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Digital Tools in Psychiatry: What Are They?

Announcer:
You're listening to ReachMD. This medical industry feature titled "Digital Tools in Psychiatry: What Are They?" is sponsored by Otsuka Pharmaceutical Development and Commercialization.

Here's your host, Dr. Jennifer Caudle.

Dr. Caudle:
Digital tools have emerged as one of the newest therapeutic modalities for behavior modification in several chronic psychiatric diseases,1 such as major depressive disorder, chronic insomnia, and substance use disorders. But what exactly are these digital tools, and what does their use look like in practice?

This is ReachMD, and I'm your host Dr. Jennifer Caudle. And joining me to help answer those and other key questions surrounding the use of digital tools in mental health care is Dr. Daniel Karlin, Assistant Professor of Psychiatry at Tufts University in Boston. He's also the Chief Medical Officer at MindMed in New York City. Dr. Karlin, welcome to the program.

Dr. Karlin:
Thanks so much it's a pleasure to be here!

Dr. Caudle:
So to start us off, Dr. Karlin, can you tell us the difference between digital health, digital medicine, and digital therapeutics?

Dr. Karlin:
Of course. So first, it's important to know that the definitions for digital tools are evolving. And in many cases, the difference in terms is based on the claims of the tool, the clinical evidence used to support its use, and the level of risk.[2,3] So if we start with digital health, we're basically referring to consumer-oriented products. Common examples include exercise and diet apps, meditation and mindfulness apps, and fitness trackers,[2] and these typically don't need to demonstrate efficacy or safety.[3] On the other hand, digital medicine and digital therapeutic products both require clinical evidence. Digital medicine is defined by the Digital Medicine Society as evidence-based software and/or hardware products that measure and/or intervene in human health.[3,4] I tend to think of digital medicine as a broader category that includes digital therapeutics. But in essence, digital medicine uses technology to collect more information than was previously available in order to guide treatment decisions and improve patient care.[2] Some examples include continuous glucose monitors and Holter monitors. Digital medicine can also combine a prescription medication with a digital component, such as a sensor that detects medication ingestion. Now if we look at digital therapeutics, these products are defined by the Digital Therapeutics Alliance as evidence-based therapeutic software that intervenes in the prevention, management, or treatment of a medical disorder or disease.[2,5] Examples of digital therapeutics include apps that deliver cognitive behavior therapy for chronic insomnia or psychoeducation for opioid use disorder.

Dr. Caudle:
So now that we have a better understanding of what each of those terms refers to, what are the benefits of using digital tools in psychiatry?

Dr. Karlin:
So for us clinicians, digital tools can be used for disease prevention, screening and early diagnosis, monitoring, treatment, and even support during recovery.[6] But perhaps most importantly, digital tools capture real-time patient data.[7] Apps that record data over time can provide clinicians with a more accurate picture of a patient's mental status or treatment progress than one-time self-reports during office visits. Now digital tools can benefit patients, too, by providing training, education, and support for behavioral change.[8] And because digital tools package in-person services into a remote product,[1] they can make treatment more accessible to patients since they don't have to make an appointment or travel to a clinician's office. Additionally, some digital tools have even demonstrated cost savings. In one report, patients who used a prescription digital therapeutic as an adjunct therapy for an opioid use disorder had a net cost reduction compared with patients who did not engage with the program.[9] So to me, the real value of the entire class of digital medicine is that it represents another way of engaging in therapeutic interventions. It's adding another tool to the toolbox, and these tools provide a new way of approaching patient monitoring, diagnosis, and intervention.

Dr. Caudle:
And how well do digital tools work? I mean can you share some of the efficacy data out there?

Dr. Karlin:
Sure. So the field is relatively new, but the evidence based on the efficacy of digital tools is rapidly expanding.[7] For instance, a meta-analysis of 66 randomized clinical trials found that smartphone interventions used as digital tools significantly outperformed control conditions, like waitlist, assessment only, and informational and educational resources, in improving symptoms of social and generalized anxiety disorders and depression.[10] Overall, when studied, interventions that provide cognitive behavior therapy apps in combination with professional support were more effective than interventions that did not provide professional guidance and support.[7] And this holds true for studies of patients with symptoms of depression and anxiety[7] as well as those with serious mental illnesses, such as major depressive disorder and bipolar disorder.[7,10] There's also some evidence that digital tools can improve symptoms and cognitive outcomes in patients with even more serious mental illnesses like those that include psychotic symptoms.[7] In general, however, I think we're likely to find greater efficacy in cases in which the digital tool enables a measurement or intervention that is unique to the capabilities of digital devices.

Dr. Caudle:
So with that being said, Dr. Karlin, let's focus on something that I'm sure is on a lot of clinicians' minds right now: and that is, are digital tools safe for patients? And is there any regulatory oversight?

