Chapter 1: Introduction

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A comparison of pediatric with adult trauma, using the National Pediatric Trauma Registry, indicates that a greater proportion of pediatric than adult trauma involves traumatic brain injury (TBI) (1). However, because of difficulty in evaluating treatments across age groups and developmental phases for children with TBI, little substantial research has been conducted to specify standard treatments for acute care as well as inpatient and outpatient rehabilitation (2). The persistence of some federal funding agencies to devote their resources exclusively to studies of adult populations with TBI highlights the fact that pediatric brain injury remains underinvestigated. Pediatric physicians are left to make deductions from guidelines developed for adult populations (3) or to call upon their clinical experience to make individual treatment decisions.

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The sections Degrees of Certainty, Classification of Evidence, and Correlation Between Evidence and Recommendations closely mirror the adult "Guidelines for the Management of Severe Traumatic Brain Injury."

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DOI: 10.1097/01.CCM.0000066600.71233.01

Evidence-based medicine is playing an increasing role in the direction of medical practice. As an empirical, unbiased analysis of the state of the literature on a given topic, an evidence report summarizes vast bodies of literature such that the practitioner can more confidently base therapeutic choices on a scientific foundation. By this means, one is able to understand not only the evidence supporting various therapeutic options but also the rigor of the evidence. A management decision based on solid (class I) evidence should offer the highest degree of confidence that the correct choice has been made. At the other extreme, a decision based on much less solid (e.g., class III) evidence may be equally efficacious, but it alternatively may not be the best choice, and the results of that decision should be followed closely so that alterations can be expediently made if necessary. The majority of management decisions are not and never will be supported by class I evidence. As such, knowing the degree of support for a given decision, as well as the alternatives, should be an extremely valuable adjunct to the practice of medicine.

The evidence-based "Guidelines for the Management of [Adult] Severe Traumatic Brain Injury" for adults (4) have been exceptionally well received by a large audience of physicians, paramedical personnel, and administrators around the world. Although to a lesser extent than would be optimally expected, the adult guidelines have changed practice and improved outcome from severe TBI. Notably, however, the evidentiary foundation on which they are based did not specifically address the pediatric population. One of the most common questions asked following presentations of the "Guidelines for the Management of [Adult] Severe Traumatic Brain Injury" addresses how they apply to children. The proper answer to date has been that this is unknown. Since it is not true that "children are just little adults," it is not proper to generalize from the adult literature to the pediatric population. The present effort is an attempt to address this problem by providing a companion to the "Guidelines for the Management of [Adult] Severe Traumatic Brain Injury" that addresses issues from that work as they apply to children while additionally covering aspects of TBI care that are unique to or differently developed in the pediatric population. A number of the pediatric recommendations at the option level mirror those in the adult guidelines. In both the adult and pediatric guidelines, these were derived based on consensus.

These guidelines address key issues relating to the management of severe TBI in pediatric patients with a Glasgow Coma Scale score of 3–8. Pediatric is defined as <18 yrs of age. Traumatic brain injury is defined as primary or secondary injury to the brain resulting from a traumatic etiology. Abusive head injury (identified by a variety of different terms including inflicted traumatic brain injury and shaken baby syndrome, among others) is included in this category. Injuries due to mechanisms such as drowning, cerebrovascular accidents, or obstetrical complications are not addressed here.

There are a number of shortcomings of relying solely on evidence reports to direct medical decision making. A major factor is that such works can only state what the literature supports. If an issue has been only poorly or incompletely researched, little strong support for it will be gleaned from the literature even if it is a currently widely accepted therapy or one that is very strongly believed to be effective on a purely clinical basis. An example in the TBI literature is the use of

mannitol to treat intracranial hypertension. This is one of the oldest treatments, and there is generally a strong medical consensus that it is an effective and proper response to elevated intracranial pressure. Because it became "clinically established" before today's more rigorous medical environment, there is surprisingly little empirical, strong scientific literature on its use. This contrasts sharply with the literature on a much newer treatment for intracranial hypertension, hypertonic saline, for which there is a fair body of reasonably strong research. Such newer treatments, having to meet higher scientific standards, are often supported by higher classes of evidence. This leads to the commonly encountered but less than satisfactory situation where older and more established therapies will be found to have less empirical support than newer treatment modalities (e.g., mannitol vs. hypertonic saline or ventricular drainage vs. lumbar drainage). The proper manner of addressing this issue when formulating treatment recommendations remains an unsettled and difficult problem in developing treatment guidelines.

Another difficulty is that generalizing from a study is inconsistent with a rigorous evidence-based process. Even if it is recognized that a given factor is highly germane to a specific question, it cannot be addressed in the absence of data on that factor in particular. An example from the "Guidelines for the Management of [Adult] Severe Traumatic Brain Injury" is the list of factors that support intracranial pressure monitoring in patients with a Glasgow Coma Scale score of ≤ 8 and a normal admission computed tomography scan at the level of a treatment guideline. These include the presence of two or more of the following: age >40 yrs, unilateral or bilateral motor posturing, and the presence or history of a systolic blood pressure <90 mm Hg. In no way are these believed to be the most definitive or only factors that suggest a high likelihood of intracranial hypertension in comatose patients with normal computed tomography scans—they are merely the factors that arose from the class II study upon which the management guideline was based. Such a restriction on generalization maintains the scientific rigor of the evidence-based process. It is, however, also extremely unsatisfying because it severely limits our ability to address issues that are commonly thought to be important and it may produce statements that superficially appear to be incomplete. It is hoped that such shortcomings will be corrected through future research.

