APA Resource Document

Resource Document on Digital Mental Health

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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).

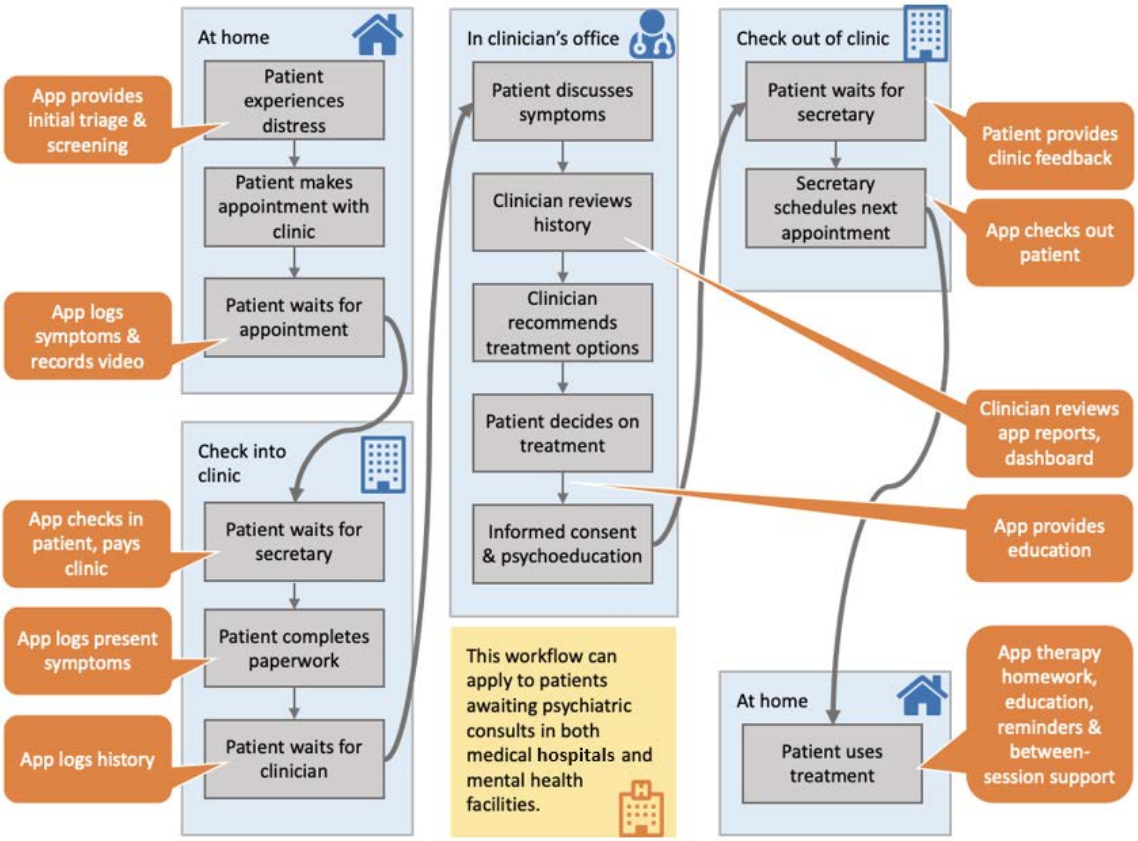

Figure 1. Opportunities for using apps in mental health care — illustration by Jennifer Favela, for APA Publishing's *Telepsychiatry and Health Technologies* (S. R. Chan, 2018).

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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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 2. Applying mHealth: Identifying and Supporting the Use of Apps

Clinical Applications and Overview of Considerations within Specific Patient Populations and Settings

A. Outpatient Psychiatric Setting

The vast majority of mental health apps currently available are intended for use in the outpatient ambulatory setting. Since the start of the COVID-19 pandemic, there has been a fivefold rise in demand for mental health treatment, while according to the 2021 GAO report, the U.S. is facing worsening shortages of mental health providers. Apps offer the potential to break down barriers to outpatient care such as accessibility, wait times, and costs.

These apps fall into various categories, varying from self-guided to being used in conjunction with a health care provider. Apps that provide digital therapy tools (e.g., electronic cognitive behavioral therapy (CBT) modules, virtual dialectic behavioral therapy (DBT) cards) and mindfulness tools (e.g., meditation, deep-breathing apps) can serve as an adjunct to psychotherapy or medication management or as scalable, stand-alone solutions to those who cannot access care. Ecological momentary assessment apps designed to capture patient's self-reported symptoms and moods in real time offer the potential to monitor and trend patients' symptoms over time. Studies have found that apps can provide valid assessments of symptomatology. A number of early promising studies examining smartphone-delivered psychological interventions have found them to be efficacious.

