Elizabeth Heetderks-Fong, PhD

vredeveld STRATEGIES

PHILANTHROPIC OPPORTUNITIES FOR ENHANCEMENT OF DIGITAL MENTAL HEALTH

VISION

Everyone deserves affordable, accessible, effective mental health care. Digital health tools for both adults and kids, if used safely and effectively, can help achieve this. Often, due to regulatory barriers and lack of reimbursement, innovative digital tools don't reach those who need them the most, especially at-risk populations.

Inadequate access to mental health care is a critical issue, an estimated 21% (52.9 million) of US adults and 16.5% (7.7 million) of children experience mental illness per year[1]. Yet more than 26 million Americans don't get the mental health care they need, including 57% of adults and 58% of children with depression who go untreated, numbers that do not take into account the many estimated unreported and undiagnosed cases[2,3]. Sadly, the average delay in treatment after onset of symptoms of mental illness is 11 years.[4]

At-risk communities, particularly communities of color, suffer most from this mental health care crisis. There is also disparity in care, especially for children, which was true before COVID-19, and was then exacerbated by the pandemic. The CDC reported a 31% increase in pediatric mental-health related ER visits after the pandemic began—visits that possibly could have been avoided with appropriate access to primary mental health treatment[5]. Poor access to care is due to several reasons including cost, insurance coverage, lack of local or culturally competent providers, stigma, undersized mental health workforce, and deficiency of specific or specialized treatment types. Children with lower socio-economic backgrounds and communities of color were grossly disproportionately affected[6,7]. The burden of inefficient mental health care is so immense that it is estimated to cost the world economy $6 trillion *per year* by 2030[8].

While schools can play a role by providing resources and training teachers to recognize crises in children, and primary care and pediatricians' offices can screen and provide referrals, additional ways are needed for all people to access mental health support and care. The solution must include better tools for early detection and diagnosis, timely access to care, access to culturally competent providers, safe, compliant data sharing, and community gatekeepers like crisis counselors, public agencies, and schools.

This is where digital tools come in. Social entrepreneurs are creating novel digital apps that bridge the access gap between patient and provider, delivering care through a computer or smartphone. A recent survey showed that 40% of people believe that virtual healthcare will continue to grow post-pandemic, showing a promising opportunity for growth in this space.

Digital health tools need to be developed with safety, privacy, efficacy, regulation, and reimbursement in mind to ensure secure handling of health data and best deliverance of mental health care. Currently,

non-prescriptive apps, such as those that connect patient and provider, are not regulated or held to standards. Enhancing these apps and making sure they are safe and effective can revolutionize the digital health market and bring mental tele-health to all people, especially vulnerable populations that need it the most.

Philanthropists can help accelerate digital innovation. They can do this by supporting the development of a dynamic, digital evaluation tool built around artificial intelligence (AI) that provides real-world feedback on efficacy and safety of telehealth apps. It can also catalogue apps that specialize in specific treatment modalities or serve specific at-risk populations by having culturally competent providers. An added benefit to this tool is that it would consider patient experience in addition to expert opinion. If built carefully, the tool could help serve at-risk adults and children, people in crisis, and many other populations that are not typically served by the for-profit sector.

BACKGROUND

In 2021, international leaders, stakeholders, insurance companies, payers, patients, researchers, policy makers, health economists, and digital health companies convened at the Banbury Center at Cold Springs Harbor to discuss the future of digital mental health[9]. They determined that digital mental health treatment could indeed address the serious and worsening gaps in mental health coverage, especially for common mental health problems. They further suggested that digital mental health should be offered to all patients and should be fully reimbursed by insurance[9]. In fact, a 2020 systematic review and meta-analysis also determined that digital mental health tools were a good option for places where usual care for mental health is minimal[10].

With the ubiquity of the internet (over 85% of US households have internet access) and smart phones (85% of American adults have a cellphone, even those in lower socioeconomic status) these apps can also narrow the critical gap in mental health equity[11]. Evidence suggests that computer-based cognitive-behavioral therapy is effective and practical[12]. But app quality varies, so proof of efficacy and safety is essential. So is accounting for risks in privacy and security. Given the speed and pace of app output, standardization, and proof of efficacy, safety, and effectiveness is paramount, preferably using an approach built on real world evidence.

The FDA remains wary of approval in the digital space, and apps often don't fall into the traditional "medical device" category, as this novel format has emerged quickly in a vacuum of need created by COVID. It takes time for regulators to keep in pace with technological advancement. But, without formal regulation, there are no standards to ensure that these tools are effective at treatment, if they are private, or if they are safe.

