

Youth-focused Design and Regulation in eHealth Can Help Address the Mental Healthcare Crisis

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Executive Summary: An ongoing mental healthcare crisis has been exacerbated by COVID-19, particularly for youth. However, one unexpected effect of this pandemic is that access to digital mental healthcare has rapidly expanded. We argue that eHealth interventions, including telehealth and mobile interventions (mHealth), can effectively address mental health challenges, reduce costs for individuals and institutions, and broadly expand access to mental healthcare. For the promise of eHealth to be fully realized, FDA regulation must thoughtfully balance the promotion of evidence-based interventions with broad public accessibility. Furthermore, youth involvement throughout the design process and consideration of youth-specific needs when establishing regulations are critical to the success of eHealth in addressing youth mental health in the United States.

I. eHealth, mental health and youth

Digital health interventions (i.e., eHealth, which can include mobile interventions (mHealth), telehealth, and other web-based services) are growing in both popularity and as a focus of development in mental healthcare. In 2020, as digital technology usage continued to increase globally, the World Health Organization (WHO) adopted its Global Strategy on Digital Health (2021), which aims to improve the quality and reach of healthcare on a global scale (United Nations n.d.). Furthermore, eHealth interventions for mental health specifically have been demonstrated to be effective across several modalities, including mHealth, telehealth, and other web-based services (Carl et al. 2020; Karyotaki et al. 2018; Wagner et al. 2014).

Developments in digital mental healthcare have been driven by an ongoing global mental healthcare crisis, exacerbated by the advent of COVID-19 and the onslaught of associated stressors, as well as growing socioeconomic inequities (World Health Organization 2022). Youth have struggled with their mental health throughout the COVID-19 pandemic, exacerbating already unprecedented rates of mental

health challenges (Barendse et al. 2022; Racine et al. 2021). This issue highlights a dire need for mental healthcare solutions and scalable interventions.

Within the United States, federal policymakers and other regulatory bodies, as well as institutional review boards and the companies that distribute eHealth interventions, can help increase both the quality and accessibility of eHealth interventions for youth. We focus here primarily on regulatory oversight by the Food and Drug Administration (FDA) as one pathway to promote effective eHealth interventions. eHealth holds substantial promise as one avenue for addressing youth mental health in effective and scalable ways; however, increased youth involvement in design and awareness of youth-specific needs in regulatory guidelines could help promote the accessibility of effective eHealth interventions for youth.

II. eHealth can help address gaps in youth mental healthcare

i. Reducing barriers to accessing care

Digital mental healthcare may offer solutions to several barriers faced by youth in accessing care, particularly for those who are socially and economically disadvantaged.

A first important barrier to consider is appointment-related commuting (Mongelli et al. 2020). This barrier may be especially problematic for youth without reliable access to transportation, or those with greater schooling, work, or caregiving demands. The option to utilize an eHealth intervention could surmount this barrier to care.

A second significant barrier is the cost of therapy sessions (Mongelli et al. 2020). Finding a provider with reduced fees or who accepts insurance is not always possible. Even then, it still may not be financially feasible, especially for youth dependent on a caregiver to pay for their sessions. mHealth interventions in particular can allow youth to access care with less time with a provider and provide a more affordable option than weekly one-on-one in-person sessions.

A third substantial barrier is the frequent need for specialized care. Finding any available providers can be challenging, let alone providers who offer specialized care such as dialectical behavior therapy (DBT), which is a recommended intervention for youth experiencing severe emotion dysregulation, suicidality, and self-harm (MacPherson et al. 2013). Need for specialized treatments may significantly limit provider options, thus requiring people to travel farther or pay more to get needed care. This discrepancy disproportionately impacts those in areas with limited care options, such as more rural areas: recent estimates show that 123 million Americans live in mental health professional shortage areas, an even greater number than those living in medical or dental shortage areas (Smith-East and Neff 2020).

ii. eHealth to reduce insurance costs

Not only does eHealth expand options for individuals seeking care, but it may also reduce costs for insurance companies and the public. For instance, a white paper from SilverCloud Health indicated that

their iCBT (cognitive behavioral therapy for insomnia) mHealth intervention reduced crisis visits to emergency rooms by 5%, representing a cost savings of \$1,105,000 (Palacios and Richards 2019). Other economic analyses point to the cost-saving potential of digital interventions for eating disorders (Kass et al. 2017) and generalized anxiety disorder (Jankovic et al. 2022). In many cases, cost savings for mHealth interventions come from fewer individuals needing in-person psychotherapy or more resource-intensive interventions (Kass et al. 2017). While there is early evidence of eHealth interventions saving costs on an institutional level, more evidence is needed to support an economic argument for broad cost-effectiveness of digital interventions (Hollis et al. 2017; Lehtimaki et al. 2021). Thus, additional research on the economic outcomes of eHealth interventions should be promoted in tandem with the continued development of these technologies.

