



May 14, 2008

Neurotech Network Responds to Centers for Medicare and Medicaid on NeuroRehabilitation for Stroke

In a public forum to the Centers for Medicare and Medicaid, Neurotech Network will present a user's perspective on neurorehabilitation for stroke for clinical trials. Issues such as control group active participation, the gap between U.S. Food and Drug Administration approval and CMS coverage decision for reimbursement and long term care economics will be the topics at hand.

The Centers for Medicare and Medicaid Services (CMS) posted a [Federal Register Notice](#) for a meeting of the Medicare Evidence Development and Coverage Advisory Committee. The meeting will focus on the design and methodological issues that challenge clinical research regarding innovative neurorehabilitation techniques. It will be held on May 21 at the CMS campus in Baltimore, MD.

"Financial access is a key issue. This is a first step opportunity for people who use neurotechnology devices and therapies to have a voice to the policy makers who directing influence financial access for many Americans," states Jennifer French, Executive Director of Neurotech Network. "Part of our mission is to advocate for access."

The submitted comments from Neurotech Network are below.

Comments from Neurotech Network for the Federal Register FR Doc. E8-5882
CMS-3197-N
Medicare Program; Meeting of the Medicare Evidence Development
and Coverage Advisory Committee--May 21, 2008

We know that stroke is the leading cause of disability among older Americans. We also know that this disabling event can not only lead to lost mobility, balance and endurance but also many secondary health complications and early entry into full nursing care facilities. Neurotech Network believes the topic of clinical trial design and analysis of neurorehabilitation has three issues from a patient's perspective that the committee should consider: 1) face validity for defining a control group, 2) the gap between FDA approval and CMS reimbursement and 3) long term health care of a stroke survivor.

1) Unlike a drug trial, rehabilitation is faced with a challenge of defining the placebo group. In clinical trials of a pharmaceutical drug, the patient will not know if s/he is receiving the placebo. However, in terms of rehabilitation, the patient is aware of whether or not the treatment is being applied. In terms of exercising a muscle, executing gait training or using rehabilitative equipment, the patient is involved in the treatment and needs to be an active participant. Herein lies the challenge of rehabilitation clinical trials. In clinical trial design, our recommendation is to use the control group as those receiving conventional rehabilitation established at the time of the trial design. This will help

overcome the challenge by allowing recruitment of a control group from a realistic setting that patients experience in standard care.

2) Understanding that the FDA approval process is different from the CMS approval process is not clear. It is difficult for a patient to understand why a treatment may be FDA approved but not covered by CMS. The time frame between approval from both agencies may be a few months or several years. In clinical trial design, the FDA has a pre-IDE process. If CMS has a similar process, it is not well known. If such a process exists, our recommendation is to have an inter-agency collaboration to aid in the early design of clinical trials in an effort to reduce the gap between FDA approval and CMS reimbursement review.

3) There needs to be an account for the long term care of the person and the economic impact. The effect of a stroke does not just impact the stroke survivor but also the social network. For instance, if one member of a household has a stroke, another member of that household must become the care giver. If there is not a person to take the role of the care giver, then there is either a paid care giver brought into the home or the stroke survivor is placed in a skilled nursing facility. In the case of a household member becoming the care giver, this economic impact may not be realized in the CMS system but it is realized in other social agencies. In addition to daily care giving, treatments for stroke survivors are not autonomous. Treatment and therapy after a stroke is a long rehabilitative process. As new treatments are considered, they need to be viewed as a complement in the overall care and not as a stand alone treatment. This long term view can help to understand how the treatment being tested may impact the care, cost and quality of life of the post-acute stroke survivor. Ultimately, a short term investment in the rehabilitation of a stroke survivor can convert to long term savings in the overall healthcare cost of that person by not only improving function, but also reducing secondary complications and maintaining independence to reduce the need of a care giver. In the analysis of clinical trials, our recommendation is that the impact of a therapy on long term patient cost to all stakeholders be considered.

We hope you will take these points into consideration of the clinical trial design, methodology and analysis in the context of stroke rehabilitation.

About Neurotech Network

Neurotech Network of The Society to Increase Mobility, Inc. is a 501(c)(3) non-profit organization focusing to improve the education of and the advocacy to access neurotechnology devices for persons with impairments. Charged with a mission to provide information to and for the users and potential users of neurotechnology, this organization fills a needed void to better serve those that may benefit from technology advancements. Hundreds of thousands of people with neurological or psychiatric disorders have already been helped; such as cochlear implants to restore hearing to the deaf, neuroprosthetics providing movement to the paralyzed, and spine stimulators give relief to those with chronic pain.

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