Banbury Forum Consensus Statement on the Path Forward for Digital Mental Health Treatment

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A major obstacle to mental health treatment for many Americans is accessibility: the United States faces a shortage of mental health providers, resulting in federally designated shortage areas. Although digital mental health treatments (DMHTs) are effective interventions for common mental disorders, they have not been widely adopted by the U.S. health care system. National and international expert stakeholders representing health care organizations, insurance companies and payers, employers, patients, researchers, policy makers, health economists, and DMHT companies and the investment community attended two Banbury Forum meetings. The Banbury Forum reviewed the evidence for DMHTs, identified the challenges to successful and sustainable implementation, investigated the factors that contributed to more successful implementation internationally, and developed the following recommendations: guided DMHTs should be offered to all patients experiencing common mental disorders, DMHT products and services should be reimbursable to support integration into the U.S. health care landscape, and an evidence standards framework should be developed to support decision makers in evaluating DMHTs.

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Each year, nearly 20% of Americans experience a diagnosable mental health condition (1). Many people experience barriers to care (2–5). The United States has a shortage of mental health care specialists, with nearly 120 million Americans living in federally designated areas experiencing shortages of mental health providers (6, 7). The recent COVID-19 pandemic, which has increased the incidence of mental health problems, has further highlighted the challenges of mental health care access (8). Tele–mental health has been expanding for more than a decade to overcome regional disparities (9), and it has now been expanded more broadly under COVID-19 (10), with calls to make this expansion permanent (11). Although this expansion reduces regional challenges in access to care, it does not address the overall lack of mental health providers in the United States.

Digital mental health treatments (DMHTs, i.e, apps and Internet-based care) could overcome both access problems and provider shortages (12). DMHTs are delivered remotely and have shown effectiveness in more than 100 randomized controlled trials (RCTs) (13–15). Although DMHTs have begun to be integrated into health care systems in Europe and Australia (16–20), they have not been well integrated into the U.S. health care system. The Banbury Forum for Digital Mental Health Treatment was formed to uncover the reasons why DMHTs have not been broadly adopted by the U.S. health care system and to provide recommendations to overcome these challenges.

PROCESS AND METHODS

The Banbury Center convened a meeting, led by two cochairs (D.C.M., P.A.A.), of 23 international leaders and

HIGHLIGHTS

- Although digital mental health treatments (DMHTs) have consistently demonstrated effectiveness for common mental disorders, they have not been broadly integrated into the U.S. health care system.
- The Banbury Forum made three recommendations for DMHTs: DMHTs should be broadly adopted in the U.S. health care system, reimbursement mechanisms should be established to enable that adoption, and an evidence standards framework for evaluating DMHTs should be developed.
- The integration of DMHTs into care pathways could improve the efficiency of mental health services and would extend effective treatment to many people with mental health problems who are currently unable to access treatment.

stakeholders representing health care organizations, insurance companies and payers, employers, patients, researchers, policy makers, health economists, and DMHT companies and the investment community. The forum met October 6–8, 2019, to review the current state of the evidence, identify the primary challenges to adoption of DMHTs in the U.S. health care system, and make recommendations to facilitate the successful and sustainable implementation of effective digital mental health interventions in the United States. Each stakeholder group identified core challenges and opportunities. The forum reconvened remotely June 1, 2020, in response to the challenges that COVID-19 raised for this report, adding new representatives with expertise in the pandemic. An initial draft of this consensus report was discussed and refined in light of the current challenges in accessing mental health services during the COVID-19 pandemic.

RESULTS

Definition

DMHTs support patients and clinicians in managing mental health through the use of smartphone and Web applications, with growing research investigating therapeutic videogames, virtual reality, and conversational agents (12). Although all DMHTs are patient facing, the degree to which a provider is part of the platform varies on a continuum ranging from "adjunctive" (e.g., to support psychotherapy), to "guided" (key aspects of care are delivered by the technology and supported by a clinician, coach, or peer, who provides low-intensity support), to "fully automated" (used without human support, such as apps available from app stores) (21).

Opportunities

There was broad consensus that DMHTs provide an effective and scalable method for extending the reach of effective mental health care. This consensus was based on two areas of evidence: effectiveness and cost-effectiveness.

Effectiveness. Results from meta-analyses of at least 66 well-designed RCTs have indicated that guided DMHT has treatment efficiency for common mental health conditions such as depression and anxiety disorders that is comparable to the efficiencies of standard face-to-face therapies (13, 22, 23). A meta-analysis of eight RCTs has shown effectiveness of DMHTs for posttraumatic stress disorder (24). DMHTs for depression and anxiety are effective for mild, moderate, and severe symptoms (25, 26); moreover, they can be effective across the life span, with a growing number of RCTs indicating effectiveness among children and adolescents (27) as well as older adults (28, 29).

