HHS Public Access

Author manuscript

Psychiatr Serv. Author manuscript; available in PMC 2019 December 01.

Published in final edited form as:

Psychiatr Serv. 2018 December 01; 69(12): 1204–1206. doi:10.1176/appi.ps.201800193.

Dichotomies in Digital Mental Health

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Unstructured Abstract:

The uptake and clinical adoption of digital mental health tools like smartphone apps remain limited. While some technology barriers remain, the greatest challenges are no longer technical but rather the dichotomous directions and efforts dividing the space and limiting its potential. This paper focuses on six of these dichotomies including randomized versus pragmatic studies, precision versus population health, free market versus regulation, consumer versus clinical uses, big data versus privacy, open versus proprietary software. Realizing that there is no panacea, the authors suggest a more flexible approach towards digital mental health which offers a pragmatic solution to better appreciate the landscape and pave the way towards progress.

Introduction:

Despite the clear potential of digital mental health tools to advance monitoring, extend care, and augment interventions, today in 2018 the real-world impact of digital mental health tools remains aloof. While there is promising pilot data for using smartphone apps in all mental health conditions -- ranging from eating to psychotic disorders, child to geriatric populations, and inpatient to community settings -- the translational potential of these technologies has not yet been realized. In this perspective piece, we argue that challenges of bench to bedside, or here code to clinic, are not related to the technology so much as the numerous unresolved dichotomies in digital health that are fragmenting the field. These dichotomies center on randomized vs pragmatic studies, precision vs population health, free market vs regulation, consumer vs clinical uses, big data vs privacy, open vs proprietary software. Our goal in presenting these dichotomies is not to propose specific solutions but rather to suggest a need to adapt a flexible mindset in this evolving space. We encourage the reader to identify which position a certain digital mental health tool is closer to, what are the advantages and disadvantages of that position, and what is a transition path to embrace the opposing perspective.

Dichotomy 1: Randomized Controlled Trials vs Pragmatic Outcomes

Despite over 10,000 mental health related app directly available for download today on the Apple and Android marketplaces (1), recent meta-analysis identified only 22 apps for

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Disclosures: None

depression symptoms (2) and nine for anxiety disorders (3) that have been assessed in randomized controlled trial studies. Given the time and expense of conducting randomized controlled trials, compounded by the rapidly evolving nature of technologies like smartphone apps, experts in the field like David Mohr have argued for new study methodologies such as ‘trials of intervention principles’ (4) or Erik Heckler for an iterative evaluation framework called ‘agile science’ (5). Still, large scale funders, regulatory bodies like the Food and drug Administration (FDA), and payers such as insurance companies continue to ask for randomized controlled studies. There is good reason for these demands, as many digital psychiatry and app intervention studies report high effect sizes that quickly vanish when an active control group is considered (2) as seen in a recent study of the popular mindfulness app Headspace (6), perhaps because of a strong digital placebo effect (7).

Dichotomy 2: Precision Medicine vs Population Health Tools

The potential of technology and smartphone apps is so vast that these tools can be used for both personal medicine and well as population health. Efforts like the NIH All of Us Research Program (a major component of the Precision Medicine Initiative) use smartphones and wearable sensors to understand unique and personal differences among individuals. With the sensors in today’s smartphone and smartwatches, it is feasible to quantify critical health behaviors like psychical activity and sleep as well as capture previously challenging to assess behaviors such as socialness based on smartphone communication logs. However, most large app based research efforts continue to report results on a population level such as the recent 8,000 participant Asthma Mobile App study (8) and the 9,500 participant Parkinson’s Disease mPower study (9). Delivering personalized insights requires a strong understanding of the digital signature of smartphone data in relationship to each unique individual, a challenge given the still evolving science behind digital phenotyping methods and analyses. It is theoretically possible to design a mobile health platform to offer both precision and population health, but the dichotomous scope and clinical targets often create a difficult choice for app developers and researchers.

Dichotomy 3: Free Market vs Medical Regulation

At the time of this writing there is one single mental health related smartphone app with FDA marketing approval, in contrast to the above mentioned over 10,000 smartphone apps on the commercial marketplaces. The lack of FDA oversight is in part due to sheer challenge of regulating these apps which often update on a monthly basis and are constantly changing in functionality. While the FDA is piloting a new precertification program to regulate smartphone apps, the vast majority of smartphone apps today remain unregulated despite often making bold and likely misleading medical claims. A2016 lawsuit by the Federal Trade Commission (FTC) against Lumosity for deceptive marketing around its brain-training program highlights the potential for real world harm. Yet asking every app developer to submit FDA quality evidence pre-market data and FTC quality post market data could stifle innovation, delay implementation, and not allow smaller app developers and research teams to compete. The currently regulatory landscape has led some companies like Pear Therapeutics and Akili to pursue the formal regulatory pathway but many others have picked the dichotomous path of labelling their apps instead as general wellness tools.

