

Unlocking the Power of Digital Health: Advancing Solutions to Tackle the Mental Health Crisis

Consensus Paper

Fall 2024



AMERICAN
PSYCHOLOGICAL
ASSOCIATION



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Digital Mental Health

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"If we seize this moment, step up for our children and their families in their moment of need, and lead with inclusion, kindness, and respect, we can lay the foundation for a healthier, more resilient, and more fulfilled nation.¹"

- Vivek H. Murthy, M.D., M.B.A

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Executive Summary

The 21st century has witnessed an unprecedented era of technological advancement and increased social connectivity. We have a staggering array of tools and platforms at our fingertips to stay in touch, share our experiences, and access information like never before. At the same time, biomedical research has advanced dramatically, preventing, or curing diseases in ways once thought impossible. And yet, paradoxically, amidst this extraordinary growth in standard of living, we find ourselves confronting an alarming surge in mental health conditions. Anxiety, depression, and loneliness have reached record levels, with structural inequities and barriers to care exacerbating these and other ailments. Furthermore, a scarcity of healthcare providers, exacerbated by an aging population within the profession, is contributing to a crisis in access.¹ The result is a mental health emergency that requires solutions and approaches as novel and bold as other public health crises.

Digital Therapeutics (DTx) offer significant potential. These evidence-based therapeutic interventions are driven by clinical-grade software programs to prevent, manage, or treat a medical disorder or disease. They offer complementary support to traditional psychotherapy- and medicine-based treatments, accessible on people's mobile devices and built for scalability and personalization. With 85 percent of Americans owning a smartphone, the prospective outreach of DTx can guide innovation.²

Together with other interventions, DTx can help provide a more holistic approach to treating mental health conditions, provided they are grounded in sound scientific evidence and created in collaboration with individuals with lived experience. A large and growing evidence base has established the clinical effectiveness of DTx, especially for common mental health problems such as depression and anxiety, and emerging results indicate they are also cost effective.

Urgent priorities to advance equitable access to DTx, particularly for the most burdensome mental health conditions and disadvantaged patients, include:

- Understanding the needs of patients, caregivers, and providers to shape the development of DTx.
- Promoting and continually refining evidence-based solutions.
- Leveraging DTx to increase accessibility and inclusivity.
- Enabling a wider range of public health professionals to provide DTx.
- Fostering cross-sector collaboration, including with patients, families, clinicians, payers, healthcare companies, social workers, criminal justice workers, governments and more.

This paper explores how supporting these efforts can pave the way for evidence-based digital health solutions to address the growing mental health crisis. It is not the goal of this paper to advocate for certain solutions, but to draw attention to the areas that digital mental health stakeholders should prioritize to move the conversation forward.



PART 1: INTRODUCTION:

The U.S. Faces A Mental Health Emergency

"The scientific progress in the mental health field was stunning, but while we studied the risk factors for suicide, the death rate had climbed 33 percent. Our science was looking for causes while the effects of these disorders were playing out with more death and disability, incarceration, and homelessness, and increasing frustration and despair for both patients and families. Indeed, many of the most refractory social issues of the decade—homelessness, incarceration, poverty—could be tracked, in part, to our nation's failure to care for people with mental illness.⁴"

- Tom Insel, M.D.

Former Director of the National Institute of Mental Health

The Mental Health Emergency

Given the astonishing intricacy of the human brain, it is no surprise that psychological well-being is an equally complex construct. Shaped by genetics, environmental influences, social interactions and individual experiences, mental health has fluctuated in the U.S. throughout its history. However, in recent years, the prevalence of mental health conditions has continued to grow or persist at alarming rates (see Box 1).