Dr. Karlin:
Yes, so in general, digital tools can be categorized based on a risk-versus-benefit assessment. For example, digital health products are used by consumers for their personal wellbeing. They don't claim to treat disease, and, in general, pressing one's fingers on a smartphone carries a low risk of harm. That's why the FDA considers the need for oversight to be low, and so they don't evaluate digital health apps.[3] But digital tools that claim to intervene or treat a medical condition do require evidence of safety and efficacy,[3] among other things. Now I want to note that an important consideration in the risk: benefit equation is whether the digital tool is an open or closed loop. For example, an EKG readout from a smartphone is an open-loop system. If erroneous data are provided, the clinician might notice it; they might be suspicious of the results and double check them or use their clinical judgment to make a treatment decision. And I'd like to point that most digital tools currently available in psychiatry are open-loop interventions. Some closed-loop interventions, on the other hand, can increase risk significantly.[11] For example, operational failure can cause serious injury or death, which is why closed-loop interventions

have greater requirements for safety and efficacy.[12] An example of a closed-loop intervention is an "artificial pancreas"[12] consisting of continuous glucose monitoring, an insulin pump, and a software-generated algorithm that automatically adjusts the level of insulin. As responsible developers, clinicians, and treaters, we should do our best to demonstrate favorable safety profiles by looking for potential safety risks, particularly in closed-loop systems. We need to ensure that any purported benefits are greater than any risks to which we might expose our patients.

Dr. Caudle:
So Dr. Karlin, now I'd like to switch gears a bit and focus on digital tools in practice. Can you share an example of their use in the real world?

Dr. Karlin:
Of course. For some background, college students reported increased mental stress during the COVID-19 pandemic—due in part to virtual learning and social isolation. And in the face of overwhelming demand for mental health services, some colleges turned to apps.[13] So in this particular study, smartphones were used to capture real-time behavior and symptoms related to mental health status in students studying remotely. The colleges in these studies hoped to use the information gathered to identify students in need of mental health services[13] and to help offer more personalized care.[13] To help them achieve this goal, both active and passive data were collected in real time. Active data were collected through conscious user engagement, such as answering a short survey assessing their mood, anxiety, and stress levels,[13] while data such as location and number of steps taken, screen time, and app and browser history were gathered passively, without conscious user engagement.[13] Assessments of students' mental health status were then made based on the data. The authors concluded that such personalized data collection can directly benefit students' mental health, but it's not sufficiently well developed for widespread use just yet.[13]

Dr. Caudle:
Thanks for sharing that with us, Dr. Karlin. Now clearly, that example was specific to patient care, but do you see other uses for digital tools beyond that?

Dr. Karlin:
I do. In clinical trials—just as in clinical care—the fidelity of the data and their ability to reflect real-world conditions are incredibly important, which is why smartphone technology coupled with wearable, ingestible, and/or implantable sensors are increasingly being used to capture data in clinical trials. After all, smartphone technology can capture and analyze real-time data continuously, which provides the ability to identify day-to-day variability, measure data precisely, and generate objective endpoints to supplement subjective assessments.[14] It may even lead to less frequent study visits.[14] But although the use of digital tools in clinical trials is expanding, its use is hampered by a lack of data standards, uniform analytical procedures, and variability of reporting methodology.[14] That's why a number of organizations like the Clinical Trials Transformation Initiative and the Digital Medicine Society are working to improve clinical trial quality and efficiency with mobile technology.[14]

Dr. Caudle:
And now we're almost out of time for today, Dr. Karlin, so to bring all of this together, can you summarize your perspective on digital tools in psychiatry?

Dr. Karlin:
Yes, so overall, I think we're in a really exciting time. The capacity for digital tools to measure and intervene to help patients seems increasingly high and, given the proliferation of technology, is certainly higher than it's ever been before. Of course I also have to say that these advances, particularly when they pertain to human health, will naturally bring additional risks. That's why responsible treaters along with medicine and digital product developers must carefully investigate the products they're bringing to market and defend any claims they're making around the products. It's essential that this evidence generation is done in a way that is representative of how the devices and medications could be used in the real world. This is

so clinicians and patients alike know that any product that claims to help patients with their psychiatric illness has demonstrated that it actually does what it claims to do, that it is helpful, and perhaps most importantly, that it is not harmful to the patient. And the last thing I'll say is that I've only scratched the surface when it comes to all of the considerations surrounding digital tools, so if you're interested in learning more, I recommend checking out the next two modules in this series called "Incorporating Digital Tools into Mental Health Treatment" and "Evaluating Digital Medicine and Digital Therapeutics."

Dr. Caudle:
Thanks so much for summarizing all of that for us, Dr. Karlin. And as that brings us to the end of today's program, I'd like to thank my guest, Dr. Daniel Karlin, for helping us better understand the use of digital tools in mental health care.

Dr. Karlin, it was great speaking with you today.

Dr. Karlin:
Yeah, totally my pleasure. I could talk about this stuff all day and like I said there's so much more we could say here but I really appreciate folks taking the time to dig in and start to learn about this world of digital medicine.

Announcer:
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