ALTERNATIVE APPROACHES FOR ESTIMATING HEALTH-RELATED QUALITY OF LIFE IMPACTS:

CHILD RESTRAINTS REGULATION CASE STUDY

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PREFACE

This case study was one of three developed to support the work of the Institute of Medicine's Committee to Evaluate Measures of Health Benefits for Environmental, Health, and Safety Regulation. The Committee's summary of this case study, as well as the results of its other investigations and deliberations, is provided in its final report, *Valuing Health in Regulatory Cost-Effectiveness Analysis (2006)*.

This more detailed version of the case study contains additional information that may be of interest to regulatory analysts and other researchers. However, it was largely completed prior to the articulation of the Committee's conclusions and recommendations and thus does not reflect all of the views presented in the Committee's final report.

The case studies were undertaken as a learning experience, to provide the Committee with information on the challenges associated with applying different health-related effectiveness measures in a regulatory context. Due to time and budget limitations, they do not replicate the full complexity and level of detail required for regulatory analysis under current government-wide guidance or under the Committee's final recommendations. The case studies relied extensively on the voluntary efforts of many individuals.

ACKNOWLEDGEMENTS

This case study could not have been completed without the hard work and dedication of a number of volunteers. The Committee is grateful for the extensive efforts of those who assisted in its completion, which contributed enormously to the Committee's understanding of the challenges and opportunities associated with conducting cost-effectiveness analysis in a regulatory context.

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SECTION 1.0: INTRODUCTION

The Institute of Medicine's (IOM's) Committee to Evaluate Measures of Health Benefits for Environmental, Health, and Safety Regulation commissioned three case studies as part of its investigations related to the use of cost-effectiveness analysis to assess the impacts of economically significant federal health and safety regulations. These case studies allowed the Committee to explore the application of alternative approaches to estimating health-related quality of life (HRQL) impacts in the regulatory context, and were one of many inputs into its deliberations.

This report provides a detailed account of the Committee's first case study, which addresses the National Highway Safety Administration's (NHTSA's) 1999 regulation requiring anchoring systems for child restraints. We selected this regulation as one of the Committee's case studies so that we could explore issues related to valuing effects on children as well as alternative approaches for assessing the impacts of injuries.

However, we were unable to use data from NHTSA's regulatory analysis for our assessment. NHTSA uses very broad injury categories in its economic assessments; it considers five classes of non-fatal injuries as well as fatalities. Because the NHTSA estimates do not provide the detailed descriptive information on individual injuries needed to apply different HRQL indices, we used information from an alternative NHTSA data set in the case study.

These data provided information on injuries incurred by 22 restrained children over a five year period. We assessed the impacts of these injuries under four generic indices. For the EuroQol (EQ)-5D and the Health Utility Index (HUI) Mark 2, we asked medical experts to match the characteristics of each injury to the relevant attribute scales. We then used the standard community weights associated with each index to determine the value of each health effect.

For the other two indices, we used values from available research. We applied estimates from the Quality of Well-Being (QWB) scale based on research undertaken by Troy Holbrook of the University of California, San Diego. We also considered the Functional Capacity Index (FCI), which is being developed by Ellen MacKenzie of Johns Hopkins University and her associates.

In the case study, we assumed that all 22 injuries occurred in a single year for simplicity. Some of these injuries will have long term impacts; we take these future year impacts into account and use discounting to reflect their timing. (Agency regulatory analyses generally take a longer term view and assess impacts over a multi-year period as well as on an annual basis.) Because the cost estimates developed by NHTSA for its child restraints rule relate to preventing injuries that may differ in number and type from the injuries represented by these 22 cases, comparing the NHTSA costs estimates to our estimates of health impacts could provide misleading information on the cost-effectiveness of the NHTSA regulation. Hence we did not include estimates of cost-effectiveness in this case study.

