Issues in Access to New Treatment Options for Individuals with Severe Depression

A White Paper

National Task Force
on Consumer Access
to Emerging Neurotechnologies

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A wide range of new technologies will soon be available to consumers to address mental health, neurological health, and intellectual disability problems. Even as emerging therapies are made accessible to consumers, it is likely that these new treatments will not have the maximum clinical or financial impact on health conditions due to several potential obstacles. One such obstacle is the absence of standardized payer policies in place to address the appropriateness of new technologies, an issue that needs to be considered sooner than later. Additionally, challenges regarding adaptation of these new technologies to clinical and administrative management structures need to be reviewed. To proactively address these pending challenges, the National Task Force on Consumer Access to Emerging Neurotechnologies was formed.

Focus of the Task Force

The purpose of the Task Force is to review and respond to issues of policy, financing, and practice that are shaping consumer access to emerging neurotechnologies. The Task Force is comprised of health plan executives, academic researchers, clinical professionals, policymakers, and program administrators devoted to exploring the future of neurotechnologies. These stakeholders are interested in assuring, and capable of affecting, appropriate and equitable access to emerging neurotechnologies for consumers with mental health, behavioral health, and neurological conditions.

The focus of the National Task Force is three-fold:

- To increase understanding within the payer, provider, and consumer advocacy communities of the available and appropriate use of new neurotechnologies
- To promote standardized clinical decision making criteria, consumer access processes, and reimbursement policies for appropriate neurotechnologies
- To promote parity and equity in consumer access to new technologies for treatment of these conditions

Inaugural Meeting of the Task Force

The inaugural meeting of the Task Force specifically focused on some of the first technologies to be developed, those emerging neurotechnologies for the treatment of depression. The discussion centered on four main areas:

- The state of current research on depression treatment efficacy and implications for depression treatment guidelines
- Whether a standardized definition exists for severe depression that is resistant to currently available treatment options

- The cost of treatment-resistant depression

- Current thinking on the standards of scientific evidence required to make new depression treatment technologies available to consumers

A number of key factors in shaping policy arose from these discussions including the following issues: The majority of health care-related costs associated with depression can be attributed to the comorbid conditions of consumers with treatment-resistant depression. As a matter of fact, 33% of consumers with depression do not achieve remission with currently available treatments and are referred to as having 'treatment-resistant depression.' [1]

Unfortunately, existing depression treatment guidelines are outdated and do not address the needs of treatment-resistant consumers. Assuming that safety is demonstrated, consumers with behavioral and neurological conditions who are not able to achieve remission with currently available treatments should have provisional access to emerging neurotechnologies. Additionally, the need to expand research methodologies should be considered when evaluating the efficacy of new treatments for chronic health care conditions.

Depression Treatment Efficacy—Research Implications for Treatment Guidelines

Researchers have studied depression and its related treatment for decades. The most recent research was conducted by the National Institute of Mental Health (NIMH). The Sequenced Treatment Alternatives to Relieve Depression (STAR*D) Study[2] has provided the health care community with new perspectives on the effectiveness of currently available treatment options for depression. STAR*D was a seven-year, 4,000-consumer study to determine the best "next-step" treatments for patients failing to respond to prior treatment attempts. STAR*D was also designed to compare relative efficacy of different treatment strategies and specific treatments; and to provide important information on the long-term course of depression, including its nature and the timing of relapses.

The STAR*D research findings are numerous and compelling. One critical finding for health care policy is that after using four different courses of currently available treatment options, only 67% of patients achieved remission of their symptoms. The Task Force members discussed the implications of this finding on policy and practice. It is clear that no one medication (or combinations of medications and/or cognitive therapies) is a panacea for all consumers, and the clinical predictors of treatment selection are weak. In addition, current depression treatment guidelines are limited in their utility for addressing the needs of all consumers with depression. Current guidelines address the use of medication and cognitive behavioral therapy (CBT) in a process involving selection of initial medication use and subsequent combination therapies. These guidelines assume that remission of symptoms is achieved. However, the current guidelines do not address interventions for the 33% of consumers who do not achieve remission of their depression using currently available therapies. These consumers have a level of disease known as treatment-resistant depression.

Indeed, this severity of illness in depression must be recognized and needs to be incorporated into the existing treatment guidelines. Also needed is the creation of a methodology for identifying consumers with treatment-resistant depression. Within the scientific community, the current definition ranges from two to four failed treatments.[3] The lack of a standardized definition creates problems for consumers, clinicians, and payers. Without consensus regarding appropriate treatment algorithms, it is difficult to determine the related costs or to evaluate the appropriateness of new treatment methodologies for consumers of different clinical profiles.

