Social Forces Shaping the Development of Mobile Health Technologies

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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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Well before COVID-19 brought attention to national health issues, Americans have endured serious public health threats: a rapidly aging population, an unsustainable rise in health care spending, and alarmingly high rates of chronic disease—nearly half of Americans are obese and nearly half have hypertension (CDC, 2020; CDC, 2021). While the aging population accounts for much of the disease burden and healthcare spending, inefficiencies contribute too. Americans appear to spend more than our public's health can justify, creating a "spend more, get less" paradox more pronounced than in other industrialized nations (Bradley and Taylor, 2013, p. 2). For example, the U.S. spends more on health care per capita than any nation in the Organization for Economic Development (which includes Canada, Germany, and the U.K.) yet has the lowest life expectancies, highest suicide rates, and highest chronic disease burdens on average (Tikkanen and Abrams, 2020).

Mobile health (mHealth) technologies, applying ubiquitous mobile communication devices, could improve healthcare efficiency and empower patients. "mHealth" refers to the use of mobile devices such as tablets and smartphones to support medical care; it is a subcategory of "eHealth," the use of all electronic technologies in medicine and public health (Dicianno et al., 2014). mHealth provides value in healthcare through data storage, vital sign monitoring, long-distance messaging, and other applications. Developers create mobile apps, as well as watches, wristbands, and other wearables, for such purposes (Eapen Zubin et al., 2016). The pace of these technological developments has far exceeded the pace of their integration into healthcare (Jacob et al., 2020).

mHealth app development involves dialogue between patients, physicians, developers, payers, and regulators — who seek to advance their interests while pursuing common ground

(Drummond et al., 2013). It is this dialogue, rather than technical limitations, that will likely shape the future of mHealth. In the Social Construction of Technology (SCOT) framework, a technology's significance is subject to the diverse interpretations of the social groups involved; SCOT can shed light on how different groups negotiate the optimum implementation of mHealth (Clayton, 2002, p. 352). While implementation can be deterred by competing interests, effective collaboration — including through organizational guidance and user engagement in app development — can promote the integration of effective apps into clinical practice.

Relevant Perspectives in mHealth Development

mHealth developers, such as IBM and QSS Technosoft, want their apps to sell widely and durably; many see their products as potentially transformative for healthcare and envision a future where mHealth is used ubiquitously (Ashall-Payne, 2020; Chatzipavlou et al., 2016; Pandey, 2020). To characterize the developer perspective, Chatzipavlou et al. (2016) propose four pillars: technical mastery, market interaction, legal compliance, and ethical application. For a technology company, designing appealing, functional software tends to come naturally. Many implement "gamification" strategies to entice users and incentivize their continued use. For example, apps have been designed with point-based reward systems and personalized messages to help users quit smoking (Ashall-Payne, 2020). Developers have also been responsive to recommendations from researchers and users; many regard usability, accuracy, and data security as essential (Becker et al., 2014; Chatzipavlou et al., 2016).

According to Silver (2015), Vo et al. (2019), and others, patients tend to welcome mHealth as a convenient way to record health data, learn, and communicate with their doctors. These functions have been found to improve patients' knowledge and self-management (Vo et

al., 2019). Through interviews, numerous patients have reported on their use of health management apps. For example, interviewed patients with arthritis have reported valuing apps' informative and communicative features, even while their doctors seriously questioned usability. One woman reported that information from the app empowered her with the knowledge to become more of a partner in her relationship with her doctor (Barber et al., 2019). In another interview-based study, Husted et al. (2018) evaluated the effects of an app called YWD ("Young with Diabetes") on patient well-being. The patients — young people with diabetes — reported that the app offered a sense of freedom and peace: they felt more comfortable sharing concerns with their providers and asking more direct questions, which helped strengthen patient-provider relationships and improve quality of life (Husted et al., 2018). Many patients appreciate mHealth, but not many apps have provided value for them in the long term. Sanger et al. (2014) found that while many apps fall into disuse, those that demand relatively little time and attention can endure.

Most physicians recognize mHealth's potential, but they tend to be more concerned than patients about accountability, privacy, and the doctor-patient relationship (Drummond et al, 2013). Citing limited personal experience or lacking research availability, most non-users do not recommend mHealth apps to patients (Kong et al., 2020). In a survey, Kong et al. (2020) found most doctors to agree that mHealth biometrics could promote healthier lifestyles (68%), track medical treatments (64%), and support research into patient well-being (56%), yet most also expected higher accuracy and precision (81%) and more efficient data integration (68%). They expressed the most satisfaction with devices that could promote better eating habits, track activity levels, and record important physiological measurements, such as heart rate (Kong et al., 2020). In a different survey, Nguyen et al. (2019) found that general practitioners typically

valued mHealth for helping patients learn about and manage chronic conditions. One practitioner stated (about an mHealth app), 'it's a source of information that they can just go to the app for, rather than just numbers and "remember to take your medication," it's a bit more information… It's a little bit more health promotion.' However, they also saw the need for technical knowledge, time, and attention as limitations. mHealth also affects the doctor-patient relationship. Abraham Verghese, M.D., a physician and author, has raised awareness to the possibility that too much focus on digital technology can impede interpersonal connection between providers and their patients. He has described the importance of reading body language and listening to patients' stories, both of which tend to be lost with an intense focus on apps. Despite these concerns, Verghese, like many other physicians, see benefits to using mHealth and other digital technologies in the right contexts (Cassel, 2019).

