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Female: Welcome to Conversations on Health Care with Mark Masselli and Margaret Flinter a show where we speak to the top thought leaders in health innovation, health policy, care delivery and the great minds who are shaping the health care of the future. This week Mark and Margaret speak with Jennifer Goldsack, Interim Executive Director of the newly formed Digital Medicine Society, which seeks to put standards in place for the multiple stakeholders entering the growing world of digital medicine. 21st century technology-driven health care that will make it possible to develop digital medicine that's more precise and effective, more experimental and more widely distributed.

Lori Robertson also checks in, the Managing Editor of FactCheck.org looks at misstatements spoken about health policy in the public domain, separating the fake from the facts. We end with a bright idea that's improving health and well-being in everyday lives. If you have comments please email us at chcradio@chc1.com or find us on Facebook or Twitter or wherever you listen to podcast. You can also hear us by asking Alexa to play the program Conversations on Health Care. Now stay tuned for our interview with Jennifer Goldsack here on Conversations on Health Care.

Mark Masselli: We're speaking today with Jennifer Goldsack, Interim Executive Director of the newly launched Digital Medicine Society or DiMe, the first professional organization for experts from all disciplines comprising the diverse field of digital medicine. She is VP of Digital Measurement at monARC Bionetworks. Prior to that, she spent several years at the Clinical Trials Transformation Initiative. Ms. Goldsack earned her master's in chemistry from Oxford University, her masters of history and sociology of medicine from the University of Pennsylvania and her MBA from George Washington University. Jennifer, welcome to Conversations on Health Care.

Jennifer Goldsack: Thrilled to be here and thank you for having me.

Mark Masselli: You know, and we've had many guests and had many conversations about digital medicine and it really seems to infiltrate every aspect of health care. We've seen a lot of things happen in this past decade that were exciting and it's kind of surprising to see that a society hadn't yet been formed, to help guide this evolving aspect of modern health care. What's DiMe's description of digital medicine and why are you and your likeminded colleagues launching this venture? Tell us a little more about it?

Jennifer Goldsack: When we describe digital medicine, I think the most helpful way to think about it is concentric circles. Broadly digital health being this very wide sphere of digital tools that support health and wellness

initiatives. Within that we would define digital medicine specifically as one those software based tools designed to support the practice of medicine, whether that's diagnosis, whether that's treatment, whether it's monitoring, assessment population health management. But critically important, we are hoping to insist on digital medicine as being an evidence based field. Specifically those digital medicine tools or those software based tools that support the practice of medicine very broadly, but are evidence based. Within that definition you would have digital therapeutics, so digital therapeutics would be a subset of digital medicine, but obviously those diagnostic, those measurement, those population health management tools, which comprise the rest of the field.

You know, when I talk with not just my colleagues within the leadership of DiMe, but frankly everyone who's been joining us is a member and many folks who have been affected by the field. What we see is huge promise, huge potential to improve health, health care, to reduce costs, to make it easier to access care. These are things that sort of as an industry we've been battling with for decades now with unfortunately quite little success. The reason I think the timing is right is the rate of innovation, the rate of growth of these digital medicine tools. On the one hand it's proven the possibility, right? I think we've started to see evidence that these tools can have an impact. But at the same time it's been really difficult to keep pace with that evidence based. How can we make sure that the tools we're being asked to put our trust within are indeed trustworthy? I think that's why this juncture is so important, and that's why the timing is right for a society like DiMe.

Margaret Flinter: Well, Jennifer, as you've made clear already, digital medicine offers so much promise, but I want to talk about these big challenges that you've laid out. I was kind of surprised at the lack of evidence being one of them. I thought we were further down the road with that. The second of three areas that you've identified as problematic doesn't surprise me at all, the fragmentation of data. The third isolated silos of progress surprises me the least. Maybe share with us what you and your organization are planning to do about addressing these specific challenges so that you can make the progress that you think digital medicine has to offer us?

Jennifer Goldsack: Let's start with evidence. I think it's not up to a society to build the body of evidence for each of the individual digital medicine tools that we expect to see being rolled out and frankly, that are currently being used. But I think one of the challenges is that these are brand new products being deployed in a very different way. Here's an example I always use, if you ask an engineer and you ask a clinician what does validation mean? They mean vastly different things. How can you build towards a common body of evidence if actually the evidence

being generated, that level of evidence, that framework of information that end users, whether that'd be a payer, prescribing clinician or a patient, how can we ask them to discern between different tools, know that they're safe, know that they're effective if actually we're not starting from the same foundation.

