

Webinar Title: Digital Therapeutics and Clinical Care: What Providers Need to Know

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Moderator: Hello, and welcome to today's webinar, Digital Therapeutics and Clinical Care: What Providers Need to Know. This topical webinar is paid for by Big Health. Big Health offers FDA-cleared, evidence-based digital treatments for insomnia and generalized anxiety, empowering psychologists to expand care delivery while maintaining clinical rigor.

Some important points before we get started. Dani Bradley and Dr. Alasdair Henry have a working relationship with Big Health, and as such, they have a financial and an intellectual interest in the webinar content today. The purpose of today's presentation is to provide a balanced view on how to integrate digital mental health treatments into your practice. APA does not endorse any products or services, and the content today was created by Big Health and does not reflect the views of APA or its editorial staff. Email advertising@apa.org to learn more.

Next, this program does not offer CE. However, we will email everyone watching live today a certificate of attendance. Certificates will only be issued to those who watch for a minimum of 45 minutes. A recording of this presentation will be emailed to everyone in two weeks' time, and the recording will also include the presentation slides. During our time together today, you will be on mute, and you can communicate with us using the Q&A box located on your webinar screen.

The Q&A is enabled for attendees' interaction with submitted questions. You'll be able to view all submitted questions and upvote those that you find important. This helps the presenters identify questions that many attendees would like to have answered. Again, a link to the presentation slides will be posted in the chat box for your webinar screen, and we'll also send those to you with the recording.

Now, let me introduce today's presenters. Dani Bradley is a public health professional and the vice president of clinical affairs at Big Health, a developer of evidence-based digital therapeutics for common mental health conditions. She leads the medical affairs research and clinical teams, focusing on demonstrating clinical efficacy and health economics outcomes, as well as working with clinicians to integrate digital treatments into clinical care.

Dr. Alasdair Henry is a chartered research psychologist and director of medical affairs at Big Health. He specializes in the scalable treatment of insomnia disorder using digital treatments and oversees clinical research and medical affairs at Big Health. Welcome, Dani Bradley and Dr. Alasdair Henry.

Dr. Alasdair Henry: Thank you for that handover. It's great to join you all today. Of course, as was mentioned, Dani and myself do have conflicts of interest, which we have shared here on the screen. Of course, today we're focusing on the role of digital interventions, namely digital mental health treatments, and particularly how they are relevant for psychologists and how they can be integrated into your clinical practice. Really just to level set today, I think it'd be helpful to highlight some key areas that digital interventions, namely in the field of mental health, really help us

close gaps and address unmet needs in mental health care, which we know is sorely needed.

We know that, despite, of course, treatments like CBT being the gold standard for many conditions amongst other psychotherapies, we know that there are common and frequently faced barriers that prevent patients from getting timely access to care. That can include things like geographical locations, mobility issues, stigma, schedule availability, and other factors. This really prevents patients from getting timely access to the care that they need.

Digital interventions, of course, do provide ways of accessing digital mental health treatment in a scalable manner, but also overcoming some of the areas that we do see preventing patients getting care. In addition, digital treatments can empower both patients and the providers to recognize symptoms early and access support before issues escalate. Again, really reinforced by the increased accessibility that digital treatments afford.

Another feature that, of course, digital treatments cater to is personalized support. Really looking to understand what a patient's individual needs are, their preferences, and circumstances, that really helps drive engagement and adherence. We know, of course, that digital treatments are not a panacea, they're not a cure-all, they're not going to solve everyone's mental health complaints or be suitable, but it really provides both patients and clinicians with an additional tool that they can use and leverage within clinical practice to make sure that they're meeting patients' needs.

Further, another opportunity afforded by digital interventions is continuity of care and support. This includes continuous support. We know that if, say, in a traditional setting, a patient is seeing a provider on a weekly basis, there's still that period between those sessions where the patient will still need ongoing support. The **[unintelligible 00:05:18]** tools, as we'll discuss later, like digital mental health treatments, can support patients between those sessions with regards to really continued skill acquisition and technique implementation. It also just provides other wraparound support, for example, at the point of discharge, too.

Today, we're going to walk through really what are digital mental health interventions, how are they regulated, as well as what factors must be considered to implement them into clinical practice, as well as the different ways in which they can be used. I'm sure that, of course, we're all familiar with the rapid increase that we've seen in digital interventions, really over the past decade. I myself have been working in the digital health space at Big Health for almost nine years. Of course, the growth has been staggering.

I think one of the things that myself and I know many others are concerned of is making sure that patients are getting access to the safest and most effective treatments. An area where we do often see conflation is evidence-based digital treatments being compared to wellness treatments or wellness programs, I should say. This is because we know that there's tens of thousands of apps available for consumers to access through commonly available app stores.

The problem is that many of these are making claims that are well beyond what they should be making and are not supported by clinical evidence. There's even some,

even here where I am in the UK, but also in the US, that are trying to position themselves as being mental health treatments or providing symptom relief, but really, they have no direct evidence supporting those claims. Beyond these misleading claims, of course, a key concern is that they could be harming the users who are engaging with these products.