While much potential exists for the use of apps in the outpatient setting, studies have found that adoption of apps in outpatient psychiatric clinic settings remains low. One consideration is that mHealth apps are not being widely recommended by clinicians to their patients. A survey of mental health providers found that although providers report a high level of interest in using websites and mobile apps to support mental health treatment, only 19% recommended use of apps in practice. Several barriers to

the adoption of apps by providers have been identified, including concern for security and privacy and a lack of integration into the provider's clinical workflows. However, clinician involvement in technology use can result in better clinical outcomes and patient adherence.

Efforts to make digital integration a reality in the outpatient setting are underway. To date, several health systems are launching "digital clinics"—outpatient psychiatry clinics that integrate digital technology into patient care. These clinics utilize smartphone apps and wearable technology to improve treatment outcomes and enhance shared decision-making between patients and providers. While these innovative clinics offer potential, continued research is needed into the barriers highlighted in other sections, such as patient engagement and workflow challenges to support the success of these models.

B. Inpatient Psychiatric Setting

Barriers to utilizing apps in the inpatient setting currently exist, as most psychiatric inpatient units restrict patient use of mobile phones and computers. However, iPad app interventions can be made available and offer the potential to provide additional therapeutic support. Geriatric psychiatry units have utilized art programs on iPads to help manage agitation. And some inpatient units are now offering "digital hours" where patients can use their smartphones under supervision. See the specific clinical population sections below for use case examples of inpatient app interventions.

C. Telepsychiatry

Telemedicine is defined by the World Health Organization as "The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies … in the interests of advancing the health of individuals and their communities."

While telemedicine can be delivered on computers through web platforms, many telemedicine platforms are app-based and allow for patients to connect with mental health providers on smartphones or tablets through video conferencing and texting. The APA, in partnership with The American Telemedicine Association (ATA), has provided "Best Practices in Videoconferencing-Based Telemental Health" for further information.

D. Integrated Care Settings

Integrated care settings offer an opportunity to leverage mobile apps to enhance access to care, yet the uptake of these devices in this particular setting appears more limited. This may be linked to the comfort or discomfort that providers have in supporting use of these tools to promote care. Since the structure of integrated care in primary care settings often involves a behavioral health provider, this seems to be the individual best suited to support incorporating patient use of mobile apps into the standard of care. However, to do this, behavioral health providers and other members of the integrated team need to gain confidence in their ability to use mobile apps.

Studies that have explored the use of mobile apps in integrated care settings have identified challenges including needing more training for both patients and clinicians, limited comfort level in using apps, and time limitations. With rapid adoption of technology around COVID-19, it is possible these barriers may now be reduced.

With integrated primary care, there is an opportunity for mobile apps to be incorporated into the standard of care and to help mitigate issues with mobile app motivation.

Patients in integrated care settings have interest in using mobile apps to self-manage psychiatric conditions; however, understanding specific population factors that will promote successful integration of mobile apps into a clinical environment such as type of smartphone device (Android or iPhone), willingness to use data plans, education needs (both patients and providers), and self-management factors are likely to affect the success of such interventions.

Patients in integrated care settings have been reported to experience barriers including access to smartphones and unlimited data plans, regular use, sustained motivation, and availability of apps in multiple languages. When exploring apps for use by historically underserved populations in an integrated, primary care setting, cost can also be a significant factor that can create barriers to app use for patients.

E. Child and Adolescent Psychiatry Setting

Mental health apps offer hope to address a growing mental health treatment gap for children and adolescents. Children are exposed to mobile devices at increasingly younger ages, with one survey finding that 25% of children had their own smartphone or tablet and more than half of children spent over one hour per day on electronic devices. This opportunity has not gone unnoticed, as numerous mHealth apps targeting younger patients have flooded the market. Researchers are exploring the use of gamification in developing digital therapeutics for conditions such as attention-deficit/hyperactivity disorder (ADHD) in children. In 2020, EndeavorRx became the first FDA-approved ADHD auxiliary treatment via video game after a randomized controlled trial showed clinical improvement in attention-related impairment.

As with apps for other patient populations, there remains a need for more evidence-based interventions. A 2020 systematic overview paper found that while there was evidence of the effectiveness of digital CBT and anxiety and depression interventions, other interventions were inconclusive. Special considerations for providers prescribing child mental health apps include data privacy as well as assessing the need for parental consent and involvement before recommending an app. Privacy considerations are elevated in apps for children and adolescents.

