SAMHSA ADVISORY
Substance Abuse and Mental Health Services Administration

JUNE 2026

HOW WEARABLES AND OTHER DIGITAL TOOLS ARE DRIVING INNOVATION IN BEHAVIORAL HEALTH

Digital tools include wearable devices (wearables), applications (apps), telehealth platforms, digital therapeutics (DTx), artificial intelligence (AI)-enabled screening tools, and chatbots. Using wearables to monitor health is a growing practice, and these devices show potential to support prevention, early intervention, treatment, and recovery for mental health conditions and substance use disorders (SUDs). Wearables can track real-time physiological indicators, such as heart rate variability and changes in sleep patterns, which may reflect increased stress or changes from a person's normal baseline. These insights can help support timely, personalized interventions through smartphone apps, tablets, or computers.

This *Advisory* will help healthcare providers, public health professionals, policymakers, and patients and their families understand:

- Emerging digital innovations that may help monitor and manage mental health challenges and SUDs.
- How wearables can improve well-being and treatment outcomes by providing people with real-time self-management tools and extending care beyond the clinic.
- Ethical and privacy considerations associated with evolving technologies and the accessibility needs of people with disabilities.

Key Messages

- Digital tools may help people manage mental health conditions and substance use disorders, but the evidence base and practical application for these tools are currently limited.
- Wearables and apps increase access to personalized interventions that support behavior change and can enhance motivation, engagement, and self-management.
- Addressing ethical, privacy, and security concerns can increase adoption and ensure the safe use of digital tools.

Behavioral Health in the United States

Behavioral health encompasses a range of conditions, including SUDs. National health data underscore the need to expand behavioral health services and show that the U.S. population has:

- **Limited access to mental health care.** In 2024, an estimated 23.4 percent of adults ages 18 and older were living with a mental illness.[1] Among those adults, just over half received mental health care in the past year.
- **A high prevalence of mental health conditions among adolescents.** Among youth ages 12–17 in 2023, about 20.0 percent had a diagnosed mental health condition, such as anxiety or depression.[2] Nearly 20.0 percent reported having an unmet mental health care need in the past 12 months, according to survey data from 2021 through 2023.[3]
- **A high prevalence of suicide.** In 2024, 14.3 million adults ages 18 or older seriously thought about suicide in the past year, 4.6 million made a plan, and 2.2 million attempted suicide.[1] More than 48,000 people died by suicide in 2024.[4]
- **An unmet need for SUD treatment.** In 2024, an estimated 16.8 percent of people ages 12 and older had an SUD in the past year.[1] Among those who needed treatment, only 19.3 percent received SUD treatment in the past year.
- **A high prevalence of co-occurring behavioral health conditions.** In 2024, approximately 21.2 million adults were living with both a mental illness and an SUD in the past year.[1]
- **Concerning rates of drug overdose deaths.** Provisional data from 2024 indicate there were 80,391 drug overdose deaths, most of which involved synthetic opioids (fentanyl).[5]
- **Promising data on recovery.** In 2024, an estimated 23.5 million adults ages 18 or older identified as being in recovery or recovered from problematic substance use.[1] Additionally, 45 million adults identified as being in recovery or recovered from a mental health condition.

Definitions

- **Artificial intelligence:** A digital system or program that imitates human learning, reasoning, or behavior using natural language processing and machine learning.[6]
- **Biosensor:** A device that detects changes in biochemical markers associated with stress, illness, or medication or substance use.
- **Digital biomarkers:** User data collected through a digital device, such as a wearable, that indicate whether the body is healthy, sick, or responding to an exposure or intervention.[7]
- **Digital phenotyping:** Passive data collection in everyday environments using personal digital devices, like wearables or smartphones, to infer a person's physical and behavioral traits.[8]
- **Ecological momentary assessment (EMA) and ecological momentary intervention (EMI):** EMA involves repeated sampling of self-reported behaviors in natural environments and in real time.[9] An EMI is a real-time intervention in response to an EMA and can be a standalone intervention or a complement to treatment.[10]

Definitions, *continued*

- **Just-in-time adaptive intervention:** An intervention that adapts to a person's context and delivers support in real time within their natural environment.[11]
- **Machine learning:** The use of computer algorithms to detect patterns in data to make predictions or solve problems.[12]
- **Remote patient monitoring:** The use of digital devices to collect and share health data for the purpose of monitoring health conditions.[13]
- **Wearable device:** An electronic device or technology that a person can wear comfortably on the body or incorporate into clothing or accessories.[14,15]

What Digital Tools Do

The widespread adoption of mobile technology presents a unique opportunity to bridge the gap between the need for behavioral health services and their delivery. In 2024, an estimated 93 percent of adults in the United States used a smartphone,[16] and nearly 40 percent used a wearable device.[17] Young adults use digital devices more than any other age group.[18] However, access to these technologies—particularly wearables—is not evenly distributed. Research indicates a digital divide, with ownership more prevalent among people who are young, wealthy, live in urban areas, and are highly educated.[19]