1 in 5 U.S. adults
(57.8 million), and
1 in 6 youth aged
6–17 (7.7 million),
experience mental illness
each year³

75% of lifetime
mental illness begins by
age 24⁵

35% of adults
with two or more races have a
mental illness, the highest
among any group, followed
by American Indian /
Alaskan Native (AI/AN)
adults (26.6%)⁶

**~40% of
incarcerated
individuals**
in the US have a mental
illness⁷

**37% increase
in US suicide**
rates between 2000 and 2018⁸

**>3x increase
in opioid
overdose
deaths**
from 2010 to 2021,
increasing from 21,089
deaths in 2010 to
80,411 in 2021⁹

The impact of mental health conditions is staggering, both at an individual and a societal level. Minority and marginalized communities, people living in rural areas and young people are particularly at risk.

Individuals living with mental health conditions face higher rates of hospitalization, unemployment, school dropout, homelessness and more.⁹ Suicide rates are rising, and in recent years, it is estimated that more than half of people with opioid use disorders have a co-occurring mental illness.¹⁰ Mental health conditions can also impact other disease areas – there is a 40% increased chance of cardiovascular and metabolic disease for people living with depression.⁹

The impact of mental health conditions extends to families, communities, society, and the economy. More than eight million people in the U.S. are caregivers to someone living with a mental health condition,

providing on average 32 hours of unpaid care a week.⁹ In total, it is estimated that serious mental illness costs the US economy upwards of \$200 billion each year.⁹

Amidst these alarming trends, there have been profound advances in the care and treatment of people living with mental health conditions. Evidence-based psychotherapy tools and frameworks, such as Cognitive-Behavioral Therapy, have proven effective.¹¹ At the same time, the next generation of medications offer more options to people living with mental health conditions than ever before. Public awareness campaigns have fought stigma and encouraged help-seeking. Yet, alarming rates of serious mental illness persist. Understanding how to complement these new tools and approaches requires a deeper understanding of the drivers of these conditions, and how to ensure equitable access to care.

Several Factors Drive the Rates of Mental Health Conditions

The extraordinary diversity of mental health conditions underscores that there is, for the most part, no single cause or factor that alone drives the development of disease. Rather, there is a complex interplay between biological and social risk factors. Here, we focus on three related factors that have exacerbated the issue in recent years:

- 1. Access to Care**
- 2. Social Drivers**
- 3. Structural Inequities**

While genetic risk factors are also a part of nearly every serious mental illness to some degree, they are beyond the scope of this review – more information is available via the National Institute of Mental Health.¹²

1. Access to Care

Simply put, far too many people at risk of, or living with, mental health conditions lack adequate access to care. More than half of U.S. adults with mental illness (28 million) do not receive treatment.¹³ After symptoms begin, it takes an average of 11 years to receive relevant treatment.⁹ Today, 18% of Americans are interested in receiving care from a mental health professional; of those, about 40% report low access (e.g., location, wait time, and provider bandwidth) and prohibitive costs (e.g., out-of-pocket co-pays and insurance coverage) discourage them from seeking care.^{14,15,16,17,13}

The insufficient and decreasing number of mental health professionals is a major driver of the access challenge. More than 50% of U.S. counties lack a single psychiatrist,¹ and many more are approaching retirement age, which will compound the shortage. Experts credit this imbalance to the growing U.S. population, burgeoning

mental health needs post-COVID, and limited psychiatric residency slots.¹ The U.S. government's own projections show that by 2030, the demand for adult psychiatrists will increase by 3% to 39,550 – but the supply will decrease by 20% to 27,020.¹⁸ Notably, while the supply of psychiatrists is projected to decrease, the U.S. government projects that the supply of working psychologists will increase by 13%, from 92,990 to 104,620 by 2030. Better utilization of the psychologist workforce could help address access issues.

Underpinning these access issues is a decades-long trend whereby the US healthcare system moved away from state-based long-term psychiatric hospitals.¹⁹ While originally pursued for well-intentioned reasons, the burden of care has shifted to other less appropriate settings, such as emergency rooms or the criminal justice system. In fact, the three largest psychiatric facilities in the country are prisons, where roughly 40% of incarcerated individuals have a mental disorder.²⁰

2. Social Drivers

The last several years have seen a combination of social factors that have exacerbated the mental health emergency. Most acutely, the COVID-19 pandemic led to a dramatic increase in stress, isolation, and lack of treatment (See Box 2). While the pandemic itself may be fading from view, its effects on mental health are expected to be felt for years or even decades to come.

