

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

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ABSTRACT

A major obstacle to mental health treatment for many Americans is accessibility: the U.S. faces a shortage of mental health providers, resulting in federally-designated shortage areas. Digital mental health treatments (DMHT) are effective interventions for common mental disorders but have not been widely adopted by the American healthcare system. National and international expert stakeholders representing healthcare organizations, insurance and payers, employers, patients, research, policy, health economics, DMHT companies, and the investment community attended two Banbury Forum meetings to review the evidence for DMHTs, identify the challenges to successful and sustainable implementation, understand factors that have contributed to more successful implementation internationally, and develop recommendations. The Banbury Forum proposed the following recommendations: (1) Guided DMHTs should be offered to all patients experiencing common mental disorders; (2) DMHT products and services should be reimbursable to support integration into the American healthcare landscape; (3) An evidence standards framework should be developed to support decision makers in evaluating DMHTs.

Highlights

- Digital mental health treatments (DMHTs) have consistently demonstrated effectiveness for common mental disorders, yet they have not been broadly integrated into our healthcare system.
- The Banbury Forum, which included a broad range of national and international stakeholders, made three recommendations based on the evidence: 1) DMHTs should be broadly adopted in the U.S. healthcare system; 2) reimbursement mechanisms should be established to enable that adoption; and 3) An evidence standards framework for the evaluation of 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.

INTRODUCTION

Each year, nearly 20% of Americans experience a diagnosable mental health condition.¹ Many people experience barriers to care.²⁻⁵ The U.S. has a shortage of mental healthcare specialists, with nearly 120 million Americans living in federally designated mental health provider shortage areas.^{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 disparities⁹, and is now expanded more broadly under COVID-19¹⁰ 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 US.

Digital Mental Health Treatments (DMHTs; apps and internet based care) could overcome both access and provider shortage problems.¹² DMHTs are delivered remotely and have demonstrated effectiveness in more than 100 randomized controlled trials (RCTs).¹³⁻¹⁵ While DMHTs have begun to be integrated into healthcare systems in Europe and Australia,¹⁶⁻²⁰ they have not been well integrated into the U.S. healthcare 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. Healthcare system and to provide recommendations to overcome those challenges.

PROCESS AND METHODS

The Banbury Center convened a meeting of 23 international leaders and stakeholders representing healthcare organizations, insurance and payers, employers, patients, research, policy, health economics, DMHT companies, and the investment community, led by co-chairs Drs. Areán and Mohr. The forum met in October 2019 to review the current state of the evidence and identify the primary challenges to adoption of DMHTs in the American healthcare system, and to make recommendations to facilitate the successful and sustainable implementation of effective digital mental health interventions in the American healthcare system. Each stakeholder group identified core challenges and opportunities in the US. The forum reconvened remotely on June 2020 in response to the challenges 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 using smartphone and web applications, with growing research investigating therapeutic videogames, virtual reality, and conversational agents.¹² While all DMHTs are patient-facing, the degree to which a provider is part of the platform varies on a continuum from *adjunctive* (e.g., to support psychotherapy), to *guided* (key aspects of care are delivered by the technology, supported by a clinician, coach, or peer, who provides low-intensity support), to *fully automated* (used without human support, such as apps available from the app stores).²¹

Opportunities

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

Effectiveness. Meta-analyses of at least 66 well-designed RCTs have demonstrated that guided DMHT is effective for common mental health conditions such as depression and anxiety disorders, comparable to standard face-to-face therapies.^{13,22,23} A meta-analysis of 8 RCTs has

shown effectiveness of DMHTs for post-traumatic stress disorder (PTSD).²⁴ DMHTs for depression and anxiety are effective at the mild, moderate, and severe ranges of symptom severity,^{25,26} and can be effective across the lifespan, with a growing number of RCTs demonstrating effectiveness in children and adolescents,²⁷ and older adults.^{28,29}

