

03 Jun 2024 | Interviews

Digital Health Apps Have Underperformed, But VR Is 'Very Different' – Cedars-Sinai Virtual Medicine

Virtual Reality Therapy Is Drawing Strong Pharma Attention, Says Director Brennan Spiegel

by Ryan Nelson

Cedars-Sinai's Virtual Medicine director Brennan Spiegel discusses the shortage of mental health professional resources and how Medical Extended Reality – e.g., immersing patients in a virtual world with an Al therapy avatar – is helping to address depression, pain, and a growing host of health and wellness needs in hospital and consumer settings.

Medtech Insight is honoring May and June awareness months for mental health, Alzheimer's and brain health by speaking with industry leaders about rising innovations to address neurological diseases and mental health, the regulatory and investment climate, reimbursement, and more.

Dr. Brennan Spiegel, director of health services research for Cedars-Sinai Medical Center, author of the book, "VRX: How Virtual Therapeutics Will Revolutionize Medicine," and Onalytica "Top 100 Influencer" for digital health and virtual reality, spoke with Medtech Insight on 30 May about the present and future of medical extended reality (MXR).

Spiegel launched the Cedars-Sinai's Virtual Medicine program in 2018. In 2023, his team combined spatial computing with artificial intelligence to create Xaia, which provides "self-administered, AI-enabled, conversational therapy in relaxing spatial environments such as a creek-side meadow or a sunny beach retreat," using the Apple Vision Pro virtual reality headset

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(see sidebar).

VRx Health, Inc. was formed the same year to commercialize Xaia, which is available through the Apple Apps Store for around \$30 per month of unlimited use.

In the following interview, which has been lightly edited for length and clarity, Spiegel discusses Xaia, MXR for treating pain, pharma collaborations, uptake and reimbursement challenges, and the impact that AI stands to have on clinician roles and so many other professions.

Q Medtech Insight: What is Cedar-Sinai's CS-Core?

A Dr. Brennan Spiegel: CS-CORE [Cedars-Sinai Center for Outcomes Research and Education] is the name of our research lab. And Virtual Medicine is our VR program. We're focused on medical extended reality, or MXR, and more broadly, virtual medicine. But it has three parts to it: There's the clinical part where we provide MXR care for patients, there's the academic research part where we do research studies, and then there's the educational curriculum.

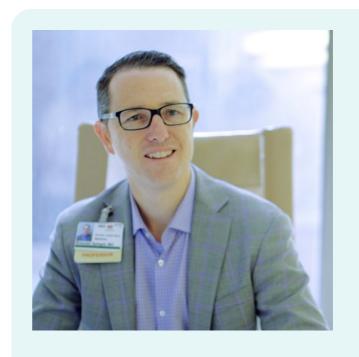
This VR/AI Therapist Stunned Creators With Advice To A Simulated Domestic **Violence Victim**

By Ryan Nelson

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Spun out from Cedars-Sinai to VRx Health, Inc., Xaia provides "AI-enabled, conversational therapy in relaxing spatial environments such as a creek-side meadow or a sunny beach retreat," using the Apple Vision Pro virtual reality headset. Its insights have been eye-opening, showing significant promise for on-demand therapy at a time when mental health resources are stretched.

Read the full article here



Your very interesting study,
"Feasibility of combining
spatial computing and AI for
mental health support in
anxiety and depression,"
suggests that Xaia is a viable
option, maybe even the best
option, for providing mental
health support in at least some
cases and circumstances. Can
you talk about how Xaia is
being used right now in
people's homes and at CedarsSinai?

Brennan Spiegel, MD, MSHS, is director of health services research for Cedars-Sinai, director of the Cedars-Sinai master's degree program in health delivery science, and the George and Dorothy Gourrich chair in digital health ethics. He directs the Cedars-Sinai Center for Outcomes Research and Education (CS-CORE), a multidisciplinary team that investigates how digital health technologies, including wearable biosensors, smartphone applications, virtual reality (VR) and social media, can strengthen the patient-doctor bond, improve outcomes and save money.

A Spiegel: Xaia is a program that uses artificial intelligence – it actually uses about six different forms of AI – to deliver mental health support. To be clear, it's not an FDA-regulated product, it's not making diagnoses, people should see their doctor if they need psychotherapy and so on. But it has been developed in partnership with psychotherapists, and right now it is available on the Apple Vision Pro for anyone to use. Not many people yet have that particular headset, but it is available.