In the U.S., healthcare payers may be individual patients or third-party insurers, and the FDA is the federal body involved with mHealth regulation (FDA, 2020; Sutton, 2020). Regulators and payers value usability and safety, but their evaluations differ (Drummond et al., 2013). Regulators expect evidence of safety and efficacy, typically established through controlled clinical trials. The FDA is currently working on a standardized approach for mHealth evaluation that focuses on the reliability of software developers (Rowland et al., 2020). Despite difficulties adapting their regulations and concerns about data privacy, they express a strong interest in mHealth for its ability to improve healthcare efficiency and facilitate patient-centered care (FDA, 2020; Larson, 2018). Payers, in addition to data reliability, expect evidence of cost efficacy. Regarding mHealth, mobile phone prevalence and internet connectivity have shed light on potential cost-saving benefits. Payers such as Humana favor mHealth because it can efficiently link health-related data (Wicklund, 2019). "Anything that we can do that will allow us

to deliver care more efficiently, meaning at a lower cost and more effectively, with a better outcome and decrease the burden on the physician as well as the member, has the potential to bring tremendous value to the table," says Worthe Holt, vice president of the Office of the CMO at Humana. Many other payers also view mHealth positively, despite a lack of long-term research supporting its cost-effectiveness (Iribarren et al., 2017).

Collaborations that Shape mHealth Development

Regulatory Efforts

The technology industry's ability to rapidly iterate mHealth apps, often at the expense of traditional clinical product design, has made it particularly difficult for the FDA to adapt. In the U.S., the use of these technologies also expands into areas that seem ambiguous from the regulatory perspective; mHealth does not clearly fit into traditional definitions of "medical device" (Matthews et al., 2019). The 21st Century Cures Act, which amended the Federal Food, Drug, and Cosmetic Act, removed some clinical decision support systems from the "medical device" definition, which forced the FDA to amend this definition and spend more time figuring out how to evaluate safety. Currently, under the Food, Drug, and Cosmetic Act, mHealth apps may be classified as Class I (low risk), Class II (moderate risk), or Class III (high risk). Because the vast majority of apps are considered Class I or Class II, they are subject to minimal pre-market testing. The FDA focuses its attention on the higher risk "subset of mobile apps whose functionality could pose a risk to patient's safety if the mobile app were not to function as intended"; Class I apps do not even require FDA approval to be on the market (Schoenfeld et al., 2016). Other Federal Agencies also impact mHealth regulation. The Federal Trade Commission (FTC) prohibits "deceptive or unfair acts or practices, including false or misleading claims about

the safety or performance." To provide clarity for mHealth developers, the FTC, FDA, Health and Human Services (HHS) Office of the National Coordinator for Health Information technology (ONC), and Office for Civil Rights (OCR) have developed tools to help them understand federal regulations (Matthews et al., 2019). However, because these regulations do not remove incentives to minimize pre-market testing, issues associated with suboptimal app quality persist. This has led medical organizations and technology developers to collaborate amongst themselves.

Collaborations between Health Organizations and Technology Companies

Since around 2010, major healthcare organizations and technology companies have worked together to negotiate the development of safe, effective mHealth (Dicianno et al., 2014; Matthews et al., 2019). Multi-stakeholder collaborations, such as Xcertia and the Digital Therapeutics Alliance, aim to improve testing and help clinicians and patients discern quality. For mHealth apps, the non-profit Xcertia has the best-known set of published guidelines. These guidelines introduce and discuss important concepts, such as usability and data privacy, which most developers and users regard as important.

In 2016, the American Medical Association (AMA), American Heart Association (AHA), DHX Group, and the Healthcare Information and Management Systems Society (HIMSS) formally came together to form Xcertia, a collaboration dedicated to improving the quality of mHealth apps (American Medical Association, 2016). Rather than certify mHealth apps, Xcertia aims to support patients' and clinicians' choice of apps, thereby increasing access to quality information to improve patient care (American Medical Association, 2016). Members of the Xcertia board, who have come from Accenture, the App Association, Mayo Clinic, and

others, first helped established a set of mHealth guidelines in 2016. In their newest set from August 2019, “App Privacy Guidelines” aim to assess whether an app sufficiently protects user’s information, “App Security Guidelines” aim to assess if an app is sufficiently protected from “external threats” to its databases, “Content Guidelines” aim to assess whether the information provided in an app is current and accurate, and “Usability Guidelines” aim to assess whether an app’s design makes it safe and easy to use (Xcertia, 2019). Usability was characterized with five key aspects: learnability, efficiency, memorability, prevention of errors and user satisfaction. Michael Hodgkins, MD, who served as Xcertia chair, has publicly discussed the importance of developers considering users throughout the app development process. He regards it as essential for avoiding user frustration and supporting their health goals. “The apps you really do use on a regular basis—do you need to spend hours learning how to use them? No. If you did, you wouldn’t use them. So, the usability of an mHealth app should generally be intuitive”, Dr. Hodgekins says (Henry, 2020).