This case study was developed as a learning experience for the Committee, and provided an opportunity to use the information available to regulatory agencies to develop different effectiveness measures. Due to time and budget limitations, it does not replicate the full complexity of a regulatory analysis. It involves the use of simplified analytic approaches and assumptions, often relying on mean or median estimates, and provides only limited information on the range of possible values and the distribution of impacts. In these and other respects, the case study does not fully adhere to the existing guidelines for regulatory analysis nor to the recommendations developed by the IOM Committee. The lessons learned from this case study are summarized in the Committee's report.

The following sections describe our analytic approach and findings in detail; a summary of this case study is available in Appendix A of the Committee's final report. First, we summarize the original NHTSA regulatory analysis. Next, we discuss our analytic approach in detail. The following section presents the results, and the last section then discusses the limitations of our analysis. The appendices provide supplementary information on selected aspects of the analysis.

SECTION 2.0: NHTSA ANALYSIS

NHTSA's child restraint rule established a Federal motor vehicle safety standard (FMVSS) that required manufacturers to provide standardized anchor systems for child restraints that are independent of safety belts. These anchors must be installed in all passenger cars and most light trucks, buses, and multipurpose passenger vehicles. Child restraint manufacturers must also modify their products so that they can be easily attached to either the new or existing vehicle anchorage systems. These standards were authorized primarily under the Motor Vehicle Safety Act (Title 49, U.S. Code, Chapter 301), which requires the Secretary of Transportation to develop practical and effective standards for motor vehicle safety.

To support rule development, NHTSA quantified the costs and benefits of both rigid and flexible anchorage systems in its economic analyses. The final rule requires rigid anchorage systems in the vehicle, but allows either rigid or non-rigid attachments on the child restraint. Two of the regulatory options assessed represent these alternate approaches to complying with the rule; i.e., one includes a rigid vehicle anchor and rigid child restraint attachment, while the other includes a rigid vehicle anchor and a non-rigid child restraint attachment. The third option assessed, which was rejected by NHTSA, includes a non-rigid vehicle anchor and a non-rigid restraint attachment. In the documents supporting the rule, NHTSA discussed other regulatory options, including standards suggested by industry groups and a design developed by an individual manufacturer.

The proposed rule was published in the February 1997 *Federal Register* and promulgated in final form on March 5, 1999. The requirements for installing anchor points on child restraints became effective on September 1, 2002. The requirements for vehicles were phased in over three years; all vehicles manufactured after September 1, 2002 are required to include anchors. Assuming that existing child restraints will be used for roughly 10 years, NHTSA indicated that most restraints in use as of 2012 would have the new mechanisms needed to attach to the car anchorage system. At that point, the rule rescinds existing requirements for automatic locking retractors on seatbelts, since the locks will no longer be needed to hold restraints securely.

The following sections briefly summarize the approach for assessing costs, estimating risk reductions, and valuing benefits for this rule, based largely on information in NHTSA's 1999 *Final Economic Assessment*.

2.1 Cost Analysis

NHTSA's cost analysis involved first examining the existing configurations of child restraints and vehicles, and then estimating the additional costs imposed by the anchorage requirements. NHTSA next multiplied these incremental costs by the predicted number of child restraints and vehicles affected to determine the total costs of the rule. In addition, NHTSA examined the impact of these costs on individual decisions to use child restraints, and concluded that usage rates were not likely to change. As required under the Regulatory Flexibility Act, NHTSA also considered the impact of the rule on small child restraint manufacturers.

Based on these analyses, NHTSA estimated that the national costs of the final rule were most likely to average $152 million annually (in 1996 dollars), with a range from $123 to $167 million. On a unit basis, NHTSA estimated that these costs would average $6 dollars per vehicle and $17 per child restraint. This best estimate reflects the option of providing a non-rigid attachment on the child restraint and a rigid vehicle anchor. The alternative approach allowed under the final rule, rigid attachments on both the vehicle and the child restraint, would be more expensive. The costs of the rejected option, which includes non-rigid vehicle and restraint attachments, would be between the costs of the two options for complying with the final rule. Exhibit 1 provides the cost ranges estimated by NHTSA for each option.