III. Regulatory options and considerations for safety and effectiveness

Given the promise of eHealth interventions for both individuals and institutions, youth-centered regulation for these programs from the FDA can help ensure that the interventions being widely implemented are appropriate and effective, as opposed to simply the ones with the most financial backing.

Regarding mHealth specifically, there are currently two regulatory approaches in the U.S.: regulation as a medical device by the FDA and unregulated open access.

i. FDA regulation

Currently, the primary mechanism of eHealth regulation involves the FDA's review and approval of mHealth applications as prescription medical devices (Software as a Medical Device Working Group 2017). FDA regulation can apply to any software that qualifies as a medical device, that is, any software that is "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease" (Food and Drug Administration 2022, 5). An example of software that qualifies as a mobile medical device under these guidelines would be a mHealth application that syncs with a patient's FDA-regulated heart rate monitor for the detection of arrhythmia.

For most mHealth applications, including, for example, those that provide coaching and reminders about healthy eating habits or smoking cessation or that provide access to telehealth, the FDA intends to exercise enforcement discretion because they pose a lower risk to the public. Recent estimates suggest that there are tens of thousands of digital health apps available to consumers, and that a very small fraction of those have FDA approval (Clay 2021; Aitken and Nass 2021; Lau et al. 2020).

An advantage of this regulatory mechanism is that such oversight can help ensure mHealth products deemed riskier by the FDA meet acceptable efficacy, safety, and privacy standards, as unregulated open access mHealth products have a history of failing to meet these standards (Nicholas et al. 2015; Rosenfeld et al. 2017; Tangari et al. 2021). However, a disadvantage of the current FDA regulation stance that Carl and colleagues (2022) noted is that in order for providers to deliver these tools to patients, they must have prescription privileges, which the majority of mental and behavioral healthcare providers do not have (U.S. HHS, HRSA, NCHWA 2015). Under this model, only those receiving care from providers with prescription privileges (primarily physicians, though some other providers such as nurse practitioners have limited prescription privileges; Lavoie and Barone 2006) could access FDA-approved mHealth interventions, which can uphold current barriers and limit opportunities for mHealth interventions to increase access to care.

ii. Unregulated open access

Though the previously discussed FDA regulatory mechanism offers a systematized, though narrowly scoped, way to evaluate and approve mHealth interventions for distribution with a prescription, many mHealth interventions are not formally regulated and instead fall under the second approach: unregulated open access, which is to say directly available without a prescription, though sometimes with a cost. This approach offers those seeking support greater agency in their care while lowering costs and barriers to treatment. Unfortunately, this lack of regulation may also result in less transparency for consumers around the efficacy of any given mHealth intervention. Many of the most popular mHealth apps, such as Headspace, Calm, and others, have been developed with clinical

guidance and their effectiveness has been evaluated through research (Mani et al. 2015; O'Daffer et al. 2022). Yet these are intermixed in app stores with mHealth apps that lack evidence and may have questionable privacy policies (Rosenfeld et al. 2017; Tangari et al. 2021). Without clear marketing and distribution guidelines, as highlighted in a review of mHealth apps, those seeking support may struggle to reliably compare the effectiveness and suitability of the options available to them, and whether they are evidence-based (Lui et al. 2017). Currently, the APA and several other organizations review mobile apps for mental health and publish lists of preferred ones, which can help guide the public in their selection of these interventions (Beth Israel Deaconess Medical Center 2020; One Mind PsyberGuide n.d.; Owings-Fonner 2022). However, these recommendations from the APA and others are not presented alongside the point of purchase for patients, thus placing the burden on patients to do their own research into the effectiveness of relevant mHealth options.

iii. Policy recommendation

We recommend a third approach integrating the oversight of FDA regulation with non-prescription open access for consumers and patients. Rather than exercising enforcement discretion for the majority of mHealth products for mental health, we suggest the FDA oversee the regulation of more mHealth apps for mental health much in the way the agency currently oversees over-the-counter medications, such that non-prescription open access rather than prescription-only interventions would constitute the bulk of mHealth interventions with FDA approval. Additionally, we suggest requiring a clear indication of FDA approval status at the mHealth applications' purchase point. This indication can assist individuals in selecting an evidence-based and higher quality intervention if one is not specifically recommended for them by a health-care provider (Hui et al. 2022; Marshall et al. 2020). Approval requirements could integrate evidence from randomized control trials (RCTs), other research, recommendations from the APA and other similar organizations, with an emphasis on findings with heavy involvement of the target population throughout the research process (see section IV).

