Digital Mental Health 101: What Clinicians Need to Know When Getting Started

This guide is an introduction to the broad considerations that should be understood by mental health professionals and patients alike when engaging with mobile health (mHealth) solutions.

Part 1. Getting Started in mHealth: The Landscape of Apps and Access

The mHealth App Landscape

A. Background, Terminology, and Concepts

Nearly half of the world's mental health patients lack access to treatment, but well over half of those diagnosed with a mental illness have access to a smartphone. This striking fact highlights the paradigm shift in care that psychiatry is poised to lead around mobile health (mHealth). While there are numerous definitions of mHealth, here we focus on asynchronous mobile technologies, including smartphone apps, text messaging, email, and online forums. The goals of mHealth are to improve health outcomes through convenient, patient-driven access to mental health support and self-management tools.

Over the past several decades, there has been widespread adoption of health information technology solutions in health care. As more clinicians and patients began using mHealth technologies, such as smartphone applications (apps), numerous use cases and patient experiences have emerged, evolving the clinical care paradigm. Some of these are well-established, and some are still emerging. Current and emerging uses are informed through a brief review of non-mHealth technology tools already in widespread use.

These traditional uses of technology to support care delivery are typically clinician-driven and operate in a clinical model, including information management (e.g., electronic clinical notes, electronic storage and transmission of patient data via electronic health records (EHRs), cloud storage); time management (scheduling); health record maintenance and access (EHRs, electronic prescribing (eRx), physician-to-physician and physician-to-patient communications and consulting (e.g., videoconferencing, secure message/texting); reference and information gathering (e.g., drug reference guides); electronic clinical decision-making support (eCDS), lab test orders; remote patient monitoring (RPM), collecting patient clinical/quality measurement data; and medical education and training.

While there are examples of mobile apps performing all of the traditional examples provided above, the most common uses for mHealth apps today are focused on promoting patient self-help and providing an auxiliary to clinical support via data and physician consultation. For these core and emerging uses, mental health clinicians are seeking guidance on the best ways to engage with and utilize apps. Because of their greater accessibility, flexibility, and convenience for patients than in-office care, digital solutions have the potential to strengthen the therapeutic alliance and improve clinical outcomes while lowering costs. But like all solutions, they also present risks, including direct patient harm, loss of privacy, fragmented care, inefficient care, and potentially increased costs. Balancing these risks and benefits requires clinical judgment, and this report aims to offer decision-making best practices around use of apps.

The app ecosphere is constantly evolving. According to one industry report, in 2020 alone over 90,000 new digital health apps were released. There is still not a well-accepted nosology to categorize health apps, but these apps can perform myriad functions such as symptom tracking, habit formation or targeted behavior change, peer support, and more. Sometimes these apps are meant to be used as an adjunct to treatment in coordination with a mental health professional—either consistently or periodically. Many "health and wellness"-focused apps are intended to be used as unguided self-help, although the evidence for their effectiveness remains unclear. In either of these cases, apps have the potential to support a patient-centered care model.

Patients and clinicians are finding apps through a variety of methods, and with more than 300,000 health-focused apps available in app stores (e.g., Apple, Android) worldwide, there are many to choose from. By some estimates there are at least 10,000 related to mental health. Many patients focus their search for an app based on a specific condition (e.g., depression, anxiety), a specific function (e.g., journaling, meditation), or by using a search term relevant to a particular need. In addition to searching in an app store, their health insurance plan may recommend downloading and using an app developed by the insurer or a health system that integrates into a specific EHR. Increasingly, patients come across advertising for apps that offer incentives for downloading or using the app. Finally, health care professionals may recommend apps based on a patient's needs, and some organizations like Kaiser Permanente use apps as frontline tools in their treatment plans.

While patients may receive app recommendations from their clinician or from another third party, app stores remain a ubiquitous way to search for apps. Yet there is clear and robust evidence that app store stars or ranking are neither a reflection of app quality nor utility. If we compare apps to medications, in that patients seek apps for help with symptom treatment, medications are not selected based on star ratings but rather by considering each patient's unique case and needs. This underscores the challenge with marketplace app ratings as a mechanism for awareness, access, and selection.