Exhibit 1

NHTSA COST ESTIMATES
(1996 dollars)

Type of Anchor	Annual Cost Range
Rigid restraint attachment/Rigid vehicle anchor	$217-256 million
Non-rigid restraint attachment/Non-rigid vehicle anchor	$149-196 million
Non-rigid restraint attachment/Rigid vehicle anchor	$123-167 million

Source: NHTSA (February 1999), p. 40, Table 15(d).
Note: NHTSA rejected the non-rigid/non-rigid option, but allows the either of the other options in the final rule.

In addition to these estimates of total annual costs, NHTSA reported the range of costs likely to be imposed given the characteristics of the connectors and anchorage systems used on different types of vehicles and child restraints. NHTSA also discussed other types of costs (particularly those related to testing requirements) and noted that the rule is likely to have negligible impact on fuel economy.

2.2 Risk Assessment

To estimate the numbers of injuries and deaths averted by the rule, NHTSA combined data on the impacts of child restraint misuse from several sources, focusing on children age zero to six. The starting point was data on the number of children in restraints who die or were injured annually in crashes. These data were reported by KABCO category, which defines four classes of nonfatal injuries based on the degree of incapacitation (none, possible, non-incapacitating, incapacitating).[1]

NHTSA then combined data from a survey on child restraint misuse, agency sled testing, and research on child restraint effectiveness to estimate the proportion of these fatalities and injuries that could be averted by the rule. To reflect uncertainty in the results, NHTSA reported a range of estimates of cases avoided.

[1] KABCO refers to the classifications used: killed (K), incapacitating injury (A), non-incapacitating injury (B), possible injury (C), and no injury (O).

Finally, NHTSA converted these estimates from the KABCO scale to the Abbreviated Injury Scale (AIS). The AIS is a simple numerical system for ranking and comparing the severity of crash-related injuries based on their threat to life; i.e., on the probability that the injury could be fatal. A score of "0" indicates that there were no injuries, whereas a score of "6" indicates that the injury was likely to be immediately fatal; intermediate scores of 1 through 5 indicate injuries of increasing severity in terms of their threat to life. When multiple injuries occur, they are scored according to most life-threatening injury; i.e., the Maximum AIS or MAIS. NHTSA converts the scoring of nonfatal injuries from the KABCO scale to the AIS using a standard algorithm derived from information on injuries from all types of crashes; this algorithm was not adjusted to reflect only those types of injuries to children that would be averted by the child restraints rule.[2]

2.3 Benefit Valuation

In its benefit analyses, NHTSA uses a standard methodology to convert nonfatal injuries to "equivalent lives saved" (ELS) and then adds the results to its estimates of the number of fatalities. NHTSA then uses the results to determine the cost-effectiveness of the regulatory options. NHTSA has historically used the ELS approach in all of its regulatory analyses that involve quantified reductions in injuries; the ELS calculations sum expenditures and monetized HRQL impacts for each MAIS class for nonfatal injuries, then compare the results to the value of statistical life (VSL).[3] These ELS values are calculated periodically for each of the MAIS classes based on estimates for all types of crashes nationally, then applied across the subsequent regulatory analyses. The data used in the child restraints rule were derived from NHTSA's report on 1994 crashes; NHTSA is currently using updated values for the year 2000 (NHTSA 1996, 2002).[4]

More specifically, in its 1994 report, NHTSA divided the economic costs of crashes into two components: "non-injury related" costs include those stemming from travel delays and property damage; "injury-related" costs include expenditures related to medical treatment, funerals, emergency services, vocational rehabilitation, lost workplace and household productivity, replacement costs for disabled workers, legal and court fees stemming from litigation, and administration of insurance claims.[5,6] NHTSA measured these values over the

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[2] Email from Jim Simons, NHTSA, to Lisa Robinson, December 7, 2004. NHTSA assumes the following distribution: AIS 1 = 82.5 percent; AIS 2 = 12.5 percent; AIS 3 = 4.2 percent; AIS 4 = 0.5 percent; and AIS 5 = 0.3 percent.

