**Title: Policy Challenges and Opportunities for Digital Therapeutics in the Mental Health and Substance Use Crisis  
Date & Time: Apr 6, 2022 02:00 PM Eastern Time (US and Canada)**

**Nathaniel Counts:** Hi, everyone. Welcome to today's webinar, *Policy Challenges and Opportunities for Digital Therapeutics and Mental Health for the Mental Health and Substance Use Crisis*. Thank you so much for joining, we really appreciate it. Today's webinar is really focused on the fact that as many have noted, we're facing a mental health and substance use crisis in this country.

They're really started over the past decade rates of opioid and other substance use deaths began rising as the deaths from suicide and other mental health-related causes. Then with COVID-19 and the pandemic, it dramatically increased. We've seen huge gaps in access and barriers, and even deeper inequities among BiPAP and rural populations able to access care.

During the same time, we've also seen exciting opportunities from the digital and virtual world as new modalities began to enter practice, but access has been limited in many cases. I think it's a very nascent and exciting field and the question are what are the opportunities here and what are the challenges, especially from a regulatory space? What is the role of the federal government in realizing the opportunity of technology to meet the current moment?

In this program, we have a really exciting two sets of panels that I'm so excited to share with you. The first panel is going to focus on the view from the field. Dr. John Torous, Director, Digital Psychiatry in the Department of Psychiatry at Beth Israel Deaconess Medical Center will be moderating a panel with Dr. Trina Histon, Kaiser Permanente Senior Principal Consultant.

Dr. Steve Chan, the Chair on the Committee of Innovation for American Psychiatric Association, and Dr. Juliette McClendon, Director of Medical Affairs at Big Health to talk through some of the issues. Then we'll move to the view from FDA and CMS with Mr. Bakul Patel and Dr. Meena Seshamani. Thank you so much. With that, we'll turn it over to John to lead us off.

**John Torous:** Excellent. I want to thank Mental Health America and American Psychological Association for gathering such an exciting panel. I'm very excited for the first half and of course, the second half to hear from the administration. I think, again, we're going to hear from Dr. McLendon, really looking at exciting work Big Health is doing. Dr. Chan is doing amazing work with Stanford in the American Psychiatric Association.

Trina Histon is leading some, I'm going to say, the largest efforts on integrating apps into care that I've ever seen. I want to jump right into questions with this amazing panel and begin to ask. Juliette, what is software's medical device, sometimes known as digital therapeutics, and how might this be useful to address mental health and substance abuse issues, especially for those populations that can't always access care?

**Juliette McClendon:** Yes, absolutely. I'm happy to speak to this. I think it was really important, Nathaniel, that we started with your overview today because really, what we're seeing now is just an overwhelming demand for care and access, and patients are really facing challenges in accessing care. That's really the origin story of digital therapeutics. What we see in action within the healthcare system is that, typically, people have two choices when they have a mental health condition.

They can take medications or they can seek care from a specialist like myself, a clinical psychologist, or another licensed mental health provider to provide psychotherapy such as cognitive behavioral therapy for that condition. What we know is that for many people, these behavioral interventions are very difficult to access even though they are the recommended first-line treatments for common mental health conditions.

Again, the pandemic and COVID has really exacerbated the challenges that people face in accessing care. For example, in many areas, the appropriate specialist doesn't exist, isn't taking new patients, or would require on average a three-month wait. I've heard of wait times being even longer than that. That makes it very clear that what we need is really a new and innovative treatment approach to fill those gaps in access and in quality.

That third approach is digital therapeutics. Digital therapeutics really allow us to offer guideline-consistent care which is typically behavioral interventions like cognitive behavioral therapy or CBT in digital formats, and as pure software, because they're fully automated and there's really no need for human intervention, they can really be offered at scale to everyone in need.

While many digital therapeutics were created prior to the pandemic, I think that they've never been needed more. Because digital therapeutics are scalable, they really help expand access to treatment for millions including those from medically underserved communities. Our digital therapeutics in particular at Big Health are Sleepio and Daylight.

They're typically accessed via patients' smartphones or desktop computer, and they're able to access the therapy meeting, the techniques that they're learning to help manage their symptoms, they can access those techniques wherever and whenever they need it. That kind of convenience really removes a lot of access and as well as stigma barriers, that can prevent people from underserved communities from seeking care.

I think as technology matures, more and more will be able to tailor these treatment approaches to patients from different genders, races, ethnicities, to be able to really deliver treatments in ways that most resonate for those specific communities and that are culturally responsive while also maximizing clinical outcomes. The last thing I'll say is that I think it's really important to emphasize, that I think we're really getting past the point of debating whether digital therapeutics are effective treatment options.

At Big Health, we have 13 randomized controlled trials showing the effectiveness of our therapeutics. The bigger question I think now is how we can really achieve widespread adoption in the United States access to digital therapeutics which I think is lagging somewhat behind other developed countries in the recognition and use of these tools. For example, we, at Big Health, have partnered with the Scottish government who're offering our therapeutics to their entire population through the NHS.

Countries like in the UK, Scotland have really recognized that need for digital mental health interventions to fill those gaps in access to care. Today, all Scottish adults can access our products free. Then the last thing I'll say is that what we really need to think about when we think about digital therapeutics is that they'll be rigorously tested and evidence-based, and that's how we define digital therapeutics.

