consistent with healthful behaviors. These access process motivations, such as identity, values, beliefs, emotions, belonging, a less-threatening risk of failure from participating in collective versus individual actions, and positive feedback loops created by changing social norms and policies supporting behavior change.

Panel Moderator: Robert Gabbay, MD, PhD

Panelists:

1. Saleh Adi, MD
2. David Ahn, MD
3. Andjela Drincic, MD
4. LaurieAnn Scher, MS, RD, CDE
5. Sacha Uelmen, RD, CDE

At the outset, the panelists discussed reimbursement models for digital health solutions and reached a consensus that the parties most likely to pay for digital therapeutics will be employers, payers, and insurance companies. To better market their products to these parties, companies producing digital tools can incorporate outcome-based guarantees, or even go one step further to value-based guarantees where the payer would not have to pay for the service if their solutions do not save a certain number of health care dollars. In addition, a key point was raised that payers and employers are more interested in digital solutions that address a wide range of chronic conditions, rather than having a different app for every disease state.

Adoption of digital care by healthcare providers has been slow. A common complaint by providers is too much data to handle with efficient clinical workflow. Organizations are increasingly working on electronic health record (EHR) integration to allow seamless access of remote monitoring data and population health tools. Payment reform, a traditional barrier, has had some progress with new Current Procedural Terminology (CPT) codes for remote monitoring and care coordination but remains underutilized. Telemedicine and virtual visits are increasingly reimbursed on a state by state basis.

Another challenge to adoption is that clinicians often struggle to determine the best technology options themselves sometimes through personally testing products. Consequently, most probably only recommend a few apps. Organizations are starting to help providers navigate this space like American Association of Diabetes Educators' (AADE) Diabetes Advanced Network Access (DANA) site. US Food and Drug Administration (FDA) cleared digital therapeutics are particularly in need of a comparative spreadsheet to assist providers with making choices.

Despite the potential benefits of digital diabetes care, disparities remain. Young adults would be predicated to be the most obvious early adopters, but recent T1D Exchange data suggests their Hemoglobin A1C levels have recently gotten worse despite the plethora of technology and digital tools now available. Maintaining engagement and reducing the burden of data are part of the roadmap to impact this population. On the other side of the spectrum are the elderly and those with cognitive issues where specific needs assessments and technology adaption will drive use and outcomes.

Session 3: Marketing

Plenary: Leslie Oley

Marketing in the Era of Value-Based Healthcare. As we move into the era of value-based healthcare, marketing has evolved to require clear definition and demonstration of value in the real world. Historically, patients and their outcomes have been characterized with episodic measurements, using limited data sets visible only to the healthcare system. The ubiquity of mobile and digital technologies now allows for continuous, passive data streams that illustrate a more complete picture of an individual's health.

In this session, we discussed the largest US virtual site, with over 3 million members, which specializes in unlocking consented behavioral data directly from individuals. This has opened up new ways to evolve medical research, and increased the speed of recruitment and scale of real-world evidence. Having a direct and transparent relationship with individuals creates an effective way to match them with opportunities to contribute to research, and places them in control of how their data can be used. We discussed several case studies, including one where the adverse impact of flu events on physical activity (steps, sleep, glucose readings, etc.) were quantified at the population level in a cohort of 54,600 people with type 2 diabetes. These new types of real-world data are transforming marketing and the definition of value healthcare.

Panel Moderator: David Ahn, MD

Panelists:

1. Ronald Dixon, MD
2. Jeffrey Klonoff, MBA, MPH
3. Ed Liebowitz, MBA
4. Peter Rule, MBA
5. Stephanie Tilenius, MBA

When finding customers, digital health startups might find employers to be ideal partners, because their interests are often most aligned with the patient/provider in that they want to minimize sick days and maximize productivity. However, different employers have different priorities when it comes to promoting healthy living in their employees, so startups should find the right type of employer which already promotes a culture of healthy living, already utilizes digital tools, and will be hands-on in advertising services to their employees.

The panelists then discussed how digital solutions addresses the various types of diabetes (e.g. Type 1, Type 2, Gestational, Prediabetes, etc), with Type 2 Diabetes predictably emerging as the largest potential market, while also being the most frequently targeted by new products. On the opposite end of the spectrum, specific comorbidities of diabetes (e.g. neuropathy,

kidney disease) are relatively under-addressed and might serve as a potential market ripe for new digital therapeutics. Using digital tools to predict who might develop prediabetes and to then prolong the progression from pre-diabetes to Type 2 Diabetes would also significantly reduce health care expenditures. Furthermore, Prediabetes and Type 2 Diabetes are most frequently managed by primary care providers who are often overburdened and might benefit greatly from digital tools that can ease the burden and provide assistance between visits.

