A Roadmap to Computer-Based Psychotherapy in the United States

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Computers can be used to deliver self-guided interventions and to provide access to live therapists at remote locations. These treatment modalities could help overcome barriers to treatment, including cost, availability of therapists, logistics of scheduling and traveling to appointments, stigma, and lack of therapist training in evidence-based treatments (EBTs). EBTs could be delivered at any time in any place to individuals who might otherwise not have access to them, improving public mental health across the United States. In order to fully exploit the opportunities to use computers for mental health care delivery, however, advances need to be made in four domains: (1) research, (2) training, (3) policy, and (4) industry. This article discusses specific challenges (and some possible solutions) to implementing computer-based distance therapy and self-guided treatments in the United States. It lays out both a roadmap and, in each of the four domains, the milestones that need to be met to reach the goal of making EBTs for behavioral health problems available to all Americans. (HARV REV PSYCHIATRY 2010;18:80–95.)

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barriers to treatment, including cost, availability of therapists, logistics of scheduling and traveling to appointments, stigma, and lack of therapist training in evidence-based treatments (EBTs). EBTs could be delivered at any time in any place to individuals who might otherwise not have access to them, improving public mental health across the United States. In this article we discuss specific challenges (and some possible solutions) to implementing computer-based distance therapy and self-guided treatments in the United States. It lays out both a roadmap and, in each of the four domains, the milestones that need to be met to reach the goal of making EBTs for behavioral health problems available to all Americans.

BACKGROUND

Mental health disorders are widespread in the United States, costing the nation, as it does many other nations, billions of dollars in lost income, reduced productivity, and disability. In the United States, mental health disorders account for four of the ten leading causes of lost productivity,[1]

and the annual cost in income not earned due to mental health disorders is \$193 billion.[2] Successful treatment of mental disorders generally returns individuals to productivity levels comparable to those who have no history of mental health problems.[3] However, only 22% of U.S. workers with high levels of psychological distress receive treatment.[3] Providing mental health services to persons who need it would improve the United States' productivity and the overall wellness of the population. These changes would, in turn, increase the competitiveness of U.S. goods sold abroad, improve our balance of trade, and lead to improvement in national morale.

Barriers to the Dissemination of Evidence-Based Treatments

Although effective EBTs for mental health disorders exist, there are barriers to their widespread dissemination in the United States, including *cost*, *availability*, *logistics*, *stigma*, and *training*. The *cost* of behavioral health and psychiatric care is often borne directly by consumers; however, paying out of pocket for ongoing mental health services is prohibitive for many.[4] Insurance plans commonly provide limited coverage, and mental health parity legislation will not apply to businesses with fewer than 50 employees.[5]

The *availability* of mental health services is limited. The number of adequately trained mental health care providers is insufficient to meet the nation's needs; approximately 19% of Americans lack adequate access to mental health care professionals.[6] Treatment options for racial minorities and non-English speakers are even more limited.[7] In the end, it makes little difference whether EBTs exist, if the individuals who need them do not have access to them.

Logistics pose barriers to receiving therapy in general and EBTs in particular. To receive psychotherapy, patients are typically scheduled for weekly or biweekly visits. Many factors conspire against individuals receiving a sufficient dose of treatment: taking time off from work, arranging child care, and potentially traveling a substantial time and distance.

The *stigma* of seeking mental health care—in self-perception and in social and employment consequences—can prevent individuals from asking for help.[8–10]

Finally, many master's- and doctoral-level mental health professionals are not *trained* in EBTs.[11] Practicing clinicians typically fail to adopt such treatments,[12] and even when they are aware of the evidence-based guidelines and do attempt to provide EBTs, the treatments are often not delivered properly.[13] To retrain and supervise existing providers in new EBTs would be costly, time-consuming, and unlikely to build the capacity needed to meet the need for these treatments in the necessary time frame. Innovative solutions are required that will enable mental health generalists to provide EBTs without requiring the modification of their own skills and behaviors.

Computer delivery of EBTs can help overcome the barriers of cost, availability, logistics, stigma, and training, and can facilitate major improvements in public mental health. Two primary routes of computer dissemination of EBTs are available: self-guided treatment and distance therapy. *Self-guided treatment programs* are interactive programs designed to treat clinical problems or help patients change their behaviors to improve their health. These programs are typically highly interactive, may utilize multiple forms of media, such as video, audio, text, and animations, and can be delivered via the Internet or as stand-alone computer programs. *Distance therapy* involves connecting patients remotely with therapists via email, asynchronous messaging, videoconferencing, or even telephone (including Internet telephony, such as Skype). Hybrid programs exist that integrate the features of self-guided treatment with those of distant therapy. These programs link online behavioral self-management programs with additional asynchronous and synchronous access to online mental health professionals 24/7 and even have the ability to pass distressed online clients along to clinicians at telephone call centers.[14] A third form of computer-assisted intervention is *in-session support* that enables generalist clinicians to offer specialty treatments during face-to-face therapy sessions. While in-session support helps to overcome the barrier of training, it does not address the other barriers that we have discussed: cost, availability, logistics, and stigma. Our emphasis in this article is therefore on self-guided treatments and distance therapy, although all three forms of computer-assisted treatment could be used in combination.