Similarly, I think that have many brilliant engineers, technical experts entering a field that's highly regulated and that perhaps they haven't previously understood that there is a certain level of evidence that needs to be introduced. Similarly on the clinical side, really getting our clinical experts comfortable with the way that software is developed, so that's the piece that we're seeking to address on the evidence side of things. I don't think it's up to society to be the decision maker on all of the different digital medicine products. But certainly take very seriously the responsibility of building a common framework for generating and evaluating that evidence.

The second piece is you mentioned is fragmentation, and as I just mentioned, it's not just the fragmentation of data, it's these disciplines colliding, and how can we facilitate communication and education across in between those fragmented disciplines and experts. The final piece that that didn't surprise you at all, Margaret, was these sort of isolated silos of progress. The reason I think that DiMe is so important is digital medicine is the most interdisciplinary field I can think of and I don't think it's an overstatement. We really need to have sort of white hat hackers at the table with payers and regulators. We need to have privacy and security experts talking with the product experts, with the clinicians, with the patients to see how the access and the functionality that they want jives with concerns about data security, data storage. How do we actually handle this? More data is not always better. How can we thoughtfully think about what we collect and how it impacts? Those isolated silos of progress, we helped to be able to convene these experts and really share in advance a common understanding and a collaborative approach.

Mark Masselli: Jennifer, you have these building blocks that are in place for the work that you're doing. The base level is that we have the advent of the scaling of electronic health records. You've got patients across the country who are connecting themselves to wearables, obviously you have some large tech companies that are pushing wearables and people are engaged in them. Then you have this whole advent of technological age of the 21st century. Tell us really where you are on your pathway of building this new society.

Jennifer Goldsack: It is an enormous task, Mark, but it's that throwaway phrase of, how do you eat an elephant and you take the first bite, and I think that's really important. We can't be paralyzed by the enormity of the task. I think there was recent data that came out that said, the digital

medicine field will be valued at 250 billion by 2023 or something and you think, well, gosh, we've got limited regulations and standards and evidence right now. How do we keep up? I'm really proud of DiMe in that respect and our leadership. We really only started talking about this in November and we pushed incredibly hard and already have members worldwide hundreds and hundreds, it's wonderful, there's a thriving community already.

I think other critically important pieces will be doing this collaboratively. The army of one approach won't work, and importantly, prioritizing which are the ones that currently are most pressing to ensure that these digital tools that we're placing our faith in are indeed safe and effective. Then the final piece that I think is really important, we are incredibly fortunate with the strategic advisory and the scientific leadership boards we have as part of our governance structure at DiMe.

I think what we would all agree is it's a new era that it's this collision of these two different fields that think very differently. But at the same time we don't have to completely tear up the playbook. There are scientific principles that should always prevail and just because we may need to extrapolate them to a new world doesn't mean we throw the baby out with the bath water. A lot of what we're doing is thinking critically about how can scientific and ethical standards, how can they be extrapolated to this new era?

Margaret Flinter: Well, one of the areas that we're particularly interested in is research. You may know that our organization's been part of the All of Us Initiatives since the beginning. Certainly thinking about how that works both for us locally as one organization, but also watching just the tremendous work being done at the national level on that project, and you've done research on leveraging technology to improve mobile clinical trials. How might clinical trials and research for the betterment of all be really transformed by digital interventions in the future?

Jennifer Goldsack: It's a really good question. There was actually a lovely piece that came out I think sometime last year by Eric Topol and Steve Steinhubl. Their op-ed I think was something along the lines of digital medicine on its way to being just pain medicine, and we don't say computers in business, they're just ubiquitous. Eventually I see that being the case in clinical trials. I'm really optimistic about how these digital technologies can affect clinical trials. Firstly I think that these tools can power better quality, more patient centric endpoints, specifically ones that will generate sort of better and more complete information about how potential new therapies work. I think that these tools could potentially support improved recruitment and retention, which we know are huge burdens in industry right now. They're driving up

costs, they're slowing progress. We can do that by developing sort of endpoints that matter to patients, measuring them remotely with far reduced participation burden.

I think another sort of way that these tools will impact clinical trials is if you can have a more sensitive measure one that is sampling almost continuously have a much greater data density. We have much more chance of making better decisions in early phase trials. We can fail faster and we can succeed much more cheaply and quickly, ultimately setting us up for sort of increased success for potentially successful treatments. Then this data density really just driving the whole trial life cycle, so I always think of Alzheimer's as being such a devastating condition, we know very well, the heartbreaking and expensive late stage failures we've had with drug development. It continues to amaze me that the gold standard endpoint in Alzheimer's, the UPDRS scale was first introduced in 1987.