A true digital therapeutic is one that has been tested using clinical trials and where we can show that they actually lead to significant health outcomes. One thing I'll just highlight just to end here is that according to clinical guidelines, Big Health, our therapeutic for sleep, for insomnia, Sleepio, which is cognitive behavioral therapy for insomnia in a digital format has more high-quality clinical evidence than Ambien, one of the top prescribed medications for insomnia. There are significant advantages to including digital therapeutics in what patients have access to along their mental health care journey.

**John:** Thank you, that's a very thorough answer. It's nice to see high-quality evidence. One paper that some of you may have seen came out this week was there was a digital therapeutic being proposed for schizophrenia and they actually did a control condition where one group got the digital therapeutic and one group got a digital placebo. They say, "What is the digital placebo?"

In this case, it was actually just a clock, it's that how much longer are you having to study. It was fascinating. The clock actually had the same results as the app. Again, this is one study in one condition, but it shows you why we want to have high-quality evidence-

**Juliette:** Exactly.

**John:** -because we certainly don't want to be prescribing patients a stopwatch. We can but it's probably not going to be an evidence-based stopwatch. Enough with corny jokes. I think this next one is for Dr. Chan. As a researcher at Stanford, you're doing excellent clinical work **[unintelligible 00:08:57]**, you're doing innovation work with the American Psychiatric Association.

How do you see this evidence developing around softwares on medical device, again, sometimes that's called digital therapeutics and formerly being used? Where are we now and where are we heading with that evidence?

**Steven Chan:** A lot of Juliette's points, I do agree with. John, you and I have seen this evolve for the last decade. We've seen how mobile health and health, all these other terms have come up and we've seen studies that assess the feasibility, pilot studies, do people want this? Are people satisfied with this move on to huge randomized clinical trials? Now, what we're now trying to figure out is how can we deploy this on a wide scale in a sustainable way such that we can continue maintaining high-quality software and also implement things in a proper fashion without burning outpatients and without burning out staff.

I know that over the past two years, we've seen COVID really dramatically change the landscape. Now we're seeing a lot of just how telepsychiatry telemental health and smartphone apps there a lot of the this have a graduation they're being blurred together too. I'm part of a group called advice health at the University of California, San Francisco, UCSF and we are putting together essentially a digital health common application, DHCA, and this common application includes a lot of elements from chief health informatics officers from systems across the nation.

One of the issues that we are facing is that now we're seeing lots of apps, lots of solutions that can be integrated into the EHR or separately. I think the statistic can't quote me on this. Exactly, but I'm hearing CMAs say that every 18 minutes, they get a pitch from a vendor in their inbox. It's very difficult for them to sort through all that. Through all these offers and solutions, so the advice health program is looking at curating and also disseminating these practices across health systems. That's advice, health.org at the American psychiatric association we're seeing that there's a lot of interest in these smartphone apps.

One of the most common questions that we have is well, which app do we use again there's a lot of apps out there. I know that even in the literature Steven Schuller and a lot of other folks have used different acronyms, are they DMHI, DHTS DMHS, digital mental health interventions, et cetera. It just shows to you that this areas evolving.

John yourself I'm signing your work and your work with the APA and a lot of our experts have put together the app evaluation model that looks at things like access equity things like security and puts together a framework but it's not enough. I think that what it's going to happen is that there will be different accreditation bodies, different evaluation bodies. It could be governmental or industry-driven. There could be a lot of different solutions, just like how we have CARF joint commission, URAC.A lot of different groups that can come together to vet these technologies.

**John:** It is a little bit overwhelming with, again, pitches people may see or apps or it can be anxiety-provoking. You look for an anxiety app. That's not a good place that we're at, but I think that really leads well to my next question again, is we point these apps is to get them used hopefully in clinical settings, we're talking about now. Trina, I think the work that you've done, I'm going to be bold. I still think it's the largest national effort I've seen to get apps into the Kaiser system. Maybe you could tell us a bit about your experience, and implement these apps in tools in a way that payers and providers are using together. What is it like to just do this at scale?

**Trina Histon:** Yes. It's certainly kept me very busy the past several years. Thanks for the question and for inviting me to be here today. I would say we started our journey in Kaiser Permanente building out our digital mental health ecosystem back in 2017. Our ecosystem has two layers. One is apps, and there's now six in the adult space that we've fully deployed across our entire care footprint.

Then the other layer is content. Really putting the topics that are top of mind that we were hearing from our clinicians that patients always ask about, but putting it in a more member-facing flow, so that can be available as well at the time of the visit. We were leaning into cognitive therapy and mind-based stress reduction in our early apps, but we recognized in the several years since that many more have come to market, I think last time I read about 20,000 apps exist for mental health.

Getting to what good looks like can be quite a challenge. We were very deliberate about leveraging human-centered design to deeply understand, on one side, how are clinicians leveraging these tools, even if they were, would they find them of value because implementation science pointed to barriers about confidence belief, and then how do I do this in my workflow? We really wanted to go into several care settings, including therapists, psychologists, psychiatrists, and primary care.

Then on our member side, we wanted deeply understand their care experience, why they were reaching out to us. Were they using digital tools where they were receptive to that? We wanted to make sure we were leaning into the member-centered signal from the clinician side and from the member side. We actually started out 25 clinicians in two of our markets.