Digital behavioral health tools encompass a range of technology-based systems, platforms, apps, and devices that support health and well-being. Collectively, these tools can provide scalable, accessible adjuncts to traditional mental health and SUD treatment. Digital tools that wirelessly connect to networks enable seamless data exchange between devices and systems and can offer healthcare providers continuous, real-time insights into a patient's health status. Digital tools can:

- Support remote patient monitoring through wearables, sensors, biometric measures, and ecological momentary assessment (EMA), enabling real-time feedback.
- Facilitate self-management, symptom tracking, and recovery planning.
- Deliver therapeutic content, such as cognitive–behavioral therapy, motivational interviewing, and psychoeducation.
- Enable peer or social support through online forums or networks.
- Allow remote interaction between patients and behavioral healthcare providers, including asynchronous interaction via messaging for which both parties need not be present at the same time.

Mobile health, or mHealth, provides infrastructure and a delivery mechanism for many digital behavioral health tools by using mobile and wireless technologies—such as wearables, virtual reality devices, and smartphone and tablet apps—to support public health and enhance healthcare delivery.[20] mHealth is expanding as healthcare providers increasingly adopt these technologies to complement in-person clinical interventions. Research suggests that many patients prefer clinician involvement, support, and guidance on how to use wearables and other digital tools.[21] Also, mHealth has the potential to broaden access to care for hard-to-reach populations, such as people living in rural and remote communities and those who are homeless.

Over the past decade, the use of digital technologies to support behavioral health has grown substantially. Providers use these tools to support assessment, diagnosis, treatment, monitoring, and recovery for people with mental health conditions, SUDs, and co-occurring disorders.[22–24] For example, DTx—interventions delivered through digital platforms—are rapidly advancing.[25] The U.S. Food and Drug Administration (FDA) has cleared some DTx to prevent, manage, or treat conditions such as depression, SUDs, post-traumatic stress disorder, insomnia, and attention deficit hyperactivity disorder.[26] The Substance Abuse and Mental Health Services Administration's (SAMHSA) *Advisory:* Digital Therapeutics for Management and Treatment in Behavioral Health provides information about DTx digital therapeutics for behavioral health.

Wearable Technology Options

Wearables can be placed on the wrist or chest or applied as transdermal patches or temporary tattoos. They can also be worn as rings, headbands, smart glasses, in-ear devices, or integrated into clothing. Some digital tools can monitor and support behavioral health through mobile apps and wearables. Wearables can be worn as:

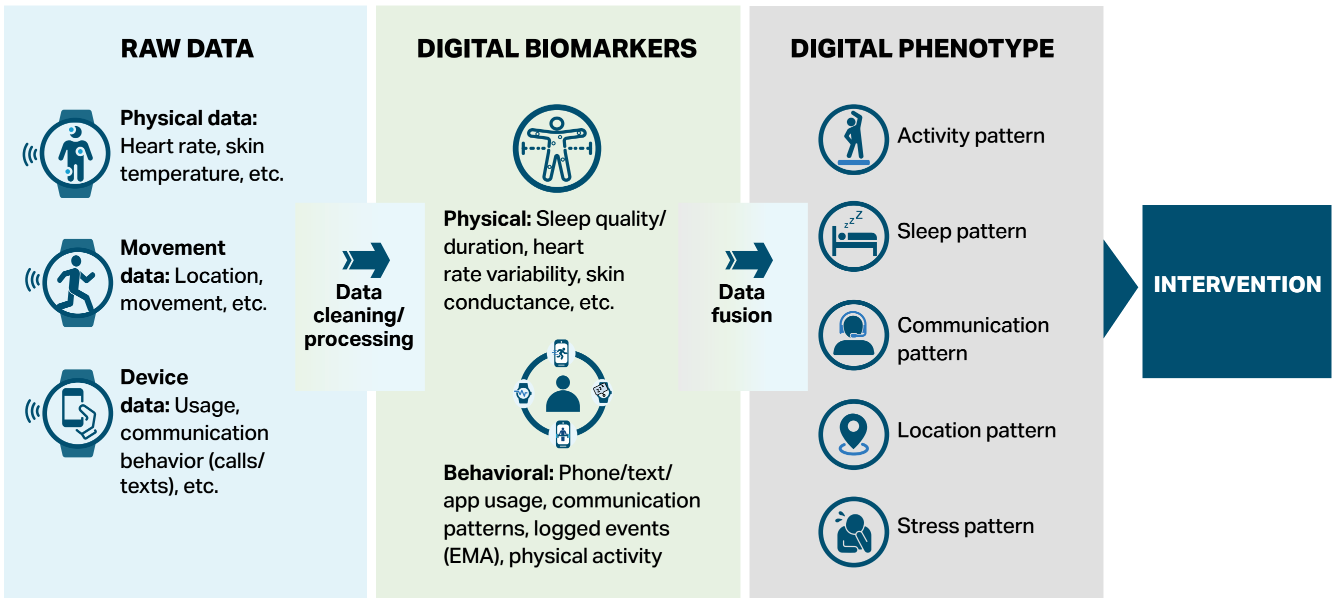
- **On-body sensors.** Fitness trackers, smartwatches, biosensors, and overdose detection devices all feature sensors. Sensors can monitor a range of physiological and behavioral indicators, including transdermal alcohol concentration, skin and body temperature, oxygen saturation, electrodermal activity (skin conductance), brain activity, heart rate, heart rate variability, perspiration, and respiration rate (breaths per minute).
- **Virtual reality headsets.** These devices can deliver interventions for various mental health conditions and SUDs by creating immersive virtual environments for therapy and recovery support. These extended reality technologies include[27]:
  - Virtual reality, which provides a fully virtual environment.
  - Mixed reality, which combines virtual and real-world environments.
  - Augmented reality, which superimposes digital content onto the real-world environment.
- **Off-body sensors.** These include smartphones and apps that measure movement, capture geolocation, or help to deliver EMAs and ecological momentary interventions (EMIs).