When considering the role that health care providers play in the expansion of digital therapeutics, the panelists agreed that providers often have significantly more influence than employers or insurance companies when it comes to patient adoption and engagement with digital solutions.

There was also a lot of discussion around the importance of the patient/consumer and how to increase their engagement with their condition. Potential solutions discussed included providing earlier access to advanced tools such as lower-cost continuous glucose monitors (CGMs) for prediabetes and also addressing socio-economic determinants of health by providing healthier foods at lower costs. The importance of the consumer led most panelists to believe that consumer technology companies like Apple, Google, and Amazon will play a larger than expected role in the management of diabetes within the next 4-5 years.

Session 4: Investment

Plenary: Bill Evans

Digital Health Investment and Technology Trends. The broader digital health venture capital investment landscape serves as a backdrop to the digital innovation and investment taking place within diabetes. Over the past 8 years, investment flows into digital health as a whole have risen from just over $1B in 2011 to just over $8B in 2018 – a significant increase, by any measure. Dramatic growth in new markets is exciting. But is this growth in investment based more on fundamentals or hype? Given what's at stake for digital health as a whole and for subsectors of investment like digital diabetes, it's worth taking a hard look. Are we in an investment bubble, or a "healthy" market?

Rock Health's market research team has approached this question – which though inherently subjective can be structured and analyzed at a component level – from two perspectives. First, we've analyzed investment activity itself and developed a six-point framework for assessing the degree to which investment activity approximates a "bubble." Second, we have examined the degree and manner of consumer adoption (i.e., healthcare market uptake of the solutions being developed by startups) through a longitudinal, four-year consumer adoption survey of U.S. adults aged 18 and over.

Our analysis of digital health venture investment suggests that current trends exhibit signs of a maturing market within a macro-economic cycle nearing its peak. As such, we do not perceive an investment bubble, but we've identified "warning lights" that while not yet flashing ought to be monitored closely going forward. On the consumer side, we uncover a nuanced picture. Consumers as a whole are adopting digital health tools and services at steadily increasing rates. But adoption remains highest in groups with the lowest levels of morbidity and highest ability to pay for care. In order to keep investment (and the expectation of future returns) in line with fundamentals, entrepreneurs and investors need to take care to both understand where consumer adoption is already high as well as where future opportunity exists (i.e. where adoption is low but rising).

Panel Moderator: Patricia Salber, MD

Panelists:

1. Leslie Bottorff, MBA
2. Casper de Clercq, MS, MBA
3. Julia Hu, MBA
4. Sunny Kumar, MBA

Investment in digital health continues to grow nicely. About $20 billion has been invested in this area to date. Recently, there has been a trend towards larger investments in fewer companies. There was agreement on the panel, however, that we are not in a bubble (yet). Although one panelist pointed out that in this digital health era, we haven't yet come upon a tough time in the greater market, such as what occurred when the dot.com bubble burst in 2001.

Exits from digital health investment are coming mostly from mergers and acquisitions. For example, small digital health companies are being acquired by an established industry player, such as a pharmaceutical or insurance company. Mergers between digital health companies are also relatively common.

Digital health companies are receiving large amounts of money from investors, but they are taking a longer time than previously thought to close deals, generate revenue, and get to profitability. This is a problem for venture capital companies who need to manage the expectations of their investors who hope to reap a return more quickly than is currently possible.

That is why one investor spoke about the need to encourage digital health companies to have a step-wise approach to building out products that can generate revenue well before the final vision for the company is achieved. Examples include companies that are able to sell digital analytic or healthy information technology (IT) type of products to pharmaceutical companies early in the company's development cycle.

Another investor pointed out that for investors to make enough money to justify their investment, the sum total of the current investments in digital health would need to generate about $80 billion. And, he pointed out that we really haven't seen companies able to generate that type of value yet.

It was noted that we really have to get back to the basics of healthcare with these companies. We have to think about who are the patients that have unmet needs without an alternative. Money has been made in Type 1 diabetes, particularly with investments in closed loop systems. But not much money has been made in Type 2. That is why some investors are focusing on segmenting the market based on better caring for complications of diabetes. An example is a company that has developed digital health solution for people who are transitioning from chronic kidney disease to dialysis. These patients can cost up to $100,000 in a normal healthcare setting. Anything to slow down the transition can result in significant savings and bring value to payers and other potential customers.