Then when the pandemic hit, we rapidly scaled because we built and tested things. We're in about 2,400 clinicians specialty behavioral health, and then we've also made two of the six apps available in primary care. We had to synthesize all of our learning so we could systemize it in to our EMR. That was a very long and important journey we're continuing to learn. How do we choose the apps? Well, back in 2017 and thank you, John and colleagues, the American Psychiatric Association had their app evaluation framework. We leveraged that. We looked at the published literature, CBT and mindfulness have modest effects sizes from the meta-analysis put published.

Of course, we've got several more since that time. We knew clinically that these tools have value and for CBT it works in all modalities. We looked at early outcomes from the app companies and then we also looked at user experience because you can have the best app with all the fines in there. If the user experience is clunky, it's never going to get used. That's super important. We've now evolved those three areas to a seven-component framework that has about 78 items. That includes company reputation, pricing, data, integration, security, privacy, ADA compliance, you name it. It's very, very complex to bring these tools into an integrated healthcare system.

The value we see with our therapists and what we hear from our psychologists is they concretize the homework or life work that they can provide. If somebody's talking about a particular issue in session, then they can be very specific in the app, go in here and do this module or leverage these resources and then we'll come back and talk about it.

They really like it for that purpose. We're hearing from our psychiatrist, it takes a couple of weeks for medications to take effect. This is a real way to get some symptom reduction in the moment while they're waiting for those meds.

Then in primary care, patients are going in, maybe they're not sleeping well, certainly in the pandemic we've seen and stress and these tools can be a way to, again, manage through those moments for them. We really see broad application. We initially thought we'd be leveraging deployment for my symptomology, but the reality is they can be leveraged across the care continuum. To be clear, not all apps or digital therapeutics, we also have digital wellness. I would love to see the creation of a framework, say like the NHS has in England, we see Germany has one.

We see Australia, Belgium, and France building frameworks to know what good looks like. It's really hard to determine that. I certainly echo the pitches that we get quite regularly as well. The app is only one component. You've got a really integrated and if you haven't succeeded in fitting it into workflow, they're just going to be great apps that nobody uses. We're looking at the data we have de-identified aggregate app data. We share that monthly with our behavioral health leaders. We're continuing looking at best practices, we're moving toward and maturing our data infrastructure.

We'll get a deeper sense of where the apps side value because that's different for the clinician side. It may look a little different from the member side. I think the value prop for me, for digital tools, including digital therapeutics, is they can give you data and insights beyond reduction in symptoms in terms of a bigger picture of how somebody's doing.

I'm personally excited by that and want to see how we can get to that reliable change. What path can I take through an app that gets me to reliable change? Lots going on in our adult deployment and where I spend my days now is in youth mental health, huge, huge need, a very, very nascent space with a lot of tools, and young people need different things than adults. Really leaning into that. That's some of their learnings. I'll pop the paper we published on this whole thing in the chat so people can access that. Thanks, John.

**John:** That's a terrific answer. It's inspiring from all three of you to see industry working on very impressive studies, very impressive academic efforts, implementation efforts getting it out. I'll open this question perhaps up to everyone to take a shot at it. Clearly, we would like to increase access to care. There's no doubt about that. We clearly want to make sure patients have things, as we said, that are safe and effective, there're not going to be harmful. How do we go about in the next stages of this to make sure we can increase access to care and keep again innovation, but not wildness, and have our patients using unhelpful things. Whoever wants to take the floor, go for it first?

**Trina:** Well, I can pop in there, John. I think what we're learning is in the several years we've been working with these companies we get to see like our psychologists and therapists would say, "Oh, I really wish we had this tool. Can they build that out?" We can get to influence the product roadmap. Then there's even a better fit to the care model. I will say in the pandemic, the other thing we did is we deployed in a self-care. Our members 12.5 million of them can access 2 of the 6 apps for self-care without even being tethered to a plan of care.

That's increasing these tools, putting them in people's hands in ways that make sense. I think we need to be judicious about how we do that and making sure we're choosing good solutions that our clinicians feel, yeps, the science is in there. I see the techniques and really if an app, for example, didn't meet our clinical needs we would be less likely to deploy it. That's one way to have an infrastructure in place to determine what good looks like and see where the value might be. What are some that clinically deployed, what are some that are self-care in terms of someone can access them without needing to see a doctor or a psychologist or a therapist, for example.

**John:** That makes sense. Again, if these are digital therapeutics, how does it work now for you all in terms of who can prescribe them or use them?

**Juliette:** At Big Health, we don't require prescriptions for people to use our digital therapeutics. We're under the FDA clearance right now based on the pandemic and so what we're able to do is offer individuals through their employers right now, primarily access to our therapeutics without a prescription. What this does is increase really access to digital therapeutics and to that high-quality evidence-based care by the fact that people don't have to seek out a prescription from a medical doctor. That is how people are accessing our digital therapeutics and then there are other digital therapeutics like prescription digital therapeutics that do require prescription as well.

**John:** Got it. This is interesting question from the audience or anyone says overall, why aren't digital therapists been developed for mental health or substance abuse conditions, widely accessible by individuals that face the greatest barriers to care?