Self-Guided Treatments

Self-guided, computer-administered treatments have existed for over 40 years, and their defining characteristic is that the intervention is delivered primarily via computing technology. They can be used at home or in health care settings to deliver interventions previously available only via specialists. Moreover, multiple language capabilities can be built into systems to provide treatment to persons who would otherwise have few therapy options in their communities.[15,16] The earliest psychotherapy programs appear to be those developed in 1966 by Colby[17] (to deliver psychoanalysis) and in 1977 by Slack[18] (using "soliloquy therapy," a nondirective approach). Both programs use natural language—typed in text or spoken words—as the primary patient input. Another program of that era, ELIZA, was developed in 1966 to study linguistics,[19] though some heralded it as a therapy program. Clinical trials

of those programs do not meet modern evaluation standards, but it is clear that the users found the programs acceptable and readily revealed personal information to them. The finding that patients are sometimes more willing to reveal sensitive, potentially embarrassing personal information to computers than human interviewers has been well supported in subsequent studies by Locke[20] and others.[21–23]

The current generation of self-guided treatment programs is based largely on cognitive-behavioral therapy (CBT) and utilizes multiple technologies. Many of these programs focus on depression, such as a 1990 program by Selmi,[24,25] which delivered CBT via text and menus. More recent programs have incorporated multimedia, such as a program by Carter[26] for the National Aeronautics and Space Administration (NASA) that uses problem-solving therapy and another by Cavanagh,[27] commercialized in the United Kingdom. Other programs have successfully treated eating disorders[28] and substance abuse.[29,30] Recent interventions have been delivered via mobile phone texting, such as programs for smoking cessation[31,32] and weight loss,[33] and home gaming consoles (e.g., Wii, PlayStation, Xbox) (with the latter being particularly geared toward youths).[34,35]

At this point, meta-analyses and systematic reviews are beginning to appear to synthesize the literature on self-guided, computer-delivered treatments. Reger and Gahm[36] conducted a meta-analysis of 19 evaluations of Internet and computer-based treatments of anxiety disorders and found a mean effect size (Cohen's d) of .76, with mean ds of various clinical measures ranging from .49 to 1.14. Additionally, a systematic review of 8 studies of self-guided treatment for obsessive-compulsive disorder was conducted by Lack and Storch.[37] While they found that the benefits of self-guided treatment varied between studies, one program was superior to treatment by clinicians. Cavanagh and Shapiro[38] conducted a meta-analysis of five depression and anxiety self-treatment studies and found strong pre/post gains for persons who used these programs, though computer-based treatments were not found to be as effective as treatment by clinicians. Finally, Kaltenthaler and colleagues[39] conducted a detailed review of four randomized clinical trials of self-guided treatments for mild to moderate depression. They found that three of the four treatments studied demonstrated efficacy, with one treatment producing better outcomes than primary care, although premature dropout from treatment was a problem for all studies. Taken together, this research suggests that the field of self-guided, computer-based treatments is in its early phases. We have learned that some treatments work better than others, and they are not necessarily better than treatment from a specialist. However, because of their scalability and the observation that dropout rates in computer-based CBT is similar to that

in face-to-face treatment, they do show promise as a means for the mass dissemination of EBTs to persons who otherwise may not access them.[40,41]

Distance Therapy

Distance therapy is treatment delivered by a live behavioral health professional (typically a master's-level therapist) who is at a remote location. It may occur synchronously via voice, videoconference, or instant messaging; or asynchronously through email, mobile phone texting, or postings on a secure Web site. Typically, the distance therapist never meets face-to-face with the patient. Computer-mediated distance therapy can overcome both the lack of local specialists in a given EBT and the logistical barriers to appointments. It may also reduce the stigma of asking for help since contact is usually not made in person, and it can connect patients with therapists who are trained in relevant EBTs. Distance therapy may not reduce the cost of treatment, however, since therapist time still needs to be devoted to each patient.

Less research has been done on Internet-based distance therapy than on self-guided treatments; however, the research on telephone therapy is pertinent. For a meta-analysis of studies on telephone-administered therapy for depression, Mohr[42] identified 12 that met inclusionary criteria. In that review, he found that persons enrolled in telephone therapy experienced, on average, substantial pre/post gains (mean Cohen's $d = .81$) and, at only a 7.5% dropout rate, remained in treatment longer than persons seen face-to-face.[42] In a meta-analysis of distance therapy that included telephone, Internet, and videoconferencing studies, Bee and colleagues[43] found pooled Cohen's d effect sizes of .44 for depression and 1.15 for anxiety disorders, although they, like others, called for larger studies with better control conditions. A recent, large, randomized clinical trial of Internet distance therapy for depression by Kessler and colleagues[44] ($n = 297$) compared treatment as usual in primary care augmented with ten sessions of CBT administered via instant messaging text (no voice) to treatment as usual in primary care. At four-month follow-up, 38% of patients in the distance-therapy group had remitted from depression, compared to 24% in the control condition; by eight-month follow-up, the difference between groups had expanded to 42% remitted for distance therapy versus 26% for treatment as usual. Other successful applications of distance therapy include treatment of bulimia[45] and even group therapy for substance abuse.[46]

In-Session Support

A variety of programs has been developed to assist mental health professionals to deliver specialized mental health

treatments during office visits. For example, a program developed by Litz and colleagues[47] at the Veterans Administration guides posttraumatic stress disorder (PTSD) treatment during the session and facilitates therapy homework. Another program, by Craske and colleagues,[48] serves as an in-session tool for clinicians to guide anxiety disorder patients through CBT. In-office computer programs have also been developed for the cognitive rehabilitation of schizophrenia patients.[49,50] Sophisticated combinations of software and hardware enable the use of virtual reality in therapists' offices, which can be used to control the patient's visual, auditory, and even olfactory experiences. Virtual reality has been used by Rizzo in the treatment of attention-deficit problems[51] and central nervous system dysfunction.[52] Other virtual reality programs can be used for exposure therapy, such as for PTSD resulting from combat,[53] or for treating phobias, such as the fear of public speaking[54] or of flying.[55,56] These in-session technologies can augment clinicians' capabilities and training, but they leave unaddressed a variety of important problems affecting the availability of EBTs: the possible shortage of available clinicians, the logistics of scheduling and traveling to appointments, the stigma of asking for help, and questions of cost. Consequently, these therapist-assistance technologies—while playing a valuable role in improving care—are omitted from our discussion of computer-based technologies, which is specifically concerned with those that will enhance the mass dissemination of EBTs.