It's a physician administrated paper tool that's done once a visit, but yet this is an episodic condition. This is a condition where we see the symptoms playing out on an irregular basis. We also know the burden to patients and caregivers of this disease. If we can stop putting the burden on patients to come into the clinic and only rely on snapshots of information to drive the trials, and instead if we can put digital measurement tools out there in the field to power these studies to get very good high quality data rich information very quickly about whether a new therapy might be successful. I think that could revolutionize the way that we think about clinical trials.

Mark Masselli: We're speaking today with Jennifer Goldsack, Interim Executive Director of the newly launched Digital Medicine Society or DiMe, the first professional organization for experts from all disciplines comprising the diverse fields of digital medicine. Jennifer, one I really like your North Star that this really needs to be an interdisciplinary collaboration.

Jennifer Goldsack: Absolutely.

Mark Masselli: That that resonates in the era of team based care, and there are a lot of folks that you've got engaged in this ethicist, clinicians, researchers, white hat hackers. I'm also wondering on the tech side, are you engaging people who are trying to advance the technology or are you pretty much letting the tech stuff happen and then monitoring it and setting the standards for it?

Jennifer Goldsack: The way we think about our leadership, the way we think about DiMe membership and the way, frankly, we think about the field and its success and advancing it for the betterment of sort of health and for patients. We really think about a setting at the intersection of healthcare and technology. For all the clinical experts we have, we

also have that representation from the tech side. We are seeking input and expertise and collaboration all the way from those infrastructure experts you've mentioned can sort of power it with those broad brush strokes. All the way through to those software engineers and data scientists who are sort of crunching those algorithms to develop very specific measures. It's funny because I feel like sometimes I'm clinical experts, are worried about being squeezed out and that's absolutely not the case. I don't think we can underestimate how important it is to remember that this is still health care, these are still health care tools, recognizing that the tools of this era, of this century and of the future are digital ones. We need to promote that common understanding.

Margaret Flinter: One of the elements that maybe needs to get teased out a bit is this, are there ethical considerations when we say digital medicine? Are there ethical considerations that are different from the other ethical considerations that we all know from, starting first and foremost with do no harm. Is there a group that's looking at whether there are specific ethical considerations to really be defined?

Jennifer Goldsack: The ethical considerations are indeed very unique in this era of digital medicine. When we are gathering data and information directly from patients when they go about their daily lives, we are obviously understanding and documenting and recording information about them that we never have done in health care. You see things like the terms of used agreements, the privacy policies that you ask patients themselves to sort of re review and agree to without that intermediary. That's extraordinary when you think about reducing costs, when you think about improving access but there's absolutely ethical implications there. Yes, I think this is very unique. The last piece of that too is the flow of the data, the data flow is different to how it existed previously in these static paper document forms where, only the people with their hands on the physical data could access it.

Now many, many people can access any given data point and there are vulnerabilities at all sorts of different points in the chain that we need to be aware of. Again, there's a tradeoff between the access and privacy. I think that that tradeoff is really important, you mentioned to do no harm and that always has a connotations with it, the hippocratic oath that clinicians swear to when they launch their career. There's a fantastic organization, I am the cavalry, who have come up with a security focus hippocratic oath for connected devices. I recommend if anyone listening hasn't read that yet, take a look at that and consider it. Then the last piece, I think we take the need for a very, very, focused ethical framework that really is sort of patient centric.

We're actually currently building a working group to advance work ethics in digital medicine right now and it really needs to be collaborative. It's interesting. I have seen some quite high profile sort of documents and ten principles spin out. Then you look at who was in the room and there wasn't a patient in sight and you're just think, well, my personal opinion is that that's a mistake. I also think that collaborative approach is because there are new problems to solve for. Some of the data access, the sheer volume of data and information we have on any individual and how that allows us to connect dots that we never have been able to before. These are new challenges and that's why we're excited to tackle this and think we're well placed to do so.

Mark Masselli: We have been speaking today with Jennifer Goldsack, Interim Executive Director of the newly launched Digital Medicine Society or DiMe, the first professional organization for experts from all disciplines comprising the diverse field of digital medicine. You can learn more about their work and add your own voice to the conversation by going to dimesociety.org or you can follow them on Twitter at @_DiMeSociety. Jennifer this is really important work. It's timely and we appreciate your forward thinking and thank you for joining us on Conversations on Health Care.

Jennifer Goldsack: Mark and Margaret thanks for having me.

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Mark Masselli: At Conversations on Health Care we want our audience to be truly in the know when it comes to the facts about health care reform and policy. Lori Robertson is an award winning journalist and Managing Editor of FactCheck.org, a nonpartisan, nonprofit consumer advocate for voters that aim to reduce the level of deception in US politics. Lori, what have you got for us this week?