**Juliette:** Yes, I'll jump in really quickly and say one of the problems is reimbursement. How do these solutions get paid for, right? The reason why big health has primarily worked with self-insured employers is because there is a way through which the digital therapeutics can be reimbursed or paid for that doesn't fall on the consumer or doesn't fall on the patient. I think that is one of the biggest hurdles we need to overcome is figuring out how do we increase access by making sure that people have access, but they also are able to afford it.

**John:** That makes sense.

**Steven:** I can jump in a little bit too. The way I was thinking about this is it's similar to, there's a really fantastic chart on dimesociety.org dime Digital Medicine Society. I'm not part of the group, but they have a very nice chart that shows a concentric circle, digital health, digital medicine, and then digital therapeutics but these are also terms and different pathways that industry and researchers are trying to carve out. For instance, I don't represent the veteran's affairs in this talk but I will say from my experience, there's so many different ways of requesting services. Do I request a consult? Do I request medication or order a medication?

Do I order a lab? Those are all boxes that we place different categories of services in but I can order a prescription box through the medications menu, but a prescription box is into medication. It just happens to be, how it was categorized and which service is taken care of him. Potentially, in the future, we could see maybe there's a digital therapeutic or digital resources ordering set in the electronic health record.

This is where we see the struggle of how do we get the access that Juliet mentioned but also do the folks who need it the most, you mentioned severely severe mental illness, severe substance use disorders. Are they able to maintain a phone or do they lose their phone every few days because of cognitive issues or substance issues and are they to afford it? There's so many different questions that need to be answered by industry, government and academics.

**Juliette:** In terms of specifically underserved communities, I think that we need to look beyond just referral by physicians and reimbursement models and think about what social determinants of health may stand in the way of people being able to use digital therapeutics and how do we address those or leverage existing structures to that exist within communities, underserved communities to help in increase access within those communities.

**Trina:** Yes, in our deployment we made the determination that we were going to cover the cost of that so our members get access to the tools at no cost to them. The things we've to consider are people's data plans and are they on a very strict data plan or in an area with poor wifi and can some of these apps have content downloaded on wifi and then leveraged offline all of these things go into how you match an app with how somebody might use the app. That's part of, again, what our clinicians think about when they're making that referral.

In addition to what the app is for I'm seeing more and more of this phrase of tech equity show up and a lot of the early apps were in English only, and we've got a very diverse member base. How are we making sure when somebody opens up that solution, that they see themselves and they feel seen, and the framing and the tools in there reflect their lived experience. I think I'm seeing more and more of that happen now, certainly in the youth mental health base, which I applaud and we need it. It's not a one size fits all, and it's not one app to rule them all either.

**John:** That makes sense. I'll quickly have a comment on one last hot take question. I think, certainly, even in our clinic where we're entering apps into care, we offer digital literacy training and support from staff. That's not reimbursable and there's no easy path to get that reimbursed that said, "I don't think anyone wants to offer a clinic to only a certain segment of population that's tech-savvy."

I think that is one, what are the supporting services that we need to go around is are important but this last question is a fun one. There's no right or wrong answer to, I promise but how would you evaluate the efficacy of digital therapeutics in real-world settings to make sure **[unintelligible 00:26:53]** valuable? Because what works in a clinical study with volunteers is that going to work in the complex world of care delivery? What type of evidence do you all want to see or what would you want to make it work?

**Trina:** Engagement's a big one. John, so looking at the arc of engagement, we know from the published literature by day 14, there's a huge drop-off. Are we keeping people on the journey long enough to get the benefit? How do we see if it's assessing depression or anxiety, seeing the clinical markers for improvement, response remission, but also the fuller sense of are people in their lives more?

I know you're doing a lot of work in digital phenotyping, which is still very early, but are people more fully in their lives, and are they doing better? Then they're reflecting back the clinic visit. Oh, I'm seeing my friends again at weekends, I'm back at my kniting group, my book group, all of those functional things that may or may not show up in an assessment in an app that we're hearing about those. There's some ways we know that they're adding value in our therapists and psychologists and psychiatrists saying, yes, I like this one because it helps.

**John:** That makes perfect sense.

**Juliette:** John, can you say the question again?

**John:** Yes, so again, understanding how do we know that these things are going to work not only in a clinical study, in a real-world where it's a little messier than a clinical study?

**Juliette:** Yes, so I think the one thing we do at Big Health with our digital therapeutics is that there is a lot of information that is gathered from users in the app, or in the therapeutic. We're able to track their progress over time because they answer questions as they log into the therapeutic and use it, and so that's one way that we can--

We at Big Health have a lot of real-world evidence of how does this work in the wild, and yes, there are going to be some differences in terms of, for example, remission rates between a clinical trial and real world. What we're doing at Big Health is really working to how do we optimize and improve remission rates in the real world as much as possible. We can do a lot of that by just using the data that we're able to collect within the therapeutic but then there are also opportunities to do that in a more with a systematic study design as well.

**John:** That makes sense. I'll give the last point to Dr. Chan and we may have to wrap up.

**Steven:** Sure. From my understanding of a real-world evidence is, it has to be something that's designed from the start. You also want to consider things like security and privacy and also full informed consent when it comes to the data that you're collecting. From, at least in my clinical practice, I'm not seeing that incorporated as well as it could with a lot of the apps that we are allowed to use.