The Expanding Availability of Computer Technology

A final point to keep in mind is that, for computers to facilitate the dissemination of EBTs, they must be widely enough available to reach a sizeable portion of the population. Access to all types of computers is growing annually across all socioeconomic strata.[57] In 2009, the majority of Americans aged 69 and younger used the Internet regularly, and since 2005, Internet use among persons over 70 has grown faster than any demographic.[58] The majority of American households at all income levels now have Internet access, including 62% with household incomes below $25,000 per year.[57] Gaming consoles can be found in 33% of households, and many lower-middle-class households invest in them as economical entertainment options for children.[59] Mobile phones are owned by 77% of American adults and by 71% of teens.[60] At present, only 15% of Americans own smartphones (mobile phones with computing capabilities, e.g., iPhone or Black-Berry); however, that number is expected to increase.[59] Even among homeless persons, mobile phone ownership is not uncommon,[61] and the use of the Internet is substantial.[62] The use of computers to deliver occupational therapy interventions to homeless persons is currently being explored.[63]

In sum, the convergence of computers, gaming consoles, and cell phones across the socioeconomic spectrum, combined with the efficacy of newer behavioral interventions, has opened the door to new treatment opportunities and has vastly expanded access to mental health care. High-quality EBTs can potentially be provided to anyone at any location, at a reasonable cost, in multiple languages, in private, while avoiding stigma. Such on-demand treatment options can promote "patient power"[64]—activating and empowering individuals to take increased responsibility for their own wellness.

ROADMAP GOAL, OBJECTIVES, AND MILESTONES

The overarching *goal* of our roadmap is to make EBTs for behavioral health problems universally available to the American public. In order for that goal to be reached, the five barriers discussed earlier—cost, availability, logistics, stigma, and training—need to be eliminated. In addition, our roadmap to implementing computer-based treatment across the United States requires advances in four domains: *research*, *training*, *policy*, and *industry*. Each has a set of milestones (see text box). Unlike strategic roadmaps for individual organizations or entities, this roadmap requires collaborative actions on the part of multiple entities with varying, but complementary, interests. As such, target dates cannot be assigned to milestones, and it is anticipated that progress will be made in some domains more quickly than others.

RESEARCH

Research in the areas of self-guided treatment programs and distance therapy needs to expand from studies focused on specific clinical problems to the identification of overarching principles and best practices that cut across clinical areas.

Self-Guided Treatment Programs

Over the past 30 years, many self-guided computer treatment programs have been developed in academic research settings.[24–26,65,66] Typically, a computer-savvy psychologist wonders if a computer could deliver a particular intervention, finds a Web developer, graduate student, or collaborator from the local computer science department (or learns programming him or herself), and writes a program. Such programs have generally been tested in small clinical trials, often showing a remarkable degree of efficacy.[37,67] However, large randomized trials are rarely conducted.[36] These initial investigators tend to be focused on

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Roadmap Milestones

Research

    Grants to support process research

    Grants to support comparative effectiveness research

    Establishment of a national center for computer-based interventions

    Development of a public domain library of validated online behavioral-assessment tools

Training

    Training programs to develop and evaluate self-guided interventions

    Clinical training programs for persons wishing to provide distance therapy

    Training in the delivery of EBTs via distance therapy

Policy

    Product liability guidelines for self-guided treatment programs

    Quality control or certification for self-guided treatment programs

    Professional licensure to permit distance therapy across state lines

    Professional certification for distance therapists

    Policies from regulatory agencies (e.g., FDA) that support innovation and protect the public

Industry

    Demonstration projects on self-guided treatments within a defined patient population

    Launch of a trial set of self-guided treatment programs as a public good

    Self-guided treatments integrated into electronic medical records

    Enforceable national regulations for the practice of distance therapy

    Demonstration project on distance therapy within a defined patient population

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particular clinical problems or disorders (and funded by institutes or agencies that specialize in those disorders), but after developing and testing the program in question, the persons involved have also tended, historically, to move on to other projects, which may or may not involve computerized interventions. And then another investigator comes along and does basically the same thing—likely without incorporating didactic or instructional design advances developed previously. Constantly reinventing the wheel does not advance the field of computer-based self-guided treatment.

    Self-guided treatment needs to be understood as a science in its own right, with its own empirical questions that cut across clinical areas. For example:

- To what extent is tailoring—the use of a person's particular characteristics to customize a computer

program—necessary, and for what types of people, clinical problems, and interventions?

- What level of health care provider involvement is needed for the treatment, in practice, to be effective, ranging from no contact or minimal contact,[68] and moving up from there?

- How can self-guided treatment programs be improved to maximize their effectiveness?

- What are the active components of a given self-guided treatment program?

If research is conducted to address these and other questions across clinical areas, a compendium of principles will emerge that can guide developers to build increasingly effective treatment programs. A new professional organization has already formed, the *International Society for Research on Internet Interventions*,[69] which is helping to connect researchers who are interested in self-guided treatment.

Distance Therapy

Distance therapy is already being practiced on the Internet by psychologists, counselors, and even psychiatrists who see patients online using the videoconferencing capability associated with Skype.[70] At the moment, research lags behind practice, and important research questions remain, such as:

- What unique risks and ethical issues exist in distance therapy, and how can they be managed?

- How must therapies be modified for computer-mediated delivery?

- How can the effectiveness of distance therapy be measured and increased?

- How can online communities ("Web 2.0" services such as online support groups) be created or utilized to facilitate behavioral health?

- How can computer-assisted therapy be most effectively coordinated with psychopharmacologic treatment?

- How can emergency situations such as suicidality be managed in an online application?

Milestones

Grants to support process research. Research requires ongoing funding and investment. Basic clinical research is traditionally conducted in academic settings with public or foundation support, whereas more-applied research is often supported by industry. At the most fundamental level, research is needed to identify the best ways to facilitate health behavior change via self-guided interventions, as well as to deliver therapy remotely. Funding opportunities should be directed at determining the best process (in general, apart from the particularities of any specific program or intervention) for

developing and delivering computer-based interventions for both self-guided treatment and distance therapy.