F. Geriatric Psychiatry Setting

Within skilled nursing facilities, there exists an urgent need for support for patients with dementia. With the aging population on the rise, the prevalence of dementia is expected to triple by 2050. Hospital settings can be particularly challenging for older patient populations, who are more susceptible to

changes in environment. Digital solutions can help meet this need by providing scalable interventions that do not require the use of pharmacologic medications with heavy side effect burdens. A small-scale study examined the feasibility and acceptability of an iPad intervention referred to as “Simulated Presence Therapy” to support dementia care in an inpatient psychiatric hospital by showing patients prerecorded video messages from loved ones. Novel technological solutions are being explored to monitor behavioral symptoms in the home, including motion sensors and smart home technologies to monitor sleep disturbances, agitation, and wandering.

Special considerations for this patient population include age-related limitations in geriatric patients’ ability to adopt new technologies such as smartphones and tablets, and the creation of easy-to-use features for tasks such as video conferencing. Such interventions will need to consider additional factors such as adequate staff assistance to be successfully implemented.

G. Serious Mental Illness

Those with serious mental illness own smartphones and are as interested in apps as the rest of the population. There are fewer apps designed directly for conditions like schizophrenia or bipolar disorder, but some do exist. Apps for wellness, anxiety, and depression are all relevant and have roles in care for those with serious mental illness. There is also substantial research around apps for these conditions, and FDA studies to assess the role of these apps in care are underway.

Examples of apps: “The SMI Advisor was created by SAMHSA and the American Psychiatric Association. The app features all the available resources of the SMI Adviser website, which can help clinicians find answers about treating patients with serious mental illness diagnosis. The app offers educational resources to patients and families. SMI Adviser also produces My Mental Health Crisis Plan, an app that enables patients to create a psychiatric advance directive” (Pellek, 2022).

H. Emergency Psychiatric Settings and Patients in Crisis

mHealth has a role in crisis care as well. Suicide is the 10th leading cause of death in the United States, affecting all age groups (WISQARS (Web-based Injury Statistics Query and Reporting System), 2021). Digital tools offer the potential to create novel approaches to suicide prevention by 1) identifying people at risk, 2) creating scalable prevention programming, and 3) increasing access to real-time interventions. Researchers are exploring ecological momentary assessment apps to better identify risk factors for suicidality and monitor at-risk patients. One pilot study of an inpatient mobile app intervention for suicidal adolescents found that it was successful in reducing the incidence of post-discharge suicide attempts. To date, several safety plan apps have emerged that allow patients and providers to create digital copies of safety plans. Further, support hotlines such as NYC Well are beginning to offer mobile text support to those in crisis, potentially reducing barriers to those seeking confidential mental health support.

Not all apps are created equal, though. While a dearth of apps targeting suicidality have emerged on app stores, studies have highlighted the potential dangers of such apps. One systematic review of 126

suicide-focused apps identified that many apps were not consistent with best-practice guidelines for suicide prevention at best, and at worst, were potentially harmful, even encouraging risky behaviors in a crisis. In January 2022, the data sharing policies of the Crisis Text Line revealed that the organization was sharing anonymized data sets with an outside company and benefitting from the revenue from the sale of this data. These issues highlight the need for careful selection and consideration by clinicians and users before utilizing such resources.

I. Peer Support Psychiatry Resources

Peer support is a well-established approach to support recovery from mental illness and can be accessed through technology. Digital peer support is defined as live or automated support services delivered through a technology medium. Peer support has been shown to increase emotional support, increasing hope, reducing the feeling of isolation, and supporting community belongingness. Peer supporters (peer support specialists, recovery coaches) may also support people being served in accessing and using technology. They can serve as digital health navigators and teach digital health literacy skills.

J. Dual Diagnosis Psychiatry Setting

Apps for substance use disorders are common and have even received FDA approval. While the value of this approval has recently been questioned, for the purposes of this report, FDA approvals suggest there is some potential for benefit and a lower risk of harm. Many apps have chosen not to seek FDA approval (see section on regulatory discretion), and there are thousands to pick from. Most offer a combination of psychoeducation, symptom tracking, and anxiety/stress reduction techniques. Others are based around CBT or behavioral activation and many increasingly offer a coach or other non-licensed clinician to support use. Some utilize passive data and track GPS to highlight when a person may be near a risky environment (e.g., a liquor store).