Alongside COVID-19, the rise of social media, remote work, and other digital platforms add fuel to the mental health emergency. While the use of social media and remote work tools had been growing for years, the COVID-19 pandemic caused a “Great Acceleration” of their adoption into everyday life.²⁵ Smartphones and social media are more “essential” than ever before, they can also be harmful. Digital technology and social media enable children to connect with each other, express themselves, and even access telehealth, but they also introduce mental health stressors, such as bullying, social comparison with peers, and false or harmful information.^{25,27} Moreover, screen time has increasingly displaced activities like exercising, reading, resting, or visiting friends and loved ones.²⁸

The Impact of COVID-19 on Mental Health

During COVID, particularly in 2020, more than four in 10 Americans experienced high psychological distress, such as anxiety, depression, despair, and traumatic stress.^{21,8,22} High mental distress was particularly strong among low-income individuals, those who had experienced job loss, or those who had a disability that prevented them from participating or contributing fully at work, school, or at home.²¹ Extreme exhaustion contributed to suicidal ideation among healthcare workers in this period.²² Broadly speaking, women experienced greater distress than men in response to forced social isolation.²³ Moreover, drug overdose and suicidal deaths increased during and post-COVID. From 2019 to 2021, death by suicide increased more in BIPOC communities than in White.²⁴ In total, prolonged social isolation, loneliness, financial instability, fear of infection, and grief upon observing of loved ones suffer from COVID-19 contributed to a “mental health pandemic” in the U.S.

3. Structural Inequities

Like many other health outcomes, mental health disparities are driven by social determinants of health (SDOH) and other structural inequities faced by minority and marginalized populations. People of color, unemployed, disabled, and low-income individuals are disproportionately affected by mental health conditions. Furthermore, mental illness in America has exacerbated systemic challenges such as poor educational outcomes, unemployment, homelessness, crime, and violence in a vicious cycle.²⁶

These disparities are driven in part by the lack of providers previously mentioned. Many patients believe providers of the same racial/ethnic background or language can better empathize with their unique trauma and stressors.²⁹ But 90% of U.S. psychiatrists are White (2% of psychiatrists are Black), which can discourage Black and Hispanic patients from seeking help.^{31,32}

The logistical burdens of visiting a physician, such as the need for reliable transportation, travel time, or childcare and eldercare, can be particularly stark for those living in rural areas or poor communities.³⁴ Other social determinants also play a role. A 2020 study revealed that Americans who experienced greater food insecurity and hunger exhibited a 257% higher risk of anxiety and a 253% higher risk of depression.³⁴

It is estimated that only **25% of Black adults** seek necessary mental health treatment compared to 40% of their White counterparts.²⁹

Black people are estimated to experience **higher rates of PTSD** compared to their White counterparts, whether from racial trauma or other sources.²⁹

Black youth (65%) are more likely to report having traumatic experiences compared to youth of other ethnicities (30%).²⁹

In recent years, **Black children** (below age 13) are nearly twice as likely to die by suicide than White children.²⁸

Hispanic adults (35%) with mental illness are less likely to receive care than those with mental illness in the U.S. overall (46%).³⁰

More than **50% of Hispanic adults** aged 18-25 with serious mental illness might not receive treatment.³⁰

COVID-19 and Opioid Responses Show the Value of Widely Accessible, Common Sense Solutions

Given the enormity of the mental health crisis, additional tools and approaches are needed to scale solutions, close gaps and overcome access barriers. Here, lessons from other public health campaigns can provide inspiration.