How Wearables Collect and Process Data

Wearables collect physical and behavioral data that can help monitor signs of well-being, detect potential symptoms, and inform early intervention, treatment, and recovery activities. Digital phenotyping passively extracts user data from digital devices like wearables and smartphones that might inform interventions. Figure 1 on page 5 illustrates this process, during which:

- Wearables and smartphone sensors gather raw data and transmit them through wireless technology (often Bluetooth) to a separate device or cloud-based location for analysis.
- Machine learning algorithms often interpret raw data to identify digital biomarkers of physical or behavioral events.
- Wearables collect digital biomarkers and combine them into digital phenotypes that show patterns of a person's current health status, risk level, or disease progression.
- Devices deploy personalized interventions.

FIGURE 1. DIGITAL TOOL DATA PROCESS



Note: Based on "Wearable Technology in Clinical Practice for Depressive Disorder" by S. Fedor, R. Lewis, P. Pedrelli, D. Mischoulon, J. Curtiss, and R. W. Picard R. W., 2023, *The New England Journal of Medicine, 389*(26), p. 2460. (https://doi.org/10.1056/NEJMra2215898).

Wearable sensors can identify physical signs of stress, such as changes in heart rate, skin conductance, body temperature, oxygen levels, brain activity, respiration rate, and perspiration.[28,29] The human body reacts to stressors through the autonomic nervous system, which affects the sympathetic nervous system and the parasympathetic nervous system.[28] Sympathetic nervous system activation causes sweat secretion, increased heart rate and respiration, and the release of cortisol, prompting a fight, flight, freeze, or fawn response. Stress can precede recurrence of substance use[30] and negatively affect health. Prolonged stress exposure can lead to chronic illness. Thus, detecting physiological symptoms of stress via wearables can create opportunities for just-in-time adaptive interventions (JITAIs).

Measuring other physical indicators can support interventions for mental health conditions and SUDs in several ways. Emotional states often produce intense physical symptoms that biosensors can detect.[31] Wearables can also measure sleep patterns and physical activity, which are important to overall mental health.

In response to data the wearable collects, it may send EMA surveys to the user's smartphone or other mobile device on a schedule, at random, or according to specific logged, user-based events. The results of the EMA, or the raw data from the wearable, can prompt the delivery of personalized JITAIs or EMIs that support behavior change. For example, if a wearable detects high stress or emotional dysregulation, it might send a mindfulness exercise or motivational message to the user's phone to help them self-regulate and manage their anxiety.[15] Collectively, these capabilities enable delivery of timely, appropriate, and precise interventions in users' natural environments, reinforcing the role of wearables as a key component of behavioral health care.

Integrating Wearables Into Behavioral Health

Technological advancements have created new opportunities to integrate digital tools across the behavioral health system. These tools deliver patient education, offer remote screening and monitoring, and help build support systems.[32] Wearables, in particular, support whole-person well-being by increasing users' awareness of stressors and enhancing their ability to learn and practice coping strategies.

Providers can use wearables to deliver direct interventions, such as immersive virtual reality simulations or performance-based skills training.[33] Virtual reality simulations are realistic, computer-generated scenarios that allow users to learn by doing in a safe environment. Similarly, in performance-based skills training, users perform tasks or solve problems to apply their skills. More commonly, providers use wearables to augment behavioral health treatment (e.g., sending reminders that reinforce treatment goals, tracking treatment adherence, supporting self-monitoring between therapeutic sessions). By collecting data over time in the user's natural environment, wearables allow providers to establish baseline readings, detect early warning signs, and encourage behavior change and self-management.[34]

Providers can use remote patient monitoring via wearables to trigger JITAIs and facilitate shared decision-making. Providers can also integrate wearable data into electronic health records (EHRs) and clinical workflows. Data from wearables and other digital tools are intended to support—not replace—a provider's clinical judgment or comprehensive behavioral health assessments, particularly when identifying risk factors.