The CEO of a startup agreed with the venture capitalists (VCs) that development of products in the digital diabetes space can take a long time. She noted that her company required 5-1/2 years to develop an AI nurse, much longer than the typical investment timeline of many investors. She did, however, point out that there has been a change in the investor space with some investors being more patient than others with respect to the timeline. She also said it was encouraging that investors are entering the space with skill sets that can bring value to their portfolio companies, such as understanding the ins and outs of Centers for Medicare and Medicaid Services (CMS) or how to negotiate with health insurers.

With respect to skill sets investors look for in companies, there was agreement that having clinicians involved in the company was important. However, the clinician did not have to be a part of the founding team, rather s/he could be an advisor. Other skill sets are also important including understanding of reimbursement in health care as well as work flow. It was acknowledged that it is very difficult to juggle all of the different elements needed for a successful digital healthcare company.

One company, however, does not need to have all the skill sets or provide the complete solutions. Rather they can partner or collaborate with other companies to provide a more comprehensive solution to the customer.

Companies should not only be thinking about solutions for patients or specific illnesses, rather they should also consider approaches that will improve access in an increasingly resource constrained environment. One example is AI powered ultrasound that would not require a skilled sonographer to do the exam. The same approach could be applied to magnetic resonance (MR) or computed tomography (CT) scanning.

The VCs were asked to share the most exciting company they have invested in during the last 1-2 years. Here are three:

1) Verona has a unique business model. They have partnered with two different non-profit medical societies, The American Academy of Ophthalmology and the American Academy of Neurology. They helped to develop robust data registries for them. The societies benefit because they get the data fed back to them and can use it to do research and improve care. In addition, Verona has contracts with pharmaceutical companies to provide them the de-identified data so that they can use it to inform their drug development efforts. It is a win-win-win.
2) Cherry has developed an AI-powered smart camera that can be placed in the home to capture a variety of activities that have implications for a senior's ability to live independently. For example, unhealthy activities could include gait abnormalities, failure to take medications, or inadequate food intake. The feed from the camera can be reviewed and responded to by home health personnel reducing the number of home visits necessary to keep the person safe and healthy in their home. The investor noted that "Humans are not going away and being replaced but they're being augmented by this technology to make one person able to monitor far more homes than was previously possible."
3) Marigold makes software that allows drug rehabilitation facilities to compete on outcomes and measure outcomes against clinically validated care pathways. This could be a huge help to families that need these services but currently have to purchase them without much meaningful information about their value.

Finally, it was noted that partnerships between nonprofits and for-profits, coming at investment from a variety of angles may be necessary to address the fact that many issues in healthcare take a long time (if ever) to be solved. There was general agreement that both investing and innovating in the digital health space is challenging. Both entrepreneurs and investors must be nimble and creative to in order to have a successful company and bring value to the different stakeholders (patients, families, providers, and payers)

Session 5: Regulation

Plenary: Marisa Cruz

FDA Regulation of Digital Health Tools. FDA defines digital health technology as the convergence of computing power, connectivity, sensors, and software applied to health care. In recent years, the Agency has seen increasing interest in applying these technologies to deliver medical care, to develop medical products, and to study medical devices. Not all applications of digital health technologies are regulated, however, and so the Agency has published a number of guidance documents to help articulate a risk-based and functionality-focused approach to regulation. Recent legislation has codified that risk-based approach, and removed some lower-risk general wellness products and clinical decision support tools from the definition of a medical device. The Agency has also recognized the need to devise a regulatory paradigm that better aligns to the software development lifecycle and allows for iterative changes that improve the performance of

algorithms while ensuring that standards of safety and effectiveness are met. To that end, FDA is piloting a Software Precertification Program and has recently published a discussion paper outlining a potential approach to regulation of artificial intelligence and machine learning technologies. FDA welcomes input from stakeholders as the Agency builds a framework to promote digital innovation and the development of high-quality, safe, and effective software-based medical devices.

Panel Moderator: Adrian Rich, JD

Panelists:

1. Perrine Janiaud, PhD
2. Yarmela Pavlovic, JD
3. Christine Sublett, MA, CISSP, CIPT, CRISC, CGEIT

The panel began by discussing the FDA Software Precertification Program, which is currently in the pilot stage for 2019. Panelists emphasized the need to collect enough evidence to test whether a device operates safely and effectively. The Software Pre-certification Program allows for an opportunity to test the construct that excellence appraisal plus streamlined review elements will yield the same level of evidence for regulatory decision making as a traditional review process. Panelists asserted the need for non-traditional approaches to regulatory decision making and net neutral for companies in order to ultimately shift the regulatory burden. Some expressed their concern of whether pre-certification products will be able to survive the high cost of user fees through the various regulatory processes. The audience asked the FDA about which attractive features a company can offer in the pre-certification program in order to make the regulatory process easier and faster. The panel responded with examples of features, such as the capability to carry out modifications rapidly, early stage interaction with the agency, and going from solely paper reviews to more holistic reviews.

