OVERSIGHT FOR MOBILE APPLICATIONS THAT ASSESS AND TREAT MENTAL ILLNESSES

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By

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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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MENTAL HEALTH APPS IN THE CONTEXT OF THE MINDTRAILS PROJECT

One-third of the US population will develop an anxiety disorder at some point in their lives (Beard, 2011). Anxiety causes individuals to have poorer quality of life, educational and occupational impairment, and higher suicide rates which plagues society with lost work productivity, disability and increased healthcare utilization (Beard, 2011). Although anxiety is highly treatable mental illness, barriers to treatment like lack of trained therapists holds people suffering back from getting treatment (Beard, 2011). Mental health apps have the potential to meet patients anywhere and anytime. This type of flexibility has the potential to reach people that might not be able to seek professional help in-person.

An example of this treatment is seen in the Technical Project, where the capstone team worked with an existing Web online intervention for General Anxiety Disorder, called CalmThinking by the MindTrails Project. The capstone team implemented design strategies to engage users and created prototypes for a working mobile application version of the Web interface.

Although this technology is developing and has the potential to help people, there are unclear guidelines for what works with mental health apps and what does not. In this trial and error phase, all of the risk and responsibility to seek out information in the mental health app space lies on the consumer. This STS research paper will gather evidence that suggests more of the responsibility to label mental health apps and standards for efficacy should be tied to app developers or doctors who can evaluate mental health apps before they are released to the market. Using Actor Network Theory to organize the stakeholders in the development of this technology, the gap for assessment before use is highlighted. Who should provide oversight for mental health applications and how should they set standards? This STS research paper will

investigate potential ways to provide standards in the mental health mobile application space by identifying what organizations could fill the current gap in oversight. In order to drive this technology to the best that it can be, there must be a way to distinguish between apps that work and those that do not, and this distinction should be made clear to the user.

POTENTIAL BENEFITS: REDUCING BARRIERS TO TREATMENT

The treatment for a disease or illness is to seek a trained medical professional; however, health apps are becoming an alternative when there is lack of accessibility to this traditional path. Even if a patient is financially able to seek a trained professional, there are simply not enough actively working therapists in the United States to fulfill demand. The graph in Figure 1 below shows the breakdown of mental health professionals practicing in the U.S. in 2017 which totals to 577,000 (Grohol, 2019). As depicted in Figure 1, not all those practicing even offer counseling. In the case of anxiety disorders, the 40 million U.S. adults suffering greatly outweighs those who could help ("Facts and Statistics," n.d.).