One of the things I think that really we should keep at the forefront of our minds when evaluating digital treatments, whether that's for use ourselves or for use with our patients, is understanding, first of all, whether they're evidence-based or evidence-informed. I'm sure many of you are familiar with this, that evidence-based treatments, regardless of the type of treatment it is, need to be evaluated in randomized controlled trials and demonstrate gold standard evidence in support of safety and efficacy. That is really where we would consider digital treatments in that bucket.

In this contrast with those evidence-informed programs, we see where the program itself has no direct evidence, relying largely on the broader literature, either for, say, CBT, for example, or digital CBT. In these places, there's really no direct evidence showing that app itself is safe or effective. Oftentimes, we do see these apps making unsubstantiated claims. A way that I think of it is that many of these apps will say, well, in-person CBT, for example, treats insomnia. My app uses CBT, therefore, my app treats insomnia effectively. I think we would know whether that's for ourselves, family members, friends, or patients. We would not want any of those people getting access or being given access to a so-called treatment if it hadn't had its safety and efficacy proven rigorously, because we want to do the best for our patients and those that we care about.

To help support this effort, myself and others have advocated for consistent and robust evidence standards for digital treatments. I'd like to walk you through these today, really to help all of you be armed with a lens to start looking through treatments or apps that you're coming across in your day-to-day clinical practice. One of the key tenets that I think is really important is that there is no need for digital exceptionalism.

We have seen across the space in the past decade or so people saying that, well, because my app is just digitally delivering a protocolized treatment, we should not be subject to scrutiny or clinical evaluation through randomized controlled trials. Really, the same level of interrogation of any treatment should apply to all treatments regardless of whether or not it's a medication, a psychological therapy, or even a digitally delivered therapy because, again, want to reinforce that patients are getting the most safe and effective treatments.

There's a framework here that we have on the slide called the WHAT criteria. It's really a set of standards you can apply to any digital treatment that you might be considering or looking at. Simply, it entails that a treatment has to work, it has to help, it has to be accessible, and it has to be trusted. In terms of working, of course, as I mentioned a couple of times now, is that any treatment should be supported by adequately powered and scientifically rigorous randomized trials. That really, of course, as we know, is level one

clinical evidence. Not only that, but there should be adherence to scientific best practices for those trials, including pre-registration of outcomes as well as publication of data following peer review.

Flowing from that, of course, the therapeutic has to help. There should be statistically clinically significant differences between groups in favour of the digital intervention on gold standard outcomes. Of course, that's really the prerequisite we should have before considering treatments. Beyond those obvious clinical standards, when we're looking at digital treatments, there's other factors that must be taken into account.

Firstly, any treatment has to be accessible. Of course, now in 2026, many of us, particularly the individuals that we'd be presenting as patients, do have quite high standards for what digital technology should look like and feel like. It should be delivered in a way that is not onerous, that is easily accessible, given the breadth of familiarity with digital technology that we'll often present within clinical settings. Really, any treatment should be able to deliver a reliable and safe patient experience within the population for which its use is intended. It really needs to be made available digitally in a way that is scalable and effectively addresses even population-level needs in the real world. Really interrogating the user experience of that treatment.

Finally, of course, any treatment has to be trusted. In the context of digital, this is really important, of course, because we're dealing with not only patient data, but oftentimes you're having to adhere to, say, quality management standards or regulatory standards. Really, we should be making sure that any treatment that is getting into the hands of our patients is adhering with those different laws and regulations before we're even considering it.

Now, I want to walk through more factors that we should be considering when differentiating digital mental health treatments from wellness products. This table really provides a helpful overview on how we can differentiate digital mental health treatments from wellness apps. Of course, a key one, particularly in the United States, is regulatory oversight. Digital mental health treatments are regulated as medical devices, and they've been through a well-vetted clearance process, which I'll be able to describe in subsequent slides.

This contrasts with wellness apps, for there's no explicit regulation of these. While they cannot claim to deliver things like CBT or even ACT or make symptom claims, many of them do, which is in violation of those regulations. Again, from an evidential standpoint, digital mental health treatments have been vetted in clinical trials for their safety, efficacy, and outcomes, and display those gold standard benefits that I just mentioned. Oftentimes, these wellness apps are lacking entirely in any clinical evaluation.

From a data and privacy side, as well as security, of course, DMHTs, as part of their quality management systems and the fact that they're dealing with healthcare data, must be compliant with HIPAA and other medical regulations, as well as quality systems regulations, whereas oftentimes wellness apps themselves are not adhering to those laws and requirements. This, of course, leaves a massive hole for things to go wrong or for patient data not to be handled appropriately.