Grants to support comparative effectiveness research. Funding opportunities to compare the clinical efficacy and cost-effectiveness of computer-based interventions to other modalities of treatment are needed. Although few grants have been awarded so far, recent interest in comparative effectiveness research may provide support for behavioral health interventions delivered via computer. Such grants can help determine the extent to which these interventions have advantages, whether in clinical efficacy or cost, over traditional methods of treatment. The Agency for Healthcare Research and Quality has established comparative effectiveness research as a priority area for funding and will be announcing funding opportunities over the next several years and beyond.[71] The agency recently released a Funding Opportunity Announcement to expand research capability to study comparative effectiveness in complex patients.[72] The agency's list of priority conditions includes depression and other mental disorders, as well as substance abuse disorders. Although not focused specifically on evaluating the use of computerized treatments for mental disorders, the funding announcement sets the stage for future telepsychiatry studies.

Establishment of a national center for computer-based interventions. Computer-based mental health treatments are only a subset of the larger field of electronic media for health behavior change, which includes such areas as diabetes management,[73,74] cancer prevention,[75,76] and accident prevention.[77,78] Beyond grant opportunities, national leadership in research on computer interventions has the potential to advance the field considerably. The Office for Behavioral and Social Science Research could champion the potential and promise of computerized behavioral treatment research as part of the National Institutes of Health Roadmap for Innovation Research.[79] Even greater advances across these and other fields would be facilitated via a dedicated center on computer-based health interventions that cuts across clinical areas within the National Institutes of Health or the Centers for Disease Control and Prevention. The proposed center could develop a public domain library of validated online behavioral-assessment tools.

TRAINING

There are no specialty tracks or training programs dedicated to the development and evaluation of computer-delivered self-guided treatment or distance therapy in the United States. Nor are these areas addressed within the American psychiatric, psychological, or counseling associations.

Even so, consumer acceptance of distance therapy and self-guided treatment resources is high.[38] To meet the demand for distance therapy and provide behavioral health interventions and EBTs to persons who may not otherwise receive them, new practitioners, scientists, and developers need to be trained and credentialed.

Self-Guided Treatment Programs

The development and evaluation of self-guided treatment programs are closely linked. Evaluators should collect data that can be used by developers to improve programs, and developers should be able to use these data to achieve meaningful clinical improvement.[80]

In practice, the developer and evaluator of self-guided research programs are often the same person; however, utilizing independent evaluators would reduce conflicts of interest—that is, situations in which developers want programs to succeed, with the consequence that evaluation results are unintentionally biased. Indeed, to move the field forward, independent validation and comparisons of programs are essential.

Faculty capable of teaching how to develop and evaluate computer-delivered self-guided treatment resources need to be interdisciplinary. On the development side, core faculty must include mental health professionals who understand both EBTs and the theory underlying health behavior change. Students must also become conversant in the technologies through which the interventions are deployed, and have enough understanding of the various professions to collaborate with a diverse set of colleagues. Their training should therefore include some rudimentary cross-training in patient education, health informatics, software architecture, instructional design, programming, video production, graphic arts, online communication ("Web 2.0") models, electronic health records, and usability evaluation. A working familiarity with the business of behavioral health care, telecommunications, health services research, and population health management would also be beneficial.

On the evaluation side, students must learn how to design and conduct clinical trials within a clinical setting, as well as online. Professionals in this area require training in clinical research design, statistics (for studies of all sizes), and the evaluation of populationwide public health interventions. Additionally, an understanding of Internet privacy, security, and data collection is needed—in particular, as they relate to Health Insurance Portability and Accountability Act regulations.

A team-teaching approach is likely to be most feasible, involving members of multiple university departments, along with apprenticeship experiences working alongside developers and evaluators of self-guided treatment programs. Use of

simulations and problem-based learning are important pedagogic modalities. Such a training program could be either a stand-alone master's degree or a specialty within a therapy or clinical psychology doctoral degree. Physicians and nurses could participate in such programs as postdoctoral fellows or through advanced practice nursing programs. Faculty development programs would enhance the opportunity to cross-fertilize the program with other training programs.

Distance Therapy

Distance therapy requires an overlapping, but distinct, set of skills from traditional therapy. Distance therapists need to communicate about emotions through text, become adept at interpreting patient's text communications, express empathy with limited nonverbal cues, be aware of the limits of the technologies, and know the laws and ethical codes that govern the practice of distance therapy. They also need to understand how and when best to use each medium (text, voice, video) and the advantages and limitations of synchronous versus asynchronous communication. Programs developed for use in clinical settings will need to be modified substantially for appropriate use in unsupervised settings such as the home or on mobile phones. Finally, they need to learn how to adapt EBTs that were developed for face-to-face use to distance media. To the degree that behavioral telehealth requires knowledge and skills beyond what is currently offered in clinical training programs, the curricula need to be defined, and a consensus of experts achieved, as a prerequisite to the establishment of a credentialing process for behavioral telehealth.

Currently, there appears to be no specialty training in distance therapy within clinical psychology or counseling programs. A few companies now offer their own diplomas or certificates courses in "cybertherapy" for persons wishing to open distance-therapy practices; it should be noted, however, that the programs are not accredited and include little or no supervision.[81] A more rigorous approach is needed to train specialists in distance-therapy modalities. This emergent field could learn from the twenty years' experience of the coaching industry.[82–85] Such training programs could be offered as a specialty track for mental health professionals within standard or postgraduate education, analogous to specialties in child therapy or behavioral medicine. Although distance therapy has so far been the domain primarily of master's-level clinicians, there is no reason that psychiatrists and psychologists should not provide distance-therapy services.

Training in the delivery of EBTs via distance therapy should be given particular emphasis. Some EBTs, such as problem-solving treatment for depression, are quite effective, yet, few practitioners are trained in them. Several companies outside the United States have been training their employees, who are typically master's-level counselors, to provide distance-therapy services via Internet and telephone. Two such companies, LifeLine New Zealand[86] and Interapy Netherlands,[87] have long track records and could provide guidance in establishing curricula in American clinical programs.