Some of the apps actually don't interface with the electronic health record and I think that that's going to evolve as a lot of these integration frameworks like FHIR, become more mature and more widely used. There's also another framework called gravity that looks at social determinants of health, whether folks are able to afford clothing or what kind of a social cultural elements are involved with their care? Those are the things I would love to see and dissect as these apps mature. [crosstalk]

**Juliette:** I'm sorry, can I say one more thing? All I want to say is that I know that there's concern about access to digital therapeutics because of lack of broadband or cell phones. I want to just say that yes, that is true and it's something we need to work on, but we also need to understand that what we have existing in the healthcare system also is extremely inaccessible and so we have to think about that more broadly.

**John:** I think this panel could go on for not hours, but days, months, but unfortunately we're going to break here because we have some exciting next panel and not to cut into them. Thank you very much Juliet, Steve and Trina it's been a pleasure.

**Juliette:** Thanks.

**Nathaniel:** Thank you so much to all of you, we really appreciate it. Just to turn it over, I can't see myself in this **[unintelligible 00:31:02]** I'm an expert in this field and I feel like I just learned an incredible amount, so thank you so much. It's hard to go half hour, I feel like it could have gone for forever.

I just want to turn it over we're so happy to have this next panel, we really appreciate taking the time we're so excited to hear from them. Moderating we're going to have Dr. Vaile Wright, Senior Director of Health Care Innovation and Practice at American Psychological Association, Mr. Bakul Patel, Chief Digital Health Officer of Global Strategy and Innovation at FDA and Dr. Meena Seshamani, Deputy Administrator and Director of Center for Medicare at CMS and with that, I will turn it over to all of you, thank you so much.

**Dr. Vaile Wright:** Thanks Nathaniel. I am so thrilled and honored to be here moderating the second panel comprised of two such accomplished individuals in this area. As Nathaniel mentioned, I'm a Vaile Wright, I'm the Senior Director of Healthcare Innovation at the APA. Over the last couple years, we've really been focusing our attention on the role digital mental health interventions may have to help expand access and improve health equity, which is again why I'm so excited to be here.

I've been please to see all the questions coming through, it's really clearly obviously energizing everybody. I'm excited that we can go with the second panel. Let me introduce our speakers, for the sake of time I'm going to provide abbreviated versions of each speaker's bio, but you can find longer versions on our website. Dr. Meena Seshamani is the Deputy Administrator Director at the Centers for Medicare and Medicaid Services or CMS. She's an accomplished strategic leader with a deep understanding of health economics and a heartfelt commitment to outstanding patient care.

Her diverse background as a healthcare executive, health economist, physician and health policy expert has given her a unique perspective on how health policy impacts the real lives of patients. She's most recently served as the vice president of clinical care transformation at MedStar Health, where she conceptualized designed and implemented population health and value-based care initiatives.

Dr. Seshamani also brings decades of policy experience to a role including recently serving on the leadership of the Biden-Harris transition HHS agency review team. Mr. Bakul Patel is the Director for the Digital Health Center of Excellence at the Food and Drug Administration or FDA. He's responsible for providing leadership development, implementation, execution management and setting strategic direction and regulatory policy and coordinating scientific efforts for digital health software and emerging technologies.

In 2013, Mr. Patel created the term software as a medical device and under his leadership the international medical device regulators forum established the globally harmonized definition of software as a medical device. Mr. Patel is currently leading the effort for the agency in developing an innovative software pre-certification program to reimagine a pragmatic regulatory approach for digital health that aims for patients and providers to have timely access, to safe and effective digital health products. Welcome to both of you and thank you for being in here today.

**Dr. Meena Seshamani:** Thank you for having me.

**Dr. Wright:** This first question is going to be directed at each of you and I'll ask Dr. Seshamani to go first, but given the current mental health and substance use crisis and the particular barriers that we've been talking about to access to effective care for historically marginalized communities like individuals from communities of color, LBGTQAI+ also rural populations. How do you see digital therapeutics fitting into the toolbox of strategies we have to respond to these needs?

**Dr. Seshamani:** Again, thank you so much for having me here today. It really is an honor to lead Medicare at this pivotal time in our nation's health and to be able to engage with all of you in these kinds of discussions. Because as you know Medicare is an accelerator of change throughout our healthcare system. Throughout its history Medicare has been at the forefront of developing new approaches that the private sector often emulates and so where we can make improvements to Medicare it can ripple across the healthcare economy.

As a doctor, I've experienced this firsthand, the difference that Medicare can make for my patients and as a health system leader understanding the tremendous opportunities that Medicare's quality and payment programs can have to bring health sectors together in partnership to truly advance health in our nation. As we are thinking about digital therapeutics and how we address the mental health crisis in our country, we really want to bring it back to what is the future of Medicare and what is the vision?

The vision really is around advancing health equity, driving high quality person centered care, and promoting affordability and sustainability of the Medicare program. Where can these kinds of innovations that have been occurring really fit in and drive towards that vision, particularly around behavioral and mental health? I don't think we can understate the extent to which COVID-19 has changed the context in which all of us are operating. Making concepts like disparities, inequities, social determinants of health. Things that we have been discussing in the healthcare world are now household phrases.