During COVID, the FDA relaxed certification requirements for telehealth apps in order to address the need for patients to access providers remotely as well as address the looming mental health crisis as a result of the virus. This step allowed some apps to erroneously advertise themselves. The FDA has removed their easement on barriers and enforced new policies on telehealth. While there are approved apps for prescriptive treatment (such as Res-ET and EndeavorRx, essentially user-app interactive tools for treatment—not user-provider connectors), the regulation of apps that provide services that allow teleconferencing do not fall under the medical device category and therefore are not widely regulated. The FDA's general rule of thumb for digital apps is a risk-categorization management and clinical safety, without as much of a focus on efficacy.[13].

The Agency for Health Research and Quality (AHRQ), recently proposed a means on how to evaluate digital mental health apps for risk, function, and features: the Framework to Assist Stakeholders in Technology Evaluation for Recovery (FASTER). It's design allows informed decision-making by advocacy organizations, payers, and health systems to use in their selection of mental health apps.[14]

Reimbursement for digital health also remains a barrier. The American Medical Association (AMA) took a step forward with an advisory group to

determine coverage for digital health. New CPT codes have been established for digital health management, evidence of utility of these programs. However, reimbursement varies widely by state and insurer, and CMS is increasing restrictions post-COVID on how they reimburse telehealth, especially in the mental health space.

Creation of the digital health evaluation tool, funded by philanthropy, will help accelerate standards and reimbursement. As with any disrupter, there needs to be a process to build this tool that draws on research and knowledge sharing and brings together the best team to do it.

PHILANTHROPIC OPPORTUNITY: DIGITAL EVALUATION TOOL

Mental health global funding reached $5.5 billion in 2021, a 139% increase from 2020. The global digital health market is projected to reach $380 billion by 2024, representing a 26% annual growth. Early-stage investments made up 68%, and offer a promising chance for growth.

Currently, apps rely heavily on ratings and downloads. Many distinguished groups, including AHRQ and APA, have proposed frameworks for how persons can self-select an app within the frame of efficacy. Both groups stress feasibility, efficacy, privacy, clinical relevance, usability, and knowledge on how apps store data. So far there is no integrated or formal system cataloging and organizing this information based on these criteria for patient and possibly insurer benefit.

Building upon the AHRQ FASTER framework, philanthropists could support the creation of a dynamic tool built around artificial intelligence (AI) to evaluate apps. It would account for both user and expert review and analysis, identify the most effective and safe digital apps, and pave the way for reimbursement. An app built by philanthropists would have the added benefit of forecasting not just the potential financial value of each app, but also its social value.

Addressing Safety and Privacy Concerns

Mental health treatment is in its nature delicate, and patients, given their vulnerability, deserve safe, effective care. Safety is essential for both for provider and patients, especially confirming provider qualifications, and ensuring patients receive safe care in critically sensitive points in their lives. Privacy must be addressed, both in terms of HIPAA compliance (third party storage may not comply) and protection of client data from potential hackers and digital blackmailers. How data are stored by these companies needs to be transparent. A data transparency requirement should be incorporated into guidelines. Data storage and sharing is especially critical, as evident by GoodRx's recent FTC fine for sharing user personal health data for personalized advertisement, despite telling customers it would not do so. There must be an expectation of privacy in the delivery of care, just as there is one in doctor's offices.

Building on this evaluation tool, one could envision a dynamic digital formulary—similar to a drug formulary or in-network provider list, that insurers could use. This formulary would help providers and patients determine the best care as well as insurance companies determining which apps to reimburse. CMS is moving to a managed care model, making this a valuable tool for Medicaid/Medicare as well

Benefits of Digital Evaluation

- Real-time user-reviews, akin to a Press-Ganey survey
- Feedback to the apps themselves to allow for improvements in efficacy.
- Helps users choose the correct and most efficient apps for their needs.
- Takes into account cultural sensitivities, earmarking, and training
- Ensures privacy of personal information and safe delivery of care for the user
- Identifies apps that specialize in specific under-served, at-risk communities.

as private insurers. The tool would be dynamic, continuously updated with user-input and software changes alike in a rapidly evolving market.

Tackling Regulation and Reimbursement

Post-covid, many big insurers pulled back telehealth coverage—including for behavioral health. In fact, while telehealth was required to be reimbursed at equal rates from the CARES act during the pandemic, now that the Public Health Emergency Declaration has ended, many of the equalities given to telehealth are being removed or restricted.

Having the digital evaluation tool could help insurers identify which apps to reimburse and include in their "formulary".