Patients and clinicians alike must consider the mechanisms and processes by which scores, rankings, and commercial recommendations are derived. A close inspection often reveals a lack of details or biases that warrant caution. These websites often offer confusing, and conflicting, reports that can cause

confusion and harm through false assertions and lack of an evidence base in suggesting specific apps. The approach advocated here is different. Instead of recommending a specific technology, platform, or solution, the goal is to offer best practices around the selection of apps that can be applied over time as criteria, technology, and preferences change. We will delve into more detail about app evaluation protocols and app selection in Section III.B.

B. App Categorization. "Health and wellness" vs. "Medical" Categories

The line between wellness and mental health care can often be blurred from both regulatory and clinical lenses, and the same challenges exist in the mHealth space. "Health and wellness" can include symptom trackers, guided meditation, breathing exercises, smoking cessation, exercise guidance, and a variety of other topics focused on promoting healthy behaviors. The "Medical" regulatory category is a narrower category, often used as an adjunct to treatment by a health care professional. Apps within this category have often completed a more rigorous clinical and research assessment, but there are exceptions and many apps that serve a medical purpose are not directly regulated, falling under the hands-off "regulatory discretion." Many of the examples offered by the U.S. Food and Drug Administration (FDA) as low-risk apps that are eligible for regulatory discretion (e.g., low level of oversight) are directly focused on mental health use cases such as those listed below:

- Software functions that help patients with diagnosed psychiatric conditions (e.g., post-traumatic stress disorder (PTSD), depression, anxiety, obsessive compulsive disorder) maintain their behavioral coping skills by providing a "skill of the day" behavioral technique or audio messages that the user can access when experiencing increased anxiety;
- Software functions that provide periodic educational information, reminders, or motivational guidance to people who smoke and are trying to quit, patients recovering from addiction, or pregnant people; or
- Software functions that use GPS location information to alert people with asthma of environmental conditions that may cause asthma symptoms or alert a person with a substance use disorder when near a pre-identified, high-risk location.

As the line between wellness and medical apps is blurred, patients and clinicians need to carefully consider all apps and not just those that claim to be medical or non-medical. Further, the value of different apps in clinical care is contingent on the features and setup of the app itself, the needs and condition of the patient, and the match between app and patient. FDA approval or other regulatory oversight does not provide the information required for that shared decision-making, so regulatory oversight is only one consideration in incorporating apps into care.

Another category of apps is those with FDA approval. Unfortunately, FDA approval for apps is not an indicator of app quality or effectiveness, and there are currently many loopholes. Around COVID-19, the FDA noted that it would allow apps—what it terms "Software as a Medical Device" (SaMD)—to make medical claims without any data if they are related to a psychiatric disorder and are seeking a lower-risk 510(k) approval. As of July 2021, companies had already taken advantage of this reduced regulation, although it is unclear what will happen when such temporary restrictions are removed. For those apps

that do undergo a more traditional approval (510(k) or DeNovo), recent independent reports have questioned the level of evidence presented and even raised doubts about the quality of the submitted science. Many of these apps are developed quickly and without a plan for sustainability and long-term upkeep considerations. A recent statement from leaders in the field noted a "[c]onsensus among relevant forum participants that FDA clearance, which focuses on safety and minimal effectiveness thresholds, does not provide adequate information for decision-makers." The FDA had plans for an entirely novel regulatory system called PreCertification, but in September 2022 announced the pilot was over without concrete next steps. Until then, the current approval process remains less helpful for assessing the efficacy and utility of mental health apps.

C. Apps, Privacy, HIPAA, and OCR

While regulation seeks to catch up to apps, there are other components of the mental health care system that provide some degree of governance. Health care professionals and patients alike should consider how using an app might expose personal identifiable information—including electronic protected health information (ePHI). For instance, many apps may collect or share data in ways that are not immediately clear to the average user. This lack of transparency on behalf of the app developer may cause confusion as to whether using an app puts users and clinicians at risk for a HIPAA violation under the Privacy or Security Rules. It can also be confusing for users to know how their personal identifiable information is being used or potentially exploited.

