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Supplement on Pediatric Trauma Care

This supplement of the Journal of Trauma presents the papers and discussions of a March 2007 Conference on Pediatric Trauma sponsored by the Agency for Healthcare Research and Quality. The conference participants represented the broad spectrum of disciplines involved in the management of injured children. The presentations and discussions bring forth a clear picture of the current status of pediatric trauma care in the United States and accurately describe the present day organization, delivery and outcome assessments applied in the care of pediatric trauma patients. A particular strength of the supplement is the emphasis placed on expanding the assessment of outcomes beyond survival to include age-specific quality of life measurements. That benchmark information will allow hospitals and pediatric trauma centers to assess their effectiveness in delivering quality trauma care and more importantly, identify deficiencies and those areas where expenditure of funds and support of focused research will most effectively and efficiently improve care of the injured child.

The format of the conference mandated brevity, but it is hoped that a second conference will be convened in the near future at which the information from this conference can be used to prioritize research initiatives, describe evidence-based assessments, refine trauma care delivery, and develop estimates of the costs to achieve the improvements needed. Future consideration should be given to the possible integration of pediatric and adult trauma care systems to conserve resources and maintain quality of care in the treatment of lesser injuries. The role of pediatric trauma centers in mass casualty and disaster situations must also be defined.

The organizers of the conference and all of the participants are to be applauded for the success of the conference. These proceedings will be frequently cited and the information contained is certain to accelerate improvement in the organization, delivery, and quality of pediatric trauma care.

Basil A. Pruitt, Jr., MD, FACS
Editor, Journal of Trauma
Pediatric Trauma Care: Defining a Research Agenda

Frederick P. Rivara, MD, MPH, and Keith T. Oldham, MD

This conference was organized by Frederick P. Rivara, MD, MPH, Keith Oldham, MD, Karen Guice, MD, Ellen MacKenzie, PhD, and Gregory J. Jurkovich, MD, with the generous support of the Agency for Health Care Research and Quality, and the Emergency Medical Services for Children program of the Maternal and Child Health Bureau.

Our ultimate goal is to improve trauma care. Nine years ago, Mullins and colleagues organized what has become known as the Skamania Conference to evaluate the evidence on the effectiveness of trauma centers and trauma systems, and to formulate a research agenda to answer the important questions around trauma care.1 The Skamania Conference directly led to the National Study on the Costs and Outcomes of Trauma (NSCOT), the most comprehensive study on trauma care in the United States conducted to date. NSCOT was limited to patients 18 to 84 years of age and compared the outcomes of patients treated in Level I trauma centers with those treated in large urban or suburban nontrauma centers. Findings from the study thus far indicate that mortality is 25% lower for similar patients treated in trauma centers,2 and functional outcome is improved for patients 18 to 55 years of age with serious lower extremity injuries.3

This study, by design, did not examine trauma care among children and adolescents. Trauma is the most important cause of morbidity and mortality in this latter age group, accounting for nearly 16,000 deaths; 250,000 hospital admissions; and 9 million emergency department visits annually. The human and financial costs to individuals, families, the state and federal government, and to society as a whole are enormous.

All agree that primary prevention is the optimal “treatment” for pediatric trauma. However, it is only one component in the broader field of injury control, and will never be sufficient without treatment systems. The outcome of acute care of the injured child is dependent upon every phase of care, including prehospital care, emergency department stabilization, the operating room process, intensive care unit and inpatient care, as well as rehabilitation. All are important factors in limiting mortality and morbidity. For many children, the acute phase of care must be followed by rehabilitation for weeks to months to limit the sequelae of trauma and return the child and family to their full potential.

The organizers of this conference believe that there are many unanswered questions around the care of the injured child and adolescent. Our goal was to gather experts from a wide variety of disciplines to review the current state of knowledge about pediatric trauma care and outcomes after trauma, and to develop an innovative, collaborative research agenda to improve this care and the subsequent outcomes. Some of those questions arise from the NSCOT study but differ substantially because of differences in pediatric when compared with adult trauma. Mortality rates in injured children are substantially lower than in adults, and a higher proportion is caused by severe central nervous system (CNS) injury. Thus, survival is an inadequate measure of the quality of care. Therefore, the focus of any study on pediatric trauma must be on functional outcomes and the relationship of process of care to those outcomes.

The important questions encompass the structure, process, and outcome of pediatric trauma care. What are the characteristics of hospitals and trauma systems that yield optimal clinical care for injured pediatric patients? What training, personnel, and resources are needed in the prehospital, emergency department, intensive care unit, inpatient ward, and rehabilitation unit to provide optimal care? How should care be organized in each of these settings? How do these resources vary with the type and severity of injury?

What is optimal clinical care for the pediatric trauma patient? In an era when medicine is increasingly focused on outcomes, optimal care must be that which produces the best outcome for a child and family, given the type and severity of injuries sustained. How should those outcomes be defined? Is it health-related quality-of-life, success in school, social skills, and participation in activities that are routine for non-impaired children? What are the effects on other members of the family as well?

Can these outcomes be measured in such a way that is sensitive enough to detect variations in care as well as improvement over time? Are there current measures available that meet these requirements or must new ones be developed? Can the same measures be used for all ages encompassed within the pediatric age group? Given that children are developing organisms, how long must follow-up be conducted to obtain a complete and accurate assessment of the outcome from trauma?
Outcome from trauma must also include cost and some evaluation of cost-benefit ratios, and other resource utilization analysis. Costs of care almost certainly vary, if not vary widely, in different settings. How do these costs relate to functional outcome? Is there a relationship between higher cost and improved quality of life?

Prior research has clearly demonstrated that outcome from a variety of types of trauma in both children and adults is greatly affected by the context in which the injury occurs. What pre-existing comorbidities interact with the injuries and care to affect short- and long-term functional outcome? How do resources and function within the family modulate the consequences of trauma? How do resources in the community influence whether impairments result in disability?

What are the ethical, confidentiality, and institutional review board issues with conducting such a study? How will data collection occur in light of contemporary Health Insurance Portability and Accountability Act (HIPAA) regulations? If a study were to collect genetic material, what consent procedures will be necessary?

The questions posed offer fertile ground for meaningful research into pediatric trauma care in the United States today. These were formulated and discussed in detail at the conference. Oral presentations and relevant discussion are presented in this supplement for the use of all health care providers interested in pediatric trauma care.

We hope that this special supplement to the Journal of Trauma will expand the discussion of these important questions to all of us who are concerned with the health and welfare of injured children.

REFERENCES

The National Study on Costs and Outcomes of Trauma

Ellen J. MacKenzie, PhD, Frederick P. Rivara, MD, MPH, Gregory J. Jurkovich, MD, Avery B. Nathens, MD, PhD, MPH, Katherine P. Frey, MPH, Brian L. Egleston, MPP, PhD, David S. Salkever, PhD, Sharada Weir, DPhil, and Daniel O. Scharfstein, ScD

The National Study on the Costs and Outcomes of Trauma Care (NSCOT) was designed to address the need for better information on the value of trauma center care. It is a multi-institutional, prospective study that involved the examination of costs and outcomes of care received by over 5,000 adult trauma patients 18 to 84 years of age treated at 69 hospitals located in 12 states. The study had three major objectives: (1) to examine variations in care provided to trauma patients in Level I trauma centers and nontrauma center hospitals; (2) to determine the extent to which differences in care correlate with patient outcome, where outcome is defined not just in terms of mortality and morbidity, but also in terms of major functional outcomes at 3 months and 12 months after injury; and (3) to estimate acute and 1-year treatment costs for trauma center and nontrauma center care, and to describe the relationship between costs and effectiveness for trauma centers and nontrauma centers. In this article, we describe the design of the NSCOT study and point to some of the methodological challenges faced in its implementation and in the analysis of the data. We also present a description of the study population to serve as a basis of future reports. We conclude with lessons learned and some recommendations for future research.

of mortality and morbidity, but also in terms of major functional outcomes at 3 months and 12 months after injury; and (3) to estimate acute and 1-year treatment costs for trauma center and nontrauma center care, and to describe the relationship between costs and effectiveness for trauma centers and nontrauma centers.

In this article, we describe the design of the NSCOT study and point to some of the methodological challenges faced in its implementation and in the analysis of the data. We also present a description of the study population to serve as a basis of future reports. We conclude with lessons learned and some recommendations for future research.

### DESIGN OF THE NSCOT STUDY

#### Setting and Selection of Hospitals

The NSCOT study was conducted in 15 regions defined by one or more contiguous Metropolitan Statistical Areas (MSAs) located in 12 states (Table 1). The MSAs were selected from among the 25 largest MSAs located in 19 states for which routinely collected hospital discharge data were available for analysis. We excluded MSAs in which the larger nontrauma centers collectively treat fewer than 75 major trauma patients per year as defined by International Classification of Diseases (ICD) derived Injury Severity Score (ICD/ISS) >15.6,7

Within each MSA, a random sample of Level I trauma centers and large nontrauma center hospitals were identified for inclusion in the study. Hospitals were identified as Level I trauma centers if (as of July 2001) they were designated by a state or regional authority or verified by the American College of Surgeons Committee on Trauma (ACS/COT).8 Nontrauma center hospitals were hospitals that were neither designated nor verified as a trauma center at any level and treated at least 25 major trauma patients per year. Restricting the sample of nontrauma centers to those treating a higher volume of cases was necessary for the efficiency of the study design.

A total of 27 Level I and 124 nontrauma centers were selected and approached for their willingness to participate. Eighteen of the trauma centers (67%) and 51 of the nontrauma centers (41%) agreed to participate and received approval for the study from their institutional review boards (IRBs). The principal reason for nonparticipation among the trauma centers was the inability to obtain IRB approval (7 of 9 nonparticipants) whereas a larger proportion of the nontrauma centers (48 of the 73 nonparticipants) refused to participate, most often citing the lack of sufficient hospital staff to facilitate the study.

All participating hospitals were asked to complete a questionnaire to characterize their organizational structure and resources available (both general and trauma specific). A summary of these characteristics is provided in Table 2. As would be expected, nontrauma center hospitals are, on average, smaller than trauma centers and less likely to be members of the Council of Teaching Hospitals (COTH). They also treat fewer major trauma patients per year. It is important to note that 17 (34%) of the nontrauma centers have a designated trauma team and eight of these have a trauma director. However, among these 17 nontrauma centers with a trauma team, only 77% have a written protocol for activation and even fewer (40%) require that a general or trauma surgeon be present at major resuscitations.

### Table 1 Number of Participating Trauma Centers and Nontrauma Centers by NSCOT Region

<table>
<thead>
<tr>
<th>NSCOT Study Region</th>
<th>Level I Trauma Centers</th>
<th>Nontrauma Centers</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Met Criteria</td>
<td>Selected</td>
</tr>
<tr>
<td>Boston, MA; Providence-Fall River-Warwick, MA-RI</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>New York, NY</td>
<td>18</td>
<td>3</td>
</tr>
<tr>
<td>Philadelphia, PA-NJ; Allentown-Bethlehem-Easton, PA; Reading, PA; Williamsport, PA; Scranton-Wilkes-Barre-Scranton, PA</td>
<td>8</td>
<td>3</td>
</tr>
<tr>
<td>Pittsburgh, PA</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Baltimore, MD; Wash DC, MD-VA, WV</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Charlotte-Gaston-Rock Hill, NC-SC; Greensboro-Winston Salem-High Point, NC; Fayetteville, NC</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Miami, FL; Ft. Lauderdale, FL</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Chicago IL; Gary, IN</td>
<td>13</td>
<td>2</td>
</tr>
<tr>
<td>Detroit MI; Saginaw MI</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Evansville-Henderson, IN</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Milwaukee-Waukesha, WI; Madison, WI; Racine, WI</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>San Diego, CA</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>San Francisco, CA; Oakland, CA; Modesto, CA; Stockton, CA</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Los Angeles-Long Beach, CA</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Seattle-Bellevue- Everett, WA</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>All Regions</td>
<td>68</td>
<td>27</td>
</tr>
</tbody>
</table>

Table 2  Characteristics of NSCOT Hospitals by Trauma Center Status

<table>
<thead>
<tr>
<th>Hospital Characteristic</th>
<th>Trauma Centers (N = 18)</th>
<th>Nontrauma Center Hospitals (N = 51)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size and administrative structure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>% publicly owned</td>
<td>44%</td>
<td>4%</td>
</tr>
<tr>
<td>% member, council of teaching hospitals (COTH)</td>
<td>100%</td>
<td>16%</td>
</tr>
<tr>
<td>Av. number of acute care beds</td>
<td>303</td>
<td>201</td>
</tr>
<tr>
<td>Av. number of ICU beds</td>
<td>42</td>
<td>19</td>
</tr>
<tr>
<td>Av. number of admissions (all conditions)</td>
<td>23,018</td>
<td>16,612</td>
</tr>
<tr>
<td>Av. number of major trauma admissions (ISS &gt;13)</td>
<td>319</td>
<td>37</td>
</tr>
<tr>
<td>Trauma response</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Av. number surgeons taking call with trauma and/or surgical critical care training</td>
<td>5.0</td>
<td>0.4</td>
</tr>
<tr>
<td>% with designated trauma team</td>
<td>100%</td>
<td>34%</td>
</tr>
<tr>
<td>% with trauma director</td>
<td>100%</td>
<td>16%</td>
</tr>
<tr>
<td>Of those with a trauma team, % with Written protocol for activation</td>
<td>100%</td>
<td>77%</td>
</tr>
<tr>
<td>General/trauma surgeon req. at major resuscitations</td>
<td>100%</td>
<td>40%</td>
</tr>
<tr>
<td>Inclusion of neurosurgeon on team</td>
<td>33%</td>
<td>29%</td>
</tr>
<tr>
<td>Clinical staffing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>% with in-house call 24/7 for General surgery</td>
<td>89%</td>
<td>30%</td>
</tr>
<tr>
<td>Neurosurgery</td>
<td>44%</td>
<td>16%</td>
</tr>
<tr>
<td>Orthopedic surgery</td>
<td>44%</td>
<td>16%</td>
</tr>
<tr>
<td>% Available within 30 min</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac Sx</td>
<td>100%</td>
<td>64%</td>
</tr>
<tr>
<td>Hand Sx</td>
<td>100%</td>
<td>62%</td>
</tr>
<tr>
<td>Microvascular Sx</td>
<td>100%</td>
<td>28%</td>
</tr>
<tr>
<td>Neurosurgery</td>
<td>100%</td>
<td>86%</td>
</tr>
<tr>
<td>Orthopedic Sx</td>
<td>100%</td>
<td>90%</td>
</tr>
<tr>
<td>Plastic Sx</td>
<td>100%</td>
<td>74%</td>
</tr>
<tr>
<td>Thoracic Sx</td>
<td>100%</td>
<td>84%</td>
</tr>
<tr>
<td>Oval and Maxillofacial Surgery</td>
<td>100%</td>
<td>72%</td>
</tr>
<tr>
<td>Ophthalmology</td>
<td>100%</td>
<td>84%</td>
</tr>
<tr>
<td>Operating room (OR) resources</td>
<td></td>
<td></td>
</tr>
<tr>
<td>% OR available 24 h/d</td>
<td>100%</td>
<td>72%</td>
</tr>
<tr>
<td>% OR personnel in house 24 h/d</td>
<td>100%</td>
<td>42%</td>
</tr>
<tr>
<td>Av. number of ORs</td>
<td>19</td>
<td>12</td>
</tr>
<tr>
<td>% with dedicated trauma OR</td>
<td>83%</td>
<td>16%</td>
</tr>
<tr>
<td>% with cardiopulmonary bypass available</td>
<td>94%</td>
<td>64%</td>
</tr>
<tr>
<td>% with ICP monitoring equipment</td>
<td>94%</td>
<td>86%</td>
</tr>
<tr>
<td>ICU structure and resources</td>
<td></td>
<td></td>
</tr>
<tr>
<td>% intensivist model ICU*</td>
<td>83%</td>
<td>46%</td>
</tr>
<tr>
<td>Av. number of staffed ICU beds</td>
<td>18</td>
<td>19</td>
</tr>
<tr>
<td>% with full time physician director</td>
<td>68%</td>
<td>14%</td>
</tr>
<tr>
<td>% with separate neurosurgical ICU</td>
<td>37%</td>
<td>18%</td>
</tr>
<tr>
<td>% with surgical critical care fellowship</td>
<td>83%</td>
<td>0%</td>
</tr>
<tr>
<td>Quality improvement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>% maintain trauma registry</td>
<td>100%</td>
<td>18%</td>
</tr>
<tr>
<td>% audit all trauma deaths</td>
<td>100%</td>
<td>62%</td>
</tr>
<tr>
<td>% regular morbidity and mortality review of trauma deaths</td>
<td>100%</td>
<td>26%</td>
</tr>
<tr>
<td>% use audit filters for trauma</td>
<td>89%</td>
<td>20%</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>% offering ATLS course</td>
<td>94%</td>
<td>8%</td>
</tr>
<tr>
<td>% with residency in General surgery</td>
<td>100%</td>
<td>30%</td>
</tr>
<tr>
<td>Emergency medicine</td>
<td>89%</td>
<td>16%</td>
</tr>
<tr>
<td>Orthopaedics</td>
<td>94%</td>
<td>14%</td>
</tr>
<tr>
<td>Neurosurgery</td>
<td>83%</td>
<td>10%</td>
</tr>
<tr>
<td>Anesthesiology</td>
<td>83%</td>
<td>12%</td>
</tr>
<tr>
<td>% with fellowship program in Trauma surgery</td>
<td>67%</td>
<td>0%</td>
</tr>
<tr>
<td>Critical care</td>
<td>94%</td>
<td>4%</td>
</tr>
</tbody>
</table>

* An intensivist model is defined here as an ICU where critically ill trauma patients were either on a distinct ICU service (led by an intensivist) or were co-managed with an intensivist (physician board certified in critical care).9

ISS, Injury Severity Scale; ICU, Intensive Care Unit; ATLS, Advanced Trauma Life Support.
Although there were few differences between trauma centers and nontrauma centers in their physical environment, there were substantial differences in the availability and training of clinical staff, ICU structure, and commitment to trauma specific training and quality improvement activities.

When compared with the universe of Level I and non-trauma center hospitals located in MSAs, the NSCOT sample consists of larger hospitals that are more likely to be COTH members. In addition, one of the nontrauma centers was designated a Level II trauma center half way through the data collection period and one Level I trauma center temporarily lost its ACS/COT verification toward the end of data collection. For all analyses, these hospitals are categorized by their status at the beginning of the study.

Patient Population and Sample Selection

Eligible for inclusion in the NSCOT study were all trauma patients aged 18 to 84 years treated at one of the participating hospitals for a moderately severe to severe injury (as defined by at least one injury of an Abbreviated Injury Scale [AIS] score of 3 or greater). Excluded were patients who presented with no vital signs and died within 30 minutes of arrival at the hospital; patients who did not seek treatment at a hospital within 24 hours of the injury; patients 65 years older, with a first listed diagnosis of a hip fracture (ICD 820); major burns (≥20% total body surface area); patients who were either non-English or non-Spanish speaking; non-US residents; and individuals known to be incarcerated or homeless at the time of injury. Patients were recruited into the study during an 18-month period: July 1, 2001 to November 30, 2002.

The sample was selected and eligibility determined in two stages (Fig. 1). First, administrative discharge records and emergency department logs were prospectively reviewed by the nurse study coordinators to identify all patients aged 18 to 84 years who either died in the emergency department or were discharged alive or dead from the hospital with an ICD diagnosis of 800 to 959 (excluding first listed diagnoses of late effects, ICD 905–909; foreign bodies, ICD 930–939; complications, ICD 959; burns, ICD 940–949 and [among patients aged 65 or older] hip fracture, ICD 820). A computerized mapping of ICD discharge diagnoses to AIS severity scores was then applied to select only those patients with at least one discharge diagnosis corresponding to an ICD/AIS score of 3 or greater. A total of 18,198 patients across the 69 hospitals met these initial stage 1 screening criteria (Fig. 1).

In the second stage of the sampling process, we selected all 1,438 hospital deaths and a stratified random sample of 8,021 patients discharged alive. Medical records were obtained for 1,391 (97%) of the 1,438 hospital deaths. These deaths with complete medical record information were labeled as “enrolled” in the study. On the basis of a detailed medical record review of the enrolled deaths, 290 were further excluded because they failed to meet the final study inclusion/exclusion criteria, leaving 1,104 deaths that were enrolled and met stage 2 eligibility criteria.

Fig. 1. NSCOT sampling scheme. +Excluding ICD codes 905–909, 930–939, ICD 959, 940–949, and 820 (if age 65 and older). *Estimates of the proportion eligible (among those enrolled) were computed per sampling cell within hospitals and applied to the corresponding numbers of patients not enrolled or not selected.
In selecting the sample of 8,021 patients discharged alive, we stratified the 16,760 potentially eligible cases within hospitals to facilitate balance in baseline risk between trauma centers and nontrauma centers and to ensure sufficient numbers of patients by age, type and severity of injury. Accordingly, the sample was stratified by: (1) age: <65 and ≥65; (2) ICD derived ISS: ISS ≤15 and ISS >15; and (3) principal body region injured: head injury of ICD/AIS 3 or greater regardless of other injuries; no head injury of ICD/AIS 3 or greater but one or more extremity injuries of ICD/AIS 3 or greater; all others with at least one injury of ICD/AIS 3 or greater. A quota sampling strategy was used with the goal of enrolling approximately 3,000 and 1,300 patients aged 18 to 64 years and 65 to 84 years, respectively, evenly distributed across trauma centers and nontrauma centers and within cells defined by severity and principal body region injured.

The 8,021 live discharges selected in the first stage were contacted by mail and provided information about the study. Those who did not refuse by mail were contacted by phone at 3 months after injury at which time interviewers obtained consent for access to the medical record and interviews at 3 months and 12 months after injury. Of the 8,021 live discharges who met stage 1 screening criteria, 4,866 (61%) were enrolled (1,635 could not be located; 1,177 refused to participate; and 343 completed the 3-month interview but ultimately never provided permission to access their medical record). Of those enrolled, 779 were determined ineligible upon further review of their medical record, leaving 4,087 live discharges who were eligible and for whom complete medical record data were abstracted.

**DATA COLLECTION**

The principal sources of data for the study included the medical record for the index hospitalization, telephone interviews at 3 months and 12 months, the National Death Index, hospital bills for the index hospitalization and Medicare claims data for the elderly aged 65 years and over (for 6 months to 1 year before injury, and 1 year after injury). Figure 2 summarizes the follow-up status of the 4087 NSCOT patents who were eligible for the study, discharged alive, and enrolled in the study. A total of 151 died within 12 months. Of those who were alive at 12 months, 3,156 (82.2%) were successfully located and interviewed at 12 months.

Nurse coordinators trained specifically for the NSCOT study performed the screening for eligibility and subsequent record abstraction. Training consisted of an initial 3-day training followed by a 2-day refresher course midway through the 18-month patient enrollment period. The Association for the Advancement of Automotive Medicine certified all abstractors after completing its course in injury scoring. Data were abstracted using Collector registry software customized for the NSCOT study. Internal checks were built into the software to prevent data entry of values outside plausible ranges. Additionally, the coordinating center monitored the data collected and routinely returned records for re-abstraction based on a high frequency of missing or inconsistent data.

Interviews were conducted through a contract with Westat, who trained interviewers specifically for the NSCOT study. Interview by proxy was allowed if the study subject was unable to be interviewed because of his or her physical or...
mental health status. This determination was based on a report by a proxy that the patient could not do interview or by the patient’s inability to answer the questions, “What does being in the study entail” and “What can you do if you no longer want to participate in this study?” When a proxy interview was obtained, a legal proxy was identified through a series of questions and Westat, obtained written consent to abstract all medical and billing records. At 3 months, 11.3% of the interviews were completed by proxies (10.0% at 12 months). Proxy interviews were four times more likely among the elderly aged 65 years and older (26.2% vs. 6.5% at 3 months and 23.0% vs. 5.8% at 12 months).

Data collected for the NSCOT study can be categorized as those related to (1) the characteristics of the patient and his or her injuries; (2) patient reported outcomes at 3 months and 12 months after injury; (3) course of treatment in the initial acute care hospital; (4) use of health services after discharge from the acute care hospital (up to 1 year after injury); (5) charges and costs of treatment in the acute care hospital and up to 1 year after injury. The scope of data collection in each of these categories is further described below.

**Patient and Injury Characteristics**

Characteristics of the patient and injury were obtained from the medical record and the 3-month interview (for those alive at 3 months after injury). These data were used to adjust for differences in those treated at trauma centers and non-trauma centers. Patients were characterized by their sociodemographics (age, gender, race/ethnicity, education, marital status, living arrangements); economic resources (insurance status, income levels, poverty status); preinjury usual major activity and occupation (if working); pre-existing medical comorbidities; preinjury health habits (smoking and drinking alcohol), preinjury health and functional status (self-reported health status categorized as excellent, very good, good, fair or poor), limitations in activities of daily living (ADL), and instrumental ADL (IADL); and medications patients were taking at the time of their injury (as recorded in the medical record). Given the importance of pre-existing conditions in examining after injury outcomes (especially among the elderly), we collected this information in three ways. First, the nurse abstractors listed all pre-existing conditions recorded in the medical record. At 3 months, 11.3% of the interviews were completed by proxies (10.0% at 12 months). Proxy interviews were four times more likely among the elderly aged 65 years and older (26.2% vs. 6.5% at 3 months and 23.0% vs. 5.8% at 12 months).

**Outcomes**

Outcomes of principal interest include: death in the hospital; death within 30, 90, and 365 days after injury; functional outcomes; return to usual major activity and overall well being and quality of life. Deaths after discharge from the hospital were identified in two ways. First, as part of the routine follow-ups at 3 months and 12 months after injury, interviewers identified (from relevant proxies) patients who were discharged alive but subsequently died. For these patients, consent was obtained to abstract the medical record. To insure complete ascertainment of after discharge deaths among those lost to follow-up (especially among the elderly), these individuals were cross-linked to decedents in the Social Security Death Index.

Functional outcomes, return to usual major activity and overall well being and quality of life were obtained via telephone interviews at 3 months and 12 months (Table 3). After considerable debate, we decided to include a range of outcomes to include generic (e.g., the SF-36) and condition specific (e.g., the Musculoskeletal Function Assessment and the Glasgow Outcome Scale) assessments as well as both preference based (e.g., the Functional Capacity Index and the SF-6D) versus nonpreference based assessments. We also included specific questions regarding return to work and other usual major activity. Finally, given our interest in specific outcomes we included the Chronic Pain Grade Scale, the Center for Epidemiologic Scale for Depression, the cognitive subscale of the sickness impact profile and the posttraumatic stress disorder (PTSD) checklist. To minimize respondent
bias, we administered a more limited number of batteries to assess preinjury status and function at 3 months.

**Acute Treatment**

Details regarding course of acute treatment were obtained as part of the medical record review by the nurse coordinator. To the extent information was available in the medical record of the index hospital, patients were characterized by the level of emergency medical services (EMS) transport provided (advanced life support, basic life support, or no EMS transport); mode of transport; intubation status at the time of arrival at the index hospital; prehospital procedures performed and medications administered. Transfers from another acute hospital were noted and time from injury to the index and transferring hospital were obtained.

In describing the course of treatment in the index hospitalization the following assessments were obtained: emergency department discharge time and disposition; administration of blood products within the first 24 hours; results of initial and final ABG tests; time and location of all diagnostic and therapeutic procedures performed; time and location of all consults; complications; selected audit filters; total and ICU length of stay; total ventilator days; ICP and CPP measures during ICU stay; management of ICP (use of mannitol, barbiturate coma, induced hypertension; hyperventilation); receipt of social work and therapy (physical, occupational speech, chemical dependency); DNR order issued; therapy withdrawn; discharge disposition and destination; primary and secondary causes of death; and documentation of delayed discharge.

**Postacute Care**

Although an attempt was made to retrieve and abstract the medical records associated with all rehospitalizations, this proved to be too difficult and costly. For this reason, we relied on patient- and family-reported use of postacute care services, including the following: (1) number of hospitalizations and for each: name of facility, type of facility (acute care hospital; rehabilitation facility, nursing home or long-term care facility; subacute care facility); month of admission, length of stay, reason for admission and whether it was injury related; (2) number of visits to a physical therapist and/or occupational therapist; (3) number of visits to other health professionals (and how many visits were related to the injury); (4) receipt of home health services (number of weeks and number of times per week); and (5) receipt of informal care from family or friends (number of days and number of hours per day).

### Table 3 Patient Outcomes Collected in the NSCOT

<table>
<thead>
<tr>
<th>Timing of Assessment</th>
<th>Preinjury</th>
<th>3 mo</th>
<th>12 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Functional status and quality of life (reference)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self-reported health status (EVGFP)</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Activities of daily living (ADL)</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Instrumental activities of daily living (IADL)</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Modified Glasgow Outcome Scale (GOS)</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Mobility within and outside the home and neighborhood</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td><strong>SF-36</strong></td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SF-12</strong></td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SF-6D</strong></td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Functional Capacity Index (FCI)</strong></td>
<td></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td><strong>Usual major activity (UMA)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self-reported UMA</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Overall limitations in performing UMA</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Ability to return to UMA after injury</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If Working:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of hours working</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Industry and occupation</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Difficulty with amount and type of work</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Numbers of days missed because of illness or injury</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Work limitations questionnaire</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Domain specific measures</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Musculoskeletal functional assessment (MFA) subscores for mobility and hand/arm function</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sickness impact profile (SIP) subscore for cognitive function</td>
<td>x (subset)</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Chronic Pain Grade Scale (CPG)</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Center for epidemiologic studies depression scale-revised (CESD-R)</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Checklist for posttraumatic stress disorder (PTSD)</td>
<td></td>
<td>x</td>
<td></td>
</tr>
</tbody>
</table>
Charges and Costs

A more detailed description of the derivation of costs is forthcoming. One-year estimates have been derived for the following categories: prehospital care; acute hospital care (including professional fees); re-hospitalizations for acute care (including professional fees); inpatient rehabilitation; nursing home stays; outpatient services (rehabilitation and other); home health care; and informal care giving. Notably excluded from our estimates are costs related to prescription drugs and durable medical equipment.

For patients aged 65 years and older, Medicare claims data were used as the primary source of information to estimate costs for all categories except informal care and prolonged stays in skilled nursing facilities. For patients less than 65, index hospital costs were derived from UB92 hospital bills. For all other categories, costs were estimated by multiplying units of utilization (length of stay, number of visits) obtained from the patient interviews by per unit cost. Per unit costs were obtained from a variety of sources including, Medstat’s MarketScan commercial database,36 Medicare Cost Reports,37 American Hospital Association data and other sources. Inpatient charges were stepped down to costs by matching revenue center data from hospital bills with cost-to-charge ratios from the hospital’s Medicare Cost Report at the cost department level. Where Medicare claims were available, outpatient costs were estimated as allowed charges. The cost of informal care was estimated from Expectancy Data’s publication “Dollar Value of a Day”.38 All costs are expressed as constant 2005 dollars using appropriate price indices (e.g., Hospital PPI, Nursing Care Facility PPI, Professional Services Component of the CPI for Medical Care).

CHALLENGES IN THE IMPLEMENTATION OF THE NSCOT

The major challenges in implementing the NSCOT study were related to its national scope and the reliance on retrospective identification of patients eligible for inclusion in the study. The first challenge involved the recruitment of hospitals into the study. As indicated above, only 18 of the preselected trauma centers (67%) and 51 of the nontrauma centers (41%) agreed to participate in the study and were able to receive approval for the study from their IRBs. Principal reasons for nonparticipation were the lack of sufficient hospital staff to facilitate the study and the inability to obtain IRB approval. Although HIPAA had not yet been fully implemented when we began the study, hospitals were concerned about its implications. Therefore, some hospitals were unwilling to provide the requisite personal identifiers needed to contact patients after they had left the hospital. Such a design now requires a formal partial waiver of authorization based on the argument that (1) the study is of minimal risk to the study patients and (2) any other mechanism for identifying and contacting potential subjects using clinical staff or obtaining prior authorization from the patient would be impracticable. In addition, some hospitals required that we obtain written permission from patients to access their medical records (as opposed to relying on telephone consent). As a consequence, we interviewed 343 study participants (or their proxies) at 3 months who either refused to provide consent to access their medical record or never returned the written consent form (even after multiple follow-up calls and letters).

Clearly, a prospective design would obviate the need for a HIPAA waiver and would have the added advantage of establishing a personal contact with the patients and their families that would facilitate follow-up (see below). Prospectively identifying patients in 69 hospitals around the country would have been prohibitively expensive, however.

Hearing secured the participation of the hospitals, we then faced the challenge of screening and enrolling patients. Again, because of the limitation imposed by retrospective identification of patients, we had to screen for eligibility in two stages – before and after obtaining access to the medical records. Only after we obtained permission to access the medical record were we able to apply the final criteria for inclusion in the study. This design led to some inefficiencies (i.e., we enrolled 779 individuals who were subsequently judged ineligible based on more complete data) and necessitated a complicated weighting procedure as described below.

Successful tracking of trauma patients has been noted as a formidable challenge in many follow-up studies, both prospective and retrospective. We were particularly challenged in this study as the only information available to us was that recorded in the discharge abstract. Because we were first contacting patients 75 days to 100 days after injury, the addresses and phone numbers provided in the discharge abstract were often out of date. We followed standard procedures for tracking patients, but in the end were only able to locate and interview 64.9% of the patients we selected in the first stage of screening. (14.7% refused and 20.4% could not be located). Limited discharge abstract data indicate that when compared with patients enrolled, patients who were not enrolled were slightly older (mean age, 49.8 vs. 48.8) but with injuries of similar severity. Of those enrolled at 3 months, we successfully followed and interviewed 82.2% at 1 year. As has been reported in other trauma studies, complete 1-year follow-up was higher among female patients than male patients (85.3% vs. 80.7%), older versus younger participants (87.6% for ages 65 and older vs. 80.7% for those less than 65), among those with greater financial resources (86.2% among those who are not poor vs. 73.9% among those who are at or below the poverty line), among white, non-Hispanic participants (86.1% for white, non-Hispanics, 75.8% for non-white, non-Hispanics and 74.4% for Hispanics) and among those with and without some college education (86.7% vs. 79.4%).

Again, prospective enrollment of patients would enable one to establish rapport with the patients in the hospital before discharge and obtain better information on their likely residence in 3 months as well as their email addresses, and cell phone numbers that often remain unchanged. In other prospec-
tive follow-up studies of trauma patients, follow-up rates at 3 months and 6 months after injury have been reported as high as 75% to 90%.\(^{39-42}\) Clearly, engaging a survey research firm that is staffed and equipped to handle large surveys and has interviewers available around the clock is critical to the success of a large national study like the NSCOT.

**CHALLENGES IN THE ANALYSIS OF NSCOT DATA**

As with any observational study of this magnitude, the analysis of the NSCOT data posed several challenges. Below we describe four challenges, in particular, which are often common to any large, observational clinical outcomes study.

**Weighting the Data Back to the Population**

For two reasons it was necessary to weight the 5,191 eligible study participants with complete medical record data (1,104 hospital deaths and 4,087 live discharges) back to the population of all eligible patients. First, the sampling protocol selected all patients who died in the hospital but only a sample of patients who were discharged alive. Second, not all patients selected for potential inclusion in the study were enrolled. To weight the study sample to the population of eligible patients, it was necessary to project the following: (1) the number of patients eligible among those selected but not enrolled (i.e., 47 hospital deaths and 3,155 live discharges); and (2) the number of live discharges eligible among those not selected (i.e., 8,739 live discharges). To project these numbers, estimates of the proportion eligible (among those enrolled) were computed per sampling cell within hospitals and applied to the corresponding numbers of patients not enrolled or not selected. Thus, the population to which inferences are being made for the NSCOT study consists of 15,444 patients (1,135 hospital deaths and 14,309 live discharges) who met or were projected to meet the inclusion and exclusion criteria for the study (Fig. 1). Of these, 7,881 were selected for inclusion in the study sample and of these; complete data necessary for the analysis of death outcomes were available for 5,191 (65.9%). All analyses were performed using data weighted to the population of 15,444 eligible patients. The weights consist of the reciprocal product of two probabilities: the probability of being selected for the study and the probability of being enrolled and having complete data (i.e., medical record abstract), given that the patient was selected.

**Missing Data**

As in all studies of the magnitude of NSCOT, there are data missing because of many different reasons, including lack of documentation in the medical record, data entry errors, and survey nonresponse. Common practices for dealing with missing data include (1) list wise deletion of all cases with any missing data; (2) substitution of missing values with a mean value; and (3) substitution of missing values with an estimate based on single imputation techniques. List wise deletion can reduce the power available for the analysis, but more importantly can introduce nonresponse bias if study participants with missing data are fundamentally different from those with complete data. Substitution with either a mean value or single imputation does not take into account the uncertainty of the estimates being derived. Multiple imputation techniques, on the other hand, create plausible imputations of missing values and inflate the SE to account for uncertainty. In applying multiple imputation techniques, we assume that the reasons for the missing of data were related to certain observed, but not unobserved, covariates.

It should be emphasized that we were selective in choosing when to apply these multiple imputation techniques. No missing data on patient outcomes or hospital treatment were imputed. Additional criteria that were applied in selecting variables eligible for imputations included (1) the variable must be important in determining outcome, (2) there must be good prognostic factors available for imputation; and (3) no more than 30% of the values in any given variable could be missing. In general, the percent missing for any one covariate was less than five except for prehospital intubation (7% missing), first ED GCS motor score (13%), and prehospital GCS motor score (30%). Finally, all imputation results were reviewed and subjected to diagnostic checks.

We imputed data using the IVEware software developed by Raghunathan et al.\(^{43}\) and available for free download at http://www.isr.umich.edu/src/smp/ive/. IVEware has the advantage that it is fairly easy to use and has a great deal of flexibility in restricting the range of values that imputed variables could have. Further, IVEware had fewer convergence problems in fitting models than other similar imputation software. Ten imputed datasets were created. For each dataset, robust standard errors for the trauma care effect were computed to account for clustering within centers. Across datasets, estimates and standard errors were computed using Rubin’s combining rules.\(^{44}\)

**Adjusting for Referral Bias**

Previous studies of trauma center effectiveness have been inconclusive and hampered by limitations in study design and reliance on hospital patient fatality. Most problematic has been the difficulty in adequately adjusting for referral bias. When compared with patients treated in trauma centers, those treated in nontrauma centers are older, more likely to be female patients, white, non-Hispanic, and insured (Table 4). Because they are older, nontrauma center patients also have more comorbidities. Their injuries, on the other hand, tend to be less severe as measured by AIS severity, GCS motor score and first ED pupils or shock (Table 5). The present study addressed this issue by (1) stratifying the sample of patients by type and severity of injury and by age; (2) collecting detailed information on important covariates; and (3) using the
inverse probability of treatment weighing approach of Robins et al.45

In the inverse probability of treatment weighting approach, each subject is further weighted by the reciprocal of the conditional probability of receiving trauma center care given demographic and injury characteristics (i.e., a propensity score). These “adjustment” weights serve to create an “adjusted population”, which has two important characteristics: (1) the receipt of trauma center care is not confounded by the covariates and (2) the effect of trauma center care is the same in the adjusted population as it is in the original reference population. This methodology hinges on the correct specification of a model for the propensity score. To check the adequacy of this model, we evaluated the balance on covariates in the adjusted population.46 We also trimmed the adjustment weights to reduce the impact of influential obser-

Table 4 Distribution of Selected Patient Characteristics by Place of Treatment (weighted to the population of eligible patients): All Patients and Survivors at 12 mo

<table>
<thead>
<tr>
<th>Patient Characteristic (references)</th>
<th>All Patients</th>
<th>Survivors at 12 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Nontrauma Center (n = 4,172) (%)</td>
<td>Trauma Center (n = 11,272) (%)</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;55</td>
<td>51</td>
<td>78</td>
</tr>
<tr>
<td>55–64</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>65–74</td>
<td>11</td>
<td>7</td>
</tr>
<tr>
<td>75–84</td>
<td>21</td>
<td>5</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>57</td>
<td>72</td>
</tr>
<tr>
<td><strong>Race/ethnicity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White, non-Hispanic</td>
<td>72</td>
<td>57</td>
</tr>
<tr>
<td>Non-white, non-Hispanic</td>
<td>16</td>
<td>25</td>
</tr>
<tr>
<td>Hispanic</td>
<td>13</td>
<td>18</td>
</tr>
<tr>
<td><strong>Educational status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than high school</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>High school or GED</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Some college</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td><strong>Health insurance preinjury</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicare only</td>
<td>12</td>
<td>6</td>
</tr>
<tr>
<td>Medicare plus private</td>
<td>24</td>
<td>9</td>
</tr>
<tr>
<td>Private</td>
<td>36</td>
<td>39</td>
</tr>
<tr>
<td>Medicaid</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td>Other</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>None</td>
<td>16</td>
<td>32</td>
</tr>
<tr>
<td><strong>Poverty status (ref)</strong></td>
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<td></td>
</tr>
<tr>
<td>Poor</td>
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</tr>
<tr>
<td>Near poor</td>
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</tr>
<tr>
<td>Not poor</td>
<td>NA</td>
<td>NA</td>
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<tr>
<td><strong>Usual major activity preinjury</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Working</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Laid off or looking for work</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Going to school</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Managing a household</td>
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<td>NA</td>
</tr>
<tr>
<td>Retired</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Other</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td><strong>Number of comorbidities</strong></td>
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<td></td>
</tr>
<tr>
<td>0</td>
<td>45</td>
<td>65</td>
</tr>
<tr>
<td>1</td>
<td>21</td>
<td>21</td>
</tr>
<tr>
<td>2</td>
<td>14</td>
<td>9</td>
</tr>
<tr>
<td>3 or more</td>
<td>21</td>
<td>5</td>
</tr>
<tr>
<td><strong>Limitations in activities of daily living preinjury</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td><strong>Limitations in instrumental activities of daily living preinjury</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td><strong>Self-reported health status preinjury</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Excellent or very good</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Good</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Fair or poor</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

NA = Not applicable since data are not available for those who died within 3 mo of injury.
vations on the overall results. The degree of trimming was chosen to minimize mean squared error.47

Taking Account of the Competing Risk of Death in Measuring 1-Year Functional Outcomes

When investigating the effect of trauma center care on functional outcomes, it is important to take into account the competing risk of death. Examining the effect only among those who are observed to survive could lead to biased results. Such bias could occur if trauma centers were to save lives of patients with poor functional outcomes who would otherwise die in a nontrauma center. One might then observe that nontrauma centers have better functional outcomes, driven by their higher mortality.