In response to emergencies like COVID-19 and the opioid epidemic, the U.S. has implemented “common sense” solutions that have expanded patients’ access to care and reduced overall health system costs. For instance, governments authorized state-licensed pharmacists to distribute Paxlovid and Naloxone, respectively, as well as vaccines.^{35,36,37} Mobile testing and pop-up clinics were established everywhere from city streets to libraries and places of work. These efforts brought the public health system to the people, instead of trying to bring people to the public health system.

Mental health needs a similar approach. Expanding the toolset for psychologists, social workers, counselors, and the criminal justice system could have an equally dramatic impact.





PART 2:

The Opportunity of Digital Therapeutics in Mental Health

"What I liked best about [using digital mental health tools] was that I could use it on my own schedule whenever I wanted to. I could always access it, and that helped me incorporate it into my morning routine, or my travel schedule, because these tools didn't require me to have to go somewhere or be somewhere at a certain time."

- Brandon Staglin, M.S.

Co-founder and Chief Advocacy & Engagement Officer, One Mind

Digital Solutions to Scale Mental Health Care

In the face of the mental health emergency, democratizing the use of digital mental health technologies offers a promising path forward, especially evidence-based, regulator-backed Digital Therapeutics (DTx). Digital interventions delivered through smart phones and other mobile devices can turn a liability into an asset – making the phone a delivery mechanism that meets people where they are.

Like other digital tools, the use of digital mental health solutions has accelerated in recent years. An American Psychological Association report from 2021 estimates that between 10,000 and 20,000 mental health apps may exist today and predicts that number to continue to increase.²⁸ A 2021 survey found increased use of digital mental

health tools and other technologies during the initial stages of the COVID-19 pandemic.³⁹

Confidence in the value of DTx in mental health is driven in part by their success in other therapeutic areas. For example, DTx for diabetes that provide insight driven coaching or recommendations on prescription management have been shown to reduce patient HbA1c levels.⁴⁰ The use of these tools is expected to grow significantly, as is evident by the FDA's recent launch of a Digital Health Advisory Committee. In the following section, we explore how these tools might be used specifically to address mental health conditions.

Defining Digital Mental Health

The field of digital mental health is broad and can be daunting to patients and providers alike – particularly given overlapping definitions and inconsistent lexicon. There are thousands of solutions, and their function, goals, and evidence of benefits can vary greatly. Generally speaking, they fall into one of five distinct but related categories:



Mobile Health (mHealth):

A broad category of technologies that deliver health services through mobile devices like mobile phones, tablets, wearable devices, and sensors.³⁸



Telehealth:

A subset of mHealth that virtually connects providers and patients and delivers care using text messaging, audio communication, or video interfacing.⁴¹



Health Information Technology:

The processing, storage, and exchange of health information in an electronic environment. This includes electronic medical record systems, electronic prescribing and order entry, and consumer health IT apps.⁴²



Digital therapeutics (DTx):

Evidence-based therapeutic interventions driven by high-quality software programs to prevent, manage, or treat a medical disorder or disease. These products can require prescriptions for use in the case of provider-directed interventions known as prescription digital therapeutics (PDTs), or they can be used without a prescription.⁴³



Wellness Applications:

Mobile apps that are not meant to treat a disease but instead assist with day-to-day living, provide coaching, and help increase a person's well-being. They are typically patient- rather than provider-directed and do not require prescriptions or FDA/HIPAA regulation.⁴⁴

Each category of digital solutions has its own opportunities and drawbacks, and there are several common pitfalls across tools. While digital tools can help bridge the gap in care, particularly for rural areas with limited providers, they depend on access to and familiarity with mobile devices and broadband internet.⁴⁵ Internet connection can be less reliable in low-income and/or rural areas, and the people who live in these areas often do not have adequate data plans for existing DTx tools. Most products are also designed for English speakers and may not address cultural nuances or sensitivities. Nevertheless, many of these barriers are either addressable or more limited in impact compared to the shortcomings of traditional healthcare services.

