Regulating Mobile Mental Health Apps

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Abstract

Mobile medical apps (MMAs) are a fast-growing category of software typically installed on personal smartphones and wearable devices. A subset of MMAs are aimed at helping consumers identify mental states and/or mental illnesses. Although this is a fledgling domain, there are already enough extant mental health MMAs both to suggest a typology and to detail some of the regulatory issues they pose. As to the former, the current generation of apps includes those that facilitate self-assessment or self-help, connect patients with online support groups, connect patients with therapists, or predict mental health issues. Regulatory concerns with these apps include their quality, safety, and data protection. Unfortunately, the regulatory frameworks that apply have failed to provide coherent risk-assessment models. As a result, prudent providers will need to progress with caution when it comes to recommending apps to patients or relying on app-generated data to guide treatment.

1 INTRODUCTION

While information and data technologies have successfully disrupted various "bricks-and-mortar" (legacy or traditional) industries, such as retail and music or video distribution, they have been less successful in

This is the author's manuscript of the article published in final edited form as:

Terry, N. P., & Gunter, T. D. (2018). Regulating mobile mental health apps. *Behavioral Sciences & the Law, 36*(2), 136–144. https://doi.org/10.1002/bsl.2339

disrupting healthcare delivery (Terry, 2013). Notwithstanding this, mental healthcare remains a prime candidate for disruptive technologies that can provide access to care of some kind to a population that has continually challenged the healthcare system. In large part this may be triggered by the relative failure of legacy healthcare and its financing models to deal with increasing mental health populations that are not infrequently marginalized and distant from centers of care. In the United States alone, more than 43.4 million adults (about 18%) suffer from mental illness (National Institute of Mental Health, 2015) In addition to formally diagnosed mental illness, some authors express concern about behaviors that may signal mental health issues, such as increases in self-harming behavior and suicidal ideation among young people (Mercado, Holland, Leemis, Stone, & Wang, 2017).

This article places the current generation of mental health apps in their technological context and suggests a basic typology. After an introduction to general categories of apps, the article focuses on some of the quality, safety, and data protection issues raised by these apps and explores the fragmented approaches taken by regulatory agencies. Of course, utilizing mental health apps to diagnose or manage mental health conditions is not without the potential for adverse events given that excessive media screen time has been linked to depression and suicide-related outcomes, particularly when combined with decreases in socialization and other terrestrial activities known to be associated with wellness (Twenge, Joiner, Rogers, & Martin, 2017). Nonetheless, for the purposes of this article we shall assume that apps may have a role in facilitating access to services without raising risk. As noted by David Dobbs in his interview with Dr. Tom Insel, the former director of the National Institute of Mental Health, “At any given moment, roughly one in seven of the world's 7.5 billion people is struggling with mental illness. ‘We're not going to reach all those people by hiring more psychiatrists,’ says Insel. But we might reach them with smartphones” (Dobbs, 2017).

2 PROVIDER-FACING TECHNOLOGIES AND PATIENT-FACING MOBILE MEDICAL APPS

Emerging data-driven healthcare technologies such as MMAs can be classified as either provider-facing or consumer/patient-facing (Terry, 2016, 2017). Provider-facing technologies remain under the control of

legacy healthcare providers while consumer-facing technologies tend to be marketed directly to consumers or patients by developers or non-healthcare service providers to meet self-identified needs and/or promote products or services to meet those needs.

There has been exponential growth in the use of MMAs by both clinicians (Lewis & Wyatt, 2014) and patients (Taylor, 2015). Now, data-driven MMAs are rapidly iterating (Terry, 2017). Healthcare providers are increasingly utilizing data-mining to gain insights into their patient populations (Hede, 2016), and fast-emerging technologies such as virtual reality offer considerable promise for future mental health diagnosis and treatment (Freeman et al., 2017). In the mental health space, one of the largest technology deployments is the Veterans Administration's Recovery Engagement and Coordination for Health (REACH VET) program (Office of Public Affairs Media Relations, 2016). The program is attempting to reduce the 20-a-day veteran suicide rate by scanning six million patient records with predictive modeling software designed to determine which veterans are at the highest risk of suicide. There is growing evidence that AI/Machine Learning platforms fed large clinical databases produce more accurate prediction of suicide attempts than traditional methods (Walsh, Ribeiro, & Franklin, 2017).

Smartphones, their operating systems, and app ecosystems are what technologists label “platforms.” Platforms have value in connecting consumers to available apps and the services they perform directly (such as diabetes management) or link to (such as a home visit from a physician). Other platforms connect persons with other persons for some kind of mutual benefit (Church, 2017). Thus, social media networks such as Facebook are platforms. Some of these apps or other platforms may rely on data-mining.