To account for this potential bias, we estimate the survivors’ average causal effect (SACE),48–52 defined in terms of “potential outcomes”. For each individual, two mortality indicators at 1 year are defined, one as if she or he had received trauma center care and one as if she or he had received nontrauma center care, irrespective of the true care received. Only the mortality outcome for the care received is observed. If an individual is to survive to 1 year under trauma center (nontrauma center) care, the functional outcome at 1 year as if she or he had received trauma center (nontrauma center) care is also defined (the functional outcome for someone who would die is not well defined). If an individual is observed to survive, the functional outcome for care actually received is observable. In our context, SACE is defined for the (unknown) cohort of individuals who would survive to 1 year regardless of the care received. For this group, both potential functional outcomes are well defined (albeit, never jointly observable) and SACE is defined as the mean difference in the potential functional outcomes. By focusing our inference on this cohort, we account for the problematic individuals who would live if provided trauma center care and die if provided nontrauma center care.

Estimation of SACE requires the specification of two regression models. First, logistic regression is used to model survival status as a function of: trauma center status, characteristic...
teristics of the patients and their injuries known to impact mortality, and interactions between trauma center status and these characteristics. Second, for 1-year survivors, regression (linear for continuous outcomes, logistic for binary outcomes) is used to model functional outcomes (e.g., SF-36 subscores, the presence of depressive symptoms) as a function of the above terms together with measures of education, poverty status, preinjury ADL and IADL limitations, self reported health status and other variables hypothesized to influence functional status at 1 year.

As might be the case in other follow-up studies like NSCOT, we did not have information on preinjury function for the large proportion of the deaths that occurred in the hospital or before the baseline interview at 3 months after injury. This was of concern as preinjury functional status (over and above the presence of multiple pre-existing conditions) may impact probability of survival and 1-year functional outcomes. We initially assumed that preinjury function (as measured by limitations in ADL) was not related to mortality after adjusting for severity, co morbidities, and sociodemographics. We did, however, perform a sensitivity analysis to investigate the robustness of our findings to this assumption and found no change in results even under extreme scenarios.

SUMMARY AND DIRECTIONS FOR FUTURE RESEARCH

As with any study, limitations in the available resources will dictate the size and the scope of the study, and thus the generalizability of its findings. For sake of efficiency of the design, we only included nontrauma centers that treated at least 25 major trauma patients each year. Most nontrauma centers, on the other hand, are smaller where quality of trauma care may be lower. In addition, 17 of the study nontrauma centers had a designated trauma team and eight had a trauma director. Both of these factors may have biased the results toward a more conservative estimate of the treatment effect.

It is also important to emphasize that NSCOT is a study of trauma center effectiveness in urban-suburban America. The results cannot be readily extrapolated to rural areas of the country. In addition, the NSCOT study does not address the relative effectiveness of intermediate levels of trauma center care, specifically Level II and Level III trauma centers. Although resources available at Levels I and Level II trauma centers are comparable in most states, centers categorized at a Level III are typically designed to provide initial evaluation and assessment of injured patients with transfer of the more severely injured to a higher level of care. They have traditionally played a critical role in more rural areas where there are no Level I or Level II centers immediately accessible. Since the early 1990s, however, the numbers of Level III, IV, and V centers have proliferated in both urban as well as rural areas of the country in an attempt to develop more inclusive systems of care. Further work is needed to assess the relative effectiveness of care provided at these different levels of trauma center care.

Finally, the study does not address important issues regarding treatment of pediatric trauma patients.

Further studies similar to the NSCOT are needed to better address these and other critical gaps in our understanding of the value of trauma center care. In moving forward with such studies, there are lessons to be learned from the design and conduct of the NSCOT study. First and foremost, the use of a prospective design would have greatly facilitated the recruitment, enrollment and follow-up of patients. It would also have provided an opportunity to collect more detailed information on potential risk and protective factors related to recovery, such as baseline assessments of depressive symptoms, anxiety, PTSD, self efficacy and social support.

The study could have benefited from additional sources of data. Resources were not sufficient to obtain prehospital records and records from the transferring hospital. Instead, we relied solely on the information that was available in the record maintained by the index hospital. Similarly, except for the subset of elderly who were Medicare eligible, we were unable to retrieve data on rehospitalizations to better document the reason for these rehospitalizations and more adequately identify injury related complications. Death certificate and autopsy data would have provided an important source of data on the cause of death, especially among those who died up to 1 year after the injury. Finally, data more specific to the type and extent of rehabilitation received would have been helpful in explaining variations in 1-year outcomes.

Although very detailed information about the nature and severity of the injury was abstracted form the medical record, we could have benefited from additional physiologic data such as serial GCS scores. It is now feasible in most hospitals to obtain copies of all X-rays on CD-ROM. This information would have been invaluable in assessing the extent of brain injury and the severity of fractures. In future studies, every attempt should be made to obtain these data and have X-rays read by a centralized reading center.

The NSCOT benefited from multiple assessments of patient outcomes from all injuries except possibly those involving moderate to severe brain damage. The study would have benefited from face to face neuropsychological testing of at least a subsample of patients to assist in the interpretation of the patient (or proxy) reported outcomes.

Despite the limitations of the NSCOT, its success demonstrates the feasibility of conducting a national study where costs and effectiveness are examined.

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Traumatic Injury and Children: A National Assessment

Karen S. Guice, MD, MPP, Laura D. Cassidy, MS, PhD, and Keith T. Oldham, MD

Before beginning a study of trauma care for children, it is necessary to understand contemporary injury patterns of children, specifically the volume and types of injury, injury severity, and institutions where children are hospitalized for trauma. This article was designed to address these issues using the Healthcare Cost and Utilization Project (HCUP) Kids’ Inpatient Database (KID) 2003 that contains over 7 million discharge records from hospitalized children in the United States. Our classification of hospitals into pediatric experience and trauma experience are a first step in better defining what hospital characteristics are important to the optimal care of an injured child. In an era of limited resources, we would like to assure that the right child received the right treatment at the right place.

Key Words: Trauma, Children.

J Trauma. 2007;63:S68–S80.

In January 2006, the investigators of the National Study on Costs and Outcomes of Trauma (NSCOT) evaluating the effect of trauma center care published their findings on mortality. Their results showed a significantly lower risk of death for injured patients receiving care at designated trauma center hospitals compared with hospitals without trauma center designation. Based on these findings, the authors argue that further regionalization of trauma care, including trauma center designation, is needed.

Injury is a significant problem for America’s children. Unintentional injury is the leading cause of death for individuals 1 to 17 years of age, accounting for 7,469 deaths in 2003. In fact, more children in this age range die from their injuries than the total number of children dying from the next nine leading causes. Of the estimated 39.9 million injury-related emergency department visits made in 2001, approximately 6.6 million were individuals under the age of 18 years. In 2000, the direct medical costs associated with injury regardless of age were estimated at $117 billion or 10% of all medical expenditures. The lifetime costs of injury (those that are accrued from the onset of injury until death or resolution) that occur in a single year in the United States are estimated at $406 billion, and include medical costs and productivity losses.

The NSCOT study’s results call for a similar study of trauma-related injury in children. However, before beginning such an endeavor, it is necessary to understand contemporary injury patterns of children, specifically the volume and types of injury, injury severity, and institutions where children are hospitalized for trauma. This study was designed to address these issues using a database that contains over 7 million discharge records from hospitalized children in the United States.

METHODS

Data from the Agency for Healthcare Research and Quality (AHRQ) sponsored Healthcare Cost and Utilization Project (HCUP) Kids’ Inpatient Database (KID) 2003 was used for analysis. Records in the KID are a sample of pediatric (age 20 years or less) discharges from community nonrehabilitation hospitals in 36 states that have agreed to participate in the HCUP data collection effort. Weights are provided to obtain national estimates.

To create an analysis file that provides national estimates of trauma-related hospitalizations for children in the United States, we included only those KID discharges with trauma ICD9-CM codes of 800–959 in the primary discharge diagnosis field. Discharges were specifically excluded if the record contained (1) a primary diagnosis (first diagnosis field) of ICD9-CM codes of 905.00–909.99 (injury late effects), 910.00–924.00 (superficial injury), or 930.00–939.99 (foreign bodies); (2) missing ages or where the age was ≥18 years of age; (3) missing injury severity scores (ISS) values or where the ISS could not be calculated; (4) a maternal or neonatal diagnosis or procedure code; or (5) discharge to another short term hospital. Each record was coded for ISS scores of 0 or 99 if there are no valid codes on the record and ISS = 99 if there are no valid codes with both a
known severity and a known ISS body region. Records with 
valid codes and a severity of 6 are coded as ISS = 75.

AHRQ provides a collection of tools and software for 
research using the HCUP databases. One of these is the 
Clinical Classifications Software (CCS) which groups similar 
ICD9-CM codes into categories for diagnoses and proce-
dures. We used the CCS system to group diagnoses for our 
analyses and reporting, and the Comorbidity Software tool to 
identify and create comorbidity variables. We also used the 
programming provided by the National Center for Health 
Statistics to create a Barell Injury Diagnosis Matrix.7 Addi-
tionally, we grouped ICD9-CM E-codes into the National 
Center for Injury Prevention and Control’s recommended 
framework for presenting injury morbidity data.8

Where possible, results are expressed as rates, calculated 
using the number of specific trauma events as the numerator 
and the corresponding US Census estimate of population for 
the matching age. Trauma-related injury rates for age and sex 
were calculated using weighted frequencies and age matched 
population data from the National Center for Health 
Statistics.9 Generally, the weighted relative frequency of trau-
ma-related injury is presented. SAS 9.1 was used for survey 
subpopulation analyses.10 Results are presented as weighted 
frequencies with standard deviations; means and percentages 
are presented with standard errors. Because the data are 
public use and do not contain identifiers, they were exempt 
for IRB review.

RESULTS

Using the methods and resources described above, 
146,358 weighted discharge records met our inclusion/exclu-
sion criteria. This is 2.25% of the total number of discharges 
under the age of 18 contained in the KID 2003.

Demographic Characteristics of Children Hospitalized 
for Trauma

The average age for all the discharges was 9.75 ± 0.08 
years. The injury rate for men was higher than that for women 
for every year of age (this rate is represented by the narrow 
bars in Fig. 1). Peaks rates of injury are seen at 2, 7, 12, and 
16 years of age, and were similar for men and women. For 
subsequent comparisons, ages were grouped into five age 
ranges (<1, 1–4, 5–9, 10–14, and 15–17 years of age) as 
recommended by a National Institute of Child Health and 
Human Development conference11 (Table 1; age group re-
lated rates are represented by the broad bars in Fig. 1). Race 
information was missing in over 25% of the KID 2003 dis-
charge records and was not analyzed.

Over 57% of discharges was associated with private 
insurance as the primary payer (less than 1% of discharges 
had missing data for this variable) (Table 1). We stratified 
insurance coverage by the five age groups to identify insur-
ance coverage trends (Table 2). The proportion of Medicaid 
as the primary payer was highest for discharges in the <1 and 
1 to 4 years of age groups and decreased for each subsequent 
age group. Conversely, private health insurance coverage was 
lowest in the younger age groups and increased with age. The 
proportion of self-pay also increased with age.

Based on the KID coding convention for primary payer, 
we assumed that discharges where the primary payer was 
“self-pay” or “no charge” were equivalent to discharges with-
out insurance coverage. Government programs (Medicare,

![Fig. 1. Rate of injury by sex and age.](image-url)
### Table 1 Trauma-Related Discharges

<table>
<thead>
<tr>
<th>Parameter Evaluated</th>
<th>Weighted Frequency ± SD Percent of Total Weighted Discharges ± SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td></td>
</tr>
<tr>
<td>&lt;1</td>
<td>6985 ± 356</td>
</tr>
<tr>
<td>1–4</td>
<td>4.70% ± 0.15%</td>
</tr>
<tr>
<td>5–9</td>
<td>25590 ± 1268</td>
</tr>
<tr>
<td>10–14</td>
<td>17.20% ± 0.39%</td>
</tr>
<tr>
<td>15–17</td>
<td>32088 ± 1358</td>
</tr>
<tr>
<td>21.57% ± 0.34%</td>
<td></td>
</tr>
<tr>
<td>27.39% ± 0.27%</td>
<td></td>
</tr>
<tr>
<td>Health insurance</td>
<td></td>
</tr>
<tr>
<td>Private</td>
<td>84,095 ± 2,819</td>
</tr>
<tr>
<td>Medicaid</td>
<td>57.46% ± 0.88%</td>
</tr>
<tr>
<td>Medicare</td>
<td>45,293 ± 2,246</td>
</tr>
<tr>
<td>30.95% ± 0.79%</td>
<td></td>
</tr>
<tr>
<td>Medicare</td>
<td>129 ± 30</td>
</tr>
<tr>
<td>Self-Pay</td>
<td>9,165 ± 604</td>
</tr>
<tr>
<td>No Charge</td>
<td>6.26% ± 0.36%</td>
</tr>
<tr>
<td>Other</td>
<td>6,951 ± 537</td>
</tr>
<tr>
<td>Source of admission</td>
<td></td>
</tr>
<tr>
<td>ZIP income quartile</td>
<td></td>
</tr>
<tr>
<td>$1–$35,999</td>
<td>39,340 ± 1,880</td>
</tr>
<tr>
<td>$36,000–$44,999</td>
<td>26.87% ± 0.83%</td>
</tr>
<tr>
<td>$45,000–$59,999</td>
<td>36,698 ± 1,430</td>
</tr>
<tr>
<td>$60,000+</td>
<td>25.07% ± 0.50%</td>
</tr>
<tr>
<td>Other</td>
<td>34,872 ± 1,365</td>
</tr>
<tr>
<td>Rural or urban location of hospital</td>
<td></td>
</tr>
<tr>
<td>Rural</td>
<td>28.33% ± 0.46%</td>
</tr>
<tr>
<td>Urban</td>
<td>31,898 ± 1,601</td>
</tr>
<tr>
<td>Rural</td>
<td>21.79% ± 0.81%</td>
</tr>
<tr>
<td>Rural</td>
<td>12,838 ± 574</td>
</tr>
<tr>
<td>Urban</td>
<td>8.77% ± 0.47%</td>
</tr>
<tr>
<td>Teaching status of hospital</td>
<td></td>
</tr>
<tr>
<td>Teaching</td>
<td>36,698 ± 1,430</td>
</tr>
<tr>
<td>Not teaching</td>
<td>129,696 ± 4,911</td>
</tr>
<tr>
<td>Comorbidity present—identifies record</td>
<td></td>
</tr>
<tr>
<td>Injury Severity Score</td>
<td></td>
</tr>
<tr>
<td>≤1</td>
<td>125,015 ± 4,188</td>
</tr>
<tr>
<td>16–24</td>
<td>85.42% ± 0.39%</td>
</tr>
<tr>
<td>25–34</td>
<td>15,521 ± 765</td>
</tr>
<tr>
<td>&gt;34</td>
<td>10.61% ± 0.28%</td>
</tr>
<tr>
<td>3.14% ± 0.12%</td>
<td></td>
</tr>
<tr>
<td>1.231 ± 87</td>
<td></td>
</tr>
<tr>
<td>0.84% ± 0.05%</td>
<td></td>
</tr>
</tbody>
</table>

Excludes the ICD9-CM codes relevant to foreign bodies, late effects of injury, and foreign bodies, either occurring singly or in combination.

### Table 1 (continued)

<table>
<thead>
<tr>
<th>Parameter Evaluated</th>
<th>Weighted Frequency ± SD Percent of Total Weighted Discharges ± SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximal AIS score, overall</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>23,953 ± 1,120</td>
</tr>
<tr>
<td>2</td>
<td>16.37% ± 0.46%</td>
</tr>
<tr>
<td>3</td>
<td>77,446 ± 2,587</td>
</tr>
<tr>
<td>4</td>
<td>52.92% ± 0.56%</td>
</tr>
<tr>
<td>5</td>
<td>26,544 ± 971</td>
</tr>
<tr>
<td>6</td>
<td>18.14% ± 0.23%</td>
</tr>
<tr>
<td>Type of admission</td>
<td></td>
</tr>
<tr>
<td>Emergency</td>
<td>92,028 ± 4,167</td>
</tr>
<tr>
<td>Urgent</td>
<td>62.88% ± 1.89%</td>
</tr>
<tr>
<td>Elective</td>
<td>18,581 ± 1,249</td>
</tr>
<tr>
<td>Trauma center</td>
<td>10,715 ± 1,632</td>
</tr>
<tr>
<td>Other</td>
<td>7.32% ± 1.07%</td>
</tr>
<tr>
<td>Missing</td>
<td>1,593 ± 482</td>
</tr>
<tr>
<td>Source of admission</td>
<td></td>
</tr>
<tr>
<td>Emergency department</td>
<td>1,162 ± 4,327</td>
</tr>
<tr>
<td>Another hospital</td>
<td>76.27% ± 1.01%</td>
</tr>
<tr>
<td>Other health facility</td>
<td>8,705 ± 907</td>
</tr>
<tr>
<td>Court/law enforcement</td>
<td>5.95% ± 0.57%</td>
</tr>
<tr>
<td>Routine and other</td>
<td>1,571 ± 241</td>
</tr>
<tr>
<td>Missing</td>
<td>1,07% ± 0.16%</td>
</tr>
<tr>
<td>Routine dispositions</td>
<td>74 ± 17</td>
</tr>
<tr>
<td>Discharge destination</td>
<td>48 ± 17</td>
</tr>
<tr>
<td>Discharge alive; unknown destination</td>
<td>0.03% ± 0.01%</td>
</tr>
<tr>
<td>Missing</td>
<td>22,947 ± 1,093</td>
</tr>
<tr>
<td>1.56% ± 0.71%</td>
<td></td>
</tr>
<tr>
<td>1.29% ± 427</td>
<td></td>
</tr>
<tr>
<td>0.89% ± 0.29%</td>
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</tr>
</tbody>
</table>

The Journal of TRAUMA® Injury, Infection, and Critical Care
Medicaid and other) provided health insurance for 35.78% ± 0.83% of discharges and 6.46% ± 0.36% were uninsured.

Median household income quartiles by the patient’s ZIP code are provided in KID 2003 and allow an estimate of the socioeconomic environment. Close to 27% of the total number of discharges were associated with the lower income quartile and almost 22% were associated with the upper income quartile (Table 1). We also compared discharges by quartiles to the primary payer. The percentage of discharges from households with private insurance increased as median household income increased, with a higher percentage of discharges from households covered by Medicaid in the lower income quartile. For reference, the 2003 median household income for the United States was $43,318 (90% CI 43,009 to 43,627).12

To identify the presence of a comorbidity code on the trauma-related discharge records, we used the Elixhauser coding convention for administrative data.13 Almost 13% of the total number of trauma-related discharges had at least one comorbidity code identified (Table 1). The most common comorbidity diagnosis groups were chronic pulmonary disease (4.46%), fluid and electrolyte disorders (2.08%), substance abuse (1.76%), and deficiency anemia (1.32%). Because these were present on the discharge data, it is unknown whether these were preinjury comorbidities or were other diagnoses that occurred during the trauma-related hospitalization. For trauma-related discharges without any comorbidity, less than 1% died (Table 1). For discharges with at least one comorbidity code listed, the proportion dying during their hospitalization increased to over 3%.

Injury Characteristics

In our first assessment of the trauma-related injuries in our study population, we used E-codes to assign mechanism of injury by intentionality, using the first of four possible E-code variables listed. Most trauma-related injuries are unintentional, with falls as the most frequent mechanism (Table 3). Despite our ICD9-CM inclusion code criteria, several records listed adverse effects, late effects and poisoning as the primary E-code on the record. Over 7% of the weighted discharge records in our study did not have any E-code listed.

We grouped CCS trauma-related injury categories by age group to identify diagnosis trends according to age (Fig. 2). Burns were more common in the 1 to 4 years of age group, whereas fractures of the upper limb were more common in the 5 to 9 years of age group. Lower limb fractures were high in both the 10 to 14 and the 15 to 17 year old age groups. Intracranial injury increased with age and, therefore, was highest in the 15 to 17 year old group, as was the category of crushing injury or internal injury.

To evaluate the nature of injury by body region, we used the Barell Matrix (Table 4).14 Fractures of various body regions are the most common injury (58%), with extremities as the most frequent body region represented. The next most common is internal injury (20.95%), with traumatic brain injury and torso injuries as the highest body regions represented.

The distribution of ISS was highly skewed toward the lower values of the scale, with a median and mode of 4. We initially grouped discharges into 4 ISS subgroups: <15, 16 to 24, 25 to 34, and ≥35 (Table 1). Over 85% of the total had ISS scores below 15. Furthermore, trauma-related discharges with ISS scores <15 represent a high proportion of discharges in every age group (Fig. 3). When we compared ISS scores with the CCS diagnosis categories, higher proportions of the total number of trauma-related injuries with ISS scores ≥16 were in the categories of intracranial injury and crushing or internal injury.

A single traumatic injury with AIS score <4 will result in a low overall ISS score. To evaluate the impact of single injuries on our data, we divided discharges into two groups: those with only one trauma diagnosis code listed (approximately 54%), and those with more than one listed (approximately 46%). For discharges with only one trauma ICD9-CM diagnosis code, over 90% had an ISS score <15 and 9% were between 16 and 24. Almost 80% of discharges with more than one ICD9-CM trauma code present had ISS scores <15 with approximately 12% having an ISS between 16 and 24 and 8% had scores greater than 24. We then evaluated the AIS scores for each body region in records with a single trauma ICD9-CM code (Fig. 4). Upper and lower extremity fractures occur with the greatest frequency among single body region injuries and most of the corresponding AIS scores are 3 or less. Isolated head injuries occur in 10% of all discharge records containing a single trauma code, and most of these have an AIS score of 4. Isolated abdominal injuries

| Table 2 Primary Health Insurance Coverage for Trauma-Related Discharges |

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Medicare (%)</th>
<th>Medicaid (%)</th>
<th>Private Insurance (%)</th>
<th>Self-pay (%)</th>
<th>No Charge (%)</th>
<th>Other (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1</td>
<td>0.21 ± 0.07</td>
<td>54.33 ± 1.36</td>
<td>37.60 ± 1.39</td>
<td>3.36 ± 0.39</td>
<td>0.10 ± 0.08</td>
<td>4.23 ± 0.63</td>
</tr>
<tr>
<td>1–4</td>
<td>0.12 ± 0.05</td>
<td>44.08 ± 1.14</td>
<td>45.98 ± 1.16</td>
<td>5.59 ± 0.44</td>
<td>0.22 ± 0.05</td>
<td>3.82 ± 0.48</td>
</tr>
<tr>
<td>5–9</td>
<td>0.06 ± 0.02</td>
<td>32.15 ± 1.06</td>
<td>56.60 ± 1.08</td>
<td>6.28 ± 0.43</td>
<td>0.16 ± 0.04</td>
<td>4.55 ± 0.42</td>
</tr>
<tr>
<td>10–14</td>
<td>0.10 ± 0.03</td>
<td>26.45 ± 0.74</td>
<td>62.12 ± 0.89</td>
<td>6.13 ± 0.42</td>
<td>0.18 ± 0.04</td>
<td>4.72 ± 0.38</td>
</tr>
<tr>
<td>15–17</td>
<td>0.06 ± 0.02</td>
<td>22.71 ± 0.67</td>
<td>63.74 ± 0.90</td>
<td>7.24 ± 0.37</td>
<td>0.25 ± 0.05</td>
<td>5.56 ± 0.31</td>
</tr>
</tbody>
</table>

The percent and SE are for each row. Data across the rows may not sum to 100% due to exclusion of those records where the primary payer was missing information or where the value was recorded as invalid.
Table 3 Trauma-Related Mechanism of Injury by Intentionality

<table>
<thead>
<tr>
<th>Adverse effects</th>
<th>Unintentional</th>
<th>Self-Inflicted (Suicide)</th>
<th>Assault (Homicide)</th>
<th>Undetermined</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse effects</td>
<td>501.94 ± 45.34</td>
<td>0.34% ± 0.03%</td>
<td></td>
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</tr>
<tr>
<td>Cut/pierce</td>
<td>2891.00 ± 126.22</td>
<td>183.00 ± 20.15</td>
<td>1573.00 ± 120.60</td>
<td>29.59 ± 7.23</td>
<td></td>
</tr>
<tr>
<td>Drowning/submersion</td>
<td>41.83 ± 8.41</td>
<td>0.12% ± 0.01%</td>
<td>1.06% ± 0.07%</td>
<td>0.02% ± 0.00%</td>
<td></td>
</tr>
<tr>
<td>Fall</td>
<td>43269.00 ± 1769.00</td>
<td>59.33 ± 10.03</td>
<td>3.42 ± 2.43</td>
<td>114.41 ± 15.29</td>
<td></td>
</tr>
<tr>
<td>Fire/flare/smoke</td>
<td>29.08% ± 0.70%</td>
<td>0.04% ± 0.01%</td>
<td>0.00% ± 0.00%</td>
<td>0.08% ± 0.01%</td>
<td></td>
</tr>
<tr>
<td>Firearm</td>
<td>910.16 ± 63.76</td>
<td>92.36 ± 14.26</td>
<td>1810.00 ± 187.49</td>
<td>253.98 ± 40.69</td>
<td>14.53 ± 5.43</td>
</tr>
<tr>
<td>Hot object/substance</td>
<td>0.61% ± 0.04%</td>
<td>0.06% ± 0.01%</td>
<td>1.22% ± 0.12%</td>
<td>0.17% ± 0.03%</td>
<td>0.01% ± 0.00%</td>
</tr>
<tr>
<td>Late effects</td>
<td>269.13 ± 55.86</td>
<td>0.18% ± 0.04%</td>
<td></td>
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</tr>
<tr>
<td>Machinery</td>
<td>649.56 ± 45.34</td>
<td>0.44% ± 0.03%</td>
<td></td>
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</tr>
<tr>
<td>MVNT pedal cyclist, other</td>
<td>34.67 ± 8.57</td>
<td>0.02% ± 0.01%</td>
<td></td>
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</tr>
<tr>
<td>MVNT pedestrian, other</td>
<td>1225.00 ± 81.84</td>
<td>0.82% ± 0.05%</td>
<td></td>
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</tr>
<tr>
<td>MVNT motorcyclist</td>
<td>1622.00 ± 89.84</td>
<td>1.09% ± 0.05%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MVT occupant</td>
<td>20968.00 ± 972.48</td>
<td>4.75 ± 2.74</td>
<td>3.00 ± 2.11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MVT other</td>
<td>400.09 ± 33.20</td>
<td>0.27% ± 0.02%</td>
<td>0.00% ± 0.00%</td>
<td>0.00% ± 0.00%</td>
<td></td>
</tr>
<tr>
<td>MVT pedal cyclist</td>
<td>2400.00 ± 138.87</td>
<td>1.61% ± 0.06%</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>MVT pedestrian</td>
<td>6676.00 ± 419.27</td>
<td>4.49% ± 0.20%</td>
<td></td>
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</tr>
<tr>
<td>MVT unspecified</td>
<td>675.10 ± 46.50</td>
<td>0.45% ± 0.03%</td>
<td></td>
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</tr>
<tr>
<td>Natural/environmental</td>
<td>2325.00 ± 112.37</td>
<td>1.56% ± 0.06%</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Other land transport</td>
<td>6711.00 ± 286.34</td>
<td>4.51% ± 0.12%</td>
<td></td>
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</tr>
<tr>
<td>Other specified or unspecified</td>
<td>5640.00 ± 203.11</td>
<td>65.28 ± 10.65</td>
<td>1761.00 ± 108.96</td>
<td>444.11 ± 44.93</td>
<td>7.67 ± 3.67</td>
</tr>
<tr>
<td>Other transport</td>
<td>8115.00 ± 335.19</td>
<td>3.79% ± 0.10%</td>
<td>0.04% ± 0.01%</td>
<td>1.18% ± 0.06%</td>
<td>0.30% ± 0.03%</td>
</tr>
<tr>
<td>Overexertion</td>
<td>2191.00 ± 97.14</td>
<td>5.45% ± 0.16%</td>
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</tr>
<tr>
<td>Poisoning</td>
<td>108.78 ± 14.46</td>
<td>3.22 ± 2.29</td>
<td>1.37 ± 1.37</td>
<td>3.08 ± 2.20</td>
<td></td>
</tr>
<tr>
<td>Struck by or against</td>
<td>10838.00 ± 400.73</td>
<td>0.00% ± 0.00%</td>
<td>0.00% ± 0.00%</td>
<td>0.00% ± 0.00%</td>
<td></td>
</tr>
<tr>
<td>Suffocation</td>
<td>19.73 ± 5.67</td>
<td>1.91 ± 1.91</td>
<td>5.47 ± 3.16</td>
<td>4.98 ± 2.89</td>
<td></td>
</tr>
<tr>
<td>0.01% ± 0.00%</td>
<td>0.00% ± 0.00%</td>
<td>0.00% ± 0.00%</td>
<td>0.00% ± 0.00%</td>
<td>0.00% ± 0.00%</td>
<td></td>
</tr>
</tbody>
</table>

†Weighted frequency ± SD of weighted frequency.
1Percent ± standard error of percent.

occur in over 3% of all discharges containing a single trauma code, and most of these have an AIS score of 2.

Hospital Care

Almost 90% of trauma-related discharges were from hospitals located in urban areas (defined as a metropolitan statistical area, Table 1) and close to 67% were from teaching hospitals. Most hospitalizations were classified either as emergency or urgent (Table 1). However, over 7% of the hospitalizations were classified as “elective”. Similarly, although a majority of hospital admissions were from emergency departments, the next most frequent source of admission was classified as “routine or...
other”. Over 80% of discharges for injured children were classified as routine. Just over 1% of the total discharges were classified as in hospital deaths.

Trauma rates are highest for <1 and 10 to 14 year old age groups in the Northeast, whereas the rate for the 5- to 9-year old group is highest in the West (Fig. 5). Children between the ages of 15 to 17 have a higher trauma rate compared with the other age groups regardless of region.

The average length of stay for all discharges was 3.59 ± 0.07 days. We stratified the length of stay into two groups: ≤2 days (62.73% ± 0.59%) and >2 days (37.26% ± 0.59%). We chose 2 days because trauma registry inclusion criteria often include only those patients whose in hospital stay is greater than 2 days. Two days was also the median value of the length of stay variable for all discharges records in our model. We compared the length of stay categories with an ISS grouping that captures more of the single trauma records with moderate ISS scores (<9, 9–14, 16–24, 25–34, and ≥35). The results are shown in Figure 6 and suggest that almost 80% of trauma-related discharges hospitalized for ≤2 days have low ISS scores (<9). For those trauma-related discharges hospitalized >2 days, almost 50% also have low ISS scores (<9). For trauma-related injuries with ISS scores 9 and above, a higher proportion are hospitalized for more than 2 days.

To further characterize the hospitals where injured children received care, we classified the hospitals by their experience in caring for children or trauma patients. Because there is no such identifier contained in the KID, we derived an estimate for these parameters using the volume of pediatric and trauma discharges for each hospital. We based our definition of pediatric trauma experience on the American College of Surgeons’ Committee on Trauma’s definition of patient volume for pediatric trauma designation. Hospitals were stratified into one of three groups based on the volume of pediatric trauma discharges (<100, 100–199, and ≥200 pediatric trauma discharges/year, Table 5). We used the mean discharge pediatric volume to identify pediatric experience based on hospitals identified in the KID 2003 as children’s hospitals, children’s unit in general hospitals or hospitals not identified as children’s hospitals. Hospitals with high pediatric experience were defined as having >8,400 pediatric discharges/year. Hospitals defined with low pediatric experience had 1 to 1,782 pediatric discharges/year. We defined moderate pediatric experience as hospitals with a volume of pediatric discharges between 1,782 and 8,400 (Table 6). In assigning hospitals to these categories, we assumed that volume equated to experience.

The majority of trauma-related discharges were from hospitals with a moderate experience in caring for pediatric trauma. Yet almost 15% of the discharges were from hospitals with low pediatric trauma experience and low pediatric experience. We divided ISS scores into two groups (ISS <9 and ≥9) to compare the severity of injury according to hospital pediatric trauma experience and pediatric experience (Table 7). Over 8% of trauma-related discharges with an ISS ≥9 were from hospitals with low experience in both pediatric and trauma care. Almost 23% of trauma-related discharges with an ISS <9 were from hospitals with high experience in both pediatric and trauma care. 

![Fig. 2. Diagnosis categories by age group.](image-url)
### Table 4 Barell Matrix: Trauma-Related Discharges by Nature of Trauma and Body Region

<table>
<thead>
<tr>
<th></th>
<th>Fractures</th>
<th>Dislocation</th>
<th>Sprains and Strains</th>
<th>Internal Wound</th>
<th>Amputations</th>
<th>Blood Vessels</th>
<th>Crush</th>
<th>Burns</th>
<th>Nerves</th>
<th>Unspecified</th>
<th>System-wide and Late Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Head and neck</strong></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>Traumatic brain injury (TBI)</td>
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<td></td>
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<td></td>
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</tr>
<tr>
<td>Type 1 TBI</td>
<td>5.69%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>11.58%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
</tr>
<tr>
<td>Type 2 TBI</td>
<td>1.52%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>5.49%</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Type 3 TBI</td>
<td>2.27%</td>
<td></td>
<td>0.38%</td>
<td>1.04%</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Total TBI</td>
<td>9.48%</td>
<td>0.52%</td>
<td>0.00%</td>
<td>6.09%</td>
<td>1.90%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
</tr>
<tr>
<td><strong>Other head, face, and neck</strong></td>
<td></td>
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<tr>
<td>Other head</td>
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<td></td>
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<tr>
<td>Face</td>
<td>3.31%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
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</tr>
<tr>
<td>Eye</td>
<td>0.00%</td>
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</tr>
<tr>
<td>Neck</td>
<td>0.00%</td>
<td>0.38%</td>
<td>0.00%</td>
<td>1.04%</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Head, face, neck unspecified</td>
<td>3.31%</td>
<td>0.01%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
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<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
</tr>
<tr>
<td>Total other head, face, and neck</td>
<td>3.31%</td>
<td>0.01%</td>
<td>0.00%</td>
<td>11.58%</td>
<td>3.46%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.07%</td>
<td>0.16%</td>
<td>1.31%</td>
<td>0.04%</td>
</tr>
<tr>
<td>Total head and neck</td>
<td>12.79%</td>
<td>0.01%</td>
<td>0.38%</td>
<td>11.58%</td>
<td>3.46%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.07%</td>
<td>0.16%</td>
<td>1.31%</td>
<td>0.04%</td>
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<tr>
<td><strong>Spine and back</strong></td>
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<tr>
<td>Spinal cord injury (SCI)</td>
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</tr>
<tr>
<td>Cervical SCI</td>
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<td></td>
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</tr>
<tr>
<td>Thoracic/dorsal SCI</td>
<td>0.12%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Lumbar SCI</td>
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<tr>
<td>Sacrum coccyx SCI</td>
<td>0.01%</td>
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<td>0.00%</td>
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<tr>
<td>Total spinal cord injury</td>
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<td><strong>Vertebral cord injury (VCI)</strong></td>
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</tr>
<tr>
<td>Spine + back unspecified SCI</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
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<tr>
<td>Cervical VCI</td>
<td>0.60%</td>
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<td></td>
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</tr>
<tr>
<td>Thoracic/dorsal VCI</td>
<td>0.41%</td>
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</tr>
<tr>
<td>Lumbar VCI</td>
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</tr>
<tr>
<td>Sacrum coccyx VCI</td>
<td>0.14%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
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<td></td>
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<tr>
<td>Spine, back unspecified VCI</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
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<td>0.00%</td>
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</tr>
<tr>
<td>Total vertebral cord injury</td>
<td>1.85%</td>
<td>0.33%</td>
<td>0.38%</td>
<td>0.02%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
</tr>
<tr>
<td>Total spine and back</td>
<td>2.24%</td>
<td>0.33%</td>
<td>0.38%</td>
<td>0.27%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
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<tr>
<td><strong>Torso</strong></td>
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</tr>
<tr>
<td>Chest</td>
<td>0.37%</td>
<td>0.02%</td>
<td>0.01%</td>
<td>2.14%</td>
<td>0.22%</td>
<td>0.05%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.61%</td>
</tr>
<tr>
<td>Abdomen</td>
<td>6.83%</td>
<td>0.43%</td>
<td>0.04%</td>
<td>0.04%</td>
<td>0.04%</td>
<td>0.29%</td>
<td>0.00%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pelvis + urogenital</td>
<td>1.52%</td>
<td>0.00%</td>
<td>0.02%</td>
<td>0.13%</td>
<td>0.46%</td>
<td>0.01%</td>
<td>0.06%</td>
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<td></td>
</tr>
<tr>
<td>Trunk</td>
<td>0.00%</td>
<td>0.12%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.24%</td>
<td>0.12%</td>
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</tr>
<tr>
<td>Back + buttoc</td>
<td>0.02%</td>
<td>0.16%</td>
<td>0.38%</td>
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</tr>
<tr>
<td>Total torso</td>
<td>1.89%</td>
<td>0.02%</td>
<td>0.05%</td>
<td>9.10%</td>
<td>1.39%</td>
<td>0.10%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.15%</td>
<td>0.00%</td>
<td>0.12%</td>
</tr>
<tr>
<td><strong>Extremities</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shoulder and upper arm</td>
<td>10.64%</td>
<td>0.05%</td>
<td>0.02%</td>
<td>0.25%</td>
<td>0.01%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.01%</td>
</tr>
<tr>
<td>Forearm and elbow</td>
<td>7.85%</td>
<td>0.09%</td>
<td>0.01%</td>
<td>0.44%</td>
<td>0.02%</td>
<td>0.01%</td>
<td>0.02%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hand and wrist and fingers</td>
<td>0.95%</td>
<td>0.07%</td>
<td>0.03%</td>
<td>1.13%</td>
<td>0.38%</td>
<td>0.05%</td>
<td>0.05%</td>
<td>0.05%</td>
<td>0.05%</td>
<td>0.05%</td>
<td>0.05%</td>
</tr>
<tr>
<td>Other and unspecified upper extremities</td>
<td>0.01%</td>
<td>0.05%</td>
<td>0.14%</td>
<td>0.00%</td>
<td>0.22%</td>
<td>0.21%</td>
<td>0.21%</td>
<td>0.21%</td>
<td>0.21%</td>
<td>0.21%</td>
<td>0.21%</td>
</tr>
<tr>
<td>Total upper extremities</td>
<td>19.45%</td>
<td>0.21%</td>
<td>0.06%</td>
<td>0.00%</td>
<td>1.87%</td>
<td>0.41%</td>
<td>0.14%</td>
<td>0.06%</td>
<td>1.63%</td>
<td>0.21%</td>
<td>0.02%</td>
</tr>
</tbody>
</table>
DISCUSSION

In this study, we present data to help define and characterize children under the age of 18 years hospitalized for trauma-related injury in the United States. Because there is no current trauma data collection effort that provides national estimates for children, we used the HCUP KID 2003 database. This database is a sample of pediatric discharges from a sampling frame that includes all pediatric discharges from community, nonrehabilitation hospitals participating in the HCUP. In 2003, data from 36 participating states and 3,438 hospitals was used to derive the KID sample resulting in 7,409,162 weighted pediatric discharges. Limitations of the KID include data release restrictions imposed by participating states, over-sampling of large hospitals resulting from the sample design of the KID, and a hospital sampling frame that does not include all US hospitals. However, these limitations are offset by HCUP’s uniform coding and access to a large number of hospital discharge records.

In our analysis, peaks of trauma-related discharges for 2, 7, 12, and 16 years of age were evident. In a separate analysis, we used data from the National Hospital Discharge Survey and found age-related rate peaks similar to those we observed using the KID data. In 2001, Agran et al. reported rates of pediatric injury using hospital discharge data from 1997. They observed age-related injury peaks at 1 and 18 years of age. Our age-related peaks may be different because of age rounding, a different data year (2003 compared with 1997), exclusion of out of hospital deaths, and limiting our review to trauma-related discharges. We did analyze the mechanisms of injury for the four age associated peaks. For trauma-related discharges 2, 7, and 12 years of age, the most common mechanism was a fall. For trauma-related discharges 16 years of age, the most common mechanism was being an occupant in a motor vehicle crash. Regardless of age, 63.8% of the trauma-related discharges in our study were men, consistent with previously published data.

Socioeconomic status has been correlated with a higher rate of injury among children. Over 30% of our trauma-related discharges had Medicaid listed as the primary payer and over 6% were uninsured. For the same year (2003), the US Census Bureau reported that 11.4% of children under the age of 18 years were uninsured, 26.4% were covered by Medicaid and 65.9% were covered by private health insurance. The lower rate of uninsured in this review is likely a result of enrollment of eligible children into a government health insurance program during hospitalization.

Additional information relating socioeconomic status with trauma-related discharges in our study comes from the median household income quartile classification provided in the KID 2003. Over 20% of our total weighted discharges were classified into the lowest household income quartile. In 2003, all US poverty income levels for families of 8 or less would be included in the KID lowest household income quartile. The relationship between poverty level and an in-

<table>
<thead>
<tr>
<th>Fractures</th>
<th>Dislocation</th>
<th>Sprains</th>
<th>Contusion/superficial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower Hip</td>
<td>1.51%</td>
<td>0.37%</td>
<td>0.07%</td>
</tr>
<tr>
<td>Upper leg and thigh</td>
<td>0.13%</td>
<td>0.02%</td>
<td>0.01%</td>
</tr>
<tr>
<td>Knee</td>
<td>0.16%</td>
<td>0.04%</td>
<td>0.01%</td>
</tr>
<tr>
<td>Lower leg and ankle</td>
<td>1.02%</td>
<td>0.02%</td>
<td>0.01%</td>
</tr>
<tr>
<td>Foot and toes</td>
<td>1.02%</td>
<td>0.02%</td>
<td>0.01%</td>
</tr>
<tr>
<td>Other and unspecified lower extremities</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
</tr>
<tr>
<td>Total lower extremities</td>
<td>21.71%</td>
<td>0.67%</td>
<td>0.06%</td>
</tr>
<tr>
<td>Total unspecified by site</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
</tr>
<tr>
<td>Total unclassifiable by site</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
</tr>
</tbody>
</table>
creased injury rate has been previously documented. In 2000, Faelker et al. demonstrated that the injury rate increased with the percentage of individuals living below the poverty line in Canada. The results presented here suggest a similar relationship between poverty and hospitalization for trauma-related injury in the United States.
Fig. 5. Trauma related discharge rates by age group and hospital region.

