The Ethical Use of Mobile Health Technology in Clinical Psychiatry

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Abstract

The rapid rise of mobile health technologies, such as smartphone apps and wearable sensors, presents psychiatry with new tools of potential value in caring for patients. Novel diagnostic and therapeutic applications of these technologies have been developed in private industry and utilized in mental health, although these methods do not yet constitute standard of care. In this paper, we provide an ethical perspective on the practical use of this novel modality by psychiatrists. We propose that in the present context of limited scientific research and regulatory oversight, mobile technologies should serve to enhance the psychiatrist-patient relationship, rather than replace it, in order to minimize potential
clinical and ethical harm to vulnerable patients. We analyze areas of possible ethical tension between clinical practice and the consumer-driven mobile industry, and develop a decision-tree model for implementing ethical safeguards in practice, focused on managing risk to the therapeutic relationship, informed consent, confidentiality, and mutual alignment of treatment goals and expectations.

**Keywords:** Mobile Health, Technology, Ethics

**Introduction**

With over 165,000 healthcare-related smartphone apps already developed (IMS Institute, 2015), mobile technology offers new opportunities for enhancing the clinical care of individual patients and for improving the health of populations. Smartphones, tablets, and wearable devices, such as digital watches and sensors, have been broadly embraced (Marzano et al., 2015). Customized programs, called apps, can run on these mobile devices, gathering information such as self-reported symptoms of mood or anxiety, behavioral data such as step count and geographic mobility, and physiological measures including heart rate and sleep patterns. Other apps have been proposed to offer emotional support, behavioral coaching, medication reminders, and even psychotherapy. The potential of these mobile technologies to transform psychiatry through expanded access to care, new monitoring tools, and novel adjunctive interventions has been widely touted (Eapen and Peterson, 2015; Proudfood, 2013). Especially in underserved areas, the use of mobile technology to address mental health needs has been identified as a way to overcome significant barriers to care. Indeed, the potential problem of lack of mobile technology device ownership among psychiatry patients is rapidly diminishing (Firth et al., 2015). Currently 64% of the United States’ population owns a smartphone, and ownership rates are expected to escalate (Smith, 2015).

Interest in mobile technology for psychiatry is rapidly growing within the industry, as individuals from different sectors of society appear to be increasingly invested in using their smartphones for mental health (Torous et al., 2014a; Torous et al., 2014b). Most apps are marketed directly to
individuals, consistent with a general movement toward empowering patients as consumers of health care. At best, these developments could promote more timely access to self-directed clinical intervention, as well as greater collaboration with physicians in clinical decision-making. At worst, these technologies could misinform or deceive patients about their care, resulting in substandard clinical intervention that may precipitate harmful outcomes. In October 2014, for example, a British mental health group called Samaritans introduced a mobile app that sought to screen social media postings for signs of depressed mood or suicidal ideation, and to utilize social network members as safety contacts (US Federal Trade Commission, 2016). Samaritans withdrew the app 9 days later, after a backlash of consumer fears that this non-clinical arrangement could lead to targeting of vulnerable, depressed individuals (Orme, 2014). In January 2016, the company Lumosity, which sells cognitive training programs and apps directly to consumers, settled charges by the United States Federal Trade Commission (FTC) that it deceptively claimed company products could delay cognitive symptoms associated with dementia (US Federal Trade Commission, 2016). According to the FTC, the company “preyed on consumer fears” about aging-related cognitive impairment, and failed to provide scientific evidence to support its claims (US Federal Trade Commission, 2016). In both examples, the pace of mobile app development in industry exceeded the rate at which clinical responsibilities and evidence-based practice could adapt to this new technology.