In addition, we're testing it out in the hospital, and now we have it where it can actually write a clinical note. So this is being used for research purposes, where we provide the headset to people in the hospital and they interact with this conversational avatar in beautiful spatially computed worlds. And the AI uses something called generated reality, or GR, where it will create environments specific to that individual depending on what they're talking about or what's on their minds. No two experiences are ever the same. Afterward, Xaia will compose a note and put it in their chart, it'll show up in the electronic health record and the inbox of a clinician, who then can review it, edit it, and of course go and see the patient on their own.

Q Whom is most likely to benefit from Xaia, and what makes it and other MXR



developments so promising in today's mental health care landscape?

A place like Cedars, we have about 1,000 beds, and we have a very high demand for behavioral health support services. But like most hospitals, there's only so much staff available. So we can extend their ability through what I call a paratherapist model. Just like a paramedic is a liaison between patients in the field and doctors in the emergency department, a paratherapist is an extender of the therapist that can, you know, check in on people and collect information from them and write notes and send them back to the clinician or therapist who's otherwise quite busy.

So that's one model. We're now looking at other models to do this with other conditions. We're working right now with Geriatric Oncology at UCLA to develop a system that could help evaluate people in the geriatric oncology clinic being evaluated for chemotherapy. In the emergency department, we're looking at it for people who need to have a history taken while they're waiting around in the waiting room. We're using it for people with alcohol use disorder, or on the liver transplant waiting list, people who have had weight reduction surgery and are struggling with the postoperative consequences of new lives. The list goes on and on of ways that this can be used to engage people in a completely different way than ever before possible.

- You mentioned that Xaia is something like six forms of AI wrapped into one. I understand that one form is an "Appropriateness Classifier," which essentially serves to prevent potentially dangerous or unhelpful responses from reaching users. What more can you say about the importance of quality control measures taken with Xaia and other MXR applications?
 - Anyone working with AI has to be keenly aware of the potential risks of interfacing AI systems with patients. Even with the most careful controls, there's always the risk of a black swan event where AI does something unpredictable. But there are ways to mitigate that. We work very closely with our computer science team, our AI team, computational biomedicine, people who have really developed some incredible approaches to mitigate this. And we've tested it. That's the key, really to make sure

that there has been extensive testing and documentation.

ChatGPT, for example, is not a very good therapist if you use it right out the box. It jumps to conclusions, it doesn't establish a rapport, it just makes a lot of mistakes. So we had to start by creating a large language model approach that aligned with best practices and had checks and balances, and then we have that second AI that is constantly monitoring the first AI for any kind of unexpected verbiage. At this point with certainly thousands of users, it's never once triggered the backup AI system. But it's there if we need it. And we have tried to trigger it on purpose. Even when we tried to make Xaia say crazy stuff, so far she has been able to stay on message – and really in a way that no human can easily do. You can offend her, you can insult her, and she'll keep bringing it back to you and trying to understand, why is it important to you to have this conversation?

- Q Can we revisit the regulatory piece? How do you avoid a regulatory compliance issue with Xaia, which you noted is not FDA-approved, and might you be pursuing an FDA submission down the line?
 - The FDA has very clear guidance that we follow very carefully. At Cedars-Sinai, we have outstanding regulatory experts, and everything we do here is very carefully aligned with regulatory guidance. If you're going to make a claim on a specific disease, like this can diagnose this condition or treat this condition, or can improve the symptoms of this condition, you're treading very quickly into the space of the FDA. Whereas if more broadly you're referring to a health and wellness tool that can help people feel better and, ideally, improve their quality of life, now it's nonspecific and trending away from regulatory oversight.

In the case of Xaia, for at least this initial launch, we're very careful in our websites to emphasize that this is not a diagnostic tool, you should always see your doctor, this isn't going to provide specific treatment for specific patients. That said, we can certainly still examine Xaia in a research capacity, and that's what we're doing right now – can it improve the symptoms of depression or anxiety? And if we find that something like Xaia really does improve specific conditions, or could diagnose

conditions, then the strategy would potentially turn into an FDA type of approach.