Fig. 6. Age group and injury severity by length of stay.
An assessment of comorbidity factors, or pre-existing conditions, is essential for comparing health outcomes. Unfortunately, pediatric risk adjustment strategies and coding algorithms have lagged behind those for adults. For this study we used the comorbidity measures derived from adult data for use with administrative data. Using these coding conventions we identified approximately 13% of the total number of trauma-related weighted discharges with at least one comorbidity factor present. The presence of at least one comorbidity factor was associated with a higher in hospital death rate. Because of the overall low mortality rate among hospitalized trauma-related injuries, these results should be interpreted with some caution. A recent study by Tai et al. identified diagnosis categories associated with higher mortality rates within 1 year after hospital discharge for children from 1 to 14 years of age. Although still requiring validation in an external population, this study holds promise for identifying comorbidity factors important to children. A similar effort for children with traumatic injury would be an important contribution.

In this study, mechanism, intent and trauma-related diagnoses were similar to previously published findings. Overall, falls were the most frequent trauma-related injury mechanism. Being an occupant in a motor vehicle crash occurred in over 14% of the trauma-related discharges. Falls are the leading cause of emergency department visits and the 10th leading cause of injury-related mortality for children 0 to 14 years of age. Being an occupant in a motor traffic crash ranks first for mortality and seventh in emergency department visits. E-codes were missing in over 7% of the trauma-related discharges presented in this review, consistent with previous findings in large administrative databases. Inconsistencies in the coding between the first E-code and the primary diagnosis were apparent. However, this may be a result of our assuming that the first of four listed E-codes was the “primary” E-code and directly related to the primary diagnosis code.

Most injuries are unintentional, with a national calculated hospitalization rate of 439 (per 100,000) in 2003. For ages <17 years, the unintentional injury hospitalization rate was 191. In this study, the overall unintentional trauma-related discharge rate was 173, but ranged from a high of 312 for 16 year olds to a low of 107 for 8 year olds. Reported patterns of injury-related discharge diagnoses vary according to study design (i.e. the ICD9-CM codes and age range included).

The overall pattern of ISS distribution in our study was similar to previously published data by Segui-Gomez and colleagues. In their study comparing pediatric trauma-related injuries in 18 states, discharges with an ISS <15 ranged from 88% to 97% among the four types of hospitals included. Stevenson and colleagues in their study comparing ISS and NISS reported a range of 85% to 95% of discharges with ISS scores <15 from three data sources (National Pediatric Trauma Registry, Massachusetts hospital discharge data, and a single trauma center’s registry). Almost 54% of our trauma-related discharges had only one trauma ICD9-CM code listed on the record; almost 56% of those discharges were for extremity fractures and another 14% had isolated intracranial injuries. Segui-Gomez et al. reported that 50% to 75% of hospital admissions among the four different types of hospitals in their study were for single injuries. In her report, extremity injuries accounted for 22% to 52% of single injuries, with head and neck injuries accounting for an additional 10% to 18%.

Over 80% of trauma-related discharges were classified as a routine discharge and only 1.1% were recorded as an in hospital death. The low incidence of death in our analysis is consistent with data reported by Segui-Gomez et al. In their study, in hospital death accounted for between 1% and 2% of trauma-related discharges. The in hospital death rate ob-

### Table 5 Characterization of Hospitals by Pediatric and Pediatric Trauma Experience

<table>
<thead>
<tr>
<th>Pediatric Experience (Pediatric Discharges/Yr)</th>
<th>Pediatric Trauma Experience Pediatric Trauma Discharges/Yr</th>
<th>Low (&lt;100)</th>
<th>Moderate (100-199)</th>
<th>High (≥200)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low (1-1,450)</td>
<td></td>
<td>17,525 ± 647</td>
<td>40,233 ± 1,370</td>
<td>1,063 ± 345</td>
</tr>
<tr>
<td>Moderate (1,451-8,400)</td>
<td></td>
<td>476 ± 349</td>
<td>19,901 ± 2,030</td>
<td>5,785 ± 1,156</td>
</tr>
<tr>
<td>High (≥8,400)</td>
<td></td>
<td>360 ± 360</td>
<td>24,481 ± 3,348</td>
<td>35,949 ± 4,944</td>
</tr>
</tbody>
</table>

### Table 6 Injury Severity by Hospitals and Pediatric Trauma Experience and Pediatric Experience

<table>
<thead>
<tr>
<th>Pediatric Trauma Experience/Pediatric Experience</th>
<th>ISS</th>
<th>&lt;9</th>
<th>≥9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low/low</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate/low</td>
<td>13.20% ± 0.64%</td>
<td>6.34% ± 0.60%</td>
<td></td>
</tr>
<tr>
<td>High/low</td>
<td>28.96% ± 1.37%</td>
<td>19.72% ± 1.43%</td>
<td></td>
</tr>
<tr>
<td>Low/moderate</td>
<td>0.79% ± 0.24%</td>
<td>0.53% ± 0.18%</td>
<td></td>
</tr>
<tr>
<td>Moderate/moderate</td>
<td>0.31% ± 0.24%</td>
<td>0.36% ± 0.26%</td>
<td></td>
</tr>
<tr>
<td>High/moderate</td>
<td>12.58% ± 1.33%</td>
<td>16.44% ± 1.85%</td>
<td></td>
</tr>
<tr>
<td>Low/high</td>
<td>3.88% ± 0.79%</td>
<td>3.93% ± 0.88%</td>
<td></td>
</tr>
<tr>
<td>Moderate/high</td>
<td>0.31% ± 0.30%</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>High/high</td>
<td>15.13% ± 1.98%</td>
<td>21.53% ± 2.80%</td>
<td></td>
</tr>
<tr>
<td>Total*</td>
<td>22.79% ± 2.70%</td>
<td>29.41% ± 3.32%</td>
<td></td>
</tr>
</tbody>
</table>

* Approximately 3% of records could not be coded into Pediatric Experience.
served in our analysis is lower than that recently reported by Mullins et al. 31 In their study of regional differences in hospitalized injured patient using the National Inpatient Sample (NIS), 2.4% of the discharges were recorded as in hospital deaths. The difference is likely caused by their inclusion of all ages, particularly those over the age of 65.

Most trauma-related injury hospitalizations were ≤2 days, and most hospitalizations had low ISS scores. Given the limited variables contained in the KID, we were not able to determine the underlying cause for these admissions. Factors may include whether or not other family members were injured or if the child lived some distance from the admitting hospital.

Our classification of hospitals into pediatric experience and trauma experience are a first step in better defining what hospital characteristics are important to the optimal care of an injured child. In an era of limited resources, we would like to assure that the right child received the right treatment at the right place. Treating relatively minor injuries at hospitals with high pediatric and high trauma experience may be just as inappropriate as treating severe life threatening injuries at low pediatric and low trauma experience hospitals. Clearly, more work needs to be done to carefully define hospitals’ resources and to align triage and transfer guidelines with those resources.

CONCLUSION

The positive effect of trauma systems for adults has been documented. Trauma systems generally include a network of prehospital providers and transport services, designated trauma centers, and rehabilitation services. We simply do not know how trauma systems impact the care of injured children. Compared with adults, fewer children are injured. In 2003, approximately 21 million individuals, ages 18 to 85+, were injured in the United States, resulting in approximately 1.4 million hospitalizations. During that same time period, approximately 8.5 million children, ages 0 to 17 years, were injured and just over 161,000 of these children were hospitalized.

REFERENCES

9. United States Department of Health and Human Services (US DHHS), Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS). Bridged-Race Population Estimates, United States, 1990–2004, By Age Groups. Compiled from the April 1, 2000 resident population developed by the Bureau of the Census in collaboration with the NCHS on CDC WONDER On-line Database; Query Date: Feb 11, 2007 10:36:30 AM.


Dr. David Clark: It’s a great privilege to be invited into this group of professionals who have dedicated their careers to the care of injured children. I feel it is my duty to provide some perspective on behalf of the general surgeons and general hospitals that treat the majority of these younger patients. The organizers of this conference have instructed us to be “something provocative”, so forgive me if I overstate my case at any point.

I know that we all share a desire to reduce the number of children who die as a result of injuries. According to the CDC, there are more than 11,000 each year, and by far the most important cause is traffic crashes.

Discussants have also been told to be “evidence based”, so most of my remarks will refer to the figure as well as to the presentations we just heard.

FARS data show that traffic mortality under age 18 occurs mostly among teenagers, mostly from crashes in counties without a children’s hospital, and mostly before the victim can be brought to any hospital. Clearly the greatest benefit we could obtain is in the area of injury prevention, and no amount of EMS development or hospital care will be equivalent.

Those of us with experience in the management of severely injured patients have the credibility to be effective advocates, and we should support our colleagues who work primarily to prevent childhood injuries. Nevertheless, our special obligation as surgeons, emergency physicians, or intensivists is to maintain the best possible system for those young people who do suffer major injuries and whose outcomes depend upon emergency care.

I think we can all agree that the smaller the child and the more complex the injury, the greater is the need for specialized expertise. The challenge is to integrate this expertise with maximal effectiveness into existing or developing trauma systems in the various parts of our country. In a few mostly urban areas, the ideal would seem to be immediate transport of all seriously injured children to a pediatric surgical service that is prepared to deal with acute injuries. Local resources can lead to a rational decision about what constitutes a child. In my own hospital, the age was recently reduced from 16 to 12 years, and I have been impressed that the results cannot be generalized to nonmetropolitan areas.

The analysis of the Kid’s Inpatient Database just provided by Dr. Guice and colleagues found that a subset of patients 18 to 54 years old with severe injuries were more likely to survive if treated at trauma centers than if treated at other nontrauma centers. The convenience sample of metropolitan areas in the NSCOT study contains some of America’s most prominent and well-established Level I trauma centers, so it is not clear whether a similar difference would have been found in other trauma systems, and the authors explicitly state that the results cannot be generalized to nonmetropolitan areas.

The analysis of the Kid’s Inpatient Database just provided by Dr. Guice and her colleagues also implied that it might be better if more children went to specialized hospitals. A more “provocative” study from the same group using the same database was presented at the American Pediatric Surgical Association (APSA) and published last year. That earlier study concluded explicitly that children under 10 years old with ISS over age 15 had lower mortality if admitted to pediatric hospitals. Of course, the use of hospital discharge data to evaluate inter-hospital differences in outcome opens up many methodologic problems, as was pointed out by APSA discussants and acknowledged by Dr. Guice this morning.

For this pediatric conference, I’ve been asked to consider these articles and my own understanding of the evidence and
discuss what a study would need to contribute to optimize the current system of trauma care in the United States. I would strongly urge that such a study should not try to prove that general surgeons and general hospitals are inferior in their management of pediatric trauma. That was the last war. Indeed, an increasing number of general surgeons already seem to be looking for excuses to avoid trauma patients and would be only too happy to have them diverted or transferred elsewhere. Even pediatric surgeons are not immune to this trend. However, the optimal system for the youngest victims of trauma will need to maintain at least some commitment and at least adequate training among all of our surgical colleagues in the next generation.

So what kind of study would be useful? I have a few recommendations, which apply to any study of emergency care, but for the reasons I’ve mentioned, they apply even more to a study addressing injured children.

A useful study should:

1. be population based, including victims that don’t make it to a hospital. It should try to identify recurring patterns of potentially preventable injury.
2. consider whether technologic improvements in communication or transportation might overcome some of the geographic barriers to timely care, especially in rural areas.
3. not focus on individual hospitals but should look at regional systems of care, including inter-hospital relationships and transfer practices and determine what injuries at what ages are associated with better results if treated in specialized centers of different kinds. For example, what lessons can we learn from our experience with burns and spinal cord injuries?
4. recognize that for injured children, mortality is an outcome mostly determined before the patient can reach a hospital, and it would be more valuable to measure functional outcomes over as long a term as possible. None of this will be easy, but perhaps some part of it can be attempted.

Dr. James O’Neill: It’s appropriate to point out that the NSCOT study fits the pattern of changing healthcare in the United States as we look ahead to any potential pediatric study. It also recognizes that societal attitudes regarding the healthcare system are changing. For example, the classic paradigm for major centers, particularly academic centers, of patient care, education and research mainly being separate enterprises and very loosely linked, is changing. Those are being linked as a system directed to the benefit of society. In a similar fashion, the systems of patient care for complicated illness are changing from care by individual physicians to care by integrated, collaborative teams so that the benefits of advances in multiple specialties can be brought to bear on the patient. In any study of the value of trauma centers, you must acknowledge this changing paradigm.

Dr. Guice and her group attempted to determine how injured children differ from injured adults by retrospectively analyzing the KID 2003 inpatient database. The overall mortality was only 1.08%, so any study of mortality may be an elusive goal.

As we look at the next step, it’s appropriate to consider the current status of pediatric trauma care in the United States and something about its evolution. I’d like to mention five areas.

1. The first real advance in the management of pediatric trauma was in the organization of care. Before 1965, there was little in the way of organized trauma care, particularly pediatric trauma care. Publications by the National Research Council, the Committee on Trauma of the American College of Surgeons, and other professional organizations gradually led to virtually all state legislatures promoting the establishment of regional trauma systems. By the late 1980s, pediatric trauma centers began to be developed. Trauma registries and trauma scoring systems were developed and applied to children; TRISS methodology was evaluated for use in the pediatric age group; and, numerous research studies specially designed for children were published.

At the present time, there are over 30 Level I pediatric trauma centers as well as a large number of adult centers with pediatric capability. In rural areas, pediatric standards and pediatric education modules for nurses and physicians have been developed, so that some degree of pediatric expertise is available in most parts of the United States, although the experience level is clearly not uniform.

2. The second major advance in both adult and pediatric trauma care has been understanding trauma physiology as a basis for care. The problems resulting in mortality in the first hour or two after injury are respiratory, cardiovascular, and central nervous system in nature, and each of these factors has significant metabolic and other consequences over the ensuing hours and days, that if left untreated may lead to infection, multiple organ systems failure and mortality.

Although there are numerous similarities between injured children and adults in terms of physiologic effects of trauma, the younger the child, the more differences exist. For example, there’s very good evidence that severely injured or burned children under the age of 2 years have different responses to injury and require different resuscitation approaches. Efforts are continuing to better understand how the treatment of severely injured children should be designed to address physiologic derangement. Treatment is now much more based on evidence.

3. The third major advance has been the selective management of blunt trauma. That will be addressed later, but certainly it’s well established in adult as well as pediatric trauma care.

4. Probably the largest advance have been in the management of burn injury in children, based on understanding
deranged physiology and constituting today one of the most evidence-based types of care we have.

5. In the last 20 years or so, there have been numerous advances in public education and prevention, for example the promotion of seat belts and helmets.

As a new pediatric NSCOT study is designed, I might suggest the following:

1. The fact that pediatric capable Level I trauma centers compared with nontrauma centers have lower mortality rates is well established. Although some have argued that a good Level I adult center without pediatric expertise can equal the mortality rates of Level I pediatric capable centers, there is inadequate information to support that view. But the real difference may be in comparisons of morbidity, complications and long-term outcomes, for which there is little data.

2. There are good reasons to examine the outcomes in different age groups, and my suggestion would be birth to 2, 3 to 12, and 13 to 18. The under 2 age group deserves special scrutiny.

3. Dr. Guice’s and other studies have clearly shown that most children sustain mild to moderate injuries, so a comparison of outcome groupings by ISS strata of <15 and ≥15 will be important.

4. We also must examine racial and socioeconomic disparities in trauma care. I do not think that any of the studies performed to date have really addressed the disparities we know exist. We need to know if outcomes are different in different socioeconomic groups, by variations in insurance coverage, and whether there are racial differences.

5. The NSCOT studied outcomes at 3 and 12 months after injury; this is clearly not long enough for the pediatric age group. Regardless of the type of illness, long-term growth and development are critical considerations in children. For the mild to moderate injury cohort, follow-up for 12 months may be fine. But for severe injury in children, five-year outcomes may be more appropriate.

   For example, recent data indicate that in burned children, catabolic, inflammatory and genomic-related changes may continue for as long as a year. It is well known that patients with severe head injury have long-term cognitive deficits; a recent study has also demonstrated long-term cognitive, emotional, and functional deficits in trauma intensive care unit survivors without intracranial hemorrhage.3

6. The usual measure of success in adults is return to work, but school performance over time would probably be a better parameter for study in children. Quality of life measurements specifically designed for children will need to be used so that a broad description of functional outcomes can be examined.

7. It will be useful to compare facilities in terms of how fully information technology is used and to what extent they add value to diminishing errors.

8. Another recent trend that should be considered is that more patients are currently being transferred directly to pediatric trauma centers, as is the case with burn units, rather than as inter-hospital transfers. Studying this pattern will be important.

9. Finally, we need to do everything we can to make a future pediatric NSCOT study prospective as much as possible. A prospective study will be more expensive than a database study, but it will be more valuable because it will be more accurate, and make it more possible to take into account the current changing trends in care, including physiologic care. We need to know if children treated with early intervention treatment and rehabilitation strategies do better than those not so treated.

In essence then, I think a pediatric NSCOT study should be performed, but it must be prospectively designed. There is a model for that. A number of hospitals and physicians have collaborated to examine outcomes for specific surgical disease entities. This kind of multicentered, collaborative model will be necessary.

Dr. Dean: My question concerns the need for stratifying as you sample within a metropolitan statistical area (MSA), because my understanding of the number of pediatric trauma centers that are American College of Surgeons (ACS) verified as Level I pediatric trauma centers is about 10.

Dr. O’Neill: If you take the total number that meet ACS standards, there are over 30. For example, PA, WA, and Tennessee, all use state agencies for verification, but all are based on ACS standards or higher.

Dr. Dean: If we’re going to actually study pediatric trauma centers, whether we decide they’re ACS verified or not, the numbers available are such that we probably cannot afford to stratify within an MSA. How important is that going to be?

Dr. MacKenzie: The important question is whether or not we want to do a study of systems care as opposed to hospital care. In NSCOT, we decided, I think appropriately, to study hospital care. The argument that was made by the speakers was pretty compelling in terms of, for the pediatric population, looking at a more systems approach. But the issue of transfers is going to be critical for the pediatric population. We need to think of a fairly different type of design for pediatric study.

Dr. Tepas: My first comment has to do with the issue of age and risk for injury. The problem of juvenile violence is still large in this country, and the needs of adolescents are not being adequately addressed. If there is one area that is the quintessential example of the effect of early intervention and prevention, it’s that group whose behavior and risk taking gets them into our system.

Second, I completely and enthusiastically agree that this study should be done prospectively. There are X number of pediatric trauma centers. There are Y number of hospitals to take care of children, because they’re the only hospitals in
town. What we really need to do is focus on the disease of injury in children and look at it from the entire horizontal perspective. Because what we’re really attempting to do is to identify factors in the progression of this disease, just like factors in the progression of other diseases where we can find places to intervene and improve outcome.

Finally, having a study that relies not just on administrative data are absolutely critical. When we examined the diagnoses of approximately 3,400 patients admitted to the Florida state trauma registry, and compared them to the same patients’ data in the administrative data of the Agency for Healthcare Administration in the state, the diagnoses were quite different and clearly reflected a different level of severity and mortality risk.

**Dr. Stylianos:** For the NSCOT study, what was the level of funding that was required to produce such an incredible study? You also were honest enough to point out the study limitations; what type of funding would have allowed you to meet those challenges?

**Dr. MacKenzie:** It was approximately $7 million total (direct and indirect costs). Although most of that came from CDC, we were able to leverage that to obtain more funding from the CDC as well as form the National Institute on Aging.

**Dr. Rivara:** Given what we have discussed in terms of the need for prospective data collection in an era of HIPAA, a pediatric NSCOT will likely be more expensive. It may require having research people in the individual centers enrolling these patients while they’re in the hospital.

**Dr. Jaffe:** Dr. MacKenzie, one of the things you conscientiously disclosed about NSCOT were the limitations in terms of knowing the preinjury status. In examining outcomes, we need to have a broad-based sense of preinjury status for individuals as well as for families. The variability in outcome is wide and the number of confounders extensive. This too speaks to the issue of designing a prospective study.

**Dr. MacKenzie:** I agree. Coupled with that challenge is determining the kind of preinjury measures of functioning which should be collected. Is it school performance; is it just physical functioning?

**Dr. Pollack:** I’m interested in the comments that have been made about the issue of hospital versus systems studies and the factors that go into them, as well as some of the comments about money and how expensive such studies would be. We have focused in the past, and certainly in my own work, very much on specific quality factors or system factors or pediatric hospitals versus nonpediatric hospitals. I’m wondering whether or not the future for defining good quality care is going to be in system evaluations; it really doesn’t matter what the characteristics of that system are as long as it performs very well. We should try to figure out how to assign a quality label to a system; it really doesn’t matter whether it’s a pediatric hospital or not in that system, only how it performs. Obviously, quality factors go into any good system, and if you were designing a system, you would build in those quality factors.

**Male:** What you’re suggesting actually has some precedent, although not at a system level. In the 1980s, the major trauma outcome study set benchmarks (albeit not pediatric specific) that allowed others to examine their outcomes.

**Dr. Pollack:** In critical care, increasingly the focus is on outcomes. For example, in examining ventilator-associated pneumonia, the quality measure is not whether respiratory therapists are well trained or not. Rather, the question being asked is, “What’s the incidence of casemix-adjusted ventilator-associated pneumonia?” That’s the information that you want to know. You want to know whether there’s a standard and what the standardized outcome is for a healthcare system; that’s how you assign quality.

**Dr. MacKenzie:** But are you suggesting a kind of “black box evaluation?”

**Dr. Pollack:** It’s a methodologic challenge, but it’s not as big a methodologic challenge as the idea of evaluating functional status; that is a much large methodologic challenge. There’s a solution to this.

**Dr. Nathens:** When I think of the NSCOT and the labor cost that went into data collection, it was extraordinary. Considering all the centers that might participate in a pediatric trauma study, they’re already collecting the type of registry data that most of us typically have. I think they’re also going to have their registries linked to prehospital care data as well. I don’t think it’s necessary to put all the dollars into a data collection system for the study. You might want to collect data as well. I don’t think it’s necessary to put all the dollars into a data collection system for the study. You might want to have abstractors focusing on very discrete fields that otherwise aren’t collected, perhaps CT data or radiographic data, and maybe some means of validation before going into these centers to make sure their registry data are reflective of their chart data.

I also think that the time horizon for any particular study with children should be different from that for adults. The NSCOT followed patients for a year, but there are many other things that happen with pediatric patients during their formative years. One year is too short a time horizon when thinking about the impact on education and social integration that probably evolve over years.

Lastly, the initial idea for the pediatric study, like the NSCOT, was comparing freestanding pediatric trauma centers with those centers that are affiliated with adult hospitals. There is a very large geographic imperative, and as David Clark was mentioning, I don’t think we’re going to be able to have policy reflect whatever we find in the study. We can’t change how patients are flowing because these hospitals just don’t exist. They’re structured in the environment because that’s the way they are. So I think that we won’t be able to change flow as much as we would like to, as with the adult NSCOT study.

**Dr. Cooper:** It is worth stating that research is generally performed where there are resources to perform that research. Whether one is an adult-oriented trauma center with strong...
pediatric expertise or a children’s hospital, in general we’re talking about institutions that have the resources to perform the research that’s needed. Those concentrations of resources and bright people to take care of sick patients generally develop best practices that are relatively similar.

In terms of altering or improving the quality of pediatric trauma care in this nation, we need to identify best practices. What constitute these best practices are the concentration of bedside resources, hospital providers, nurses and their level of expertise and training that may make a huge difference in terms of outcomes of care. Different types of hospitals may just be proxies for best practices in and around groupings of resources. If one is to undertake a study of this magnitude, to fail to identify what the groupings of resources are that seem to result in best practices would be to miss a major opportunity. This study is going to take a long time, it’s going to be costly, but we all know what’s riding on it: better trauma care for our children. This is a study we can’t afford not to do, and do right, because we’re probably not going to have another opportunity to do it for 20 years or 30 years.

**Dr. Wesson:** Even though we all agree that the study should be prospective, a child doesn’t become a case until they’ve already been injured. It thus becomes a problem right at the outset to determine their baseline status. If you ask parents and teachers how the child was before the injury, they’re already biased by the fact that the child was injured. It’s not quite as easy as you might think to do a truly prospective study. Identifying the cases as early as possible and getting the information as much as you can about the preinjury state of the child is very, very important. If you ask the parents 3 or 6 months later what the child was like before they were injured, it’s not going to be nearly as useful.

Secondly, it is not feasible that all injured children will be cared for in pediatric trauma centers, and thus the whole question of whether a patient gets better care in one type of trauma center versus another trauma center is irrelevant. The real question is why some patients do better than other patients, no matter what the context in which they’re treated. If we refocus on why some children do better than others, controlling for the kind of injury that they suffered, we might find out much more useful information.

Following up on what Dr. Pollock and Dr. Cooper said, we’ve assumed that trauma centers provide the best care in these kinds of studies, but what is it about care in trauma centers that defines that care or that determines the outcome? Is it because the patients get there faster because of the prehospital system that is in place wherever there is a trauma center, or is it something about the care that’s actually given to the patient in the trauma center? I don’t think we know the answer to those kinds of questions; we have an opportunity to find out what determines the best outcomes, thereby defining best practices. These can be disseminated around the country, regardless of the type of hospital.

**Dr. Rivara:** Should we be measuring genomics? Should we be measuring genes in these patients to look at their particular genetic makeup that might explain some of the variations and outcomes? Is it going to be possible to do that with children, given IRB requirements?

**Male:** My comment actually referred to genomic changes that related to physiologic changes that might be the basis for interventional strategies to diminish the effects of trauma. I was not so much referring to chromosomal abnormalities or preexisting conditions, as I was the physiology itself.

**Dr. Dean:** We may want to concentrate on a cohort that we actually prospectively enroll and not worry too much about the price, given that once you have the cohort, follow-up funding is something that might be possible to obtain.

In Salt Lake City, there are two fairly large Level II adult trauma centers within 20 miles of the pediatric trauma center, a couple of Level I trauma centers in the same city, and then about 25 to 30 to 50 hospitals in a four-state region in which general surgeons perform trauma resuscitation. None of those outlying areas keep these injured children. The places that keep these children are actually often places that are close enough that a child could go to a pediatric center and they choose not to. The disparity that you can observe in the data are that well-off, affluent, insured children are less likely to get referred to a trauma center, the opposite of what we might expect in the usual disparities of care.

**Dr. Landgraf:** This reminds me of a conversation that took place at the American Academy of Pediatrics about 25 years ago, when we were developing asthma-specific instruments. There was a great deal of debate over what asthma really was and how we could define it; in each of the condition areas that we’re looking at in regard to TBI, we come back to that same issue. How is the diagnosis made?

One of the issues that I wanted to pick up on in Dr. MacKenzie’s presentation was the use of proxies. This will be a very critical issue in a pediatric study, because you will need proxies and you need to pay attention to the gender of the proxy, the relationship of the proxy to the patient, and so on.

Another issue is the mode of questionnaire administration. In NSCOT, data were collected by phone, although national norms for some measures were based on paper and pencil questionnaires. We do know that there is a mode of administration difference, so that would be something else to bear in mind. Another consideration is the use of internet-based responses.

We also need to address the representation of minorities and we might want to also begin to assess regional differences, because I think those are pronounced. Finally, when considering age strata, I would argue that in the 3 to 12 years age range there are vast differences in functional outcomes and quality of life that must be considered as well.
Dr. Yeates: I agree with some of the comments made about taking into account premorbid status, but I’d broaden that to include the community. Functional outcome for children after trauma has less to do with trauma care than it does with whether we keep them alive and then what kinds of resources are available to them educationally, and socioeconomically in their communities. The problem is that this is potentially confounded with the availability of trauma care. Unless we do something to try to measure the kinds of resources that are made available to patients after discharge from the hospital, you may end up showing that trauma care at a pediatric trauma care center looks better than others when, in fact, that’s just because of the availability of other resources in the community, including resources in the family. It’s not that easy to measure those sorts of environmental factors, but I think it would be important to do so, particularly for children because they’re so dependent on the systems in terms of outcomes.

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Prior Studies Comparing Outcomes From Trauma Care at Children’s Hospitals Versus Adult Hospitals

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Current evidence suggests that the majority of injured children are not treated in a pediatric trauma center. This review failed to provide a definitive answer to the question of whether injured children treated at children’s hospitals or adult hospitals with a dedicated pediatric unit have better outcomes than those treated at adult hospitals. However, it identified areas that have been addressed, and more importantly, uncovered others that are largely unanswered. In lieu of a prospective randomized trial, the next best way to address these unsolved issues would be a prospective collection of data with careful attention to assessing injury severity, physiologic response to the injury, associated injuries and comorbidities, along with resuscitation techniques, hospital resources, and manpower training.

In the United States, pediatric trauma is the leading cause of long-term disability and death in children. One in five children is injured every year.1 Annually, there are approximately 14 million episodes of injury to children less than 15 years of age, resulting in 9 million emergency room visits and 250,000 hospital admissions.2 In addition, injury is the leading cause of death among US children between the ages of 1 and 14 years, accounting for 6,500 deaths. In 2004, nearly 15,000 children below the age of 18 years died from major unintentional injuries. We should note, however, that death is not the only outcome of interest, because injury is also a leading cause of pediatric physical disability and psychologic morbidity. Furthermore, the total economic impact of childhood injuries is estimated at $347 billion.2

Our assignment for this symposium was to review the existing data comparing outcomes for children treated at pediatric versus adult hospitals. The question we are trying to address appears straightforward: “do injured children treated at children’s hospitals or adult hospitals with a dedicated pediatric unit receive better trauma care than those treated at adult hospitals?” The importance of this question is underscored by the significant public health problem posed by childhood injuries. The central premise to this question is that injured children have unique physiologic characteristics or specific requirements that are best served in an environment that has the expertise and the necessary equipment to provide pediatric care. There are important differences in the physiology, clinical presentation, and management of specific injuries in children. The American College of Surgeons Committee on Trauma recognizes this difference and states that injured children have special needs that “may optimally be provided in the environment of a children’s hospital with a demonstrated commitment to trauma care”.3 However, current evidence suggests that the majority of injured children are not treated in a pediatric trauma center. Although a comprehensive national survey has not been performed, a study by Segui-Gomez and colleagues evaluating pediatric trauma care in 18 states shed some light on this problem. The authors demonstrated that 47% of pediatric trauma care occurred in nontrauma centers; only 13% of injured children were treated in pediatric trauma centers, with some variance depending on the maturity of the state’s trauma system. Densmore and colleagues corroborated these findings in their recent review of the KID 2000 database, which showed that 89% of injured children received care outside of a children’s hospital.4

Not surprisingly, our review has failed to provide a definitive answer to this question. However, it has identified areas that have been addressed, and more importantly, uncovered others that are largely unanswered. This report will summarize our literature review, highlighting current best evidence data, and will identify areas in need of further data collection, analysis, and investigation.

Types of Trauma Centers

The main goal of regionalized Pediatric Trauma Centers (PTC) is to care for the injured child. Because there are not enough PTC to care for all injured children, many of these children are treated in Level I or Level II Adult Trauma Centers (ATC). However, questions have been raised regarding the quality and delivery of pediatric trauma care at ATC.

Potoka and colleagues conducted a retrospective analysis of 13,351 children who were treated in accredited trauma centers in the state of Pennsylvania from 1993 to 1997, and were entered in the Pennsylvania Trauma Outcome Study.5 The majority of the children in the study were treated at Level I or Level II ATC, or at ATC with added qualifications (AQ) to care for injured children (ATC AQ). The authors reported...
significantly better outcomes for injured children treated at PTC or ATC AQ, compared with those treated at ATC. Injured children treated at PTC or ATC AQ had a lower mortality rate compared with those treated at ATC I or at ATC II. In addition, for the more severely injured children with Injury Severity Score (ISS) >15, the mortality rate was significantly lower at PTC (11.9%) or ATC AQ (12.4%) compared with ATC I (21.6%) or ATC II (16.2%).

Sherman and colleagues used the same database Pennsylvania Trauma Outcome Study (PTOS) to measure “unexpectedness of survival outcome” at PTC versus ATC or ATC AQ. The authors used TRISS methodology to derive probability of survival (Ps) for specific injuries and compared it with the actual survival (As). Unexpectedness of survival was thus defined: “As-Ps”. The authors argue that this is a better approach to examine differences across trauma centers than looking at overall survival because mortality is low in pediatric trauma and the more severely injured children were unequally distributed across the various trauma centers. Although the authors reported that actual survival for children, with an ISS ≤16, or with an ISS >16, was worse at ATC, they concluded that unexpected survival was significantly higher at ATC I and ATC AQ than at PTC. The authors dismiss the criticism that TRISS probability of survival is derived using the Major Trauma Outcome Study (MTOS) database, which is heavily skewed toward the adult population, by quoting two studies that attempt to validate this methodology for children. Moreover, in their analysis, they employ mean rather than median values to look at skewed data, and do not use abbreviated injury score or Glasgow Coma Scale to grade the severity of solid organ or head injuries.

Osler and colleagues used the National Pediatric Trauma Registry to evaluate outcome of children treated at PTC compared with those treated at ATC. The authors reported a lower overall mortality rate for children treated at PTC. However, this survival advantage disappeared when they controlled for injury severity score, pediatric trauma score, and American College of Surgeons verification status. Indeed, the PTC had fewer severely injured children than ATC. The authors reported that American College of Surgeons verified trauma centers had significantly higher survival rates compared with non-verified centers.

More recently, Densmore et al. used a large database (KIDS) to evaluate outcomes of children treated in various settings. This heterogeneous group of 79,673 children was treated in a variety of settings including children’s or adult hospitals, with or without trauma center designation, and dedicated pediatric units in adult hospitals. The overall mortality, length of stay, and total hospital charges were significantly higher in children’s units and adult hospitals compared with those in children’s hospitals, even after adjusting for injury severity. For all injury types, the lowest mortality rates for the most common diagnoses occurred in a children’s hospital. This study corroborates previous reports by Potoka et al., and Segui-Gomez et al., who showed that the mortality rate for injured children treated in ATC AQ was higher than for those treated in PTC.

Most studies that suggest that ATC have similar or better outcomes than PTC use TRISS methodology to estimate probability of survival and compare actual with predicted survival rates, as discussed previously. In fact, during the early 1990’s, single institution studies argued that there was no difference between observed and predicted mortality for injured children treated at these centers and therefore, it was unnecessary to triage acutely injured children to PTC. However, mortality is a rather crude measure of outcome. As described below, the emphasis on nonoperative management of blunt splenic injuries in children, in particular, at PTC, has forced some of these centers to re-examine their initial position.

Management of Abdominal Trauma at Adult and Pediatric Trauma Centers

The management of intra-abdominal injuries has evolved during the past decade with more trauma centers demonstrating the effectiveness of nonoperative care. For instance, Patrick and colleagues reported that pediatric commitment in an adult trauma center resulted in a declining trend in operative treatment of blunt pediatric trauma, commensurate with that observed in PTC. Their retrospective review of pediatric trauma admissions during a 6-year period at Denver Health Medical Center demonstrated that 7% of injured children required laparotomy. During the first 3 years of the study, 6% of children age less than 5-years underwent operative management, whereas during the last 3 years, the rate dropped to 1%, even though overall ISS and types of injuries did not change significantly during the study period. Similarly, children 6 to 11 years of age also experienced a decline in operative intervention for blunt injury (4% for the first 3 years, 2% for the last 3 years of the study; not statistically significant).

The spleen is the most frequently injured intra-abdominal organ during blunt trauma. Before the 1970s, splenectomy was the standard treatment for patients with splenic trauma. The first report of successful nonoperative management (NOM) of splenic injuries was in 1968. Since then, NOM has become the standard of care. When operative intervention is required, splenic preservation utilizing partial splenectomy or splenorrhaphy has become the preferred approach. Currently, the success rate for NOM of splenic injuries without blood transfusion is above 90%. Even though many surgeons are using nonoperative treatment algorithms to manage splenic injury, there are differences in the utilization of this strategy depending on surgeon, hospital, and trauma center designation.

The majority of children with splenic trauma are treated in community hospitals and ATC. Historically, children with splenic injuries had higher rates of operation when treated at ATC than at PTC or ATC AQ. Potoka and colleagues have shown that the rate of operative intervention for blunt splenic injuries increases in patients who are treated at ATC compared with those treated at PTC or ATC AQ. The
same trend was also observed for liver injuries. In their study, they looked at all children (0–16 years) who sustained blunt splenic trauma during a 5-year period, as recorded in the PTOS registry. They stratified the patients into three groups based on their initial management: (1) nonoperative treatment, (2) splenorrhaphy, or (3) splenectomy. In their study population, overall, 15.1% of the patients required splenectomy. However, the incidence of splenectomy was less than 3% for children treated at PTC. In addition, children were less likely to undergo splenectomy at PTC than at ATC AQ, ATC I, or ATC II (OR: 0.26; CI: 0.09–0.72), regardless of spleen injury grade. Children who underwent successful nonoperative treatment were younger than those who required intervention. Predictors of splenectomy included patients with a Glasgow Coma Scale (GCS) score less than 8, (OR: 2.54; CI: 1.19–5.38), nonspleen abdominal injury (OR: 4.11; CI: 2.10–7.99), spleen AIS score 3 (OR: 3.59; CI: 1.54–8.35), AIS score 4 (OR: 4.62; CI: 1.91–11.20), AIS score 5 (OR: 10.72; CI: 4.53–25.38), and age 15 to 16 years old (OR: 2.07; CI: 1.07–4.02).

Failure of NOM can have serious consequences; therefore, patient selection is important. A recent multi-institutional review sought to evaluate the timeline and the characteristics of patients who fail NOM.13 During the 6 years of study, the failure rate for NOM was 5%; the overall mortality was 0.8%. Pediatric patients who sustained pancreatic injuries were more likely to fail nonoperative management (RR: 7.49; 95% CI: 3.74–15.01) compared with those who suffered other injuries. The patients who failed had higher ISS (28 ± 17) than those who underwent successful NOM (14 ± 10, p < 0.001). Severely head injured patients with GCS score ≤ 8 had a higher failure rate for NOM (RR: 5.09; 95% CI: 3.04–8.52). Factors associated with increased failure rate include bicycle-related injury, isolated pancreatic injury, more than one solid organ injury and an isolated grade 5 solid organ injury. The time to failure of NOM peaked at 4 hours and then declined during 36 hours from admission. Thus, continued surgical evaluation and assessment during the entire hospital stay is required to limit morbidity and mortality of the pediatric trauma patient.

Konstantakos and colleagues evaluated the success of NOM for splenic injury at ATC AQ. Children with higher ISS and Splenic Injury Scale score were more likely to fail NOM and require surgery.14 Nevertheless, the majority of children had successful splenectomy salvage (42 of 45 children). The variable that likely determined success of NOM was the Splenic Injury Scale score.

Potoka and colleagues also demonstrated in a previous study that the lower splenectomy rate at PTC was associated with improved outcomes.3 Thus, the higher incidence of splenectomy at all ATC compared with PTC in this study suggests that surgeons at ATC may use different criteria to perform splenectomy than those at PTC. Among patients treated at PTC who required operative intervention (7.2% of patients), less than a third of them underwent splenectomy; the others underwent splenorrhaphy. In contrast, the majority of children treated at ATC AQ, ATC I, or ATC II underwent splenectomy. More recently, these findings were corroborated by Mooney and colleagues, who reported a lower rate of splenectomy for children treated at freestanding pediatric hospitals compared with those treated at an adult hospital.11,15

Mangus and colleagues reported that the rate of splenectomy was lower for children with splenic injuries treated at a rural hospital compared with adults treated at the same hospital.16 In contrast, using a national population-based sample of inpatients (Healthcare Cost Utilization Project-NIS), Todd and colleagues demonstrated that pediatric patients with splenic injuries treated at urban nonteaching and rural hospitals had a higher rate of splenectomy than those treated at urban teaching hospitals.17 They postulate that urban teaching hospitals have more resources and manpower, such as an in-house operating room staff. However, the key determinant may be trauma center designation.

Recently, using multistate discharge data, Stylianos and colleagues demonstrated lower rates of operation for pediatric patients treated at trauma centers versus nontrauma centers.18 They conclude that benchmarks and consensus guidelines regarding splenic management should be distributed to trauma centers that do not specialize in pediatric trauma (as well as to nontrauma centers) given a trend toward failure of NOM in younger adults.19

The above assertion by Stylianos and colleagues is clearly supported by a study by Davis et al., who used statewide hospital discharge data to characterize differences in management of blunt splenic injury in children treated during a 9-year study period in the state of Pennsylvania.20 They reported that 23% of the children underwent operative intervention for splenic trauma. The majority of these children underwent total splenectomy or splenorrhaphy. As expected, children with higher ISS, grade of injury, or older age required more operative interventions. Not surprisingly, mortality was higher in this group. An increased likelihood of operative management was observed in ATC AQ and ATC I, compared with PTC. However, the frequency of operative intervention for splenic injuries progressively decreased during the years without any increase in mortality. According to the authors, the increase in successful nonoperative management of splenic injuries could be attributed to increased exposure to the literature promoting this approach. This report corroborates a previous study by Potoka et al. who showed that significantly more children underwent surgical exploration (especially splenectomy) for spleen and liver injuries at ATC compared with PTC, despite similar mean Abbreviated Injury Scores for spleen and liver.21

The surgeon’s training can also influence the management of a child with splenic injury. Mooney and Forbes examined the rate of operation for splenic injuries between pediatric surgeons and nonpediatric surgeons in New England, during a 9-year period. The probability of operation for splenic trauma was three times higher when the child was
cared for by a nonpediatric surgeon, even within a trauma center.21 Similarly, Keller and colleagues demonstrated that in the state of Vermont, pediatric surgeons had a 50% lower rate of operative intervention for blunt splenic injury compared with adult trauma surgeons, even when controlled for ISS.22 Mortality rates were similar for children treated by pediatric and nonpediatric surgeons. On the other hand, Jacobs and colleagues reported a 98% success rate with NOM of pediatric patients with splenic and hepatic injuries (average ISS 14.9) treated in a Level II community trauma center, and managed by nonpediatric trauma surgeons.23 This corroborates data obtained by D’Amelio and colleagues who reported that pediatric trauma outcomes by “adult” surgeons compared favorably with national standards.24

**Head and Neck Injury and Pediatric Critical Care**

The disparity in outcomes between PTC and ATC AQ, compared with ATC may be related, in part, to the management of pediatric head trauma. An estimated 50,000 children are permanently disabled each year because of traumatic injuries; most of them result from head and central nervous system injuries. Potoka et al. reported that children who sustained head injuries and who had a GCS score <8 had a mortality rate of 21.1% and 20.5%, respectively when treated at PTC or ATC AQ, compared with 31.3% and 27.5%, respectively, for those treated at ATC I or II. In contrast to the trend toward successful NOM of blunt abdominal injuries in pediatric trauma, more neurosurgical interventions, including decompression of epidural or subdural hematomas, and repair of skull fractures or open wounds, were performed at PTC than at ATC I or II combined. The mortality rate for children with severe head injuries who required neurosurgical procedures was lower at PTC and ATC AQ (13.5% and 15.7%) than at ATC I or II, (18.2% and 23.9%). For children with a GCS score >9, the type of trauma center where they were treated had no effect on overall mortality.3

Less common than head and cervical spine injuries are injuries to the anterior neck structures, including the larynx and trachea. A retrospective review of pediatric trauma patient treated during a 5-year period at the Children’s Hospital of Pittsburgh revealed a total of 9 blunt and 14 penetrating neck injuries, which accounted for 0.5% of all pediatric trauma admissions.25 All blunt neck trauma patients in this series underwent direct laryngoscopy and bronchoscopy; most of them showed positive findings, for example, including esophageal and tracheal laceration, laryngeal transection and laceration of the main stem bronchus. These injuries were treated promptly without significant morbidity or mortality. Children who sustain blunt neck trauma may not be adequately evaluated at ATC, because they may not have the proper instruments to perform laryngoscopy or bronchoscopy on a small child. The authors argue that children with these types of injuries should be evaluated at PTC or ATC AQ as soon as possible to reduce the morbidity and mortality associated with delay in diagnosis.25

A recent multistate epidemiologic study revealed an incidence of severe sepsis of 0.56 cases per 1000 population per year with more infants (5.6 per 1000) affected than older children (0.20 per 1000).26 The annual national cost of sepsis in the pediatric population was nearly $2 billion. There are differences in the incidence and mortality of sepsis between children and adults.27 Sepsis is the principal cause of delayed mortality in the injured patient. The outcomes for pediatric trauma patients managed at institutions that do not have a dedicated pediatric intensive care unit (PICU) may be inferior. A retrospective study by Farrell and colleagues, using data from the New York State Trauma Registry, showed that children (<13 years), who suffered blunt trauma, were triaged appropriately to dedicated centers with a PICU.28 This led to a lower mortality rate for the more severely injured children treated in PICUs than those treated in an adult intensive care unit.