Clinical research on mobile technologies in psychiatry remains a nascent field, consisting primarily at this time of feasibility studies for use in depression (Bindhim et al., 2015), post-traumatic stress disorder (Kuhn et al., 2015), bipolar disorder (Faurholt-Jepson et al., 2014), schizophrenia (Benzeev et al., 2014), substance use disorders (Gustafson et al., 2014), and many other psychiatric conditions, although initial randomized clinical trials are underway. Numerous questions remain about the validity, efficacy, side effects, and even safety of mobile apps. Preliminary research suggests that smartphone interventions are not simple digital translations of existing tools, but rather complex and
dynamic instruments and processes that will require serious clinical investigation. Even basic psychiatric scales such as the PHQ-9 may record significantly different scores when captured on a smartphone (Torous et al., 2015), and therapies delivered in person may not always remain efficacious when digitally delivered (Heffner et al., 2015). Some apps can even cause harm to patients, as in the case of one blood alcohol level calculation app that appears to have encouraged a subset of patients to drink more instead of less (Gajecki et al., 2014). There is even less data for wearable technologies like fitness trackers with little known about their benefits and risks for use in clinical psychiatry.

Presently, the United States’ Food and Drug Administration (FDA) offers minimal regulatory oversight for smartphone apps and wearables. The FDA states that it plans to regulate those apps which pose high patient risk, or apps that turn a smartphone into a medical device with the purpose of diagnosing or treating a specific medical condition (U.S. Department of Health and Human Services, 2015). In psychiatry, however, where self-reported symptoms may be considered diagnostic and psychosocial interventions are therapeutic, it can be easy for consumer-marketed apps to blur the line between wellness and clinical care, or between self-enhancement tool and medical device. There are also limited professional society guidelines or recommendations in the use of mobile technology for patient care. App rating services, such as the British government’s National Health Service App Library, have recently closed due to difficulty curating healthcare apps (Sunyaev et al., 2015). There are few resources for psychiatrists to turn to for evaluating the role, value, and impact of apps.

Given the gaps in clinical knowledge about specific benefits and risks of mobile apps in psychiatry, and the general lack of regulatory standards in this area, how should psychiatrists safely incorporate mobile technologies into clinical practice? How can psychiatrists best protect patients from anticipated, but currently unproven or unofficial, clinical harms from a technology that does not yet constitute standard of care? We propose here an ethical framework, grounded in an analysis of potential ethical conflicts between clinical practice and the consumer-driven mobile industry, to help
guide the use of mobile apps in patient care today. We present an ethical rationale for this framework with selected case examples of mobile app use in psychiatry, and propose safeguards that psychiatrists can apply to ensure safe and ethically appropriate incorporation of this novel modality into standard clinical practice.

**Ethical tensions between psychiatry and the mobile industry**

There are many conceivable situations where business motivations and psychiatric care priorities overlap in mobile health, and the adoption of mobile apps in these cases will be straightforward. However, there are also possible areas where ethical conflicts may arise – specifically along fault lines where ethical values do not align precisely – and it is these situations that may lead to ethical risk and even clinical harm at later stages of patient care.

For the consumer-driven mobile industry, conflicts may arise in how patient autonomy is balanced with clinical care needs. Direct-to-consumer products assume that customers are autonomous individuals with the right to choose which products to purchase at any given time (Carroll and Buchholtz, 2003). In contrast, clinical psychiatry views each patient as a medical imperative – an individual with unique vulnerabilities, resiliencies, and goals, exhibiting an unmet health need for the physician to address (Beauchamp and Childress, 2001). The physician’s duties are to “do good” and to “do no harm” in serving the health and wellbeing of the patient, which may involve varying degrees of accommodating patient preferences within appropriate standards of care (Siegler, 1981). In some cases, the business paradigm will be at odds with the accommodation model of the physician-patient relationship, particularly in situations where a patient’s mental health condition limits his or her insight, and therefore affects the authenticity and rigor of personal decision-making.

Pharmacological agents such as antipsychotics, for example, are often marketed directly to consumers, but cannot be accessed by patients without a physician’s prescription. This measure allows for appropriate medical evaluation of the patient, who may be experiencing symptoms of severe mental
illness, and for careful balancing of clinical risks, benefits, goals, and necessities in an open and professional manner (Siegler, 1981). The same does not apply to mobile apps that are available directly to consumers, creating a gap in protection for vulnerable patients.