- I wanted to touch on VR use in reducing pain, as there's a lot of research happening currently in this area, including at Cedars-Sinai, and a growing marketplace of digital solutions that purportedly help with pain. In your experience, what sorts of cases are most likely to respond to VR as pain therapy?
 - We have a number of studies ongoing right now looking at this. First of all, when we talk about does VR work for this, or does VR work for that, that's sort of nonspecific. It's kind of like saying does medicine work for this, does medicine work for that. Well, which medicine are you talking about? Which VR program are we talking about? What is its mechanism of action? How does it work? VR itself is just a headset, it's like a syringe. It's not the syringe that matters, it's the medicine that goes through the syringe that matters. So what we're trying to figure out is what is the right VR program for the right patient at the right time what I call precision immersion. And that is where AI can be very helpful to modify environments and interactions specific to each individual, taking advantage of the psychological presence one feels in VR. We've seen some very effective interventions for pain with VR, and we're not seeing positive responses too it's not a panacea. But when it works, it works great. Then other people have been nonplussed by it. Like I gave it to somebody recently who said, 'This is psychobabble.' Okay, it's probably not going to work for them.
- It seems that VR almost certainly will have a role in the future of pain management in combination with, or even independent of, drugs. Are you seeing interest from the pharmaceuticals industry?
 - A Pharma has definitely come to us; they've been quite interested in what we're doing, and from different angles. For example, some see it [VC] really as an educational tool for patients or providers, but others see it as a way to augment their therapy. So we're doing research now with one pharmaceutical company examining, when we combine our GI-focused VR program with a GI-focused drug, if the whole is better than the sum of the parts. Like is it synergistic to use a brain-directed VR program and a gut-

directed pharmacotherapy for a condition like irritable bowel syndrome, which is a disorder of gut-brain interaction? What if we literally go beyond the pill and augment it, and are there regulatory opportunities to create digiceutical-pharmaceutical combination therapies? So this is a really important area.

- Pharma collaborations do seem like a bright possibility for digital therapeutics at a time when developers of these technologies continue to face obstacles with regard to acceptance and uptake, as well as reimbursement. What is your view on current challenges?
 - A I think it comes down to adoption and uptake, and those are the same answers I've been giving for the better part of 10 years. We now have plenty of science – it's not like we need 20 more meta-analyses. We have science, the FDA recognizes that, there's a new branch of the FDA called *Medical Extended Reality*. (Also see "FDA" Launches New Webpage Dedicated To AR And VR Medical Devices" - Medtech Insight, 8 Dec, 2022.) So it's not really about the science, it's about emphasizing, you know, insurance coverage and payer coverage and access to these devices. We can't expect people to just pick up a \$3,500 Vision Pro to get treatment, they need to be able to have insurance covering these kinds of devices. Now we do have an ICD 10 code for virtual reality therapy, which is very exciting, and we're learning more about how payers will interact with that code. And we're seeing more interest from Medicare to potentially cover certain VR therapies. So that's where we need to go next. It's really about getting traction with payers and for them to understand the value of these interventions. These are not just simple apps. Apps have underperformed in terms of the impact of traditional smartphone apps on chronic disease management, not that there haven't been successes. But the digital health revolution that we saw 10 years ago is still kind of evolving. I do believe that VR is very, very different, in terms of its effects on the human mind and body.
- Returning to Xaia and in light of the growing conversation around the future of AI and its implications for humans, I have to ask: Are Xaia or future generations of AI therapists going to squeeze out human therapists?

Α

Yeah, I mean, that's the question for every profession. My sense is that every profession has to figure out how to be the best version of itself possible. Because that's what AI is going to demand of us. Like, what does a therapist do? A therapist looks people in the eyes, establishes a rapport, demonstrates deep human wisdom, pauses and thinks and, you know, the human component of interaction, that's why we go to see a human. And doctors too – what do doctors do? They make differential diagnoses. Yeah, well, so can the computer now. They check patient history. Well, I've got a computer that's probably better. Okay, then what can we do that's left? Well, we do a physical exam. Computers don't do that just yet. I don't know if people want a robot doing a rectal exam. So maybe we need to actually get good at the things we used to be good at, like doing a physical, holding people's hands and looking them in the eye, being wise, doing procedures that computers can't do yet.

No human is going to know more than AI in terms of just pure knowledge. And right now, this is the worst [least effective] AI is going to be. And she's already making people cry routinely. We already have people telling us, she doesn't care what color my skin is, she doesn't care what I say, she's so non-judgmental, she gets right to it, she doesn't chitchat, I've never actually had a human talk to me like this before. So it's going to demand from all of us that we be the best version of ourselves that we can possibly be and then let the computers help us, not compete with us.