Wearable Device Examples

- **Biochemical detection:** Transdermal biosensors are widely used to detect alcohol and are often used in the justice system and in research. These devices measure alcohol concentration from perspiration on the skin.[35]
- **Risk prediction:** One device combines a wrist-worn biosensor with a smartphone app that uses machine learning to interpret biomarkers and guide interventions.[30] This wearable matches EMAs with EMIs that offer "just-in-time and just-in-space treatment."[36] These interventions include journaling prompts, guided breathing exercises, and emergency audio or video calls to a support network. Geolocation data preprogrammed with specific locations (e.g., workplace, recovery meeting, liquor store) can prompt a response—either reinforcement for positive behaviors or check-ins following risk detection.[30]
- **Withdrawal monitoring:** The first wearable cleared by the FDA to treat opioid withdrawal is a small device that adheres behind the ear. It delivers electrical nerve stimulation through tiny needles inserted into the ear, relieving opioid withdrawal symptoms over the course of 5 days.[37]
- **Sleep monitoring:** Smart rings pair with an app to monitor health and sleep. One such FDA-cleared device facilitates in-home sleep testing. Sleep disorders are common among people with mental health conditions like anxiety and depression.[38]

Note: Many wearables and apps are available to support behavioral health—these examples do not constitute or imply endorsement or recommendation by SAMHSA, the U.S. Department of Health and Human Services, or the federal government.

Benefits of Wearable Integration

Compared to traditional treatment, wearables can support lower cost mHealth options that enhance the flexibility and accessibility of behavioral health interventions.[21] Many patients may prefer mHealth-delivered interventions over face-to-face therapies because they prefer using technology. Others may prefer mHealth approaches because they minimize perceived stigma or eliminate other obstacles to accessing treatment, such as cost or the need for childcare, reliable transportation, or work schedule adjustments. People who have unfavorable attitudes toward conventional mental health treatment because of perceived stigma, previous experiences, or an aversion to face-to-face therapy might be more open to using a wearable.[21] mHealth interventions delivered via wearables and apps can expand access to SUD treatment or support, particularly for people living in rural areas or locations with few treatment options.

Cost

Wearables and other digital tools may help lower monitoring or support costs when used alongside in-person or telehealth services. These tools may also reduce other costs associated with conventional treatment—such as those related to transportation, childcare, or taking time away from work to attend appointments—and can be an affordable, accessible option for many patients.[39] However, providers should consider start-up costs and ongoing expenses related to devices, infrastructure, system integration, and reimbursement limitations prior to implementation.[39] Other accessibility considerations for patients include:

- Are the apps available for all types of smartphones, not just high-end devices?
- How much does the wearable cost? Are there options to help cover the cost?

Wearables and related apps make interventions available at any time, so users can engage with them in their natural daily environments. Many apps use games or challenges among a support network to foster community and accountability. Some apps have dashboards that allow users to visualize their progress, which helps promote engagement.

Other benefits of using wearables and apps to address behavioral health and wellness include:

- **Enhanced self-management:** Wearables improve feelings of self-efficacy,[40] self-monitoring,[41] and self-regulation,[15] and can help patients better understand their condition, improve treatment adherence and motivation, and engage in self-management.[34,42] Real-time feedback gives users a sense of control over their health and wellness.
- **Individually tailored interventions:** Reactive (also called connected) interventions collect data to provide real-time feedback tailored to the user's needs.[36]
- **Complementary treatment:** Wearable sensors and smartphone apps capture behaviors in real time and in natural environments to deliver prompt interventions and connect healthcare providers with their patients.[30] These tools inform clinical decision-making[42] and augment behavioral interventions.[30] Wearables may be a cost-effective strategy for detecting risk and promoting preventive interventions.

When paired with smartphones or other mobile devices, wearables can monitor precursors to substance use. For example, one study used a biosensor wristband and an app that prompted device users to self-report their levels of craving.[43] Machine learning analyzed the data to predict the presence or absence of drug craving or stress. In a small pilot study, participants wore a wrist sensor during waking hours and reported—in real time—feelings of craving or stress that interfered with daily activities.[44]

(continued on page 9)

The table below describes additional research on the use of wearables in behavioral health.