"Digital therapeutics are valuable tools for treating mental health conditions, even compared to traditional types of care. Side-effect profiles can be better, it is easier to monitor compliance, there is greater accessibility, and we can personalize treatment in ways not possible with other care options. On the accessibility side, you can charge less for DTx and reach places where it is difficult to see doctors but can access devices and Wi-Fi. And, with adaptive closed-loop systems, you can target aspects of treatment to the individual and not just use the one-size-fits-all approach that we often see with molecular medicine."

- Adam Gazzaley, M.D., Ph.D.

Founder & Executive Director of Neuroscape at UCSF;
Co-Founder, Board Member & Chief Science Advisor
at Akili and JAZZ VP

DTx Solutions Offer Promise

DTx hold perhaps the greatest potential for mental health care, as they undergo rigorous review to ensure evidence of benefits and are easily accessible through common technology like smartphones. The evidence of benefits represents a critical difference from health and wellness applications, which are not held to the same evidentiary standards or used to treat a specific disease. Yet, while differing in its use cases and evidentiary standards, DTx still shares the primary benefit of health and wellness applications: accessibility through personal devices.

The difference between DTx and other general health apps is in many ways analogous to the difference between an FDA-approved medicine to treat a disease compared to a supplement which may make claims about health benefits but without having to demonstrate efficacy or gain regulatory approval.

DTx use clinical-grade "software-as-a-service" (SaaS) to help prevent, manage, and treat disease, either alone or in conjunction with medication and/or behavioral therapy.³⁸ They include web-based cognitive-behavioral therapy, games, and/or patient-physician dashboards. Within mental health, DTx have so far been created to treat mood disorders like anxiety, depression, substance abuse, and more (see the below case study on reSET).⁴⁶

Critically, all DTx products - whether prescription or non-prescription - are reviewed and cleared or certified by regulatory bodies, such as the FDA (Food and Drug Administration), for product claims regarding risk, efficacy, and intended use. DTx may require a prescription or to be ordered by a licensed practitioner (these DTx are known as Prescription Digital Therapeutics or PDTs) if their primary purpose is to treat disease, or they may not require a prescription/order if their primary focus is disease management, prevention, or improving a health function.⁴⁷

In a clinical setting, PDTs augment traditional care by leveraging technology that patients are typically familiar with, and they do not tend to cause side effects. PDTs are scalable and have the potential to be more equitable since they do not require significant training on how to use them and do not require manufacturing capabilities.⁴⁷ Providers report positive experiences with PDTs, including access and convenience. Similarly, patients report valuing the effectiveness and ease of use of PDTs. Early evidence suggests DTx can be both clinically and cost effective, particularly in mental health.^{49,50,51,52} Taken together, the evidence of efficacy, safety, cost-effectiveness, and positive patient and provider experiences suggest DTx could help to overcome the barriers fueling the mental health crisis.



DTx Case Study: reSET to Treat Substance Abuse

The landscape:

Drug overdose deaths have reached epidemic levels in the United States. 107,081 Americans died of a drug overdose in 2022, the highest total in history, killing more than twice as many people as car accidents.^{53,54} Prescription medications treating substance use disorder (SUD) are widely inaccessible in the U.S., as 46% of American counties, including 71% of rural counties, do not have a single provider who can administer approved SUD medications.⁵⁵

The DTx:

reSET is an FDA-cleared prescription digital therapeutic targeting SUD. reSET delivers therapy based on the community reinforcement approach (CRA), an intensive form of validated neurobehavioral therapy for SUD, along with contingency management and fluency training to enhance learning.⁵⁶

reSet's impact:

reSET offers safe, effective treatment accessible to anyone with a smartphone and a prescription. Among patients whose primary addiction was not opioids, adding reSET to outpatient therapy more than doubled abstinence rates (40% vs. 18%). Among all patients, adding reSET to outpatient therapy improved rates of retention (76% vs. 63%).⁵⁶

Barriers to reSet:

The adoption of reSET and similar digital therapeutics can be hindered by regulatory complexities, limited reimbursement options, and resistance to change in healthcare practices.

reSET's Status:

As of February 2024, reSET is not presently on the market. Pear Therapeutics, a company focused on developing PDTs, including reSET, went bankrupt in 2023. Pear cited barriers to the widespread adoption of PDTs in explaining the company's downturn.