CMS requires in-person appointments within six months prior to a tele-behavioral health appointment with their specific provider, excludes SUD co-morbid mental health disorders, and restricts audio-only appointments[15]. Reimbursement varies by state and entity (different states have different parity and coverage laws regarding telehealth), and most private insurers follow CMS when it comes to reimbursement. The re-introduction of restrictions on reimbursement erode the access that digital mental health provides. Having the digital evaluation tool could help insurers identify which apps to reimburse and include in their "formulary".

Proving efficacy and safety for mental telehealth via the evaluation tool will pave the road for regulatory standards and practices, which is the standard of all other deliveries of medical and mental health care. Telehealth needs to be held to the same standards and treated as if it is occurring in-office. This will support global reimbursement. And this will stimulate insurers, both CMS and private insurers, to fully cover services. The standardized measurement tool outlined above would support regulatory decisions and a regulatory body that approves apps.

Reimbursement significantly impacts mental health care equity. Availability of and reimbursement for digital health gives access to those with challenges accessing "usual" care, such as those in rural areas, or those in jobs that make it hard to take time off for appointments.

As young as digital health is, there are now CPT codes to support it. This is a huge win. A digital evaluation tool can help take this one step further by integrating standards into development. There are already models that show what's possible: UK, Netherlands, and Australia all currently fully reimburse digital mental health care.

KEEPING HEALTH EQUITY FRONT AND CENTER

The most powerful rationale for building a tool with philanthropic funds is that it keeps health equity front and center. An evaluation tool that provides data about user interest, usage, and satisfaction predicts future sales revenue. This data will be of great interest to investors. A tool that captures this data for special populations—at risk youth or people in crisis, for instance—increases the likelihood of investment in tools built specially with these populations in mind. Some apps with a high potential social impact are already being developed. They offer tremendous promise for more equity in mental health.

- **Culturally Competent Workforce**: One big hurdle in obtaining mental health treatment for particularly vulnerable communities is finding a culturally competent providers[1,16,17]. Persons seek treatment from those who have shared lived experiences. The literature is substantive and conclusive on this topic. A "gold star" could be awarded through the evaluation tool to apps that meet the professional competency standards. It may employ an expert panel to help identify what constitutes cultural competency and catalogue these requirements for specific communities.
- **Taking 988 a Step Further**: The 988 launch provided a quicker, easier-to-remember way for individuals in crisis to reach Lifeline crisis counselors. It's been largely successful in its

launch, with a 45% increase in calls compared to the old 1800 number[18], with lots of additional funding to increase awareness and usage. While historically thought of for only those with suicidal ideation, 988 is also for those with SUD and mental health crisis beyond suicide. Operators guide callers through their crisis and connect them with help. Many people have understandable fears about police involvement and escalation for people in crisis, especially from communities of color. In reality, only about 2% of calls need law enforcement involvement. What if the evaluation tool provided Lifeline counselors the ability to connect persons in need to the best app for quick referral and quick triage and counseling? With a list of proven efficient apps, and resources regarding cultural competencies and specific treatment options, Lifeline counselors could connect those in crisis with the right digital interface to get quick follow-up treatment, utilizing phone and text. It's something SAMHSA could integrate directly into the lifeline.

- **Integration of Schools and Pediatrics with Specialty Care:** For children in lower socio-economic backgrounds, mental health care is oft provided by school counselors and PCPs. Digital mental health could allow a collaboration between these providers and medical professionals to further expand the care for this community in need. The care could be tailored to the communities' specific needs via a "gatekeeper" such as a school counselor, religious leader, or primary provider. Once again, having the digital evaluation tool could steer school counselors and primary care doctors to apps that provide services for pediatric mental health, as well as specialty treatment they may need, bringing care more quickly to children in need.

PATHWAY TO COMMERCIALIZATION

Building on this evaluation tool, one could envision a dynamic digital formulary—similar to a drug formulary or in-network provider list—that insurers could use. This formulary would help providers and patients determine their best care, and insurance companies decide which apps to reimburse. CMS is moving to a managed care model, making this a valuable tool for Medicaid/Medicare as well as private insurers. One can imagine many paying customers: State Medicaid departments, CMS, and private investors looking for the next big thing. They would all benefit from a dynamic evaluation tool that is continuously updated with user-input and software changes alike in a rapidly evolving market.

CONCLUSION

It's time to close the gap on unmet mental health needs, especially for children. Philanthropists can be the catalyst for change. They can set the standards, promoting cultural sensitivity, and identifying the most impactful solutions for at-risk populations. By building a tool around very high standards for privacy and safety as well, they can also make sure apps get to the places they need to be. Apps need to bridge the diverse systems that serve people in need—social supports, schools, and the emerging crisis system –with the general medical system. High standards will help spur these business-to-government and business-to-business solutions. While young and niche, the field of digital mental health is also full of possibilities. By investing in a tool that social entrepreneurs, regulators, and investors can all use to track innovation, compliance, and uptake, philanthropists have an opportunity to take action, empower patients, and shape the future of mental health.