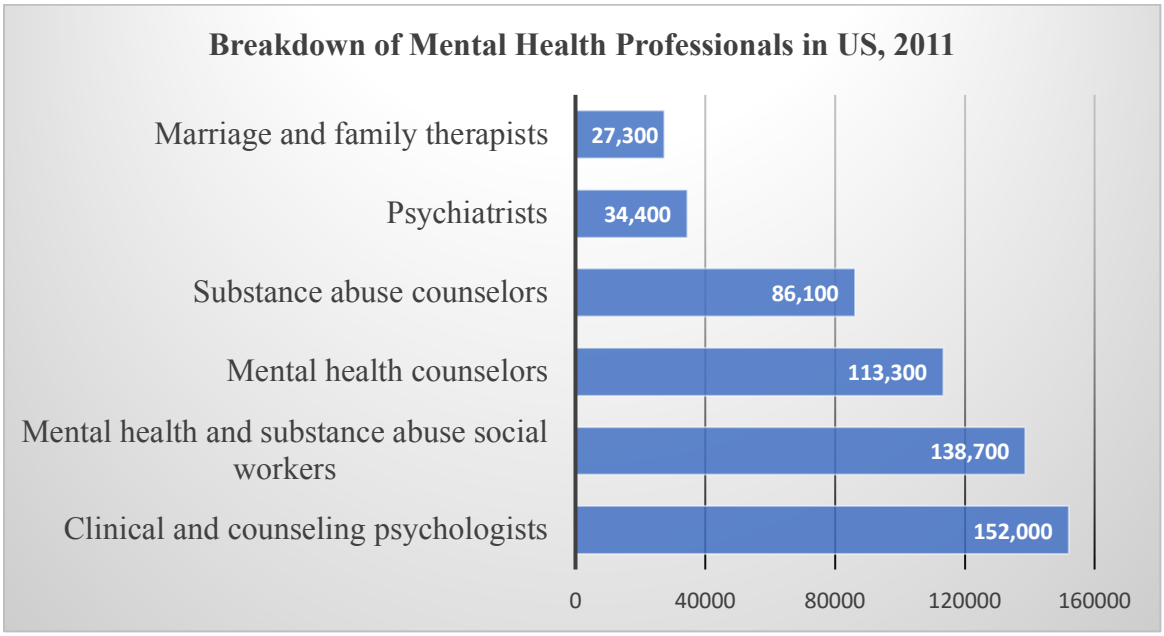

Figure 1: Lack of Trained Therapists: This graph gives the breakdown of the types of mental health professionals practicing in the US in 2017 (Adapted by T. Luong from data given by the Department of Labor (Grohol, 2019)).

In the case of anxiety disorders and treatments, there are proven techniques that in-person therapists use. Mental health apps, like the MindTrails Project, are now trying to replicate the techniques and understand how they translate automatically rather than with a live trained therapist. Cognitive-behavioral therapy, referred to as CBT, is a type of psychotherapy that is meant to challenge the patient's cognitive distortions and provide coping mechanisms to them. This type of training has demonstrated efficacy in treating anxiety disorders; however, a lack of trained therapists and unwillingness to engage in exposure therapy are two initial barriers to patients seeking this kind of treatment (Beard, 2011). Online interventions are possible outlets for the dissemination of Cognitive-Behavioral Therapy with less barriers to access than traditional in-person therapy. The MindTrails Project has an ongoing study to compare electronic delivery of cognitive behavior modification techniques with that of in-person therapy. However, clinical trials to prove the program works and science-based techniques are **NOT** requirements for mental health programs delivered online.

CURRENT ENVIRONMENT FOR HEALTHCARE APPS

Regulations for mobile applications that treat or assess physical diseases are continuing to emerge as this form of healthcare delivery enters the market. Regulations in place for all app developers are: the Health Insurance Portability and Accountability Act or HIPAA; the Federal Food, Drug, and Cosmetic Act, or the FD&C Act, enforced by the Food and Drug Administration; the Federal Trade Commission Act, or the FTC Act; and the Health Breach Notification Rule enforced by the Federal Trade Commission ("Mobile Health Apps Interactive Tool," 2016). These regulatory bodies provide guidelines for app developers to follow and monitor apps in the marketplace.

The Health Insurance Portability and Accountability Act protects the privacy and security of users' health information, requiring certain entities to notify them in the case of a breach ("Mobile Health Apps Interactive Tool," 2016). Certain businesses are also required to notify the Federal Trade Commission in the case of a breach under the Health Breach Notification Rule.

The FD&C Act and the FTC Act regulate safety and effectiveness. However, many mental health apps are not subject to FDA review. Through the FD&C Act, the Food and Drug Administration have developed different categories for Software as a Medical Device, or SaMD, which includes applications that are not part of a hardware medical device but are intended for a medical purpose to treat or to diagnose diseases or inform clinical management ("Software as a Medical Device: Possible Framework," 2014). Mobile medical applications under this definition are examined for quality control processes related to their software (Bates et al, 2018, p. 1975). The FD&C Act does not cover apps that treat or diagnose mental illnesses as most do not qualify to be mobile medical apps since they are not connected to a hardware medical device.

The FTC Act prohibits deceptive or unfair practices that affect commerce ("Mobile Health Apps Interactive Tool," 2016). To enforce this act, the FTC files lawsuits against false claims. Mike Brunker, a correspondent of NBC News, reported in 2016 that Lumos Labs would pay $2 million to settle charges brought by the Federal Trade Commission (Brunker, 2016). Their program named Lumosity had estimated sales of over $1 billion by marketing games that could delay "cognitive impairment associated with age and other serious health conditions" (para. 1) and that these games could even "stave off memory loss, dementia, and even Alzheimer's disease," (para. 3) but Lumosity did not have any evidence to back up the ads (Brunker, 2016). The company targeted vulnerabilities in a population possibly approaching these diseases as they purchased hundreds of keywords, through Google AdWords, related to

memory and cognition diseases. Lumos Labs claimed that they had made contributions to the Human Cognition Project initiative that "explores the impact of mental exercises on cognitive task performance" (Brunker, 2016, para. 7). They blamed the marketing language as the reason for discontinuing the product.