Milestones

Training programs to develop and evaluate self-guided interventions. At present, graduate students who enter the field of self-guided computer-based interventions likely do so because they happen to have access to a faculty member working in the area. A clinical training program with a formal curriculum in self-guided treatments is needed, as is mentorship for faculty members who are interested in entering the field.

Clinical training programs for persons wishing to provide distance therapy. Learning to provide distance therapy requires the development of expert knowledge, a unique set of skills, and appropriate supervision, just as with any clinical specialty. A weekend seminar or brief course is not sufficient to prepare therapists to address the clinical and ethical issues presented through various synchronous and asynchronous media. Rigorous curricula and training programs are needed.

Training in the delivery of EBTs via distance therapy. Clinicians who are proficient at delivering EBTs are a subset of the profession.[11] Training them to deliver those same EBTs via distance media will help consumers to overcome the barriers of availability (i.e., no trained providers in their locale) and logistics (i.e., difficulties in scheduling or traveling to face-to-face appointments). Through distance therapy, EBTs could reach a greater number of persons who need them.

POLICY

The United States' governmental agencies, insurance companies, and public as a whole must decide whether it is important for behavioral health care services to be available to everyone. If mental health treatment is a priority, the next questions are: what works best for whom at what cost, and how can universal access be achieved? The effectiveness of various approaches to treatment need to be compared in as objective a manner as possible. If computer-based self-guided treatment and distance therapy are part of the answer, policies need to be established to make those services available to the largest possible segment of the public.

Implementation costs and disruption to existing systems will occur with both distance therapy and self-guided treatments. However, if access to computer-based interventions can be shown to produce not only improvements in health, but also direct cost savings or medical cost offset savings and greater workforce productivity, then widespread dissemination and adoption will occur. Some countries, most notably the Netherlands and United Kingdom, are already moving toward disseminating computer-based treatments nationwide,[88] and they can provide models. To some extent, revolutionary and disruptive technologies must accommodate current health care structures; however, the existing structures must also adapt to new technologies.

Some policy groundwork has already been laid for self-guided treatments and distance therapy in the United States—in particular, with respect to standards for protecting data integrity and patient privacy. For patients and consumers to trust behavioral telehealth applications and systems, they need to believe that security and privacy protection is effective and reliable.[89] As with all systems that rely on patient-provided data or information obtained from electronic health records, protection of the privacy and security of protected health information must be addressed through careful adherence to state and federal regulations (e.g., the Health Insurance Portability and Accountability Act).

Self-Guided Treatment Programs

Product liability is an open question for computer-delivered self-guided treatment programs. Whereas health care professionals may be held liable if the patient receives improper care, authors of self-help books are not held liable if they do not provide useful advice. In the worst-case scenario, a depressed person might commit suicide while reading a self-help book—perhaps after acknowledging suicidal ideation on a questionnaire in the book. It is unlikely that the reader's family would prevail in a malpractice lawsuit, claiming that their loved one was under the care of the book and that the book or its author did not take adequate steps to intervene. Should developers of interactive computer programs be held to a higher standard? If a computer program *can* notify someone of a user's suicidal ideation, *must* it do so? And if so, notify whom? Would this issue restrict the use of self-guided treatment programs to health care settings, even if they could be used effectively on one's own without supervision? Is the potency of a self-guided treatment program more analogous to an over-the-counter medication or to a prescription drug? Are there decision-support features of a computer-based treatment program that trigger the application of Food and Drug Administration (FDA) policies regulating the use of medical devices or software?

Where computer-based self-guided treatment programs fall along the liability continuum may differ from program to program. On one hand, it could be argued that an individual interacting solely with a computer program is in no more of a helping relationship than the reader of a book. On the other hand, if the program is deeply tailored, responds "intelligently" to the user's input, calls him or her by name, and perhaps guides the user via a friendly, animated, and personalized character, the user may feel or even believe that he or she is in a helping relationship—despite any disclaimers to the contrary. Indeed, a fundamental distinction between self-help books and computer-based self-guided treatment programs is the extent to which the latter are personalized and tailored, which increases their adoption and impact.[90]

What a developer calls a self-guided treatment program may not matter. They may label their computer applications "educational" rather than "therapeutic" in an attempt to avoid liability issues; however, terms such as "supported self-care" or "self-coaching," as distinct from "treatment" or "telemedicine," are not well defined at present.[91] The sparse case law that exists is generally no more than a patchwork of conflicting decisions, inadequate for guidance—a long way away from the point of having definitive legal precedents. As an alternative to the slow process of developing the law through litigated cases, Congress could intervene and provide legislative relief though the establishment of federal policies tied to Medicare reimbursement for self-guided treatment programs.

Related to product liability is the need for quality control. It is not difficult for a skilled Web developer to put together a plausible-looking self-guided treatment program with no scientific validation. The consumer needs a way to tell snake oil from real help, as do health care professionals who might recommend these programs. The National Committee for Quality Assurance[92] offers review and accreditation of disease-management programs, and their accreditation process could be adopted for use with behavioral telehealth programs. "Seals of approval" are difficult to enforce on the Internet, however, since graphics can be copied and used on non-approved Web sites (for example, the Better Business Bureau seal is frequently pirated).[93] This problem could be addressed by linking sites to the accrediting organization, thereby improving the security of these seals.[94]

A number of other federal regulatory questions may arise. Related to both liability and quality control is whether computer-based self-guided treatment programs will require FDA approval as medical devices. A medical device is defined as "an instrument, apparatus, contrivance . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease . . . and which does not achieve any of its primary intended purposes through chemical action within or on the body."[95] Some software is regulated by the FDA, but

primarily only if it is used to control other medical devices. It would be unfortunate if the FDA decided to regulate self-treatment programs; they are often built on a shoestring budget, and the FDA approval process is expensive. High compliance costs could stifle the growth of this nascent industry. Finally, the U.S. International Trade Commission may also take an interest in computer-based self-guided treatment programs because of issues regarding tariffs and the protection of intellectual property; Internet-delivered self-guided treatment programs, as well as Web-based therapy, can be imported and exported instantly. Parallel to the case of FDA regulation, substantial tariffs or burdensome reporting requirements could hold back this industry.