Health Care Related Costs of Treatment-Resistant Depression

The cost of depression in the United States in the year 2000 was estimated to be $83 billion. Of this figure, $26 billion was associated with treatment costs and the remaining $57 billion in costs was due to absenteeism, reduced productivity at work, and the value of lifetime earnings lost as a result of suicide-related deaths.[4] While the costs of depression are certainly significant, the major portion of costs can be attributed to the condition of treatment-resistant depression. A recent study found that the annual treatment costs for individuals with non-treatment-resistant depression were $6,500 while the annual costs for individuals with treatment-resistant depression were over six times that amount, or $42,300.[5] (In this study, individuals with treatment-resistant depression were defined as those who switched medications at least once, were hospitalized, and/or had a recorded suicide attempt.) Another study found that total health care costs for individuals with treatment-resistant depression (defined as eight medication switches) were $14,000 versus $6,200 for those with two medication switches or less.[6] For those organizations that provide health care benefits, whether corporations, government entities, or health plans, treatment-resistant depression is a major cost contributor.

From an ethical and moral standpoint, in addition to being arguably more important than the issues surrounding health care costs associated with chronic depression, one must consider the issue of suicide. In 2001, in the United States, suicide took the lives of 30,622 people; 132,353 individuals were hospitalized following suicide attempts; and 116,639 were treated in emergency departments and released.[7] Depression is a major risk factor for suicide and individuals whose depressive symptoms are not relieved through conventional treatment are at elevated risk for suicide.

Standards of Scientific Evidence and Consumer Access to New Technologies

Given the limited efficacy of currently available treatments for a third of the consumer population with depression, and the costs of treatment-resistant consumers to health plans, the question of treatment alternatives arises. There is an emerging group of non-pharmaceutical neurotechnology treatments for consideration in patient care. There are two related questions to contemplate as health care payers and policymakers evaluate the issues of evidence required to make decisions to facilitate consumer access to these emerging neurotechnologies. The first is a question relevant to all chronic health care conditions—what evidence and related policies are required to determine that a new treatment is safe and/or efficacious for individuals with chronic health care

conditions? The second question is one of treatment options—how should this evidence be evaluated in situations where consumers have a life-threatening disease and no other treatment options?

With regard to evaluation of treatments for chronic disease, there has been discussion of alternatives to the use of randomized controlled trials (RCT). RCT has long been the 'gold standard' of evidence for approval by the Food and Drug Administration (FDA). However, RCT has limitations in the evaluation of treatment interventions for chronic diseases. RCT designs are typically short-term, consider a single variable, and do not evaluate efficacy in the context of complex, multi-factor chronic diseases. In fact, RCT study designs typically exclude individuals with chronic illness because of design requirements to withhold treatment from a 'control' group—a clinical situation that is neither practical nor ethical for individuals with a chronic life-threatening disease.[8]

As the scientific and regulatory community considers the effectiveness of emerging treatments for chronic disease, research design should move beyond RCT. STAR*D is one such example—a "practical trial" that assessed effectiveness in real-world clinical situations.[9] Another such methodological option is the practice-based evidence (PBE) study design.[10] PBE is a prospective, observational, cohort study methodology that allows analysis of 'real world' treatment factors (interventions, processes, professionals, etc.) and consumer factors (diagnoses, functionality, demographic characteristics, etc.) over time. These types of approaches can employ severity adjustment methodologies to remove selection bias, a critical factor for evaluating chronic conditions, and have the benefit of comparing active treatments in terms of a number of clinical outcomes. Research approaches like practical trials and PBE are better suited to evaluate new treatments for chronic diseases than traditional RCT models.

For consumers, payers, and regulators, the juxtaposition of limited treatment options, costs of the illness, and ill-fitting standards of evidence have created a 'perfect policy storm.' A third of consumers suffering from depression do not respond to available treatment options and are at high risk for increased illness and mortality at a significant cost to health plans. At the same time, the standards of evidence typically used to assess new health care interventions are not appropriate in a population with a chronic condition like depression.

To resolve this situation, the health care field needs a collaborative industry initiative—representing regulators, payers, and consumers—to develop a shared set of standards for addressing the issues of policy, financing, and practice for these emerging neurotechnologies. For each emerging treatment intervention, a collaborative consensus is needed to specify the instances where conditional use should be permitted and to establish shared clinical criteria for conditional use. In addition, a collaborative consensus is needed on standards of evidence for chronic health care conditions and a scientifically valid model for measuring the efficacy of each intervention in the population that is granted conditional use to the new treatment intervention.

In the near future, the fruits of extensive clinical research will yield an expanding array of new neurotechnologies that will be available to consumers. These new technologies

enter a health care policy environment where the standards of evidence must be re-evaluated to address the growing proportion of health care conditions that are chronic rather than acute. This evaluation must also consider the rapid growth in health care spending on these chronic conditions. To address this situation, payers need new clinical guidelines and standards of evidence to assure appropriate use of health care resources and safety for their members. These guidelines and standards must be forged by a consensus with regulators and consumer advocates. At the same time, these new standards must provide consumers who suffer from life-threatening conditions, and no other treatment options, with timely and appropriate access to these new treatment alternatives.

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