Another thing, of course, anything that is going to be integrated into a healthcare system has to be a smooth process, not only for patients but the providers using them. As part of digital mental health treatments, as we'll see in a couple of minutes, there's requirements that these have certain ways of displaying data or communicating feedback to the providers in addition to the patients. Really making sure that there is ease of integration to allow that monitoring for the provider that is ordering that device for that patient, whereas wellness apps really function as a bit of a black box. It's not really clear what's going on or what information is being input by the patient in there or what's happening to that information.

Then, finally, and most importantly for practicing clinicians, is the questions around reimbursement. Digital mental health treatments are reimbursable, as Dani will explain later on in this webinar. Whereas wellness apps really have no established reimbursement pathway, which then can cause challenges, of course, for their use within clinical settings. Now, building on some of the points that I was discussing there, this whole concept of a digital mental health treatment is a relatively new treatment class. It was established last year with the launch of new reimbursement codes for digital mental health treatments by Centers for Medicare & Medicaid Services.

In order to be classified as a digital mental health treatment, a device must be cleared by FDA under 21 CFR 8825801. To achieve an FDA clearance, there has to be a significant review conducted by FDA to make sure that it is safe and effective. This includes a review of clinical evidence through prospective clinical trials that are evaluating performance on gold standard outcomes, as well as interrogating software quality and cybersecurity, really to make sure that any treatment that is getting into the hands of patients is meeting all those requirements that I've mentioned over the past couple of slides.

This isn't an easy process. This process often takes a number of months for FDA to review and carefully consider with multiple interactions because, again, if a regulator is putting their seal of approval on a device, you have to meet those quality, security, and clinical efficacy standards. As I mentioned, we don't want digital mental health treatments being a black box for the providers that are ordering them. There needs to be a way for providers to be able to understand what's going on with patients and how they're faring throughout their journey with that treatment.

In order to be cleared under that regulatory clearance and also be considered then digital mental health treatment, any app or device must have both patient-facing interventions as well as provider-based feedback, where providers can look at both engagement with the device and progress, as well as clinical outcomes.

Of course, importantly for these types of treatments is that these can be prescribed both by traditional prescribers like MDs, but also importantly by non-traditional licensed prescribers, so those that would routinely be engaging in developing behavioral health plans and implementing behavioral interventions, so psychologists, clinical social workers, marriage family therapists, and licensed counselors as well. It really ensures that the providers that are experts in behavioral health care are able to use them in their clinical settings.

To date, there have been seven programs that have been cleared by FDA and meet the digital mental health criteria. These span a range of different indications and age groups. Importantly, all of these are eligible for reimbursement under those digital mental health codes that CMS released last year. This includes two of our own devices that we've developed here at Big Health. SleepioRx, which is indicated for the treatment of insomnia disorder in patients 18 plus, and DaylightRx, which is indicated for the treatment of GAD in patients aged 22 plus.

These other devices here, as mentioned, span a number of clinical indications and age groups. It really goes to show the breadth of which digital treatments can be developed to address a range of commonly encountered clinical conditions within patient populations, including Rejoyn for major depressive disorder, MameLift Plus for postpartum depression, Somryst for insomnia disorder in patients age 22 plus, reSET for substance use disorder in patients 18 plus, and reSET-O for opioid use disorder in patients aged 18 plus.

We'll obviously continue in the next couple of years to see more devices coming through a similar pathway, but we're really at a point now where devices like SleepioRx and DaylightRx, and others can be reimbursed and easily integrated into the clinical pathway. To focus a bit more on our two devices, SleepioRx and DaylightRx, SleepioRx is the only FDA-cleared treatment with an indication for the treatment of insomnia in patients aged 18 plus and DaylightRx, for the treatment of GAD in adults aged 22 and older.

One of the things that we've kept at the heart of our mission over the past 14 years is ensuring that we're rigorously testing these devices to the same standards and even higher standards than we'd expect for most treatments to go through. Over the past 14 years, we've had SleepioRx evaluated in over 17 RCTs conducted by institutions such as Stanford, University of Oxford, UCSF, evaluating its performance in a range of clinical populations.

For Daylight, it's been launched a lot more recently than SleepioRx, but to date, we've evaluated it in over three RCTs. It's these data that have really served us in getting access to or providing access to clinical populations both in the US and elsewhere. For example, where I am, here in the UK, SleepioRx and DaylightRx are available nationally to all 4.5 million adults here in Scotland. It's really helped in a country where we do have quite remote patient populations, where it could take, say, a day travel for someone in one of the islands or in the highlands, to go and get access to a therapist locally. It's really begun to show the value of these.

As you can see here, to date, we've had both of these treatments used by over 600,000 people. Really showing the value that digital treatments bring. As we'll get onto later, we haven't replaced psychologists here in Scotland. I'll discuss more on that in a minute. Before I hand over to Dani, one of the things, of course,

that I've heard from my colleagues, we've seen across the news, is a concern that digital mental health treatments could replace psychologists. I think this has largely been accentuated by the media trying to look for a quick headline.

