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Evaluating Mental Health Apps & Digital Tools

Announcer:
Welcome to ReachMD. This medical industry feature, titled “Evaluating Mental Health Apps & Digital Tools” is sponsored by Otsuka Pharmaceutical Development and Commercialization. Here’s your host, Dr. Charles Turck.

Dr. Turck:
The recent emergence of novel digital tools may change the way we approach mental health treatment. In additional to potentially improving access to mental care, digital tools have also been shown to improve symptoms in many types of mental illness,[1] and can serve as an adjunct to psychotherapy or pharmacotherapy. Despite this, these tools have not yet been widely adopted in the United States. This is ReachMD, and I’m Dr. Charles Turck. Joining me to discuss digital mental health treatments and their application in clinical practice is Dr. David Mohr, a Professor in the Department of Preventive Medicine at Northwestern University Feinberg School of Medicine in Chicago. He’s also Director of the Center for Behavioral Intervention Technologies. Dr. Mohr, welcome to the program.

Dr. Mohr:
Thank you and it's a pleasure to be here!

Dr. Turck:
To begin, Dr. Mohr, can you give us some background on your experience with mental health apps and digital tools? And what do you think is limiting their widespread use in the United States?

Dr. Mohr:
Sure and thank you. So, I’ve been working in digital mental health treatments, or DMHTs for short, in some fashion for about 20 years now. I’m also President of the Society for Digital Mental Health. So, before I start talking about the limitations to widespread use, I want to start by looking at the root of the problem. We have a shortage of mental health providers in the US, and that leaves many patients without access to proper care.[1] So, DMHTs provide an alternative to traditional mental healthcare that can potentially help overcome barriers to access.[1] There have been many randomized control trials that have shown DMHTs, when supported by a coach, are effective at treating common mental health problems like depression, anxiety, and PTSD.[1] But one of the obstacles to the implementation of these tools is the lack of established billing codes in the US, an obstacle The Society of Digital Mental Health is looking to overcome.[1] If we look at other countries, such as the United Kingdom, the Netherlands, Australia, they’ve begun integrating DMHTs into their healthcare systems and have procedures in place that ensure treatments are safe and effective.[1] So to figure out why DMHTs haven’t been widely adopted here, I co-chaired the Banbury Forum meeting with Dr. Pat Arean, a psychologist from the University of Washington, in 2019. We met with 23 international opinion leaders and stakeholders from various healthcare organizations, payers, researchers, and digital tool companies and reviewed the published evidence for digital mental health treatments.[1]

Dr. Turck:
Is there anything you learned about the use of DHMTs from this evidence?

Dr. Mohr:
First, I should clarify that DMHTs can either be fully automated without human support, or they can be guided by low-intensity support from a clinician, a coach, or a peer.[1] Particularly with coaching, they show efficacy similar to standard face-to-face therapy for common mental health problems such as depression and anxiety.[1] And so based on these findings, we recommended that DMHTs be broadly adopted in the US healthcare system.[1] Of course to make this work, we’d need some sort of reimbursement mechanisms in place, as

well as an evidence standards framework to support decision makers in evaluating DMHTs for safety and efficacy.[1]

Dr. Turck:
Now before we dive into what we learned about the application of these tools, can you give us some background on how tools such as these are typically assessed?

Dr. Mohr:
The U.S. Food and Drug Administration, or FDA for short, may assess the safety and efficacy of tools like this, but that also depends on the type of tool. Most digital mental health apps don't provide specific treatment recommendations, rather, they focus on supporting people in developing effective coping strategies. So therefore they're considered low risk by the FDA. Accordingly, they fall under the category of "enforcement discretion," which means that the FDA has elected not to require review and certification of safety and efficacy.[1-3] On the other hand, for software functions that are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, those may meet the definition of "medical device", and the FDA also exercises enforcement discretion due to their low risk to the public.[4] The FDA refers to these as software as a medical device, or SaMDs for short.[5]

SaMDs that diagnose or treat disease and use software functions that fall under the FDA's regulatory oversight require either FDA clearance or approval. The terms "clearance" and "approval" refer to different regulatory pathways. The primary purpose of the FDA clearance or approval is to provide assurance that safety for products where there may be risks to the user if the device were not to function as intended.[6] So class I devices are considered low risk, Class II are considered moderate risk, and Class III devices pose the highest risk.[7] Most DMHTs are categorized as Class I or Class II devices.[8]

For Class I and Class II devices, if the FDA assumes that the probable benefits of the device outweigh the probable risk based on its review of the premarket submission, the FDA grants permission to market the device.[8] At the Banbury Forum, stakeholders from healthcare systems, insurers and payers, employers, and others felt that FDA clearance was insufficient for a "digital formulary" decision-making.[1] To address this need, the Banbury Forum recommended that a framework of standards be developed to support digital formulary decision-making.[1] The Forum stated that this framework should integrate core ethical principles of respect for persons, beneficence, and justice; include standards for effectiveness and patient engagement; and address equity, including barriers to access due to language, income, or disability.[1]

Dr. Turck:
For those just tuning in, you're listening to ReachMD. I'm Dr. Charles Turck, and today I'm speaking with Dr. David Mohr about digital mental health tools. Now that we understand how these tools are typically assessed, let's apply the Banbury Forum's recommendations to clinical practice. Dr. Mohr, what are some strategies we can use to implement these tools in the US and develop an improved framework?