Because these profound health inequities have been laid bare by the pandemic. We are talking about behavioral and mental health and social isolation more than we ever have. This administration is committed to policies that will invest mental health and strengthen equity in healthcare as described in the recent president's budget. We're talking about how to deliver care where people need it more than we ever have before. The pandemic has taught us that it's so important to meet people where they are and that caring for people.

Not just within the four walls of a hospital, our office visit, but across the experiences of a person is key to keeping people healthy. For digitally enabled and virtual services more broadly, there is an opportunity to more holistically care for people, to bring care upstream, to prevent a hospital visit in the first place and for us to be able to leverage this, to drive that vision of the future of Medicare around health equity, high quality person centered care and creating an affordable and sustainable program.

**Dr. Wright:** Thank you. I often say we can't individual therapize away out of this crisis, it's just not going to work. Mr. Patel, the same question to you, how do you see digital therapeutics fitting into the toolbox of strategies we use to respond to the mental health crisis and the needs of the variety of populations that we serve?

**Mr. Bakul Patel:** I think it's a incredible honor to be on this panel with fellow panels Meena and you and listening to the previous conversation, I think I was completely inspired by some of the conversations that were going on. I have to say, I think I'll just echo everything that Meena just said, but I'll add onto it by saying that I think that the agency, the Food and Drug Administration especially we've been very forward looking and forward thinking in terms of how do we enable technologies, in general, to be in a way that we are evaluating, so that's evidence that are being generated that we can evaluate it and people can have trust in those technologies?

I think trust can go further along as we think about digital health tools. I'm going to start at the top level of digital health tools before we get to digital therapeutics. We can actually reach many people. I think we were talking about how ubiquitous cell phone usage have become, how ubiquitous internet access have become and some of the challenges we know that exist into a system.

As you said, it very rightfully we cannot therapize like one patient at a time and I think these technologies are going to be a pivotal strategy for our entire nation to start adopting, but I think we need to also sort or balance it with the evidence that we require this products to be available. I'm going to touch on trust a little bit and it's a little bit different than safety and effectiveness because trust is going to require us to educate patients, educate providers and clinicians along the way, so they can also give the right context of use to the people who are going to be using it.

I think that's going to be something that we all have to think about strategically. How do we advance? To FDAs credit, I would say that we have been clearing and authorized products to go to market with these technologies and we've seen game-based technologies, we've seen other types of technologies from substance abuse and the entire potential for these technologies to be ubiquitous available to people who can download things from the internet or download things from the app store, have the that's the potential we are seeking for. Now, truth is going to be in the real world data that we are going to collect and evidence that's going to get generated from this over time.

That how we harvest that and use it for the next level of interventions that we would want to see that can be adjunctive to the therapy that a person receives with the person with the clinician in front of them. I think in from my perspective, I feel digital therapeutics tools can potentially be standalone, but also it can be an adjunct to our current therapies that exist today and can be delivered today.

How do you maximize? I think in my mind, it's not going to be one and one equals two, it's going to be one and one equals three, which is going to take the challenge that you just laid out nicely. It's not just about, LGBTQ+ population or the rural America population. It's going to take us all to think about in a very holistic way.

**Dr. Wright:** That concept of trust is really interesting, especially when we think about our climate right now as a country and the misinformation and disinformation and the lack of trust that I think has been fostered in such an unfortunate way. I hadn't really thought about it when it relates to digital therapeutics. How about Dr. Seshamani, CMS has frequently been in the position of accommodating advancements and technology that weren't considered when the program was created.

As one might expect, technology moves very quickly and it's hard to anticipate. What do you see as the novel challenges and opportunities for CMS that you might face in considering digital therapeutics to augment, mental health and substance use disorder treatment. I hear a lot from other payers about concerns about fraud and waste. I'm thinking about from your point of view of CMS, what do you see as the novel challenges and opportunities?

**Dr. Seshamani:** Yes, without a doubt, the pandemic has accelerated innovations and care delivery. A recent report from the department of health and human services detailed a 63 fold increase in traditional Medicare telehealth visits in 2020, a result of public health emergency waivers and new statutory authorities that were granted during the pandemic. Now these flexibility helped maintain access to care as well as support provider financial sustainability during the pandemic when in person visit declined dramatically.

Importantly, this report also found that some individuals with Medicare, including black individuals and those living in rural areas had lower telehealth use compared with white and urban living individuals, respectively. A more recent report showed that among telehealth users access to video services was significantly lower among black and Latinx, populations, as well as those with lower incomes and less education.

It's important for us moving forward when we want to average new technologies like digital therapeutics, but we make sure that they advance access while also addressing existing disparities and not exacerbating or causing further harms. For example, for digital tools or telehealth enabled services, considerations of broadband access, the cultural and linguistic appropriateness of service, the familiarity and comfort with technology among the diverse population of people with Medicare, all of these things should guide efforts for development, for dissemination and for evaluation of innovations.

I think another important point is something that I feel strongly about as a physician, the usability for the end user, including for me as a doctor and my patients. During the pandemic I saw how my patients were able to use telehealth to engage from their home, increasing access to care, improving quality of life. I also know that if the greatest idea isn't integrated into a practice's workflow and how a person engages with their care team, then nobody will use it.