Lori Robertson: Recently two democrats, Senator Kirsten Gillibrand and former president Barack Obama distorted the facts on the public health issue of guns. Gillibrand a democratic presidential candidate claimed President Donald Trump failed to keep his promise after a mass shooting in Las Vegas in 2017 to ban bump stocks. Trump may not have moved as quickly as Gillibrand would have liked, but Trump did enact a bump stock ban, which went into effect in March. At a town hall event hosted by Fox News in June Gillibrand said Trump was "beholden to the NRA" claiming he said he was going to ban bump stocks but didn't because of the NRA.

Shortly after the Las Vegas shooting, the NRA said it didn't support a total ban on bump stocks or legislative action. It preferred revised regulations from the Bureau of Alcohol, Tobacco, Firearms, and Explosives. A bump stock is a plastic or metal device that can be

attached to the rear of a semiautomatic rifle to make it shoot almost as fast as a fully automatic weapon. It did take some time, but ultimately on December 18th, 2018 the Department of Justice and ATF issued a new federal regulation officially banning bump stock. The rule required the owners of any bump stocks to destroy the device or turn them in at an ATF office prior to March 26th when the rule went into effect.

An NRA spokeswoman said the organization was disappointed with the rule because it didn't provide a grandfather clause for those who already had the devices. Gillibrand's campaign told us she was referring to the time right after the Las Vegas shooting when Trump initially supported a bump stock ban and then faced NRA criticism. At a technology conference in Brazil former president Obama misrepresented US gun laws claiming that, "Anybody can buy any weapon without much if any regulation." including he said, "Machine guns. Machine guns have been tightly regulated since 1934 and banned since 1986 except for the sale or transfer of such a weapon that was lawfully owned and registered before May, 1986.

A machine gun is defined by law as one that can shoot automatically more than one shot with a single trigger function without manual reloading. A spokesman for Obama said the former president used the term machine gun when he meant semiautomatic weapons that are currently illegal to purchase in the US such as AR-15 rifle. That's my fact check for this week. I'm Lori Robertson, Managing Editor of FactCheck.org.

Margaret Flinter: FactCheck.org is committed to factual accuracy from the country's major political players and is a project of the Annenberg Public Policy Center at the University of Pennsylvania. If you have a fact that you'd like checked, email us at www.chcradio.com, we'll have FactCheck.org's Lori Robertson check it out for you here on Conversations on Health Care.

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Mark Masselli: Each week Conversations highlights a bright idea about how to make wellness a part of our communities and everyday lives. One in five Americans will suffer a diagnosable mental health condition in a given year and most often don't seek treatment. Seeing a rise in mobile apps aimed at behavioral health entering the marketplace, the University of Washington researcher Dror Ben-Zeev thought a comparative effective analysis study would be a good idea.

Dror Ben-Zeev: My team and I conducted a three year comparative effectiveness trial, with the objective of having a head-to-head comparison between a mobile health intervention for people with serious mental illness called Focus and a more traditional clinic based group intervention.

It's conducted at a clinic setting, people with similar diagnoses. The study really gets at some of the core differences between mobile health and clinic based care.

Mark Masselli: More than 90% of the mobile app group engaged in the online program which was a series of text messages offering coping strategies and self-monitoring of symptoms along with weekly call-ins with the behavioral health clinician.

Dror Ben-Zeev: We measured to see whether involvement in both interventions for a 12 week period would that create some sort of difference in psychiatric symptom severity and 90% of the individuals who were randomized into the mobile health arm actually went on to meet a mobile health specialist to describe the app to them and train them how to use it and use the intervention app that's assigned to them at least once. Whereas in the clinic based arm, we saw that only 58% of the participants assigned to that clinic based intervention ever made it in for a single session.

Mark Masselli: Ben-Zeev says, this suggests that mobile therapies may provide a useful tool for clinicians having trouble getting those with serious mental health issues to engage with the clinical interventions.

Dror Ben-Zeev: The group dynamics that on its own is quite potent for people, but for others the interaction is anxiety provoking. When it comes to the clinical outcomes in both intervention arms, people improved both in terms of reduction in their symptoms and the distress associated with symptoms and improvements in their recovery.

Mark Masselli: A targeted mobile app aimed at facilitating access to clinical care for those experiencing serious mental illness symptoms, proving equally effective in managing the condition, improving access to intervention for behavioral health needs. Now that's a bright idea.

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Mark Masselli: You've been listening to Conversations on Health Care. I'm Mark Masselli.

Margaret Flinter: And I'm Margaret Flinter.

Mark Masselli: Peace and health.

Female: Conversations on Health Care is recorded at WESU at Wesleyan University, streaming live at www.chcradio.com, iTunes, or wherever you listen to podcasts. If you have comments, please email us at chcradio@chc1.com, or find us on Facebook or Twitter. We love hearing from you. This show is brought to you by the Community Health Center.