Distance Therapy

Practitioners who wish to provide distance therapy also face policy issues in the United States, particularly in relation to practicing across state lines. With the advent of telenursing and telemedicine, the fields of nursing and medicine have already begun to address this issue. Twenty-four states have joined the Interstate Nursing License Compact,[96] through which a nurse licensed in any of those states can practice in any other member state. Within medicine, a general (though not unanimous) consensus among states is that telemedicine is practiced where the patient, not the physician, is located.[97] This policy could present problems even for traditional health care providers, however—for example, when a patient calls with a medical concern and happens to be in another state. It seems unlikely that the ethical provider would refuse to speak with the individual, conduct an assessment, and make recommendations just because the patient was calling across state lines. Moreover, the health care professional would not even know from which state the patient was calling unless the patient mentioned it. Other helping professions, including psychology and counseling, have yet to make decisions regarding licensure and distance therapy.

Since the geographical location of treatment can no longer be verified, another system is needed to ensure that a practitioner is practicing where he or she is licensed. One way of accomplishing that goal would be through a system of national licensure for telehealth (or all) practitioners. Some questions related to practice across state lines include:

- Does therapy provided at a distance occur where the provider or where the patient is located?
- What if the patient lives in a state where the therapist is licensed but logs onto the therapy Web site from another state? What if a patient emails his or her therapist while traveling by bus, train, or plane and does not know which state he or she is currently in?

- In asynchronous distance therapy, does therapy occur when the therapist clicks "send" or when the patient clicks "open"? How can a therapist control where a patient reads a therapy message (i.e., to control where therapy is occurring)? Is it feasible and ethical to restrict patients from logging on based on their location?
- Is the patient's welfare served by the therapist not being allowed to interact with him or her from certain states (or countries)?

In addition to questions about defining the geographical range of a health provider's license to practice, there is the separate question concerning the need to regulate distance therapists. Currently, there is no certification or training required to conduct treatment at a distance, and it may be an empirical matter whether special training is needed at all. At present, however, it is the "Wild West" for therapy online: recent reviews of online therapy Web sites indicate that the majority fail to provide information about the professionals' licensure (or even their names and training), do not discuss the limits of confidentiality, and do not provide a parental consent process for minors to receive treatment (other than in some cases requiring the user to affirm that he or she is over 18 years old).[98,99] The uninformed consumer may make a decision based solely on the appearance of the Web site, leaving the field open to persons practicing online who would not be qualified to do so in person. A society has already been formed for professionals who provide therapy via the Internet, the International Society for Mental Health Online, which has proposed standards of practice to improve the quality of online care.[100]

The Agency for Healthcare Research and Quality has already supported computer-delivered CBT as an "intervention worth consideration,"[101] and other nations—including the United Kingdom,[102] New Zealand,[86,103] and the Netherlands[104]—have taken larger steps to make computer-based interventions (both self-guided treatment and Internet therapy) available to their populations. As policies are put into place that reduce barriers and promote the dissemination of computer-based interventions, industry can devise and implement solutions to bring these resources to the individuals who can benefit from them.

Milestones

Product liability guidelines for self-guided treatment programs. In the effort to disseminate computer-based treatments, product liability and the fear of litigation loom large. The ability to measure and protect oneself from legal risk is crucial.

Quality control or certification for self-guided treatment programs. Some indication is needed—one that is immediately

recognizable to consumers and health care professionals, and that is difficult to counterfeit—to identify programs that have met evaluation standards to deliver EBTs for various behavioral health problems.

Professional licensure to permit distance therapy across state lines. Currently, since distance therapists typically do not even know the precise geographical location of their clients, they can easily end up practicing across state lines without even realizing it. A new standard—independent of geography—is needed.

Professional certification for distance therapists. Quality control is necessary for distance therapy, just as it is necessary for self-guided treatment programs. Accredited training programs and specialty tracks could meet this need.

INDUSTRY

Commercial ventures and health care industry partners could provide computer-delivered EBTs on a scale that would be impossible to achieve in any other way, resulting in large public health benefits.

Self-Guided Treatment Programs

The need for expanded access to EBTs for behavioral health problems in the United States is clear, and self-guided treatment programs provide a promising means to disseminate them. Nevertheless, industry is held back by three major factors: (1) the large initial capital outlay required to develop and evaluate the programs, (2) an uncertain market for the products, and (3) uncertainty about potential corporate liability exposure through defects in software or malpractice by clinician-users.

Regarding initial capital outlay, compare the investment to build and evaluate a self-guided treatment program to the development of a new face-to-face therapy. Whereas the development phase of a new treatment for face-to-face delivery typically consists of writing a detailed treatment manual, that is just the starting point for self-guided treatments. Multiple individuals from different professions are involved in the development of interactive programs, representing a substantial cost in skilled labor. Beyond development, however, the expense of running clinical trials is high. Although therapists may not need to be hired to implement the treatment, skilled staff is needed to coordinate trials and participants, fix program bugs, and maintain databases—all in addition to the statisticians and clinical researchers involved. These upfront and recurring costs are not easily borne by small businesses.

Research grants, common sources of funding for program development, most frequently are awarded to universities—creating a disconnect, from the very outset, in the development-to-market chain. The simple fact is that universities seldom commercialize the self-guided treatment programs that they develop. Universities are in the business of education and research, not marketing, deal making, and product distribution. The challenge is to make a successful transition from translational research in the academic clinic to sustainable models that support broad dissemination into the community. Ideally, industry partners would acquire research prototypes from universities, improve and evaluate them, and then disseminate them. What typically happens, instead, is that the treatment software remains locked up in institutions with intellectual property policies that impede commercialization as a strategy for dissemination, with the consequence that industry partners are not sought. Even if industry partners are found, they may resist investing in the further development and evaluation required to bring programs to market; the revenue models remain too uncertain. The overall result is that promising research prototypes often languish on defunct university computers. Researchers—dependent upon grant funding—have no choice but to move on to the next study.