Government entities enact fewer privacy and security regulations around these apps, especially if self-declared as a wellness app. However, in September 2021 the Federal Trade Commission (FTC) noted it would begin to hold even wellness apps accountable under HIPAA laws. While the Office for Civil Rights (OCR) within the U.S. Department of Health and Human Services (HHS) has the regulatory authority for the HIPAA Privacy and Security rules, this action by the FTC highlights the rapidly evolving landscape for privacy and related regulation.

Still, the Office of the National Coordinator for Health Information Technology (ONC), the OCR, and the FTC have acknowledged that limited guidance exists in this area. Particularly complicating this issue are the high number of apps, the rapid pace of development, and a lack of resources to perform rigorous enterprise-level testing on each app.

The OCR has several resources to help physicians, as HIPAA-covered entities, determine whether using a patient-to-physician app requires them to follow HIPAA protocol around storing and transmitting patient data. In sum, if a physician has entered a business associate agreement (BAA) with a software developer who has designed an app specifically for use in clinical practice for that physician (or on behalf of a covered entity), then that ePHI falls under the purview of HIPAA. While the physician should always complete a security risk assessment under the HIPAA Security Rule for keeping all practice-related patient information secure from a breach, using a mobile app itself is unique (for more information, see APA's HIPAA Security Primer). This is in addition to ensuring compliance with the physician institution's organizational information technology compliance standards.

These health information technology rules have continued evolving—at the time of this publication—due to the COVID-19 pandemic. At the start of the public health emergency (PHE) declaration, the U.S. Food and Drug Administration declared they would not "object to the distribution and use of" computerized behavioral therapy devices and digital health therapeutic devices for psychiatric disorders during the duration of the PHE. They also did not intend to enforce regulations for "low-risk general wellness" apps and functionality. This essentially removes barriers for SaMD and software in a medical device (SiMD) for specific psychiatric disorders. Given the scope of the market, technology, and regulatory shift during the COVID-19 PHE, the future of regulating these apps in a post-pandemic environment remains uncertain.

While the HHS temporarily allowed the use of "any non-public facing remote communication product that is available to communicate with patients," the American Psychiatric Association continues to recommend HIPAA-compliant security for video visits to preserve the confidentiality of sensitive patient discussions. Thus, widely available consumer video chat apps—such as "Apple FaceTime, Facebook Messenger video chat, Google Hangouts video, Zoom, or Skype"—would not be appropriate for telehealth care unless a provider signs a BAA and has permission to use that platform for health care purposes and the software contains appropriate privacy and security protections.

These ever-evolving changes in security, privacy, and health policy continue providing challenges, constraints, and opportunities for health care. This underscores the importance of clinical informatics training and curricula for all mental health professionals and a solid understanding of applicable government laws. This technical knowledge will allow the field of psychiatry to explore, research, and adopt new apps, devices, and technologies in a safe manner to the benefit of our colleagues and our patients.

D. Understanding the technology: a quick roadmap

1. Hardware Considerations

While access to devices that can download apps and connect to the internet (e.g., smartphones, tablets) are widespread, they are not universal. Providers can avoid making assumptions about patient technology access and use by asking a few questions in establishing patient abilities and preferences, including:

1. Do you have regular access to a device that can download apps?
2. Do you have enough internet access (WiFi, data) to use the device on a regular basis?
3. Do you share the device with someone, or is it just yours?
4. Do you feel comfortable using the device?
5. Is it reliable to use? Do you use it for things like texting and social media?
6. When you encounter problems with the device, do you have ways to address it, like asking a family member or friend for help?
7. If you have access to a device, are there any challenges you are encountering in using it that we can help with?
8. Are you interested in using your device for some activities that may support your mental health?

Establishing if the patient has adequate access to a device that works well enough for simple, regular usage, or can be supported in achieving that objective, is the first step in incorporating apps into care.