Conflicts in confidentiality are also unique concerns to mobile health. Physicians must adhere to privacy guidelines, most often with the expectation that patient consent is required prior to disclosing private or clinical information to a third party, with important legal exceptions (Beauchamp and Childress, 2001). Purchasing a consumer product, however, involves an implicit assent to the product’s presence within a consumer’s daily life. For a mobile app, this may include an entire "behind-the-scenes" mechanism for data encryption (if any), handling, storage, analysis, and even sharing. In addition to self-reported data, these systems can also capture passively acquired data, with variables such as geographic location of the mobile device, call logs, purchasing history, or wireless connection signals that the user does not need to actively input. Together, these large aggregate datasets have become a commodity today, as technological advancements in data mining offer an enhanced ability to predict consumer behaviors, motivations, and interests. Mobile companies and app developers may base their entire business model around and reap significant financial rewards from access to and the selling of personal data, for example, in providing patient profiles to the pharmaceutical industry (Glenn and Monteith, 2014). From a business perspective, there is often great incentive to collect consumer data through mobile devices, in contrast to the medical obligation to uphold patient confidentiality (Carrns, 2013).

Companies may also engage in deception (as in the case of Lumosity mentioned above), where information about product technology or data access is selectively disclosed, or even silenced, in an attempt to attract a customer. This stands in contrast the physician’s duty to be truthful and to not leave patients with misimpressions of their clinical care (Roberts, 2016). Physicians also have a duty to honor their commitment to patient care (Roberts, 2016), whereas companies have a legal obligation to honor
their contracts – written agreements that may suit patient needs at a specific time point in their illness, but which may not easily adapt as patient goals evolve.

**Mobile health as an adjuvant tool**

As a foundation for ethically sound care, we propose first that mobile health technologies serve as an adjuvant to the psychiatrist-patient relationship (Hsin et al., 2016). To illustrate, we provide a series of case examples (Table 1). Ideal use of these technologies, as exemplified in Case 1, occurs when these tools enhance the psychiatrist’s ability to deliver high-quality clinical care. Open discussion and use of mobile technologies within the therapeutic relationship ensures that potential benefits and harms can be weighed while remaining faithful to standard of care, and while appropriately balancing patient autonomy with clinical needs. The therapeutic context also allows for confirmation of the mobile app’s veracity (Case 2), and the proactive examination of confidentiality concerns (Case 3). Finally, the therapeutic context can clarify how mobile technology aligns with treatment goals, so as not to introduce potential gray areas of therapeutic misconception (Appelbaum et al., 1982) where patients may believe that their interaction with the mobile app constituted standard of care, when in fact it did not (Case 4).

**Table 1. Cases of mobile technology use in psychiatric care**

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<th>Therapeutic role of mobile health</th>
<th>Benefit exceeds risk</th>
<th>Risk exceeds benefit</th>
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<td>Case 1: A 22 year-old man struggles with new-onset panic attacks, but is unable to find a local therapist. He sees a psychiatrist who prescribes fluoxetine, and recommends that he download a mobile application for cognitive behavioral</td>
<td>Case 2: A 33 year-old man with post-traumatic stress disorder from childhood physical abuse experiences a recurrence of flashbacks after he was violently assaulted in the street. His psychiatrist prescribes him sertraline but he is unable to find a local</td>
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Guided by this technology, the patient is able to identify triggers and automatic thoughts associated with each panic attack successfully, and to perform cognitive re-appraisal techniques on his own. Four weeks later, the patient follows up with his psychiatrist and his symptoms have improved greatly.