One of the comparisons that I like to make is that, of course, when we started seeing things like robotic surgery being created for use in heart procedures or other types of

surgical specialists, we didn't suddenly lose the need for surgeons. Really, this technology helped augment clinical care, speed up efficiency of surgery, but also increase the availability of surgeons because they weren't having to spend as long doing procedures that would take longer than they would with robotic assistance.

I know that this is something that some providers do have some fears around. Really, the way that I'd like to position it and that Dani will expand upon is that by incorporating digital mental health treatments into routine clinical practice, it really helps expand providers' capabilities by increasing efficiencies, but also allowing providers to give quicker access to care for those that need it.

As I mentioned, of course, digital treatments are not going to be suitable for everyone. There's going to be people who need more specialized care, but by incorporating digital treatments, it would allow providers to utilize that specialized care more efficiently and allow patients that have clinical presentations or even preferences that would suit a digital treatment to be given that and be given access in a quick fashion rather than being stuck on waiting lists. Now I'll pass it over to Dani. He'll be able to expand more on how you can implement Sleepio, Daylight, and other digital mental health treatments into your clinical practice.

Dani Bradley: Thanks, Alasdair, for that great introduction to what digital mental health treatments are. I'm excited to share with you a little bit more about how clinicians are incorporating these treatments into their practice today in ways that you and your colleagues can consider to do the same. As Alasdair mentioned just a minute ago, digital mental health treatments are not designed to replace the role of a therapist. They are designed to expand access to patients who need evidence-based support and to expand clinicians' ability to deliver care to their patients.

This slide is intended to visualize for you the way that many clinicians who we work with and who use our products integrate those tools into their practices. For example, in a traditional practice, a provider is somewhat limited in the capacity that they have to see a certain number of patients and the amount of care that they can provide to those patients who they are seeing. In a traditional practice, a provider has a set number of patients for whom they meet with at a regular cadence, and that is typically the extent to which they are interacting with that patient.

In a DMHT-enabled practice, a provider has the discretion to determine what the most appropriate course of treatment is for a patient, and that may be that they take a traditional path, which is clinician-delivered care over a set course of sessions, meeting weekly or every other week. They may choose to take a digital mental health treatment-only approach, either initially or permanently, and that might look like an initial intake visit with a patient and then setting them up to use one of these devices that we've mentioned just a minute ago.

Another pathway is to integrate those two delivery models. A provider could be seeing a patient and then augmenting those sessions with a patient using a tool either outside of session or incorporating that into session. I'll go into more detail about that in a moment here. Here are a couple of different ways that providers and psychologists in particular can and do integrate digital mental health treatments into their practices. First-line care is a common use case. Again, we're focusing on

SleepioRx as an example here to give really tangible examples of how these tools are used in practice.

SleepioRx is delivering cognitive behavioral therapy for insomnia, which is listed as a first-line recommended treatment for insomnia disorder. As you all are well aware, clinicians can also deliver CBTI to patients. However, access to those clinicians is extremely limited for many patients around the country. Tools like SleepioRx can be used to offer that first-line care to patients so that they are not either being placed on a waitlist to see a provider who can deliver that care or being given second-line recommended treatments as a first-line option.

Waitlist support is also a very common way that providers are using SleepioRx and other DMHTs in their practice. Many behavioral health clinicians, in particular, have very long waitlists given the high demand and the inadequate number of providers who are available and trained to meet that demand from patients. In a way to address that waitlist before availability frees up to actually see that patient consistently, providers can offer DMHTs to patients on that waitlist to at least get them started with a course of treatment that provider may choose to continue, or the patient may remit with just the use of the DMHT.

It can also be used as a way to reinforce techniques that are being taught during therapy session. If a provider is doing CBTI, for example, with a patient, they could recommend that the patient use SleepioRx between sessions or use it to collect their sleep diary data, for example. They could ask them to practice certain techniques that they've learned during session with the clinician in between sessions. As Alasdair mentioned at the top of this discussion, providers are typically meeting with a patient at most, maybe once a week, which leaves six other days of the week where patients really can use some more hands-on support. That's where DMHTs can come in and expand that clinician's ability to interact with patients more regularly.

Comorbid condition treatment is also another very useful way to incorporate DMHTs into practice. Many providers who we work with are addressing another complaint from the patient during session, whether that's depression or anxiety, or something else, but that patient is also presenting with insomnia. As you all are well aware, insomnia and other behavioral health conditions can be highly comorbid. Being able to tackle two of these conditions is really important. Being able to tackle two conditions at once while reserving in-session time for the primary complaint is another way that DMHTs can be enabled in practice.

Then, finally, maintenance support is also a very common way to incorporate DMHT into practice. After discontinuing regular sessions with a patient, you can offer them a DMHT to allow them to continue to practice the techniques that they learned from you or from the tools that you made available to them, so that they are not left without resources once the care with you has discontinued.