**Functional Outcome of Injured Children**

As stated earlier, overall mortality is a relatively insensitive marker of outcome for pediatric trauma because of the low mortality rate of injured children. However, the resulting morbidity from childhood injuries may be significant. The impact of head injury on disability, for example, can be quite severe and is heavily influenced by the type of treatment provided in a trauma center. Furthermore, financial, social, and personal strain may be quite severe for families whose children have suffered long-term disability as a result of injuries.29 Therefore, measuring functional outcome in surviving patients may provide a more sensitive marker of outcome in this group. Potoka and colleagues sought to determine the impact of PTC and ATC on the functional outcome of the injured child. Using Pennsylvania data, the authors determined that severely injured children (ISS >15) had significantly lower dependency for feeding, locomotion, social interaction, and expression categories, if they were treated at PTC compared with ATC AQ.30 Severely head injured children with a GCS score <8, treated at PTC, showed significantly improved social interaction and expression categories, compared with those treated at ATC AQ and ATC I. The improvement in functional outcome for head injured patients may have been caused, in part, by the presence of dedicated neurosurgical staff performing necessary interventions that ultimately led to improved results, as well as by an experienced critical care staff.3

**Summary**

Our task was to determine whether injured children treated at PTC have a better outcome than those treated at ATC. Our review of the literature suggests that this question is still unanswered. Although the data suggest better overall mortality rate, more successful nonoperative treatment of blunt abdominal injuries, and improved functional outcome for severely injured children treated at PTC, others have failed to demonstrate such differences for children treated in ATC AQ or ATC in general. A major difference between the
conflicting reports centers around the use of TRISS methodology to predict probability of survival for pediatric trauma victims; a subject that has been hot-contested because of the perception that the MTOS database used to establish the normative values is skewed. Still, there have been reports that validate MTOS for children. Thus, the controversy persists. In lieu of a prospective randomized trial, the next best way to address these unsolved issues would be a prospective collection of data with careful attention to assessing injury severity, physiologic response to the injury, associated injuries and comorbidities, along with resuscitation techniques, hospital resources, and manpower training.

Nonetheless, our analysis revealed some important observations: (1) most injured children are treated in adult facilities; (2) injured children treated at a children’s hospital had a better overall outcome than those treated in an adult hospital, when trauma center designation was not available; (3) injured children treated at a trauma center did better than those treated at a nontrauma center, or at a children’s hospital that was not a verified trauma center; and (4) injured children treated in PTC may have improved survival and functional outcome compared with those treated at ATC. However, the paucity of PTC makes it impractical to care for all injured children in PTC. Consistent with the recommendations by Stylianos et al., educating practicing adult trauma surgeons on the nuances of pediatric care may ultimately erase the apparent differences in outcome between PTC and ATC.

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Dr. Fallat: This talk incorporates the consensus comments of Drs. Richard Mullins and Brian Diggs of Portland, OR, and myself.

I live in Kentucky, where there are four and a half million people and three trauma centers verified by the American College of Surgeons; my hospital is not one of them. Kosair Children’s Hospital is the defacto regional pediatric trauma center serving Western Kentucky. There are two Level I trauma centers, an adult center in Louisville and an adult and pediatric center in Lexington, and a Level III center in Campbellsville. We have vast expanses of the state that are not served by trauma centers in proximity.

Why is our free standing pediatric hospital not verified? There are only four surgeons, and one doesn’t take a full component of call. We often work 3 or 4 days in a row. The limited number of surgeons precludes in-house call, so we may get there 21 minutes after a trauma activation instead of 15, and thus will not meet the criteria of the American College of Surgeons for a Level I or II center. This doesn’t necessarily mean that we don’t render good trauma care. I live in a rural state without an organized trauma or EMS system. I think that any study designed to focus on systems issues should also include data from states that are still struggling with system building, since I doubt that Kentucky is alone in this regard.

The task of our group was to discuss the limitations of prior studies comparing outcomes and to discuss how a new study might be structured to address these prior limitations. We were working under the hypothesis that the care of injured children is superior in pediatric hospitals; however, we all separately concluded that the pediatric trauma literature is so diverse in definitions, organization, and structure of analyses that drawing a specific evidence-based conclusion is currently impossible. There is a lack of consensus about age limits, types of injuries, relevant outcomes, and the methodology of comparing these outcomes.

First let me pose this question: When do children become adults and is it important to have consensus? The American Heart Association has made a physiologic distinction into pediatric and adult age groups based on puberty. Sociologically, some people think adulthood is reached when an individual can vote, drink alcohol, or live independently. Perhaps it’s the age when an adult surgeon is comfortable taking care of a child. To some surgeons, it is mechanism dependent, e.g., when someone can drive a car or commit intentional, violent trauma. In some communities, EMS uses judgment to determine where to take patients (pediatric vs. adult center) based on the mechanism of injury or behavior that led to the event.

What injuries are relevant for a pediatric study? Should we be looking at only high-risk injuries, such as traumatic brain injury and blunt abdominal trauma? Should we exclude or include burns? Dr. Guice told us that young children die from burns, but burn care is not available at every trauma center. Should orthopedic trauma be included, considering the paucity of specialists in this discipline? The most common cause of death is traumatic brain injury, but orthopedic trauma is an important cause of long-term disability. The spectrum of injuries should include those where expertise is needed and often lacking.

Next consider the definition of a trauma patient. When we refer to trauma system development, we are technically talking about the 10% of injured patients who require rapid diagnosis and treatment by a team of professionals supported by appropriate resources to decrease the risk of death or disability. However, this definition is subject to local interpretation. Many times each month, a child with minor head trauma is transported by air to our hospital and goes home the next day. Although the reasons for transfer may be multifactorial, it may simply be because no one at the referring hospital will take care of the child. Many providers are afraid of children, think they don’t have the necessary intellectual skills, or they don’t have the necessary equipment in their emergency department or hospital. Any study we design should examine the question of how we can change the system to make individual providers more comfortable taking care of children who don’t need to come to a trauma center.

What outcomes are relevant? In-hospital and late mortality are certainly important, but the main emphasis should be on functional outcome, both at discharge and late, as well as rehabilitation concerns—where children can get it, how much does it cost, and how far do they have to travel to get the treatment they need.

How should outcomes be analyzed in a pediatric patient population? Two methods we’ve heard about are TRISS methodology and population-based studies. Only 8% to 10% of the patients were children in the original methodological development of TRISS, and children were not included in developing the models. Most pediatric analyses using TRISS methodology have shown that the outcome of hospitalized children is better with more survivors than predicted, suggesting that the use of this methodology in children’s studies may be flawed. Ideally, children need to be included in the...
future development of mathematical models for outcome assessment, and the models should be applicable to population-based studies.

What have been the outcomes to date using population-based methodology? There seem to be certain trends in the data: crude death rates are lower in pediatric centers; survival may be improved (although not consistently) for severe traumatic brain injury; children are less likely to have a splenectomy; children may have improved functional outcomes after certain anatomic injuries. But as we’ve heard, all of these differences may be situational and caused by multiple influences including what services an individual hospital can provide, and the resources that are available to children, both before and after injury.

A national pediatric trauma study should recognize the concept of regionalization, provide consensus definitions, and collect sufficient data to allow for meaningful conclusions. Children account for 27% of all ED visits in the United States, but the majority of children receive care in general hospitals, and only 6% of EDs have all of the essential pediatric supplies and equipment. Many emergency providers receive little training or CME in pediatric emergency care. Pediatric competencies have yet to be defined in many disciplines, including prehospital care, nursing, and some of the medical subspecialties. One way to improve pediatric trauma care would be to appoint pediatric coordinators to provide more leadership in hospitals, and to employ the regionalization concept by categorizing hospitals based on pediatric capabilities. There is a wide and variable spectrum of pediatric care available that could stand to improve at all levels.

Ultimately, we also need to define who benefits from pediatric trauma care rendered in a pediatric hospital. We must define pediatric capabilities. What criteria could be used to define a pediatric trauma capable hospital: pediatric ICU, number of annual admissions, freestanding versus “hospital within a hospital”, pediatric trauma center designation, and specialist availability may all be relevant in this definition. Initially, data should be collected beyond the assumed relevant age and include physiologic, sociologic, and mechanistic factors that will help qualify some of the issues being discussed at this conference. Relevant outcomes need to be considered, including late functional outcomes, and the social and financial repercussions of trauma on the family.

Should this be an inclusive or exclusive study? An inclusive study would enroll all injured children. An exclusive study would be limited to the 10% to 20% of seriously injured children with the highest risk of death. The former design would allow a bigger picture of who benefits from pediatric trauma care, and how regionalization can have an impact on the delivery of care.

As individuals and leaders interested in the global delivery of health care to children, we should strive to raise the level of education of all medical practitioners who might encounter a hurt child. Providers need enough knowledge and skill to increase their comfort level so that they can make adequate clinical decisions about injuries and their treatment, to transfer children when appropriate, and to keep them at home when injuries are minor, thus employing the concept of regionalization. We should design a study to ask questions that will enable system changes to improve care for all injured children.

**Dr. Cooper:** I have little to disagree with in any of what has been said. Many of us as pediatric trauma professionals have advocated that general surgeons in the community who do not have the benefit of a pediatric ICU and no consistently reliable means of getting patients transferred to big centers, manage injured children operatively, because that’s the safest thing to do in your community. I then find it a bit strange that we then publish articles critical of this operative management. I certainly agree with Dr. Jurkovich that basing our construct on one little organ resting in the left upper quadrant may not be the wisest course.

**Dr. Tepas:** I want to emphatically agree with what Dr. Fallat said about the statement, “it is what it is”. We’re trying to design a study that lets us demonstrate a return on investment, which has two aspects. One is the cost for care to achieving return of injured children to normalcy. The other part is the child itself, and defining quality of life.

We need to move far beyond discussion of mortality and treatment of splenic injuries and pay attention to brain trauma, outcomes, and subtle impairments. All of these are critical metrics. Our mission is to convince society that the return on investment is worth the effort. We have to define what that return on investment looks like and then refine the effort.

**Dr. Dean:** We spend a lot of time talking about how the other hospital should have done a better job and how we’re going to improve our management at levels 3, 4, and 5 trauma centers. When a children’s hospital says that it can’t become a Level I trauma center, there’s a commitment question. We need to ask these administrators why is there not that commitment? If we’re going to tell the rest of the trauma system that it ought to improve, children’s hospitals, which are the de facto referral network for serious pediatric illness and injury, have to be committed to providing high quality trauma care as well.

**Dr. Fallat:** A portion of my colleagues in pediatric surgery lack interest in taking care of trauma patients. In some cases, this is because of lack of time and manpower. There are pediatric surgeons who participate by taking care of the inpatient victim after the adult trauma team resuscitates the patient. This fractionated care feels inappropriate to some, but is not completely unlike that rendered by the adult orthopedic surgeon or neurosurgeon who takes part time trauma call because they are the only one in their specialty in a given community. Other surgeons may be worried about litigation, or decline to take care of trauma patients because the hospital administration doesn’t support them financially to take call.

**Dr. Henri Ford:** Just to voice a dissenting opinion, I do think that it’s an issue of leadership. If we really look at trauma as the number one disease of childhood, those of us...
who are running pediatric surgery programs need to bring it to the forefront and establish it as a priority. If it is indeed a children’s hospital, if we’re really committed to the well being of children, then we have to address the leading killer of children, and not just pay lip service to it.

Dr. Oldham: The objective of gathering here today includes defining where we are with pediatric trauma care in 2007, but also to lay out a roadmap for how it ought to be in years to come. As we design a study, we should start by acknowledging and accepting our limitations currently, whether it’s our training, our resources, or our institutions. I did make an appeal for us to be pragmatic, but I think that we should look forward to what we think will serve as the best system of care.

Dr. Jurkovich, I will take issue with your comment about the variation in care that exists and the fact that we potentially need to accept something that’s less than ideal. In the United Kingdom a few years ago, a study examined anesthesia services in their regional hospitals and asked each of the participants to define how the care was provided, and then asked if they would have their child cared for in this environment? More than half of the respondents said no. I would challenge all of us to answer that same kind of question with regard to pediatric trauma care. I don’t have the illusion that it will ever be perfect, but it can surely be better, and it’s our charge to design systems, whether it’s education or transport or changing the training and the personnel and the systems to do that. I do think we should be looking to change some of those variations.

Dr. Clark: Trauma care is difficult, and trauma studies are difficult for many of the same reasons. We’re dealing with a dynamic process and intervening at different times in the process of the disease. It’s like dealing with different stages of cancer. It’s a lot easier if we could do elective surgery on patients whose status is well defined anatomically and by the stage of the cancer that progresses in their body. With trauma patients, we need to pay attention to what point we get the patient; the splenectomy rate might be very different if you’re seeing the patient while they’re acutely bleeding versus after they’ve been transferred to you because of an abnormal CAT scan and all you have to do is just watch them get better.

If we’re going to plan a study, we need to include something to reflect this dynamic situation. How long has it been since the patient was injured? Have they been treated somewhere else before they get to you? That’s why I made a plea earlier for including all the patients in the whole EMS system in any study, so that we’re not just looking at some little window of time where the patient is on their downward curve and we’re just catching them at a different location in that curve.

It’s also very easy to lower the splenectomy rate by having a more sensitive CT scanner that identifies very small lesions of the spleen. The technology makes a difference in categorizing patients. My plea would be to look at the whole picture, so that a child who is injured in DuPont Circle and the child injured in rural Kentucky, both have the best possible chance, given the resources and the geography that’s available. We need to have a very broad view of what we’re hoping to accomplish, and let’s try to address the big picture and not just get focused on those small differences between hospitals that probably have nothing to do with quality of care.

Dr. Adelson: I would agree with Dr. Fallat that there is a very limited resource in pediatric neurosurgery. There are only approximately 150 pediatric neurosurgeons in the American Society of Pediatric Neurosurgery who have met the accreditation requirements to gain membership; perhaps this number could be expanded to 180 or 200 who are really specifically interested in pediatric neurosurgery and would be willing to participate in pediatric neurotrauma. If we’re trying to involve specialists in the care of the trauma patient, particularly in pediatric trauma, we need to begin to look at the best allocation of those resources. I think that pediatric neurosurgeons are proponents of needing to localize where that specialty care is being done. However, in addition, we need to insure that care being delivered is of the highest quality. I would agree with the concept of education, proper equipment, and obviously empowering individuals to be a part of a trauma system. I also agree with Dr. Ford that we need leadership in that area.

Although we likely agree with these concepts, how do we translate that into, first, a study, and how do we then define where we are now and where we want to be? I would posit that by the time the study gets funded, finished and all the data analyzed a decade from now, are we really in the same position as we are now? We need to weigh doing a study that may be out of date by time it is done versus going forward now, from a policy standpoint, to really try to begin to address some of these other issues.

Dr. Vavilala: In anesthesiology, as part of the acute care team, we long ago recognized that specialized care or expertise provided better outcomes. But we recognize that acute care for children probably wasn’t impacted that much, if you look at the entire pediatric age group. However, children under the age of 2 probably have better outcomes if they’re treated at facilities where a pediatric anesthesiologist provides care for them. I would argue that instead of looking at all children requiring care at a particular institution, in this study we try to identify which children specifically need to be sent where, not necessarily treat children as a single group. We should identify those specific factors, whether demographic characteristics or procedures or disease processes, then make our decisions based on that.

The other issue is that it’s very important to identify the processes that lead to better outcomes, because that is what will eventually improve the system as a whole. I don’t see this as a battle between process and structure relating to outcome if we look at quality of care, but I think this study should focus on process driving the change.

Dr. Kurt Newman: I was struck by Dr. Jurkovich’s question asking why the spleen is the index injury. I think it
is because splenic trauma may be the injury for which care seemed to be most different in the different types of hospitals. If we looked at pelvic injuries or vascular injuries, I worry that if we weren’t part of a system that had an adult trauma center, our outcomes might not be as good. In addition to the resource and training issues that we’ve just heard about in pediatric neurosurgery and pediatric anesthesia, there are some other manpower issues. There are only 8, 9, or 10 pediatric orthopedic surgeons being trained per year, and they’re not interested necessarily in trauma. The progression of vascular surgery toward a much more interventional-based approach that most pediatric surgeons aren’t necessarily comfortable with anymore requires resources that children’s hospitals may or may not have. For the more severe injuries such as pelvic injuries and vascular injuries, defining a center as a Level I trauma center or pediatric trauma center may not be as useful an analysis as identifying the resources that can be brought to care for that particular patient with that particular injury.

Dr. Mooney: As part of my work for the American College of Surgeons, I’ve been to most pediatric trauma centers in the United States. There’s tremendous variation in resources available even within the categories we call a Level I or a Level II pediatric trauma center. Some places have in-house pediatric surgeons who respond to the patients’ bedside. Some places have adult trauma surgeons that respond and do the initial resuscitation. Some places have a whole host of pediatric surgeons. Some places scrape by with one and a half surgeons and rely on adult-oriented people to cover.

So as we move forward in trying to look at this area, it’s very important to look at the specific resources that are applied to the trauma patient and focus less on the very nebulous terms “adult hospital” and “pediatric” or “children’s hospital”, because those definitions really don’t mean what they used to mean.

Dr. MacKenzie: At this time it may be a little bit premature, given where we are in our overall discussions, but I wanted to summarize the discussion to date. Many people have talked about the importance of taking a systems-oriented or community-oriented approach to looking at this problem of treating pediatric trauma. There’s an ongoing effort for more than 10 years funded by the Robert Wood Johnson Foundation, the Community Tracking Study that involves over 50 communities around the country. It tracks the healthcare resources in the community as well as population-based outcomes. This could possibly be an opportunity to look at the communities involved in this study and maybe use that as a basis for selecting communities. By doing so, we already would have a lot of information about those communities in terms of their resources. It’s not just trauma centers or trauma resources, but it’s community resources, and I think this could give us a rich place to start.
Comparing Processes of Pediatric Trauma Care at Children’s Hospitals Versus Adult Hospitals

Steven Stylianos, MD, and Avery B. Nathens, MD, PhD

Comparing treatment of pediatric injury by hospital type or physician expertise has often created more controversy than conformity. Three key components that help define quality of care include infrastructure, process, and outcome. This report highlights studies that compared processes of care by physician and hospital expertise with regard to injured children. During the past 15 years, numerous studies have compared both hospital and physician expertise in the processes of pediatric trauma care. From these studies, it is clear that evaluation of processes of care is equally important as evaluating outcome, especially when mortality is the outcome variable. Future studies should examine other aspects of care in addition to surgical processes that might impact either rates of complications or long-term outcomes.

Ernest Amory Codman, an American surgeon, introduced the concept of “the end result idea” to encourage scrutiny of outcomes in hospitalized patients in the early 1900s. Codman suggested that this new approach be used to compare hospitals and surgeons. Thus, the era of benchmarking began.1 Let’s jump ahead 60 years to the reports of Wennberg who reported remarkable differences in the rate of carotid endarterectomies, tonsillectomies, and hysterectomies in various geographic regions within the United States.2,3 These early reports ushered in the era of evidence-based medicine in surgery.

The issue of significant variation in clinical practice patterns has attracted the attention of specialty organizations, payors, government health agencies, and the public. This variation raises questions of concern about efficacy and cost relative to the care provided. The establishment of national benchmarks is an increasing priority.4 With this in mind, comparing treatment of pediatric injury by hospital type or physician expertise has often created more controversy than conformity. Three key components that help define quality of care include infrastructure, process, and outcome. This report will highlight studies that compare processes of care by physician and hospital expertise with regard to injured children. We will look briefly at pediatric neurosurgical, orthopedic, and nonsurgical processes of care but focus primarily upon the treatment of children with blunt spleen injury.

OPTIMAL PEDIATRIC TRAUMA CARE: COMPARING HOSPITAL AND PHYSICIAN EXPERTISE

The contemporary debate regarding the optimal setting for pediatric trauma care delivery has existed for more than two decades. The Major Trauma Outcome Study (MTOS) and Trauma and Injury Severity Score methodology have been used in several studies to highlight care of the pediatric trauma victim in adult trauma centers (ATC). These studies often described the experience at a single center and relied solely on mortality and Z statistics, which can fall short in defining efficacy.5–8 The expectation that pediatric trauma centers (PTC) would have better results than ATC caring for injured children seems logical, but it may be argued that the higher volumes seen at an ATC could more than offset the potential advantage of a dedicated PTC. The controversy over the optimal setting for the delivery of care for injured children is complicated further when one considers that trauma surgeons might work at an ATC, yet provide call coverage for a PTC; alternatively, pediatric surgeons might provide care for pediatric patients in ATC. Finally, few studies have gathered data prospectively to allow adequate adjustment for differences in case mix.

During the past 15 years, numerous studies have compared both hospital and physician expertise in the processes of pediatric trauma care. Although not considering potential differences in the risk of death, Rhodes et al. found equivalent mortality and no difference in the incidence of preventable deaths among pediatric trauma patients treated at a Level I ATC from 1986 to 1991 when compared with benchmarks established in the MTOS.5 When compliance with audit filters was evaluated, performance in children was no different than that in the adult population. An alarming finding in this cohort was that nonoperative treatment of liver and spleen injuries was employed in only 53% of patients, a substantial
difference with published pediatric institutional experience. D’Amelio et al. found survival of pediatric trauma patients treated by adult trauma surgeons to be statistically similar to MTOS benchmarks. However, the incidence of nonoperative treatment of spleen injury was 62%, whereas concurrent rates of nonoperative treatment for liver and spleen injuries were 80% to 85% in PTC. From these studies, it is clear that evaluation of processes of care is equally important as evaluating outcome, especially when mortality is the outcome variable.

In contrast, a recent study by Potoka et al. analyzed >13,000 injured children from the Pennsylvania Trauma Outcome Study (PTOS) treated between 1993 and 1997 and used mortality as the major outcome variable to compare care at two regional PTC versus 24 ATC. Mortality was significantly less ($p < 0.001$) at PTC and ATC with added qualifications in pediatric trauma care than in Level I or II ATC. Using a national US sample, Densmore et al. found that in-hospital mortality, length of stay, and hospital charges were all significantly higher when seriously injured children (Injury Severity Score >15) were treated in adult hospitals compared with children’s hospitals.

## PROCESSES OF CARE

### Treatment of Blunt Spleen Injury

Early attempts at comparing processes of care in pediatric trauma focused on treatment of blunt spleen injury. Hospital and physician expertise were used as the basis of comparison in the treatment of children with blunt splenic injury in six studies between 1985 and 1998 (Table 1). Keller and Vane reported a marked difference in the incidence of operative treatment of spleen injury within a single trauma center, depending on physician expertise (pediatric surgeon vs. nonpediatric surgeon). The overall splenectomy rate nearly doubled in children treated by adult surgeons (24% vs. 13%, $p < 0.05$). Transfusion requirement, as well as hospital cost, was lower for patients managed nonoperatively. Frumiento and Vane showed a significant increase in the use of nonoperative treatment for pediatric splenic injury in Vermont between 1985 and 1995 after institution of state-wide educational programs. The rate of nonoperative treatment of pediatric splenic injury at the state trauma center remained significantly higher (77% vs. 57%, $p < 0.001$) than at rural hospitals. This disparity remained despite the overall improvement. Mooney et al. reported upon the treatment of 126 children with splenic injury using the New Hampshire Uniform Hospital Discharge Data Sets. The large majority of patients (84%) were treated by adult surgeons at general hospitals. Adjusted operative rates were 10% at the Children’s Hospital compared with 41% at general hospitals ($p < 0.005$). The authors concluded that the overwhelming majority of splenectomies and splenorrhaphies could have been avoided if general hospitals treated children with splenic injury in a manner similar as the treatment at the Children’s Hospital. In the Potoka analysis noted earlier, >13,000 injured children from the PTOS were treated from 1993 to 1997 at two regional PTC and 24 ATC. Significantly more children had successful nonoperative treatment for spleen (91.5% vs. 62.1%, $p < 0.001$) and liver injury (96.6% vs. 84.1%, $p < 0.05$) at a PTC compared with an ATC despite similar injury severity.

In contrast, two reports on children treated at single institutions during the mid to late 1990s found rates of nonoperative treatment for pediatric splenic injury by adult trauma surgeons similar to the above-referenced pediatric centers. These two studies highlight the fact that dedicated trauma surgeons familiar with contemporary processes of care advanced in pediatric centers, can achieve excellent results.

However, several recent studies provide a basis for ongoing concern regarding disparity of treatment in children with blunt spleen injury. Using large nonselected databases and adjusting for risk, these studies indicate that the disparity is substantial and continuing on a regional and national basis (Table 2). Todd et al. used the Healthcare Cost and Utilization Project’s National Inpatient Sample, which contains a sample of discharges from 1,300 hospitals in 28 states (representing 20% of all hospital discharges in the United States). Children with splenic injury treated at rural hospitals had a risk-adjusted odds ratio for laparotomy of 1.64 (95% CI 1.39–1.94) when compared with those treated at an urban teaching hospital. The American Pediatric Surgi-

### Table 1: Studies Comparing Operative Rates for Pediatric Blunt Spleen Injury

<table>
<thead>
<tr>
<th>References</th>
<th>Study Period</th>
<th>No. of Patients</th>
<th>Study Site</th>
<th>Rate of Operation</th>
<th>$p$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Keller</td>
<td>1985–1991</td>
<td>41</td>
<td>Single center</td>
<td>17% PS vs. 61% NPS</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Frumiento</td>
<td>1985–1990</td>
<td>127</td>
<td>State UHDDS</td>
<td>64.5% TC vs. 92.3% RH</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>1990–1995</td>
<td>140</td>
<td>State UHDDS</td>
<td>23.1% TC vs. 43.1% RH</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Mooney</td>
<td>1991–1994</td>
<td>126</td>
<td>State UHDDS</td>
<td>10% PTC vs. 41% GH</td>
<td>&lt;0.005</td>
</tr>
<tr>
<td>Potoka</td>
<td>1993–1997</td>
<td>772</td>
<td>State Trauma Outcome Study</td>
<td>8.5% PTC vs. 32% ATC</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Jacobs</td>
<td>1992–1998</td>
<td>54</td>
<td>Single center</td>
<td>8% PS vs. 23% NPS</td>
<td>NS</td>
</tr>
<tr>
<td>Myers</td>
<td>1993–1998</td>
<td>35</td>
<td>Single center</td>
<td>8% NPTR vs. 11% NPS</td>
<td>NS</td>
</tr>
</tbody>
</table>

PS, pediatric surgeon; NPS, nonpediatric surgeon; UHDDS, Uniform Hospital Discharge Data Set; TC, trauma center; PTC, pediatric trauma center; ATC, adult trauma center; GH, general hospital; RH, rural hospital; NPTR, National Pediatric Trauma Registry.
Table 2 Studies Comparing Operative Rates for Pediatric Blunt Spleen Injury

<table>
<thead>
<tr>
<th>References</th>
<th>Study Period</th>
<th>No. of Patients</th>
<th>Database</th>
<th>Adjusted Odds Ratio (95% CI) For Operation</th>
<th>Ratio</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Todd17</td>
<td>1998–2000</td>
<td>2569</td>
<td>HCUP-NIS</td>
<td>1.64 (1.39 – 1.94) RH vs. UTH</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Stylianos18</td>
<td>2000–2002</td>
<td>3232</td>
<td>State UHDDS</td>
<td>2.1 (1.4 – 3.1) NTC vs. TC</td>
<td>34:66</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Mooney19</td>
<td>1990–1998</td>
<td>2631</td>
<td>NEPTD</td>
<td>3.1 (2.3 – 4.4) NPS vs. PS</td>
<td>68:32</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Bowman20</td>
<td>2000</td>
<td>2851</td>
<td>KID2000</td>
<td>5.0 (2.2 – 11.4) GH vs. CH</td>
<td>87:13</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Davis21</td>
<td>1991–2000</td>
<td>3245</td>
<td>State UHDDS</td>
<td>6.2 (4.4 – 8.6) ATC vs. PTC</td>
<td>84:16</td>
<td>&lt;0.0001</td>
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</tbody>
</table>

HCUP-NIS, Healthcare Cost and Utilization Project’s National Inpatient Sample (1,300 hospitals in 28 states; 20% of all hospital discharges in United States); RH, rural hospital; UTH, urban teaching hospital; NEPTD, New England Pediatric Trauma Database; PS, pediatric surgeon; NPS, nonpediatric surgeon; UHDDS, Uniform Hospital Discharge Data Set; PTC, pediatric trauma center; ATC, adult trauma center; KID2000, Kids’ Inpatient Database of the Healthcare Cost and Utilization Project, Agency for Healthcare Research and Quality (2,784 hospitals in 27 states; 2.5 million pediatric discharges); CH, children’s hospital; GH, general hospital; TC, trauma center; NTC, nontrauma center.

Table 3 Operative Rate in Children with Spleen Injury18

<table>
<thead>
<tr>
<th>Injury Description</th>
<th>Trauma Center (%)</th>
<th>Nontrauma Center (%)</th>
<th>p</th>
<th>APSA Benchmarks (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiple injuries</td>
<td>15.3</td>
<td>19.3</td>
<td>&lt;0.001</td>
<td>11–17</td>
</tr>
<tr>
<td>Isolated spleen</td>
<td>9.2</td>
<td>18.5</td>
<td>&lt;0.0001</td>
<td>0–3</td>
</tr>
<tr>
<td>Injuries (n = 1299)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Isolated spleen</td>
<td>9.2</td>
<td>18.5</td>
<td>&lt;0.0001</td>
<td>0–3</td>
</tr>
<tr>
<td>Injuries (n = 1933)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total (n = 3,232)</td>
<td>12.1</td>
<td>18.8</td>
<td>&lt;0.0001</td>
<td>5–11</td>
</tr>
</tbody>
</table>
injury, so that these results are not limited to highly selected centers. Focusing educational programs and evidence-based management guidelines on centers with higher rates of splenectomy may be the next step to improve the rate of splenic conservation. Although the impact on in-hospital mortality might not be a relevant endpoint because it is infrequent, these patients are at higher risk for overwhelming post-splenectomy infection (OPSII) and complications related to laparotomy such as adhesive small bowel obstruction and incisional hernia.

**Neurosurgery and Orthopedics**

The recent study by Potoka et al. noted previously, analyzed >13,000 injured children from the PTOS treated from 1993 to 1997 and used mortality as the major outcome variable to compare care at two regional PTC versus 24 ATC. Mortality was significantly less ($p = 0.001$) at PTC and ATC with added pediatric qualifications than in Level I or II ATC. Further analysis revealed significant differences in processes of care. Children who sustained moderate or severe head injuries were more likely to undergo neurosurgical intervention (12% vs. 7.2%, $p < 0.05$) and had decreased mortality (21.1% vs. 31.3%, $p < 0.005$) when treated at PTC. Unfortunately, risk adjustment was difficult retrospectively and is perhaps insufficient to allow definitive conclusions.

Optimal management of severe traumatic brain injury might differ considerably in adults and children. For example, aggressive use of decompressive craniectomy has resulted in a better functional prognosis with a better functional prognosis. Aggressive use of decompressive craniectomy has resulted in an improvement in outcomes. For example, radiation exposure in adult trauma patients is sufficiently high that estimates of almost 200 excess deaths resulting from cancer per 100,000 population have been made. In another analysis, radiation exposure seems less in pediatric patients, but the extent to which this varies across centers or PTC and ATC is unknown. Given that the risk of cancer is highly correlated with the age and dose of radiation exposure, this seems to be an important process measure requiring further evaluation in pediatric trauma.

Additionally, there might be considerable variation across types of centers where there are very specific equipment needs in pediatric trauma patients. For example it relates to interventional radiology, the lack of availability of pediatric introducers and other similar equipment in adult centers might impact on the decision making as it relates to the use of this resource. Similarly, familiarity with the pediatric airway and the necessary equipment may alter the approach or risks in pediatric patients cared for in ATC as compared with PTC.

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**Table 4** Pediatric Surgery Benchmarks for Operative Rate in Children with Spleen Injury

<table>
<thead>
<tr>
<th>References</th>
<th>Database</th>
<th>Study Period</th>
<th>No. of Patients</th>
<th>Operative Rate: Pediatric Surgeon or Children's Hospital-PTC (%)</th>
<th>Spleen Injuries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bowman20</td>
<td>KID 2000 – AHRQ</td>
<td>2000</td>
<td>363</td>
<td>3</td>
<td>All</td>
</tr>
<tr>
<td>Davis21</td>
<td>Pennsylvania Trauma Outcome Study-UHDDS</td>
<td>1991–2000</td>
<td>507</td>
<td>5</td>
<td>All</td>
</tr>
<tr>
<td>Mooney19</td>
<td>New England Pediatric Trauma Database-UHDDS</td>
<td>1990–1998</td>
<td>866</td>
<td>11</td>
<td>All</td>
</tr>
<tr>
<td>Stylianos23,24</td>
<td>APSA Trauma Committee-Multicenter registry</td>
<td>1995–2000</td>
<td>652</td>
<td>3</td>
<td>Isolated</td>
</tr>
<tr>
<td>Mooney22</td>
<td>Children's Hospital-Boston Trauma registry</td>
<td>1993–1999</td>
<td>82</td>
<td>0</td>
<td>Isolated</td>
</tr>
</tbody>
</table>

KID2000, Kids’ Inpatient Database of the Healthcare Cost and Utilization Project, Agency for Healthcare Research and Quality (2,784 hospitals in 27 states; 2.5 million pediatric discharges); UHDDS, Uniform Hospital Discharge Data Sets; PTC, Pediatric Trauma Center.
The risk of pediatric adverse drug events seems to be higher than that seen in adult patients. Given the complexity of drug dosing in children, it is plausible that the rates of errors are significantly higher in pediatric patients cared for in adult centers. Additionally, the perceptions of the potential risks and benefits associated with analgesia differ when adult and pediatric patients are compared, leading to less aggressive approach to pain management in children. The extent to which this might affect both short and long-term nonmortality outcomes is unknown and warrants further exploration.

**DISCUSSION**

The optimal care of pediatric trauma patients requires that the responsible trauma surgeon and treating institution have specific expertise and resources. Dissemination strategies to insure expertise should include presentation at meetings and publication in journals influencing adult trauma surgeons and general surgeons. Incorporation of benchmarks as part of a state or regional trauma system QA/QI process and as a site verification audit filter are also possible strategies. Funding would be required to create audio/visual educational tools that could be sent to state trauma leaders for distribution. Finally, reimbursement decisions will be influenced by performance when quantifiable evaluation is possible. All of these suggestions are intended to optimize care of injured children across all hospital types and by all trauma providers.

**REFERENCES**

Role of the Pediatric Intensivist in the Management of Pediatric Trauma

J. Michael Dean, MD, MBA

There is a substantial body of evidence supporting the importance of the intensivist, and the importance of active involvement of the intensivist in day-to-day management of patients, although there are much fewer data for pediatric trauma. Postoperative management of the pediatric trauma patient is complex and includes many nonsurgical areas of expertise, such as management of respiratory and renal failure, nutritional support, metabolic support, prevention and management of infection, and sepsis. Collaborative multidisciplinary care of these children should include the active and officially acknowledged involvement of pediatric intensivists side by side with their surgical colleagues.

What is the appropriate role for the pediatric intensivist in the management of pediatric trauma? In this discussion, our goal is to achieve optimal outcomes for infants and children who have suffered traumatic injury. The role of the pediatric intensivist will be discussed as an integral part of how the outcome of traumatized children can be improved. Given the paucity of objective data in this regard, I will offer certain personal views as will become apparent.

The role of the intensivist is actually a logical part of a progression of steps that have, or should, be taken to organize and improve trauma management in pediatrics. Collaborative multidisciplinary care of these children should include the active and officially acknowledged involvement of pediatric intensivists side by side with their surgical colleagues. This approach will enable us to continually seek improvements in trauma care with the goal of achieving best, optimal care for our patients.

GENERAL HOSPITALS, CHILDREN’S HOSPITALS, AND TRAUMA CENTERS

Access to trauma centers is not uniform, and not all trauma centers choose to be designated by the American College of Surgeons (ACS). In a recent inventory of trauma centers, 169 centers were ACS-designated (89 Level I and 80 Level II), but an additional 284 centers claimed to be designated or certified by their state. A study from the National Pediatric Trauma Registry (NPTR) included 53 centers that contributed data on pediatric trauma; 22 were pediatric centers (children’s hospitals), of which only six were ACS verified. Of the adult trauma centers that contributed to the NPTR (31) only six were ACS verified. Regionalization of care via a statewide trauma system does improve pediatric trauma care, but pediatric trauma care often occurs in children’s hospitals, regardless of trauma center designation. In 2003, it was reported that the majority of pediatric trauma is handled by nontrauma centers, and in states with trauma systems, 77% of pediatric trauma patients were handled by centers with no pediatric designation.

The National Study on the Costs and Outcomes of Trauma (NSCOT) is the most recent and most rigorous project to address the effect of trauma centers on outcome, and demonstrated a clear beneficial effect of trauma center care on in-hospital mortality. However, NSCOT deliberately focused on adult patients and excluded pediatric patients. Because most pediatric surgeons are in children’s hospitals, with their pediatric subspecialist colleagues, and as many ACS Level I and II trauma centers do not claim to have added qualifications in management of pediatric patients, trauma management often occurs in children’s hospitals. In many states, pediatric designation is omitted, and children’s hospitals play the role of pediatric trauma center with implicit state approval, without formal designation. Is this adequate for pediatric trauma?

In 1999, we examined this question at Primary Children’s Medical Center, located at the University of Utah. In our setting, there are no competing institutions for pediatric trauma and emergency resuscitation has been performed by attending physicians. Emergency medicine faculty assessed patients, contacted relevant surgical colleagues, and management proceeded with collegial and informal relationships among the attending faculty. We assessed our outcome using Trauma and Injury Severity Score methodology and showed a z score of −0.81. In 1996, we chose to formalize our management, so that when the emergency medicine attending became aware of a seriously injured patient, a “trauma one” response was initiated, resulting in a trauma team response. The trauma team consisted of the same faculty who had previously cared for these children, but the entire team re-
sponse was immediate, and specific responsibilities were assigned to team members. Within one year, survival became significantly better than Major Trauma Outcome Study norms (z score 2.1). Several years later, we re-assessed our outcomes, reviewing 5 years of experience, and our z score was 4.39. Our experience clearly demonstrated that organizing trauma care is a key ingredient to improving outcomes.

Pediatric trauma patients receive different care in adult trauma centers without pediatric qualifications. In Utah, management of splenic injury is systematically different at Primary Children’s Medical Center, and similar differences in operative management have been noted by others. There is some evidence of superior outcome for children who are in pediatric trauma centers, rather than adult trauma centers. It is reasonable that pediatric-specific trauma centers should provide better care for children, based on combined expertise in pediatric surgery, intensive care, and pediatric nursing, but proof remains elusive. One of the components that may enable better outcomes for children is the near-universal existence of pediatric intensive care units (PICU) in pediatric centers.

**DOES THE EXISTENCE OF A PICU MATTER?**

Existence of an intensive care unit is a reasonable step to help manage critically ill patients in many respects, primarily for purposes of having adequate numbers of nurses adjacent to sophisticated technology required for life support. In 2004, Farrell reviewed the New York State Trauma Registry, comparing the outcome associated with blunt pediatric injuries treated in hospitals with and without a PICU. Because mortality is low in pediatric trauma, this study was inadequately powered to demonstrate a statistically significant difference in mortality between these categories of centers. However, most of the pediatric trauma was actually managed in institutions with a PICU (59%), and in all analyses (total patients, patients with head, liver or spleen injuries, children under 4 years, or children with abnormal systolic blood pressure), mortality in hospitals with a PICU was lower than in hospitals without a PICU. Pollack demonstrated that the presence of a PICU in a tertiary setting is an important determinant of mortality and outcome for critically ill children. But how should a PICU be organized?

**ORGANIZATION OF CRITICAL CARE**

For many years, intensive care units were completely open to physicians in all specialties, allowing the child access to a highly skilled nursing staff, adjacent to expensive life support equipment. The physician component of intensive care was not defined, and intensivists have had to prove their value. We can now draw on a large body of evidence supporting the importance of the intensivist, and the importance of active involvement of the intensivist in day-to-day management of patients. The installation of an intensivist has been demonstrated to reduce mortality and morbidity in medical, pediatric, and neurosurgical intensive care units. But are these improvements a result of the intensivist or other factors? The intensivist may bring better organization to the nursing staff, improve the quality of equipment, initiate protocols for various aspects of critical care, encourage active quality improvement, and enable the open model of intensive care to function well. In this case, it would remain reasonable for a trauma surgeon to completely manage traumatized patients who are in the intensive care unit, even while he or she is repairing an inferior vena caval tear in another trauma patient, using a highly dependable network of surgical residents to communicate decisions to the ICU nurses.