The panel then discussed the topic of cybersecurity in digital health. Panelists brought up FDA's premarket and postmarket guidance documents as well as the cybersecurity bill of materials (CBOM), which requires devices to show exactly what they are secure against. The importance of cybersecurity was further emphasized by mentioning the public and private partnerships between the FDA and other agencies such as Homeland Security. The Health Care Sector Coordinating Council, a joint public private enterprise, and its Joint Security Plan were also mentioned as valuable resources for those searching for guidance in cybersecurity. The FDA clarified their primary focus in cybersecurity to be patient safety and risk, which is the basis of all guidance documents currently available. The panel ended their discussion by agreeing that cybersecurity is a shared responsibility.

The panel moved on to discuss interoperability in the diabetes realm. The biggest benefit of interoperable devices is that interoperable devices lead to synergy between different types of connected devices that produces data for patients and health care providers to meaningfully use and interpret. While the clinical potential is big, interoperability also opens up many cybersecurity risk points when devices are linked together and more data is combined into a single site. The struggle between interoperability and cybersecurity is visible in many areas, especially in Do-It-Yourself (DIY) artificial pancreas systems. For the FDA, the intended use and range of the interoperable data are absolutely necessary in order for devices to be approved for interoperable use. By restricting the usage and range of interoperability, FDA hopes to lessen the risk while maximizing the benefits of interoperability.

Finally, the panel discussed the importance of real world evidence in regulatory processes. The FDA is now using real world evidence to not only monitor post-market performances, but also to make regulatory decisions about the benefits of devices. The audience mentioned how difficult it is to build precision medicine datasets about scenarios not specified in randomized controlled trials, since minorities do not participate in as many trials, and the data is often not fully representative of some populations. The panel responded by saying that demographic information is needed about patients in order to make decisions about the user population based on data interpretation and analysis. All real world evidence is dependent on the patient population that was directly tested. The panel wrapped up the discussion by emphasizing that reliability is a concern in the current realm of technology, and the focus should be on whether health care providers understand the evidence basis of the recommended products.

Session 6: Who Owns the Data?

Plenary: David Brailer

Consumer Health Data Ownership Comes of Age. Digital health data is important and David Brailer, MD, PhD, an entrepreneur, educator and the first National Health Information Technology Coordinator presented his thoughts on the matter. It matters because the goal of health IT is improved health and longevity and we have not yet met that goal. Interoperability and sharing of clinical data across the health care spectrum leads to this goal but we have little sharing. The amount of data has exploded, both within the medical system and from personal health information devices, worn by the patients. The EHR has not kept up, in large part because it is not "patient-centric" but rather developed to improve billing.

There have been some health improvements from digitalization of data, such as ordering of medications and tests, but Fortune and Kaiser recently published a scathing report on the electronic health record, and they were particularly critical of interoperability. Data should follow the patient, but if there is a transition to a new provider or specialist, an ER visit to a new hospital, a change in health plan or a drug

or device recall, the data follows the patient as a paper report or PDF or not at all. Data is glorious when it is integrated, but paper and PDFs cannot be integrated, cannot be searched, and cannot be used to improve care.

A few months ago CMS and the Office of the National Coordinator (ONC) made a set of eight proposals. These included that: 1) Fast Healthcare Interoperability Resources (FHIR) by Health Level-Seven (HL-7) should become an application program interface (API) standard; 2) patients should be allowed to view their personal health information in a standardized fashion; 3) payers should be required to make PHI available through standardized, open APIs; 4) payers should be required to electronically exchange data whenever patients change plans, 5) payers should be required to provide information about in- network providers through APIs; 6) payers should be required to participate in "trusted exchange networks" such as health Information Exchanges; 7) Medicare-funded hospitals should be required to share electronic admission discharge transfer notifications; and 8) these hospital should be required to codify information blocking rules and limit exceptions for providers. These regulations are currently still held up in an extended comment period. We hope the requirements will prevail; they will be good for medicine and for patients.

The presentation ended with four questions for the audience: a few thoughts: 1) How do we avoid weak data requirements so that we can have robust data interchange for improved healthcare by pressure from non-medical sources? 2) Who will manage the entire set of personal health information on behalf of consumers? 3) How can we assure that both health data access and privacy are achieved? 4) How do we avoid an interoperability gap between technically sophisticated providers and others?