Making sure that we are thinking about that usability, which again comes back to issues of language and culture and comfort with technology for us to keep in mind. I think coming to the second point, as we about how we can provide person-centered care. I do think that with all of the innovations that have occurred, we want to be able to evaluate them for how they can better enable us to better coordinate care, to move care upstream, to address health disparities, to be able to keep people healthy by providing a more comprehensive approach for caring for people.

We have various holistic care models including our accountable care organizations, where groups of providers come together to take care of a population and meet quality and, savings metrics. Our accountable care organizations have often been at the cutting edge of incorporating new technologies to drive changes in care and we want to further harness that.

Equity and then person centered care and now to fiscal stewardship. I do think that with all of these technologies, we need to be mindful of fiscal stewardship of the American tax payer dollar. I want to challenge innovators to not just replace an in-person visit with one using audio visual technology, but to create new technologies that will fundamentally drive better care, smarter spending and healthier populations.

Where can new technologies keep people healthy? Where can they prevent them from getting sick and keep them out to the hospital? Where can they reach people who have thus far not been able to access care? I think this is how we can make sure that the innovations that are being developed or with an eye towards getting more out of the dollars that are spent and that we really do keep people healthier.

**Dr. Wright:** Yes. I really think of it as a population health issue in a lot of ways is how do we reach people before they reach a diagnostic condition? How do we reach people when they're subclinical? How do we reach people before they even get to that point? I do think technology won't solve all our issues, but I think offer some opportunities. Mr. Patel as we think about the reimbursement and the regulatory challenges that were brought up in the first panel. How do you think about the FDA's role in balancing access to effective products and patient safety with this unprecedented rise in digital therapeutics?

**Mr. Patel:** Yes, it's a great question. I'm just thinking about this response, and I'm considering some of the challenges in the regulatory system as we evaluate safety and effectiveness comes from the point you just raised, right? It's a population health issue, which means prevalence is going to be one factor in our considerations of evaluating safety and effectiveness of a product, right?

The challenge in this space is because it's such an emerging area. We don't have, at least to my knowledge, don't have numbers to use to say, here's the prevalence for mental health in this population that we should directly outweigh, benefits would outweigh the risk of the product of being used for being misdiagnosed or delayed in diagnosed are in perhaps even treatment. I think that's one challenge that our reviewers how to pay attention to while they're reviewing this products.

The second thing, I would say the regulatory from a regulatory perspective, for FDA to start thinking about, is this going to be better than the clock example that John was talking about in the previous panel panel? Is it going to be a placebo that we need to get over and understand so on. I think there's so much science being developed as we speak.

As we starting to understand what interventions did used to happen with humans, if I were to say clinicians as the general population humans, and sometimes families play a role in that intervention as well. That's way using that word, but as we start to understand how that works and how technology and tools can supplement, or maybe perhaps even compliment it to some degree. I think that's the challenge that we'll have to get to.

It goes back to comfort with technology is going to change over time, our tolerance to information is going to be very different over time. As we start to see this moving paradigm over that changing in front of our eyes actually, and pandemic just accelerated, is going to help us understand. All this to say that we and the community who's building this technology, how to pay really big attention to, how do you monitor and collect real world performance and evidence from these tools.

We as a community can learn and inform ourselves and if you're in a cardiology world you know what the gold standard is for EKG and you can compare it to, is it actually done something better. For drugs It's really easy because it's affected or not and you can do some trials with that. In this space I think the challenge is the science, the population, the interventions are all evolving.

I think, I feel as we are evolving together, we all need to learn from each other and we need to create this learning system that we all have been talking about for a very long time.

**Dr. Wright:** I think that was part of the impetus for wanting to bring this panel together was to start getting these people all in the same room, talking about these issues, and really coming at it from a more holistic place than I think where each of our stakeholders might live in terms of their priorities. Dr. Seshamani and I were talking a lot about exciting work in primary care integration, the role of federally qualified health centers, expanding access, and what is your vision for how payers including CMS can appropriately incorporate digital therapeutics as a tool for addressing mental health equity?

We heard in the first panel, how challenging it is to get reimbursed in a scalable way that often products go through the employment benefits. Where's your vision? I would ask, from CMS' point of view?

**Dr. Seshamani:** To build on what we've been talking about, the pandemic definitely necessitated many changes to ensure that we could provide care virtually including in people's homes to protect Americans from COVID-19 while maintaining access to health care services more broadly. Moving forward, we must evaluate and harness lessons learned from this. For example, I mentioned the HHS report that was done looking at telehealth utilization for people with Medicare.

Another key point of that report was that behavioral health had the largest increase in telehealth use in 2020. A third of behavioral health visits were done by telehealth. Moving forward following congressional action, we have implemented policies to permanently allow people with Medicare to stay in their homes to access telehealth services for mental and behavioral health disorders.

We will continue to pay for telehealth including audio-only so that people will not be limited by lack of broadband access. This comes back to you know those pillars that I mentioned about where we want to drive the future of Medicare, around improving equity, because mental and behavioral health services are particularly important for vulnerable populations, including people in rural areas, because we want to have person-centered care so that we're really trying to address the mental health crisis that's created by the pandemic. It extends beyond just telehealth, we are thinking about how we can provide care outside of the four walls of the clinic or hospital in other ways.