Published evidence suggests otherwise. Active involvement of the intensivist with patients, at least in a consultative manner, is associated with improved outcome after abdominal aortic aneurysm surgery, esophagectomy, intracerebral hemorrhage, and in ICU settings of neurology and neurosurgery, pediatrics, general surgery, and adult trauma. The actual physician staffing pattern of an intensive care unit is associated with differences in mortality and complications in surgical intensive care as well as trauma intensive care, and in a recent meta-analysis, 16 of 17 studies demonstrated lower in-hospital mortality when the involvement of an intensivist was required for all patients. Recently, involvement of an intensivist was demonstrated to reduce mortality from 25.8% to 14.4% in a Combat Support Hospital in Iraq. No study has demonstrated a deleterious effect, in any field of medicine or surgery, from involvement of intensivists in care of critically ill patients. In a recent review by Gutsche and Kohl, the authors conclude “All of the published data, thus far, support the contention that trained intensivists are best suited to care for patients in an intensive care environment. Critical care units that have designated intensivist-led teams that round daily benefit from decreased mortality, morbidity, and LOS”.

**SIZE OF THE EFFECT**

There are obstacles to mandatory involvement of intensivists in trauma care, including perceived loss of autonomy of the primary physician, expense to the hospital, loss of income to surgeons, loss of continuity of care, and significantly, a shortage of intensivists. A financial analysis by Pronovost demonstrated that intensivist staffing was associated with lower overall costs; however, loss of autonomy or income was an infrequent response from trauma surgeons surveyed by Nathens. An unacknowledged obstacle may be wording used by the ACS when designating trauma centers, insisting that the trauma surgeon must personally manage all aspects of care, including critical care. But is it worth our effort to overcome these obstacles, real or perceived? The answer to this question is related to the size of the effect of having an intensivist involved in patient care.

After abdominal aortic aneurysm surgery, failure to have daily rounds with an intensivist was associated with a threefold increase in mortality, threefold increased incidence
of cardiac arrests, twofold increase in sepsis, twofold increase in renal failure, sixfold increase in platelet transfusions, and a twofold increase in re-intubation of patients. Odds ratios of death were increased in the absence of a full time board certified medical director (2.1), having fewer than 50% of caregivers certified in critical care (2.0), not having daily rounds with the intensivist (3.0), and decreased nursing staffing in the evening (1.9). Pronovost concluded his article, “Meanwhile, patients should consider how ICUs are organized when choosing a hospital in which to have a major surgery”. These findings after abdominal aortic aneurysm surgery were not unusual; a systematic meta-analysis demonstrated similar effect sizes in medical, surgical, and PICU. Compelling data demonstrate that the effect size was clinically significant, justifying our efforts to overcome the obstacles to involvement of the intensivist.

**WHY DOES PHYSICIAN STAFFING MATTER?**

Postoperative management of the pediatric trauma patient is complex and includes many nonsurgical areas of expertise, such as management of respiratory and renal failure, nutritional support, metabolic support, prevention and management of infection and sepsis. Because volume has an effect on the outcome of trauma management by surgeons even within ACS-designated trauma centers, it is not conceptually difficult to think that physicians who have a higher practice volume in areas of intensive care, such as mechanical ventilation, will have a superior outcome for their patients. Indeed, it is obvious that trauma surgeons who have a higher operative volume must, based on the universal constraint of 168 hours in a workweek, have a lower nonoperative volume. But the pediatric trauma surgeon has a great deal of knowledge about pediatric critical care, and the effect of an intensivist is not solely based on clinical knowledge.

First, the pediatric intensivist is present in the PICU, whereas the trauma surgeon faces many responsibilities outside of the PICU, including general surgery. Presence of physician expertise at the bedside is probably the most important reason for improved outcome in critical care during the last several decades. It is not the case that the intensivist at the bedside is the only individual who has requisite knowledge about what to do, but rather, the effect of improved outcome is the ability for that knowledge to be immediately applied to the patient without delay.

Second, communications may be hampered when the responsible attending physician is in the operating room with another trauma patient. When the status of a critically ill pediatric trauma patient changes, bedside staff must page the responsible members of the surgical team, often a trainee, who then conveys the information to his or her superior, or in ideal circumstances, directly to the surgical trauma attending. Therapeutic decisions are then made, possibly without direct assessment, and the plan is transmitted to the PICU via the same network of communication. In some instances, this is inadequate, because the decision may be affected by some other physiologic factor or because of a delay in an urgent situation. The presence and involvement of an intensivist in management of pediatric trauma patients can eliminate this communication bottleneck, enabling more rapid titration of care for the unstable patient.

Third, most pediatric intensive care is rendered by nursing staff that receive orders from housestaff, whether pediatric or surgical. The presence of an intensivist in the PICU assures the continuous supervision of these caregivers, especially of the housestaff. The existence of training programs improves outcomes for trauma patients, and the presence of an intensivist enables education of housestaff in critical care. To enable pediatric surgical trainees to acquire competence in post-operative critical care, the Accreditation Council for Graduate Medical Education (ACGME) program requirements for pediatric surgery training state “...the coordination of care and collegial relationships between pediatric surgeons, neonatologists, and critical care intensivists concerning the management of medical problems in these complex critically ill patients is essential”.

Fourth, communication with families is an integral part of pediatric intensive care. Trauma patients have significant mortality and morbidity, and often have prolonged hospitalizations. The intensivist who is present in the PICU is positioned to provide frequent updates to families, and to be able to establish and maintain an important relationship between providers (including the trauma surgeon) and parents.

Finally, the intensive care unit can be a very disorganized location, with vast amounts of information and large numbers of individual providers. The setting has been characterized as chaotic, and an important role of the pediatric intensivist is to provide leadership of the entire critical care provider team, such that a relative order is maintained. Diringer writes “Not only is clinical expertise required, but the intensivist needs the ability to organize and manage the ICU environment and wage a never-ending battle against chaos”. This is a fundamentally different environment than the operating room.

The most important component of these five aspects of intensive care is the focused attention and ready availability of the physician to the PICU patient. Various institutional initiatives have been developed to meet these needs and fulfill the principles outlined.

**AN ETHICAL IMPERATIVE?**

Terry has made a compelling ethical argument for staffing a trauma intensive care unit with an intensivist. Citing evidence that critical care, with active involvement of an intensivist, is associated with better outcomes in many settings, Terry asks the question of whether we are seeking “right care” or “best care”, and argues that “the ICU structure and management should embrace the ethical requirements incumbent on physicians to provide the best care for their patients to optimize outcome”.

Because our goal is to improve the care of children after trauma, this implies a continuous drive toward “best care”,...
not “good care”. Thus, although our Utah children’s hospital was performing within “Major Trauma Outcome Study norms” before organizing our care, there was an ethical imperative to improve our care. We subsequently became an ACS-designated Level I trauma center because we thought we could further improve the quality of our trauma service. If the United States ever achieves the goal of having adequate numbers of pediatric ACS-designated Level I centers and Level I adult trauma centers with added qualifications in pediatrics, what is the next step in our ethical imperative to continue to improve the outcome for pediatric trauma? The NSCOT database was analyzed to assess the delivery of critical care to patients in trauma centers, and only 61% of Level I and 22% of Level II centers had obligatory involvement of intensivists in management of trauma patients. Nathens et al. clearly suggested that provision of critical care by an intensivist should become a component of ACS trauma center designation;30 but what kind of intensivist?

WHAT KIND OF INTENSIVIST?

Pediatric trauma surgeons, certified in surgical intensive care, would clearly provide an excellent provider of PICU care for pediatric trauma patients. This would combine the ideal physician provider with the ideal nursing providers (pediatric nurses). Indeed there are inadequate numbers of surgical intensivists to accomplish this goal for adult patients, and Nathens et al. concluded “In the face of a limited number of trauma surgeons and surgical intensivists, this limitation might require that surgeons share critical care responsibilities with nonsurgical intensivists”.30 Donald Trunkey commented on the Nathens et al. article, and separated the concept of the traumatologist and the intensivist.30 Although arguing that the traumatologist should always be a surgeon, he stated “Clearly, the intensivist does not always have to be a surgeon”. Later, Trunkey commented on the Leapfrog initiative, and although indicating that the components of the Leapfrog initiative are based on weak evidence, “I would also agree that most are grounded on common sense”. Trunkey’s conceptual distinction between traumatologist and intensivist is helpful in designing an effective model for improving pediatric trauma care.

THE COLLABORATIVE MODEL

The pediatric intensivist is not the right physician to determine the precise surgical intervention for the acutely injured child, nor to time the re-explorative surgery after an initial stabilizing operation. Many authors who espouse a “closed ICU model” are interpreted as endorsing a system in which a surgeon would not be able to make important decisions about ICU patients. This concern about loss of autonomy and authority is not only an obstacle to convincing trauma surgeons to work with intensivists, but is also simply wrong. There is a side-by-side role for the pediatric trauma surgeon (traumatologist) and the pediatric intensivist (intensivist). The surgeon should be a welcome partner in the PICU, and I think that the intensivist should put on surgical scrubs and join the surgical team in the operating room. Intimate knowledge of events in the operating room will improve the ability of the intensivist to care for that patient after surgery; likewise, knowledge of the ICU course will help the surgeon provide optimal care.

The postoperative management of the injured child is not conducted in isolation by the intensivist, but rather, is coordinated with the pediatric trauma surgeon during the daily morning rounds. The traumatologist and the intensivist agree prospectively on the strategy and goals of management for the day, and the intensivist assures optimal critical care in parallel to the surgeon’s assurance of optimal operative management.

The economics of children’s hospitals and the requirements of ACS designation (in house surgeons, for example) may make it difficult to develop full pediatric trauma centers with Level I or II ACS designation. In Utah, for example, despite published data,7,8 the state adopted ACS designation for its trauma system, recognizing that the ACS was the only organization that had the expertise to rigorously designate trauma centers. Primary Children’s Medical Center, the only children’s hospital in the state, achieved ACS-designation as a Level I trauma center, one of only a handful of children’s hospitals that have succeeded in this goal.

ACS designation was an interesting process because of requirements about responsibility for care outlined by the ACS. The goal was accomplished by creating a trauma service, headed by a pediatric surgeon, but including all the attending staff of the emergency department and intensive care unit. These nonsurgical faculty were required to take Advanced Trauma Life Support (ATLS), maintain ATLS certification, attend monthly trauma quality improvement meetings, and in essence, to function as full members of the trauma service. Patients are admitted to the trauma service, which has enabled the collaborative management of these children from the emergency department through the rehabilitative stage, while satisfying the requirements of the ACS. We think that our collaborative trauma service will enable us to continue our quest for optimal, best care for traumatized children.

REFERENCES


Dr. Meredith: We ought to look at what we know in these discussions that can help us improve our ability to design a study that would be a pediatric NSCOT. I’ve spent a great deal of time working with the Committee on Trauma of the American College of Surgeons and I’ve spent an even greater amount of time writing and editing the latest revision of the books that are the requirements.

We now have a classification system that describes pediatric trauma centers, adult trauma centers treating injured children, and nontrauma centers. This adds a degree of complexity to any study that would use these classification systems now, because the category of “trauma centers with added qualifications” will no longer exist in the future. However, given that certification is a 3-year cycle, that problem is short-lived.

In this new set of requirements, it is important to consider the structure, process, and outcomes of care. The resources that will be necessary for pediatric trauma centers include: age-specific equipment required in multiple places; a pediatric resuscitation area specifically designed to do so; specifically trained pediatric specialists; a pediatric intensive care unit (PICU); a pediatric-specific performance improvement process; and, volume performance criteria (200 patients per year under age 15 for Level I pediatric trauma centers and 100 patients per year under age 15 for Level II pediatric trauma centers). I left out the research requirements for Level I pediatric trauma centers because I’m not sure how to fold that into a presumption of alteration in clinical care as much as it is presumed to serve as a resource to add to the knowledge base of the pediatric community.

We have already discussed at length the process differences between adult and pediatric centers. I do not think one should design a study to compare the differences in processes between, let’s say, pediatric trauma centers versus adult trauma centers, or children’s hospitals versus adult hospitals. I would propose that designing a study around that issue doesn’t make any sense.

On the other hand, outcomes would be worth studying. What would they be? Mortality is a very difficult outcome to be the sole parameter upon which one would try to power a pediatric NSCOT study, because the incidence is so low. Frankly, most of that mortality is going to be central nervous system (CNS) related, and half of it is going to occur prehospital.

We see many people who have residual functional impairment from injuries that are CNS related, but rarely any functional residual impairment related to soft tissue injuries, solid organ issues, or to a lesser extent musculoskeletal injuries. Long-term effects will probably be in the CNS category.

There are some other things that we don’t think about in a typical trauma study that I think are even more important in the pediatric area. The important outcomes are related to self-efficacy, posttraumatic stress disorder, and cognitive performance of individuals. The problem is they’re hard to measure, I’m not sure how to scale them, and some of them take a long time to figure out. But these would be outcomes that one could compare among hospitals or treatment schemes. Cost is also another important outcome to measure.

That brings us to the issue of should we study centers or systems? Whichever of those you do, how do you find meaningful controls where you can account for the intrinsic biases that exist? For instance, if you look at an area with a verified pediatric trauma center surrounded by adult trauma centers where patients have equal access geographically to either one, there is a great deal of bias because that’s a very specific type of hospital and a very specific type of place. Finding a control group where they’re not transferred is going to be very hard, because the only place where that doesn’t occur is places like Montana or Georgia. The selection bias among those patients is large and it will be very difficult to find controls.

We must not omit prehospital data, because half of the children who die are dying before they get to a hospital. This will require a large amount of resources and may affect the ability to do other aspects of the study such as the amount of follow-up data collected or the number of areas or centers included. This is an important question not yet discussed here, and it falls under process of care. Is there proper emergency medical service (EMS), are they equipped, are they trained, are they regionalized and is it effective, do they identify the patients that ought to go to the children’s hospital or identify the patients that ought to go to the nearest hospital?

How long is long-term follow-up? We need to keep in mind that we are raising adults. What about the injured child who would have become CEO of a corporation but who survives and ends up working at a convenience store? There are many metrics by which one would consider that success: survived, went back to school, graduated from high school, and subsequently fulltime employment. But I would claim that we could do better than that for that child who could have been a CEO of Microsoft.
Discussion of Presentations by Stylianos and by Dean

So how long is long-term follow-up? There’s a compromise we’ve got to make and somewhere figure out how to draw that line. It’s going to be a pragmatic decision, but it needs to be asked and answered, and the consequences of that decision need to be assessed and weighed.

What would you compare in terms of hospitals? There are pediatric trauma centers, children’s hospitals, adult trauma centers treating injured children, and general hospitals. This classification could be extended to include Levels I and II pediatric trauma centers at children’s hospitals and Levels I, II, and III adult trauma centers treating injured children.

A study that compares pediatric trauma centers to children’s hospitals strikes me as an interesting study but one much smaller than the scope of what NSCOT was or tried to be. NSCOT was forced by resource constraints to make the pragmatic decision of comparing Level I trauma centers with nontrauma centers because it had the greatest difference to measure and was easier to define. This strikes me as too small for a pediatric study.

Comparison of pediatric trauma centers versus adult trauma centers treating injured children is a legitimate study and probably where I thought this would be meant to go eventually. In a properly designed system, if this is a choice that the EMS could make, they would opt for a pediatric trauma center depending on the patient, injury, and distance. However, there are not many places where this is the practical on-the-ground question about what to do with injured children.

Another comparison is pediatric trauma center versus general hospital. There is also the comparison of a children’s hospital nontrauma center versus each of these, but I think that neither of those are meaningful questions.

Another way might be trying to create a classification system of trauma systems. We could look at how pediatric injury care is delivered across the country, examining the spectrum of the way that it is done, starting with the ideal of a well-defined trauma patient, well-defined transfer guidelines, and a committed pediatric trauma center. We could use this to define the traits of such a system that would need to be measured. This can then be applied to examine other systems in the spectrum, for example, adult trauma centers in the middle trying to achieve this ideal, and those at the other end of the spectrum where none of those components are in place. You could search for metropolitan statistical areas (MSAs), which have those three systems, and compare them. That’s a more attractive study to do in terms of what would one do with an answer, but it’s a much less attractive study to do in context of how would you ever get an answer. How could you ever design that study, and if you designed it, what would you measure to get the outcomes? That’s a question we need to ruminate today. I think it must examine process of care, because there’s a much greater impact on outcome of how children are treated than where they are treated.

We need to consider systems, and to define hospitals within that system; even if we decide to do a hospital-based study, we need to control for the kind of system in which that hospital exists. This includes examining EMS both in terms of training and equipment, and examining systems in terms of how well defined and implemented are triage and inter-hospital transfer guidelines. We either have to design the study around these variables or control for these variables in the setting in which the hospitals we’ve chosen exist.

In terms of characterizing the resources at the hospitals, this should include the types of hospitals that are available, what pediatric specialists do they have, presence of a PICU, and whether the hospital is designated versus verified versus nonverified.

Another piece we’ve not talked enough about is pediatric-specific social and environmental support. As I look at what happens when our pediatric surgeons are treating patients in our children’s hospital, much of what happens differently for that child than would have happened in an adult hospital is having nurses that understand and are comfortable with children. The environment has a lot to do with their care.

In addition to all the physical problems children must face in surviving an injury, there may also be substantial emotional impacts on young children that are difficult to overcome. If you have cancer, during treatment there are supports and when you make it 5 years, you are a survivor and everybody celebrates that. If you’re injured, you have some of that support while you’re in the hospital. You might have some of that support if you have to have a few follow-up visits, but there’s never a party, there’s never a celebration, if you’re a trauma survivor. You never have anybody to help you through all that other stuff or getting over the fact that you had totally lost control over how your life was lived, that you are no longer invincible. There are many issues that we don’t necessarily address in trauma systems in any way. We must measure these other effects of trauma. The one I think is most important is self-efficacy. We also must measure some of these confounders, such as preinjury functioning and self-efficacy, and preinjury social and socioeconomic support.

We also have to decide how much to examine subgroups by age because the 2-year-old is definitely not the same as a 12-year-old, who is definitely not the same as an 18-year-old.

I’m sorry I’ve asked more questions than I’ve answered, but I appreciate the opportunity to be able to speak.

Dr. Mooney: I’d like to talk about today the ICU, and specifically the role of the intensivist and comment on Dr. Dean’s statements.

Pediatric intensive care is a new field; the first boards were in 1985, 22 years ago. Their role has been rapidly expanding, and their numbers steadily increasing. The numbers of people eligible for the board examination in pediatric critical care medicine, markedly increased each year between 2002 and 2006, especially when you consider that now there are more than 10 times as many pediatric critical care phy-
physicians coming out of training as there are pediatric surgeons. The manpower assessments that have been done in the past for pediatric surgeons tend to be more based on the operative requirements and the numbers of children born with congenital anomalies and not as much on care of trauma patients.

However, whether the intensivist should take care of the patient or whether the surgeon should do so is really a false dichotomy. It should be based on who is the optimal person to be standing at the bedside and caring for that patient. To say that someone completes a pediatric surgery fellowship does not mean that they are interested in pediatric trauma care. Many pediatric surgeons want to take care of congenital anomalies. Similarly, there are intensivists who love to use the oscillating ventilator for meconium ileus or have an area of interest that has very little to do with trauma care.

The important question is what residency did that person participate in, which pathway did they take to get to the bedside, what training do they have in trauma to take care of an injured child in an ICU, and what qualifications do they have to do that, and what experience do they have? Are they fresh out of training? Do they have sufficient experience to independently practice at the bedside of an injured child? Are they interested? Are they there because they have to be, or is that something that they’re interested in? Those are things that are very hard to ferret out, and instead we tend to drop back to proxy measures. We presume that if you are boarded in pediatric critical care medicine that you have the skills required to take care of a child with a severe brain injury. Similarly, we presume that if you have your certificate or special qualifications in pediatric general surgery, that you’ve obtained sufficient critical care training during your fellowship that you are qualified to stand at the bedside and care for that injured child.

Age also enters into this. It’s not unusual in the same PICU for some injured children to be cared for by the pediatric surgeons with critical care intensivists, but then the adult team cares for the older adolescents, because many pediatric surgeons may want to care for someone only up to 12 to 14 years of age. The PICU team treats patients up to 18 years, whereas the adult team cares for the 16 and 17 year olds in the ICU.

No physician is an island; we all operate within our environment of the facility, physician staffing, nonphysician staffing, and processes of care. There are a variety of facility types that may affect outcome. We presume that free-standing PICUs will have more pediatric-specific training than dedicated beds in an adult ICU than mixed age ICUs. The staff in surgical ICU’s would be expected to be more focused on issues related to trauma care than multispecialty units. The size and volume of the unit could be used as proxies for experience.

Another factor to be considered is the experience of the unit, the size of the unit, and the volume of trauma patients within that ICU (presumably a proxy for experience). We presume that volume of the unit is a proxy for the experience level of the actual provider for that patient.

There are a host of different staffing patterns. In house availability of attendings doesn’t necessarily mean at the bedside. There are many situations where the attending is in-house, but the PGY2 on the pediatric service who is doing their ICU rotation is at the bedside providing the care, not the attending. In private practice, there are hospitals where there’s a trauma surgeon in the ED who takes care of all adult trauma patients who go to the operating room, and another trauma surgeon in-house for the ICU. That’s a great model we’ll probably never replicate in the pediatric world. But is the attending physician at the bedside? Are they the one doing the primary calls, or are they backing up someone else? And if they’re backing up someone, is it a fellow, a resident, or a nurse practitioner?

Where do nurse practitioners fit in this hierarchy? Are they above a resident? Are they at the fellow level? Are they above the fellow level because of their experience, especially after 5, 10, or 15 years of being a pediatric ICU nurse practitioner?

Some ICUs have 30 beds and one attending at night. Can that one attending caring for 30 critically ill and injured children provide a better level of care than a surgeon does over the phone? Can they actually see and touch those 30 patients during the nighttime? Is this person on-service or just covering, and how well does he or she know the patients?

It would be difficult to overstate the importance of nursing expertise in the care of injured children. Training and experience levels vary broadly. There’s a difference between nurses who are allowed to focus on specific issues and those who have to understand the range of maladies that could affect people of any age. Respiratory therapy has assumed an increased role in many ICUs. The active presence of pharmacists and nutritionists could also be meaningful variables.

Equally important are the processes of care. Beyond the people present, how do they communicate with each other: joint or separate rounds? Is there a training program or not and for what specialties that directly affect ICU care? Have the providers taken the time to develop standardized care plans and are those plans routinely reviewed and updated as needed. Family psychosocial markers have been found to affect outcome. Are these issues addressed by the ICU?

Has the unit committed themselves to standardizing their communication systems and standardizing their plan of care? This takes a great deal of work. In my institution, it took 20 months to develop a standardized plan for the care of cervical spine injuries. To do a standardized pathway for the management of increased intracranial pressure took almost 36 months. The primary determinant of outcome of pediatric injury care is neurotrauma. Is a hospital so committed to pediatric trauma care that they’re willing to spend that kind of time on it? That might be more important than the residency the person did.
I am glad to see Dr. Meredith mention this, because I hadn’t heard it discussed earlier, but posttraumatic stress disorder affects one out of six children admitted to a hospital after an injury. How does the hospital address that problem?

In consideration of the role of the pediatric intensivist in pediatric trauma care, the package must be considered: the facility, MD certificate as a proxy for knowledge, in-house versus at home as a proxy for presence, volume as a proxy for experience and a willingness to develop standardization as a proxy for interest.

**Dr. Cooper:** The last few presentations that we’ve heard, particularly with respect to intensive care, underscore an important direction that whatever study is undertaken should probably embrace: examining a series of tasks to be performed with pediatric trauma patients. It’s probably less important who performs those tasks, as long as they conform to what we collectively sense is best practice.

I’ve long thought that the reason others were able to find that care in “adult centers” for children was as good as care in pediatric centers, at least using the outcomes measured, was that all the studies were performed in institutions that had pediatric intensive care units staffed by pediatric intensivists, pediatric emergency departments staffed by pediatric emergency physicians, and a whole range of pediatric infrastructure available in those studies.

I really do think we need to be focusing not so much on the processes of care per se, but more on the context of care, if you will, that we recognize as important for the care of injured children.

**Dr. Meredith:** There’s also a lot to be said for how you work together, not just what do you know and what’s your training. I’d much rather have an incompetent assistant than a skilled opponent.

**Dr. Adelson:** I wanted to discuss the same thing. Understanding communication between services would be an important question to ask. I know within our system that there were many times in which we could actually attribute lower quality of care to miscommunication or independent people writing separate orders on the same patient.

With respect to what Dr. Mooney was saying about neurotrauma, I don’t think you can standardize the care yet. Having been involved in the pediatric guidelines process for severe traumatic brain injury in children, even the group putting together the guidelines had a hard time coming up with a consensus.

There are two questions that would be very important for a future study. One is to examine how services communicate. We’re not only talking about how EMS communicates with centers and how patients come to specialized care, but even within the hospital, how communication is translated. The second area is translating the evidence base in the literature into the management of these patients.

**Dr. Mooney:** A fascinating variable for outcome would be whether there’s a neurosurgeon dedicated to trauma care or not within the institution, rather than someone focused on myelomeningocele or shunt management. I suspect that’s probably a valuable variable in itself. Bumps in the night tend to be bad. I came in one morning to round on a patient with severe head trauma in the unit and found that the residents during the night had downloaded from Trauma.org a little vignette on how to take care of a brain injury, and that they were basically making it up at night. That’s when we decided to standardize our care to minimize these bumps in the night.

**Dr. Adelson:** I agree with you. If you have different people managing patients or no one clearly responsible directing that care, then you’re going to end up with problems. The way we eliminated at least some of those issues was developing the team approach toward rounds at 7:00 in the morning so that everybody had the same plan and used the same algorithm to follow. We put in place our own standardized care; it didn’t take us 36 months to develop. I wrote it down and said this is what we’re going to do and, although there was discussion, we did it, a brute force approach.

**Dr. Oldham:** Communication problems are by no means limited to the world of trauma or ICUs. If we were to do a study and that was something we were interested in, how would you go about quantifying that?

**Dr. Dean:** The way to study it might be based on some work done by Draper and Knaus, in which they looked at communication styles. They interviewed people in ICUs and came up with an organizational appraisal of how they communicated and how they interacted. The centers where the intensive care units had better performance had better organizational aspects identified by the people and better aspects of communication. Places that had less rigid communication tended to have better outcomes than places that had very strict interdisciplinary barriers and formalized communications that weren’t readily accessible.

**Dr. Pollack:** The study you’re referring to was spearheaded by Stephen Shortell, a professor at the Kellogg School of Business. His “Shortell Scale” was a method of evaluating structure and process of unit functioning. In this case it was designed specifically for ICU nurses. They found that they could not relate measures of structure and process to mortality, but they could relate it back to communication, shorter length of stay, family satisfaction, and those sorts of factors. I used that scale in a study of eight ICUs in the District of Columbia. It’s a very noisy scale and took a great deal of statistical manipulation to get results. We could find that structure and processes of care were related to incidences of bronchopulmonary dysplasia and intraventricular hemorrhage. But it’s an interesting scale.

**Male:** If we had the opportunity in the year 2015 to have a reunion of this group, I think we would be most proud if we defined, delivered, and coordinated the implementation of standards of care more than having teams that communicate better. We’re so lacking in standards of care in pediatric trauma that we would make a huge impact if we could just define two or three key areas and really fleshed it out and had that as the deliverables.
Dr. Nathens: I was actually going to respond to Dr. Cooper’s comments about tasks. I think the answer is not in single tasks, but in some measure of interdisciplinary teamwork, which you already mentioned. But it isn’t only physicians working with nurses working with respiratory therapists, it’s actually how the administration responds to the need for change, how they provide resources to make changes, and how they respond to quality assurance issues that arise. When you look at top performers outside of trauma, how their administration behaves when confronted with adversity is actually a very important indicator of how good they’re going to do. It’s the entire structure, the vertical structure and the horizontal structure; you need some way to quantify what it is about hospitals that leads to their top performance.

Dr. Owens: I agree with Dr. Adelson. I don’t think standards ought to be the metric used to decide whether or not somebody has best practice, because particularly in pediatric neurotrauma, we don’t really know what those standards are. We can’t seem to define hypotension nor can we define what the optimum CO₂ ought to be based on given the level of evidence. The data collected during this study would actually help define the best practice. It would involve collecting data from the prehospital period; however, current EMS systems have very different forms. Working to standardize EMS data collection will be a very important part of collecting the information regarding the early influence of secondary insults, particularly relevant to head injury, on long-term functional outcome.

Male: I wouldn’t pretend that I have any knowledge of which specific variable would lead to an improved or worsened outcome other than anoxia and shock. The process of standardizing care is helpful to eliminate those bumps. I thought there was a 15% or so improvement in mortality with standardization from the prehospital period; however, current EMS systems have very different forms. Working to standardize EMS data collection will be a very important part of collecting the information regarding the early influence of secondary insults, particularly relevant to head injury, on long-term functional outcome.

Female: It is very useful to avoid what we can all agree is bad care, but I would submit that with the lack of mechanistic and physiologic data, we can’t really define optimum care at present.

Dr. Fallat: I wanted to expand on Dr. Meredith’s idea that we should study systems of care rather than compare trauma centers with other trauma centers, because this will give us a better opportunity to look at epidemiologic factors and disparities in trauma care. Using Kentucky as an example, we have 120 counties but only 99 hospitals. These 99 hospitals may have emergency department physicians who never took advanced trauma life support (ATLS) or pediatric advanced life support (PALS) and probably are not capable of putting in a chest tube. We need to consider where the child originated, whether there was 9-1-1 availability in the county, whether there were basic life support (BLS) or advanced life support (ALS) services, and how far the ambulance or family had to travel before the child was first seen. There are other issues such as ethnic and racial disparities that Dr. MacKenzie addressed. Do we just include Spanish-speaking populations or do we try to look at other ethnic groups, because within these ethnic groups, there are higher injury rates. Insurance status also seems to matter. Uninsured children are twice as likely to die from a brain injury, only one-third as likely to get an intracranial pressure monitor if they have a traumatic brain injury, and 44% less likely to get rehabilitation services when they leave the hospital. These all relate to system issues that will be important to flesh out in the context of a pediatric study.

Dr. Meredith: How would you do it? Would you take a spectrum of systems and characterize each one on a scale where you give every system a score? Or do you look at each axis within a system, rank it and then compare which of the axes make the most difference in some kind of complicated regression analysis?

The attractive part to me about looking at centers is you can then define what you have to start with. However, it is much harder to define what you do with anything you learn. In contrast with a systems analysis, it’s much easier to figure out what you would do in terms of policy, but it’s much harder to figure out how to characterize what you’re going to measure.

Dr. Fallat: I agree. Could you take a couple of states that have no system, a couple of states that have a very well-established system, and a couple that have developing systems? You then would look not at centers, but rather at injured children, and try to evaluate their path within the system. This sounds difficult, but would enable us to examine the path from injury to discharge or rehabilitation, to look at both minor injuries and major injuries, and to determine outcomes in a variety of systems. The data generated might then be meaningful enough to determine what really makes a difference in outcome.

Dr. Nathens: I am not sure if that is the right way to do it. But I do agree that we need to think about systems of care rather than compare one center to another and then define what you have to start with. However, it is much harder to figure out what you would do in terms of policy, but it’s much harder to figure out how to characterize what you’re going to measure.

Dr. Meredith: Dr. Nathens, could you create those samples? Could you make that population based?

Dr. Nathens: You could. You’d have difficulty risk adjusting, because the data on a population basis doesn’t exist. You can do your best, but there will be limitations.

Dr. Creamer: My comment revolves around how to measure team collaboration. We can measure who is present such as intensivists, pediatric surgeon, or pediatric trauma surgeon, but should we or could we measure how they work together, whether or not they work together well. Dr. Dean referenced the Iraq experience at the Combat Support Hospital. In that experience, there was an intensivist present for a large portion of time. When the intensivist was consulted but was not part of the team, he did not significantly impact care and mortality went up. When he integrated as part of the team, mortality declined. As a pediatric intensivist leading the ICU team in Afghanistan, we had a completely collaborative environment with surgeons. Because we worked together, our mortality was significantly reduced compared with the previous care model.

Should we be looking at the general hospital with a general surgeon and a general pediatrician and measure how
well they work together? Do they do as well as a pediatric center where the intensivist and the surgeon don’t collaborate as well, or a pediatric trauma center where the intensivist and the pediatric trauma surgeon don’t collaborate as well.

**Dr. Meredith:** That’s a study we ought to do. I’m not sure it’s this study, but I think that’s a study we ought to do. We need to get an accurate and sensitive measure of collaboration assessment.

**Dr. Dean:** The only difficulty is that we’re talking about intensivists. I’ll take any intensivist, and I’ll take any surgeon over a general pediatrician in the ICU setting, because general pediatricians really don’t pretend to be trained in this. I’m not sure you could find a comparison group that was precisely what you talked about, but communication and how integrated the people are together are very important. If you have a hospital where the surgeon and the intensivist don’t talk to each other except through their residents, I have a strong suspicion the outcome is worse than if those two people talk directly to each other on a regular basis.

**Dr. Creamer:** Our experiences in Afghanistan were that most of the subspecialty physicians only went for 6 months. In the first half of the year, a pediatric intensivist and an adult chest surgeon were the main people on the team. The second half of the year, there was a general pediatrician, an adult pulmonary critical care physician and a surgeon. You have a pediatrician who knows pediatrics and intensivist who knows critical care, a surgeon who knows trauma, if they work together, they can be better than the sum of the parts.

**Dr. Wright:** I’m a pediatric emergency physician who has worked as an EMS medical director in a mature state system. I was glad to hear Dr. Meredith’s commentary about looking at the prehospital component of the system, but if nothing else, being in the EMS system for 10 years has taught me that when you see one EMS system, you see one EMS system. The on-the-ground decision making about triage is something that I don’t think you could ever standardize in our system. It is very highly protocolized in terms of destination, based on physiologic and other parameters. However, I think that there are aspects of care and procedures that do happen in the prehospital environment such as the role of rapid sequence intubation in the field that has not been adequately studied in terms of outcomes, particularly in children.

**Dr. Meredith:** Do you think it would be possible, if we can’t standardize prehospital care, to characterize it? Could we characterize processes of care into well defined and implemented, well defined but poorly implemented, and haphazard or chaotic or dangerous?

**Dr. Wright:** I think it would be difficult, because first of all, even in terms of characterizing structure, there are statewide systems where you do have potentially a population base that is being served versus much smaller systems that are jurisdictional managed by areas where we would not have input or control. So I’d be hesitant even to suggest that we could in a meaningful way characterize systems.

Again, I happen to think that there are specific procedures that happen in the prehospital environment that dramatically affect what happens to children in the emergency department and in the intensive care environment.

**Dr. Landgraf:** I wanted to speak to the issue of communications. Rather than creating new measures, you might want to examine the literature in the field of communications, because there’s been a great deal of work on communication, language analysis, both ethnographic and quantitative work that have combined both public health and communications.

Secondly, about 10 years ago, we began working with the neonatal intensive care unit in a mid-Atlantic hospital. We went into the neonatal intensive care unit and interviewed, at all different times of the day and night during a two-week period, neonatologists, nurses, respiratory therapists, discharge planners, social workers and families, and then created a benchmark and outcome system. As a measure of process, we found that communication was essential for outcomes measured after discharge. In other words, communication is not only important within the clinical parameters, but the degree to which families are spoken to and counseled and communicated with plays an important factor in outcomes. If you’re going to be looking at outcomes, health and wellbeing, communication might be a component that you might also consider.

**Dr. Jurkovich:** We’ve spent a lot of time today talking about the outcomes we want and about the process of care to get those outcomes. The outcomes we want are very clear: no mortality, no morbidity, return of function, and short length of stay at low cost. The outcomes we’re looking for are not hidden; they’re very straightforward.

The process of getting to those outcomes, though, may be different from hospital to hospital or from place to place or from region to region. The Committee on Fractures, subsequently the Committee on Trauma of the American College of Surgeons and the Joint Commission on Accreditation of Healthcare Organizations have had the most experience with trying to assure quality of care in this country. Dr. Meredith, as the head of the Committee on Trauma, your organization has long measured process of care and not outcome. Why is that? Why do you not measure outcome? Why do you measure process?

**Dr. Meredith:** Our goal was to help trauma centers come into existence and do better, and not just to characterize them. If you just measure outcome and say you pass and you fail, there’s no way to improve that. I would argue over the years we moved from structure to process and then outcome. In terms of trying to improve trauma care, first we said you need procedures that happen in the prehospital environment that dramatically affect what happens to children in the emergency department and in the intensive care environment.
operate on these things, etc. I would agree that if you wanted to simply characterize hospitals as good, bad, medium, A, B, C, or D, you would do that by outcome.

**Dr. Jurkovich**: Correct. That’s backwards, right? What you should look for is the best outcome, because we know what outcome you want, and then explore centers that provide the best outcome and examine what they are doing to get that best outcome, not the other way around.

**Dr. Stylianos**: If we look at one of the greatest achievements in pediatrics in the last 30 to 40 years, it is the treatment of children with cancer. Regardless of urban or rural, black or white, rich or poor, if you have a childhood malignancy, you will have access to a Children’s Oncology Group protocol, and that has profoundly affected outcome. If we came up with a children’s trauma group that developed the best protocols it could and then nurtured that through and changed it as evolution required, what a contribution we would have made to pediatric care!

**Dr. Mooney**: Every children’s hospital is different with different components and all sorts of resources, except enough surgeons who are interested in trauma. It’s going to be much more important to determine which process is associated with which outcome than the particular title that the hospital has when we try and correlate it with outcome.

**REFERENCES**


Measuring the Cost-Effectiveness of Technologic Change in the Treatment of Pediatric Traumatic Brain Injury

John M. Tilford, PhD, Mary E. Aitken, MD, MPH, Allen C. Goodman, PhD, and P. David Adelson, MD

Substantial variation exists with respect to the management of traumatic brain injuries (TBI) in children. Centers that practice aggressive treatment of TBI may improve survival, but it is not clear that the outcomes can be justified using cost-effectiveness criteria. This study illustrates the use of cost-effectiveness analysis to assess interventions for improving outcomes in children by assessing the cost per quality-adjusted life year (QALY) gained from technological change in the treatment of TBI. Cost and survival data associated with technological change in the treatment of pediatric TBI was based on nationally representative hospital administrative data for all children <21 years with a TBI who required endotracheal intubation or mechanical ventilation. With QALYs of pediatric TBI survivors based on life expectancies ranging between 5 and 30 years and on an estimated preference score of approximately 0.5, the estimated incremental cost-effectiveness ratio ranges between $19,000 and $109,000 per QALY gained. Adding estimated rehabilitation costs increases the cost-effectiveness ratio to between $57,000 and $244,000 per QALY. Sensitivity analysis indicates that estimates of life years gained are critical to the estimated ratio. If TBI survivors live more than 5 years, then the estimated cost-effectiveness ratio seems favorable.

Cost-effectiveness analysis (CEA) can be used to evaluate interventions for improving health outcomes in injured children in relation to the costs of the intervention. For example, a trauma system change (intervention) that ensures children are treated in the most appropriate setting likely will increase system costs, but may improve outcomes. A CEA evaluates the cost per life year gained or the cost per quality-adjusted life year (QALY) gained from the trauma system change. CEA is most useful when cost-effectiveness ratios can be compared across different interventions such as the cost per life year gained from treating children in pediatric facilities relative to the cost per life year gained from more aggressive treatment for heart failure in elderly adults. If a treatment has a high cost per life year saved, especially relative to other treatments, one could use this information in evaluating whether a given treatment or system change seems warranted. Such comparisons, however, are valid if and only if CEA is performed according to standard methods.

The US Public Health Service (USPHS) convened a panel of experts to provide guidelines for conducting CEA of health interventions. The resulting reference case analysis developed by the panel embodied the set of standard procedures for conducting CEA. Tilford described issues associated with incorporating the USPHS guidelines in evaluations of emergency medical services for children, especially the recommendation to use QALYs as the metric for measuring health outcomes. In particular, the USPHS panel recommended that QALYs be calculated using generic instruments so that health state values (variably referred to as preference weights or utilities) reflect community preferences. Generic instruments to measure QALYs, like other instruments to measure health-related quality of life, need to be age appropriate. Current instruments cannot be administered to young children and are not appropriate for children less than 5 years of age irrespective of whether a proxy is used to ascertain health states. Issues with the measurement of QALYs in children raised concerns as to whether the USPHS guidelines were appropriate for pediatric populations.

QALYs are recommended for use in CEA because they combine gains in life years with a measure of health-related quality of life that can be scored to reflect preferences for health states. Most health state valuation techniques include a range from death (a preference weight of 0) to perfect health (a preference weight of 1). If QALY-based outcomes are used in CEA, then interventions used in the treatment of pediatric traumatic brain injuries (TBI) can be compared with interventions involving distinct patient groups such as elderly patients with acute myocardial infarction. In general, an incremental cost-effectiveness ratio (ICER) is calculated as \((\text{Cost}_b - \text{Cost}_a)/(QALY_b - QALY_a)\) or the difference in costs divided by the difference in QALYs for patients in an intervention group \((b)\) relative to a control group \((a)\).
Thus, generic instruments to preference-weight health outcomes are essential for calculating QALYs following the USPHS guidelines. To date, only two studies have measured preference-weighted health outcomes in children after a TBI with generic instruments. One study examined outcomes in children after decompressive craniotomy using the original Health Utilities Index.8 Recently, Tilford et al. reported TBI outcomes using the quality of well-being (QWB) scale.9 Given the lack of studies describing preference-weighted outcomes in children (or adults) after injuries, it is not surprising that only one economic evaluation provided information on traumatic injuries that followed the USPHS guidelines. Stein et al. examined indications for cranial computed tomography scanning after mild TBI using CEA.10 They used a decision-analytic model with outcome probabilities for the Glasgow Outcome Scale. The Glasgow Outcome Scale was assigned preference weights to permit a ranking of decisions based on the cost per QALY gained.

The primary goal of this study was to illustrate the issues involved in the measurement of ICERs associated with interventions to improve pediatric trauma outcomes that follows the USPHS guidelines. In particular, we focus on measuring the effectiveness of an intervention, the outcomes of the intervention, life expectancy for survivors of the intervention, and costs associated with the intervention. We illustrate these measurement issues in an evaluation of technological change in the treatment of pediatric TBI patients, which improved survival in this population over time. The study calculates costs based on changes in acute hospitalization costs and rehabilitation costs discounted to present value terms. QALY gains are based on recent descriptions of preference-weighted health outcomes in children after TBI. The findings provide an assessment of whether recent survival gains from technological change in the treatment of pediatric TBI are justified using cost-effectiveness criteria. Finally, the article provides a discussion of the critical issues that need to be addressed to assess the cost-effectiveness of interventions to provide optimal care to children such as a proposed study on the costs and outcomes of trauma for kids.