Panel Moderator: Shannon Yavorsky, JD

Panelists:

1. Pratik Agrawal, MS
2. Deven McGraw, JD, MPH
3. Christine Sublett, MA, CISSP, CIPT, CRISC, CGEIT
4. Catherine Williams, JD

With exponential growth in diversity and applications of digital diabetes technology, the need for interoperability has become crucial for its widespread adoption. Because of that need, the question "who owns the data" is frequently posed, and yet, to this date there is no clear answer. Some say that patients own the data. Alternatively, do entities who collect and store that data such as hospitals, doctors, insurance or pharmaceutical companies and other business entities own the data. Is there more than one owner? The question of data ownership is closely tied to that of privacy and security. On the other hand, ownership is connected to the value and compensation, furthering the need for legal clarity.

The panelists also made a point that the ownership questions really come down to who has the right to the data, rather than who owns it. They also illustrated the complexity by asking the following. If the patient owns the data in collaboration with different organizations that own devices apps and data analytic platforms, then how can one even determine which entity is legally responsible for the data and in turn, what triggers data security responsibility. The panelists used an analogy of a hot potato to illustrate the dynamic nature of this process, where contractual arrangements between multiple entities with differing levels of sophistication of information security are in place and data transfers are on the continuum.

Finally, the panelists also pointed out that the obligation towards the patient is not only legal, but also ethical and while privacy consents are integral to data handling and transfers, those are for practical purposes meaningless to an average user faced with lengthy and incomprehensible language.

The panelists focused on the following questions throughout their discussion:

1. **Who owns the data?** The panel started by considering whether data ownership is not a useful concept. In Europe, with the General Data Protection Regulation (GDPR) the patients have extensive rights to their data. In the US, some states allow legal ownership of data, but health data is shared with so many others, who also have rights and often have dominion over the data, that ownership is not meaningful. It may come down to who has the data, rather than who owns it. The holder of the data needs to ensure that the data is accurate, private, secure and available for appropriate sharing. In the Corporate World data ownership is complex since it is not proscribed by law. Frequently, data ownership is defined by contract, but data security is paramount. In Europe data ownership is usually defined by contract, it is sort of like intellectual property even though it isn't.
2. **How do you determine what entity is legally responsible for the data and when and what triggers this responsibility?** There is not much law about what to collect or how, but clearly once you acquire the data, then you are responsible for the privacy and security of the data. But data is fluid and trying to determine liability is challenging. Keeping data secure when patients determine the data holders is difficult. The Civil Rights division of the US Department of Health and Human Sciences has, however, stated that once the data has been passed in an appropriate fashion the initial data holder is no longer responsible for it. The GDPR is very prescriptive about how this data is transferred and the obligations of both parties. When the receiving app is run by the patient, then none of these rules apply and often these 'cool' apps lack appropriate security. There is however, an ethical obligation to be sure the patient understands what is happening.

Another important type of data is non-health data that can be used to make health inferences. This data is largely held by entities outside the health field and there is little law covering this.

3. **What is the federal government doing to facilitate access to data by patients and others for important individual and population health issues or uses?** ONC and CMS through the Office of Civil Rights (OCR) put out a request for information about obligations to make data available as opposed to obligations to keep it protected. There is the obvious need to share data with patients, but also a need to share data with other health care providers, researchers, public health authorities, payers, and others. Sharing through the API is obvious, but blocking rules are more controversial. They are part of the Request for Information (RFI) and are now very stringent and affect data entities, whether Health Insurance Portability and Accountability Act (HIPAA) covered entities or not and all identifiable health information but the dynamic is being flipped. Unless you have a good reason not to share (seven categories), then you must share the data. We are shifting the culture from: 'you know data is mine I need to protect it' to obligations are to share this data unless: 'I have a legitimate excuse not to'. This is hugely game changing.

In Europe if the data is anonymized (a high bar), then the data GDPR rules do not apply, making research much easier. Psuedo-anonymized data is still covered by GDPR rule. HIPAA also has a similar system. The challenge with anonymous patient and pseudo-anonymization is that rich data analytics of longitudinal analysis of individual patients is lost when you're dealing with aggregate data sets. We also need to be careful about a re-identification process.