Publicly available mental health apps—developed by the National Center for PTSD within the U.S. Department of Veterans Affairs (VA)—have been tailored to address both substance use disorders and PTSD—such as VetChange for alcohol use disorder and Stay Quit Coach for relapse prevention in those who have quit tobacco. These apps reduce use of the problematic substance use. Other apps within the VA App Store—such as PTSD Coach, Mood Coach, and COVID Coach—can allow patients to better manage symptoms of anxiety, depression, anger, and insomnia, which have comorbidities with substance use disorders. CBT-i Coach—which reduces insomnia—has additionally been used to reduce cannabis use. These apps are designed with elements of motivational interviewing, cognitive behavioral therapy, contingency management, community reinforcement, goal setting, and social bond facilitation.

K. Psychiatric Nursing Considerations

In nursing, one use of mHealth is to facilitate workflows in the hospital. For organizations that use the Epic EHR, nurses have access to an app called “The Brain” that keeps track of required documentation, medication, dressing changes, assessments, and other tasks necessary to provide comprehensive care to

their patients. In the psychiatric setting, this app helps with safety check documentation, medications, and sending important messages to physicians.

Nurses can help facilitate the implementation and adoption of mHealth within a health care system. In the most recent release of the American Association of the Colleges of Nursing Essentials, a document which explicitly outlines competencies for the nursing profession in practice and in information and health technologies is one of the 10 domains identified for nursing competencies. Included in this domain is ensuring that nurses at entry and advanced practice levels are able to describe, use, incorporate into delivery of care, communicate, and adhere to ethical and organizational policies when it comes to information and communication technologies.

In order to achieve these competency expectations, the profession must provide learning opportunities that readily adapt to the changing technological landscape. It is important to empower nurses to help them gain comfort and competence in the use of technology to promote patient care because they are often the patient's first line of contact, assisting in developing rapport and increasing trust in the health care process.

Goodness of Fit: Reviewing App Options

As detailed above, the breadth of available health-oriented apps in the various app stores covers a wide range of use cases designed with different types of users in mind. These apps, for example, may promote 1) clinician-to-clinician interaction (e.g., sharing patient data, consultative functions), 2) patient-to-clinician interaction (e.g., sharing or tracking symptom data and other pieces of the patient's electronic record), and 3) patient-facing behavior (e.g., for self-management of symptoms or other uses).

It should be noted that patient-facing apps designed to support a patient in the management of their own health do not always function in a vacuum. For instance, any ePHI information collected by these patient-facing apps can potentially be incorporated into clinical- or health-related care. However, the overarching use of this type of app is intended to support the patient without the need to incorporate its functionality with electronic tools used by the patient's clinician. In contrast, apps that are designed around patient-to-clinician interaction support and incorporate the use of the application with this relationship in mind**.**

A. Evaluation Models, Rating Systems, and Other Evaluative Tools and Concepts

1. The American Psychiatric Association App Evaluation Model

Recognizing the challenges of identifying the right apps for your practice, multiple entities have undertaken efforts to objectively characterize or recommend apps. The American Psychiatric Association's expert consensus-driven APA App Evaluation Model provides guidance for psychiatrists and other health care providers when choosing an app to recommend for patient use drawing from

earlier efforts to draft a framework for mental health app evaluation. Early iterations evolved into a consensus-driven framework and an online toolkit, APA App Advisor, with case examples and sample reviews. Because providers and patients may have differing needs and priorities, the guidance does not necessarily restrict or set quantifiable measures. Further, the high frequency of updates for consumer-available apps can lead to outdated ratings. It can also be difficult to quantify many of the metrics around apps that matter the most. For example, we want to find apps that are easy to use, but ease of use will vary from person to person (as outlined in the digital inclusion sections above). As a further example, the degree and nature of evidence required for an app in one use case are likely very different for a second use case.

Instead, open-ended questions allow providers and patients to assess an app at a moment in time to ensure fit with objectives. The goal is not for the clinician or patient to answer every single question, but rather to be aware of key considerations and use available knowledge to make an informed decision. These items include:

- Basic facts about the app and its developer
- Risks, privacy, and security
- Clinical evidence
- Ease of use
- Interoperability

These categories are meant to be considered in a hierarchical order with the intent that if an app is not accessible, then further considerations do not matter. By the same logic, if privacy and security protections are not acceptable, then the evidence, engagement style, and interoperability likewise do not matter.

Figure 2. APA App Evaluation Framework. Adapted from Torous, JB, Chan, DR, Gipson, SY-MT, et al. (2018).