Other development funding options exist, such as the federal Small Business Innovative Research Grant and Contract program. These funding mechanisms have supported much work in the field, enabling many businesses to be established.[105–108] It can be a challenge, however, for small businesses to find profitable distribution channels for their programs. Some organizations that develop treatment or training programs distribute them themselves,[109,110] though their market penetration and reach is likely to be small. Large infrastructures are needed to disseminate products, and these infrastructures have little in common with the development and evaluation side of bringing a product to market.

Another option is for developers to seek the backing of large companies, such as the recent acquisition of HealthMedia by Johnson & Johnson.[111] Such large companies, particularly pharmaceuticals, may be willing to directly fund the research and development as a means of complementing their core businesses. Venture capital may be another option; however, from the authors' experience, investors tend to be interested in self-guided treatment programs only after they are built and validated. They are rarely willing to invest in early-stage technologies in this field.

In building a revenue model, the first question to ask is: who will benefit from these programs? The answer certainly includes the user of the program (whose mental health may well improve) but may also include employers (through increased productivity), insurance companies (through decreased utilization of face-to-face therapy),

disease-management organizations (through reduced patient care costs), government-sponsored health programs (through reduced costs and increased access to care), government agencies (e.g., the Department of Defense and NASA, through improved mission success), unions or professional associations (to serve members by providing self-treatment programs as a benefit), the criminal justice system (through reduced recidivism), and even the U.S. economy (through increased gross domestic product).

The next question to ask in building a revenue model is: who will be willing to pay for self-guided treatment programs? The answers to "who will benefit?" can provide a starting point. Some consumers will pay out of pocket for these services; from the authors' observations, however, it appears to be difficult to base a business on direct-to-consumer sales of self-treatment programs, despite their potential benefit. Advertisements on Web sites may result in a revenue stream, though one unlikely to provide sufficient support for online self-guided treatment ventures. Other business models and payers are needed.

Insurance companies or health-management organizations may pay for self-guided treatment programs in the hope of reducing the cost of providing care to their constituents; for example, patients might try self-guided treatment instead of seeing providers. It is unclear, however, whether self-guided treatment resources will function as a temporary diversion strategy or, instead, provide a gateway for persons to enter treatment who might otherwise not have sought help. Employee-assistance programs and disease-management organizations are other potential purchasers of self-guided treatment and distance-therapy services. However, not everyone is served by these organizations, and there needs to be a better way to deliver these services to those individuals who would benefit from them.

Regardless of the customer (that is, who pays), building a good program may not be enough. Stand-alone self-treatment programs are unlikely to succeed commercially unless they are bundled in systems with an integrated user interface that addresses common behavioral comorbidities, such as anxiety, posttraumatic stress disorder, insomnia, chronic pain, and substance abuse. A purchaser, such as an insurance company, is unlikely to buy these programs from different vendors because of the challenge and cost of integrating them (without which, the end-user experience is likely to be unsatisfactory). Examples of such bundled systems are suites from LifeOptions Group[14] and HealthMedia,[112] and a system being developed for NASA (to include self-guided programs for detection and self-management of depression, anxiety, and interpersonal conflict).[26] Nonetheless, a successful and sustainable business model for self-guided treatment programs will require a foundation of data to demonstrate the clinical and cost-effectiveness of each program—that is, that they are EBTs.

The most successful business models for rolling out self-guided treatments can be found abroad, where governments provide programs as a public good. Countries such as the Netherlands and the United Kingdom have made these programs part of an investment in public mental health that may reduce medical-utilization costs and improve workforce productivity.[88] Developers sell licenses to health districts,[113,114] for profit and to raise capital to improve the programs and develop new ones. In the United Kingdom, innovative treatments are evaluated by the National Institute for Health and Clinical Excellence. That institute recently evaluated and approved two computer-based CBT programs (*Beating the Blues* for mild-moderate depression and *Fear Fighter* for panic and phobia) for inclusion among the approved treatments for depression and anxiety in the National Health Service.[115]

If health care reform legislation is passed in the United States and if it supports universal access to EBTs for mental health problems, it could stimulate the self-guided treatment industry. Not only would it help the United States catch up to other countries in this technology, but the United States could also become an exporter of programs. Programs can be customized to national languages and cultures while maintaining the same core functionality,[116] enabling greater return on initial development investment. A federal initiative to make self-guided treatment programs available to all members of the public—through the Internet, gaming console programs, mobile phones, and other devices—could create a strong market for developers. And instead of making available a static set of self-guided treatment programs, the government could encourage developers to compete and to create the best, most appealing, and most effective programs. More generally, if an accessible, lively marketplace could be created, growth of the science and industry of self-guided treatment programs would accelerate. The public would benefit, in turn, as EBTs made their way to people who would otherwise not have access to them.

Distance Therapy

Distance therapists may attract a different population of patients from those who seek live treatment. Whether due to stigma, logistics, or the local availability of therapists, the potential patients of distance therapists might not otherwise seek or obtain the care that they need. Nonetheless, the industry of distance therapy is miniscule. In part, it is held back by the policy issues described above, but it is also held back by a lack of third-party payment options.

Two business models for distance therapy have emerged in the United States: independent practice and "call centers." Independent practitioners typically have master's- or doctoral-level training. Some provide distance therapy as

a major part of their work, though it appears that many do so as a sideline. Since one can work from home during off hours, it is a convenient way to practice while maintaining a flexible schedule. For independent practitioners, turnkey Web sites are available that provide secure communication channels along with advertising, scheduling, and billing support.[117] Payment is almost always out of pocket by consumers, conveyed via standard e-commerce means (PayPal, credit cards, etc.).