4. **Is data sharing a feature that differentiates the product or a mandate and how much can you mandate?** In the RFI the OCR is asking the public how much of the sharing rules should be mandatory. Much of the sharing is going to become mandatory, but additional sharing could become a feature of some systems. From a device perspective, the FDA is also involved and if we are sharing data with another device, then is that device going to be included in our regulatory consideration of our device [Reviewer: FDA interoperability regulations may take care of this].
5. **What issues do health care entities face when they have devices in their environments and they don't have full access to them?** Insulin pump and CGM manufacturers have a lot of data that we share with the patient. Not all patients want to share this data with their physicians and it creates some tension when their physicians ask for the data. Devices may contain data on device performance that they do not share with HCPs. In some cases, this data may be a safety issue if the data logs show device malfunction or inappropriate patient usage of the device.

Audience Questions:

1. **What happens when social media and other non-medical data is publicly available but because of its nature becomes PHI? When does HIPAA apply?** The FDA has leaned into this and it is expected that with their current leadership that this agency will lean further to making very clear that once you begin making a health claim from the data or the algorithm or the inference, that they're going to regulate it and they're going to be aggressive. CMS, however, has taken a more *laissez faire* approach. Outside the medical field, Congress has given the Federal Trade Commission more authority over regulation of the use of this kind of data. Perhaps the best solution would be for there to be an overarching regulation like the Gramm Leach Bliley Act (GLBA) regulation of the use of commercial customer information and then individual regulation for different segments of the industry.
2. **How much is data worth (in dollars)?** Data does not have a value on your balance sheet. In partnerships it has a value, but only as a negotiating point, not with a dollar value. The industry has data producers (20%) and data consumers (80%). Data production is a 700-billion-dollar industry, so the data should be worth at least that amount. One attendee later questioned whether their data was worth $2000, which is 700 billion spread over US population of 350 million.
3. **Since the topic is who owns the data, then where does the patient fit in with ownership?** Under HIPAA they have a right to their data, but this is poorly understood by patients and the industry. CMS, ONC and OCR will reward for sharing and punish for not sharing. Block chain may actually allow you to sell your data for money or benefits. The next 5-10 years will be exciting. Interestingly, a few genomics companies tried a data marketplace and it failed.
4. **Comment on re-identification of data.** We were involved in a data merge between an EMR and a social media company. The social media company set the rules that both parties would send their data to a third party for anonymization and joining. The new anonymized file could NEVER go back to the original parties (who could easily re-identify the data) but could only be analyzed by other independent researchers. The project never went forward because the EMR company wanted the anonymized joint file. Those of us that have seen behind the Wizard of Oz as curtain

what goes on in some of the tech companies these behaviors are rampant and you know there's a lot of data integration that's happening to test and train A.I. that nobody really wants to talk about.

5. **Privacy disclosures are so complex that no one can read them. Are there ways to ensure they are simple enough to understand?** Medicare has readability regulations, but other groups have so much mandated material that it is virtually impossible to simplify. Some companies have a simplified, 5th-8th grade level readable digest of the agreement and a link to the full policy.

Session 7: Engagement

Plenary: Korey Hood

Types of Engagement That Drive Digital Uptake and Diabetes Outcomes. There are three different perspectives of looking at patient engagement: the person engaging with diabetes, the person engaging with digital health that's focused on diabetes, or more broadly about the person engaging with the healthcare system. Despite these different approaches to defining engagement, the focus must be on engaging the patient with diabetes and assessing their current relationship with the disease. Including the patient as a partner and co-designer is crucial in engaging the patient and encouraging effective treatment methods via digital tools. Listening to patients is the most important step, as engagement is not only an outcome but a process of its own.

To assess the diabetic patient population and their perceptions on digital tools, Dr. Korey Hood and his team at Stanford University conducted interviews with 300 individuals, including adults and children with Type 1 Diabetes and their families and partners. They found that adolescents want devices to be discreet and wearable, since they are conscious of their social settings. On the other hand, adults were more concerned about device safety and reliability rather than the comfort and wearability of these devices. These results show that different methods of engagement are needed to target these diverse populations. Listening is needed before incorporating relevant data into clinical or digital tools.

Dr. Korey Hood further conducted surveys for these individuals and used cluster analysis to categorize them into four profiles with different levels of engagement with diabetes digital technology. Some of them "de-embrace" diabetes in the sense that they did not see diabetes as a stressor or burden in their lives. They did not seek out new technology but did not disprove them either. They are satisfied with what is available to them. Another group, called data minimalists, push back on new data regarding diabetes technology since they are not distressed or dying due to diabetes. They are overwhelmed with the load of data being thrown at them from emerging technology. The third group is actively distressed due to diabetes and currently do not use a lot of devices. They perceive many barriers in managing their condition, which leads to a passive perspective. They lack proper education and support in overcoming their distress and finding proper treatment. The last group, called the "free rangers," have negative perception on technology and how useful it is to diabetic patients. They are extra careful in trusting devices and question the risks of using them. Every one of these groups require different approaches to address each of their concerns. Especially for the last group, a co-design of technology and a map to guide them is necessary to help lessen their negative perceptions.