The current version of the model was finalized in January 2020. The consensus-building process relied on an expert panel, convened by the APA and composed of a diverse representation of mental health and technology experts. The original framework (1.0) was discussed, evaluated, and changed. Panelists renamed the five hierarchical categories within the model and revised the questions embedded within each level. For example, “Background Information” was changed to “Accessibility.” “Privacy and Safety” was changed to “Privacy and Security.” “Evidence Base” was changed to “Clinical Foundation.” “Ease of Use” was changed to “Engagement Style.” “Interoperability” was changed to “Therapeutic Goal.” The newly revised framework contained a series of 42 questions in the various categories to assist individuals in evaluating mobile apps. This framework has been adopted by health systems and public entities that strive to apply APA’s model when determining which apps to recommend to patients or stakeholders.

Evaluating the Evaluation: Other Frameworks

In addition to the APA’s framework, several other resources have been developed to assist clinicians, researchers, and the general public in evaluating and exploring mental health apps. These approaches often differ as they seek to provide a score or direct recommendation that is counter to the goals of the APA framework of empowering individuals to make informed decisions. For instance, the American Psychological Association has convened a panel of its member-psychologists to review software and mobile applications. The intended audience for these reviews is other psychologists and the reviewers. They ultimately use their criteria to assign an overall rating of apps reviewed using a scale from 1-5. This

final score takes into consideration the purpose of the app, content appropriateness, cultural responsiveness, ease of use, and functionality.

Another resource offering reviews of apps is the website One Mind PsyberGuide. This website provides reviews for apps within three domains: “Credibility,” “User Experience,” and “Transparency.”

The Organization for the Review of Care and Health Applications (ORCHA) is a digital health review platform that uses a 350-point measure to collect information on health apps. Their model collects information pertaining to Clinical & Professional Assurance, Data & Privacy, and Usability & Accessibility for a particular app.

The Division of Digital Psychiatry at Beth Israel Deaconess Medical Center (BIDMC) operates the M-Health Index & Navigation Database, mindapps.org, that utilizes the questions of the APA framework and transforms them into a searchable database of mental health apps.

Many of the existing app evaluation frameworks, tools, and other resources (some of which are noted above) rely on some common themes explored within the empirical research pertaining to what might be important to know about a mobile app before using it. In general, however, these overarching themes encompass a multidimensional approach to evaluating apps. These dimensions, or functional categories, typically focus on components of an app’s usability, how it maintains a user’s privacy with respect to any health data collected, accessibility, any clinical or other evidence, design, and engagement with its content, and so on. Some of these tools offer a cumulative report of the application based on their framework, resulting in a valence or numeric score.

It is up to the clinicians applying these evaluative tools and methodologies to determine the criteria necessary for their practice. Ensuring information is timely and that reviews are updated recently are often a quick means to assess these resources. In addition to the above resources and tools, there are other more research-oriented products for mobile app evaluation that focus on screening apps for research purposes. While these will not be explored within this document, examples include the mHealth App Usability Questionnaire (MAUQ) and the Mobile App Rating Scale (MARS).

Outside of evaluation systems offered by professional associations, nonprofits, and other NGOs, the ratings systems with which users are probably most familiar are those included within commercial app stores such as the Apple App Store, the Google Play Store, and Samsung’s Galaxy Store. Often, app stores offer multiple layers of review. For instance, apps must follow specific app store rules and policies that can restrict the use of customers’ location and automatically generated data. Only customers who have downloaded the app can rate and review apps within the store. App stores will display aggregate scores of the reviews and allow consumers to sort and filter reviews based on cost, popularity, and other factors. App stores may also group apps together as part of a seasonal promotion. For example, the Google Play Store featured specific apps for mental health week events. App stores’ internal teams may promote specific apps with “Editor’s Choice” badges and editor summaries.

In general, it is important to bear in mind that commercial rating systems are user-driven rather than reflective of any expert or objective measures of effectiveness or usefulness. Further, summary ratings are specific to each territory on the App Store and can be reset when the app developer releases a new version of the app. However, resetting an app's summary rating does not reset the app's written reviews. Users can rate iOS, iPadOS, and macOS apps on the app's product page on their device, and they can rate watchOS apps on the app's product page on their iOS device.

Sustainability and Engagement Factors

As discussed above, there are many factors to consider when approaching app integration into a clinical workflow. Implementation factors will vary by clinic, but a comprehensive list of considerations can be found in a 2021 paper by the Veterans Affairs team as it sought to boost implementation (Armstrong et al, 2022). The integrated Promoting Action on Research Implementation in Health Services (i-PARIHS) framework is a commonly used tool to guide implementation projects. Its overall message is that health care research is a complex, nonlinear, unpredictable process that requires a flexible and responsive approach when incorporating new tasks or tools.