| Monitoring role of mobile health | Case 3: A 56 year-old woman with a history of chronic depression and low suicidal risk has trouble recalling her mood fluctuations at her clinic appointments. She also occasionally forgets her daily dose of medication. Her psychiatrist recommends she download a mood-monitoring app on her mobile device. He reminds her that he will keep any recorded clinical data confidential; however, the app’s terms and conditions indicate that the app’s creator may record her data anonymously. The patient | Case 4: A 19 year-old woman with chronic depression and borderline personality disorder downloads a mood-monitoring app so that her psychiatrist can monitor her symptoms remotely. She frequently reports thoughts of self-harm at baseline, but does not always act on them. One day her boyfriend broke up with her and she feels the urge to cut herself again. When her mobile phone automatically prompts her to record her symptoms, she reports thoughts of self-harm and then begins to cut her arm with a razor. Her psychiatrist receives notification of |
consents to use of the app. With daily prompts from this device, she is able to record her mood and the data is automatically uploaded to the psychiatrist’s computer. The app also prompts her to take her medications daily, thereby boosting her adherence. At her next visit, the psychiatrist notes that her mood measurements have improved on her current dose of psychotropic medication, and consequently he continues her current treatment regimen.

her last mobile entry but does not respond because it appears no different than her previous entries.

Provider education is a critical component of mobile health. Much like how a provider must understand the pharmacology of a medication before prescribing it, providers should educate themselves about the functions and terms of a mobile app before they recommend it. For provider- or health system-based models of mobile health, physician vetting and training of mobile apps may already be part of the product package. For the thousands of direct-to-consumer apps, however, this may not be the case.

An ethical framework

For the psychiatrist faced with increasing patient interest in mobile health, what are some safeguards that can be implemented in practice to prevent potential harms? A framework, such as the safeguards proposed for off-label novel uses of pharmacologic agents (Hoop et al., 2009), would be useful in this role. Within the context of the psychiatrist-patient relationship, therefore, we propose a
series of steps to help ensure ethical use of mobile technologies in psychiatric care (Figure 1). First, the psychiatrist should begin by asking whether mobile technology use could provide a benefit to the patient under his or her care. Is there a potential for the mobile technology to improve patient health, or to enhance the efficacy of the psychiatrist-patient relationship? In the absence of clinical outcomes data, clinical benefit can be referenced with respect to the therapeutic relationship.

Figure 1: Ethical safeguards for use of mobile technologies in clinical practice

If there is a potential benefit, the psychiatrist can next ask whether there are potential risks to the psychiatrist-patient relationship. This involves consideration of both the limited evidence base
documenting potential clinical risks of mobile technology use, as well as the recognition of the broad spectrum of severity characterizing psychiatric illnesses, which often necessitates a personalized approach to care. Patients at high safety risk, for example, or patients with chronic mental health conditions with high risk of relapse or recurrence and potentially limited insight or judgment, may be uniquely vulnerable to perturbations in the therapeutic relationship. At the extreme, a patient may not have the capacity to provide informed consent to use mobile technology. Other patients may have decisional capacity to consent, but are so impulsive with a history of dangerous consequences that the added sub-context of mobile health may complicate clinical care, or create unwanted space for misimpressions or miscommunication to flourish. We can conceptualize a “sliding scale” of patient vulnerability, subject to change over time, with respect to the therapeutic relationship. At higher levels of vulnerability, the psychiatrist may consider whether to incorporate additional risk management strategies, such as increasing access to the psychiatrist, involving patient collateral or family members, or liaising with additional safety resources (e.g., patient groups, other health service providers).

If potential benefits are clear and potential risks are deemed manageable within the therapeutic relationship, then the psychiatrist should next obtain informed consent from the patient for use of the mobile technology. This step is important to help inform and protect vulnerable patients. Ethical elements of informed consent include the sharing of information with the patient, the assessment of decisional capacity of the patient, and the consideration of a patient’s authenticity of choice (i.e., voluntarism) (Roberts, 2016). The information sharing process should include disclosure of known and theoretical benefits and harms, as well as the limits of the evidence base given the nascent research thus far regarding clinical effectiveness of mobile technologies. With respect to voluntarism, the psychiatrist should be aware of potential coercive pressures on the patient to incorporate mobile technology into his or her care; examples include direct-to-consumer advertising from the mobile
industry, or social pressures to engage with new technology. Proactive discussion of these potential conflicts may mitigate unanticipated consequences of coercion.