More than 250,000 mobile medical apps (MMAs) are available for download. More than half of mobile phone users have downloaded a health-related mobile app (Krebs & Duncan, 2015). Regarding mental health applications, a simple search of the “medical” section of the U.S. App Store (Apple, Inc., 2017a) using the term “depression” yielded in excess of 100 apps. A broader “mental health” search of the same section returned an apparently random collection of apps promising help with anxiety, promoting hypnosis, recovery guides, bipolar symptom charting, alcohol consumption trackers, meditation guides,

suicide assessment, and so on. Given the sheer number of these apps and the anticipated growth in this market, a frame for thinking about what these apps do and how they might be regulated is proposed.

3 TYPOLOGY

There are already general typologies for MMAs (Terry, 2015) and it is now possible to identify at least four types of MMA or web-based app that concern mental health.

3.1 Self-assessment or self-help

Many MMAs focus on depression with algorithms initiated by a complaint of depression or one of its synonyms by the user. These apps may be mood charts seeking primarily to identify symptoms and make the user aware or they may attempt to leverage cognitive-behavioral therapy or behavioral activation to treat symptoms or problems entered by the app user. Many of the apps are essentially electronic "wrappers" built around the Patient Health Questionnaire (PHQ-9; Kroenke & Sptizer, 2002), which is a tool that catalogs symptoms of depression, asks users to rate the frequency of nine symptoms, and then asks users to estimate the level of disability caused by these symptoms. Self-help apps are also emerging. For example, one such app asks how you are feeling and suggests "missions" designed to improve your mood (Bakker & Rickard, 2017).

There is evidence that app-collected results correlate with those from clinical administration of the instrument (Torous et al., 2015). Other such assessment tools, such as Ecological Momentary Assessment, are also migrating to app platforms (Firth, Torous, & Yung, 2016). In late 2017, the FDA approved the "reSET" MMA, a prescription digital therapeutic designed to aid the treatment of substance abuse (United States Food and Drug Administration, 2017).

3.2 Connecting patients with online support groups

There is growing interest in designing social media support groups or other services designed to connect those with mental health problems to terrestrial or virtual sources of peer support (VanHemert, 2017). For

example, there are MMAs under development that have users enter contact information for their real-world friends and support group. Thereafter, a tap on the screen alerts the support group that the user needs help (SocialCode, 2014).

3.3 Connecting patients with human or virtual therapists

A similar model underlies MMAs that connect patients to mental health providers with the goal of providing video-based counseling or providing more general medical services. (Doctor On Demand, 2017). Other services are specific to mental health counseling (AbleTo, 2017). There is some indication that future therapy platforms will replace human therapists with AI-based models using analysis of empathic communications and non-verbal communications. For example, "Woebot is an automated conversational agent (chatbot) who helps the user monitor mood and learn about him or herself drawing from a therapeutic framework known as Cognitive Behaviour Therapy" (Molteni, 2017; Woebot Labs, 2017).

3.4 Predicting mental health issues

As is the case with MMAs generally, the controversial goals of some mental health app developers are patient-specific diagnosis and/or avoidance of dangerous behaviors. Current predictive apps tend to use physiological signs such as increased pulse or respiration as "tells" specifically indicating times of increased mental health symptoms. For example, Spire is a wearable electronic device that attempts to detect tension from breathing patterns (Spire, 2017). Future apps include ones that monitor facial expression and suggest a food type designed, for example, to reduce anxiety (Knapton, 2016). However, AI (specifically data-mining feeding predictive algorithms) will be increasingly important in predicting mental health issues before they occur or, at least, before they are diagnosed (Franklin et al., 2017).

Facebook, although not an MMA, does have platform characteristics. It combines several MMA-like features, integrating suicide prevention tools to in its "apps" such as Facebook Live and chat support through Messenger with crisis support organizations such as the National Suicide Prevention Lifeline. Its

approach to indications of possible suicide initially relied on “friend” reporting. However, increasingly it is turning to AI and pattern recognition to flag posts for review by the company's community operations team (Constine, 2017; Facebook, 2017).

4 APP-BASED MENTAL HEALTH INTERACTIONS: CONCERNS AND REGULATORY MODELS

There are well-established concerns surrounding MMAs, such as their quality, safety, and data security (Terry, 2015). Just as these technologies broadly tend to be either provider-facing or consumer/patient-facing, so that distinction is also helpful in determining the type or level of regulation. In general terms, the Food and Drug Administration (FDA) has shown more interest in regulating provider-facing MMAs as medical “devices” than in pursuing those that are consumer/patient-facing, which are often considered to be self-help, education, or recreation. As discussed in the following, this tendency has been confirmed by recent legislation and policy statements from the agency.