DMHTs are also effective for 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.^{31,32} Research on DMHTs for severe mental illness such as bipolar and psychotic disorders have shown feasibility, although efficacy data remains more limited.^{33,34}

Automated vs. Guided vs. Adjunctive DMHTs. 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 monitor progress through periodic symptom assessment, but may also include assisting the patient in understanding concepts or skills training, and 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. While these 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 can treat common mental health conditions with substantially less provider time than is typically required for standard psychotherapy. For example, stepped care programs that initiate treatment with a DMHT and move non-responders 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 In addition, there is no difference in outcomes for DMHTs supported by non-mental health specialists compared to DMHTs supported by mental health specialists,⁴³ which allows for task sharing options at lower levels of licensure and cost.

While 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 EHR integration, licensing), required for both guided and automated DMHTs, to 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, automated DMHT have been shown to cost less overall.⁴⁴

Challenges

Around the globe there has been an increased in the adoption of DMHTs, owing to their

effectiveness and potential to improve efficiency of mental healthcare delivery. For example, the English National Institute for Health and Care Excellence (NICE), which issues guidelines for clinical practice and health technologies in their National Health Service (NHS), approved the use of 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 treatment of depression.¹⁷ In Australia, the federal government has funded a number of initiatives to deliver DMHTs for common mental health problems since at least 2010, such as MindSpot.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 of DMHTs. A primary challenge in reimbursement of DMHTs is in the variability of payment methods that exist in the US. Some healthcare providing organizations such as Kaiser Permanente or the Veterans Health Administration operate completely outside the fee-for-service model. This 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, the vast majority of Americans are served by healthcare organizations that operate with a mix of payment models. In 2018, approximately 36% of healthcare payments were tied to bundled payments, shared saving, and other alternative payment methods (APMs), and the remainder were fee-for-service (some tied to value and quality and some not).⁴⁶ APMs focus on improving outcomes and reducing costs, which could favor effective deployment of DMHTs. While the United States is gradually adopting APMs, the fee-for-service model is likely to remain a dominant form of payment for the foreseeable future. Fee-for-service relies on Current Procedural Terminology (CPT) codes or the Healthcare Common Procedure Coding System (HCPCS) to bill for services.

Currently there are no billing codes for DMHTs, making broad adoption of DMHT services financially unworkable in American healthcare organizations.⁴⁷ However, in response to social distancing measures during the COVID-19 pandemic, the entire American healthcare system has made a remarkably rapid transition 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, new CPT codes 98970-98792 were opened for online digital evaluation and management services.⁵⁰ While these 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 could be handled in a number of ways, including through device codes and/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 While the 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 NICE that evaluates effectiveness and cost-effectiveness of services and treatment,⁵² however this role is sometimes filled by non-governmental 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 must be specific enough to protect stakeholders, including patients, families, providers, and payers, and also being flexible enough to be applied to new forms of DMHTs that harness the affordances of technological advancements. A number of exemplar frameworks exist, which cover core principles for DMHT standards,^{52,54,55} upon which we elaborate below.

Benefit/Efficacy: The best practice standard for effectiveness consists of at least one well-powered, well-designed RCT, conducted in a relevant setting, using an accepted condition-specific clinical outcome with participants who are representative of 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 previously validated DMHT method. For instance, because there is a strong evidence base for guided internet based cognitive behavioral therapy (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 CBT-based actually contain the core elements of CBT.⁵⁶ When indirect scientific evidence might suffice, some evidence through non-experimental 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. While some trials have shown strong patient engagement in healthcare settings,⁵⁹ others have had high dropout rates.^{60,61} Challenges in maintaining the engagement of healthcare workers tasked with coaching guided DMHTs can occur from difficulty 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 demonstrate 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, and may also include user experience evaluations with representative users.

