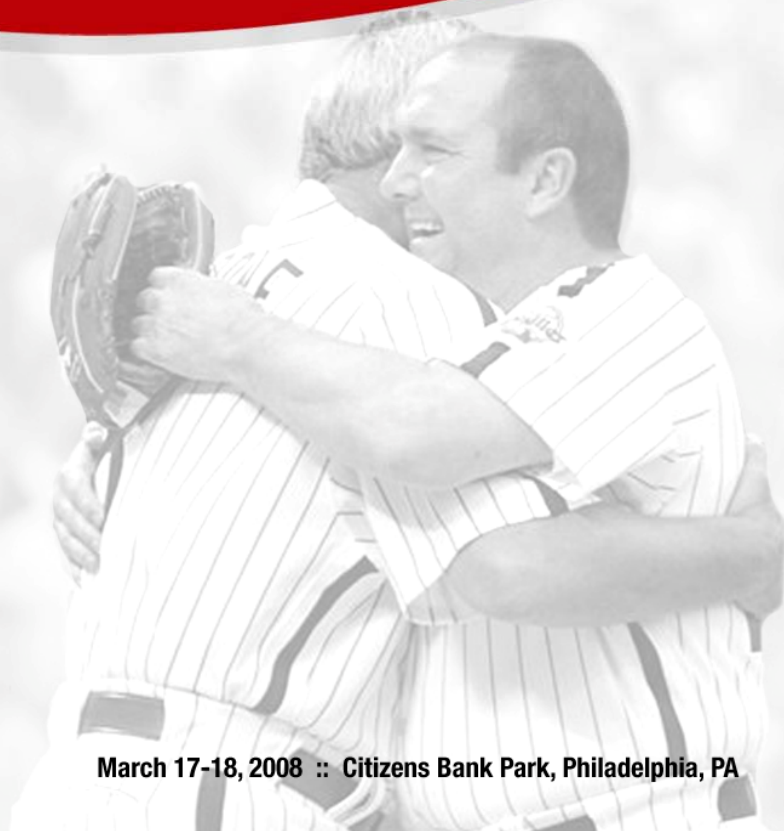




TUG MCGRAW
FOUNDATION

**A Report from the Tug McGraw Foundation
Brain Tumor Quality of Life Summit**

**BRAIN TUMOR
QUALITY OF LIFE
RESEARCH SUMMIT**



March 17-18, 2008 :: Citizens Bank Park, Philadelphia, PA

A Call to Improve Quality of Life Research For Primary Brain Tumor Patients

Each year, more than 21,000 Americans are diagnosed with primary brain tumors and some 13,000 Americans die from this disease. Malignant primary brain tumors are among the most aggressive and lethal of all cancers. Although new treatments have increased survival rates, patients and their families face many challenges in the months after receiving a brain tumor diagnosis.

One major challenge is the battle to maintain quality of life while enduring the debilitating effects of the disease and its treatments. Currently, the majority of research is focused on finding a cure or to extend the ‘quantity’ of life, while critical issues surrounding the ‘quality’ of life like the impact of fatigue, lack of sleep and/or appetite, and depression on patient outcome often go unheeded. In fact, the lack of agreement about the importance of a brain tumor patient’s quality of life and knowing how to improve it is striking in light of the growing body of research documenting quality of life care for other cancers and cancer treatments..

In an attempt to address this issue, the Tug McGraw Foundation (TMF) has committed to raising awareness of brain tumor quality of life issues - - for patients and their caregivers. One important component of this mission is to improve the quality of brain tumor quality of life research and to disseminate these findings into clinical practice. To that end, TMF sponsored the first ever Brain Tumor Quality of Life Research Summit, held at Citizens Bank Park in

Philadelphia, from March 16-18, 2008. The Summit brought together nearly 30 experts representing key fields in brain tumor care, including surgeons, neuropsychologists and social workers, to discuss pertinent issues and develop a plan to propel the field forward.

The group identified four major barriers that impede high-quality research on quality of life issues in brain tumor patients:

- There is no universally accepted definition of what constitutes ‘quality of life’ for brain tumor patients;
- A disconnect exists among clinicians and frontline caregivers, clinical researchers, and bench researchers;
- Healthcare practitioners are not sold on the importance of quality of life issues to brain tumor patients; and
- Funding levels are inadequate to conduct meaningful brain tumor quality of life research.

Disease management remains difficult and long-term survival, if achieved, is often accompanied by significant disability. “This was a meeting that was long overdue,” said Lee Jones, Ph.D., director of the Tug McGraw Research Center at Duke University and co-chair of the Summit. “The investigation of quality of life in primary brain tumor patients has lagged behind this type of research in other cancer populations despite the fact that a good quality of life is one of the most important goals for both patients and families dealing with this devastating disease.”