Benefits of Wearable Devices in Behavioral Health—From the Research	
Mental Health	Wearables have been shown to: • Correlate positively with self-care, which reduces psychological distress.[45] • Collect data—such as on sleep and activity—that can augment clinical decision-making and inform the assessment and treatment process.[42] • Capture novel and reduce symptoms of obsessive–compulsive disorders.[46] • Detect anxiety, reduce stress, and help manage post-traumatic stress disorder.[47] • Improve treatment for anxiety by allowing users to identify and record anxious feelings in an app.[15] Virtual reality headsets can be used to: • Provide tailored therapeutic environments that meet individual needs or challenge users' responses to certain stimuli within a shared, multi-user environment that enables social interaction and engagement that is not possible with other digital tools.[27] • Allow participants to interact with environments to enhance clinical assessments and interventions.[48] • Help support social skills training for people with autism spectrum disorder,[48,49] conduct exposure therapy for people with social phobias,[50] address intimate partner violence,[51] address negative body perception among people with eating disorders,[52] and conduct self-compassion exercises for people with depression.[53]
Alcohol Use	Wearables have been shown to: • Detect alcohol consumption through the skin or sweat when worn on the wrist, ankle, or other parts of the body and paired with a smartphone.[54] • Improve treatment adherence when combined with positive behavioral reinforcement strategies, such as incentives.[55] • Reduce alcohol cravings or consumption and increase confidence in managing alcohol use.[40] • Detect and monitor transdermal alcohol concentration via noninvasive, temporary tattoo-based sensors and transmit blood alcohol level data to a smartphone.[56] Virtual reality headsets can be used to: • Provide virtual scenarios involving alcohol (e.g., bars, parties, other social situations) that could induce craving so users can apply coping skills within an immersive environment.[57]
Other Substance Use	Wearables can: • Monitor heart rate and rhythm, skin temperature, skin conductance, and sweat to help predict cravings and detect withdrawal symptoms or substance use.[23] Wearables transmit information to a smartphone to prompt a behavioral intervention or alert medical personnel of an emergency. • Monitor heart rate and sleep and—when paired with an EMA questionnaire that logs mood, craving, and pain—predict recurrence of substance use and prompt an intervention.[58,59]

(continued from page 7)

Participants reported that:

- Using the app to log cravings or stressors made them feel more mindful.
- Logging their experiences was a therapeutic distraction from their feelings.
- Using a wearable would be helpful to people in early recovery.

Combining data from wearables with mobile device data can also support mental health interventions. For example, cognitive–behavioral interventions that address social relationships and spending behaviors were developed based on analyses of wearable data. Researchers analyzed location, movement, skin conductance, and heart rate data, along with mobile device data on app usage, screen time, spending habits, and call and text message activity.[42]

Selecting a Digital Tool

The rapidly expanding digital health landscape can feel overwhelming to providers and patients. Selecting wearables and associated apps in partnership with patients helps ensure these tools support prevention, treatment, and recovery goals. Providers should consider:

- Establishing baseline measurements and goals related to the measured behaviors (e.g., sleep, physical movement, stress levels, other lifestyle factors that promote well-being).
- Addressing informed consent, privacy, confidentiality, and encryption of wearable and app data with patients before integrating data into the EHR.
- Incorporating data review into patient visits—in-person or via telehealth—to tailor interventions and help patients understand their progress toward their goals.
- Training care teams on wearable integration, data interpretation, and troubleshooting.
- Staying informed about Medicare and Medicaid reimbursement for remote patient monitoring with wearables. See the Centers for Medicare & Medicaid Services' Remote Patient Monitoring guide for more information.

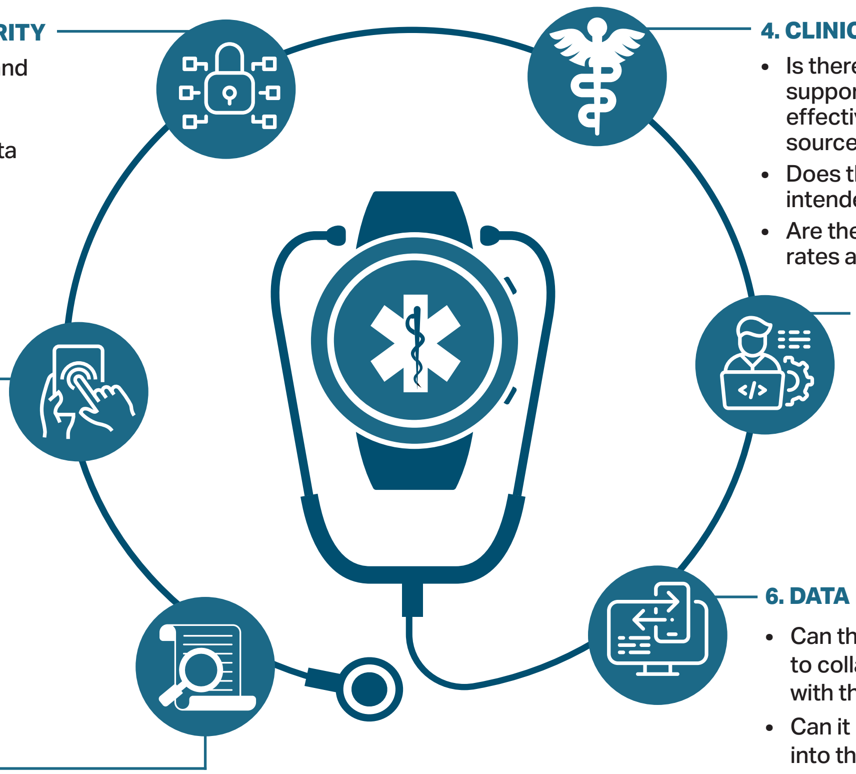
Developers and providers should also explicitly consider the accessibility needs of people with visual, hearing, mobility, cognitive, and intellectual disabilities to prevent widening gaps in behavioral healthcare access.