A review of health apps on the marketplace from Van Ameringen (2017), of the Department of Psychiatry and Behavioral Neurosciences at the Canadian McMaster University, noted inconsistencies among mental health apps that aimed to treat, track, or assess illnesses such as major depressive disorder, bipolar disorder, post-traumatic stress disorder, general anxiety disorder, and combinations. Some of the apps reviewed were created based on published evidence in clinical trials, but others were created with no published evidence to justify their methods.

The American Psychiatric Association has an App Evaluation Tutorial that includes a Web page of a video and a five step model to rate an app: gather background information, risk/privacy and security, evidence, ease of use, interoperability ("App Evaluation Model," n.d.). The reader can expand sections of the steps to find questions. If they look into risk/privacy and security, they will find questions like: "Is there a privacy policy?", "Are personal data de-identified?", and "Are cookies placed on your device?" ("App Evaluation Model", n.d.). This Web page provides guidance, but assumes that all potential users of an app understand what these terms mean. This is a presumptuous list by length and terminology when most users will not have a background in data privacy and will not commit the time it takes to properly vet an app.

POSSIBLE FRAMEWORKS FOR OVERSIGHT

In order for these groups to work towards a way to provide guidance for the public, there must be a common way to categorize apps in this field. The National Institute for Mental Health segments mental health apps into the following categories: self-management, cognition improvement, skills-training, social support, symptom tracking, and passive data collection ("Technology and the Future of Mental Health Treatment," 2017).

Lisa Parker, Lisa Bero, Donna Gillies, Melissa Raven, and Quinn Grundy (2019) published an article in the International Journal of Health Policy and Management, titled, "The 'Hot Potato' of Mental Health App Regulation: A Critical Case Study of Australian Policy Arena." Parker and colleagues digest the current state of mental health app regulation in Australia and develop a framework for policy-makers and commercial groups to consider. The document seems to be meant for Australian policy-makers as it gives recommendations and calls for legislative change, but can exemplify a way to create policy in other countries.

The authors created a framework for policy action based on an analysis of 29 policies in 5 sectors: medical device, privacy, advertising, finance, and digital media content. Although the article is focused on Australian policy, the identified 29 policies examined came from Australia, the United States, Europe, and other international bodies. Background about the health app market from the article notes that it is rapidly releasing content, but under-regulated, which causes potential problems with consumer privacy and health safety. As the title suggests, the document warns about the gaps in the regulatory framework for health apps. Other implications for policy makers that it notes are a focus on reducing burdens of consumer choice rather than protection for users, lack of responsibilities of commercial app stores, and lack of communication between different sectors.

The suggested framework classifies three levels or types of policy barrier and names them with examples: upstream such as government guideline, midstream or app store guidance for developers, and downstream such as certification program for 'high quality' apps according to pre-defined criteria (Parker, L. et al, 2019). The most preferred apps would be compliant with downstream policy barriers, the legally acceptable apps would be compliant with midstream, and the best practice apps would be compliant with upstream barriers. The article also compares the power and influence stakeholders have with the responsibility for harm they possess. This comparison is displayed in Figure 2 below.