Dr. Korey Hood and his team also launched DiabetesWise.org, an initiative that seeks to assess each patient and offer them personalized treatment guidelines. First, patients take a long online quiz that profiles them. After, they receive a tailored response based on their answers. An actionable report, with different treatment options and pointers to discuss with their primary care physicians, are provided to each user. If they do not feel comfortable with devices or feel overwhelmed with devices, they are not loaded with new device advertisements. If they indicate that they are distressed but unable to find useful devices, then they are able to access and compare different devices, and review the advantages and disadvantages of each one. The biggest goal of DiabetesWise.org is to encourage people in their diabetes journey and move them along in the process as new devices are developed every day.

In closing, Dr. Korey Hood asserted the importance of using qualitative questions to measure engagement instead of solely depending on quantitative metrics. While the number of clicks on a website indicates the extent of usage, qualitative responses such as the reason they subscribed to the website or the value of a new feature represents the emotional engagement that patients have with diabetes and digital tools. Dr. Korey Hood ended by emphasizing the need for personalized patient engagement plans and the potential it may have on lessening the burden of diabetes on patients.

Panel Moderator: Saleh Adi, MD

Panelists:

1. Shelagh Mulvaney, PhD
2. David Shearer, MD
3. John Welsh, MD, PhD

Diabetes is a self-managed condition, relying on the patient or parents to perform many daily tasks. This requires a high level of constant engagement. There is ample evidence that more engagement results in better outcomes. The essential question is how to initiate, increase, and maintain engagement in people with diabetes.

Within the context of Digital Diabetes, the panel addressed the following topics:

1. *Should diabetes management tools be like smart phones, or even fully integrated into smart phones? Will this increase engagement?*

The panelists felt that most diabetes devices are already digitized; however, they lack the advanced design aspects that we see in most digital devices we use today. Greater migration into smart phones enhances patient engagement by eliminating the need to carry one more device, and permits automatic transfer of data for storage or sharing with caregivers. For example, CGMsutilize smart phones to receive, display, and share the data. In the future, insulin pumps will be controlled from software on smart phones.

2. *How much do device manufacturers consider the importance of the design aspects that promote and maintain engagement?*

Representatives of major device makers on the panel affirmed that their design teams seek feedback from targeted users before designing their products, and users in the post market provide valuable real world experience. They embraced the concept of considering people with diabetes as co-designers. Comments from the audience pointed out the importance of getting feedback from the clinical providers and diabetes educators as well.

3. *What about the question of Quantity vs Quality? Different patients benefit differently from levels of engagement.*

Recent findings demonstrate distinction of patients into groups with inherently varying degrees of engagement and desire to spend time "dealing" with their diabetes. From the D-Embracers (diabetes-embracers) to the Data Minimalists, the Wary Wearers (of devices), and the Free Rangers, we must consider these personality traits, tailor our expectations, and ask for a level of engagement that is practically achievable by different types of people. One example of "quality intervention" is the single task of ensuring a bedtime insulin dose, which can result in significant overall improvement in average blood glucose and percent time in range.

4. *Could automation be a bad thing, because it minimizes "engagement"?*

The panel agreed on the importance of lessening the burden as much as possible, perhaps by automating some tasks, but there was a good discussion regarding the value of staying engaged with someone's own data and occasionally reviewing the data to fine tune and optimize the performance of those automated tools. We felt that retrospective review is a task that should be shared between the providers and the patients. Once again, we stressed the importance of presenting the data in the most effective and actionable way to facilitate this process.

Session 8: Future of Digital Health

Plenary: David Armstrong

The Diabetic Foot in Remission: How Technology Can Maximize Ulcer-Free, Hospital-Free and Activity Rich Days. Because neuroischemic complications of diabetes are associated with a high rate of recurrence, we propose a slight shift in the mechanism by which we counsel and communicate risk daily with our patients. If the epidemiology of this problem is comparable with that of cancer, and recurrences are common, then perhaps language commensurate with such risks should follow. After initial healing of an index wound, our unit now refers to patients not as being cured but rather as being ''in remission.'' This concept is easy for the patient and the rest of the team to understand. We believe that it powerfully connotes the necessity for frequent follow-up and rapid intervention for inevitable minor and sometimes major complications. This lecture will review tried and true as well as up-to-the moment advances in biologics, consumer electronics, mechanics, medicine and surgery that are "pushing the envelope" in extending ulcer-free, hospital-free, and activity-rich days in our efforts to make prevention pay.

