
What should be done to get consensus in Europe?

George A. Zitnay
Charlottesville, VA. USA

Introduction

Brain injury, a clinical problem treated frequently by neurosurgeons, is a major cause of disability, death and economic cost to society. In the past two decades, there has been a remarkable increase in our understanding of the pathophysiology of head injury. One of the central concepts that emerged from clinical and laboratory research is that all neurological damage does not occur at the moment of impact, but evolves over the ensuing hours and days. Furthermore, we now recognize the deleterious effects of these various delayed insults to the injured brain at the clinical and biochemical levels. This has led to an interest in developing better monitoring and treatment methods as well as the development of new pharmaceuticals, all of which show great promise in improving the outcome for patients who have suffered a brain injury.

Past efforts to develop guidelines for the management of patients with brain injury relied on expert opinion and practice experience and, therefore, had an element of subjectivity. Recently, with the advent of a methodology to develop guideline documents based on scientific method, there has been a dramatic increase in clinical practice guidelines with subsequent reports showing improvement in patient care and a reduction in medical time and cost. The interest in developing guidelines for brain injury intensified after a study documenting con-

siderable variability in the management of patients with brain injury depending upon the place of treatment, training of professionals and philosophy of care.

Developing guidelines for the management of brain injury requires a meticulous process relying on scientific evidence rather than expert opinion. In addition, representatives of national and international medical societies and individuals with demonstrated expertise in the care of patients with brain injury must be included in the process if the guidelines are to be used. Guidelines address key issues relating to the management of brain injury in adult patients. Guidelines are by no means an exhaustive treatise on brain injury. Due to the enormous effort required to develop evidence based guidelines, only selected topics that were deemed to have an impact on outcomes in patients with brain injury were chosen for inclusion.

The intent is that guidelines will clearly state the current scientific basis for clinical practice. For most clinical practice parameters, scientific evidence is insufficient for standards of care, as is generally the case in most of current medical practice. Upgrading clinical practice parameters from option to guideline to standard will require focused, well-designed and carefully implemented clinical research trials.

What is a guideline? According to *Stedman's Concise Medical Dictionary* a "guide" is any device or instrument by which another is led into its proper course. And the *American*

Heritage Dictionary says a "guideline" is a statement or other indication of policy or procedure by which to determine a course of action. In other words, a guideline is a tool, something to assist the practitioner. It is not a law or regulation. Guidelines are intended to encourage all of us to work for better outcomes in persons with brain injury.

The purpose of this paper is to demonstrate that "practice guidelines" can assist in improving outcomes in persons with traumatic brain injury and to recognize that all so called "practice guidelines" have merit but will not be effective unless there is consensus on those critical areas that are common to neurosurgical care of patients with brain injury.

The professional community in Europe has the opportunity to lead the way in developing a consensus document for practice guidelines in the treatment of brain injury because of widespread interest and willingness to work together for a common goal. Is there a place for Italian guidelines, EBIC guidelines, Lund Concept guidelines, and so on? Of course, local conditions, cultural issues and resource allocation play a role in implementation of "practice guidelines" so local options are necessary. But without consensus on those critical points of "practice" outcomes will not improve. Yes, there are some practices that are detrimental and should be discarded, and yes-new emerging technology and equipment require consistent practice. One most promising direction is the increased desire by professionals to engage in practice guideline development for brain injury and the increasing interest on the part of health departments and neurosurgical societies to engage in guideline development. Recently the Neurotrauma Committee of the World Health Organization has begun to review guidelines, especially the Guidelines for the Management of Severe Head Injury developed by the American Association of Neurological Surgeons (AANS) and the Brain Trauma Foundation. WHO is interested in upgrading

the care, treatment and consistency of persons with brain injury worldwide. In evidence based guidelines there are three levels of evidence.

**Class I.
Studies provided by one or more clinical studies of:**

1. A diverse population
2. Using a "gold standard" reference test (prospective randomized controlled trial)
3. Using a blinded evaluation appropriate for diagnostic applications
4. Enabling the assessment of sensitivity, specificity, positive and negative predictive value, and where applicable, likelihood ratios

**Class II.
Studies provided by one or more clinical studies of:**

1. A restricted population
2. Using a "gold standard" reference test
3. Using a blinded evaluation appropriate for diagnostic applications
4. Enabling the assessment of sensitivity, specificity, positive and negative predictive value and where applicable, likelihood ratios

**Class III.
Evidence provided by:**

1. Expert opinion
2. Studies which do not meet the criteria to delineate sensitivity, specificity and positive and negative predictive value
3. Studies based on retrospectively collected data

Using the above criteria, evidence based guidelines then classify evidence as a standard (class I), a guideline (class II) or an option (class III). *Standards*: represent accepted principles of patient management that reflect a *high degree of clinical certainty*.

Guidelines: represent a particular strategy or range of management strategies that reflect a *moderate clinical certainty*.

Options: are the remaining strategies for patient management for which there is *unclear certainty*.

Perhaps it would be a good first step if the European Professional Community could agree on what is or is not a *standard*. This could be a good place to start.

RECOMMENDATIONS FOR CONSENSUS BUILDING

1. Utilizing professional organizations and societies, conduct panel discussions on "practice guidelines" for the management of brain injury at every meeting to work toward clarification and better understanding of how guidelines are being developed and used.
2. Use the print and broadcast media to discuss how guidelines can improve outcomes. This will result in more interest and support for guidelines.
3. Develop a consensus document that clearly spells out what guidelines are all about, what they are not about and how they can help the *local* practitioners.
4. Communicate, communicate, communicate. This will clear up misunderstandings and develop trust.
5. Recognize and respect differences as long as these differences *do no harm*.
6. Invite representatives from the various groups working on guidelines to nominate

two persons to represent their interest at a European Working Group on the Development of Consensus in Guidelines for the Management of Brain Injury.

7. Utilize an organization such as WHO to assist in consensus planning.
8. Use the guidelines process to advance the science of brain injury to gain support for research.
9. Conduct training courses on guideline use and development at medical schools and hospitals.
10. Help scientists develop research that meets the "gold standard".

There is no simple solution to the problem but if we can all agree that we are interested in saving lives and improving outcomes then we can move on to quality of life following brain injury which, after all, is what is most important to the person with a brain injury and his or her family.

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Address for correspondence:
Prof. George A. Zitnay, PhD
400 Ray C. Hunt Drive, Suite 300
Charlottesville, VA22903
USA