Confusion Around Prescriber Guidelines Limits the Greatest Strengths of PDTs

Despite the potential of PDTs, the field faces a central challenge: too few mental health professionals are prescribing/ordering these interventions, making them largely unavailable to the public. While there is limited, technical guidance from the FDA outlining who can prescribe/order PDTs, there is a lack of awareness or clarity about these and other state guidelines, which may lead to confusion among practitioners.

The FDA's regulatory guidance creating the prescription device category (21 CFR Sec. 801.109(a) (2)), provides, in part, that a prescription device must be "sold only to or on the prescription or other order of such practitioner for use in the course of [their] professional practice." The required labeling must include "The symbol statement "Rx only" or the statement "Caution: Federal law restricts this device to sale by or on the order of a ___", the blank to be filled with the word "physician", "dentist", "veterinarian", or with the descriptive designation of any other practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device...."

Under this guidance, the FDA allows for prescription devices to be prescribed or ordered. Additionally, rather than "prescription-only"

labeling, the regulatory language allows a broader category of healthcare professionals to order the device beyond only those who have prescribing authority under state law. Access to PDTs can be managed by practitioners licensed by state law to practice a particular type of healthcare, and who are identified at least generally in the intended use statement submitted to the FDA at the time of clearance or approval. This includes a variety of individuals covered by state health professional regulation, including but not limited to physical therapists and psychologists. These practitioners are licensed by law to provide certain health services and thus authorized by the FDA regulation to order the use of devices intended for their health specialty and their patients.

Despite the regulations in place, there is a common belief among healthcare practitioners that PDTs can only be prescribed by licensed physicians (MDs, PAs, or NPs) who have prescribing authority under state law. Prescribing/ordering requirements for mental health PDTs can be conflated with those for pharmaceuticals, where the ability to prescribe is typically limited to authorized prescribers like psychiatrists, and not others like psychologists.

These issues undermine PDTs' greatest potential strengths – access, convenience, and scalability. As previously mentioned, many Americans struggle to access care and treatment. According to the Association of American Medical Colleges (AAMC), 72% of Americans live in an area without enough psychiatrists and other mental health professionals to meet the population's needs.¹ Even among Americans living with a mental illness who are insured and live in an area where they can access a psychiatrist, 30% report they did not receive psychiatric care because their health insurance did not cover any mental health services or did not cover enough of the cost.⁵⁷

Innovative solutions are necessary to expand access to digital mental health solutions with the scale and urgency demanded by the mental health crisis.





PART 3:

Five Urgent Priorities to Advance Equitable Access to Digital Health Solutions

The U.S. mental health crisis has had devastating consequences on the health, economic conditions, and social well-being of the American people. It is difficult to articulate the complete impact of the crisis on society because it is connected to every aspect of living and is compounded by historic discrimination, generational trauma, and social stigma.

Digital therapeutics offer immense potential to treat mental illness, address provider burnout, reduce barriers to care, reduce costs, and close equity gaps. These solutions also meet the growing urgency from policymakers and other stakeholders to address the crisis, especially with cross-sector solutions that can rapidly provide proven interventions to the millions of Americans who are suffering.