Credibility is one factor that works against independent-practice distance therapy. An Internet search of "distance therapy" will turn up not only licensed providers, but also "past life therapists," "primal scream therapists," "crystal therapists," and other persons who practice treatments of questionable validity. Moreover, the new field of "coaching" is ubiquitous online, is generally unregulated, requires little training, and is easily confused with therapy and counseling.[91] Leaders in the coaching industry, however, are beginning to establish training standards and credentialing organizations.[82–85] Finally, as found by Heinlen and colleagues,[98] few distance-therapy Web sites follow all of the professional guidelines that are required of live therapists, and patient abandonment may be a major problem, as approximately 37% of online-counseling Web sites disappear within eight months of being established. If trust is not there, the public will not come, and major payers will not participate. Implementing and enforcing regulatory policies is consequently critical to the growth of the industry. Consumers and referral sources need to be able to identify reputable, qualified, licensed clinicians.

Assuming that trust is present and professional standards are enforced, people still will not come if they cannot afford it. Paying out of pocket is viable only if fees for distance therapy are low (which is unlikely) or the customer is well off (which rules out a large segment of the population). Distance therapy is largely not covered by insurance companies, Medicaid, or Medicare. Persons who pay outright for therapy receive four times *less* mental health treatment than those who do not pay.[118] Although individuals of modest means seek assistance from distance therapists when they are in distress, they will probably not receive a sufficient dose of an EBT. Clinical and cost-effectiveness studies in Medicare and Medicaid populations are necessary to permit those major payers to determine if they should support this evolving care model. If Medicare conducts a demonstration project and the results are convincing, that may lead to a procedure code and coverage for e-therapy under circumscribed conditions, with other insurers then likely to follow suit.

Another business model of distance therapy is subscription to "call center" therapy or counseling services by entities such as large companies, disease-management organizations, outsourced employee-assistance programs, or entire nations. In this model, consumers can access live therapists via telephone, email, online chat, text messaging, or other media. Calls are routed to a central location or office and then connected to therapists, who may be on-site or off. In some settings, the services are considered "coaching" rather than clinical; however, the line between these concepts is blurry in practice.[91] The largest companies offering these services appear to be overseas and have government contracts to provide services to the entire population, such as LifeLine New Zealand[86] and Interapy Netherlands.[87] At least two companies have established a distance-coaching practice in the United States to provide services to their clients, which are primarily health insurance companies and large corporations.[14,119]

Assuming the hurdle of interstate licensing to practice distance therapy can be overcome, one can imagine distance-therapy centers specializing in particular EBTs, analogous to the specialized practices found in some medical centers. For example, a distance-therapy center could focus on EBTs for depression, another on anxiety disorders, and another on substance abuse, with coordination between therapists and centers. Such centers could be associated with research programs to ensure the currency of treatments and could provide a revenue stream to support research.

Milestones

Demonstration projects on self-guided treatments within a defined patient population. A reasonable near-term expectation is that the Centers for Medicare and Medicaid Services, the Department of Defense, or the Veterans Administration will pay for demonstration projects to determine if access to self-guided treatments can improve access and quality, produce good clinical outcomes, and save money. If successful, these projects would be a first step in moving those organizations—and insurance companies—toward paying for self-guided treatments.

Launch of a trial set of self-guided treatment programs as a public good. Whether independently or in the wake of successful demonstration projects as described above, a limited suite of programs—along the lines of those being developed for NASA—could be made available to the public, enabling the overall reaction to, and utilization of, them to be gauged. On a limited basis, the public could be offered no-cost access to the government-sponsored self-treatment Web sites and mobile phone interventions.

Self-guided treatments integrated into electronic medical records. As electronic medical records become tools for providers and patients to communicate and mutually access information, they could be expanded to provide direct

access to behavioral interventions. Funding initiatives from the Office of the National Coordinator for Health Information Technology have already been launched to advance the "meaningful use" of electronic medical records (for example, providing patients with information in electronic format about their conditions).[120] The incorporation of self-guided treatments could be a next step.

Enforceable national regulations for the practice of distance therapy. Initial sets of guidelines for distance therapy have already been proposed by professional organizations, including the American Psychological Association,[121] the American Counseling Association,[122] and the International Society for Mental Health Online.[100] Those guidelines do not, however, regulate the practice of distance therapy. State laws are difficult to interpret and enforce since distance therapy can easily be conducted across state lines. Federal regulation is needed, which will foster the growth of this industry.

Demonstration project on distance therapy within a defined patient population. As with self-guided treatments, a demonstration project within the Centers for Medicare and Medicaid Services, Department of Defense, or Veterans Administration could assess the benefit of distance therapy. If the evidence shows convincingly that evidence-based behavioral telehealth services improve care while lowering costs, insurers and Medicare are likely to consider using procedure codes that will permit reimbursement for such services. Until third-party payment for distance therapy becomes available, it will not be a major channel of dissemination for EBTs.

CONCLUSION

Unlike roadmaps for a single entity, this plan requires the alignment of multiple stakeholders with different, but complementary, interests. While challenging, the milestones identified can be reached. Universities, industry, and government are the major players, and any one of them can take leadership. At present, the greatest obstacles to rolling out computer-delivered interventions across the United States are related to policy and commerce, not science or technology. If the pathway is cleared for the industries of distance therapy and self-guided treatments to grow in this country, training and research initiatives will follow.

Some professionals have felt threatened and have raised concerns that self-guided treatments may put them out of business. However, in the words of medical informatics pioneer Warner Slack, "Any doctor who can be replaced by a computer should be."[123] With or without self-guided treatments, we are moving into a world of greater patient autonomy—and responsibility—where treatment decisions

are being shifted from the therapist's office to the patient's home.[124] If less complex cases can be treated with less therapist time, and perhaps without even contacting a clinician, that frees up clinicians to see the more challenging (and interesting) patients. Waiting lists would be trimmed, patients would be empowered, and major barriers to accessing EBTs, such as cost, stigma, logistics, and the availability and training of therapists, would be reduced.

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