Now we wanted to show you a couple of examples of how DMHTs have been incorporated into specific clinical care settings. This example comes from Henry Ford Health, which is a large health system in the Detroit area. Here, the problem that they were facing were that they had very few trained clinicians who were delivering CBTI to their patients. They had patients coming from a variety of different

departments to that clinician's waitlist, whether it was from the sleep center, primary care, behavioral health, even cardiology, sending patients to this limited number of providers who were responsible for delivering CBTI to all of them.

As a result, their waitlist exceeded five months, which meant that those patients had to delay access to care. Oftentimes, it meant that the referring clinician was forced to offer a second-line form of treatment, like a medication, to allow the patient to find some relief in the meantime. We know that starting on a medication can often make it more difficult to pursue first-line treatment later on because many patients will stay on that medication once it's begun. Getting patients timely access to first-line recommended care was a priority for this system so that they could avoid that path.

The solution was to implement SleepioRx as a first-line recommended treatment for insomnia, both in their internal medicine and their sleep medicine centers. What this resulted in was nearly 5,000 orders being placed for SleepioRx over the course of the first several months of the partnership. What it did for the way that they cared for their patients was it reduced the time to CBTI from five months down to one day. A patient could go in and see their primary care provider and have a discussion about sleep disturbance, and they could be offered CBTI immediately upon leaving that visit.

About 60% of the patients who were offered SleepioRx by their provider proceeded to start the program, and nearly 80% of patients saw improvement. Many digital mental health treatment programs use validated screening assessments in the program to track patient progress. The same is true for SleepioRx. The sleep condition indicator is used in SleepioRx to assess baseline severity of insomnia, and then it is used again every week thereafter to assess progress towards symptom improvement and eventually remission. That is where that 79% improvement rate comes from.

Another case study here is looking at a neuropsychology practice, a much smaller setting than the Henry Ford Health System that we just discussed. This is a practice with about 15 clinicians who see patients, typically middle-aged and up, a lot of older adults as well, who are dealing with both mental health and cognitive impairments. They had one provider who was specialized in delivering CBTI to their patients, but again, limited bandwidth and did not have enough clinicians available to offer CBTI to all of the patients who needed it.

Many of their other providers were trained in delivering CBTI, but they did not have the capacity to schedule sessions for that purpose, given the other demands of their patient panel. Many of the providers, and also of note, the patients, were reluctant to use pharmacological interventions given the presentation of the patients that they see. The cognitive and the neurological profile of many of their patients made it such that the pharmacological interventions would be contraindicated. Now, this was a particularly complex patient panel, but many older adults, in particular, are offered sleep aids counter to the guidelines. It is not recommended that anybody over the age of 65 is prescribed a hypnotic.

The solution, again, was to try SleepioRx, integrating that into their workflows. Any provider who saw a patient who was expressing a sleep disturbance was assessed for insomnia disorder. If they were diagnosed with insomnia, then they were offered

SleepioRx by that provider. They eventually actually hired a social worker whose sole responsibility was to work with patients to onboard them onto Sleepio and have those intake visits with patients because the demand was so high for folks who needed support with their sleep.

The impact of this here was that the time to care was just one hour from being assessed by their healthcare provider to initiating the program. That is typically instantaneous in the way that the patient is invited to sign up for the program. It significantly reduces the amount of time a patient has to wait and therefore reduces the risk that a patient loses motivation to pursue a program like this once a provider onboards them to it. About 90% of the patients who were offered SleepioRx in this clinical setting proceeded to enroll and use the program. 92% of folks who used the program saw an improvement rate, again, based on the assessment of the validated screening tool that is collected within the program itself.

Now talking about how this type of integration is done in a variety of different clinical care settings, it's designed, at least with our tools, to be as seamless as possible. The first stage of implementing a DMHT into your clinical setting is to design and set up the workflows. That means determining which providers will use it and how they will go about ordering it for their patients. There's a variety of different ways that can be done. It can be directly integrated into the EHR that you use, or we host a provider portal where a credentialed provider can log in and order access to DMHTs for their patients, and then also track their patient progress with the use of those programs.

The next step is to confirm the billing process. Making sure that you and your practice are getting reimbursed for your use of these programs with your patients. That means both furnishing the program to the patient as well as any time you spend overseeing their use of it, which I'll talk more about in a minute. Around the time that we would launch and actually start enabling you to order this product for your patients, we train providers on appropriate identification of patients who are suitable for this program.

The list of criteria for which patients are suitable to use DMHTs is fairly limited. They must have a personal device for which they can download the program onto. That's typically a smartphone or a tablet. They must have proficiency with either English or Spanish and a willingness to try, which is assessed by the provider who's ordering it for them. That provider then needs to diagnose the patient with the condition for which the DMHT is indicated by their FDA clearance and explain the concept of the DMHT to patients.

That typically involves explaining them a little bit more about the condition that they are dealing with. Again, using insomnia as an example. That's often explaining to them how their thoughts, their environment, their behaviors are perpetuating their poor sleep habits and how cognitive behavioral therapy is the first-line recommended treatment to deal with that. Then, explaining to them the way in which SleepyRX, if that were the DMHT you're using to address their insomnia, how that delivers the techniques that they need to treat that problem that they're dealing with.