**METHODS**

The USPHS recommended that cost-effectiveness evaluations take a societal perspective in describing costs and outcomes. The measurement of ICERs from a societal perspective requires estimates for a number of key parameters. In this section, we describe critical parameters for calculating ICERs based on the cost per QALY gained.

**Effectiveness**

Our primary measure of effectiveness in this article is changes in survival probabilities associated with improved treatment for pediatric TBI. Our recent work indicates improved outcomes associated with hospitalizations for pediatric TBI possibly because of more aggressive treatment.11 Thus, we used data from that study, which was based on the

Healthcare Cost and Utilization Project (HCUP), to obtain estimated gains in survival probabilities for children hospitalized with a TBI in this study. The HCUP is a federal/state partnership that produces a family of health care databases, including the Nationwide Inpatient Sample (NIS). The NIS contains hospital administrative data from a number of states covering the period 1988 to 2004. The data from the state inpatient databases is coded uniformly and then a 20% stratified random sample of all US community hospitals (defined as short-term, non-federal, general and specialty hospitals, excluding hospital units of other institutions) is drawn and weighted to produce national estimates.12 The NIS includes 100% of discharges for all age groups and all payers from each sampled hospital. It contains data from approximately 1,000 hospitals and includes 7 million to 8 million hospital discharges annually.

All children aged 0 to 21 years with a Centers for Disease Control and Prevention-defined TBI13 that included a procedure code for endotracheal intubation or mechanical ventilation were identified from the NIS for the years 1988 to 1999 after our prior work. ICDMAP90 software was used to generate estimates of the injury severity scores.14–16 Survival probabilities for this study were estimated from the HCUP data using a logistic regression model with the injury severity scores and other covariates to generate risk-adjusted survival during the entire study period. The “adjust” command in Stata was then used to generate predicted mortality rates for the average patient in each study period. The resulting estimates provide gains in survival probabilities for the years 1989 to 1999 relative to the reference period (1988).

**Outcomes**

The study sought to follow the USPHS panel recommendation of using QALYs as the metric for the denominator in CEA. Indeed, the panel recommended the development of “off-the-shelf” preference scores for use in CEA, recognizing that most investigators do not have the resources to collect original data on preference-weighted health states.17 This study highlights this recommendation as we use preference scores developed from our prior study.9 Preference-weighted health outcomes in children who survived a TBI hospitalization were reported from a cohort of children admitted to 10 pediatric intensive care units (PICUs) that were located nationally. Subject inclusion criteria followed the inclusion criteria for estimating survival probabilities and required that the child be less than 18 years of age and admitted to the PICU with a Centers for Disease Control and Prevention-defined TBI13 that required either endotracheal intubation or mechanical ventilation. An initial description of these outcomes and construct validity has been reported elsewhere.9 Scores ranged from 0.09 to 1.00 at 3 and 6 months after discharge from the ICU, but mean scores increased from 0.51 to 0.58 between the two periods. Scores were correlated with clinical characteristics, injury severity, and other health-related quality of life measures.
Mean scores are typically used to describe preference-weighted health outcomes because of their use in QALY calculations. However, the use of average measures of preference-weighted health outcomes based on a cohort of survivors may overstate the true gain from technological advances. Ideally, information on “marginal” patients that survived a TBI who might have died with less aggressive treatment provides a better estimate for QALY estimation. The concept of the marginal patient does not imply that the child will have a marginal existence, but that the child is a survivor who would have died without the intervention. To reflect better the preference scores of marginal survivors, this study used weights based on children with higher risks of mortality than the average patient in the cohort and then conducted sensitivity analysis for different values. In particular, we used scores only for children that required intracranial pressure monitoring because this procedure typically is associated with more aggressive treatment. Finally, we used weights from the 6-month outcome data and did not alter them during the estimated gain in life years.

**Life Expectancy**

In this study, survivors are expected to live more than 1 year, but a number of issues need to be considered in calculating life expectancy. Some studies use life tables for calculating life expectancy based on the average age of the cohort and then adjust for increased risk of mortality caused by the illness or injury. For example, using life tables, a 10-year-old child could be expected to live an additional 68.2 years on average. However, the mortality experience of survivors of a TBI, especially marginal survivors, is likely to differ considerably from population averages. Recent work on life expectancies after TBI suggests that life expectancy will differ significantly depending on the functional outcome of the patient after hospital discharge. Patients with moderate disabilities were found to have a 4-year reduction in life expectancy, whereas patients rated as extremely severe were found to have a life expectancy only 50% of the population average. A study of children and adolescents after TBI also found substantial reductions in life expectancy when severe functional limitations were present. For a child aged 15 years, life expectancy was an additional 14.9 years if the child was not mobile, 34.2 years if the child had poor mobility, and 54.8 years if mobility was fair or good.

Given the lack of precise data on life expectancy for pediatric populations, we calculated life expectancies during a wide range to account for uncertainty in actual estimates. QALYs were compared in 5-year increments in life expectancy up to a maximum of 30 years. Survival gains beyond 30 years have little impact on estimated cost-effectiveness ratios in this example because of discounting where impacts that far into the future have little weight in present terms. With discounting of life expectancy and with all costs incurred in the first year, the ICER calculation becomes $\frac{\Delta \text{Cost}}{\Delta \rho}$.

In this calculation, $\Delta \rho$ is the change in survival probability generated by the intervention, $\mu$ is the preference weight for calculating the QALY in year $t$, $r$ is the discount rate and assumed to be 3%, and $t$ is the expected life years gained for survivors affected by the intervention.

**Costs**

For this study, we captured data on two cost categories, the cost of inpatient hospitalizations and the cost of rehabilitation service use for survivors. To measure the cost of inpatient hospitalizations, we based the analysis on hospital charges in the NIS database and calculated the marginal change in charges during the study period using the same methods that were used to calculate survivor probabilities. Again, linear regression models were used to estimate hospital charges and expressed as the change in spending for the average patient during the course of the study period using the Stata adjust command. No attempt was made to generate costs from cost-to-charge ratios because the HCUP databases do not capture all of the relevant costs of the hospitalizations. Data on physician charges and emergency department charges are not captured. The approach is similar to that used in other studies where only Medicare Part A claims were used to capture changes in the cost of heart attack treatments. All charges were converted to 2000 dollars using the US implicit price deflator.

Rehabilitation services were measured at the 3- and 6-month follow-up interviews from the cohort of children recruited from the network of PICUs. A reminder card was mailed to respondents before the interview asking them to record visits to medical providers after discharge from the hospital. Respondents indicated whether their child received a particular service and the number of services during the preceding 3-month period. Service utilization was converted into cost data using Medicare pricing schedules for the particular service. The resulting cost index was correlated with severity measures obtained during the PICU stay as a test of construct validity. Rehabilitation service costs were significantly associated with severity measures. Following strategies used in the analysis of QALYs, only rehabilitation costs for children that received an ICP monitor were used in actual calculations.

**RESULTS**

Figure 1 provides estimated improvements in survival probabilities for pediatric TBI patients abstracted from the NIS during the period 1988 to 1999. By the end of the study period, survival probabilities increased 8.3% points or 8.3 per 100 TBI patients treated. This estimate is similar to estimated survival gains for elderly heart attack patients (9.8 per 100) during the period 1986 to 2002.
Figure 2 provides estimated increases in real hospital charges (in 2000 US dollars) during the same period. Hospital charges for pediatric TBI patients increased to a maximum of $19,000 and then fell to approximately $13,000. The estimates fall close to the increase in Medicare Part A claims associated with treating heart attacks in the elderly ($12,399 in 2003 US dollars).24

Table 1 reports post-acute care service utilization and costs for the first 3-month period and the period from 3 to 6 months postdischarge from the ICU using our cohort of children recruited from the 10 PICUs. The use of post-acute care services was greater during the 3 months after discharge than at 6 months. On average, children who required an ICP monitor used approximately $18,600 worth of services in the immediate period after discharge. Service costs decreased by approximately 50% between the 3-month follow-up interview and the 6-month follow-up interview. Assuming that service use declines linearly over time, the average cost per patient is approximately $35,750 in the first year after discharge from the PICU.

Figures 3 and 4 summarize the ICERs, where the increment is defined for surviving children relative to nonsurviv-
ing children. Sensitivity analysis is presented according to the cost of producing additional survival, the number of life years gained, and the preference score of the marginal survivor. In Figure 3, a utility score of 0.47 is used with a survival gain of 0.083. Under these assumptions, the cost per QALY varies from a high of over $250,000 to less than $25,000. Estimated life expectancy of survivors has a large impact on estimated ICERs. If life expectancy approaches 15 years, which seems reasonable, then the estimated ICERs fall under or close to the $100,000 per QALY acceptability threshold.26 In Figure 4, the estimated utility value was increased to 0.65, which may be consistent with the view that TBI survivors have improving outcomes over time. Changing the utility value to 0.65 reduces the amount of life years gained necessary to achieve acceptable ranges of cost-effectiveness. With this utility gain, 10 additional life years produces ICERs in the acceptability range. Thus, under reasonable assumptions concerning the cost of technical change and the utility value attributed to the child’s outcome, the ICERs seem favorable with life expectancies between 10 and 15 years.

If we calculate the costs per life year gained, following previous studies, and ignore the issue of preference-weighting health outcomes, the estimated ICERs fall between $38,000 and $115,000 over the range of assumed costs. This range clearly falls in the acceptability range for cost-effectiveness ratios and indicates that technological change in the treatment of pediatric TBI in children, like the treatment of heart attacks in the elderly, is worth the cost.

**DISCUSSION**

Technological advances in medicine that produce effective interventions in the form of better drugs, devices, or

<table>
<thead>
<tr>
<th>TBI Post-Acute Care Service Utilization</th>
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<tr>
<td>Rehabilitation Service</td>
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<tr>
<td>Probability of Service Use</td>
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<tr>
<td>Number of Visits/Day</td>
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<tr>
<td>Price per Visit/Day</td>
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<tr>
<td>Average Total Cost</td>
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<td>Inpatient rehabilitation</td>
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<td>Occupational therapy</td>
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<td>Speech or language therapy</td>
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<td>Medications</td>
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</tbody>
</table>

Fig. 3. Incremental cost-effectiveness ratios for pediatric TBI patients with utility = 0.47.

Fig. 4. Incremental cost-effectiveness ratios for pediatric TBI patients with utility = 0.65.
systems of care are generally thought to improve health care outcomes. Economists refer to these improvements as productivity changes. Understanding productivity changes in health care is particularly important as new research on the value of life suggests that increased spending on health care may generate benefits well in excess of costs. Prior research on productivity changes focused on improving survival with the majority of research addressing technological change in the treatment of heart attacks. One study examined productivity improvement in child injury from advances in child safety. Our prior research found evidence of productivity improvement in the treatment of pediatric TBI most likely because of more aggressive use of intracranial pressure monitoring over time.

Evidence of productivity improvement based on survival gains may not provide the most accurate evaluation because it ignores quality of life issues. The USPHS panel on cost-effectiveness recognized the need to incorporate both survival and quality of life changes in economic evaluations. Thus, the panel recommended the use of QALYs as the metric for conducting CEA.

This study follows the recommendations of the USPHS panel and provides an analysis of technological change in the treatment of pediatric TBI by evaluating the cost per QALY gained. The findings from this study suggest that the survival gain in children during the period 1988 to 1999 was likely cost-effective. ICERs for the cost per life year gained and QALY gained seemed acceptable under reasonable assumptions for the cost of improving outcomes. Costs were based on hospital charges and post-acute care service utilization in the year after discharge.

The findings can inform the management of pediatric TBI patients. Some clinicians may question whether more aggressive treatment of TBI provides benefit in excess of costs. This study, along with our findings on preference-weighted health outcomes in children with brain injuries, provides evidence that the outcomes of children who survive a brain injury are valuable in economic terms.

The study has a number of limitations, including the estimation of survival gains over time, the use of a small sample of children to estimate preference-weighted health outcomes and rehabilitation costs, and the lack of precise estimates to describe life expectancy for children that survive a TBI because of an intervention. Still, the study provides an excellent example of the challenges analysts need to overcome to conduct CEA from the societal perspective following the recommendations of the USPHS panel. In the remainder of this section, we describe these issues in detail to provide a framework for considering a prospective study to measure trauma costs and outcomes in a pediatric population.

**Cost Estimation**

The cost of technological change in the treatment of injuries and illness should include a number of components and rely on cost, not charges. The HCUP provides excellent data for examining trends in hospital outcomes and hospital charges over time, but lacks a number of cost components that can be captured under a claims-based system such as Medicare. It is possible to convert charges to cost with average cost to charge ratios, but such calculations are unlikely to alter findings in longitudinal data if cost-to-charge ratios are approximately constant during the study period. Advances in the HCUP database that provide average cost-to-charge ratios according to institutional characteristics would greatly improve cost estimates. Cost-to-charge ratios likely differ considerably according to pediatric and nonpediatric hospitals or teaching and nonteaching hospitals.

In a prospective study of children, it will be possible to capture cost data at the department level if institutions have the necessary capabilities. Resource-based systems for cost accounting have been used in a number of studies. Such studies often use proprietary software for capturing cost data.

In this longitudinal analysis, we also did not consider productivity costs for the child or the caregiver. This exclusion was because of two factors. First, we captured the survival gains in terms of QALY. It is standard, although controversial, to exclude productivity differences in analyses using QALYs as it is assumed that the QALYs already capture productivity gains and including them constitutes double counting. Second, we measured ICERs relative to children that die. It is not (currently) possible to capture incremental productivity differences for caregivers of surviving and dying children. Although it might be possible to relate caregiver productivity losses to QALYs of surviving children, such a procedure would capture differences between surviving children and healthy children, not surviving children and dying children.

Caregiver productivity costs could be considered in a prospective study of optimal treatment strategies for children after trauma. Strategies that improve outcomes in surviving children may impact caregiver work productivity, sleep, and leisure. Cross-sectional estimates of these differences can be used to generate lifetime values. Failure to incorporate important “family spillover effects” in CEA results in an underestimate of the full costs and benefits of effective interventions.

We also did not consider the issue of future costs that account for the difference in consumption and productivity. Such calculations require estimates of future productivity for children after a severe TBI. If marginal survivors have consumption costs in excess of productivity, ICERs would be understated.

**Preference-Weighted Health Outcomes**

We used data on preference-weighted health outcomes from a cohort of children that survived a TBI. An analysis of the correlation in preference scores with clinical data obtained from the ICU admission suggested that such scores have construct validity. In theory, the scores can be used to consider acceptable ranges for conducting CEA as presented in this study. Still, the scores have limitations in that the
average score of the cohort may not reflect the score for the marginally surviving child where marginal implies a child who survived but would have died without the intervention. For this reason, we considered scores in the lower range of the cohort in the CEA. We also considered higher scores as little data describes preference scores associated with children after injury and that data relies on relatively short time periods. It is possible that children in the cohort, even marginally surviving children, will have higher scores in future periods with recovery from functional limitations.

The outcomes of the marginal survivor merit concerns in a longitudinal study of survival, but are unlikely to be an issue in a prospective study where outcomes can be compared across types of institutions. Such estimates represent marginal changes in outcomes. This issue also is less important in decision-analytic studies of treatment strategies as outcomes can be modeled in probability terms. Stein et al. used preference scores associated with the Glasgow Outcome Scale, but it is not clear how the scores were actually obtained.10

Consistent with recommendations from the US Panel on Cost-effectiveness, additional data on the preference scores of children captured at different time periods is needed to improve overall ICER estimates. Failure to use preference-weighted health outcomes in CEA reduces the ability to compare interventions and appropriately guide the allocation of resources.

Life Years Gained

Calculation of the ICER requires an estimate of life years gained for children that survived a TBI. As was the case with estimates of preference-weighted health outcomes, estimates of life years should be based on marginally surviving children (which again, does not imply a marginal existence in functional status terms). Data on the life expectancy of children after a TBI suggest that severe functional limitations can reduce life expectancy, but even children with severe limitations will survive 15 years or more.23 It is probable that surviving children, even marginally surviving ones, might survive 30 years or more. This study calculated ICERs during a 30-year range and found that the evidence pointed to favorable ICERs if the average life expectancy exceeded 10 years or the cost of the intervention was in the lower end of the estimated range. Thus, how analysts address the issue of life expectancy can have a great influence on the estimated ICER.

Stein et al. used average life expectancy discounted to present value terms in their analysis adjusted for differences in life expectancy for TBI survivors.10 Such calculations were not possible in this study as current estimates are not available for young children. Still, it seems that remaining life expectancy of surviving children will exceed 15 years.

Effectiveness of Interventions to Improve Survival

In the case of elderly persons that suffered a heart attack, technological improvements in treatment brought about a large increase in survival during the period 1986 to 2003. Recent examination of outcome data, however, indicates a flattening of survival with increases in treatment costs. Data from this period do not suggest favorable ICERs. It is likely that survival gains are subject to the economic law of diminishing returns, especially in the relatively short run. Diminishing returns suggests that the cost of obtaining additional gains in survival will increase as productivity improves, given that gains are limited to 100% survival. The first intervention might be the least costly or most likely to improve outcomes. Subsequent gains in survival may be more difficult and/or costly to achieve. At the same time, it is possible that less-effective interventions to improving outcomes will cost less than interventions for improving in outcomes.

This study used longitudinal hospital data to estimate survival gains for children with a TBI. We relied on severity-adjusted estimates to obtain survival gains, but these estimates assume that admitting decisions at hospitals have not changed over time. A prospective study has the advantage of better control in selecting patient populations for making comparisons.

CONCLUSIONS

The US Panel on Cost-Effectiveness of Health Interventions suggested the use of QALYs as a metric in the calculation of ICERs. This study illustrates the calculation of ICERs based on QALYs to evaluate technological progress in the treatment of TBI in children. Over a range of reasonable assumptions, the ICERs are favorable and suggest that the improved outcomes that occurred during the period 1988 to 1999 were cost-effective. Estimated ICERs could be improved by better identification of marginal patients for cost and QALY calculations. The study provides a framework for considering the cost-effectiveness of other health interventions that lead to optimal care for injured children. Careful examination of the data indicates that assumptions concerning preference-weighted health outcomes and life expectancy of surviving children will have the most impact on estimated ICERs.

REFERENCES

Dr. Scheidt: A number of this morning’s comments related to aspects of the National Children’s Study, which is the largest long-term study of children’s health and development that’s ever been proposed. It proposes to follow 100,000 mother/child pairs from as early as possible in pregnancy until that child reaches adulthood, and to link a wide range of environmental exposures and genetic factors to children’s health and development. It was proposed originally by a presidential task force and convened in the late 1990s, chaired by the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency with seven other cabinet officers charged to develop national strategies for reducing environmental effects on children’s health and development. That task force very quickly came to the realization that there were not the data that would allow them to meet that charge and a program of research capable of defining the risks and guiding policy would be necessary. In the fall of 2000, Congress passed the Children’s Health Act, which authorized the National Institute of Child Health and Human Development (NICHD) and a consortium of federal agencies to go forward with the planning and implementation of this large study.

As conceived then and as planned now, the study will measure a wide range of environmental exposures, including various chemical exposures, factors of family, parenting, and neighborhood characteristics. It will examine multiple outcomes, neurocognitive development, growth, sexual maturation, behavior, mental health conditions, such as autism, attention deficit, schizophrenia, aggression, and, of course, asthma and obesity because of the prevalence of those conditions in today’s children.

What’s the relationship of this study to the comments this morning about a large study of pediatric trauma? Certainly one could see the possibility of the opportunity for collecting prospective pretrauma data from a study like this. The National Children’s Study (NCS) would enable measures of family, neighborhoods, nutritional status, and developmental status that could be important as determinants and predictors of outcomes of trauma. It offers the opportunity for long-term follow-up of development and function in the cohort as it progresses to adulthood.

Collecting detailed trauma care data are more problematic. As a matter of course in the study, we intend to collect healthcare data, but it would take some considerable enhancements to collect the trauma data that might be important for the kinds of studies that have been discussed here today.

Sample size is a bigger question. One hundred thousand seems like a lot of participants, but there would be still relatively few seriously injured children. By our estimates, hospitalized children for head trauma might be in the range of 1.5 to 2 per thousand, and that’s the low end of the capability of this study to detect effects of alternatives in management and treatment for a relative risk of about two. Much more seriously and less frequently injured participants might be even less common and have less power.

Dr. Wilfond: Even if something occurs with an incidence as low as one in a thousand, that will still be a hundred people for which you’ll have such richly collected pre and post event data. That it still strikes me as being an incredible opportunity, even to do some sort of focused evaluation.

Male: There will be 17 years before he gets data on a 17-year-old, however.

Dr. Clark: We can predict that the environmental agent that will have the greatest effect on the health of these children will be the automobile. Will your study look at risk factors for that particular agent being deleterious in their health?

Dr. Scheidt: Clearly it will capture events related to automobile injuries, including distance of residence from motorways.

Dr. Rivara: It’s going to look at neighborhood factors, parental supervision factors, socioeconomic factors, dynamics in the family, the developmental status of the child, and those factors that we see in our clinical practice as affecting risk of a motor vehicle injury. The limiting factor is going to be how many children in the first 5 years are going to be injured by motor vehicles.

Dr. Scheidt: If there are specific hypotheses that represent an opportunity to examine in more detail than would otherwise be collected as a matter of course, there’s opportunity for enhancing the study or adding adjunct studies onto this platform. The Women’s Health Initiative had more than 250 proposed and 98 funded ancillary studies in that large, longitudinal study. We anticipate that perhaps even the major contribution of this study will be the opportunity for those kinds of additional projects.
Measuring Children’s Health-Related Quality of Life After Trauma

Melissa Lee McCarthy, ScD

Consideration of children’s health-related quality of life (HRQOL) after injury is a critical aspect of outcome in assessing the effectiveness of trauma care. Numerous instruments are available today for measuring the HRQOL of injured children. HRQOL instruments reflect the subjective perspective of the impact an injury or disease has on a child’s physical, emotional, and social well being. Most studies to date have examined children’s HRQOL during the first year postinjury, relatively little is known about children’s long-term HRQOL after trauma. Most trauma outcome studies have included children with heterogeneous injuries so the impact of specific injuries on HRQOL outcomes has not been well established. The majority of outcome studies have focused on injured children who have been hospitalized, however the research should be extended to the emergency department because a large proportion of injured children are treated and released from there.

In addition to documenting recovery, investigators should use HRQOL instruments to evaluate the quality of care we offer injured children and their families. Rigorously conducted HRQOL assessment will provide valuable information that we can use to successfully optimize children’s recovery after trauma.

Key Words: Pediatric health-related quality of life, Trauma, Outcomes measurement, Child health status.

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The vast majority of children in the United States enjoy good health. One of the most common threats to the health and well-being of children are injuries. Injury is the leading cause of death among US children under 18 years of age and is one of the top five reasons that children require medical attention. In 2004, 11,716 children died, 217,906 were hospitalized, and more than 20 million children received outpatient treatment (i.e., physician’s office, emergency department [ED], or clinic) because of an injury. Despite the frequency of their occurrence, relatively little is known about the impact injuries have on children’s health and well being.

During the past two decades, consensus has emerged regarding the important role that health-related quality of life (HRQOL) assessment plays in evaluating children’s health, and the effectiveness of therapeutic interventions. Although the appreciation for HRQOL assessment has lead to the development of numerous instruments, relatively few investigators have used them to assess children’s outcomes after trauma. HRQOL outcomes complement clinical symptoms and pathology measures. Furthermore, their generic and global nature provides clinicians and researchers with the ability to use the same health outcomes instrument for many different types of injuries and severities, for a variety of treatment settings, and for all relevant time points during the recovery process. The purpose of this article is to describe generic HRQOL instruments that have been developed for children, summarize what we have learned about children’s HRQOL after injury, and recommend next steps for pediatric trauma outcomes research.

PEDIATRIC HRQOL INSTRUMENTS

HRQOL instruments have three features that distinguish them from other types of health outcome indicators. First, they are multidimensional. Although there is no universal, accepted definition of children’s HRQOL, it typically includes physical, emotional, social or behavioral, and role functioning. Second, HRQOL instruments measure children’s health in terms that are meaningful to the child and family such as a child’s ability to carry out everyday life activities. Finally, HRQOL is subjective, it is measured from the patient’s perspective whenever possible. For children, it is typically based on the perceptions of the parent or child or both.

HRQOL instruments have been developed using psychometric or utility-based approaches. A psychometric measure describes the health profile of a child across multiple health domains, yielding a score for each domain as well as one or more summary scores. In contrast, a utility measure provides an overall score, and includes death and QOL in a single metric. Utility-based instruments assign weights to different health states by eliciting preferences from patients or consumers using decision theory and economic principles. Quality-adjusted life years can be estimated from utility-based instruments, and they are used to determine the cost-effectiveness of interventions or programs. All the psychometric-based instruments included in this review were specifically developed for children, whereas all the utility-based measures except the Health Utility Index Mark 2 System were originally developed for adults and later adapted for children.
There are a variety of generic instruments that have been developed to measure children’s HRQOL (see Table 1). To choose the appropriate instrument for a specific patient population, it is important to consider the following seven factors.41 First, the conceptual and measurement foundation of the instrument must be reviewed. Does the instrument measure all health dimensions relevant to your patient population? All the instruments listed in Table 2 assess children’s physical functioning but some omit other important dimensions of HRQOL. Furthermore, one must consider the spectrum of health covered by the instrument because HRQOL measures are not equally sensitive along the full continuum. Instruments such as the Pediatric Evaluation and Disability Inventory (PEDI) and the Functional Status IIR were developed for children with chronic conditions so they include more items that reflect lower levels of function. These instruments are likely to demonstrate a ceiling effect among children who sustain minor injuries.

Second, it is critical to evaluate the psychometric properties of HRQOL instruments, namely their reliability and validity. The two main types of reliability that are relevant to HRQOL instruments are internal consistency (i.e., homogeneity of items within a scale) and reproducibility (e.g., test-retest and interrater reliability).41 Validity, which assesses the extent to which an instrument measures the construct(s) it is intended to is typically evaluated by content (i.e., scale items are appropriate), construct (i.e., demonstrates logical relationships with other measures or health indicators), and criterion-related (i.e., associated with other established HRQOL instruments) validity.42 Table 1 summarizes some types of reliability and validity as-

<table>
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<tr>
<th>Table 1 Description of Pediatric Health Status Instruments</th>
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<tr>
<td>Instrument</td>
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<td>----------------------------------------------------------</td>
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<tr>
<td>A. Psychometric instruments</td>
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<tr>
<td>Child Health &amp; Illness Profile (CHIP)8–11</td>
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<tr>
<td>Child Health Questionnaire (CHQ)12</td>
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<tr>
<td>Dartmouth COOP Charts (COOP)13</td>
</tr>
<tr>
<td>DISABKIDS14–16</td>
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<tr>
<td>Functional Independence Measure (FIM/WeeFIM)17–19</td>
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<td>Functional Status II Revised (FSIIR)20</td>
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<tr>
<td>Infant &amp; Toddler QOL Questionnaire (ITQOL)21</td>
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<td>KINDL22</td>
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<tr>
<td>KIDSCREEN23,24</td>
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<tr>
<td>Pediatric Evaluation &amp; Disability Inventory (PEDI)25–28</td>
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<tr>
<td>Pediatric QOL Inventory (PedsQL)29–32</td>
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<tr>
<td>TNO-AZL Child QOL (TACQOL)/TNO-AZL Parent QOL (TAPQOL)33,34</td>
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<tr>
<td>Vecu et Sante Percue de l’Adolescent (VSP-A)35,36</td>
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<tr>
<td>B. Utility instruments</td>
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<tr>
<td>EuroQOL (EQ-5D)37</td>
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<tr>
<td>Health Utilities Index Version 2 (HUI:2)38</td>
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<tr>
<td>Quality of Well-Being Scale (QWB)39,40</td>
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</table>

Reliability: ICC-internal consistency. For utility-based instruments only test-retest is applicable.
A third factor to consider in choosing an appropriate HRQOL measure is its responsiveness or sensitivity to change. Does the instrument detect change after an intervention or over time? Responsiveness is often examined in longitudinal studies that compare the outcomes of a group expected to change to another group that is not. A good HRQOL instrument should be able to detect the minimal change considered to be important by the child, family, or healthcare provider.

Fourth, the scores produced by a HRQOL instrument must be easily interpretable. It is important to be able to translate a quantitative score or change in scores to a qualitative category or to an external measure that has a familiar meaning. An instrument’s interpretability is enhanced when there are normative data from a representative sample of the general population or data from patients with specific clinical conditions. Likewise, interpretability can be based on the relationship between an instrument’s scores and socially recognized life events (e.g., special education services required) or circumstances (e.g., poverty). Of the instruments listed in Table 1, the Pediatric Quality of Life Inventory (PedsQL) is one of the most interpretable because of its widespread use.

Fifth, for clinical and research purposes, it is important to consider the response burden or the time, effort, and other demands that are placed on the respondent completing the instrument. Many of the instruments listed in Table 1 can be completed within a short time frame (i.e., <15 minutes) but others take 30 minutes or longer (e.g., Functional Independence Measure [FIM] and PEDI). In addition, a potential user should review an instrument to make sure that the reading and comprehension levels are appropriate for the intended population and that completing the instrument will not place undue physical or emotional strain on the respondent.

Sixth, mode of administration can make a difference in selection of an instrument. Self-report is considered the gold standard in HRQOL measurement and children are assumed to have a unique awareness of their own health. Several HRQOL instruments only have self-report versions (see Table 1). Most of the HRQOL instruments have both child and proxy versions, however the age at which self-report is available varies among the instruments. Most often these instruments are self- or interviewer-administered. Originally, the WeeFIM and PEDI were developed as performance based measures that required a clinician rater. However, now there are also self- and interviewer-administered versions available. Most recently, a computer-adapted version of the PEDI has been developed that greatly reduces the respondent time and administration costs.

Finally, it is important to consider whether an instrument has been adapted or translated for use with children who differ from the original population in terms of culture or language. If an investigator intends to use the instrument with children from different cultural backgrounds or with those who speak different languages, it is important to analyze whether the instrument has considered different cultural perspectives and has been appropriately translated and fully adapted for different languages. The KIDSCREEN and DISABKIDS are generic HRQOL instruments that were developed simultaneously in different cultures by multinational working groups. The DISABKIDS has been explicitly tested for cross-cultural comparability of measurement.

In summary, there are numerous instruments available today for measuring the HRQOL of children. These instruments vary conceptually, methodologically, and in practicality. The characteristics of HRQOL instruments must be evaluated in the context of their intended use by researchers and clinicians. Although the plethora of instruments may seem overwhelming initially, once a user prioritizes his or her objectives and reviews the instruments with the above criteria in mind, he or she should be able to find a suitable instrument.

**THE CURRENT STATUS OF HRQOL IN PEDIATRIC TRAUMA**

Table 3 lists studies that have measured HRQOL outcomes after different types of pediatric trauma. These trauma outcome studies vary significantly in terms of the instrument(s) used, the age and type of injuries included, when HRQOL was measured, and by whom. A summary of what can be learned from these studies as well as gaps that remain follows.

HRQOL instruments can play a valuable role in documenting the recovery trajectory after different types of injuries. For example, McCarthy et al. used the PedsQL to document the HRQOL of children who were hospitalized with a traumatic brain injury (TBI) during the first year postinjury. HRQOL was dramatically reduced at 3 months postinjury for all children. Children’s outcomes improved by 1 year, however, impaired HRQOL remained

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**Table 2 Dimensions Different Pediatric HRQOL Instruments Include**

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Physical</th>
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<th>Social/Behavioral</th>
<th>Role (School)</th>
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<td>DISABKIDS</td>
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<td>FIM/WeeFIM</td>
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<td>HUI:3</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>ITQOL</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>KINDL</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>KIDSCREEN</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>PEDI</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>PedsQL</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>QWB</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>TACQOL/TAPQOL</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>VSP-A</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
highly prevalent, especially among those moderately to severely injured. Stancin et al. used the Child Health Questionnaire to measure the HRQOL of children with a moderate to severe TBI at 4 years postinjury and found relatively mild effects for the TBI group as a whole, although some children’s HRQOL was clearly diminished relative to normative expectations. The results of these two studies suggest that children’s recovery after TBI continues to change significantly between 1 and 4 years postinjury. Although these findings must be confirmed empirically, it highlights the need for more longitudinal studies that generate recovery curves after different types of injuries, and identify factors associated with poor HRQOL outcomes.

In more recent years, attention is being focused on the psychosocial effects an injury can have on a child’s health and well being. Holbrook et al. found that a high proportion of adolescents hospitalized with an injury screened positive.

### Table 3 Use of Different HRQOL Instruments in Pediatric Trauma Studies

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Age at Injury</th>
<th>Study Sample</th>
<th>Time Points</th>
<th>Child/Parent</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHQ</td>
<td>6–12</td>
<td>Hospitalized, TBI, or orthopedic injuries[^46]</td>
<td>4 yr postinjury</td>
<td>Both</td>
</tr>
<tr>
<td>CHQ + ITQOL</td>
<td>1–18</td>
<td>Hospitalized, blunt injuries—no TBI or spinal cord injuries[^47]</td>
<td>1, 6 mo postinjury</td>
<td>Parent</td>
</tr>
<tr>
<td>CHQ</td>
<td>3–18</td>
<td>Hospitalized, all injury types[^48]</td>
<td>1, 6 mo postinjury</td>
<td>Parent</td>
</tr>
<tr>
<td></td>
<td>5–18</td>
<td>Hospitalized; all injury types[^49]</td>
<td>1.5 yr postinjury</td>
<td>Parent</td>
</tr>
<tr>
<td>EQ-5D</td>
<td>5–14</td>
<td>Hospitalized or treated in ED, all injuries[^50]</td>
<td>2.5, 5, 9 mo postinjury</td>
<td>5–12 Parent; 13–14 adolescent</td>
</tr>
<tr>
<td></td>
<td>15+</td>
<td>Hospitalized or treated in ED, all injuries[^51]</td>
<td>2.5, 5, 9, and 24 mo postinjury</td>
<td>Adolescents/adults</td>
</tr>
<tr>
<td>FSIIR</td>
<td>0–2</td>
<td>Hospitalized with severe TBI[^52,53]</td>
<td>1, 2 yr postinjury</td>
<td>Parent</td>
</tr>
<tr>
<td>PedsQL</td>
<td>5–15</td>
<td>Hospitalized with TBI or extremity fractures[^54,55]</td>
<td>3, 12 mo postinjury</td>
<td>Parent</td>
</tr>
<tr>
<td>TACQOL</td>
<td>6–14</td>
<td>Hospitalized with unintentional injuries; no severe TBI[^56]</td>
<td>1, 12 mo postinjury</td>
<td>Child</td>
</tr>
<tr>
<td></td>
<td>5–17</td>
<td>Hospitalized with burn injuries[^57]</td>
<td>1–13 yr postinjury</td>
<td>Parent</td>
</tr>
<tr>
<td></td>
<td>4–13</td>
<td>ED or inpatients with traffic injuries[^58,59]</td>
<td>1.5–3.4 yr postinjury</td>
<td>Parent, both</td>
</tr>
<tr>
<td></td>
<td>8–15</td>
<td>Hospitalized with traffic injuries[^60]</td>
<td>3, 6 mo postinjury</td>
<td>Child</td>
</tr>
<tr>
<td>FIM</td>
<td>2–15</td>
<td>Hospitalized, ISS &gt;12[^61]</td>
<td>6 mo postinjury</td>
<td>Parent</td>
</tr>
<tr>
<td></td>
<td>1–18</td>
<td>Hospitalized, blunt injuries—no TBI or spinal cord injuries[^47]</td>
<td>1, 6 mo postinjury</td>
<td>Parent</td>
</tr>
<tr>
<td></td>
<td>3–18</td>
<td>Hospitalized, AIS ≤2[^48]</td>
<td>Hospital d/c, 1, 6 mo postinjury</td>
<td>Parent</td>
</tr>
<tr>
<td></td>
<td>0–17</td>
<td>Hospitalized, pelvic fracture[^62]</td>
<td>Hospital d/c, 6 mo postinjury</td>
<td>Trained examiner</td>
</tr>
<tr>
<td></td>
<td>4–18</td>
<td>Inpatient rehabilitation, spinal cord injuries[^63]</td>
<td>Admission and d/c</td>
<td>Trained examiner</td>
</tr>
<tr>
<td></td>
<td>0–21</td>
<td>Inpatient rehabilitation, TBI[^64]</td>
<td>Admission and d/c</td>
<td>Trained examiner</td>
</tr>
<tr>
<td>PEDI</td>
<td>&lt;6</td>
<td>Hospitalized, TBI, or extracranial injuries[^65]</td>
<td>1, 6 mo postinjury</td>
<td>Trained examiner</td>
</tr>
<tr>
<td></td>
<td>1–19</td>
<td>Inpatient rehab, ABI[^66]</td>
<td>Admission and d/c</td>
<td>Clinician rated</td>
</tr>
<tr>
<td></td>
<td>1–21</td>
<td>Inpatient rehab, ABI[^67]</td>
<td>Admission and d/c</td>
<td>Clinician rated</td>
</tr>
<tr>
<td></td>
<td>2–21</td>
<td>Inpatient rehab, ABI[^68]</td>
<td>Admission and d/c</td>
<td>Clinician rated</td>
</tr>
<tr>
<td></td>
<td>2+</td>
<td>Inpatient rehab, TBI[^69]</td>
<td>Admission and d/c</td>
<td>Adolescent</td>
</tr>
<tr>
<td>QWB</td>
<td>12–19</td>
<td>Hospitalized trauma patients excluding severe brain and spinal cord injuries[^70,71]</td>
<td>Discharge, 3,6,12,18, and 24 mo postinjury</td>
<td></td>
</tr>
</tbody>
</table>

[^46]: Child Health Questionnaire
[^47]: Injury Severity Score
[^48]: Abbreviated Injury Scale

TBI, traumatic brain injury; ABI, acquired brain injury; ISS, Injury Severity Score; AIS, Abbreviated Injury Scale.
for acute stress disorder, and this negatively impacted HRQOL outcomes during the first 2 years after injury. At 4 years postinjury, Stancin et al. reported few physical limitations among children who sustained a TBI or extremity fracture but persistent psychosocial problems among children with a severe TBI. Not only is it important to measure the impact an injury has on a child’s psychosocial health during a defined period after the injury but also to analyze the developmental implications the injury may have on a child’s future well-being.

Trauma can affect many different domains of a child’s health, and generic instruments may not adequately measure all relevant domains. For example, fractures are common in children but most HRQOL instruments include more items that are relevant to lower extremity function compared with upper extremity function. Sexual function can be impaired after a pelvic or spinal cord injury, but generic HRQOL instruments do not measure sexual function. When measuring the HRQOL of children after a brain injury, McCarthy et al. supplemented the PedsQL with a cognitive functioning scale because the generic PedsQL does not explicitly measure cognitive function. A disease-specific scale may be more sensitive to change and discriminate better among groups that are known to differ in specific health domains compared with a generic instrument. Thus, it is important to consider using a generic HRQOL instrument in combination with a trauma-specific HRQOL measure depending on the types and severities of injuries sustained.

Studies report conflicting results regarding the relationship between HRQOL and injury severity. The majority of studies to date have not found a strong relationship between the two. The lack of correlation could be because of several reasons: HRQOL was not measured early enough postinjury; the extent of injury severity was not adequately measured; the study samples were too heterogeneous in terms of the types and severities of injuries included; or the contribution of other factors that impact HRQOL was not adequately taken into account. The PedsQL demonstrated a significant relationship between the severity of the TBI and physical and psychosocial functioning during the first year postinjury after controlling for associated injuries and other child and family factors. A strong inverse relationship was also found between the discharge inpatient rehabilitation WeeFIM/FIM scores and the spinal cord injury level of children and adolescents. The relationship between injury severity and HRQOL warrants further study with careful attention paid to how injury severity is measured and what other factors are considered in establishing the correlation.

When measuring HRQOL outcomes after trauma, it is important to control for preinjury HRQOL to analyze the extent to which problems postinjury were present before the injury. Typically, this is performed by asking the respondent shortly after the injury to think back before the injury when completing the HRQOL instrument. This method clearly has limitations because of the potential for recall bias. McCarthy et al. found that the parents of children who sustained a severe TBI reported higher preinjury HRQOL scores compared with those less severely injured even though they did not have a higher prevalence of preexisting health conditions. In reality, the parents probably overestimated the child’s preinjury HRQOL because of the dramatic change postinjury. Nonetheless, a preinjury HRQOL assessment will provide better precision in the measurement of the injury effects.

In addition to controlling for preinjury HRQOL, it is important to measure the child’s family characteristics. Trauma outcome studies conducted to date support a bidirectional relationship between the child and his or her family. Because children are dependent on their families for their physical, emotional, and social needs, family characteristics can significantly influence children’s HRQOL. Stancin et al. found that the physical and psychosocial health of children with a TBI was significantly poorer among children from socioeconomically disadvantaged families at 4 years postinjury. Good family functioning has been found to be associated with better HRQOL outcomes for children with TBI as well as children with burn injuries. In addition, a child’s health can significantly influence family well-being. Evidence suggests that children’s injuries can cause increased family burden and caregiver distress. These results suggest children’s HRQOL may be better among families that can successfully adapt after pediatric trauma.

In summary, HRQOL is assuming a more central role in pediatric trauma outcome studies. Despite the increasing use of HRQOL instruments with injured children, much remains to be learned. Most studies to date have examined children’s HRQOL during the first year postinjury, relatively little is known about children’s long-term HRQOL after trauma. Recovery trajectories for various injuries have not yet been carefully mapped out which makes it difficult to determine the impact injuries have on a child’s present health and well being as well as future development. As Taylor points out, we need to analyze to what extent improvement in children’s health after trauma is a result of physical “recovery or reorganization, environmental accommodation or development of compensatory strategies”. Finally, future studies should further explore other family traits besides family functioning and socioeconomic status that may influence children’s HRQOL postinjury.

RECOMMENDATIONS AND FUTURE DIRECTION

During the past decade, children’s HRQOL has received much attention nationally and internationally by academicians, clinicians, professional societies, and health care organizations. Constructive debate and many methodological advances have lead to a proliferation of HRQOL instruments for children. Although this diversity is productive and useful, it may be time to critically evaluate existing instruments and only develop new ones if existing ones prove inadequate. For pediatric trauma, researchers should be able to select an appropriate generic
HRQOL instrument among existing measures. However, we may need to develop a trauma-specific instrument that addresses important health domains not typically included in generic measures such as upper extremity function, sexual function, cognitive function, or physical appearance.