The American Psychiatric Association has proposed the App Evaluation Model to help providers and their patients select a behavioral health app. Although this guidance was designed for app selection, the framework might also apply to other mHealth devices. Figure 2 on page 10 includes questions providers can ask themselves during their review.

Providers who decide to adopt and integrate digital tools (including wearables) into their practice might wonder how to provide patient education about these devices. Patients who already use wearables may ask providers how data can inform their care. While clinical applications for these technologies are still evolving, providers should consider these communication strategies:

- Explain the benefits of using digital tools to support prevention, early intervention, treatment, and recovery for the patient's behavioral health condition.

FIGURE 2. APP EVALUATION MODEL



3. PRIVACY AND SECURITY
- Can the user understand the privacy policy?
- Does the app collect/use/store/transmit data securely?
- Can users opt out or delete data?
- Is AI used? If so, how?
- Is there a plan for data breaches?

4. CLINICAL FOUNDATION
- Is there evidence that supports the app's effectiveness? Are there sources available?
- Does the app involve intended users in the design?
- Are there clinical retention rates available?

2. ACCESS
- Can the app work offline/with low bandwith?
- Which mobile platforms (iOS, Android) are supported?
- Does it identify the reading level?
- What type of support is needed to use it?

5. USABILITY
- Is the app content customizable?
- Is the app easy to navigate?
- Is there technical support available?

1. BACKGROUND
- Who owns the app?
- Is the owner a trusted source?
- Is there a cost?
- Is the app updated?
- Is it a medical app?

6. DATA INTEGRATION
- Can the app be used to collaborate securely with the care team?
- Can it be integrated into the electronic health record?
- Can the user export their data?
- Are the data meaningful for patient goals?

Note: Based on information in "The App Evaluation Model" by American Psychiatric Association, n.d. (https://www.psychiatry.org/Psychiatrists/Practice/Mental-Health-Apps/The-App-Evaluation-Model).

- Discuss device-specific information, including:
    - What the device does, what type of information it collects, and how it collects that information (e.g., passive monitoring, EMA survey questions, geolocation).
    - How and when to wear the device.
    - What to do if the device stops working.
    - How to set up the device, receive notifications, and connect it to a smartphone, tablet, or computer app.
- Discuss privacy, confidentiality, and security considerations, including:
    - How privacy is protected.[34,60]
    - What information is stored, shared, and transmitted; with whom data are shared;[60] and how to manage sharing or update settings.
    - The risks associated with third-party data sharing and data breaches.[60]
    - Whether the tool uses AI to interpret data and, if so, how AI interprets those data.[60]

Considerations of Using Digital Tools

Although digital devices are an integral part of a rapidly evolving technological landscape, large randomized controlled trials and standardized methodologies that validate long-term effectiveness are lacking.[61] These emerging technologies present many challenges, such as concerns about data security, a lack of public trust, risks associated with excessive screen time, and legal or ethical issues.[32] Adoption of these emerging technologies requires careful attention to ethical considerations, data privacy and security, data governance and informed consent, and any obstacles to use.

Ethical Considerations

A review of digital tools for behavioral health noted several risks to consider carefully:

- Mental health apps may have misleading messaging or lack data and research to substantiate claims about their effectiveness.[62]
- Apps may contribute to increased smartphone use, which could worsen isolation, anxiety, or depression.[62]
- Apps may connect users to providers who lack the training and credentials to provide appropriate care.[62]
- Chatbots may offer limited or generic responses that do not tailor interventions to the patient, or they may offer inaccurate feedback or advice that endangers the patient.[63]
- The use of chatbots may also increase social isolation or create overreliance on using the chatbot, rather than seeking real-life interactions to support mental health.[63]
- Access to appropriate mental health services in real time may be limited.[62]
- Patients with limited digital literacy or knowledge of online safety could be susceptible to online fraud.[62]
- Concerns exist around data privacy and security.[64]
- Users may be unaware that their data could be used to train or refine AI algorithms, raising concerns about transparency, consent, and further use of personal behavioral health data.
- Digital tools trained on limited or nonrepresentative data may not perform consistently across populations, potentially affecting the validity or usefulness of results for some users.

Virtual reality and other immersive technologies can pose ethical challenges and could lead to[27]:

- Identity confusion, which can lead to distress and dissociation.
- A preference for virtual friends or communities over real-life relationships, potentially increasing social isolation.
- Exposure to cyberbullying or online victimization.
- Addictive behaviors, such as spending excessive time in virtual environments and neglecting responsibilities and personal relationships.
- Heightened anxiety about data security, privacy, or surveillance.