Dichotomy 4: Consumer Devices vs Clinical Tools

Related to the regulatory discussion above, the majority of smartphone apps today market themselves as health and wellness devices aimed towards consumers versus clinical tools directed towards healthcare markets. The marketing, features, and designs of these direct to consumer apps naturally force a focus on commercialization, independent of the effectiveness of the underlying intervention. Recent reviews of the quality and efficacy of apps on the marketplaces for disorders such as bipolar disorder (10), substance abuse (11), and mindfulness (12) among others have found that direct to consumer apps often lack evidence and do not follow best practices. Given the current lack of clinical reimbursement related to app use – often direct to consumer sales are the only viable pathway to sustain app related efforts. While pathways such as the NIH Small Business Innovation Research (SBIR) program do offer pathways to transition apps from consumer device to clinical tools, the dichotomy between consumer versus clinical apps still remains stark.

Dichotomy 5: Big Data vs Privacy

Much of the potential of smartphone apps is due to their ability to passively collect a myriad of real time sensor data to enable longitudinal behavioral monitoring. Early research has suggested that patterns of geolocation data automatically (or passively) collected from smartphones may be correlated with severity of depression (13) and relapse in schizophrenia (14). However, this same data can be easily misused or mishandled. For example a privacy breach could enable hackers to know where a patient sleeps at night. The recent breach of over 150 million accounts of users of the fitness app ‘MyFitnessPal’ underscores how big data and privacy can clash with unfortunate consequences. The recent Cambridge Analytica scandal resulting in the unauthorized access of over 87 million Facebook accounts due to breaches in research ethics also highlights a darker side of scalability of digital technologies. A subtler but equally important dichotomy lies in the marketing of individuals’ health data gathered from many direct to consumer apps. Because, as outlined above, many health apps live outside of federal regulations including the privacy-oriented HIPAA statue – they are legally able to share, sell, and market users’ personal data. Protecting privacy and gathering vast amounts of data from apps need not necessarily be dichotomous - but often are in today’s landscape.

Dichotomy 6: Data/Code Sharing vs Proprietary Tools

The potential of digital psychiatry and smartphone apps is also driven by scalability with the notion that what works on one smartphone has the potential to work on billions of others already in use across the world. However, this scalability is hindered by proprietary software that limits open and reproducible science. Currently, many groups are developing smartphone app related tools and data analysis methods but restricting access to source code used to create their smartphone app or resulting datasets. Only a handful of smartphone app related studies in mental health have ever been reproduced and these studies often yield contradictory results (15). Commercial funding will likely not favor open software efforts where they are asked to share code and algorithms, and grant supported efforts may not sustain open source tools and data repositories when funding expires. This dichotomy

between open and closed platforms hampers the field by limiting reproducible science during the critical development phase of the digital health space.

Conclusion

The six dichotomies in digital health presented above each embody unique paradoxes and conflicting demands. Together dichotomies one, two, and three represent awealth of new data and hypothesis powered on the potential of digital phenotyping juxtaposed with a paucity of rigorous or replicable findings – the hallmark of a mature field. Dichotomies four, five, and six represent the dynamic pace of technology change and the need to support rapid innovation juxtaposed with the need for safety, privacy, and transparency. Given how these current dichotomies, either alone or in sum, today are fragmenting the digital mental health field, limiting collaboration, and impairing reproducible science – there is an urgent need for change. There is a growing awareness of these dichotomies within federal funding agencies (16) and foundations, but a rapid solution is not readily apparent. While there will always be custom solutions to each dichotomy, the tensions driving these dichotomies are not easily resolved. Rather, we propose to reframe these dichotomies as a need to acknowledge some degree of inconsistency and to realize that successful digital psychiatry efforts will often have to pivot between competing positions. Rather than viewing this inconsistency as a weakness, the ability to adapt a ‘both/and’ instead of ‘either/or’ mindset may be more productive (17). Understanding and evaluating digital psychiatry tools from this lens may offer a more variable, but perhaps more valid, understanding of the opportunities and challenges ahead.

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