Cranial Electrical Stimulation - On January 14, 2010, the Center for Practice Innovations convened a meeting to help OMH understand the current research on Cranial Electrical Stimulation (CES) and to inform OMH about the role of CES as a potential treatment for persons with mental illness. CES is one of many forms of brain stimulation that are being evaluated as an alternative to medications to treat people with mental illness. Invited experts included: Sarah Lisanby, M.D., Edward Nunes, M.D., Angel Peterchev, Ph.D., and Peter Bulow, M.D. To see a summary of the meeting, please see below.
Planning Meeting on Cranial Electrical Stimulation (CES)
New York State Psychiatric Institute
January 14, 2010

Attendees:

OMH
Alan Holmes
Gregory Miller, M.D.
Lloyd Sederer, M.D.
Al Volo, Ph.D.

Columbia/NYSPI
Peter Bulow, M.D.
Susan Essock, Ph.D.
Carlos Jackson, Ph.D.
Sarah Lisanby, M.D.
Jennifer Manuel, Ph.D.
Edward Nunes, M.D.
Angel Peterchev, Ph.D.
Scott Stroup, M.D., M.P.H.

OASAS
Steven Kipnis, M.D.
Frank McCorry, Ph.D.

Meeting Summary:

Overview
Cranial Electrical Stimulation (CES) is one of many forms of brain stimulation that are being evaluated as an alternative to medications to treat people with mental illness. The goal of this meeting is to understand the current research on CES and to inform OMH about the role of CES as a potential treatment for persons with mental illness.

CES originated from the former Soviet Union in 1949 as a treatment for insomnia. In the 1960s, the CES device came to the US for use in public substance abuse treatment programs. CES is a noninvasive procedure, and there is considerable interest in whether it may show promise for mood, sleep, and anxiety disorders. There are no reported side effects, but biomedical theory does not explain how CES acts, and there are questions about the overall effectiveness of CES for mental health patients.

Prior Research
In 1992, a group at Harvard School of Public Health published an analysis of 18 CES clinical trials. The review found CES to be a promising treatment for anxiety, but a lack of information made it difficult to draw firm conclusions.

In a recent study conducted at Phoenix House, patients who chose to use the CES device had a better retention rate than those who did not use CES. Patients found that CES was relaxing and calming, and it reduced stress. However, the study was limited in several ways; like the Harvard study, it did not lead to definitive conclusions about the effectiveness of CES.
Current and Proposed Research
Dr. Nunes is planning a follow-up to the original Phoenix House study of CES that will examine the effects on mood, anxiety, and sleep.

Safety and Regulatory Status
CES was FDA sanctioned in 1978 for treatment of depression, anxiety, and insomnia. This means that CES can be legally marketed, but not promoted as effective. In 1990, the FDA sanctioned the Fisher-Wallace Cranial Stimulator for treatment of these disorders. CES is not very well regulated—it can be accessed via the Internet, probably without a prescription. The literature does not report adverse side effects, and patients appear to tolerate the device well. However, there have been no long-term systematic studies of CES.

Summary and Future Directions
Due to different devices, populations, and parameters used across the CES studies, it is difficult to draw conclusions about its effectiveness. Most studies of CES have focused on people with depression or anxiety. Future studies should investigate the effects of CES using different populations, especially people with psychosis who also have sleep and mood disorders. The group agreed that in order to avoid subjecting patients to the risk of side effects and/or ineffective treatment, more rigorous long-term studies on CES are needed.

Recommendations
Given the lack of strong evidence to support the use of CES, it is premature to introduce CES to OMH patients, even as a pilot. The OASAS’ Medical Advisory group came to the same conclusion after Fisher-Wallace presented the results and limitations of the Phoenix House study.

OMH will follow closely the evaluation of electric stimulation currently underway at the New York State Psychiatric Institute. If these pilot studies show favorable results without side effects, OMH will reconsider a pilot for patients with psychotic illness and anxiety, mood, and sleep distress. Along with the Fisher-Wallace device that began this inquiry, several other CES devices are available. If we consider using CES with OMH patients, we will need to decide which device to use.