Appropriate Use of Artificial Intelligence

Wearables may leverage emerging applications of AI with potential benefits, and possible unintended negative consequences. Some applications of AI have had harmful impacts on mental health. For example, AI can reinforce delusions and psychotic symptoms.[65] There have also been documented concerns with AI chatbots providing potentially dangerous material about self-harm. AI codependency is also a concern. This refers to an excessive reliance on AI that may result in increased mental fatigue and reduced independent judgment, cognitive resilience, or decision-making capacity over time.[66] Providers should consider monitoring for potentially related behaviors, such as rumination, anxiety, obsessive tendencies, or measuring self-worth through exercising excessively or restricting calories.[67]

Providers and patients should also remember that the use of digital tools in behavioral health treatment is voluntary. Discussions with patients should emphasize empowerment and avoid implying that using these tools is required. Providers should also be aware of state-specific laws and regulations related to the use of digital tools for behavioral health treatment. For example, states may have different legal requirements for using chatbots for behavioral health support.

In addition, providers need to be aware of any regulations for using AI-enabled tools embedded in EHR systems and monitor for regulatory changes. According to the 21st Century Cures Act and the Health Data, Technology, and Interoperability final rule, if a clinical record system uses AI to identify risk factors or generate recommendations, that information is considered part of the patient's electronic health information, unless specifically excluded (e.g., psychotherapy notes). Therefore, patients may have a right to access AI-generated insights.

Data Privacy and Security

FDA approves wearable devices (sensor-based digital health technology) and maintains a list of authorized medical devices. All FDA-cleared devices must comply with the cybersecurity requirements in section 524B of the Federal Food, Drug, and Cosmetic Act. Still, many users worry about data security and privacy.[27,34,62]

Data collected from apps and wearables are governed by their own privacy policies[62] and state laws that regulate data privacy. Users may not be aware of, or fully understand, these policies and how their data are stored, protected, or shared. One study found that AI-powered mHealth app privacy policies had an average reading level of grade 13 (college level), rather than a more appropriate level (around grade 8) for the general public.[68]

Regulatory Considerations for Providers

Wearable devices increasingly integrate patient-generated data into EHRs. The Office of the National Coordinator for Health Information Technology's Health Data, Technology, and Interoperability final rule (HTI-1 Final Rule) states that these clinical record systems must be able to receive, store, export, and share data in alignment with the United States Core Data for Interoperability submission system. Wearable device developers and implementers must ensure that data integration aligns with these federal requirements.

Many apps and wearables are not covered under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as HIPAA only applies to digital tools provided by covered entities and to tools that integrate data into EHRs.[62,69,70] Federally assisted SUD treatment providers must also consider additional privacy protections under Title 42 of the Code of Federal Regulations (42 CFR) Part 2—a federal law that provides additional privacy protection for patients receiving SUD treatment. For example, patients must specifically indicate that their SUD-related data can be disclosed. Although many consumer apps are not HIPAA-covered entities, 42 CFR Part 2 may still apply—even when HIPAA does not—if the data become part of a federally assisted SUD treatment program's Part 2 record set. These special protections require additional consent processes to share SUD-related data with family members, justice-system partners, apps, and third-party vendors.

When wearable data are not covered by HIPAA or 42 CFR Part 2, their privacy and security are primarily governed by the Federal Trade Commission (FTC). The FTC Act authorizes FTC to monitor and address health data privacy practices. Additionally, wearables and digital health apps must comply with the FTC Health Breach Notification Rule. Under this rule, vendors must notify FTC, affected consumers, and sometimes the media about any instance of unauthorized data sharing, such as with advertisers or through a data breach or hacking incident.

To support informed decision-making, device users and their behavioral healthcare providers should understand:

- How the device collects, stores, uses, and transmits data.
- What data are collected and whether they are shared or sold to third parties.
- Who owns the collected data and who can access that information.
- The device's vulnerabilities (e.g., susceptibility to hacking or data breaches).

Consumer data may become regulated clinical record data when a provider uses them to make decisions and incorporates them into the designated record set. For more information on consumer health data, see A Comprehensive Guide to HIPAA Designated Record Sets and What personal health information do individuals have a right under HIPAA to access from their health care providers and health plans?

Data Security Resources

- Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions: FDA guidance addressing cybersecurity risk considerations for device design, labeling, and documentation.
- HC3 Intelligence Briefing, Wearable Device Security: U.S. Department of Health and Human Services' (HHS) Cybersecurity Program presentation on the vulnerabilities of wearables used in health care.
- Health Insurance Portability and Accountability Act (HIPAA) for Professionals: HHS resource for health professionals on federal privacy regulations.
- Resources for Mobile Health Apps Developers: HHS compilation of resources on mHealth privacy and security.
- Data Privacy When Using Wearable Health and Fitness Devices: What Consumers Need To Know: A short guide on health data protection and wearable devices from the Maryland Health Care Commission.
- What Clinicians Should Tell Patients About Wearable Devices and Data Privacy: A Narrative Review: Help for providers navigating conversations with their patients about data privacy and security.

