

The Impact of GenAI on Digital Mental Health Medical Devices & MH Technologies

Vaile Wright, PhD
Senior Director
Office of Health Care Innovation

American Psychological Association



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Disclosure Statement

- I have no personal/professional disclosures
- The products used as examples do not imply an endorsement by APA

Mental Health Crisis & Workforce

- One in five U.S. adults experience mental illness each year and the long-term impact of the COVID-19 pandemic is still unfolding.
- Despite these rising numbers, in 2020 only 20% of adults received any mental health treatment in the past year.
- This is due, in part, to challenges accessing evidence-based psychological treatment.

Mental Health Crisis & Workforce cont.

- According to behavioral health workforce projections, the supply of behavioral health providers through 2037, including psychologists, psychiatrists, social workers, and mental health counselors, are projected to be insufficient to address the demand for mental health services (HRSA, 2024).
- Complicating matters even more, behavioral health providers report feeling increasingly disincentivized from taking health insurance due to low reimbursement rates and high administrative burden (APA, 2024).

Multiple solutions are necessary to address the mental health crisis

- Support existing and grow future workforce, including improving reimbursement rates & reducing burden
- Integrated behavioral health care
- Measuring quality, including Measurement-Based Care & Value Base Care
- Focus on prevention
- Community-based interventions, including peer-to-peer
- Innovative care models and treatments, including single-session interventions
- Telehealth and technology, including AI

MH Technology Landscape

- Telehealth (video conferencing/audio only)
 - Only 21% of psychologists reported using telehealth before 2020
 - Use of telehealth increased 12-fold to about 86% during the pandemic (Pierce et al., 2020)
- Online Therapy Platforms & Provider Networks
 - \$11.09 billion market share in 2025
 - Offers traditional telehealth services, but first line treatment is typically asynchronous texting or video messaging
 - Variable insurance coverage and business models (B2B, B2C, etc)

Can Increase Access But Not Reach

MH Technology Landscape (2)

- **Wellness & Direct-to-Consumer Apps**
 - Not intended to treat a mental health condition
 - Meant to aid in daily living by promoting healthy lifestyle and general well-being
 - Self-driven, public, and not regulated or subject to HIPAA
- **Digital Therapeutics**
 - Deliver evidenced-based, clinically validated psychological treatments
 - Meet classification for Software as a Medical Device
 - Make medical claims that they “diagnose, treat, cure or prevent a disease”
 - Products that undergo FDA review and clearance, require a prescription or order by a licensed provider, such as a psychologist, to be furnished to patients

MH Technology Landscape (3)

- Generative AI

- A type of artificial intelligence (AI) technology that can produce various types of content, including text, imagery, audio and synthetic data based on a prompt
- Based on large language models which are AI algorithms that use deep learning techniques and large data sets to understand, summarize, generate and predict new content
 - › Rapidly presents answers in a natural language format
- 2022 – OpenAI launches ChatGPT
 - › But first chatbot (“Eliza”) was developed in 1964
- In Spring 2025, 34% of adults had tried ChatGPT compared to 18% in Summer 2023 (Pew Research Center, 2025).

How is GenAI Being Used?

- 48.7% of participants report using LLMs for psychological support within the past year
- Users primarily sought help for anxiety (73.3%), personal advice (63.0%), and depression (59.7%)
- 63.4% of users reported improved mental health from LLM interactions, with high satisfaction ratings for practical advice (86.8%) and overall helpfulness (82.3%)
- 9.0% of users encountered harmful responses

Teens' AI Use

- 70% have used at least one type of GenAI tool
 - Four main categories
 - › Chatbots or text generators
 - › Image generators
 - › Video generators
 - › Search engines with AI generated results
- Parents' awareness of teen's use:
 - 37% said yes
 - 23% said no
 - 39% said "not sure"

Teens' Use of AI Companions

What do teens use AI companions for?

- Entertainment (30%)
- Curiosity about the technology (28%)
- Advice (18%)
- Always available when I need to talk (17%)
- No judgement (14%)
- Can share things that I wouldn't tell friends or family (12%)
- Easier than talking to real people (9%)
- Helps to practice social skills (7%)
- To feel less lonely (6%)
- Other (5%)

Opportunities for AI in Mental Health Care

- Access to scientifically validated data
- Foster early and accurate disease detection
- Increase precision & personalized medicine
- Improve population health and care access
- Provide clinical decision support
- Improve operational efficiencies
- Reduce administrative burden
- Improve clinical and patient engagement
- Reduce burnout
- Improve patient education

Two Major AI Health Care Trends

- Influx of MH AI Ambient Scribes and Support Tools marketed to providers
 - Standalone Products
 - Add-on AI features into existing EHR/EMR programs
- Adoption Challenges
 - Barriers include AI anxiety, lack of training, heightened data privacy/security concerns and unclear benefits, limiting widespread AI adoption in behavioral health
- Implementation and Ethics
 - Successful AI use requires clear goals, staff involvement, training, and compliance with data privacy and ethical standards (APA, 2025).

Trend #2: Consumer-Facing AI Chatbots

FDA regulated MH chatbots

Chatbots that make medical claims that they can “diagnose, treat or cure” a mental health disorder and have to demonstrate efficacy and safety to be cleared

Not aware of any AI or generative AI chatbot currently cleared by FDA but can anticipate some soon

Direct-to-consumer MH chatbots

These are unregulated AI or generative AI chatbots that do not make medical claims but are developed to address MH concerns (i.e., stress) or emotional wellbeing

Some are grounded in evidence-based theories and developed by SMEs (e.g., **Woebot** which used closed loop AI) while others are less transparent (e.g., **Sonia** which is Gen AI)

Direct-to-consumer entertainment/general chatbots

These are also unregulated generative AI chatbots that do not claim to be developed to address MH concerns but are being used by people for “companionship” or as a “friend”

As far as we know, none of the products on the market (e.g., **Character AI**, **ChatGPT**) have little to any evidence-base, SME input, or post-market surveillance

Challenges/Threats of AI in Mental Health Care

- Biased input leads to biased output
- Need to protect sensitive data
- Potential spread of misinformation and disinformation
- Replace and/or change human labor
- Hard to anticipate unintended consequences
- Lack of transparency and trust in AI tools
- Lack of rigorous testing and validation to mitigate risks
- Does not offer pitch-perfect accuracy (i.e., “Black Box”)
- Impact on vulnerable populations (APA, 2025: *AI and Adolescent Well-being*)

Challenges to Scalability

- Lack of regulatory bodies & legislation to ensure safety and efficacy
- Traditional coverage and reimbursement models not designed to fit innovative technologies
- Data privacy, HIT infrastructure and monitoring
- Lack of trust & understanding

Current regulatory frameworks do not address the realities of AI in mental health. We urge policymakers to:

- Require following existing FDA transparency guidelines as a baseline expectation to address gaps in transparency
- Modernize regulations to address the critical discrepancy between the stated intent of these technologies and their actual use
- Strengthen requirements around premarket evidence and postmarket monitoring for all digital tools in mental health
- Establish clear, enforceable standards for all digital tools used for mental health
- Address gaps in FDA oversight via a new or inter-agency approach to assess therapeutic validity of GenAI for MH
- Establish public repository of products that have received FDA clearance and those operating under enforcement discretion, which includes clearer guidance (for the public and developers) about what it means (and does not mean) to fall under enforcement discretion and who makes that determination (e.g., FDA vs. the company)



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Thank you

Office of Health Care Innovation

OHCI@APA.ORG