Five priorities can drive progress in realizing the potential of DTx.^{58,27}

Five urgent priorities to advance equitable access to digital health solutions:

- 1. Understand the needs of patients, caregivers, and providers to shape the development of DTx.**
- 2. Promote and continually refine evidence-based solutions.**
- 3. Leverage DTx to increase accessibility and inclusivity.**
- 4. Advocate for a wider range of public health professionals to provide DTx.**
- 5. Foster cross-sector collaboration, including with patients, families, clinicians, payers, healthcare companies, social workers, criminal justice workers, governments and more.**

1. Understand the needs of patients, caregivers, and providers to shape the development of DTx.

While DTx offer significant potential, the field is still in many ways in its infancy. As stakeholders develop new tools and solutions, they must determine and incorporate the most urgent needs among people living with mental health conditions, caregivers, and providers. Within the mental health space, patient-centered care (PCC) has been shown to be effective – integrating the patient’s goals and feedback from loved ones to create a dynamic, personalized care pathway. Collaborative care models have also proven effective, having been consistently shown to improve outcomes, as they coordinate care, and adjust level of care to meet that patient's needs.

Taking a similar mindset in the development and implementation of new DTx will ensure tools are fit for purpose.

In addition to hearing directly from patients, DTx design and development would benefit from linking research insights on the social determinants of health (SDOH). SDOH research can reveal which patients are most affected by equity gaps, such as access to healthy housing and reliable transportation, particularly burdensome within non-White, impoverished communities.⁵⁹ DTx offer a unique opportunity to close many of these gaps.

"Incorporating the patient voice is critical in the development of digital solutions. When working with highly marginalized or vulnerable populations, like indigenous communities or individuals with a serious mental illness, we employ a community-based participatory research approach, which we call 'participatory human-centered design'. This involves equal partnerships throughout the software development process."

- Karen Fortuna, Ph.D.
Assistant Professor of Psychiatry,
Dartmouth Geisel School of Medicine



2. Promote and continually refine evidence-based solutions.

DTx and PDTs are distinguished from other digital health tools by their clinically demonstrated efficacy and regulatory agency backing. This strength is especially important for time-strapped providers and caregivers, who need to quickly and easily understand which tools are more effective and reliable.

Consortiums and other disease advocacy groups can play an unbiased role across DTx to help educate providers and caregivers on how to know which tools meet these criteria. One example of a database that can support individuals in finding DTx is MIND (mindapps.org). Created by the Beth Israel Deaconess Medical Center in Boston, a teaching hospital of Harvard Medical School, MIND is an interactive database that helps anyone find mental health and brain apps that meet the unique preference

and needs of each individual. Policymakers will also play a key role in promoting coverage and reimbursement with payers and health systems, so that cost does not become a barrier to access.


As DTx are used more widely, they offer an added benefit of rapid data collection to refine their usage and tailor for individual patient needs in real time. Of course, this requires appropriate data collection safeguards, well-defined data standards and benchmarks, informed consent on data utilization, and proactive approaches to ensure that artificial intelligence and machine learning algorithms combat rather than perpetuate biases. Public, private, and non-profit stakeholders recommend evaluating and monitoring DTx and PDTs on an ongoing basis to ensure their improvement, safety, and efficacy.^{60,27,61}

MIND (mindapps.org) is a database to equip users with the information necessary to make informed decisions when selecting mental health apps. The platform uses the American Psychiatric Association's App Evaluation Model, which introduces Accessibility, Privacy & Security, Clinical Foundation, Engagement Style, and Interoperability as major categories to consider.

3. Leverage DTx to increase accessibility and inclusivity.

DTx offer promise to expand access, support inclusion, and close infrastructure, logistical, and operational gaps between stakeholders.⁶² To that effect, DTx can be integrated at strategic access points where patients naturally convene, such as homes, schools, workplaces, community centers, churches, hospitals, and clinics.^{63,20} Stakeholders might successfully reach neglected patient populations by deploying digital interventions in niche or remote locations, such as homeless shelters, libraries, and prisons.⁶³

At a systemic level, the federal government is working to integrate mental health care into primary care settings and equip these offices with the skills and sensitivity to treat patients with co-occurring conditions, such as physical disabilities and substance abuse disorders.²⁷ Healthcare stakeholders report that closing health equity gaps requires facilitating a continuum of care and warm handoffs of patients to providers. The accessibility of DTx can help ensure that patients receive timely care and do not get lost in the healthcare system.