Other frameworks exist as well, such as the Replicating Effective Programs framework. Workflow implementation needs the full support of staff, and any process should begin with their full engagement. Specific workflow issues raised have included training, workload, time- or cost-efficiency, collaboration and coordination, tech skills and experience, roles and responsibilities, leadership support, infrastructure, process standardization and planning, staff competencies, data access and management, job security, incentives, and more.

A. Barriers and Challenges to Use and Adoption

The non-adoption, abandonment, scale-up, spread, and sustainability (NASSS) framework is a useful reference to help avoid common but frequent mistakes made in deploying technology into any health care setting. It covers seven domains including "the condition or illness, the technology, the value proposition, the adopter system (comprising professional staff, patient, and lay caregivers), the organization(s), the wider (institutional and societal) context, and the interaction and mutual adaptation between all these domains over time." Focusing on the condition, apps for mental health need to be usable for those who may have neurocognitive or physical disabilities. The value of the technology is often a barrier, as hidden costs or fees are a leading reason for ceasing app use among users. Organizations are still working to determine if apps offer value, and to date there is a dearth of high-quality economic analysis regarding apps. As noted earlier, digital literacy and other exclusionary factors are often not considered.

B. Implementation and Engagement

Key to engagement is working with the end user as an equal partner. In doing so, it is essential to select the appropriate participatory approach for the population of interest. While multiple, varying models of

participatory medicine exist (e.g., community-based participatory research, active community engagement continuum, rapid assessment and response evaluation, diffusion of innovations), commonly, researchers employ for disadvantaged groups participatory approaches that have been successful among non-disadvantaged populations. This leads to subsequent failure in accomplishing desired results, as these approaches do not take into consideration factors that affect disadvantaged groups such as phone speed, availability of data, or language. Equity-based approaches require greater stakeholder involvement with the decision-making and research activities at all stages of research—from observation, problem definition, hypothesis development and testing, and revision per results—to produce relevant results and wide scale uptake. Thus, collaborating with people from disadvantaged populations, utilizing the appropriate participatory framework, and demonstrating substantive engagement elevate our capacity to address health disparities.

Human factors in technology can facilitate engagement. One such type of human factor is peer support specialists. Peer support specialists are people with a mental health condition who are also trained and accredited to provide peer support services using technology. As digital peer support quickly expanded across the globe in the wake of the COVID-19 pandemic, standardization in the training and delivery of digital peer support has advanced the professionalism of this field. While telehealth competencies exist for other fields of mental health practice such as social work, psychiatry, and psychology, limited research has been done to develop and promote digital peer support competencies. Digital peer support specialist competencies include: 1) protecting the rights of service users, 2) technical knowledge and skill in the practice of digital peer support, 3) available technologies, 4) equity of access, 5) digital communication skills, 6) performance-based training, 7) self-care, 8) monitoring digital peer support and addressing digital crises, 9) peer support competencies, and 10) emerging health literacy.

There have been and remain many efforts to improve app engagement. Common strategies include gamification and social engagement, although neither has transformed engagement. A non-health example with the app Pokémon GO highlights the limits of gamification on long-term engagement. Social networks often require resource-intensive monitoring and moderation. Evolving research in chatbot and other AI-driven technologies represents a new frontier for engagement efforts with results still not back. A less technical but perhaps more important consideration around engagement is how the app is used in partnership between clinicians and patients. Using apps in a manner that boosts the therapeutic alliance is likely to lead to longer and more sustained engagement. Of course, different populations will seek different experiences. One review of apps for youth reported “videos, limited text, ability to personalize, ability to connect with others, and options to receive text message reminders” were the most important factors for the youth studied.

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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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 3. What's Next: The Future of mHealth Ethics, Coverage, and Practice

Ethical and Legal Considerations

Nota bene: This section is not intended to provide legal advice. Please contact your malpractice carrier for specific legal questions.

As any treatment involves some examination of risks and benefits, so, too, does the use of apps in mental health care. These include concerns around the mobile health app use itself, how to effectively use these apps in the treatment process, and any considerations unique to providing mental health care.

A. Ethical Concerns and Patient Privacy

Of particular concern from an ethical perspective in using apps with patients is the degree to which the app adheres to expectations of the patient's privacy and confidentiality. A 2021 *Consumer Reports* guide suggested that even apps that appear at the top of app store searches do not offer complete or adequate privacy. This finding is supported by recent research studies highlighting that the majority of mHealth apps, mental health or not, suffer from privacy flaws. The health care professional and the patient should review the app's privacy policy to determine how it is using patient information (storing/transmitting) to ensure that it meets the expectations of both.