REFERENCES

1. Center For Behavioral Health Statistics and Quality Behavioral health equity report 2021: Substance use and mental health indicators measured from the National Survey on Drug Use and Health (NSDUH), 2015–2019 In: Mental SAa, Administration. HS, eds. Rockville, MD2021.
2. Takayanagi Y, Spira AP, Roth KB, Gallo JJ, Eaton WW, Mojtabai R. Accuracy of Reports of Lifetime Mental and Physical Disorders: Results From the Baltimore Epidemiological Catchment Area Study. JAMA Psychiatry 2014;71(3):273-280. DOI: 10.1001/jamapsychiatry.2013.3579.
3. Mental Health America. The State of Mental Health in America. 2021.
4. Wang PS, Berglund PA, Olfson M, Kessler RC. Delays in initial treatment contact after first onset of a mental disorder. Health services research 2004;39(2):393-415. (In eng). DOI: 10.1111/j.1475-6773.2004.00234.x.
5. Leeb RT BR, Radhakrishnan L, Martinez P, Njai R, Holland KM. Mental Health–Related Emergency Department Visits Among Children Aged <18 Years During the COVID-19 Pandemic — United States, January 1–October 17, 2020. MMWR Morb Mortal Wkly Rep. 2020.
6. Fortuna LR, Tolou-Shams M, Robles-Ramamurthy B, Porche MV. Inequity and the disproportionate impact of COVID-19 on communities of color in the United States: The need for a trauma-informed social justice response. Psychological trauma : theory, research, practice and policy 2020;12(5):443-445. (In eng). DOI: 10.1037/tra0000889.
7. Pearrow M, Berkman, T., Walker, W., Gordon, K., Whitcomb, S., Scottron, B., Kurtz,, K. P, A., & Hall, A. . . Behavioral health capacity of Massachusetts public school districts: Technical report. 2020. (. https://www.umb.edu/birch/research_evaluation).
8. The Lancet Global H. Mental health matters. The Lancet Global Health 2020;8(11):e1352. DOI: 10.1016/S2214-109X(20)30432-0.
9. Mohr DC, Azocar F, Bertagnolli A, et al. Banbury forum consensus statement on the path forward for digital mental health treatment. Psychiatric Services 2021;72(6):677-683.
10. Fu Z, Burger H, Arjadi R, Bockting CLH. Effectiveness of digital psychological interventions for mental health problems in low-income and middle-income countries: a systematic review and meta-analysis. The Lancet Psychiatry 2020;7(10):851-864. DOI: https://doi.org/10.1016/S2215-0366(20)30256-X.
11. Pew Research Center . Mobile Fact Sheet. April 7, 2021 ed2021.
12. Andrews G, Basu A, Cuijpers P, et al. Computer therapy for the anxiety and depression disorders is effective, acceptable and practical health care: An updated meta-analysis. Journal of Anxiety Disorders 2018;55:70-78. DOI: https://doi.org/10.1016/j.janxdis.2018.01.001.
13. FDA. Digital Health Policies and Public Health Solutions for COVID-19. FDA's Digital Health Policies Support COVID-19 Related Public Health Solutions. Food and Drug Administration2022.
14. Agarwal S JM, Wilcox HC, Sharma R, Hill R, Pantalone E, Thrul J, Rainey JC, Robinson KA. . Evaluation of Mental Health Mobile Applications. Technical Brief 41. (Prepared by the Johns Hopkins University Evidence-based Practice Center under Contract No. 75Q80120D00003.) AHRQ Publication. Rockville, MD: Agency for Healthcare Research and Quality, 2022.
15. CMS. CY 2023 Medicare Physician Fee Schedule (PFS). Baltimore, MD: Centers for Medicare & Medicaid Services, 2022.
16. Taylor RE, Kuo BC. Black American psychological help-seeking intention: An integrated literature review with recommendations for clinical practice. Journal of Psychotherapy Integration 2019;29(4):325.
17. Moghaddam JF, Momper SL. Integrating spiritual and Western treatment modalities in a Native American substance user center: provider perspectives. Substance use & misuse 2011;46(11):1431-7. (In eng). DOI: 10.3109/10826084.2011.592441.
18. Saunders H. Taking a Look at 988 Suicide & Crisis Lifeline Data, One Month After Launch.