Dr. Mohr:
One of the ways this can be done is by providing guidance to decision-makers in healthcare settings on these mental health apps. There are a number of important evidence frameworks to evaluate DMHTs that have been published since the Banbury Forum. Perhaps the most important is the FASTER framework from the Agency for Healthcare Research and Quality, or AHRQ, as this is a document published by the federal government. It provides the most comprehensive set of questions to evaluate the risk, safety, technical functionality, and mental health features of mental health apps.[9]

In implementing DMHTs into the healthcare system, coaching can be important in promoting engagement and integrating DMHTs into the healthcare system. And this can be done in a variety of ways. Low-intensity coaching involves minimal phone contact, with most communication taking place via messaging either via text or in-app messaging. And as I mentioned earlier, DMHTs guided by low-intensity support from a coach, clinician, or peer have efficacy similar to standard face-to-face therapy for common mental health problems such as anxiety or depression.[1] So even though we consider this type of coaching to be low intensity, it can have a high impact. In other words, clinicians provide more support through more frequent phone calls.

In my experience, coaching generally is intended to help patients use the digital mental health service to their best advantage. Some users have "low digital health literacy," meaning they have difficulty using the technologies. To address this issue, coaches, or digital navigators, can train patients how to use the technologies[10] and help them stay "adherent," or connected to the app,[10] while ensuring that the patient is benefiting from the app.

Dr. Turck:
With that in mind, how can we integrate these coaching methods into clinical practice?

Dr. Mohr:
Now, as I mentioned, coaches may play an important role in integrating DMHTs digital mental health treatments into the US healthcare system. In order to do so, we need to ensure digital mental health services fit into the care pathways in ways that support the continuity of care. We need to manage how data from the apps are moved into the system, who should see the data, and what actions should or should not be taken based on the data. Pathways for moving patients who do not respond to DMHTs to more intensive treatment have to be established. And coaches could play a role in this process. They could review incoming data, identify patients who are not improving and who need a change in their treatment plan, and refer these patients for additional clinical care. I think this is something that warrants further exploration.[11]

Dr. Turck:
Now given that the current framework for approval through the FDA has received criticism, can you tell us about some of the other sources that can help not only clinicians, but patients, evaluate digital mental health apps?

Dr. Mohr:
Sure, there are a number of credible sources that evaluate digital mental health tools. For example, PsyberGuide, led by Stephen Schueller at the University of California Irvine, is funded by One Mind, a leading nonprofit organization in brain health research. PsyberGuide evaluates apps based on credibility, transparency of data policy, user experience, and professional reviews.[12-14] Another is called MIND, or the Mobile Health Index and Navigation Database, led by John Torous from the Division of Digital Psychiatry at Beth Israel Deaconess Medical Center/Harvard Medical School. This database is based on the American Psychiatric Association's App Evaluation Model and allows users to sort apps based on the presence or absence of various features.[15] And finally, the American Psychological Association's Division of Trauma Psychology, in conjunction with other divisions, has created the Mental Health Mobile Phone Application Review Database.[16] And many of the apps in this database focus on treatment of PTSD. I want to mention that there's a lot of turnover in digital mental health. Apps come and go from the app stores and many apps are updated frequently. While app rating services should update their reviews periodically, it is a good idea to check the date of the review to ensure the information is current.

Dr. Turck:
And before we close, Dr. Mohr, do you have any final thoughts or takeaways you'd like to share with our audience?

Dr. Mohr:
The value of guided use of DMHTs is well-validated and well-established.[1] That being said, DMHTs may be evaluated by the FDA for safety and to confirm that they do what they say they do, but most don't require clearance or approval. It's not the role of the FDA to recommend specific devices. As we move towards broader adoption of DMHTs in the US healthcare system, an important next step is to disseminate the recently published frameworks of evidence standards to help clinicians, payers, and policymakers select digital mental health products and services that are effective and usable. In addition, a number of resources, such as PsyberGuide and MIND, are available to help clinicians and patients evaluate DMHTs. Efforts are currently underway, including by the American Psychological Association and the Society for Digital Mental Health, to work with the Centers for Medicare & Medicaid Services to establish billing codes that would enable reimbursement for the apps, digital navigators, and coaching. And finally, coaches can promote the effective use of DMHTs and could help integrate DMHTs into our healthcare system.

Dr. Turck:
That's a great comment for us to think on as we come to the end of today's program. I want to thank my guest, Dr. David Mohr, for helping us better understand the need for DMHTs in the United States. Dr. Mohr, it was great speaking with you today.

Dr. Mohr:
Thank you!

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