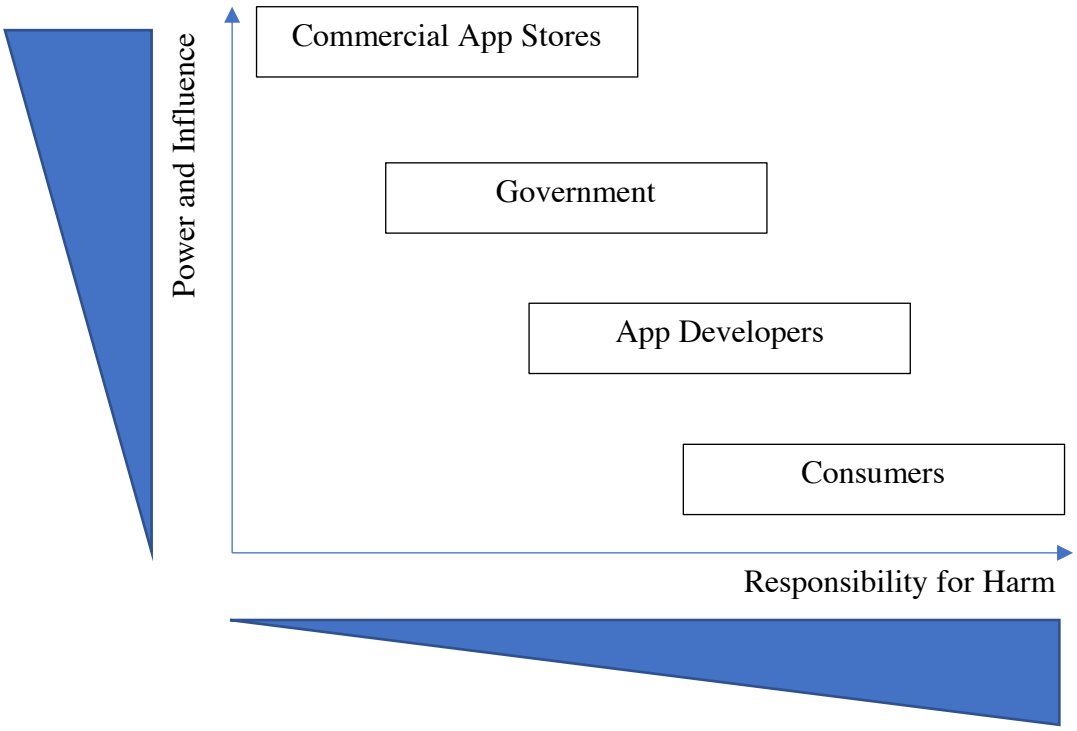

Figure 2: Graph of Power and Influence vs. Responsibility for Harm.
Displays stakeholders on this scale (Parker et al, 2019, p. 172).

In this, they graph commercial app stores having the most power and influence, but the least responsibility for harm. On the other end, consumers have the least power and influence,

but the most responsibility for harm. Government and app developers are included as middle-leveled balance between the two axes. The article concludes with an urge to regulators and policy-makers to be more aware of the influence that commercial entities in the health app market have over consumer outcomes, noting that the enthusiasm for health apps assumes they will deliver more benefits than harms. They finally call for consumer advocacy groups, app developers, health professionals, and governments to end the silos felt in this field and to work together to avoid regulatory gaps for improved consumer privacy and safety.

In addition to oversight by these groups, primary care doctors should be knowledgeable about the current recommended apps in order to refer their patients to a mental health app that works and that can meet their needs. Benjamin Miller and Benjamin Druss briefly comment on the dynamic between patients and family physicians in terms of seeking mental health care in the United States in the article, "The Role of Family Physicians" (2013). They claim primary care is the "largest platform of health care delivery" (para. 1), which would allow primary care doctors to provide mental healthcare, behavioral healthcare, and aid for substance abuse problems (Miller and Druss, 2013). However, Miller and Druss blame historical fragmentation for dividing the health care system into physical healthcare and mental healthcare. The silo between these systems "can result in high costs, low satisfaction, and poor outcomes, including premature mortality" (Miller & Druss, 2013, para. 1). They note that new legislation including the Patient Protection and Affordable Care Act, the Mental Health Parity, and the Addiction Equity Act have required mental health benefits to meet the same standard of coverage as physical health benefits (Miller & Druss, 2013, para. 2). However, these acts do not fix the lack of trained therapists. Additionally, this gap widens in more rural settings (Miller & Druss, 2013, para. 2). Family physicians are limited in providing mental health care due to lack of knowledge,

competing work demands, and payment and reimbursement issues (Miller & Druss, para. 5). Miller and Druss provide a possible team-based solution to include psychologists, social workers, and nurses to assist physicians (2013, para. 6). The authors reinforce that primary care doctors have a greater potential and are underutilized in effort to provide mental healthcare.

CONTEXTUALIZING A FRAMEWORK FOR OVERSIGHT

There seems to be an emphasis on regulations for mobile applications that can cause damage to a person's physical health, as this falls within the FDA's jurisdiction. This regulation forces companies that create mobile medical applications to be pre-certified for the market by providing evidence and conducting studies up to the FDA's standards depending on the type of software. A level of transparency and trust between the product and the user forms when they can understand the methods behind the app. Alternatively, there is no standard for proven efficacy with apps that can claim to reduce mental illness symptoms. The result is a lack of transparency and no clear direction to move forward among developers in this area.