Obstacles to Use

Patients may experience obstacles to using wearables, including device design and cost,[34] limited access to smart devices, a lack of reliable internet connectivity, difficulty sustaining engagement, and resistance to integrating the technology into existing routines.[36] Patients may also have older or less sophisticated smartphones that are incompatible with many apps.

Other technology-related issues include:

- Delays in data syncing due to poor internet connectivity or limited battery life.[71]
- Interruptions in continuous data monitoring that lead to incomplete data.[71]
- Inaccurate algorithms or sensor errors.[34,62]
- Factors that introduce noise into measurements or compromise data quality or accuracy.[71]

Additionally, user errors like forgetting to charge a device or to put it back on after showering can affect adherence and the collection of reliable measurements. User-related challenges include:

- Improper device placement and adherence issues related to device comfort or appearance.[72]
- Less interest in or comfort with new technology among users with limited technological literacy.[62,72]
- Discomfort with disclosing sensitive data, such as mental health information, or concerns about data security.[62]

Thoughtful device selection, patient education, and clear communication about ethical and privacy considerations can address these challenges and improve adoption and adherence.

Future Directions

As wearables become more common and research evolves, digital tools are more likely to be used to help prevent, monitor, and manage mental health conditions and SUDs. By enabling real-time insight and personalized support, these tools can facilitate proactive responses to emerging challenges—promoting health, rather than managing illness. Continuous monitoring of mood and stress using wearable sensors offers promise for preventive care.

Emerging studies suggest that clinicians may be able to use wearable-generated data to identify early warning signs of distress that could lead to a return to substance use or mood destabilization, enabling timely outreach or digital interventions. For example, wearables that track sleep quality and circadian rhythm disturbances can help identify patients whose disrupted sleep could contribute to depression, anxiety, or substance use recurrence.[73]

Monitoring suicide risk is another area in which wearable technology has shown promise. Emerging research suggests that wearables that track physiological signals—such as heart rate and skin conductance—could help identify people at increased risk for suicide.[74–76]

Wearables also exhibit potential in overdose prevention by detecting physiological signs of respiratory depression or distress. Beyond overdose detection, wearables can support long-term recovery by tracking stress, cravings, or return-to-use indicators and prompting self-management or peer support when risk patterns arise.[58]

As AI technology evolves, predictive modeling using data from wearables could enhance the ability to identify people at risk of developing an SUD, detect potential recurrence of substance use, and enable early intervention.[77] Continued research and patient-centered integration are essential to realizing the full potential of wearables and other digital technologies in behavioral health care.

Resources on Digital Tools

Review the following resources to learn more about digital tools for behavioral health.

From SAMHSA

- *Advisory:* Digital Therapeutics for Management and Treatment in Behavioral Health introduces digital therapeutics research and reimbursement implications, as well as selection and implementation considerations.
- *Advisory:* Using Technology-Based Therapeutic Tools in Behavioral Health Services provides information on synchronous and asynchronous telehealth technologies and addresses technology access and implementation.
- Telehealth for the Treatment of Serious Mental Illness and Substance Use Disorders distills research into practice recommendations and includes implementation examples for telehealth modalities.

Other Resources

- Digital Health Center of Excellence offers resources to advance digital health technology use. This FDA center connects stakeholders with the latest technological and regulatory information.
- Digital Healthcare Research, from the Agency for Healthcare Research and Quality, highlights research on digital health tools.
- Health Technology Ecosystem, from the Centers for Medicare & Medicaid Services, offers resources for health information networks and exchanges and other health technology platforms.
- Technology and the Future of Mental Health Treatment, from the National Institute of Mental Health, highlights the pros and cons of mental health apps and research and development processes.
- *Telehealth and Remote Patient Monitoring* is an HHS guide for providers interested in developing a strategy to use digital tools; it includes billing codes and conversation tools.
- Telehealth.HHS.gov is an HHS resource for patients and providers who are interested in learning more about using virtual care options.

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Acknowledgments: This *Advisory* was written and produced for the Substance Abuse and Mental Health Services Administration (SAMHSA) under contract number 75S20322D00049/75S20323F42002 with SAMHSA, U.S. Department of Health and Human Services (HHS). CAPT. Donelle Johnson, Ph.D., served as contracting officer representative. Charles Reynolds, with SAMHSA's Center for Behavioral Health Statistics and Quality, served as product lead. Stephanie Carreiro, M.D., Ph.D., University of Massachusetts Chan Medical School, provided subject matter expertise.

Recommended Citation: Substance Abuse and Mental Health Services Administration. How Wearables and Other Digital Tools Are Driving Innovation in Behavioral Health. *Advisory*. Publication No. PEP26-07-005. Rockville, MD: Center for Behavioral Health Statistics and Quality.

Publication No. PEP26-07-005
Released June 2026