In addition to helping consumer decision-making, this approval status could influence the development

and research of these products to align with the priorities set out in this FDA approval process. Such changes may also assist app marketplaces and other purchase points for these interventions in how they present various products (such as placing interventions with FDA approval at the top of search results) and potentially increase consumer confidence in, and improve consumer experience with the selection of mHealth applications. Consumers preferentially purchasing FDA-approved products would also incentivize app developers to seek approval in order to be more competitive on app marketplaces. Furthermore, while many of these mHealth interventions would still require the consumer to pay for access and as such, insurance providers, including Medicare and Medicaid, could be incentivized to cover approved interventions to improve the effectiveness of the allocation of their resources, further diminishing financial barriers to evidence-based, FDA-approved products. While imposing additional regulations on mHealth interventions could necessitate added research testing, potentially increasing costs and slowing development time to release, these must be carefully weighed with the risks inherent in ineffective, or even potentially harmful, interventions.

IV. Youth-focused policy recommendations

While eHealth interventions have shown promise and rapidly developed in design and reach within the last few years, increased youth involvement in the design of, and consideration of youth in the regulation of these interventions may increase both their value and reach. We recommend youth inclusion in the design of these mental health interventions. An expansion of needs assessments and focus group research amongst this population can help improve the efficacy of interventions targeted toward youth, support greater engagement and retention, and increase the efficiency of developers' efforts and resources, as noted in Bevan Jones's and colleagues' (2020) review of existing models of co-designing digital mental health technology with youth. For instance, there may be group differences in technological literacy for youth compared to adults, as well as different barriers to accessing care (e.g., access to a private space or their own personal device) and different settings for intervention dissemination (e.g., at the school level, such as pairing remote healthcare providers with

specific schools). Design preference may also vary by age (Schwarz et al. 2020).

This process could involve youth at multiple phases of product development, such as generating ideas or refining prototypes, and employ methods such as focus groups, interviews, questionnaires, or crowdsourcing (Bevan Jones et al. 2020). Some challenges that may arise related to further including youth in the design of these interventions include time and monetary costs of additional participants and integrating their feedback. Given that co-design may result in more effective interventions, these drawbacks of co-design can be counterbalanced with incentives.

The FDA and insurance companies can further support youth-centered design by encouraging youth involvement throughout the development and testing of such interventions to align with the priorities of the FDA approval, and also limiting support or reimbursement for interventions that are not demonstrated to be both effective and safe for this population with its own distinct needs.

Additionally, research suggests that youth are more vulnerable to the influence of now widespread digital advertising due to their still-developing abilities to identify, assess, and make decisions related to digital marketing, which appears to be even more prominent among children from lower-income backgrounds whose parents may be less critical of such digital marketing themselves (Radesky et al. 2020). Thus, greater regulation supporting informed consumer decision-making throughout their search for and use of mHealth interventions may be particularly advantageous for youth and their families.

V. Evoking change through FDA regulation

Changes to the reach of FDA regulatory oversight can work to expand the range of interventions that are available without a prescription yet meet the FDA's rigorous safety and effectiveness standards, as well as further increase public literacy around evidence-based interventions through publicly accessible indicators. Broad insurance coverage of these interventions also assists with maintaining consistent access to established care for this population which possesses less control over their

healthcare provider choices and insurance status than working adults.

Governments, the private sector, healthcare providers, and, most importantly, patients all stand to benefit from the greater implementation of eHealth interventions. Many digital interventions can provide care at a much greater patient-to-provider ratio than traditional models, which can reduce costs to both patients and institutions, as well as increase reach to patients in need. Though eHealth interventions have proliferated, the federal regulation of these tools has settled into stringent regulation on one end and an

unregulated open marketplace on the other. We recommend a middle-ground approach for the regulation of mHealth applications by the FDA that involves a consistent, readily accessible indication of the mHealth interventions that are supported by evidence that involves youth stakeholders throughout the process and encourages insurance companies to include such interventions in their coverage. Such changes, alongside a broader effort to increase attention on youth-specific needs, have the potential to improve the efficacy and reach of these interventions and, therefore, maximize their ability to bridge the gap between need and available, effective mental healthcare for youth.

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