We train providers how they are going to order the program, which is either, again, done through the EHR or through our provider portal. Then we also show providers

the data that we make available back to providers, so that they can follow along with how their patients are doing with the program. Also, so that they can intervene as they see fit to encourage continued participation or engagement, or check in with patients and make sure that they're getting what they need from the program, or whether they need to be escalated to another form of care.

Post-launch, as a part of this implementation process, we offer ongoing support to answer providers' questions, make sure that they're comfortable with the way that their patients are using the program, and that they feel equipped to answer questions they may get from patients about the program. We refine our feedback, making sure that you have the data you need to track how your patients are doing in the program and the opportunity to intervene, should that be appropriate.

Integrating into a private practice or a smaller-sized practice is far less complicated than integrating into a large health system. For example, this is a comparison of the two case studies we just went over. Henry Ford Health being an example of the large health system, and the private neuropsychology practice being an example of a smaller group. Now, that practice was 15 clinicians. We work with people as small as just one provider who operates their own practice. Really, a large spectrum of different clinical care settings that can benefit from using DMHTs.

The process for getting started really starts with identifying who's making the decision at the practice and who needs to feel comfortable with and understand how a DMHT works, and whether or not the patients of that practice would be appropriate for using it. The second step is setting up those ordering workflows that we just discussed, whether that's the portal that we offer or direct integration into the EHR. Then, setting up billing workflows to make sure, again, that you are being reimbursed for the care that you are delivering to patients.

Navigating integration with large health systems is slightly more complex. This is for anybody who works in one of these settings to understand how you can bring this to your system. First, it's identifying who an internal champion might be to lead the effort. That may be you, it may be a colleague, but anybody who is invested in expanding access to first-line recommended care through innovative interventions like DMHTs.

From there, mapping out the decision makers. That might be the head of a department. It might be a procurement team. It really depends on the particular care setting that you are working in, but identifying who those people are so that they can be informed and brought along is the next important step. Now, alongside that process, collaborating with your colleagues and other clinicians to build awareness of these interventions as an opportunity to expand access to patients is another really important step, so that other clinicians are on board and are enthusiastic about using these tools with their patients.

From there, identifying who the right contacts are on the contracting, billing, and coding sides so that the administrative functions that are required to allow DMHTs to work seamlessly in your care setting can be accounted for. Then that also includes things like EHR integration, should that be the path that you choose, which would involve getting the IT team involved to scope the work required to set up an integration with the DMHT that you choose.

The patient

experience is designed to be as seamless as possible. Putting ourselves in the shoes of a patient, they are having a visit with a clinician, discussing their difficulty, again, using sleep as an example, with sleep. That provider then assesses the patient for insomnia disorder, and if they decide that a DMHT would be appropriate for them, they would place an order through whatever mechanism has been set up for them. Then the patient receives an instantaneous invitation via both text message and email right there during the visit.

That is very intentional because getting a patient to agree to participate and sign up for the program in session with the provider who's offering it to them is one of the most impactful ways to ensure that a patient is going to follow through with the treatment that they've been recommended. From there, they just download the program onto their personal device, whether that's a smartphone or a tablet, and then they enter a unique access code and create an account the way they would with any other program. They can start treatment immediately from there.

Now talking about how DMHTs are reimbursed and who can be reimbursed. We've alluded to in this conversation the new codes that were established in 2025 by CMS. I'm going to go over what those codes are here. The first is G0552. This is the supply of a digital mental health treatment device and the initial education and onboarding of that program for the patient. This is a dual-purpose code that covers the cost that the provider has incurred to procure that device for the patient, as well as the provider's time spent onboarding the patient to the program.

Now, that time spent onboarding the patient to the program can be highly variable. Many providers do it pretty quickly, or sometimes they'll even have support staff who continue the conversation with the patient if that patient does require any hand-holding to get started. Some providers will spend time with the patient showing them how to download the program onto their phone, and more importantly, explaining to them the value of the program and what they, as their clinician, hope that the patient will get out of it. All of that is covered under G0552, which is billed one time and gives the patient access to the treatment for 12 months.

In addition to that initial supply code, G0553 and G0554 have been established to compensate providers for any additional time they spend with patients who are using a DMHT to oversee their use of the program. Now, these codes are completely optional and up to the discretion of the provider whether or not it's something that they want to use as a part of their practice, but it compensates them for every 20 minutes of time spent in a month overseeing the patient's use. That could be a synchronous discussion with the patient about how it's going or answering any questions that they might have about the program, or it could be your time spent reviewing the patient's data that the DMHT makes available to you so that you can track that patient's progress.