DMHTs are also effective for addressing common problems associated with mental health, such as insomnia (30). Several RCTs of guided digital treatments for alcohol and substance abuse have shown significant but more modest benefits of DMHTs (31, 32). Research on DMHTs for severe mental illness, such as bipolar and psychotic disorders, has shown feasibility, although efficacy data remain more limited (33, 34).

Guided DMHTs, which include low-intensity support from a clinician or coach via messaging or telephone, produce much larger benefits than fully automated DMHTs (22). Typically, this support aims to maintain patient adherence to the app and to monitor progress through periodic symptom assessment; however, support may also include assisting the patient in understanding concepts or skills training as well as triaging patients who do not respond to the DMHT to a higher level of care (35).

People can benefit from fully automated, unguided DMHTs (36); however, at a population level, they show small benefits, likely because dropout rates are higher in unguided than guided interventions (37, 38). Only a few studies have examined the use of DMHT tools as adjunctive support for psychotherapy. Although these studies have found that patients improve in treatments that blend DMHT with face-to-face psychotherapy, it is unclear whether the addition of DMHT tools results in any greater improvement or reduction in the amount of time required in psychotherapy (39, 40).

Cost-effectiveness. Emerging evidence supports the cost-effectiveness of guided DMHTs (20, 41). Guided DMHTs use substantially less provider time to treat patients with common mental health conditions than is typically required for standard psychotherapy. For example, stepped care programs that initiate treatment with a DMHT and move nonresponding patients to traditionally delivered psychotherapy use about half the clinician time required for programs that do not have a stepped care option and use psychotherapy only (42). Moreover, outcomes for DMHTs supported by non–mental health specialists do not differ from outcomes for DMHTs supported by mental health specialists (43), which allows for task-shifting options to lower levels of licensure, education requirements, and cost.

Although some guided DMHTs met cost-effectiveness criteria, automated DMHTs typically have not, in part because their effectiveness is lower (41). However, whether to use fully automated or guided DMHTs remains controversial. The ratio of fixed costs (e.g., costs of integrating electronic health records and of licensing), required for both guided and automated DMHTs, to the number of patient users decreases as a DMHT is scaled up. However, variable costs (e.g., therapists or care managers providing guidance), primarily associated with guided DMHTs, increase with each new patient. Indeed, even though automated DMHTs are less effective than guided DMHTs, automated DMHTs have been shown to cost less overall (44).

Challenges

Around the globe, the adoption of DMHTs has increased, owing to their effectiveness and potential to improve

efficiency of mental health care delivery. For example, England's National Institute for Health and Care Excellence, which issues guidelines for clinical practice and health technologies in their National Health Service, approved the use of Internet-based cognitive-behavioral therapy (iCBT) for depression and anxiety in mental health services in 2006 (16). In 2009, the recommendation for the use of DMHTs was integrated into the guidelines for depression treatment (17). In Australia, the federal government has funded several initiatives, such as MindSpot, to deliver DMHTs for common mental health problems since at least 2010 (45). In the Netherlands, insurance companies are required to cover payments for DMHTs, and the government provides funding for the delivery of DMHTs, free of charge, for those who do not want to use treatments offered through usual care venues.

Reimbursement for DMHTs. A primary challenge in reimbursement for DMHT provision is the variability of payment methods existing in the United States. Some organizations that provide health care, such as Kaiser Permanente or the Veterans Health Administration, operate completely outside the fee-for-service model. This method creates greater flexibility in decisions around the adoption of new treatments and technologies but imposes strict budget constraints. For instance, Kaiser Permanente has begun offering DMHTs and views them as clinical tools and services that are part of a new standard of care. Some states, such as California, are also piloting the use of DMHTs in public mental health. Self-insured employers are adopting DMHTs as part of their service packages for employees. However, most Americans are served by health care organizations that operate with a mix of payment models.

In 2018, approximately 36% of health care payments were tied to bundled payments, shared savings, and other alternative payment methods (APMs); the remainder were fee-for-service methods (some tied to value and quality and some others not) (46). APMs focus on improving outcomes and reducing costs, which could favor effective DMHT deployment. Although the United States is gradually adopting APMs, the fee-for-service model is likely to remain a dominant payment form for the foreseeable future. The fee-for-service model relies on Current Procedural Terminology (CPT) codes or the Healthcare Common Procedure Coding System to bill for services.

Currently, DMHTs do not have billing codes, making broad adoption of DMHT services financially unworkable in U.S. health care organizations (47). However, in response to social-distancing measures during the COVID-19 pandemic, the entire U.S. health care system has rapidly transitioned to remote care by relaxing the rules around telemedicine (48). The American Medical Association has an advisory group working on similar coverage issues for digital health tools (49). Recently, the new CPT codes 98970–98972 were opened for online digital evaluation and management services (50). Although these codes are only for physicians, physician assistants, and nurses, they could be expanded to cover a broader range of practitioners who would support DMHTs. Reimbursement for the cost of DMHT products will also be required, and it could be handled in several ways, including through device codes or embedding the cost of the product in the CPT code.