Despite guidance from Xcertia and others, many mHealth apps of suboptimal quality proliferate and persist, causing confusion amongst users and a lack of integration into clinical practice. Limitations of current app guidelines, the “fail fast, fail often” mentality of many technology start-ups, and the confusing regulatory landscape surrounding mHealth all contribute. Xcertia’s guidelines provide quite “high level” guidance and fail to include clinical outcomes validation, which other researchers and organizations see as critical in refining app development (Matthews et al., 2019). The Network for Digital Evidence in Health (NODE.Health) was founded in 2016 with the purpose of supporting evidence-based validation of mHealth. They actively help developers validate their designs through clinical trials and facilitate dialogue between developers and healthcare systems (NODE.Health, 2021). The Digital Therapeutic

Alliance also facilitates the use of evidence-based, clinically-validated mHealth technologies. This organization promotes more rigorous clinical testing, such as randomized control trials, where companies continually collect and analyze data with the hopes of demonstrating clinical efficacy. RankedHealth, a collaboration between medical researchers, clinicians, and patients, even established a numerical ranking system for mHealth apps. On their website, prospective mHealth users can read the reviews of past users and observe a numerical score associated with each app (Matthews et al., 2019). This work to enhance clinical testing and guide users' choices complements the more "high level" approach taken by Xcertia and its members, which is also bound for revision. Since August 2019, Xcertia's formal collaboration ended, but under the leadership of HIMSS, a new Health App Guidelines Workgroup aims to inform and evolve their 2019 guidelines (HIMSS, 2020).

User Participation in App Development

Organizational guidance helps lay the groundwork for safe, usable mHealth development, but it is up researchers and developers to find practical solutions. This seems to require that they begin by studying prospective users and pursuing a shift away from *internal validity* (the ability of a study to control for extraneous variables) towards *external validity* (the clinical significance of a study) (Becker et al., 2014; Drummond et al., 2013; Jacob et al., 2020). Developers can improve the external validity of their mHealth studies by measuring what matters most to users and engaging them directly (Chatzipavlou et al., 2016; Drummond et al., 2013).

User engagement in mHealth development has been improved by the application "co-design" principles. Eyles et al. (2016) define "co-design" as a process where "users and other relevant stakeholders form partnerships with researchers to work together on all aspects of

intervention development." This iterative process involves assessing users' needs, developing content in accordance with those needs, testing prototypes, and repeating. It allows apps to be tailored to users better than more traditional approaches to tend to omit contact with patient users during development. Co-design has informed mHealth implementation for numerous purposes, including the management of arthritis, diabetes, and chronic conditions. Mrklas et al. (2020) investigated an app for patients with knee osteoarthritis, where participants included family physicians, industry stakeholders, and patients with knee osteoarthritis. After negotiating and coming to a consensus, study participants agreed that the app should track symptoms and activities and include guideline-based self-management strategies; using these findings, a mobile app was developed with a customizable dashboard displaying goals, plans, and strategies. For diabetes management, Bradway et al. (2020) reported on an app design following two sets of meetings: brainstorming amongst patients and physicians separately and a "joint meeting" with patients and physicians together. In the joint meeting, participants created and described prototypes of ideal data-sharing systems. These prototypes, which included cartoon representations and concept maps, revealed which data types should be gathered and displayed, as well as how this could facilitate shared-decision making. Bird et al. (2021) describe similar benefits to engaging family caregivers and doctors in the design of an mHealth tool for childcare. Participants gave feedback on the shortcomings of current care models and engaged in a design process to create a shared vision for mHealth-based interventions. They then re-convened at the end to share their perspectives, which directly informed app design (Bird et al., 2021).

Engagement of users via co-design is becoming more common, but mHealth developers in the U.S. tend to gather feedback through usability surveys and interviews post-design (Georgesson and Staggers, 2016). Common strategies include the System Usability Scale, the

Post-Study System Usability Questionnaire, and self-written questionnaires. However, none of these have been widely validated for mHealth studies, and efforts are underway to help developers gather feedback more systematically (Zhou et al., 2019). Compared to co-design, surveys and interviews may save time and money, but they also may sacrifice long-term user satisfaction.

Conclusion

mHealth could be used to improve patient care and address healthcare inefficiencies, but it is not always clear which apps provide value to users. These users, usually clinicians and patients, do not always agree on what is most beneficial either, and the influences of developers, regulators, and payers can complicate their discernment. In the absence of strong regulatory oversight, guidance from professional organizations and insights from user-centered design have facilitated mHealth implementation. Usability and safety (data privacy) seem to be important shared values, and participatory design approaches, including co-design and post-design surveys and interviews, seem to allow developers to better understand and support users. Ultimately, supporting users with mHealth may mean supporting a more inclusive and efficient healthcare system.

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