All three of these codes can be billed for by any qualified licensed healthcare provider who can oversee a behavioral health treatment plan. Most notably, that includes clinical psychologists, even those who are not traditionally prescribing. These are eligible for behavioral health clinicians to use. Now, what is required to get reimbursement for these codes is that a relevant diagnosis code needs to be present

on the claim that's submitted for G0552. Again, using our example of insomnia, a diagnosis of insomnia disorder needs to be included as a diagnosis on that claim. It does not need to be the primary, but it needs to be in the top three diagnoses for that patient.

The billing practitioner needs to order the DMHT for the patient. These patients cannot directly sign up for the program. A provider needs to authorize their use. The billing practitioner incurs the cost of the DMHT and then gets reimbursed for that cost, which I'll talk more about in a minute. This is the typical workflow for how that exchange of services and goods works.

An agreement would be put in place between the provider and the manufacturer of the DMHT. In this case, we can use one of the examples that we talked about today. An agreement between Big Health for the use of SleepioRx and any practice who would like to use SleepioRx with their patients is put in place. What that means is that the DMHT would be put in place. What that agreement stipulates is simply an exchange of data, so a BAA allowing for patient-level data to be shared between the two entities, as well as an agreement that the provider will incur the cost of any license that they order for their patients, which will, again, subsequently be reimbursed by that patient's payer.

Agreement is put in place. The provider then orders the DMHTs for their suitable patients and submits claims for G0552 alongside those orders. The provider then gets reimbursed for those DMHTs under that code, G0552, by that patient's insurance. Then the provider's payment to us at Big Health or the other DMHT suppliers. That payment comes due thereafter. Then, on an ongoing basis, providers have the option to continue to remain involved in their patients' use of the program using G0553 and G0554 to allow them to be compensated for every 20 minutes of their time spent.

We will pause here for any questions. I think the APA team is going to facilitate this part of the program. Thank you so much for listening, and looking forward to your questions.

Moderator: Thank you, Dani and Alasdair. We are going to now move into the Q&A, and there have been a number of questions. We have some that were pre-submitted, and then others that have been coming in during your webinar today. One of the questions was how to integrate DMHT into your clinical practice, but I think the case studies that you provided were great examples of how to do that. One of the questions that we have is what is the cost to patients?

Dani: That's a great question. The cost to patients is typically nothing, but it can be whatever their health insurance plan typically charges for a patient visit is the most analogous version. For example, a Medicare patient, they have across the board a 20% coinsurance. Many of those Medicare patients have supplemental plans that cover that 20%, so the patient is not paying it themselves. Many patients who are on commercial plans will have lower than 20% coinsurance. It might be \$30 copay. It's really dependent on each patient's individual plan that they're on, but the cost for a patient is designed to be nominal, and that is why DMHTs have taken this path so that these kinds of treatments can be offered alongside other forms of treatments

that patients do not have to pay for out-of-pocket, so within the scope of traditional health care.

Moderator: As you can imagine, we've gotten a number of questions around reimbursement. One of them is how many insurance companies in the US are incorporating this into their plans at this point?

Dani: It's a great question. It's an evolving number of insurance companies that are actively covering it. CMS, as we mentioned before, released these codes only last year, which means that all 65 million Medicare patients in the country are covered. Now, the commercial plans adopt these codes after CMS releases them, and that is happening on an ongoing basis.

Many of the major national plans are covering these codes on what they call a claim-by-claim basis. Basically, they may not have a coverage policy publicly stated as a part of your contract, but if you submit a claim, they review that claim individually. Then what we've at least been seeing from our partners is that those are being paid based on the submission amount. Then, other regional plans are operating similarly, many of which have actually established positive coverage policies themselves.

Moderator: Do DMHTs need a prescription?

Dani: They need to be authorized by a qualified healthcare provider. Now, the term prescription is not quite right because it does not need to be processed through a pharmacy the way that a medication or a drug would be, but it does need to be authorized by a licensed, qualified healthcare provider. That is done through one of the ordering processes that we just discussed. Any of those providers are then eligible to submit a claim for reimbursement once that's been done. It's not technically a prescription, but it does need to be authorized and overseen by one of those providers.

Moderator: This is somewhat related. Dani or Dr. Henry, do you know if there will be a credentialing process for psychologists? I know that, for example, APA has been doing some educational work around DMHTs, but could you address that a little bit?

Dani: Yes. It's my understanding that, like you said, APA is considering offering something like that, but beyond that, there does not seem to be a requirement for credentialing.

Moderator: Then let's go to some additional questions. One of them, and I should also add, again, I just want to mention that all of these slides today will be provided with the recording. They are also in today's chat so that you can access those there. I believe that you addressed some of this in today's presentation, but are there studies on the validity of DMHTs?

Alasdair: I can take this one. As I said, that's really something we see as integral across the field. If we look at ours, for example, as I mentioned, SleepioRx has been evaluated in over 17 published RCTs. I actually believe the amount of data we have on SleepioRx being published is more than clinician-delivered CBTI has in literature. They're extremely well validated, and we're seeing similar trends across the field, so really supporting their safety and efficacy in the published literature.