Many studies report HRQOL outcomes after pediatric trauma without evaluating the psychometric properties of the instrument for their study sample. Although the reliability and validity of the majority of HRQOL instruments have been established for the original population, their performance with pediatric trauma patients has not been evaluated with the exception of the PEDI, WeeFIM, and PedsQL among children with TBI. The results could vary significantly depending on the types and severities of injuries sustained. As we begin to use these instruments more with injured children, we need to understand how well these instruments reliably and validly measure children’s HRQOL because it can significantly influence the results we obtain.78

To date, HRQOL instruments have rarely been used to assess the effectiveness of a therapeutic intervention on children’s recovery after an injury. One study to date used the PEDI to analyze the impact of physical therapy services on the mobility of children with TBI during inpatient rehabilitation.69 Assessing the effectiveness of therapeutic interventions is challenging in children, because of the developmental changes that children experience and the response shift that can occur as children and parents change their HRQOL appraisals because of accommodations they make to their HRQOL rather than real improvements in HRQOL as a result of a specific treatment.79,80 Regardless of these methodological challenges, assessing therapeutic interventions in terms of HRQOL outcomes is of great value to the child, family, and society.

Most pediatric trauma outcome studies have relied on parental report of children’s HRQOL despite the importance of children’s own assessment of their HRQOL. There is adequate evidence that children more than the age of seven can understand and provide reliable and valid reports of their own HRQOL.53,81 Forrest et al. found that children’s ratings of their HRQOL were a better predictor of future physician visits compared with parent-reported data.82 Because parents often decide which healthcare services to seek for their children, eliciting their views is also important. Furthermore, some children are too young, too severely injured, or lack awareness because of their neurologic injury to be able to evaluate their own health. Whenever possible, obtaining HRQOL ratings from both the child and parent is advantageous, despite the imperfect concordance that may be present between the two perspectives.

To date, pediatric trauma outcomes studies have largely focused on children hospitalized for an injury and relatively few investigators have used HRQOL instruments in the ED setting even though most injuries that require medical attention are treated there. Polinder et al. used the EuroQOL to document the health status of 1,221 injured children who presented to an ED in the Netherlands for treatment.50 At 9 months postinjury, 8% of the cohort still reported functional limitations, especially in the areas of pain and usual activities. Slightly more than one-third of the subjects were hospitalized but three-quarters of all residual problems at 9 months postinjury were among the nonhospitalized children. These findings suggest that HRQOL assessment should be extended to the ED setting.

In conclusion, researchers and clinicians should take advantage of the advances made in the measurement of children’s HRQOL and begin to incorporate HRQOL assessment in pediatric trauma outcome studies. Rigorously conducted studies will greatly advance our ability to describe and quantify the short- and long-term disability associated with different types and severities of injury. In addition, we should begin to use these instruments to evaluate the quality of care we offer injured children and their families. The more we use these tools and weigh the results, the more we will learn how to successfully optimize children’s recovery after trauma.

REFERENCES
Discussion of Presentation by McCarthy

Dr. Aitken: I hope that there is general agreement that the use of a good measure of overall health is needed for a pediatric NSCOT. Despite rapid evolution in this area and encouraging application of the now wide variety of instruments to assess HRQOL, there is probably no single existing measure that will completely address all the desired aspects of health we would want to capture in the proposed study. To do this, Dr. McCarthy has suggested the possibility of developing a trauma-specific instrument. I would endorse this. Such an instrument would ideally have the following characteristics: use one of the best studied multidimensional instruments (child health questionnaire [CHQ], PedsQL, or one of the newer European instruments), adequately reflect cognitive abnormalities (PedsQL), and address family functioning (CHQ).

One thing I find puzzling is that despite the numerous studies now in the literature none of these instruments has been widely used in clinical applications. What are the barriers? Is this caused by lack of awareness, time constraints, money, or simply lack of buy-in? Biggest barriers exist with regard to respondent burden for some of the instruments (CHQ), potential for analytic burden in general settings (not for this study), and in interpretability. This is an issue that can only be resolved with greater experience with the instruments on the patients we’re interested in.

We must work out many methodological issues, but when we do incorporate into trauma registries and otherwise make—through incentive or requirements for trauma designation—measurement of this information as part of the standard of care? This will probably require collaboration with our colleagues in physical medicine and rehabilitation to implement. Without establishment of systems that require and support their use, these HRQOL will remain in the province of research, even after their applicability for the trauma population is better defined.

How we present our findings is also important. I would also emphasize that these tools, used more broadly or in research contexts, can provide very valuable data that can be used to inform policies. Awareness can lead to increased support for trauma systems, state and federal prevention strategies, institutional investment in caring for these patients, and might influence payers to change policies to more broadly address needs of these patients. We owe it to our patients to put their experiences into a context that people can understand so we can better advocate for their needs. It’s very difficult to go to a hospital administrator to support your trauma program and say that the psychosocial summary score on my patients are 30 points lower than normal; that doesn’t mean anything to people, even if we can interpret it. However, you can go to a state senator and say I’d like you to support a primary seat belt law state because TBI patients are as sick as cancer patients are. Our patients really need us to put their experience in terms that other people can understand. These kinds of measures afford that, clinical measures really don’t.

Other aspects of function that should be used to complement generic instruments are very important, and should be included in the proposed study as economically as possible. These include the following:

1. Mental health and behavioral issues. Most of these patients will be healthy physically but are at risk for both PTSD and depression. Premorbid or new ADHD, and behavior issues may be the most important adverse outcomes experienced with impacts at home and in educational settings.

2. Specific measures of family function should be measured, both in the premorbid case and longitudinally.

3. An assessment of family and patient social support, including financial burden, is also crucial—evidence from the adult and pediatric literature for general trauma and TBI demonstrate the importance of this. If they survive through good prehospital care, then have adequate inpatient management, the deciding factors in return to function are likely to rest not with the explicit trauma designation of their healthcare facility but in the ability of the family to cope with the short and long term needs of the patient, the availability of needed services, the responsiveness of the school setting, and ongoing assessment of any emerging issues with behavior and cognition over time. I would even assert that the factors on either side of the entire hospital-based care phase—prehospital management and discharge planning and parental education—are really where the rubber hits the road in terms of functional recovery for most patients. We must attempt to capture whether and how well we do these things and include them in standards of care that are developed.

Finally, some editorial comments, the adult NSCOT project focused on urban and suburban populations for a number of practical reasons. For the pediatric study, I hope that consideration is given to include representative centers (like KY, UT, AR, and others) that serve a substantial pro-
portant of children from rural areas. These children face disparities in both injury risk and management and should be identified and evaluated carefully in any pediatric study.

Yesterday there was some discussion of the somewhat intangible value added by care in pediatric-specific environments. The value of family centered care, increased recognition of the importance of parental education, and access to pediatric specific rehabilitation services should be measured explicitly in this study. When assessing communication, it will be important to include how well primary care providers/general pediatricians are included. Pediatricians can offer expertise in child development and experience with family communication that can improve the system. When considering dissemination, general pediatricians also should be included, through the American Academy of Pediatrics (AAP) or other venues. They also need to be aware of potential problems and outcomes since they will be the ones who end up identifying them and managing them, not surgeons or ED physicians. The care spectrum does not end at the hospital door—we have heard this loud and clear from qualitative studies of family burden after trauma care—and we should capitalize on the opportunity to evaluate systems that work best with this study.

Dr. Yeates: I wanted to take a little broader perspective on thinking about outcomes and ask ourselves a series of questions. When thinking about outcomes assessment, what outcomes do you want? Why do you want to assess them? When are you going to assess them? The timing of assessment postinjury is very important. It may actually be that you want to measure different things at different times because the importance of different types of outcomes varies across time. Who are we assessing—the target of the assessment or the respondent? There has been a lot of discussion for including families in the assessment, both in assessing the child, but also assessing family functioning per se. Where do we do the assessment? Do we do it on the rehab unit? Do we do it in the home? Do we do it in the school? Finally, what kinds of methods and indicators are we going to use?

There are potentially multiple levels of analysis. Frequently in studies of outcomes for trauma, and particularly TBI, there’s been a great deal of focus on biological or medical types of outcomes. We obviously need to broaden that in a study of children to include psychological and potentially social and cultural outcomes as well. One of the things that’s a big challenge for children with trauma, is that they generally don’t look any different after they’re injured, but may function very differently. Cultural issues having to do with disability and neglect of children with injuries are important to consider.

I would suggest that we need to think about the conceptualization of outcome assessment. The World Health Organization (WHO) International Classification of Functioning, Disability and Health provides one model that might be considered in trying to think about the level of outcomes assessment. The quality of life measures look at levels of participation, what somebody is actually doing out in the community or with peers or in school. But we’re actually interested at times in function, whether that is physical or cognitive ability of someone to do things, not necessarily whether they do them on a day-to-day basis. The WHO model does take into account some of the risk and resilience factors at a personal environmental level that I think are going to play important roles as moderators of outcome from any sort of trauma care.

Why assess specific outcomes? In children with TBI, we might be interested in trying to look at impairment in brain function. On the other hand, we might want to document functional deficits. We may be interested in looking at environmental obstacles and supports that have a lot to do with the ability of whether or not a trauma program is even going to be able to affect children’s outcome. We need to think seriously about what we’re trying to assess and why to select particular instruments; it does help to have theory as a guide as much as possible. One of the concerns I have about the generic quality of life measures is that there is not a particular theory behind them; they’re just generic measures. The other problem with them, from my perspective, is that although they’re broad based, they assess most outcomes in a fairly generic, general way without a whole lot of specificity. So, saying someone has poor school function or poor social function or poor cognitive function at a very generic level tells you relatively little about the nature of the problem.

When should we assess outcomes? At least with TBI, recovery is obviously a process of change, the goals of which may change over time. Acutely, often we’re interested in structure and function—what is the brain doing. During postacute rehabilitation, we’re focused on activity. What can the child do? What are we trying to restore or ameliorate in terms of deficit? After community re-entry, we’re most interested in participation. What are they doing in school, neighborhood, and at home? So sometimes it’s not necessarily the case that we want to assess the same outcomes across time, although there are certainly benefits to that. We may actually want to target assessment differently at different times.

Who should be assessed? I would argue we really don’t want to focus just on children; there seems to be good agreement about that. We need to focus on the caregivers, the parents, and at times we need to focus on the extended family, siblings, and grandparents. Extended family plays a major role for many children in urban areas as well as rural areas, and it’s often been unattended to in studies of outcome in TBI and other trauma. We need to think about the targets of assessment versus the respondents for assessment. Children are not necessarily very good self-reporters, particularly after they’ve had a brain injury. Obtaining perspectives of parents, peers, teachers, and others is potentially very important. We also want to look at the family specifically, because the burden that’s placed on families after TBI or any severe trauma is fairly significant, and we know that the family’s

Discussion of Presentation by McCarthy
response to that trauma plays an important role in moderating the outcomes of TBI.

We need to think a little bit about where we assess outcomes. We can focus on the hospital, we can look at rehabilitation, but what we’re really interested in long-term is how children do at home, in their neighborhood, with peers, at school and for older adolescents, at work.

Many methods are available to assess outcomes. The quality of life measures provide a subjective perspective that is very valuable. We can use questionnaires and rating scales. Qualitative interviews may not be realistic for the sort of study that we’re talking about here, but they can provide useful data. Objective measures that might involve direct observation or standardized tests provide a complementary perspective. Sometimes my colleagues will argue that we should only use objective measures, but I think that’s wrong. We want actually a combination.

I want to argue, at least for traumatic brain injury, that social development is really a key outcome. Prior studies of families of children with traumatic brain injury demonstrate that the most troubling problems and those that cause the most distress are behavioral and social in nature. The cognitive and physical changes that happen after trauma are not particularly distressing to families, nor are they necessarily very predictive of the actual long-term problems patients have. Social development in normal populations and as well as in children with central nervous system disorders predicts many, many different important long-term outcomes, including psychological adjustment, academic performance, and overall health status.

State-of-the-art models and methods are now available to look at social outcomes in children with TBI. If we combine models and methods available from social neuroscience as well as from developmental psychology, we can begin to put together a more comprehensive look at social development in children with TBI. I’m not going to suggest that we can do all of this in a study of this particular type, but I think we need to think about what kinds of measures might be drawn from models like this.

In TBI despite the fact that it’s a diffuse injury, there’s a predilection for damage in the frontal and temporal regions of the brain. Those same regions are heavily implicated in social cognition. We know that social cognition is a distributed network, but the network involves multiple structures that are particularly vulnerable to TBI and suggest that we need to pay more attention to social outcomes in patients with TBI. There are also good models of social skills available to us from developmental psychology that suggest the kinds of skills that we want to potentially measure including social problem solving, pragmatic language, and executive functions.3

This is an integrated model that we’re now using.4 Social competence involves social information processing, the social skills children bring to interactions. The actual interactions that they have with other children and with adults, and their social adjustment are a function of both self-perception and perceptions of others. We see these aspects of social competence as moderated by both injury-related risk, severity of injury, and the nature of that injury, as well as environmental risk factors, some of which have already been mentioned here today such as parenting style, family functioning, and socioeconomic status.

From my perspective, the questions that we need to answer in this particular context are what factors in trauma care, if any, actually account for social outcomes. I’m skeptical whether major medical care per se really plays a major role in terms of the variance of outcomes at this level. Can we identify specific factors that place children at risk for poor social outcomes or that reduce that risk?

Much the work that we’ve done with my colleague Gerry Taylor has shown that family functioning plays an important role in moderating the outcomes of TBI, particularly for behavioral and social functioning.5 Families that are above average in terms of their cohesion and functioning actually often show little or no effect of the trauma on some of those domains, whereas families that have poor functioning have children who turn out much worse than expected. The variability and outcome in children with TBI or any trauma is immense and certainly is not being totally accounted for either by the severity of the injury or the nature of medical care that’s provided.

Current best practices in terms of assessment then would suggest that we would need to look at multiple levels of analysis, that assessment of outcome should be theoretically grounded, and if possible, should be time referenced and developmentally referenced. In addition, there is the problem in a study like this of trying to assess children across a very wide age range. Although some of the measures may be applicable across a wide age range, they’re not necessarily capturing the same constructs across the entire age range.

Future needs include better theories and models, better standardization and norms. One of the reasons these tests don’t get used clinically is the lack of good norms. Another reason is the cost to use them in a clinical setting, since many of these must be purchased for each use. There is also the need for instruments with better sensitivity to change and development. These measures weren’t really developed to assess change and response to intervention or necessarily change developmentally. Most of the quality of life measures, for example, are not developmental measures, but rather measure status at a particular time.

My recommendations would be that we need to assess multiple levels, including structure and function, activity, and participation. I think we should focus on high risk outcomes, the things that are really predictive of day-to-day disability and related to long-term quality of life. It would be important to include not only subjective measurements but also some objective measures if possible, if only with a sub-sample of the population, and to assess multiple targets using multiple respondents.
Dr. Vitale: During the last 7 years, we’ve been looking at ways to measure health-related quality of life in children with problems ranging from trauma to cerebral palsy, clubfoot, and scoliosis. We have used the Child Health Questionnaire, as well as disease-specific measures. The American Academy of Orthopedic Surgery developed a condition-specific measure called a pediatric outcomes data collection instrument (PODCI); we should think about including at least a couple of domains on this measure if we really want to capture some upper-extremity issues.

In orthopedics, we conceive health-related quality of life as related to the domains of physical function, pain, and psychosocial functioning. Disability probably has more to do with psychosocial functioning than physical functioning. That’s certainly been true for many conditions we’ve looked at.

John Ware taught us a lot about quality of life and measurement, and told our national Academy to stop looking at just clinical markers, including X-ray films, and to think more broadly about specific symptoms like pain, disease-specific impact like physical limits, and global impact, all of these things that comprise health-related quality of life. But I think from what you’ve heard from people today, is that health-related quality of life may not even be a broad enough construct, and outcomes probably require an even broader construct, specifically the impact on caregivers and the family unit.

There are difficulties in measuring quality of life in children. Because of developmental issues, we need age-specific norms. Another question is whether parents are a valid proxy for the responses of children? We need a long period of follow-up; a number of studies have shown that even 1 to 2 years after pediatric trauma, there are still problems in health-related quality of life.

We need to clearly define the patient population of interest, because that drives the scales that should be used to measure outcome. Are we looking at traumatic brain injury or are we looking at a broader group of patients? Are we looking at high-functioning children or children with many disabilities? The challenge is being able to measure both ends of the functioning spectrum and still maintain responsiveness in the range that you want to measure.

There are two issues that are larger than health-related quality of life: posttraumatic stress and caregiver burden. When following-up on a child 6 to 9 months after multiple trauma, it’s obvious that there are posttraumatic stress issues that we’re not doing a good job capturing and need to emphasize. One study, for example, found 27% of adolescents report posttraumatic stress disorder symptoms 2 years after injury.6,7

Finally is the issue of caregiver burden. The injured or disabled child affects the family and stresses the family, and at the same time the stressed family can impact the child’s health as well. I think it’s an important dynamic that we need to better understand. Caregiver burden is defined as “the negative emotional, cognitive, physical and financial consequences of providing care for others.” It is a concept that came out of mental illness and geriatrics and only very recently has come to the pediatric world. We’ve developed a caregiver burden instrument as part of a study on quality of life. Burden of care is most affected by pain, upper extremity function, and ability to transfer; walking is much less important.

And there has been a little bit in the literature about burden of care. Parental emotional burden persists for at least 6 months after childhood injury. A study by Winthrop documented significant strain in the family unit after injury as measured by the CHQ and the Impact on Family Scale.8

One way of dealing with the problem of measuring outcome in a heterogeneous population is to use dynamic assessment. It’s based on a statistical concept called item response theory, in which each question helps to generate tighter and tighter confidence limits around point estimates, allowing questions to then be focused on measures relevant to that particular respondent. You can funnel in on each of the specific domains in the quality of life measure in a much more efficient way. It lends itself to internet use and is potentially much cheaper and more practical than traditional measures, and certainly has less administrative burden.

In summary, it’s clear that new quality of life measures seem to work. We absolutely have to consider posttraumatic stress disorder and caregiver burden if we’re going to look at broadly defined outcomes in this population. Finally I would consider using and developing a dynamic assessment tool to do this with a heterogeneous population.

Dr. O’Neill: Are there physiologic parameters that may be predictive of quality of life?

Dr. Vitale: That’s a good question. The traditional markers such as seen on X-ray film don’t always seem to correlate with the more broadly defined quality of life outcomes. The amount of displacement, type of fracture, and fracture location don’t necessarily drive long-term outcomes. This is frustrating to clinicians, because they ask how they can impact something if it can’t be measured in a palatable way. We need to measure both the traditional markers and also look more broadly at quality of life measures.

Male: The same holds for traumatic brain injury. Very sophisticated imaging quantitative analysis does correlate with quality of life or other outcome measures, but it’s far from perfect.

Dr. Adelson: Dr. Aitken, what do you think is the biggest barrier to routinely obtaining these outcomes assessments?

Dr. Aitken: I don’t think there’s any one factor. Time availability and understanding of how these measures work are part of the reason. These measures can be incorporated into routine care but measuring outcomes once is not as useful as measuring over time.

Dr. Adelson: I agree with you, but I think funding is the biggest issue. No one wants to pay for it.

Dr. Yeates: A few years ago, Current Procedural Terminology (CPT) codes were created for these outcomes as-
sessment. In Ohio, we’re reimbursed for assessments by pediatric psychologists and neuropsychologists.

Dr. Jurkovich: I want to propose that the reason these tests aren’t being used is that, from a clinician standpoint, there has been no study that shows what we do clinically in the hospital makes a difference for any of these outcomes. If that’s not true, I want to hear where it’s not true, so that we can focus our efforts on those activities that make a difference clinically during the acute care phase. We struggled in the NSCOT study with trying to look at what it is about our clinical care paradigms that make a difference in long-term functional outcomes.

Dr. Vitale: You’re speaking to the responsiveness of the measures. Many of these measures do respond to clinical intervention, at least in the range of health status intervention that I operate in. If I take a child who has cerebral palsy and lengthen their Achilles tendons, there are dramatic differences in health-related quality of life and caregiver burden before and afterward. If we really want to hone in on responsiveness, it will require development of a disease-specific measure that allows us to target the specific range of clinical intervention that we’re looking at.

Male: At least for TBI, I’d say better management of secondary injury is probably where acute care will make the biggest difference potentially in outcomes. The secondary injury that occurs from trauma care is probably going to have the most likely burden on outcome. We don’t have a good literature on what works in rehab much less in acute care. I would submit we don’t know what works.

Female: It’s pretty low tech what patients actually ask for and say is going to make a difference. One of the most troubling problems for patients is pain, despite the fact that we really can manage pain very well. In the acute and in the follow-up phase, there are clinical interventions that may not address global health function completely but can certainly make things better. Communication is a big piece of it.

Dr. Wesson: There are often many artificial restrictions on injured children’s physical role and social functioning that are imposed upon them by their parents and by other caregivers, based on concerns that they have about their residual injuries, the effects of the injuries, and their risk of suffering another injury. This is a confounding variable, and it depends on the severity of the injury and on the nature of the injury that the patient suffered in the first place.

Dr. Rivara: It’s related to two things. First is the issue of the vulnerable child syndrome, in which these patients may have been close to death or parents at least perceive them as being close to death, so therefore they’re treating them as vulnerable for the rest of their lives. Secondly, it is partly because of what we as physicians say to parents, which has great implications.

Female: I think that we also need to figure out who is giving them that message. Is it something that happened during the acute phase or is it because we haven’t adequately guided the general pediatrician or family physician, who is going to manage many of the long-term follow-up issues? It begs the question how well we’re communicating what we know to people who are taking care of the patient.

Male: We tell families the relevant information while they’re still in the hospital, but sometimes they’re not ready to hear it. It’s not until later that they’re ready to hear it, but they do not have providers that know what to communicate at that point.

Dr. Landgraf: Marie McCormick published a study quite a number of years ago looking at vulnerability and its persistence in low-birth-weight infants and found that vulnerability lasted about 12–18 months, and then dropped off. The low-birth-weight literature might be useful.

Responsiveness was something that certainly was forefront in everyone’s mind when they were developing these measures, but these measures have been released probably for only about 10 years. There are ongoing studies now looking at responsiveness to change, and responsiveness is only one aspect of validity.

I worry that disease-specific measures may not provide the specificity that you need. For example, if you’re going to look at cognitive functioning, that in itself is a global concept. If you’re going to develop a new measure, be very careful that there is some multidimensionality within that construct and that you capture the full construct.

As someone who is a generalist and has seen tools used in a variety of different conditions, both physical and psychosocial, I would argue that, to increase public awareness about trauma, you may want to include a generic instrument to be able to place traumatic brain injury and other trauma in context with other child/adolescent conditions.

The last thing that I found really interesting was this whole notion of persistence of abnormality. Dr. McCarthy and Dr. Aitken showed it using two different instruments, the Pediatric Quality of Life score and the Child Health Questionnaire, so it’s not a measurement issue. Don’t overlook that. The expectation that these children can be returned to a certain normality may indeed not be the case. So bear in mind this whole issue of persistency of abnormality.

Dr. MacKenzie: I wanted to return to Dr. Jurkovich’s question about why can’t we see differences in these health-related quality outcome measures based on differences in acute care. I think that it is a result of all the other factors at play in the patient, the family, the environment. Unless we do a really, really good job of measuring these factors, we’re not going to be able to tease out these differences. In some of the role function and social function measures, there’s so much else going on, that trying to see an impact of acute care on those outcomes is almost impossible. The best example is the study we did on whether it’s better to reconstruct or amputate a very severely injured leg. We do not see any differences in the Sickness Impact Profile at 2 and 7 years after injury. Outcome was related to all sorts of other factors and not whether or not their leg was amputated. There were differences, for example, in walking speed between the amputees and the reconstruction patients, but those differences disap-
pear in the overall quality of life measures because of everything else. This is a critically important issue as we move forward in thinking about this study, it’s really, really hard to show differences in these global outcome measures.

**Dr. Christensen:** Since certain injuries, such as traumatic brain injuries, are the major determinants of morbidity and mortality, over-sampling of these populations should be considered. Also, in certain diagnostic groups, the inclusion of multiple-level outcome batteries that assess impairment through quality of life and participation are extremely important, although expensive.

**Dr. Hunt:** In the development of the Centers for Disease Control and Prevention’s (CDC’s) acute injury care research agenda, one thing that was really striking is how it went far beyond acute care treatment strategies and system issues into the psychosocial aspects. This is exactly what is being discussed here. When I look at the seven priority areas for acute injury care research, treatment strategies are at the top and at the bottom are the outcome issues discussed here. So what I grapple with in the CDC research agenda and how to move that forward is whether this is a whole new paradigm for trauma research. Does it need to be a continuum so that, for example, the evaluation of bag valve mask ventilation versus endotracheal intubation includes return to school? How do you get to those important outcomes when you’ve got those very, very clinical real issues on that front end? Are they connected issues or separate silos of research, which they are right now?

**Dr. Rivara:** That’s obviously the critical question, and one reason to do the study is to see how they are connected.

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Effect of Emergency Department Care on Outcomes in Pediatric Trauma: What Approaches Make a Difference in Quality of Care?

M. Denise Dowd, MD, MPH

Deriving evidence-based best practice for each phase or setting of trauma care is necessary to maximize best outcomes. There is a paucity of studies examining the association of provider training on pediatric trauma outcomes. Pivotal decisions (whether and where to transfer, diagnostic workup, and initial resuscitation) occur in this setting, yet there is little evidence relating to best practices in those areas. Classic process-performance measures such as time intervals during care (e.g., time to computerized tomography scan, time to operating room, etc.) or utilization measures (American College of Surgeons designation) are commonly used in the trauma center certification process, yet process-outcome links relevant to children are lacking. Although great advances have been made in the trauma care delivered to children, scientific proof is lacking and much more needs to be done to establish the evidence-based need to deliver the highest quality of pediatric trauma care.

Population-based studies comparing systems of pediatric trauma care are few and have primarily focused on mortality as the outcome measure. Initial studies provide evidence that regionalized pediatric trauma care using state and/or American College of Surgeons (ACS) designation result in decreased mortality.1–4 Studies are limited by several factors, including focus on the relatively rare outcome of mortality, and comparison to Major Trauma Outcome Study population, which may be considered questionable for pediatric analyses.5 An additional limitation inherent in trauma system comparisons is the inability to determine the effect of the various components of trauma care. An episode of care delivered to the injured child spans a multitude of settings (prehospital emergency department [ED], in-patient, rehabilitation) with each having a potential significant and independent impact on outcomes. Deriving evidence-based best practice for each phase or setting of trauma care is necessary to maximize best outcomes. This discussion focuses on the care delivered to the traumatically injured child in the ED. The recent Institute of Medicine report on the emergency care of children makes clear that the time to critically examine practices system-wide is long overdue and imperative as the system of emergency care throughout the country is at the “breaking point” with fragmented, overburdened, and underfunded care becoming the rule.6

SOURCES OF VARIATION IN THE ED CARE OF INJURED CHILDREN

Provider

There is a range of providers staffing EDs who provide the initial hospital care of injured children. Their training may span a broad range of specialties from pediatric emergency medicine subspecialists to general practitioners with a family practice background. ED providers may or may not be certified in Advanced Trauma Life Support (ATLS)7 or Pediatric Advanced Life Support. In some communities, depending on the severity of injury, surgeons may respond initially; they may or may not have trauma or pediatric subspecialty training or ATLS certification. There is a paucity of studies examining the association of provider training on pediatric trauma outcomes. Members of the National Pediatric Trauma Registry demonstrated that although the presence of a pediatric emergency physician in the ED reduced the amount of time the injured child spent in the ED, there was no effect on mortality.8 The same study showed that in-house surgeon reduced mortality in children 7 years of age or older and severely injured (injury severity score ≥36) children.9 Studies examining the impact of standardized training such as ATLS or Pediatric Advanced Life Support are also lacking.

Institution

Injured children present to one of three types of EDs: (1) departments devoted solely to the care of children such as those found in children’s hospitals; (2) pediatric units “within” general EDs; or (3) general EDs without designated pediatric beds. Each type of department may or may not carry a state or ACS trauma center designation. Closely related to the type of ED is the availability of pediatric equipment in the ED. Concerningly, it is estimated that only 6% of EDs in the United States have all of the equipment necessary for a full pediatric resuscitation.9 Associated with type of department

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are the nonphysician staff, who vary both in terms of the range available (child life, social worker, chaplain), to the type of training they have had, e.g., Trauma Nursing Core Course for nurses. A single study has examined the impact of the type of ED on the care of the pediatric trauma patient and found that an ED solely devoted to the care of children resulted in a reduced amount of time spent in the ED by the patient but had no effect on mortality.8

The manner in which the injured child is initially treated on arrival to the ED is also considered to be important to delivering optimal trauma care. The trauma team approach is widely used among designated pediatric and adult trauma centers but few studies in pediatric populations have examined the contribution that the trauma team approach makes to outcome. Vernon et al. demonstrated that an organized trauma response team in a children’s hospital decreased treatment time and improved survival compared with the reference Major Trauma Outcome Study population.10 Delay in diagnosis of injuries in the pediatric patient with multiple injuries may also be reduced with a team approach.11 Other studies have examined the criteria chosen for initiating the activation of the trauma team and have demonstrated that refined criteria using anatomic and physiologic indicators or a two-tier response12–15 can help direct limited resources to refined criteria using anatomic and physiologic indicators or a two-tier response12–15 can help direct limited resources to the injured child when they are most needed without compromising patient outcome. Research is lacking examining the contribution that the trauma team approach makes to the ED with potential impact on the outcomes of the injured child.16–18 The impact of such decision-making has not been well-defined on a national level nor do we have an adequate understanding of the factors associated with the decision not to transfer a critically injured child. The timing of the decision to transfer child trauma patients is also important and understudied. The ubiquitous computerized tomography (CT) scanner has made obtaining studies easy for most community hospitals but may add to the delay in transfer to definitive care.

**Diagnostic Testing**

An area consistently lacking in strong evidence is the diagnostic workup in pediatric trauma care. ATLS guidelines dictating standard laboratory and radiographic studies are largely based on experience in the adult population.7 Children, because they are different physiologically, anatomically, and emotionally, should ideally be treated according to diagnostic testing guidelines based on evidence from pediatric populations. Although pediatric, emergency medicine, and surgical colleagues may frequently disagree over the various aspects of the ATLS protocol as applied to children, there is a large, concerning gap in the published evidence. Some knowledge has been gained in the area of diagnostic approach to injuries of the cervical spine,19–21 chest,21–23 routine “trauma labs,”24–26 and utility of the digital rectal examination in the trauma survey.27–29 Newer modalities used commonly in the adult population, such as focused abdominal sonography for trauma (focused abdominal sonography for trauma examination) to screen for free intraperitoneal hemorrhage, are appealing. The utility and accuracy of the focused abdominal sonography for trauma examination in children is debatable as solid-organ injury in children without free peritoneal fluid is common, and the majority of children with hemoperitoneum do not require surgery. Initial studies have demonstrated that sonography does have a role in the management of the acutely injured child.30,31 and that patients can be managed clinically without complications on the basis of negative ultrasonography finding without CT.32–34

**Processes and Protocols**

Several aspects of the process of pediatric trauma care require key decisions by providers. An analysis of factors contributing to preventable death in a small sample of pediatric trauma cases in Montana found an alarmingly high rate of what was considered inappropriate care (decision making) in the ED.16 Four major areas of decision making in the ED with potential impact on the outcomes of the injured child are (1) decision to transport the patient to a higher level of care; (2) diagnostic testing; (3) resuscitation and treatment, including engaging specialists; and (4) comfort measures, to include relief of both pain and anxiety and grief management. A comprehensive treatment of each of these key decision areas is beyond the scope of this discussion; however, some examples are given below.

**Decision to Transfer**

A majority of injured children do not present for care to a pediatric trauma center and may receive suboptimal care as a result.17 Each day, providers in community EDs make critical decisions on whether local capacities are appropriate for the care of injured children. Although many localities follow standards in accordance with existing pediatric trauma care regionalization directives, it is not known how well those plans are followed and also the effect of failure to follow transfer plans. The majority of hospitals that admit pediatric patients do not have facilities devoted solely to pediatric care and the majority of such facilities do transfer critically injured pediatric trauma patient. However, it is estimated that 10% of hospitals without pediatric intensive care services admit critically injured children to their own facilities.18 The impact of such decision-making has not been well-defined on a national level nor do we have an adequate understanding of the factors associated with the decision not to transfer a critically injured child. The timing of the decision to transfer child trauma patients is also important and understudied. The ubiquitous computerized tomography (CT) scanner has made obtaining studies easy for most community hospitals but may add to the delay in transfer to definitive care.

**Comfort Measures**

Although studying pain and anxiety is difficult in children, it is imperative that pediatric trauma care make comfort measures a high priority. Much is known about safe and effective management of pain in children but this knowledge has not been widely or effectively translated into routine clinical practice in all aspects of pediatric medical care, including trauma care.35–37
The presence of a parent or other family can be of great comfort to both the child as well as the family member. Locally, protocols and custom allowing family members to be present during the resuscitation phase of trauma care are becoming more common and a national consensus conference recently released an official statement in support of the practice and discussing considerations for care. Published studies are limited to single-center descriptions of experiences or surveyed opinions about the practice. Few studies have examined the impact of family presence on the patient, family member, or the delivery of care. A recent trial, examining the impact of family presence on the efficiency of trauma care in the pediatric ED found no negative impact on resuscitation time and further found that it is highly valued by families.

DEFINING RELEVANT OUTCOMES

A comprehensive approach to the delivery of highest-quality hospital-based acute pediatric trauma care must extend beyond the usual measure of mortality as well as have relevance to the ED. Morbidity should be measured and include pain and suffering as well as the less-tangible patient and family psychosocial measures such as posttraumatic stress disorder and quality of life. Intermediate outcomes, also important in the emergency care of children, have been suggested by others and include ED length of stay, inappropriate admissions, unplanned ED visits, unplanned visits to the primary care provider, use of diagnostic testing (under- and over-utilization), and use of ED personnel. One way to organize the large information gap that exists in pediatric trauma outcomes research is by relating trauma care quality measures to the six quality domains as defined by the Institute of Medicine (Table 1).

CONCLUSION

Although the care that takes place in the ED is an essential element of the larger continuum of trauma care of children, there are currently many unknowns about the overall impact of that care on intermediate and distal outcomes. Pivotal decisions (whether and where to transfer, diagnostic workup, and initial resuscitation) occur in this setting, yet there is little evidence relating to best practices in those areas. Classic process-performance measures such as time intervals during care (e.g., time to CT scan, time to operating room, etc.) or utilization measures (ACS) are commonly used in the trauma center certification process, yet process-outcome links relevant to children are lacking. Although great advances have been made in the trauma care delivered to children, scientific proof is lacking and much more needs to be done to establish the evidence-based needed to deliver the highest quality of pediatric trauma care.

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Effect of ED Care on Outcomes in Pediatric Trauma


Improving Outcomes in Pediatric Trauma Care: Essential Characteristics of the Trauma Center

M. Margaret Knudson, MD, FACS, and Jennifer McGrath, BS

The best outcome after pediatric injury can be anticipated when the entire trauma team is prepared, knowledgeable, and appreciative of the unique aspects of pediatric trauma and pays strict attention to all aspects of the care of the injured child. Five aspects should be considered essential elements in the delivery of care by any trauma team: preparation, equipment, and training; prevention of secondary insults after brain injury; the ability to recognize when nonoperative therapy should not be attempted or when it should be abandoned; consideration of the psychological impact of injury on a child; and, the role of trauma centers in injury prevention. Each of these areas encompasses important unanswered questions.

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The best outcome after pediatric injury can be anticipated when the entire trauma team is prepared, knowledgeable, and appreciative of the unique aspects of pediatric trauma and pays strict attention to all aspects of the care of the injured child. The processes of acute care are critical elements in determining the outcome of trauma, regardless of the type of center in which they are delivered. This brief review will focus on five aspects that should be considered essential elements in the delivery of care by any trauma team.

PREPARATION, EQUIPMENT, AND TRAINING

When a severely injured child is admitted to the trauma center, especially a center where the care of such children is not an everyday occurrence, there is a certain level of anxiety that is associated with simply the “size” of the patient. Much of that anxiety can be eliminated by having instruments, equipment, and drug dosages all carefully precalculated and at easy disposal for the trauma team. A simple solution used at many centers is the so-called “extended” Broselow system; that is, equipment and drug doses organized by “color” on a chart, with the colors corresponding to the Broselow tape that estimates the weight of the child and drug dosing based on the child’s length. Broselow-based resuscitation carts have had promising results in ease of use and accuracy in equipment selection in simulation.1 It is nevertheless still uncertain, in real-world settings, the degree that use of the Broselow system can improve care. This is an issue that clearly needs further research.

Another helpful plan to put in place before the child arrives is the protocol for obtaining IV access, which is often very traumatic for both the child and the trauma team. In general, there should be a time limit and a personnel limit to IV access at progressive sites. Typically, this would entail allowing 3 to 5 minutes for two attempts at a peripheral IV; if both fail, then either intraosseous or femoral catheterization should be performed (with the choice depending upon the size and the condition of the child and the experience of the team).2

It is not unusual for the trauma team to get caught up in the details of the resuscitation and lose sight of both the time lost and the overall plan for the patient. Adherence to the basic resuscitation algorithm of the American College of Surgeons’ Advanced Trauma Life Support Course is appropriate for injured children of all ages. Routine reviews of video recordings of pediatric trauma resuscitations can assist in identifying management errors.3 Trauma team training can also be performed in simulation, using techniques for crisis management training as developed by the airline industry.4–6 Pediatric trauma simulation training should be offered to all members of the team, including emergency and trauma physicians, ED and ICU nurses, and anesthesiologists. This may be especially important in centers with low volumes of pediatric trauma, or centers that primarily treat adults. Nevertheless, the degree to which such simulation training can improve outcomes in pediatric trauma is unknown.

PREVENTION OF SECONDARY INSULTS AFTER BRAIN INJURY

Traumatic brain injury (TBI) is the major cause of death and disability in injured children. Retrospective studies have confirmed that the secondary insults of hypotension and hypoxia significantly worsen outcome in pediatric patients with TBI.7,8 Thus, avoidance of these insults during all phases of trauma center care could have a major impact on outcome. Guidelines for the acute medical management of severe TBI...
in infants, children, and adolescents have been developed, but have yet to be tested in a prospective, multicenter study. Similarly, protocols aimed at optimizing cerebral oxygenation deserve rigorous scientific study to analyze the "ideal" level of brain tissue oxygen to be achieved and the best therapy to use to obtain it. The current guidelines for the treatment of severe TBI in pediatric patients and the level of data supporting them are summarized below.

- Prehospital airway management: There is no evidence to support an advantage of endotracheal intubation over bag-valve-mask ventilation in the prehospital management of pediatric patients with TBI (Data class-Level II).
- Intracranial pressure (ICP): There are insufficient data to support a treatment standard or a treatment guideline for the use of ICP monitoring in pediatric patients with severe TBI. Data are also lacking on the threshold for treatment of ICP (Level III).
- A cerebral perfusion pressure of >40 mm Hg should be maintained in children with severe TBI (Level II).
- In the setting of refractory elevated ICP in children, ventricular cerebrospinal fluid drainage, hypertonic saline, barbiturates, and decompressive craniotomy are supported by Level III data only.
- Hyperthermia should be avoided; there is no data to support the use of hyperthermia for elevated ICP in children.
- Early nutritional support is supported by Level III data; prophylactic anticonvulsants are not recommended (Level II).

**OPERATIVE VERSUS NONOPERATIVE THERAPY**

The surgical techniques needed to treat an injured child are not significantly different from those needed for adults. Fortunately, many pediatric injuries, particularly the liver, spleen, and kidney (solid organs) are amenable to nonoperative therapy. However, the most important skill needed to treat children successfully is the ability to recognize when nonoperative therapy should not be attempted or when it should be abandoned. Unfortunately, to date the literature is primarily focused on the differences in management of pediatric splenic injuries from hospital to hospital depending upon their location, their population (adult versus pediatric), and their personnel (general trauma surgeon versus pediatric trauma surgeon). Prospective studies in an all-inclusive trauma system and the development and dissemination of standardized resuscitation protocols are needed. Additionally, the role of the interventional radiologist in the care of the multi-injured child needs further examination, as well as the indications for angio-embolization in children. The role of damage control surgery and the recognition of the abdominal compartment syndrome after pediatric trauma also remain areas ripe for study and education.

**BARRIERS TO FULL RECOVERY**

The psychological impact of injury on a child cannot be underestimated. Studies performed at our institution have demonstrated that 69% of injured children have posttraumatic stress disorder symptoms right after their injury, 60% have persistent symptoms 6 months later, and in 38%, these symptoms are still present 18 months after the injury. Studies focused on interventions to decrease posttraumatic stress disorder symptoms in these children are sorely needed and could have a major impact on long-term outcome. Pediatric trauma centers have specific resources to facilitate a child’s rehabilitation and reintegration that community hospitals may lack. These include age-specific occupational, speech, and physical therapists to aid in posttrauma rehabilitation, social workers, child protection services, dietary specialists, and pediatric psychiatrists. The availability of play therapy allows children to engage in activities with peers. Socialization through school-oriented activities, play, arts and crafts, and other similar activities aids in the child’s reintegration after discharge.

**PREVENTION**

The trauma center must recognize its essential role in injury prevention. The family of the injured child enters during a “teachable moment” and the trauma team can have a significant impact with appropriate interventions. In teens, both drug and alcohol screening and intervention could have a major impact on injury recidivism rates for both the injured and those who associate with him/her. Although studies addressing alcohol problems have been conducted in adult trauma patients, none have been performed in this setting with adolescents.

However, there are numerous examples of successful injury prevention interventions in children. In the most widely cited case control study of bicycle safety helmets, Rivara et al. demonstrated an 88% reduction in the risk of brain injury and an 85% reduction in the risk of head injury when riders were wearing bicycle helmets. Booster seats reduce the risk of injury by 59% compared with seatbelts in the 4 to 7 years old group. Barlow et al. and the Injury Free Coalition for Kids have successfully introduced the ABC model of injury prevention to numerous trauma centers that begins with surveillance and activism and results in instating and evaluating interventions.

**Table 1 Research Agenda Items**

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CONCLUSION

Based on the above discussion and the identification of the five areas in the trauma center that affect outcomes after pediatric injury, research agenda items can be identified as outlined in Table 1.