DMHT evidence standards framework. An evidence standards framework is needed to support "digital formularies," which allow provider organizations and payers to identify preferred products (51). Although the U.S. Food and Drug Administration (FDA) does not currently enforce regulatory requirements on the kinds of software and functionality used by most DMHT tools, some companies have elected nonetheless to seek FDA clearance. However, there was consensus among relevant forum participants that FDA clearance, which focuses on safety and minimal effectiveness thresholds, does not provide adequate information for decision makers. The United States does not have a body such as England's National Institute for Health and Care Excellence that evaluates effectiveness and cost-effectiveness of services and treatment (52); however, this role is sometimes filled by nongovernmental organizations such as the Institute for Clinical and Economic Review.

An evidence standards framework should integrate core ethical principles of respect for persons, beneficence, and justice (53); be specific enough to protect stakeholders, including patients, families, providers, and payers; and be flexible enough to be applied to new forms of DMHTs that harness new knowledge, design, and affordances from technological advancements. Several exemplar frameworks exist that cover core principles for DMHT standards (52, 54, 55), which we elaborate on next.

Benefit and efficacy. The best practice standard for effectiveness consists of at least one well-powered, well-designed RCT, conducted in a relevant setting, in which an accepted condition-specific clinical outcome is used with participants who represent the target population. This level of evidence should be required when a DMHT represents a novel intervention or new technological medium.

In the absence of data for a given tool, a minimum evidence standard may be applied if the DMHT is based on a previously validated DMHT method. For instance, because there is a strong evidence base for guided iCBT (37), a new iCBT product might be considered evidence based if it has fidelity to core elements of iCBT platforms, for example, by meta-analysis of previous trials. For iCBT, very few of the products that claim to be based on cognitive-behavioral therapy (CBT) actually contain the CBT core elements (56). When indirect scientific evidence might suffice, some evidence through nonexperimental studies, such as single-arm pilot studies with an appropriate sample of participants, should be conducted to evaluate the feasibility, acceptability, and safety of a platform (56–58).

Engagement. Patient engagement has been a challenge for some DMHTs. Although some trials have shown strong

patient engagement in health care settings (59), others have had high dropout rates (60, 61). Challenges in maintaining the engagement of health care workers tasked with coaching guided DMHTs can arise from difficulties of fitting tasks into the workflow, lack of adequate training and support, and reluctance to taking on new tasks with unclear productivity metrics (62).

A best practice standard would be high levels of sustained patient engagement with the tools in a well-designed RCT. Because provider engagement from RCTs may be difficult to generalize, as providers often work closely with research staff in trials, an evaluation of the user experience, including how useful it is, ease of use, efficiency, and satisfaction, may be conducted with representative providers (63). Minimal standards for user engagement may include evidence that representatives from intended user groups were involved in the design and testing of the DMHT; standards may also include user experience evaluations with representative users.

Data sharing and interoperability. DMHTs involve platforms that share data seamlessly among electronic health records, DMHT tools, and community-based sources for comprehensive population health management. Guided DMHTs should collect relevant data from the patient, which should be delivered to the provider to inform care. In most cases, these data should include validated self-reported symptom severity. This component is critical for measurement-based care, allowing the provider to monitor improvement and to intervene and triage to a higher level of care (64). It is also useful for providers to be able to see usage of the technology so that patient engagement is supported (35, 65). Thus, DMHTs need requirements for data interoperability that support their intended aims and align with the larger movement in health care (66).

Risk management. Although there is no evidence from trials that DMHTs themselves are harmful or pose a risk (67), some DMHTs have been be found to provide advice that is potentially harmful (68). Mental health conditions also can increase risks, most notably for suicide (69). Standards should include a careful review to ensure that no content is potentially harmful. DMHTs should include functionality that supports the identification and management of suicidality or other relevant risk factors.

Data security and privacy. Evidence standards should ensure that all data collected are kept confidential. Although some companies have not been transparent about the use, sharing, or sale of data (70), vendors also may be interested in using the data for a variety of reasonable purposes, including continuous improvement of the product. Privacy policies should be available to the patient that explain data management processes, including what data are being stored; where, how, and for how long the data are stored; who has access to the data; and for which purposes the data will be used.

Equity. In addition to the evidence standards described earlier, the forum also felt that issues addressing equity should be considered, including access barriers due to income, language, or disability. The Americans with Disabilities Act of 1990 directs most health care settings within the United States to ensure that patients who are blind, deafblind, or visually impaired have equal access to participate in and benefit from all the goods and services provided by the health care facility. Standards should ensure that screen readers can parse content on a page to make DMHTs usable for visually impaired populations.