"We need a shift in our cultural mindset. We must move away from the belief that the initial treatment for psychological issues always requires high-touch, weekly 45-minute psychotherapy sessions. It's time to explore alternative approaches. How can we address people's needs while they're on a waitlist? How can we provide support to individuals in primary care settings when they require solutions beyond medication?"

- C. Vaile Wright, Ph.D.

Senior Director of the Office of Health Care Innovation,
American Psychological Association

4. Enable a wider range of public health professionals to provide DTx.

Addressing the shortage of mental health care professionals is a long but necessary journey to expand access to both DTx and traditional mental health care. More immediately, DTx can help alleviate the burden if a broader set of stakeholders prescribes or orders them, possibly including psychologists, social workers, and DTx are used to connect points of care rather than fragment them. As noted, when certain non-physicians were granted the power to deliver critical medicine or vaccines during the opioid or COVID-19 crises, patients were increasingly likely to use these solutions.

The case for similar changes with DTx is even more pronounced, given that these interventions do not have the same side effect profile as medical treatments. Research and stakeholder interviews reveal that the field overall favors allowing non-physicians to prescribe PDTs.^{27,65,66} What's more, given the current FDA guidelines, many non-physicians including psychologists can currently order PDTs. The community must address any misconceptions that exist around what PDTs are and who can order them in order to democratize patients' access to PDTs and treat mental health conditions on a population-basis.

"Allowing non-physicians to prescribe prescription digital therapeutics is crucial. The limit on who can prescribe was a significant barrier in expanding access to the PDTs I've worked on. Take ADHD, for example, which is often diagnosed and treated by school psychologists. These professionals would need to refer out to a psychiatrist to get students access to a tool that could help them, delaying or possibly even preventing care."

- Adam Gazzaley, M.D., Ph.D.

Founder & Executive Director of Neuroscape at UCSF; Co-Founder, Board Member & Chief Science Advisor at Akili and JAZZ VP

5. Foster cross-sector collaboration.

DTx will be most successful if they are supported by collaborations across sectors, specialties, and disciplines. Providers might consider partnering with social workers, community health workers, peer support workers, and teachers to detect patients' early signs of mental illness and monitor their progress over time. If a broader set of stakeholders begin to prescribe/order PDTs, better communication between those

stakeholders and the patients' doctors will be needed to ensure everyone has a full picture of the patient's treatment journey. Together, these professionals might develop new holistic, multidisciplinary approaches to mental health treatment.²⁷

"Promoting cross-sector collaboration is a key step to effectively advance the development and ethical utilization of digital tools and interventions. The Society for Digital Mental Health is committed to advancing both research and practice in digital mental health by convening diverse stakeholders – individuals with lived experience, researchers, clinicians, policy makers, and more – with a particular emphasis on innovation, education, and evidence-based approaches to enhance mental health care."

- David Mohr, Ph.D.

President of the Board, Society for Digital Mental Health

Conclusion



Mental health conditions are becoming increasingly prevalent and pervasive across the United States. As the demand for mental health services continues to rise, the healthcare system will not be prepared to meet patients' needs unless it becomes more efficient, effective, and – most of all – accessible.

Digital mental health technology has the potential to catalyze mental health care. Certain technologies, such as Digital Therapeutics and Prescription Digital Therapeutics, are especially promising given the research data backing their effectiveness, their scalability, and their ability to meet individual patients' needs.

To achieve this vision of better mental health care in the U.S., experts recommend bringing several priorities to the forefront, including conducting research on patients' needs, continuously improving DTx and PDTs, improving the accessibility of evidence-based solutions, expanding and empowering the public health workforce, and fostering cross-sector collaboration. We urge stakeholders to collaborate in the growing effort to address the U.S. mental health crisis. This issue cannot be solved by any one sector or stakeholder. We are committed to assisting the public, private, and not-for-profit sectors to leverage digital therapeutics and close gaps in mental health care.



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