Provider-facing apps also are somewhat more likely to be covered by the federal Health Insurance Portability and Accountability Act (HIPAA) privacy and security rules (HIPAA Administrative Simplification Regulation Text, 2013) because they are prone to use or prescription by healthcare professionals (“covered entities”). However, app developers, data storage or processing companies, and consumers will seldom fall under that regulatory language. As a result, most MMAs exist in a relatively unregulated “HIPAA-free zone.”

In contrast, the jurisdiction of the Federal Trade Commission (FTC) is not limited by sector and applies to data custodians both inside and outside the HIPAA “zone” (*In the Matter of LabMD, Inc., a corporation*, 2016). However, in general the FTC's consumer protection powers are limited to cases involving deceptive or misleading conduct or claims by developers or data companies and not applicable to the intrinsic quality or data protection properties of MMAs. Overall, because of gaps in regulatory models

and different priorities followed by regulators, the quality, safety, and data protection concerns regarding MMAs are amplified by regulatory indeterminacy (Terry, 2016).

In addition to concerns about specific apps, mobile hardware and software platforms are still relatively immature. For example, at least one of the mobile platforms is still plagued by multiple security flaws such as malware (Greenberg, 2017) and remote code execution (Nichols, 2017). Furthermore, some mental health apps are attempting to leverage features that are still new enough that they should be viewed as almost experimental. This is particularly the case with voice interactions: "When asked simple questions about mental health, interpersonal violence, and physical health, [conversational agents] responded inconsistently and incompletely" (Miner et al., 2016).

5 QUALITY AND EFFICACY

It is relatively simple for even a novice user of, say, GPS or social media mobile apps to determine whether they are efficacious (i.e., they do what they claim) and possess an interface or feature-set of appropriate quality. It is far harder to judge the efficacy and quality of MMAs. Indeed, the evidence base for mental health MMAs is extremely low. This is true even for apps that are recommended or curated by responsible third parties. For example, only 15% of U.K. National Health Service (NHS)-accredited app-based psychological interventions, were backed by effectiveness data (Leigh, 2016). It would be expected that the applicable metric and process for judging MMA quality is the randomized and controlled human clinical trial (RCT). However, it has been suggested that participatory research frameworks would be better suited to MMA development and would increase preliminary appraisal (Nicholas, Boydell, & Christensen, 2016).

Regarding MMA regulation, the FDA tends to focus on safety issues. Therefore, the question of whether apps do what they claim to do is an area that has essentially been ceded to the FTC. The latter agency has successfully argued in the courts that an RCT evidence base is required to adequately substantiate health claims (*POM Wonderful, LLC v. F.T.C.*, 2015). The FTC has consistently applied this standard in MMA

cases. For example, in the case of an app that used a camera phone to photograph a mole and then determined the mole's melanoma risk, the developers settled the agency's claims of deceptive marketing (Federal Trade Commission, 2015a). Similar results were reached in cases involving developer claims that their apps could improve users' vision (Federal Trade Commission, 2015b) or train specific areas of the brain, thereby protecting against dementia and Alzheimer's disease (*FTC v Lumos Labs, Inc*., 2016). Mimicking the FTC's federal role, state consumer protection laws and regulators are assuming greater importance. For example, in 2017 the New York Attorney General settled claims with three MMA developers over misleading claims regarding efficacy and irresponsible privacy practices (New York Attorney General, 2017).

6 SAFETY

Broadly stated, the legal system takes two approaches to the safety of medical hardware and software: pre-marketing regulation by the FDA; and post-marketing state tort (liability) law. As to the former, the Federal Food, Drug, and Cosmetic Act views most medical software and hardware as "devices," and so subjects them to some form of pre-marketing scrutiny (21 U.S.C. ch. 9 § 301). Beginning in 2013, the FDA has treated MMAs on the basis of sub-regulatory "Guidance" (Terry, 2015). Essentially, the FDA took the position that some MMAs involve such low risk (e.g., coaching, prompting, or communication apps) that the agency could exercise its regulatory discretion. This approach, particularly as it applied to fitness and other health apps, was confirmed by Congress in the 21st Century Cures Act (Pub.L. 114–255, 2016). Subsequently, the FDA Commissioner has outlined a less onerous regulatory model for all MMAs, abandoning pre-marketing approval in favor of pre-certification of some app developers or post-marketing surveillance (Cortez, Terry, & Cohen, 2017).

As to the latter, tort liability is a matter of state law and so is not uniform. However, in general terms, strict product liability could apply to the developers and manufacturers of defective hardware and software. Such liability could extend to healthcare providers who sponsor or commission MMAs. Potentially, healthcare providers who recommend or supply apps to patients could face negligence-based

medical malpractice liability (Terry & Wiley, 2016). Prudent providers should refrain from recommending MMAs they are unfamiliar with and favor those that are FDA-approved, that are curated by well-informed institutions, or that have been subject to favorable peer-reviewed research.