B. Harms, Risks, and Benefits

When evaluating apps, it is important to consider the amount of harm or risk versus benefit to the patient. This requires a personal analysis and highlights why it is important to evaluate apps in the context of the user at hand rather than apply a static rating score. What benefits could be expected from using this app? What evidence has been gathered for the benefits, and what are the possible harms of use? As noted above, one of the most common harms associated with use of any app in general is a breach of privacy or confidentiality and transmission of data to third parties. A more subtle

harm is a waste of time or the potential delay of more-effective treatments. When thinking of recommending an app, it is also important to assess the user's access to technology and their digital literacy. It can also be helpful to inquire about any current or past mHealth app use. This can be approached during visits in the same way one may inquire about herbal supplements or alternative treatments.

C. Patient Autonomy, Patient Consent, Liability, and Use of mHealth

A patient has the discretion to decide whether they want to use an app as a part of their treatment plan. Health care professionals should discuss with them the possible risks and benefits of any recommended therapy. Patients should not be coerced into using an app if they do not wish to use it. It is recommended that health care professionals incorporate an informed consent process stating the potential risk of loss of personal privacy and other risks when using apps.

Patients may assume that an mHealth app would adhere to the same privacy standards as health care entities, but this is often not the case, and it is important to share this difference with patients. Consent to use mHealth apps should be informed and voluntary. A patient's decision to use an app should be a genuine reflection of their autonomous choice. Many apps are not transparent in their methods of data collection, use, and sharing. Clinicians can play a vital role in educating patients on the risks and benefits of mHealth apps.

Liability, like informed consent for the use of technology, can also be addressed by the APA's ethics document: "Before they embark on innovative technology usage in practice, we advise that clinicians consider the potential liability connected with such usage and engage in an informed consent process with the patient, including disclosure of any financial interest the psychiatrist may have in the app. The app is an aid to the overall care delivery for the patient and not a replacement of the interactions with the provider. There is also some potential for boundary crossings or violations when the therapeutic relationship steps outside the confinements of a traditional setting."

Health apps in general have areas of relevance in health care law, such as medical malpractice and personal privacy. Private health apps are also subject to product liability laws. However, existing laws are not necessarily suited to the unique aspects of health apps. The Office for Civil Rights of the Department of Health and Human Services (HHS), the Federal Trade Commission (HHS), and the Food and Drug Administration (FDA) have been the most involved in regulating health apps. HHS plays a major role in monitoring HIPAA violations, while the FTC has the capacity to regulate false and deceptive advertising and has acted against several apps making false health claims. It has also expressed "the sensitive nature of health information and noted that lack of attention to privacy could lead to an erosion of trust in the mobile marketplace," and in 2021 the FTC noted it would enforce the HIPAA breach rules even for wellness apps that do not typically fall under HIPAA. For a complete discussion of guidance offered by the FDA on mobile medical apps, as well as an explanation of HIPAA adherence in using mHealth, please refer to Section I of this document.

Given the absence of the aforementioned—and other—formal governing bodies' oversight of the development and use of apps, some sources have taken a stance that the responsibility for ethical use rests solely on the licensed clinician and that it is advisable to include information related to mHealth apps in informed consent. Developers of private mHealth apps may be subject to available product liability claims that are related to design defects, breach of warranty, or a failure to warn.

D. Other Legal and Ethical Considerations

The Computer Fraud and Abuse Act of 1986 prevents unauthorized access of data from a person's computer. The Electronic Communications Privacy Act of 1986 bars unauthorized interception of communications and accessing of stored communications with the exception of user consent. User consent allows apps to bypass this act and transmit data to third parties. The issue is that many privacy policies could be considered ungenuine reflections of autonomous choice, where they are not written in plain language to explain practices that highly affect users such as data collection, storage methods, risk of data leak to the public, unexpected consequences of data leaks or transmission, potential of data use for research, data ownership, access, profit agreements, and options to quit or remove data after collection starts. Each person has the right to decide how risk-averse to be, and many software agreements and app use agreements are not sufficiently clear and transparent to enable this decision-making.

As many mHealth apps do not have an evidence base supporting their use, it is important for clinicians who are considering using apps in clinical care to evaluate the app themselves before recommending it to a patient. Children and adolescents are most likely to gravitate toward mHealth app use given preferences toward digital communication, convenience, accessibility, discretion, and low cost of these services; however, some developers may take advantage of this vulnerable population. Vetting an app prior to use can be helpful. The way an mHealth app incorporates safety is also important: Does the app tell patients to seek professional help in case of an emergency or suicidal ideation? Does the app provide a working suicide crisis line number? Does the app have a disclaimer stating that this app is meant to complement not replace professional health care? Apps that do not include these disclaimers are at increased risk of jeopardizing a patient's safety.