2. Software and connectivity considerations

a. Platforms and broader connectivity; Connection to telemedicine

The next consideration when determining whether to use an app is whether it will work on a particular device or operating system (OS). To that end, physicians must consider not only whether an app will work on their personal or clinic device, but also whether the patient's device will support the app. Most popular apps are designed to function on either the Android or Apple iOS smartphones or tablets. Moreover, as the clinician and patient use an app over time, both must consider how often an app might be updated. For example, as an app is updated over time, will it continue to function in the same manner—or at all—on the devices in question? Have software updates led to changes in the usability of the app? Sometimes software updates can lead to problems within apps and developers may not receive advance notice or have the ability to adapt to system updates immediately, resulting in runtime errors. Larger telehealth software firms may have more advanced knowledge and capability in adapting to operating system upgrades. Has the privacy policy changed? Is the app still using or sharing data in the same way as when it was first downloaded onto the device in question?

Reliable and accessible internet connectivity is another key consideration. Some apps require no access to the internet to run or can work in "airplane mode." For patients with limited internet access (i.e., rural areas) or phone plans that provide little data, this is a critical consideration.

Finally, digital literacy and language of the app itself are important to actively consider. Here, we refer to digital literacy as the knowledge, skills, and confidence to use technology for accessing and engaging with health care services. Many patients are not able to easily download, set up, or engage with apps. Asking patients about their comfort in using apps and preferred language can offer a brief screening and highlight whether further exploration is necessary. In addition, many apps are not offered in languages other than English or do not include accessibility features for individuals with visual or physical limitations, reading difficulties, color blindness, or other characteristics necessitating accommodation. These features are important to consider when selecting apps for patients. It is, of course, possible to teach digital literacy, and digital navigation programs focused on the needs of people with mental health disorders are expanding.

3. Active and passive data collection and data use

There are many types of data that apps can capture including active and passive data. Active data refers to data that are only collected when someone actively and purposefully engages, like populating a mood journal. Passive data are different in that they may be collected without active engagement, like step count.

In the simplest terms, active data are any type of survey or journal that the patient must fill out. Passive data are often sensor data collected via a wearable or phone sensor (e.g., step count) where the device collects the data automatically. Passive data offer more functional data (e.g., sleep duration, exercise

patterns) that can be useful for medical decision-making, but is also more novel in the mental health fields. Passive data can present new privacy risks from sensors' constant data collection, and given the large amount of data captured, could lead to expensive internet-related charges if not configured properly. While there have not been any publicly noted breaches or malicious uses of smartphone passive data, the novelty of this form of data capture warrants discussion with patients. The table below offers more details and considerations of uses.

Table 1. Smartphone Passive Data Sensors and Clinical Uses. Adapted from APA Publishing's *Telepsychiatry and Health Technologies* (S. R. Chan, 2018).

Sensors	Mainstream application examples	Potential clinical uses
Accelerometers to detect person's movement, number of steps	Fitness tracking	Exercise, weight loss, activity level, movement and gait detection, falls
Location triangulated through global positioning satellite (GPS), phone cell tower, and WiFi networks	Maps, driving directions, location-specific photography, social media, augmented reality games	Activity level, movement, wandering behaviors, peer support locator, addiction trigger avoidance
Cameras to detect light, the person's face, and the person's movements	Security, social media and chat, exercise, nutrition tracking, augmented reality	Light exposure, photographic self-reflection and photo journaling, peer support
Cameras with depth perception and 3D mapping	Augmented reality games, indoor mapping, 3D object scanning	Graded exposure to stressful environments or objects with response prevention
Compass	Maps, driving directions	Movement, wandering behaviors
Humidity	Weather	Environmental comfort indicator
Temperature of environment	Weather	Environmental comfort indicator
Microphone	Telephone calls, audio recording, social media and chat, voice dictation	Activity level, speech assessment, ambient noise for environmental comfort, voice dictation for physical impairments
Screen taps with touch-pressure intensity	Games, secondary controls	Activity level, cognitive exercises