For example, we recently approved additional payment for a home dialysis device. It's the first-ever technology to be approved under this policy that allows for enhanced payments for innovative technologies because again, our end-stage renal disease patients tend to be some of our most vulnerable, and we want to make sure that they have access to care, especially in their home, especially during the pandemic, but even outside of the pandemic, where oftentimes they don't have easy transportation to get to a dialysis facility or they need something that's easy to use, because they may not have the resources or support.

I think overall, the administration is committed to studying these new innovations in health care delivery so that we can understand what services will support a stronger Medicare. We know that new technologies and services that are software-based, have been emerging over several years. They've raised questions about how providers are using them and considerations for Medicare coverage and payment.

Ultimately, this comes back to what I was saying earlier about how we need to understand how these new innovations can help us drive better care, smarter spending, and keeping people healthy. This is where all of you can help us. Through our policies, Medicare can help create the conditions for changes needed in our health system, but we need others to bring their perspectives and experiences to the table to look for ways to connect sectors and organizations that historically haven't talked with each other.

This is particularly important for behavioral health and mental health. Where can we create connectivity between previously siloed work, for example, between a health care provider and a community-based organization? Where can we harness data as a common language for all of us engaged in improving health and advancing equity to use? Because we can't improve what we don't measure.

Because having that data can then serve as a way for all of us to see where there are opportunities for improvement, to understand the needs of a person and the population, and to work together to address those needs. If there's anything at my work as an economist, a physician, a policymaker has taught me it's that we're never going to be able to solve these problems if we're thinking about the solutions on our own by ourselves.

We know that Medicare can't solve complex problems on its own. We really need a coordinated multi-sector effort that bridges silos across the healthcare ecosystem to create lasting change.

**Dr. Wright:** I absolutely agree. I do also want to say that we really appreciate you keeping the telehealth turned on, including the audio-only. I think that that really does have an important trickle-down effect for other payers as well, in terms of keeping those services and that continuity of care going so I absolutely agree. We're running out of time. I want to get a couple more questions in, I'm incorporating questions that I'm seeing coming in into the questions that I'm asking just so people know.

Mr. Patel, we've talked about this a little bit, but what are your thoughts about how the real-world evidence generated could be incorporated into regulatory approaches that you're thinking about and developing for digital therapeutics?

**Mr. Patel:** I think the way I think going back to the concept of if you cannot measure you cannot improve, I think Meena just said that. I think it applies to technology as well. If you're not going to instrument your products, to measure outcomes, or measure the performance of the products, or how users and we talked about usability in the previous panel as well, if you can measure usability of products, the stickiness of patients sticking to that therapy, or the CBT tool that's been available.

Such measures will actually go a very long distance in terms of evidence that people are able to extend the therapy for a longer period of times so that it's effective, and just about what works and what doesn't work, would also be a signal to our safety of what the products are going to be. When we were creating this pre-certification program, we created three buckets of real-world performance man monitoring, and one of the buckets was health outcomes, health benefits outcome, even though it was a general very large bucket, that's the most difficult bucket to collect because the outcomes are more downstream. There's two other buckets that I really felt like would be really, really easy to track. One is user experience.

There's plenty of metrics available today, that gives people access to how well a user is interacting with the product. I think just to think about from that perspective, and then the second, the first bucket was how are people using the product, what's the performance of the product look like? If it's telling you, "Yes, do this." Is the user actually conforming to what the instructions were or was not right, you can start looking at the instructions, in the right context at the right time would be something to monitor.

If you can think about it from that perspective, I feel like if people started to instrument their products from the get-go from designing in, you will be enriched with lots of information that could be then synthesized, for perhaps, I'm just speaking from a regulatory perspective, you can then come in, and what we call real-world evidence and combined get an expansion of claims, or work with us to figure out how do you get an expansion of claims? I think that's one of the things we can look at.

Second is I think you're going to learn, going back to my previous discussion about we have to create this learning health system, and the way to create a learning health system is to understand how these products are going to be used are being used while they're being deployed. What better opportunity it is, than having visual health technologies that can talk back to the developer, about exactly what the experience is going to look like, or is happening at the time of use.

Every time somebody opens up the phone and uses the app you can measure how long the person actually took from going from screen one to screen two, or how many taps? All those measures can be automated. Of course, you have to take caution of the privacy of the patient and not traceable back to the patient and all that stuff. I think there's an opportunity, a huge opportunity, and especially in the digital world that we can take into account and make this a truly learning system.

I'm completely on board. We've been talking about personalized healthcare and people-centered healthcare for as long as I can remember for at least 10 years if not more, and I think this pandemic has flipped the switch on-off and I think we are able to now really take the therapies, the diagnostics to the patients, as we have seen in other cases. I think that's how I would see this.

**Dr. Wright:** Thanks. Unfortunately, we're out of time, just like the first panel I think we could have talked about this for another couple of days. I really again, I want to thank you so much for participating in this panel for both of you. On behalf of Mental Health America, the American Psychiatric Association, and the American Psychological Association, we want to thank all of you in the audience for spending the last hour with us in this co-hosted webinar entitled Policy Challenges and Opportunities for Digital Therapeutics and the Mental Health and Substance Use Crisis. We hope you found it as enlightening as we did and thank you again, be safe and be well.

**[01:00:45] [END OF AUDIO]**