Defining Quality of Life

First and foremost, settling on a definition would enable the research community to formulate well-defined quality of life studies and help investigators determine which measurement tools to select and how best to use them in specific drug clinical trials. The fact that quality of life is a subjective and complex concept and that it changes repeatedly over time makes defining quality of life a challenge for the research community. Nonetheless, the Summit's participants developed a four-stage plan to define quality of life:

Stage 1: Convene a consensus conference of leaders from the brain tumor and quality of life fields to prioritize various components of quality of life, making a point to involve researchers who study other types of cancer and neurodegenerative disorders, and to thoroughly review existing definitions of quality of life before settling on a standardized definition that could be tested rigorously and then used. Participants might include stakeholders such as the Tug McGraw Foundation and other brain tumor non-profits, the National Cancer Institute (NCI), the National Institute of Nursing Research (NINR), the National Institute of Neurological Disorders and Stroke (NINDS), the National Institute of Mental Health (NIMH), the American Association of Cancer Research (AACR), and the U.S. Food and Drug Administration.

Stage 2: Widely disseminate the results of the consensus conference relying on publications, conference sessions, patient support groups, and the wide variety of non-profit organizations involved in brain tumor research and advocacy.

Stage 3: Encourage stakeholders such as NCI and other agencies to include quality of life in requests for grant applications.

Stage 4: Refine the initial definition, as needed, based on evaluation and feedback from the broader community. These efforts would be judged a success if quality of life research became part of all clinical trials.

Getting Clinicians Involved

Summit participants discussed the disconnect between clinicians and researchers as a significant barrier to conducting quality of life research. Specifically the need exists to integrate quality of life research, brain tumor research and clinical care. Bringing these fields together would create multidisciplinary research teams with the intellectual power to conduct meaningful quality of life research with brain tumor patients. This integration also would drive clinician buy-in across the clinical care continuum with the ultimate goal of developing new interventions and strategies to improve quality of life. According to Christina Meyers, Ph.D., ABPP, professor and chief, section of Neuropsychology, department of Neuro-Oncology, M.D. Anderson Cancer Center and co-chair of the Summit, “Longer life and better life should be integrated; longer life is only truly beneficial if it is better life.”

A first step toward accomplishing this ambitious goal would be to examine models from other fields in which quality of life is considered a mainstream part of care and research, such as the NCI’s Specialized Programs of Research Excellence or SPOREs. Funds would be available for a pilot project examining one aspect of quality of life that would be conducive to a multidisciplinary approach. These pilot projects, conducted in conjunction with a biomarker

study or a drug clinical trial, would operate in a clinical practice setting and serve to invite buy-in from various research and clinical constituencies, and from hospital administrators and the health care insurance industry. “For healthcare providers treating patients with brain tumors, understanding the *value* of living better during treatment and beyond should be a key consideration,” said Brian P. O’Neill, MD, professor of Neurology, Mayo Clinic Cancer Center. “Including quality of life endpoints in clinical trials, as well as designing trials in which quality of life is the primary endpoint, not only underscores its importance but reinforces the message that all healthcare providers need to be thinking about it as part of the standard of care.”

The NCI has provided a strong signal that it wants to play an active role in quality of life research. One way the Institute can motivate clinician buy-in is to disseminate information through its SPOREs and Cancer Centers. The nursing and social work communities need to be courted aggressively, too, since nurses and social workers will likely be on the front lines of quality of care research.

New Research, New Resources

Though every field of research can use more funding, brain tumor quality of life research also needs to attract new talent. This will only happen if funding for this type of research is available. One approach might be to earmark a percentage of all clinical trial research funding specifically towards quality of life. This would occur by default if quality of life became an endpoint for drug clinical trials. With a flat NCI budget, however, and new funds in short supply, the field must look for new partners to drive brain tumor quality of life research forward.

Some will argue that patients would benefit more from spending limited research dollars on developing new cures for brain tumors rather than on studying quality of life in what is an almost invariably terminal disease. New treatments have shown modest increases in survival ranging from 12-16 months for patients with glioblastoma multiforme, one of the most lethal brain tumors. However, future treatments may turn brain tumors into a chronic disease, extending survival by years. Given this, improved quality of life is likely one of the most important, if not *the* most important outcome, for patients and families.

Indeed the NCI is already in the process of revamping its clinical trials infrastructure to focus more on quality of life issues associated with the next generation of cancer therapies. According to NCI Deputy Director Anna Barker, Ph.D., who presented a keynote address at the Summit, in a world where earlier detection and improved therapies will mean that more patients will survive their disease and that more patients will live with cancer as a chronic illness, quality of life will take center stage. “It is important, then, that the field lay the groundwork now to bring quality of life research to the forefront,” said Dr. Barker.

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