Heart rate	Fitness tracking	Exercise, weight loss, activity level, biofeedback
Electrodermal activity (skin conductance)	Stress testing	Biofeedback

4. Change management and mHealth

One of the largest barriers to mHealth is changes to the clinical workflow. Simply adding apps into already busy clinical practices is likely not to succeed, and careful planning is required as the initial step. For instance, operational leaders can map clinic and hospital operations to identify time points, clinical situations, and workflows that could be enhanced with apps. Several implementation frameworks have been applied to mHealth for psychiatry and offer useful examples to study. Mental health professionals implementing apps must consider factors beyond their clinical workflow as patients' own personal schedule and preferences, the patient's culture, and the patient's interest in mHealth can be common barriers. Factors that may also influence patient app engagement include app-associated costs, provider recommendations, and the patient's schedule.

When considering any app, clinicians should not use assumptions and stereotypes of users and workflows. Ideally, an app and potential changes in workflow would be informed by ethnography, user interviews, focus groups, surveys, and quality improvement techniques such as Plan-Do-Study-Act (PDSA).

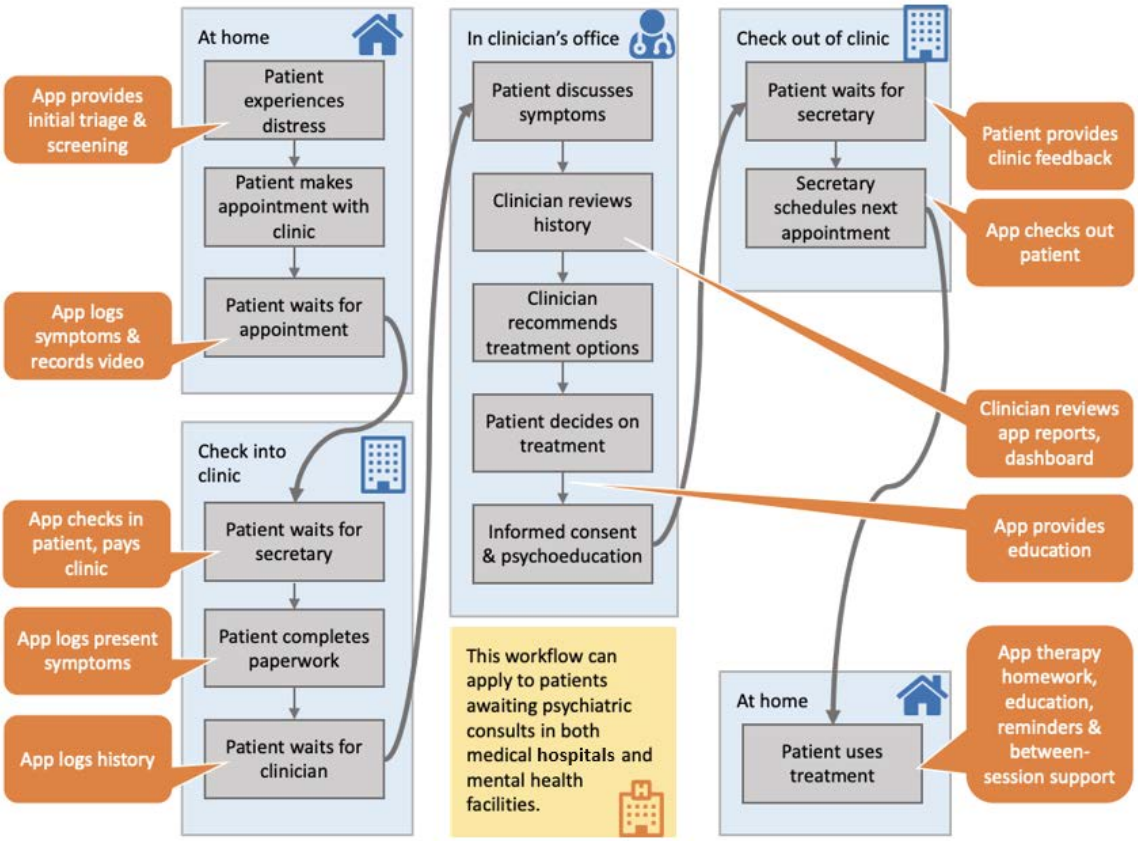

Figure 1. Opportunities for using apps in mental health care — illustration by Jennifer Favela, for APA Publishing's *Telepsychiatry and Health Technologies* (S. R. Chan, 2018).