7 DATA PROTECTION

Mobile medical apps have attracted considerable critical attention from privacy advocates. Frequently they lack adequate privacy policies and exhibit critical security vulnerabilities, such as failing to employ encryption. Most importantly in the U.S., the HIPAA privacy and security rules only apply to "covered entities" (essentially legacy healthcare providers) and their business associates (U.S. Department of Health and Human Services, 2013). However, as discussed earlier, MMAs tend to be developed outside of traditional healthcare spaces with the result that they exist in a lightly regulated, "HIPAA-free zone" (Terry, 2015).

Even well-meaning app developers can discover that their MMAs have serious unintended consequences. For example, in 2014, the Samaritans, the well-known U.K.-based suicide prevention organization, launched a predictive app called "Radar" that scanned a user's Twitter feed looking for keywords suggesting depression or suicidal ideation (Orme, 2014). However, some users complained that the app might expose vulnerable targets to bullying or shaming. The Samaritans ended up closing the app and deleting all of the data associated with it (Orme, 2014).

Mobile medical apps populating the "HIPAA-free zone" are not completely unregulated. For example, the FTC possesses general powers to regulate "unfair or deceptive acts or practices" (15 U.S. Code § 45, 2017). While the agency has exercised those powers against corporate entities with multiple security lapses (Federal Trade Commission, 2015c), most of its data protection cases involve entities failing to live up to their own privacy policies (Federal Trade Commission, 2017). The agency also has published data protection guidance for app developers (Federal Trade Commission, 2013) and, in cooperation with the

FDA and the Department of Health and Human Services, created an interactive guidance for MMA developers (Federal Trade Commission, 2016).

Arguably of greater practical importance in ensuring that data collected by MMAs is protected is "private ordering," whereby app developers are bound by contractual rules. For example, Apple's App Store rules prohibit the use of "data gathered in the health, fitness, and medical research context … for advertising or other use-based data mining purposes other than improving health management." Additional protections apply to apps that use HealthKit to support clinical research (Apple, Inc., 2017b). In contrast, doubts have been expressed about how effectively Android apps in the Google Play store are screened for malware or other security flaws (Castillo, 2017).

Increasingly, healthcare providers may find themselves drawn into similar roles as the app stores. One survey found that more than a third of physicians had recommended a health app to a patient (Comstock, 2014). The prudent provider should check to see if apps they are asked to recommend are the subject of "best practices" publications or have been approved by well-informed intermediaries. For example, some public healthcare systems such as the NHS in the U.K. (Meek, 2015; National Health Service, 2017) and VicHealth in Australia (VicHealth, 2017) now curate apps in recommended "libraries." Overall, with regard to data protection, the takeaway for the prudent provider is that in many cases satisfactory data protection (e.g., that provided by the HIPAA rules) simply does not apply to many MMAs, suggesting that considerable caution is required before making recommendations to patients.

8 CONCLUSIONS

Mobile medical apps, including mental health apps, remain in their infancy. Despite this, consumers are downloading them in their millions and increasingly trusting them (Elias, 2015). The technology platforms they rely on (e.g., phones and wearables) are iterating at an astounding rate of innovation (Papillon, 2017). New technologies that will be added to those platforms, such as AI (Reichert, 2017) and augmented reality (Elgan, 2017), will be transformative. The next generation of diagnostic and condition-

monitoring mental health apps may well (and controversially so) rival trained professionals and challenge the primacy and our understanding of the physician–patient relationship. For example, the DARPA-funded SimSensei project features virtual agents that display high levels of artificial emotional intelligence and engage convincingly in back-and-forth interactions with people (Cremin, 2016).

However, reviews of the risk-assessment literature suggest that regulatory agencies have been less than helpful in developing workable risk frameworks to assess MMAs (Farr, 2014; Lewis & Wyatt, 2014). In part, this is a substantive problem. For example, the privacy and security rules that regulate traditional provider–patient interactions are inapplicable to most app–patient interactions. Similarly, the FTC has relatively limited jurisdiction (and resources) leading to enforcement actions against only the most flagrant offenders who mislead consumers. There are also political considerations. Notwithstanding the passage of the 21st Century Cures Act, the FDA still has extensive regulatory authority that can be levied against many MMAs and wearables. However, the agency seems to be taking a different path, attempting to make regulation more palatable to high-tech companies. The deficiencies of these regulatory frameworks must not be allowed to mask the effectiveness, safety, and data protection issues that are raised by MMAs.

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