Next, the ethical tension in confidentiality between psychiatry and the mobile industry needs to be shared prior to initiation of mobile technology use. An informed discussion about risks to patient confidentiality with respect to data collection, archival, sharing, and even selling with additional parties should take place, and patients should be encouraged to know the terms of contract for their mobile application package. This information should be located on the terms and conditions or privacy policy page of an app, although a recent research study found that only 30% of the 600 most commonly used health apps actually had a privacy policy (Sunyaev et al., 2015). Many patients may be surprised to learn that many apps make no guarantees of privacy, and instead may actually sell any patient reported data (Carrns, 2013). Passively acquired data, in particular, presents the possibility that user data may be acquired without the patient’s direct knowledge. Many companies also contract with cloud services, where data is uploaded to third party servers that may or may not honor their own privacy contracts. Additionally, patients may also need to be aware of other individuals with access to their mobile device or mobile data. Discussing potential lapses in confidentiality will assist patients and psychiatrists in making an informed decision about mobile technology use in their care.

Last, the psychiatrist is advised to both initiate and maintain an ongoing dialogue with the patient about whether mobile technology use mutually aligns with treatment goals and expectations. Similar to how pharmacological agents are evaluated and re-evaluated in the context of a treatment plan, mobile technologies should also be appraised within this framework. For example, what are the goals of care improvement by technology use, and how can efficacy be assessed? At what point can the psychiatrist and patient agree that the technology is causing more harm than benefit, or that benefit is no longer present? By defining the precise aims of mobile technology use, the psychiatrist can help to ensure that the technology is used in a manner faithful to the patient’s overall goals of care.
Conclusion

There is rapidly growing interest in the use of mobile technologies to advance mental health. As these technologies are embraced by patients and the public at large, psychiatrists will need to be able to incorporate these methodologies into ethically sound clinical practice. As with any form of clinical innovation, there is the potential for benefit and for risk – and, in this case, the risks relate to clinical considerations, as well as challenges in fulfilling ethical standards fundamental to medical practice. We suggest that there may be ethical tensions in the use of mobile technologies in psychiatric care because of the differences in the ethical basis of the psychiatrist-patient relationship and the mobile industry-consumer contract. Nevertheless, mobile technologies for monitoring and therapeutic purposes may have great value if they are integrated into the therapeutic relationship and goals in patient care. As an adjuvant to existing therapeutic modalities, and with careful safeguards, these new technologies may strengthen patient care practices.

Mobile technologies occupy a unique clinical space today – similar to a treatment tool with respect to the need for informed consent, confidentiality discussion, and treatment goals, yet different with respect to a lack of clinical need above standard of care that could inform a clear risk-benefit ratio. Currently, it appears that mobile technologies are responding to a strong preference among patients for greater autonomy and participation in health care decisions. We therefore propose that benefits and harms of mobile technology at this time should be weighed in terms of impact on the psychiatrist-patient relationship, the source of autonomy in clinical decision-making today (Siegler, 1981). In the future, mobile health could evolve toward a clinical function, especially as the clinical evidence base develops, or the FDA occupies an enhanced regulatory role, or professional organizations like the American Psychiatric Association develop standards. With additional data in the future, the benefits and harms of mobile technology may become more salient with regard to clinical outcomes rather than the therapeutic relationship, and appropriate safeguards for mobile technology may evolve toward a more
clinically oriented framework for incorporating innovative tools into practice – much like how pharmacological treatments are conceptualized today (Hoop et al., 2009). Until then, psychiatrists are advised to apply a distinct, ethically motivated framework for clinical use of mobile technologies.

References