Clinicians can benefit from training on how to incorporate apps into the workflow as this training can promote or inhibit the uptake of mobile apps into the clinical care model. Within patient-clinician encounters, it is important to allow clinicians (or other members of the care team) time to, first, learn how to use the technology themselves, and second, teach patients how to use apps. Such training can occur before, during, and after appointments. Beyond clinical time for teaching, monitoring app usage and data is important. If the app provides patient-generated health data (PGHD) that is relayed 24/7 to the health system, then clinicians must be given sufficient time to understand, grasp, and take action on any data provided by the app. This will require additional staff resources.

Onboarding patients can help them understand and use apps to the fullest and enhance engagement. Among three approaches for onboarding, clinicians can recommend the app, perform hands-on exercises in the clinic, or perform onboarding outside the clinical encounter.

- In *prescribing an app*, a clinician can meet face-to-face with a patient, explaining to them the features of the app and explaining how it will help them. Helping patients understand why the app is important for their care is critical toward ensuring higher rates of engagement with that app. Outlining the safety plan (if any) around the app and when (or if) data will be reviewed are also important and should be documented. For apps offered as self-help, expectations should be fully understood by all parties.

- *Hands-on exercises* involve using the digital app with a patient to guide them through exercises in the clinic and then discuss their progress afterwards. This may not always be feasible and can also be accomplished through use of support staff or digital navigators as one of many examples.
- Finally, *onboarding outside the clinical encounter* can occur by clinicians who conduct outreach to patients and guide them through their needs. For instance, this occurs within the Department of Veterans Affairs when onboarding patients to the VA Video Connect app and health devices through the Digital Divide consult.

By following an onboarding process, clinicians can help patients moderate expectations, reduce anxiety, and overcome failure fears.

5. Addressing app and technology literacy

Onboarding and change management processes need to be structured for the user's technological literacy. Engagement with an app may be influenced by disparities in income, education, and access to telecommunications infrastructure. The user's own mental health history may influence their engagement, confidence, and familiarity with the internet and connected devices. Adequate support should go beyond the app to include assistance with basic technology functions such as accessibility, battery charging, operating system issues, and device security.

The user's culture and environment can influence how an app functions. For instance, apps may need to adapt to be inclusive of family settings, adapt to internet outages, adapt to electricity outages, and otherwise be aware of varying levels of community infrastructure. App content should also be tailored to the appropriate level of clinical knowledge and education; for instance, using structured surveys for those providers with minimal psychiatric training. We discuss digital literacy and access to mHealth more in the following section.

Access to Mental mHealth

mHealth can help reach many, but not yet all, people. Understanding who still cannot connect is important to ensure these new tools are equitable and truly accessible. As of 2021, 7% of U.S. adults said they do not use the internet. Gaps in usage and access to information communication technologies (ICTs) continue and are collectively referred to as the "digital gap" or "digital divide."

A. Moving from Digital Divide to Digital Inclusion

The digital divide is characterized by inequity in access to digital services, including electronic government, commerce, health, education, and other programs. Those without ready access to technology are excluded from the benefits of electronic engagement with programs and services. The greatest barriers to ICTs include accessibility, affordability, and awareness. Ongoing government and social service programs have encouraged internet adoption in underserved areas. Mobile phones are

also decreasing the divide as they are now widely available, but the speed and quality of the devices vary greatly. Additional contributors to the divide include user age, bandwidth/speed, disability, education, language, immigration status, income, location, mobile access, and useful usage (what people do with their access according to their abilities). Usage can be broken down into different levels: access, skills, beneficial use, participation, and co-creation. Access alone does not always correlate to beneficial use, and there are opportunities at each level to promote digital inclusion.