When introducing an app to a patient, it is recommended that the app be used in conjunction with traditional care. For instance, if the app is used to improve safety, the clinician should complete their own safety assessment and create a safety plan with the patient. Then, the app may be incorporated as additional support, not to replace treatment**.**

When in doubt, core medical ethical principles of beneficence, nonmaleficence, justice, and autonomy can be used to guide decision-making. Apps can enable vast data collection, especially those using digital phenotyping, and consideration for use of the data to benefit care outcomes must be weighed against risks. Capturing data for the sake of data capture will likely not be supported when considering the ethical principle of beneficence. Using apps to augment care but not to replace evidence-based care is well-aligned with the ethical principle of nonmaleficence and even current FDA approvals, which are

only for apps to augment ongoing clinician-directed care. Assessing digital literacy and ensuring equal access aligns with justice and autonomy.

Finally, with respect to informed consent, there are a number of factors that a clinician should consider and discuss fully with patients in an informed consent process prior to use of a mental health app in treatment. While this document will not enumerate those in detail, these considerations are identified in Opinion N.32 of the APA Ethics Committee, which is available within the Opinions document.

Payment Models, Billing, and Coverage

Many payers, including federal (Medicare), state (Medicaid), and private insurance companies are investing in a transition in payment models from "volume" to "value." This topic remains under active consideration and in flux at the time of this report. As a part of incentives for providers to make this transition, payers are beginning to adopt reimbursement models that include the use of technology in reimbursement and may reflect any improvements in health outcomes that arise from the incorporation of technology into care. Since the passing of the HITECH (Health Information Technology for Economic and Clinical Health) Act in 2009, health care professionals and hospitals have been incentivized to adopt various technologies into care, including electronic health records, electronic prescribing, and more.

Moreover, this move to adopt technology was further integrated into payment models with the passage of additional legislation via the Medicare Access and CHIP Reauthorization (MACRA) Act of 2015 by providing incentives for health care providers to adopt alternative payment models (APMs), featuring the use of technology in reimbursement calculations.

However, there are still only a limited number of use cases where various mHealth solutions are specifically enumerated in medical coding for reimbursement via Current Procedural Terminology (CPT®). While some remote patient monitoring (RPM) codes have been in place for some time for the purposes of monitoring patient physiologic symptoms (e.g., portable EKG, and other sensor technology), the specific application of CPT for mobile apps remains in development by the American Medical Association (AMA). New proposals such as draft federal mental health legislation and various local and state efforts suggest that there is interest in soon beginning to reimburse clinicians for the incorporation of apps into care delivery. With broad changes in regulations around telehealth, it is likely there will be rapid progress in this area.

A. Future Possibilities for Digital Health Payment Models

In development at the AMA are "Category III" CPT codes that seek to address how mHealth technologies might be reimbursed in future CPT publications. Category III codes are those which are created to track the utilization of emerging technologies, services, and procedures. In the future, these might be used to set reimbursement policy for the use of certain apps. Also, it remains to be seen whether current RPM codes might be used for monitoring symptoms or physiologic states specific for mental health. As new

technologies emerge that are capable of connecting to a mobile device and capturing data via an app, CPT codes designed to set reimbursement rates for such use may evolve.

Future Directions & Other Applications for This Work

While this resource package offers a snapshot of the current digital mental health landscape, the field is evolving rapidly, bringing with it possibilities and caveats. For instance, while the use of digital health tools has the potential to complement traditional clinical intervention, evidence about the efficacy and appropriate application of these tools is still emerging. Moreover, the use of these tools is currently limited to those who have access to the technology and who can use it consistently and effectively (see the explanation of "digital literacy" and the "digital divide"). To that end, institutions such as the American Psychiatric Association must assume responsibility for continuing advocacy work on behalf of stakeholders to a) raise awareness of digital health treatments, b) promote research in digital mental health, and c) engage in robust dialogue with stakeholders around payment models for these adjunct treatments.

As technology continues to advance, we must ensure that each health profession is appropriately prepared to incorporate these advancements into practice. This means that education preparation programs need to incorporate the use of technology into curricular content. We all must be able to describe, use, incorporate into delivery of care, communicate about, and adhere to ethical and organizational policies around information and communication technologies. To achieve these competency expectations, health care professions and organizations must provide learning opportunities in addition to staying apprised of the ever-changing environment of technology. While this is not an easy task, if we keep the basic principles of high-quality care in mind, we can judge developments and continue to harness technology to benefit our patients.

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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