More information can be found out: Diabeticfootonline.com

Panel Moderator: David Kerr, MD

Panelists

1. Harry Green, OD, PhD, FAAO
2. Kristina Lee, MS
3. Divya Shah, MS
4. Patricia Salber, MD

There is no doubt that technology for consumers is being reshaped to become applicable for health. For example, ride-sharing companies such as Uber are offering to transport patients to hospital for appointments and eventually to create a home delivery service for prescription medicines. Elsewhere there are opportunities for the application of other new technologies for health including 5G, advanced cybersecurity, next generation cloud storage, integration of devices & things (Internet of Things and Internet of Medical Things to move from the quantified self to create actionable moments), voice technologies, sophisticated remote monitoring, robotics, bloodless testing, new types of wearables and implantable devices and 3D printing. The ability to miniaturize devices is also likely to add value for digital health. A likely and immediate benefit is to increase and sustain engagement with healthcare for all stakeholders. A further yet-to-be-determined consequence would be the use of micropayment systems to "reward" patients for providing their data and if positive lifestyle changes occur, although this approach has major implications for privacy and consent.

This rapid expansion of technologies being applied to health may have a secondary outcome of creating new types

of clinicians with expertise in digital health. This will require new approaches to training and education and at present the impact on traditional clinical practice is unclear.

In the next five years there are likely to be major changes in the provision of health care.
Examples include

- Seamless approach to move people with diabetes from screening for complications e.g. timely and appropriate retinopathy treatment for all that require it
- A greater proportion of care will be provided at a distance from the traditional clinic including more at home
- Increased emphasis on prevention and the use of non-invasive approaches for monitoring
- AI defined as an active intervention rather than only artificial intelligence.

Conclusion

The future of digital diabetes health looks very promising. In the near future we are likely to see the development of new ecosystems that will include increasing use of sensors providing new information beyond the measurement of prevailing glucose levels to support the –day-to-day decision-making required of people with diabetes. The use of real-world data in additional to evidence from traditional clinical trials will help to support regulatory decision-making. Clinical, technological and financial enthusiasm for digital diabetes health shows no sign of waning but there are still challenges related to data privacy and security, creating the evidence base of information required by clinicians and payers and the need to involve people with diabetes at all stages of the development of new digital health products. We look forward to highlighting future developments in the digital diabetes health space.

Abbreviations

AADE, American Association of Diabetes Educators'; API, application program interface; CBOM, cybersecurity bill of materials; CGMs, continuous glucose monitors; CMS, Centers for Medicare and Medicaid Services; CPT, Current Procedural Terminology; CT, computed tomography; DANA, Diabetes Advanced Network Access; DIY, Do-It-Yourself; HER, electronic health record; FDA, Food and Drug Administration; FHIR, Fast Healthcare Interoperability Resources; GDPR, General Data Protection Regulation; GLBA, Gramm Leach Bliley Act; HIPAA, Health Insurance Portability and Accountability Act;HL-7, Health Level-Seven; IDEAS, Integrate, Design, Assess, and Share; IT, information technology; MR, magnetic resonance; OCR, Office of Civil Rights; ONC, Office of the National Coordinator; RFI, Request for Information; UI, User Interface; UX, User Experience; VCs, venture capitalists.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Julia Han has nothing to disclose. Fraya King is a consultant to Abbott Diabetes Care. David Klonoff is a consultant to Abbott, Ascensia, EOFlow, Know, Lifecare, Merck, Novo, Roche, and Voluntis. Andjela Drincic has nothing to disclose. Keesha Perkins Crosby has nothing to disclose. Thomas Robinson serves on Advisory Boards for WW International, Inc. Robert Gabbay is a consultant to Onduo, Lark, and Health Reveal. Leslie Oley has equity in Evidation Health. David Ahn has research support, has acted as a consultant, or served on the scientific advisory board for Senseonics, Mannkind, Ascensia, and Companion Medical. Bill Evans has nothing to disclose. Patricia Salber has nothing to disclose. Marisa Cruz has nothing to disclose. Barry Ginsberg is consulting medical director for Facet Technologies and SFC Fluidics. Saleh Adi is consultant, speaker bureau, shareholder for Dexcom and a shareholder for Tandem. David Armstrong has nothing to disclose. David Kerr is an advisor to Glooko, Vicentra and hi.health. He has received payments for participation in advisory boards focusing on digital health for Ascensia, Novonordisk and Sanofi and is in receipt of research funding from Lilly.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.