Several health care agencies have recommended that the readability of English language patient education materials should not be higher than fifth- to eighth-grade level (71); in addition, services and patient materials should be provided in the patient's preferred language (72). Patients with low income may have more tenuous connectivity, with limited Wi-Fi access and data plans, resulting in additional costs to the patient and higher rates of suspended service (73). Thus, standards should consider the data requirements of a DMHT, and organizations that provide health care should consider DMHT implementation plans that mitigate the potential barriers for patients with low income or limited English proficiency.

Recommendations

The Banbury Forum unanimously made the following actionable recommendations.

Recommendation 1. Guided DMHTs should be offered as a treatment option to all patients experiencing depression, anxiety disorders, and posttraumatic stress disorder. There is a large evidence base that has consistently shown that guided DMHTs are effective across the life span and for all levels of symptom severity. DMHTs should be integrated into care pathways to increase access to mental health treatment and used to optimize the efficiency of mental health services.

Recommendation 2. DMHT products and services should be reimbursable to support integration into the U.S. health care landscape. Absence of reimbursement mechanisms is the primary impediment for DMHT implementation in many health care organizations. DMHT reimbursement must cover the cost of both the DMHT product and the provider time at rates equal to reimbursement rates for similar amounts of time spent in face-to-face treatments. Reimbursement mechanisms must be integrated into the variety of reimbursement systems used through federal, state, and commercial payers.

Recommendation 3. An evidence standards framework should be developed to support digital formularies and decision making in health care organizations, states, and commercial health plans and payers in selecting DMHT products that are effective, usable, safe, and equitable.

Although the United States does not have a centralized process for creating evidence-based standards, these frameworks can be developed through nongovernmental or professional organizations.

DISCUSSION AND CONCLUSIONS

Recognition is growing that the United States requires a more sustainable approach to ensuring affordable access to effective mental health care delivery, including expansion of access, remotely delivered mental health services, and increased adoption of measurement-based care (74). DMHTs are an effective method of delivering mental health care remotely, and they produce outcomes that support measurement-based care. Integration of DMHTs into care pathways would improve the efficiency of mental health services, for example, through stepped care models in which patients initiate treatment with lower-cost DMHTs, preserving mental health specialist time for those who do not show sufficient responses to DMHT (42).

The forum participants recognized that these recommendations, although necessary, are not sufficient to achieve integration of DMHTs into the U.S. health care system. Opening reimbursement mechanisms, such as CPT and device codes, does not guarantee that they will be used, as shown by the recent behavioral health integration codes intended to support collaborative care. To use these codes, health care organizations will require substantial procedural and billing workflow adjustments, which can be difficult to implement (75). Copayments can reduce patient uptake. Health care organizations will also require guidance on the integration of DMHTs into their care pathways. Clinicians who support patients in their treatment through DMHTs will require training to obtain optimal engagement and outcomes. DMHT integration has an additional challenge, not encountered with collaborative care, because it relies on devices and connectivity that are not equally distributed across the U.S. population. Device codes exist that could enable purchasing devices and connectivity, and infrastructure is available, such as the federal Lifeline Assistance program (e.g., Obama phones). However, because health care organizations have made few efforts to assist patients with low income in acquiring phones, tablets, computers, or data plans, policies and procedures will need to be developed to ensure that patients are aware of these opportunities to improve connectivity.

The experience with collaborative care may offer some guidance on strategies to overcome these challenges. The University of Washington's Advanced Integrated Mental Health Solutions (AIMS) Center has taken a leadership role in advancing collaborative care and, more recently, in the implementation of device codes. The AIMS Center, as part of training in the implementation of effective collaborative care, also provides training and implementation assistance to health care organizations in developing reimbursement procedures. A similar center could play an important role in supporting the effective adoption of DMHTs, including the use of CPT and device codes, definition of evidence standards for DMHTs, and strategies to make patients aware of opportunities to better connect with health services through technology. Implementation may also be facilitated by DMHT companies, which have an interest in supporting health care staff in effective implementation and assisting health care organizations in developing efficient reimbursement processes.

The United States has lagged behind other countries in integrating digital mental health into its health care system. Although interest is growing in adopting DMHTs, the absence of reimbursement mechanisms remains a primary obstacle to broad adoption. These recommendations are consistent with recent policy statements from Mental Health America, the nation's largest patient advocacy organization, calling for reimbursement of DMHTs (76). The U.S. health care system has made a remarkably rapid transition to remote care by relaxing the rules around telemedicine (48); moreover, it has begun considering codes that would support digital health administered by physicians and nurses (50). The need and momentum for the integration of DMHTs into the U.S. health care system are here. Enabling reimbursement would allow health care organizations to make DMHTs broadly available, with evidence standards that would support the selection of DMHT products and services that are effective and can be sustainably implemented.

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