Moderator: Back to reimbursement for just a moment. We have a question related to the codes. The webinar attendee is asking whether or not these are billed as add-on codes to regular therapy codes, or are they considered standalone.

Dani: That's a really great question. The first code, which is that supply code, G0552, can be billed standalone, or it can be tacked on to any existing codes that you're typically billing. Notably, G0552, the supply code, is not a time-based code. It's just that the supply has been given to the patient, and a discussion about the program has been had, that onboarding component.

Now, the two follow-on codes are add-ons. G0553 and G0554 can only be billed after G0552 has been billed. Notably, they are time-based. If you are typically billing time-based psychotherapy visits, the 20 minutes that those follow-on codes compensate you for must be distinct from the 40, 60-minute psychotherapy sessions you're having. Those 20 minutes can be spent broken up over the course of a month if that fits into your clinical workflows. Say you check the patient's progress in the program each morning or on a particular day of the week, every month, that time can add up so that at the end of the month, if you've met the 20-minute requirement, that can be billed.

Moderator: Then, looking at the questions that have been submitted during the webinar today, this one was actually upvoted by other attendees. It's, what if this digital therapeutic approach were implemented in schools for guidance and counseling teachers to address adolescent and mental health issues? For example, for students ranging from delinquent and/or underprivileged to high-achieving students. I just wanted to get your thoughts on that since that seemed to be of interest.

Alasdair: I wanted to go with that. I'll let you take it. I think while, of course, our products don't address that, I think, of course, the digital mental health treatment model can function well in a school environment. We have seen there are devices out there that are looking to address adolescent mental health because I think, of course, most adolescents are used to using their phones for things that deliver treatment in a modality they'd be familiar with, but allows ease of treatment provision through a number of school counselors or even educational psychologists.

I think it also increases that accessibility where they might be, of course, seeing their counselors on a more frequent basis, being in school. It allows that feedback from the individual's engagement with the program going to that counselor and then being able to review that synchronously. It could be a good option within those settings.

Moderator: Then what are some tips that you could provide on how to maintain motivation for clients using digital therapeutics?

Dani: It's a great question. We've done a number of implementation studies, actually, both in the UK and here in the US, to assess how to keep patients engaged and the role of a clinician in doing that. I call it the role of a clinician because what a lot of the data suggests is that a provider creating a feeling of accountability matters a lot in a patient's continued use of the program. Whether that's just sending a nudge once a week to say, "Hey, just want to make sure that you are doing XYZ," whatever

it might be that you want them to be doing in the program that week, that plays a large role in the patient's motivation to do it.

A lot of it is also taken off of your plate as the clinician. We, as the makers of these DMHTs, spend a tremendous amount of time evaluating the right way to engage a patient in a totally digital, asynchronous setting. The programs are, on their own, designed to encourage ongoing use and appropriate clinical use depending on the patient's presentation. That involves nudges from us. It involves patients setting notifications for themselves and opting into that reminder. It also involves patients, at the start of the program, signing commitment documents and all sorts of things that we know from the literature support patient engagement with any type of treatment, but digital included.

Moderator: Maybe we're at a point where we will do one or maybe two more questions, but this one seems to be specific to Big Health's products. The question is, do you have any data about the acceptability, usefulness, efficacy of your program with depressed older adults? If so, where would I find it?

Alasdair: Yes, we've got quite a few studies that, of course, are evaluating our therapeutics acceptability, efficacy across the age spectrum. There can sometimes be apprehension from individuals offering digital treatments to older adults because they assume that they may not engage, they may have more barriers to care. We've done a number of studies specifically looking at older adults from SleepioRx, for example. We've analysed over 300 patients and find that the clinical effects observed are the same as you would expect within a real-world setting. I think 60% remission rate, you do see good engagement.

In fact, in one of the other studies we have, older adults were actually more likely to be using digital treatments than younger adults. It really counters that narrative. Of course, across, again, the insomnia patient spectrum, you do see high rates of comorbidities, both physical and mental health. SleepioRx is considered acceptable by patients with those broad spectrum of mental health complaints as well as effective at treating their insomnia. If you would like more specific information and studies, you can feel free to email us at medaffairs@bighealth.com, and we'd be happy to help.

Moderator: There are some other questions in here that are specific related to that and related to sleep disorders. I'm glad that you just gave that out, Alasdair. Again, it's medaffairs@bighealth.com, correct?

Alasdair: Yes.

Moderator: Thank you all. Thank you so much for joining us today, Dani and Alasdair. It was a great webinar. Thank you to all of our listeners for your participation and particularly for the fantastic questions. We'd also like to thank Big Health for making today's webinar possible. As we mentioned earlier, a recording will be sent in approximately two weeks, and that recording will also include today's presentation slides. Immediately following today's webinar, there will be a survey, and we'd like to ask you if you could just take a moment to complete that and provide your feedback. We'd like to thank you again for attending, and we hope you have a great day and a wonderful weekend. Thank you so much.

[00:58:44] [END OF AUDIO]