There are numerous categories of U.S. adults who do not access the internet: 25% of adults ages 65 and older report never going online; 14% of households earning less than US$30,000 per year were more likely to not use the internet compared to 1% of households earning US$75,000 or more. However, these represent a sharp decline in nonusage from 2000 when 85% of adults ages 65 and older were offline. The percentage of Black adults reporting being offline from 2000 to 2021 has also decreased from 15% to 9%, and the prevalence of offline Hispanic adults has decreased from 14% to 5% during the same time.

While many Americans may have internet access, levels of usage and skills vary among users. In noting the skills and settings required to access ICTs, we move from thinking about a digital divide to thinking instead about technology as a tool for equity and access—or digital inclusion.

B. Digital Literacy

Digital literacy is understood to be an individual's ability to find, evaluate, and clearly communicate information through digital platforms. In the context of health and mental health, it means ensuring a person has the knowledge, confidence, and skills to engage with digital health services across a variety of mediums and platforms. While digital health solutions are rooted in direct education and hands-on training, such efforts are key to bridge a digital divide between those able to partake and benefit from apps (the focus of this report) and those excluded. While often discussed, there are few concrete proposals to boost digital literacy. One example piloted at Beth Israel Deaconess Medical Center (BIDMC), Easter Seals of Greater Houston, and the Greater Manchester Mental Health Trust (UK) is to train peer specialists as digital navigators and expert technology teachers. Other related roles include a mental health technology specialist able to offer similar benefits. These digital navigators can offer programs like Digital Outreach for Obtaining Resources and Skills (DOORS)—a series of pragmatic and interactive lessons designed to develop new functional skills for accessing and utilizing the promise of digital health. Other grassroots efforts geared beyond mental health have also emerged, and many more will meet this urgent need.

Appendix A: About the Authors and APA App Advisor

The American Psychiatric Association's App Advisor is an initiative begun in 2019 that builds on the organization's work in app evaluation that began in 2014. Its purpose is to develop guidance and resources around the use of mHealth in mental health care, targeting clinicians, patients, policymakers, and the general public. The group is comprised of an array of mental health clinicians, professionals with expertise in health information technology, and those with lived experience of mental illness.

This group was assembled through an open call for nominations and submissions issued to the general public in June 2019. Following a review and selection process undertaken by APA's Committee on Mental Health Information Technology, the group first convened in December 2019 in Washington, D.C., at the APA's headquarters. At this first meeting, the panel reviewed and revised APA's App Evaluation Model—a framework offering guidance on reviewing and selecting mental health apps in clinical care. Through consensus building, the panel revised this model to the iteration available on the APA's website today.

As a natural outgrowth to its work in app evaluation, the panel is now focused on developing guidance focused on the use of mHealth in mental health care.

Appendix B: Key Terms

A selection of key terms from this document and in the digital mental health environment include:

Applications (apps): Computer program or software application, primarily designed to run on mobile devices including smartphones or tablets.

Digital inclusion: Supporting people to achieve knowledge, confidence, and skills to engage with digital health services across a variety of media and platforms.

Digital literacy: Cognitive, technical, and physical access to and comfort with communications technology to find, use, and share information.

Digital therapeutics (DTx): An umbrella term that describes treatments or therapies that use technology to deliver behavioral treatments that support changes in patient behavior.

Mobile Health (mHealth): Patient-driven mobile health support and self-management tools.

Prescription digital therapeutics (PDT): Software-based therapies designed to evaluate or treat a medical condition and are prescribed by a provider.

Remote patient monitoring (RPM): Non-face-to-face monitoring of primarily physiologic factors to understand a patient's health status.

Telehealth: Care that is delivered using technology and without an in-person interaction, including through video chat, secure messaging and file exchange, internet-capable devices, or phone.

Virtual reality (VR): A computer-generated simulation of a three-dimensional image or environment that can be interacted with in a seemingly real or physical way.

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