Process Used in the Development of These Guidelines

The project was initiated in March 2000 during the 5th Annual Aspen Neurobehavioral Conference. Three phases of treatment for pediatric TBI were identified as priorities for guidelines development—acute medical management, rehabilitation, and school/family/community reentry. Participants at the conference who are also investigators with the Evidence-Based Practice Center (EPC) of Oregon Health & Science University (OHSU) agreed to take acute medical management as their topic. They contacted individuals who had previously worked on the topic and included additional investigators from OHSU to assemble a multidisciplinary team.

Using the 14 topics from the adult guidelines as a place to begin, we added pediatric-specific questions and arrived at a set of 18 key topics, including one that addresses a critical pathway for treatment, or a treatment algorithm. Each topic was assigned a primary and secondary author. With the assistance of the EPC's reference librarian, we conducted Medline searches from 1966 to 2001 by using a broad search strategy for each question. Blinded to each other, and using predetermined criteria, the primary and secondary authors read abstracts and identified studies for which full-text articles would be retrieved. They then read the studies and eliminated another set. They used as their general criterion the goal of obtaining the best possible evidence. If studies at the best level of randomized trials were not available, then those at the next level down were accepted. Thus, the level of evidence included for each topic in this document varies with what was available in the literature.

A baseline requirement for a study to be used for recommendations at the level of standards or guidelines was that the study be about children or contain data about children that was reported separately from data reported about adults. If we could not distinguish adult data from child data in a study, or if a study did not include children, we did not include it in this review. In the case where there was no pediatric literature for a topic or for a subset of a topic, we reviewed the adult guidelines and by consensus elected how to refer to that document in terms of recommendations for children. Thus, a number of the pediatric recommendations at the options level mirror those in the adult guidelines.

Degrees of Certainty

Regarding the degree of certainty associated with a particular recommendation, the following terminology is the most widely accepted and is used in this document.

- Standards: Accepted principles of patient management that reflect a high degree of clinical certainty
- Guidelines: A particular strategy or range of management strategies that reflect a moderate clinical certainty
- Options: The remaining strategies for patient management for which there is unclear clinical certainty

Note that "guideline" is used both in a global sense, that is, clinical practice guidelines, as well as in a more specific sense, as noted previously.

Classification of Evidence

When assessing the value of therapies or interventions, the available data are classified into one of three categories according to the following criteria:

- Class I evidence: randomized controlled trials—the gold standard of clinical trials. However, some may be poorly designed, lack sufficient patient numbers, or suffer from other methodological inadequacies.
- Class II evidence: clinical studies in which the data were collected prospectively and retrospective analyses that were based on clearly reliable data. Types of studies so classified include observational studies, cohort studies, prevalence studies, and case control studies.
- Class III evidence: most studies based on retrospectively collected data. Evidence used in this class indicates clinical series, databases or registries, case reviews, case reports, and expert opinion.

Correlation Between Evidence and Recommendations

Standards are generally based on class I evidence. However, strong class II evi-

		Developmental Category					
		Somatic		Intellectual/Cognitive		Behavioral	
Developmental Phase	Mortality	Neurological/ Hormonal	Sensorimotor	Executive Function	Language	Emotional	Social
Infancy 0 – 6 months							
Infancy 7 – 12 months							
Infancy 13 – 18 months							
Infancy 19 – 24 months							
Childhood 2 years							
Childhood 3 – 4 years							
Childhood 5 – 6 years							
Childhood 7 – 8 years							
Pre-puberty 9 – 11 years							
Early Adolescence 11 – 14 years							
Late Adolescence 15 – 20 years							

Figure 1. Matrix.

dence may form the basis for a standard, especially if the issue does not lend itself to testing in a randomized format. Conversely, weak or contradictory class I evidence may not be able to support a standard.

Guidelines are usually based on class II evidence or a preponderance of class III evidence.

Options are usually based on class III evidence and are clearly much less useful except for educational purposes and in guiding future studies.

Pediatric Conceptual Model

Three dimensions constitute the conceptual model necessary to evaluate and understand outcomes from brain injury in children and adolescents and the effect of interventions on those outcomes:

- Developmental category of outcome
- Developmental phase of child at time of injury
- Injury severity

Because outcomes from brain injury are observed in cognitive and behavioral dimensions, as well as somatic dimensions, evaluation of the recovery process in children is confounded by cognitive and behavioral changes that occur as a function of normal development (2). Furthermore, development within each dimension accelerates and decelerates during different developmental phases. Injury severity, and the presence or absence of multiple-system injuries, will also interact with the child's age to influence outcome.

The matrix in Figure 1, adapted from several sources (5–7), offers a framework for considering the complexity of measuring outcomes from brain injury in children.

The horizontal axis represents the various categories within which outcomes can be observed. The vertical axis represents developmental phases that influence expected performance within developmental category. The third dimension of injury severity, not represented on this matrix, introduces more complexity to the consideration of outcome. This model applies to all of the questions addressed in these guidelines. Its utility is to map existing research for each question; empty cells indicate topics for future study.

An additional issue specific to pediatric trauma is that of intentional injury. The nature of the trauma and secondary complications are thought to be distinct in ways from many unintentional injuries, requiring corresponding differences in appropriate treatment. The delay between injury and hospital admission, or between admission and recognition that the injury was intentional, can thwart timely treatment decisions. Although at the beginning of the project we agreed to pay careful attention to this issue in our review of the literature, no studies provided data of any kind to assist in making distinctions about treatment for intentional injury.

These guidelines address key issues relating to the management of severe traumatic brain injury in pediatric patients with a Glasgow Coma Scale score of 3–8. Pediatric is defined as <18 yrs of age.

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