Through Actor-Network Theory, a perspective outlined by B. Latour in 1990, this problem can be processed by looking at the actors, both human and non-human, and the sociotechnical networks that they work within. The agency in this network is dispersed because it relies on the relationships within the network. For example, not one entity is completely responsible for how this technology develops, but since government agencies are taking a hands-off approach to mental health apps, other organizations will start to bridge the gap in attempt to protect the public. In the current state of the network in Figure 3 on the following page, the stakeholders are categorized by enforcing regulation, creating apps, and using apps. There is a line connecting government agencies and app developers as app developers must abide by rules set by government agencies. There is no connection between consumers and the creators as there

is a lack of transparency between them. This visual explains that the groups are not well connected throughout the process of creating a mental health app.

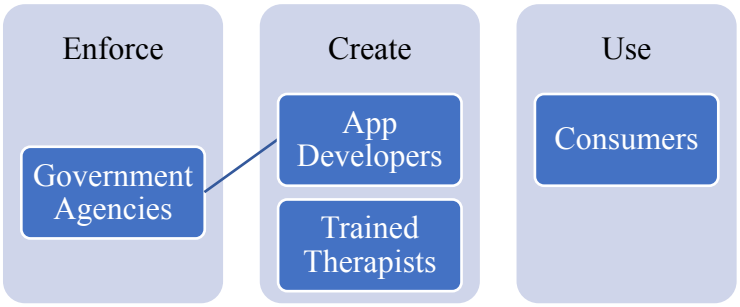

Figure 3: Current state of mental health app network. This graphic displays the main actors that have potential influence in providing oversight for mental health applications (Created by Taylor Luong (2020) based on Actor Network Theory outlined by B. Latour, 1990).

In the preferred state of the network, below in Figure 4, oversight is included. This inclusion of different groups hopefully provides insight for what methods work well in creating mental health apps and providing them to users. App developers would have more guidelines and requirements to create mental health apps. Additionally, there are groups meant to critically assess mental health apps before prescribing their use to the patient or consumer. This creates more accountability and transparency throughout the process.

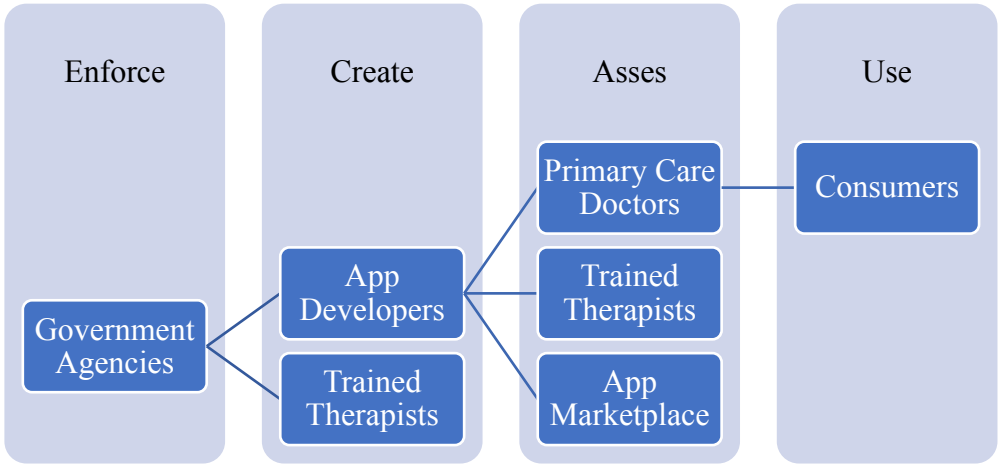

Figure 4: Preferred state of mental health app network. This graphic displays the main actors that should influence oversight for mental health applications (Created by Taylor Luong (2020) based on Actor Network Theory outlined by B. Latour, 1990).

CONCLUSION

In conclusion, more organizations need to be incorporated in the use and creation of mental health apps. Before apps are released to the public, the app developers should be required to self-identify their app in the tiered levels of credibility based on upstream, midstream, and downstream categorizations from the distinctions made in "The 'Hot Potato' of Mental Health App Regulation: A Critical Case Study of Australian Policy Arena." This categorization should be available to the user before downloading an app by requiring app stores to enforce this transparency and to create a place for this transparency on the stores' page. Additionally, primary care doctors should be able to prescribe their patients mental health apps, relieving the patient of some of the burden of discovering an app that works for them. Hopefully these requirements would be enforced by a government agency or reputable medical organization. The goal is to increase transparency of an app for consumers and to give developers more guidelines for releasing apps with the purpose of making mental health apps more reliable and trustworthy.

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