Data Sharing (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, this should include validated self-reported symptom severity. This is a critical component 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, to support patient engagement.^{35,65} Thus, DMHTs need requirements for data interoperability that support their intended aims and align with the larger movement in healthcare.⁶⁶

Risk management. While there is no evidence from trials that DMHTs themselves are harmful or pose a risk,⁶⁷ some DMHTs have been found to provide advice that is potentially harmful.⁶⁸ Mental health conditions also can increase risks, most notably suicide.⁶⁹ Standards should include a careful review to ensure there is no content that 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 is kept confidential. While some companies have not been transparent about the use, sharing, or sale of data,⁷⁰ vendors also can have interests in using the data for a variety of reasonable purposes, including continuous improvement of the product. Privacy policies should be available to the patient, which explain data management processes, including what data is being stored, where it is stored, how it is stored, how long it will be stored, who has access to the data, and the purposes for which the data will be used.

Equity. In addition to the evidence standards described above, 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 directs most healthcare settings within the U.S. to ensure that patients who are blind, deaf-blind or visually impaired have equal access to participate in and benefit from all the goods and services provided by the healthcare facility. Standards should ensure that screen readers can parse content on a page to make DMHTs usable for blind populations. Several healthcare agencies have recommended that the readability of English language patient education materials should not be higher than fifth- to eighth-grade level,⁷¹ and services and patient materials should be provided in the patient's preferred language.⁷² Low income patients 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 healthcare providing organizations should consider DMHT implementation plans that mitigate the potential barriers to low-income patients and patients with limited English proficiency.

Recommendations

The Banbury Forum was unanimous in making the following actionable recommendations:

Recommendation 1. *Guided DMHTs should be offered as a treatment option to all patients experiencing depression, anxiety disorders, and PTSD.*

There is a large evidence base, which has consistently shown that guided DMHTs are effective across the lifespan 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 American healthcare landscape.

Absence of reimbursement mechanisms is the primary impediment for implementation of DMHTs in many healthcare organizations. DMHT reimbursement must cover both the cost of the DMHT product as well as the provider time at rates that are 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 healthcare organizations, states, and commercial health plans and payers in selecting DMHT products that are effective, usable, safe, and equitable.

While the US does not have a centralized process for creating evidence-based standards frameworks, these can be developed through non-governmental or professional organizations.

DISCUSSION & CONCLUSIONS

There is a growing recognition that the United States requires a more sustainable approach to ensuring affordable access to effective mental healthcare 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 healthcare remotely, and collect 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 where patients initiate treatment with lower cost DMHTs, preserving mental health specialist time for those who do not show sufficient response.⁴²

The forum participants recognized that these recommendations, while necessary, are not sufficient to achieve integration of DMHTs into our healthcare 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. Using these codes requires substantial procedural and billing workflow adjustments that can be complicated for healthcare organization to implement.⁷⁵ Co-payments can reduce patient uptake. Healthcare 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, as it relies on devices and connectivity that are not equally distributed across the American population. Device codes exist that could potentially enable purchasing devices and connectivity, and infrastructure is available, such as the Federal Lifeline Assistance program (a.k.a Obama Phones). However, as there have been few efforts on the part of healthcare organizations to assist low income patients in acquiring phones, tablets, computers, or data plans, policies and procedures will need to be developed to ensure 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 provided a leadership role in advancing collaborative care, and more recently in the implementation of these codes. The AIMS Center as part of training in the implementation of effective collaborative care, also provides training and implementation assistance to healthcare organizations in developing procedures for reimbursement. 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 how to make patients aware of opportunities to be better connected through technology. Implementation may also be facilitated by DMHT companies, which have an interest in supporting healthcare staff in effective implementation as well as healthcare organizations in developing efficient processes for reimbursement.

The United States has lagged behind other countries in the integration of digital mental health into the American healthcare system. While there is growing interest 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, our nation’s largest patient advocacy organization, calling for reimbursement of DMHTs.⁷⁶ The American healthcare system has made a remarkably rapid transition to remote care by relaxing the rules around telemedicine⁴⁸ and 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 our healthcare system are here. Enabling reimbursement would allow healthcare 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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