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Pediatric Intensive Care Quality Factors

Murray M. Pollack, MD

Intensive care has been in the forefront of quality investigations. Outcomes researchers have taken advantage of reliable and robust methods to adjust for severity of illness and other case mix variables, and readily identifiable relevant outcomes (survival and death) to investigate quality factors associated with improved risk-adjusted outcomes. Current studies are limited by using databases of convenience, use of historical controls, small sample sizes, and inadequate case-mix adjustment. Only one study has focused on the comparative advantage of pediatric versus adult intensive care units for injured children; it demonstrated substantially improved risk-adjusted mortality rates. The effect of volume on quality of pediatric intensive care has been the subject of multiple evaluations, although each of these studies has serious limitations. Other studies have demonstrated that the experience of the bedside caregiver is important in patient outcomes.

GENERAL METHODOLOGICAL ISSUES

Before considering the literature of pediatric intensive care unit (PICU) quality factors, a general assessment of research related issues is important.

- Databases of Convenience: Most databases used for these studies were not designed and collected to directly test a specific hypothesis. Existing data bases such as statewide trauma data bases or PICU data bases such as Pediatric Intensive Care Unit Evaluations may help elucidate issues, but data bases of convenience will rarely be sufficient to conclusively answer a research question. Not only do these databases tend to be old and sometimes outdated, but the methods available for risk adjustment also may not be ideal or even appropriate to investigate the research question.

- Comparisons to “National Norms”: Some analyses have compared study results to “national norms” (i.e., historical controls). We know that the relationship between severity of illness and outcome continues to evolve in PICUs and one expects contemporary outcomes to continuously improve over time. National norms are usually relatively old and may not be relevant to the current state of medicine.

- Trauma Versus Nontrauma Patients: The trauma community tends to focus on outcomes from trauma patients rather than all PICU patients. This focus imposes very difficult sample size constraints on studies as trauma patients are a definite minority of the PICU patients.

- Controversies in Severity of Illness Methods: A crucial issue in the evaluation of PICU quality factors is the ability to control for severity of illness and other case mix factors. There is no shortage of trauma scoring systems that are designed to assess severity of illness and anatomic injury at specific time points. Methods focus on anatomic injuries, physiologic derangements, and combined anatomic injury plus physiologic derangements. The plethora of trauma severity of illness measures indicates that none of the scores have performed sufficiently well to eliminate the need for research to create new, better scores. Many of the models are overcustomized, use hospital discharge databases, or do not take advantage of very accessible and important information such as hospital admission laboratory data. For PICUs, general severity methods such as the Pediatric Risk of Mortality (PRISM) method have been validated in trauma patients, and in the one study comparing PRISM with other trauma severity methods, PRISM outperformed the Pediatric Trauma Score, Injury Severity System, and New Injury Severity System in acutely injured children.

- Unit of Analysis: One important issue that has not received sufficient consideration is the appropriate unit of analysis. Should analyses be patient-level or unit level? Although recent advances in statistical methods to adjust for clustering have improved patient-level analyses, the importance of designing a study for unit-level analysis deserves careful thought.

- Performance Standards Versus Quality Factors: Finally, are quality factor analyses still useful? In an era when severity-adjusted performance of single PICUs can be measured and tracked, isn’t it simply more relevant to specify PICU performance standards, rather than identify quality...
factors that might or might not be relevant for a particular unit?

**PEDIATRIC VERSUS ADULT INTENSIVE CARE**

As PICUs evolved, the first issue confronted by this new subspecialty was whether or not the outcomes of children treated in PICUs were better than those of children treated in adult intensive care units (ICUs). The first and still the only analysis focused on the comparative advantage of pediatric versus adult ICUs for injured and ill children in a statewide study of trauma victims and patients with respiratory failure in Oregon and southwest Washington. For low risk patients, there was no survival advantage of PICUs, but for the sickest patients, those in whom the provision of sophisticated intensive care was likely to make the largest impact, PICUs had substantially improved risk-adjusted mortality rates. Other studies have evaluated healthcare delivery systems including pediatric trauma centers versus adult trauma centers where ICU care is presumed to be only one of several important aspects of the delivery system, but only one study identified specific issues related to pediatric and adult intensive care as part of the trauma care system. This statewide study in New York evaluated severity adjusted mortality rates of children referred to hospitals with PICUs versus other hospitals. There was not a significant advantage to hospitals with PICUs although a referral pattern was already in place that concentrated on the sickest patients in the hospitals with PICUs.

**THE VOLUME-OUTCOME RELATIONSHIP**

The effect of volume on quality of pediatric intensive care has been the subject of multiple evaluations. Pollack et al. used PICU size, intensivist status, teaching status, and proportion of care to stratify 16 randomly selected PICUs. Large and small units were determined by the population median of six or fewer beds and more than six beds. This study did not find an effect of volume on outcome. Three other studies, all using data bases of convenience found a positive effect of volume. Tilford et al. and Ruttimann et al. found both improved severity adjusted mortality and reduced length of stay. Marcini et al. found improved severity of illness adjusted mortality rates in mid-to-large units (992–1491 admissions), but unit performance actually decreased as admissions increased.

A critique of these four studies demonstrates the problems with studies aimed at isolating important system-level quality factors. The study by Pollack et al., although the only prospectively collected data set designed to answer this question, was flawed because the criterion for size was chosen based on the population distribution of PICU bed numbers, not a potential positive threshold for the effect of size. Because the largest unit was 12 beds, very large units were not sampled. The Ruttimann et al. analysis combined the Pollack et al. database with another database (now a database of convenience of 32 PICUs) and found that volume was a significant determinant of improved severity adjusted mortality and efficiency. The study by Tilford et al. also suffers from serious flaws. Although it used modern methods to adjust for clustering effects, it also used a relatively old database of convenience that was collected without sufficient reliability checks. The analysis by Marcini et al. was dependent on hierarchical analysis, a type of analysis dependent on assumptions which may not have been met in their study design.

**CAREGIVER EXPERTISE AND EXPERIENCE**

Initially, the impact of the new subspecialty of the pediatric intensivist on critical care specialist was evaluated and found to be associated with significantly improved quality. Unlike adult critical care where controversy over the need for intensivists still exists, the linkage of pediatric intensive care and pediatric intensivists has become very tight. However, the expertise and experience of bedside caregivers, especially during evening, night, and weekend times continues to be controversial in PICUs. Currently, there are PICU care models utilizing residents, hospitalists, fellows, and 24/7 intensivists as bedside caregivers. The available information leads to the conclusion that the experience of the bedside caregiver is an important determinant of outcome. Pollack et al. found that risk-adjusted mortality was worse in teaching hospitals, an observation that was tightly linked to first and second year residents providing bedside care, and outcome in units where residents provided care was also worse during the first 3 months of the academic year. Arias et al. found that there was an increased risk of mortality for evening admissions compared with daytime admissions although the factors determining this difference could not be evaluated. PICUs with critical care fellowship programs generally have better outcomes than those with just residents. Recent case studies of providing coverage with pediatric hospitalists instead of residents, and 24/7 in house intensivist coverage is also consistent with the proposition that the experience of the bedside caregiver is important in patient outcomes.

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Ethical Considerations About Observational Research in Children

Benjamin Wilfond, MD

Observational research includes a subset of the broad range of benefits and risks in pediatric research. The exclusive, direct benefit of observational research is the generation of scientific knowledge. This benefit allows for easier communication with families by avoiding the misunderstanding that their child will directly benefit. However, pediatric research that does not offer a prospect of direct benefit can only have limited risks in accordance with the US regulations. The risks of observational research relate to any adverse effects from the disclosure of information from: 1) personally identifiable health information, 2) questionnaires and interviews about health related experiences and 3) data from biological samples for genetic and molecular studies. Whether these privacy and confidentiality risks exceed a “minor increase” over minimal risk, depends on the likelihood that confidentiality will be breached, the likelihood that the breach will result in harm, and the magnitude of the harm. Efforts like database encryption and linked codes can minimize these risks. These issues become more complicated when information has sufficient clinical value to warrant direct disclosure to the family. It is important to communicate basic information to parents about such risks when obtaining parental permission. Further, obtaining consent from adults who have participated in pediatric observational research shows respect for their participation and can facilitate trust. However, if such adults can not be located, when the research has sufficient social value, continual use of the data for ongoing analysis is appropriate.

The balance of potential benefits and risks to research participants is one of the central ethical issues in evaluating biomedical research. Although this balance is particularly salient in intervention studies because the intervention itself (including pharmaceutical, dietary, behavioral, or surgical interventions) can pose specific potential benefits or risks, observational studies also raise challenging ethical issues. In fact, the public reaction to the US Public Health Service’s observational study of the natural history of syphilis conducted between 1932 and 1972 became one of the driving motivations for our current system of regulation using institutional review boards (IRBs).3

Observational research is particularly important for evaluating the outcomes and effectiveness of health care in real world settings. One classic approach to observational research involves the review of previously collected data from clinical and public health settings. The ethical issues raised by observational research may appear quite distinct from those raised by interventional research. However, some observational studies have ethically relevant features in common with interventional studies.

First, some observational research includes prospective longitudinal data collection in which direct relationships between the participants and the researchers exist. Arguably, the direct engagement between researchers and participants matters ethically because that direct engagement generates some obligation to provide health care and information to participants. Practically, direct engagement is important because it presents greater feasibility to ask permission about research participation.

Second, some observational research involves “interventions” such as questionnaires, interviews and psychological assessments; blood draws for laboratory studies, including genetics; as well as imaging studies and interventions that may require sedation, such as lumbar punctures, or bronchoscopies. Such observational interventions can involve inconveniences, discomforts, psychological, or physical risks.

Finally, some observational research involves “upstream public health interventions” such as education campaigns (i.e., encouraging parents to change infants’ sleeping position or abstain from smoking), food and water supply modifications (folute in flour or fluoride in water), or legal and regulatory changes (seat belt requirements, highway speed limits, and unleaded gasoline). Such interventions implemented through public health mechanisms are not typically reviewed as research even though the benefits and risks remain to be elucidated through outcomes research. Framing observational research as “outcomes” research signals the important dimensions of the health care and social environment and their relationships with patients’ direct experiences of health.

One ethical advantage of observational research is that it can permit the generation of knowledge about important health outcomes that might otherwise be considered ethically unacceptable for a prospective trial. For example, a study that randomized children with severe persistent asthma to not...
receive anti-inflammatory medication would be considered unethical because the risk of an asthma exacerbation would be significantly increased. However, an observation study of such asthma care received in a health care setting could record information about the relationship between anti-inflammatory use and asthma exacerbations and not raise the same concerns. Full considerations regarding the ethical appropriateness of prospective randomization in pediatrics is a complex topic that is beyond the scope of this article.

Another ethical advantage of observational research is that, its almost exclusive scientific purpose is to generate important knowledge to benefit society at large, and children in particular, rather than offering a prospect of direct benefit to the research participants. This makes observational research less ethically problematic because of a lessened chance that the participants will enroll because of a “therapeutic misconception” about expectations of direct benefits from research participation.

However, for those who think that research can best be justified by direct benefits to the subjects, observational research may already be a potentially morally treacherous terrain. Nonetheless, even in observational pediatric research, there are “inclusion benefits” ranging from education, to receiving clinically relevant research results, to payment, and other explicit incentives to participate. Should these inclusion benefits be considered in justifying the risks? One of the central ethical tasks for researchers and IRBs is to decide which benefits and risks to balance when evaluating a study. Further, there may be conflicting assessments of the risks and benefits for the same study by different people.

The ethical review process for research that IRBs use is codified in the US regulations currently referred to as the “common rule”. Although there has been little change in the regulations for decades, changes have occurred in oversight of IRBs, IRB practices in response to the oversight, and investigators’ perceptions of how well IRBs serve their social mission. For observational research in particular, some contend that IRBs have focused on procedural details and have been excessively risk adverse. This article does not address the social behavior of IRBs but provides an analysis of benefits and risks based on the content of the US regulations.

**EVALUATION OF RISK IN PEDIATRIC RESEARCH**

In the pediatric research context, the US regulations require that the ethical evaluation of risks and benefits be considered quite differently depending on whether or not there exists a prospect of the direct benefit. When there is a prospect of direct benefit (typically defined as a benefit from the research intervention under study), such a benefit can be balanced with the risks of the intervention in assessing whether a study is ethical. Thus, even research classified as exceptionally high risk might be acceptable, as long as the prospect of direct benefit was great enough to justify the risk.

When a study does not offer a prospect of direct benefit to subjects and the primary benefits that justify the study are to the society, then the level of acceptable risks sufficient to justify the enrollment of children is truncated. Extreme risks to children cannot be justified by extreme social benefits of the research. In an effort to move beyond a direct balancing of risks to children and benefits to society, the US regulations offer a framework of risk categorization that is used to further limit those circumstances in which children could be exposed to particular levels of risk.

The US regulations for pediatric research categorize risk into three categories: (1) Minimal risk, (2) Minor increase over minimal risk, and (3) More than a minor increase over minimal risk. Minimal risks in the US regulations are defined as those risks “ordinarily encountered in daily life, or during the performance of routine physical or psychological examinations or tests”. These regulations fail to provide any guidance on what might be considered just a “minor increase” or “more than a minor increase”.

When an IRB determines that a risk of an intervention is a “minor increase over minimal risk” there are two additional substantive criteria. First, the intervention or procedure presents experiences to the child subjects that are reasonably commensurate with those inherent in their actual, or expected medical, dental, psychological, social, or educational situations. Second, “the intervention or procedure is likely to yield generalizable knowledge about the subject’s disorder or condition which is of vital importance for the understanding or amelioration of the disorder or condition”.

A study cannot be approved by the IRB when the risk of an intervention is “more than a minor increase over minimal risk”. Such a study can only be approved by the Secretary of Health and Human Services through a process developed to comply with 45 CFR 46.407. Very few studies have been forwarded to the Office of Human Research Protection.

Determining under which categories a particular intervention should be placed is not always done consistently. A study of 188 IRB chairs showed great variability in these decisions. Allergy skin tests were considered by IRB chairs to be classified as minimal risk (23%), minor increase over minimal risk (43%), or more than a minor increase over minimal risks (27%). Blood draws were considered minimal risk (81%), minor increase over minimal risk (17%), or more than a minor increase over minimal risks (1%). A confidential survey of sexual behavior was considered minimal risk (44%), minor increase over minimal risk (29%), or more than a minor increase over minimal risks (19%).

Although some have argued that determination of a minimal risk classification can be resolved with quantitative data about the likelihood and frequency of risks, others have argued that this determination is inherently qualitative. Clarifying which risks of outcomes research are no more than
a minor increase over minimal risk and therefore, potentially approvable by an IRB, is important.

**MINIMAL RISK AS A THRESHOLD**

The central question surrounding any particular intervention is whether the intervention is too risky to be performed in children. This vexing question remains despite many efforts to seek clarity. The US regulations do not provide clear guidance on this issue. A recent analysis by Wendler and Emanuel, and an accompanying editorial by Nelson and Ross considered this issue. Both agreed that “scientific necessity” is critical to justify the enrollment of children. Their disagreement arises out of their assessing one of the seminal works in pediatric research ethics by Freedman et al. Freedman et al. argued that when an IRB interprets the pediatric regulations, it is charged with acting as a *scrupulous parent* to decide in what research is it appropriate for their child to enroll.

Wendler and Emanuel rejected Freedman’s *scrupulous parent* metaphor because they do not think that it provides adequate guidance, suggesting that it be replaced by a criterion of *socially acceptable risk*. However, Nelson and Ross defended the *scrupulous parent* model by suggesting that risk levels are highly contextualized moral decisions that parents and IRBs need to make just as parents make other decisions for their children. They appropriately pointed out that any notion of social acceptability contains more ambiguity than Friedman’s approach.

Nelson and Ross did not address whether a parent should be willing to allow their child to receive a specific intervention. Wendler, in another article, suggested that the risks parents should be willing to accept ought to correlate with the risks considered acceptable by parents in permitting their children to participate in other charitable activities. For example, some charitable activities such as serving food at a homeless shelter or participating in Habitat for Humanity construction projects also expose children to some risk for the purpose of benefiting others. This consideration provides another direction for placing some contextual constraints on the scrupulous parent.

It follows then, that a scrupulous parent would also agree to allow for their child’s participation in an outcomes research study involving a review of medical records and blood collection for genetic research. This speculative assertion is based on the fact that parents agree to provide confidential information about their children for medical care, school, after school activities, etc. Although there is no direct benefit to children by their participation in observational research as there can be with medical care and education, it is still reasonable to assume that many parents will allow their children to be exposed to such risks for society’s benefit. The scrupulous parent metaphor is meant to guide the IRB in determining which research parents should even be permitted to consider. Each parent still must make their own decision.

**NORMATIVE CONSIDERATIONS BEYOND MINIMAL RISK**

The unresolved debate remains concerning what counts as an acceptable risk for children in research that does not offer a prospect of benefit. IRBs will continue to interpret particular risks differently. However, additional normative considerations can still guide researchers and IRBs, regardless of their views about a particular intervention and its risks.

First, the inclusion of children should be necessary to achieve the scientific objective. Even though individual children in the study may not directly benefit from the research, the research question should have the potential to benefit children in the future. The default should be to perform research on people who can consent unless it is necessary to use a population that has some constraints on its decision-making because of, for example, age or severity of illness.

Second, the risks of a particular intervention may differ depending on the researcher’s experience and efforts made to minimize risk. For example, sedation for procedures carries some risk. However, excluding certain participants, using particular equipment, and using an anesthesiologist to administer the sedation can reduce these risks. Thus, an IRB might consider sedation for a magnetic resonance imaging to be classified as minimal risk in the context of one study and more than minor increase in another study.

Third, the risks associated with interventions should be minimized. Although much of observational research will not include more than minimal risk activities, in many cases, a researcher can further reduce risk by simple measures. For example, efforts to reduce breaches of confidentiality are worthwhile, not because an alternative approach exceeds minimal risk, but because the simple efforts reduce the risk further.

Fourth, parents and children should be treated with respect. This consideration appears both obvious and meaningless. It seems obvious because no one argues against respecting participants, yet it seems meaningless because what counts as being respectful may not be clear. For example, an appeal to respect cannot resolve whether it is appropriate to provide families with the individual results from a research study. However, respect stands alongside risk as an important consideration in determining what approaches may be appropriate.

**IS OBSERVATIONAL RESEARCH MINIMAL RISK?**

The wide range of research activities in observational research makes determining the level of risk categorically difficult. Some interventions and activities may pose more risk (laboratory tests or interviews for illicit drug use) than others (laboratory test or interviews for lead exposure). For any particular intervention or activity, risk level often depends on the related measures to minimize risk. This is again exemplified by the risks of sedation for a magnetic resonance imaging that might depend on the method of sedation, the monitoring approach, and the qualifications of the person...
providing the sedation and monitoring. Risk levels vary by institution and investigator as defined by their previous experience in conducting the intervention with limited adverse events.

Three procedures likely to be employed in observational research include (1) collection of personally identifiable health information from medical records; (2) questionnaires and interviews about health-related behaviors, attitudes, and experiences; and (3) collection of biological samples for genetic and molecular studies. The common thread among all three procedures is that the potential risks relate to the information generated. The primary risk relates to whom the information is shared with and any adverse effects from disclosure of the information.

**PROTECTING CONFIDENTIAL HEALTH INFORMATION**

One set of ethical issues important to all research with human subjects regards privacy and confidentiality. Privacy refers to an individual’s interest determining with whom to share the particular information. Social norms concerning what sort of information should be considered private are quite contextual. Confidentiality refers to promissory obligations of individuals or institutions to protect the private information of others. Thus, privacy considerations may help determine the appropriateness for a researcher to analyze collected health information. Confidentiality considerations might help determine whether it is appropriate for a researcher to share collected information with another researcher.27,28

Whenever researchers use collected medical records, questionnaires or biological materials, there exists a risk for loss of confidentiality. Three broad considerations help decide whether this risk should be categorized as minimal risk: (1) likelihood that loss of confidentiality will occur, (2) likelihood that the loss of confidentiality will result in harm, and (3) the magnitude of the harm. The determination that the risk of confidentiality loss should count as more than minimal depends on a careful evaluation of all three issues. Although a risk of serious magnitude might be present, that risk alone does not sufficiently make the determination.

The risks after loss of confidentiality are typically not physical. Although physical risks such as domestic violence are possible, psychosocial risks are generally more plausible. Some psychosocial risks such as loss of employment, insurance, housing, or friends can be quite significant. Such risks are more likely when particularly sensitive information, such as human immunodeficiency virus status, is involved. The challenge often arises in considering these risks seriously enough, but not considering the potential for any risk to be sufficient to categorize the research as greater than minimal risk.

Efforts to minimize risks related to breaches of confidentiality are critical to the determination of minimal risk status. Such efforts might include database encryption, using linked codes when analyzing data, and limiting the individual data reported to minimize the identifiability of the individual. Finally, it is necessary to distinguish between an individual’s identifiability to others (such as neighbors or family members creating a breach of confidentiality) in contrast to a participant’s recognizability to himself.

Issues involving respect for participants can also be relevant in cases where confidentiality breaches might not produce any direct harm, because such actions could be considered a “harmless wrongdoing” that may still be of concern to participants.29 Family genetic studies that reveal unexpected family relationships such as misattributed parentage serve as an example. Even if such disclosures do not result in psychological harm, disclosing such information without permission might still be wrong in most circumstances. Again, the mere potential for this occurrence does not by itself categorize a study as more than minimal risk. Such risks generally only occur in the context of family studies and not in all studies involving individual genetic information.

To determine whether a study using confidential information should be classified as minimal risk, the study protocol should include a very detailed description of the plan to minimize breaches of confidentiality. This account allows the IRB to independently assess the plan’s adequacy.

Although it is critical that the study protocol provide explicit discussion about these issues, there are several reasons to more narrowly focus the confidentiality discussion on informed consent and parental permission forms. It is generally not desirable to include all the information in the study protocol that the IRB reviews in the consent form. First, there often exists an inverse relationship between the volume of information and comprehension.30 Second, the high reading levels of IRB standardized information can contribute to comprehension problems.31 Third, the key message about confidentiality can be easily lost in the details.

The key message for participants to take home is that measures will be taken to protect the confidentiality of the information but also, that there will always be some risks and some data sharing may occur (i.e., Food and Drug Administration review). A secondary message requiring clarity involves the nature of the information to be collected and protected since there may be different implications of particular confidentiality breaches. Some studies will focus on medical records. Other studies might collect information about school performance. Finally, some studies will collect genetic information.

**DOES GENETIC TESTING INCREASE THE RISK?**

Some raise questions about whether genetic information such as DNA sequences, gene expression profiles, or phenotypic information correlated with genetic information categorically increases the risk of the research beyond minimal.32 Citing the potential social consequences of breaches on confidentiality, genetic research is arguably more than a minimal risk. However, the assessment of risk includes an estimation of likelihood and the steps to reduce risk. Thus, an IRB would need to decide if the steps to reduce risk are sufficient to
consider the risk minimal. More importantly, the risk arises not because it is “genetic” information per se, but because of particular features of the information that might also be relevant to some nongenetic examples (human immunodeficiency virus), but not relevant to other genetic examples (the gene for rolling the tongue).33

Some of the ethical discussions relating to genetic research focus on whether it is ethically appropriate to permit parents to give permission for the storage and further research on a child’s DNA samples. Concern appears because of the fact that, because the specific analysis has yet to be determined, it is inappropriate to allow parents to agree to “future research” because such research may involve, among other things, unknown risks.34 Further, the federal privacy rules prohibit consent to “unspecified research”.35 Nonetheless, the permission form could be very specific about limiting the future research to only using blood for further laboratory studies. Wendler proposed a step-by-step procedural analysis that offers an approach involving subsequent IRB review that could allow “one time consent” that may meet the regulatory requirements.36

OBLIGATION TO RETURN INDIVIDUAL RESEARCH FINDINGS TO FAMILIES

One important issue in observational research regards the obligation to provide individual participants with their research results. Some argue that respect for persons requires that all research data be made available to participants requesting it.14 However, others suggest such obligations are more limited.26 One consensus conference concluded that research results should be returned only when they are likely to directly affect clinical medical management.37 Much research data will either have unclear clinical implications or the quality control methods in the research setting might be less than appropriate for clinical practice. A more recent analysis supports the view that informational characteristics are primarily determinative for returning results but modifies it by suggesting the importance of other contextual factors.5 First, participants’ ability to obtain the information through alternative modes of access can attenuate researchers’ obligations. Second, the nature and extent of the relationship between the investigator and participants may increase obligations. Third, investigators lack of capacity to perform the test according to clinical standards and effectively communicate the meaning of the results may reduce obligations.

Communicating the research findings and researchers’ obligations to provide care to the research subject are issues that have remained in focus from the Tuskegee Syphilis Study to the recent Kennedy-Kreiger Lead Abatement Study.38 Although the extent of research obligations remains contested,4 it is clear that researchers and IRBs need to explicitly consider the aforementioned issues.

IS INFORMED CONSENT NECESSARY TO CONTINUE TO USE DATA ONCE CHILDREN BECOME ADULTS?

Parental permission is considered the primary authorization for permitting children to participate in research. Typically once the children become adults, their independent consent is obtained. Such consent is both ethically and practically necessary for studies with ongoing involvement between the participants and the researchers. However, some observational research may not involve such a continuing relationship. Finding an adult who once participated in an observational study as an infant might not be feasible. Is it permissible then, to continue to use the data without the consent of such an adult?

It is important to distinguish between research conducted despite objections by a participant and research conducted without the participant’s affirmative agreement. It is difficult to justify research over the objections of the participant. Rather, research without consent refers to research with limited or no disclosure and hence, no affirmative agreement. Such an approach to consent is discouraged in many settings because of worries that the research will proceed only because the research was not adequately disclosed. This “opt-out” approach would not constitute authentic consent if many people would decline upon becoming informed. Considerable debate occurred over this opt-out approach for the research in the 1990s that used a clinical database in Iceland.39

In evaluating the appropriate role of informed consent for continued research on data collected on children, the opt-out approach might prove reasonable. Continued research on data that holds important social value should not be stopped simply because a participant could not be found. Reasonable attempts ought to be made to find the participant, notify her, and respect any requests to stop continued research.

From a regulatory perspective, if such continued research is considered “minimal risk”, the research might then qualify for a waiver of informed consent under the US regulations.40 In order for the IRB to waive the informed consent requirement the research must not adversely affect the subjects’ rights and welfare and the research could not be practically performed without the waiver in addition to the minimal risk requirement. It is beyond the scope of this article to develop the argument explaining why such research might qualify.

However even if a waiver is obtained, the investigators might still have some ethical obligations to (1) attempt to disclose to subjects that research is ongoing and (2) to honor any requests from past participants to stop any further research on their data, as feasible. Such an approach would show respect for the participants. As an example, developing a website that describes the ongoing research and provides contact information for past participants to use for opting out would go beyond what is required once consent is “waived”, yet might help promote social trust in the research enterprise.
CONCLUSION

Whether outcomes research is classified as minimal risk will likely depend on both the type of information collected and the methods developed to protect the information. In general, the risks of confidentiality losses involved with participation in outcomes research are likely to be within the range of risks to which scrupulous parents might consider exposing their children.

The key goal remains to minimize the risks of confidentiality breaches by developing explicit plans that are reviewed by an IRB. A plan should also be developed to explicitly consider which results will be returned to the subjects and this plan should be communicated to the participants. Finally, researchers should develop a plan for continued research after participants turn eighteen. Such a plan might include a maintained website that families can return to for further information about the study and its findings. Adequate plans to protect confidentiality and communication with research participants about the study’s progress, in the context of high quality research about important social topics, are what matters in making pediatrics observational research ethical.

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Dr. Nelson: I decided to really focus on a couple of aspects, based on Dr. Wilfond’s article, the other articles and the discussion about the kind of research that you are considering. The first is, some thoughts about prospective data collection that may or may not involve a direct relationship with the subjects. Even prospective data collection, absent a direct relationship, can have an impact that needs to be looked at from a moral perspective whether or not an IRB considers this. For example, a data collection instrument that has different data points may impact clinical practice. For example, if there’s a computed tomography (CT) scan from the outside hospital on that form, you might inadvertently cause people to get more CT scans, or if you leave that off, maybe they won’t get CT scans.

Secondly, depending on the sites that you enroll, you may have to ask the question of what to do if we observe below standard care? What do we think if, in fact, that’s happening with any given institution? One thing that has troubled me as I’ve listened to the conversation is the language, for example, of “optimal clinical care, barriers, solutions, tools.” That’s not the language of clinical research; that’s the language of quality improvement. That is a different paradigm, to some extent, with a lot of overlap between clinical research, but that’s not a pure model of research. It’s getting to this question of integration of clinical and research activities, which I personally think is laudable, but you’ll need to think out how that impacts the way the research is both organized and presented.

Why is that important? Dr. Wilfond mentioned a data monitoring committee. You could have a Continuous Quality Improvement (CQI) process superimposed on the data that you’re collecting. In fact, I would expect that the very data that you’re collecting in any given institution is probably the same kind of data that you would want to feed into your CQI process. Much of the systems-related data that you’re talking about collecting is information that you’d probably end up discussing within your trauma QA meetings, so that relationship has to be thought about.

This actually may be an advantage. If you’re collecting clinical data within the common rule under the IRB regulations, they can waive consent if it meets four requirements.

First, the research be minimal risk. Prospective collection of data are minimal risk as long as you’re not necessarily changing the clinical care that’s going on.

Second, the research is not otherwise feasible. There is ambiguity when IRBs think about feasibility. If you’re face-to-face with an individual, they think it’s feasible to get consent. That’s one way of viewing feasibility. The other way of viewing feasibility is whether the research is feasible if you have to get consent from everybody? If it involves 5,000, 6,000, or 8,000 people, I would argue waiver of consent would be appropriate.

Third, there can be no rights that are violated. Does the Health Insurance Portability and Accountability Act (HIPAA) establish a right? That is a debatable point.

Fourth, you have to provide information back to the individuals.

Let me discuss HIPAA. The variability in HIPAA interpretations that Dr. Wilfond mentioned is part of the difficulty. My own view is that HIPAA provides no additional protections to human subjects than the Common Rule, and it’s just a bureaucratic barrier. It’s a regulation that was designed ostensibly to protect us from insurance discrimination, and, in fact, when it was finally written, insurance companies are all exempted because it’s the provision of healthcare. It’s a law that was intended to help which has basically hurt.

We had an investigator at Children’s Hospital of Philadelphia who wanted to look at the outcome of urinary tract infections (UTIs) relative to the various procedures that are followed such as voiding cyeotourethragrams. I suggested they integrate the research team into the clinical care process by offering to do all the follow-up for the pediatrics, integrating the clinical and research team. Some pediatrics wanted to handle follow-up themselves, but many were thrilled that there would be someone else who was going to call and track down the family and make sure that things were scheduled. They didn’t care whether it was the research team or not.

This gets back to HIPAA. If a researcher is part of an institution, there are no HIPAA issues in revealing to him or her health information. It is only a problem if you are not part of the institution or not part of the health care team. To the extent that some of the research is part of clinical care (for example, optimizing clinical care and linking this to outcome measurement), you can take some of those outcome measures that you would like to be done prospectively and universally because you want the research data, link it to clinical care and to rehab referral, and as a result it is part of the clinical team and there are no HIPAA concerns. You’ll have to take into effect how you’re changing the system as you design the research, but I suspect that it’s a problem that’s solvable.

What about biochemical or genetic studies as part of this larger trauma study, such as measuring apolipoprotein e al-
leles? That’s a solvable issue and some (perhaps not all) IRBs have solved it. It does raise the issue of predictive testing. For example, since apolipoprotein E is related to risk of Alzheimer’s disease although what you’re interested in is a predictor for outcome from traumatic brain injury, what do you tell the parent? This is a difficult but solvable issue.

Dr. Wilfond said you shouldn’t have separate consent forms for different aspects of the study, such as genetic testing. Let’s imagine you have different components. You have what might be considered a CQI component with some of these outcome measures linked to getting rehabilitation et cetera, so you were able to both provide care and do research. You also have a genetic testing component which is conceptually distinct, with different logistical challenges, potentially different approaches to the ethical issues, and perhaps different sample size requirements based on effect size and outcome measurements that you want. One possible solution is a modular approach, rather than asking one person to sign five different consent forms. There may be the larger data outcomes, but then a small apolipoprotein E subproject that the sample size might not require of all the institutions. There might be a third sub-study that you’ve decided to power differently, and then approach patients differently.

Why is that important? You don’t want the genetics issues to undermine the broader feasibility of the question of outcomes related to acute care and rehabilitation. In a modular approach, you could design different linked protocols going into IRBs, without getting them confused and hung up thinking about the genetics issues for 12 months figuring that out, delaying the study.

In summary, what seems unique about this conversation, as well as challenging and interesting, is CQI around optimizing care integrated with clinical research.

Dr. Dean: I’m interested in asking about a triple-layered consent process. Fairly frequently, you actually need at least some screening or minimal data on all patients to have scientific validity at some level. You can’t only take the trauma patients that do well enough to get consent; this will result in a biased sample. In our National Institutes of Health (NIH) PICU network, we argued that the screening data ought to be waived from both consent and authorization. Our investigators have resisted combining the genetic consents because they’re worried it’s going to undermine recruitment into the main study. Is my concept right that we should be thinking in this study maybe of three layers like that?

Dr. Nelson: I would say that you would need to know the whole universe of injured patients. However, part of the question is what data are needed? If it is only some characteristics of a population that wasn’t necessarily enrolled for the more intensive data collection effort, than that is anonymous data, and so applying a waiver to that should be relatively noncontroversial. But part of this is including the ethical arguments in the protocol; don’t ever rely on an IRB to make it up on their own, which they will do.

Dr. Wilfond: I completely agree with Dr. Nelson that the initial project probably is waivable for all sorts of reasons. I want to make a distinction that’s relevant to the point that I made earlier. The reason to waive consent is because the consent form as it’s conceived is just a problematic beast. However, letting people know you’re doing research and trying to communicate with them is desirable. It’s important to distinguish between what form patients sign versus what obligations we might have to interact with them.

I want to make one additional point regarding the genetics aspect. Dr. Nelson made the comment that one reason to have a separate form is not because of IRB issues, but because of patient perceptions that maybe people won’t be as willing to be in a study. There’s actually a fair amount of data about whether or not separate consent forms actually influence people, and in general the answer is no.

Male: Do you think a short form should be considered? Additionally, should there be a certificate of confidentiality for a study like this to help assure or encourage recruitment?

Dr. Nelson: The short form in the regulations is mainly designed to be used for individuals who don’t speak English. The waiver of informed consent under the minimum risk category that I cited is a waiver of either all of the elements or a waiver of some. What are really the essential elements? When an acutely injured child is admitted, you’re not going to tell them about your research right then; you start providing care and collect data. This is a waiver of consent. But the IRB may like the fact that at the first opportunity you tell patients what you’re doing. You can decide what are the key issues that you want to tell them and ask for a waiver of all the other issues that might be in that initial approach. There may be some ways that you can use the regulations in a way that would allow some flexibility.

In terms of the certificate of confidentiality, who’s risk are you protecting? I don’t think having one or not having one would impact on recruitment. I doubt the patients are going to be worried about that. If the study involved many hospitals where you may, in fact, see substandard care, maybe the institutions might care about a certificate of confidentiality.

Male: Certificates of confidentiality were initially designed for people involved in drug abuse research or other illegal activities, and it’s rarely used. It’s unclear what protection it provides. It only sort of complicates what you have to explain, and patients have no idea what it means.

Male: I’d like to know where the pendulum is for exemption from informed consent for emergency care research. A number of institutions are involved in a trial examining the efficacy of two benzodiazepines administered in status epilepticus. We are through a community consultation process right now, with the goal being to submit to the IRBs at the various institutions for exemption from informed consent. Is there going to be a receptive attitude for this approach to this kind of work?
Dr. Nelson: Whose attitude are you referring to? Some IRBs have experience with this and others do not; it’s a learning curve that’s fairly steep for many.

Male: Dr. MacKenzie, what were the problems with the waiver of consent for the NSCOT trial and then relative to what their arguments against it were, and how that might relate to going forward from here.

Dr. MacKenzie: The NSCOT study was designed right before HIPAA came into effect. Our problem was that hospitals were preparing themselves for HIPAA and they were quite concerned about what it all meant. We tried to get waiver of consent, and that just wouldn’t work. We wanted to write patients letters and give them a chance to opt out. Most institutions enrolled granted us that permission. Some hospitals, like Massachusetts General Hospital and UCLA were going to require written permission from patients for us to send them a letter asking them about the study.

In addition, about half the institutions allowed us to consent patients over the phone. But about half the institutions required us to get written permission to then go back and abstract their medical record.

Dr. Nelson: HIPAA then was a moving target, although there may still be different interpretations of it. But the integration of the clinical and the research team can go to the issue of sending a letter. If that letter is coming from the same individuals who are, in fact, providing care, it is not an issue. Not an issue. There are ways of doing this if you have IRBs that appreciate the importance of research. You have to engage the IRBs and try to convince them.

It is interesting that there were these different approaches. It would have been a wonderful opportunity to find out whether or not respondents, regardless of how they’re approached, thought differently about the study. It would provide great data for a later study to demonstrate to an IRB that it’s not a problem to send them this letter.

Dr. MacKenzie: I do agree with you about the education of the IRB. We just went through this at Walter Reed. Initially, it was the same sort of a design, and initially the IRB said no way. After further explaining it and talking with them about the study, they ended up approving it.

Dr. Nelson: That approach wouldn’t be appropriate for every single research study; it depends upon what the study is and why it’s being done and how critical it is to do it this way. None of us would want to think that any time we see a doctor that we can expect during the next year getting a phone call from some researcher wanting to enroll us in a study.
Towards Improving the Outcomes of Injured Children

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The Institute of Medicine defines quality as “The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.” The necessary steps to achieving high quality of care for pediatric trauma patients are understanding the outcomes after trauma, determining the variations in care that do exist, relating these variations in care to variations in outcome, developing evidence-based standards for optimal care, and using these standards to change the structure and process of pediatric trauma care in this country.

The conference on pediatric trauma care held in Washington, DC, March 8th and 9th 2007, sought to examine the current state of pediatric trauma care and discuss research on how it can be improved.

KEY QUESTIONS IN PEDIATRIC TRAUMA

There are a number of key questions that must be addressed if the toll from injuries to children is to be reduced. First, it is necessary to better understand the consequences of trauma in children and define what the optimal outcome should be. As with adult trauma care, nearly all studies of injured children have focused mainly on survival and have not explored in greater detail functional outcome and disability. There was great consensus at this conference on the need to examine outcomes in children quite broadly. These outcomes should include health-related quality of life, as well as physical, cognitive, emotional, social, and behavioral functioning. The impact of injury on other members of the family must also be included.

The duration of follow-up was a key issue addressed by the conference participants. Although the National Study for Cost and Outcomes in Trauma (NSCOT) followed patients for 12 months after their injury, this was thought to be inadequate for a developing child or adolescent. Outcomes need to be examined for at least 3 years after injury, with ideally some limited follow-up for considerably longer periods.

All participants recognized that there is currently substantial variation in trauma care in the United States for children and adolescents. A prospective study is needed to use this variation in care to understand how the organization and processes of care affect outcomes. The organization of pediatric trauma care is much more complex than that of care for adult trauma, and a relatively simple comparison of two types of centers such as was done with NSCOT is neither possible nor appropriate. There are many levels of factors that need to be considered. First is the organization of pediatric care within the overall trauma system, including both systems that support a separate and parallel process for pediatric trauma care, and systems that do not. And, of course, there are areas of the country that do not support any formalized system of trauma care. Some of these are mature systems, others are more recently established. Duration of existence is important, because as shown by Nathens et al., it may take at least a decade before the implementation of trauma systems affects outcomes.

Second, the type of center must be considered. As pointed out by a number of speakers, this includes pediatric trauma centers within children’s hospitals, children’s hospitals that are not trauma centers, pediatric trauma centers within adult hospitals that are adult trauma centers, adult trauma centers with or without special qualifications for pediatric trauma, and general hospitals. Combined with the characteristics of trauma systems within the region, this variation presents a large number of different possible permutations for the organization of care.

The resources to care for injured children also vary widely. There are many aspects of care: prehospital, emergency department, operating room, intensive care unit, ward, and rehabilitation. Each of these aspects may or may not have special pediatric expertise in caring for injured and sick children. Most settings do not have pediatric trauma expertise in all of these areas; however, many centers do have pediatric expertise for some of them.

The critical question is how these variations in care received affect the short and long term functional outcomes in
the child and adolescent. Under what circumstances and using what resources are outcomes better or worse?

These injuries and these outcomes do not occur in isolation. Prior studies on burned children⁵ and children with serious traumatic brain injury⁶ have shown that preinjury functioning of the child and family have very substantial influences on function and disability. In adults, physical co-morbidities are common and many, especially older adults, have preexisting limitations in many facets of their lives. In children and adolescents, the preexisting conditions that affect outcome after trauma are much more likely to be related to family dynamics and resources, and emotional and behavioral problems in the child. Recovery is also affected by resources available in the neighborhood and community, such as schools and nonprofit agencies that can address the special needs of some injured children.

Functional outcomes may also be affected by the individual’s genotype. For example, differences in the allele for monoamine oxidase activity greatly affect the impact of physical abuse and other maltreatment on children’s subsequent behavior.⁷ Variations in Apolipoprotein E have been associated with poor outcomes after traumatic brain injury.⁸

**DESIGN OF A STUDY**

Participants at the conference were in unanimous agreement that a study on pediatric trauma care and outcome must be prospective to have the detailed data on patient, family, and processes of care to relate to outcomes. A multicenter study will provide both the necessary variation in care, which must be examined and adequate sample size to allow appropriate subgroup analyses.

The design would not be a simple comparison of patients treated in one type of center with those treated in another. The many factors discussed above that must be examined can only be done in a large prospective cohort study in which the potential effect moderators and confounders can be considered. Modern epidemiologic and advanced statistical techniques will invariably be needed to isolate the effect of different processes of care, settings, and systems on patient outcome.

**IMPLICATIONS FOR FUTURE CARE**

The long-term goal of this study is to deliver optimal care to injured children, so that they attain the best possible outcomes they can after serious trauma. Currently, most of the questions about what constitutes optimal care remain unanswered, thereby giving rise to the tremendous variations in care and settings we see today. This study will allow standards for optimal care of the injured child to be established based on high-quality evidence. These standards must then be adopted by organizations such as the Committee on Trauma of the American College of Surgeons, the Emergency Medical Services for Children program of the Maternal and Child Health Bureau, the Agency for Healthcare Research and Quality, and state and local certifying agencies to bring high quality, uniform care to injured children.

**REFERENCES**