[3] The value of statistical life refers to the value of small changes in mortality risk spread throughout a large population; e.g., an 1 in 10,000 change in an individual's risk of premature mortality. It is not the value of saving the life of an identifiable individual; rather, it is the amount that individuals are willing and able to pay for risk reductions that sum to one statistical life.

[4] NHTSA is now also using these monetary estimates to conduct benefit-cost analysis.

[5]The *Final Economic Assessment* uses the total comprehensive per-crash costs provided in Appendix A of NHTSA (1996) to derive the ELS scores for injuries, rather than solely the injury-related costs. These costs are discounted at a 4 percent rate when the duration of the functional loss or decrease in workplace or household productivity is greater than one year.

estimated duration of the impacts of the injuries, including the length of time for which functioning is impaired and individuals are unable to engage in household tasks or paid work. For most MAIS categories, lost work productivity (wages and benefits) represent the largest share of total costs per case.

The HRQL impacts are assessed based on injury-related changes in functional status over time. In both its 1994 and 2000 estimates, NHTSA used a functional capacity index that considered the effects of injury on seven dimensions: mobility, cognitive/psychological, self-care, cosmetic, sensory, pain, and ability to work.[7] The resulting scores (weighted and combined across dimensions) were then multiplied by the value of a statistical life year (VSLY), after first subtracting the value of after-tax wages and household production.[8] The resulting value of these HRQL impacts was then added to the expenditures discussed above to determine the total (or "comprehensive") per case costs of injuries in each MAIS category.

The next step involved converting these costs into ELS estimates. The 1999 *Final Economic Assessment* relied on a value per fatality of $2.9 million. The starting point for this value was derived from NHTSA's review of the willingness to pay (i.e., VSL) literature.[9] NHTSA then adjusted the VSL estimate to exclude the value of lost wages and household production but include the types of economic expenditures discussed above. NHTSA next divided the comprehensive dollar values for each MAIS category by this per fatality value to obtain the ELS ratio for injuries in that category. For example, in 1994, NHTSA estimated that the total value (expenditures and monetized HRQL losses combined) of an injury in the least severe category is $10,840. Because $10,840 is 0.38 percent of the per fatality value, NHTSA assumed that each injury in this category was equivalent to 0.38 percent of a life saved. The values used in NHTSA's child restraints analysis are provided in Exhibit 2.

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[6]The 2000 report uses slightly different methods to estimate these costs, and excludes two types of "injury-related" costs included in the earlier report: premature funerals and vocational rehabilitation (NHTSA 2002).

[7]This index was adapted from 1983 work by Hirsch et al., as referenced in Miller et al. (1991).

[8]This calculation is described on p. 74 of Miller et al. (1991).

[9]The VSL estimate used in NHTSA's 1994 report was approximately $2.8 million in 1994 dollars (email from NHTSA consultant Ted Miller to Lisa Robinson, November 4, 2005).

Exhibit 2 **RELATIVE VALUES OF INJURIES AND FATALITIES (1994 dollars)**		
Injury Severity Category[a]	**Dollar Value[b]**	**Relative Value[c]**
MAIS 1: Minor Injury	$10,840	0.0038
MAIS 2: Moderate Injury	$133,700	0.0468
MAIS 3: Serious Injury	$472,290	0.1655
MAIS 4: Severe Injury	$1,193,860	0.4182
MAIS 5: Critical Injury	$2,509,310	0.8791
Fatal	$2,854,500	1.0000

Sources: NHTSA (February 1999), p. 48, Table 16; NHTSA (1996), Table A-1.
Notes:
a. Maximum Abbreviated Injury Scale (MAIS) categories reflect the severity of the worst injury in terms of risk to life.
b. Dollar values include expenditures and HRQL impacts.
c. Relative values are calculated by dividing the dollar value for the severity category (in the previous column) by the dollar value of a fatal risk (i.e., by $2,854,500)

NHTSA then applied these weighting factors to the estimates of injuries prevented by the child restraint rule, multiplying the relative values (in the third column of Exhibit 2) by the estimated number of injuries avoided in each severity category. The results indicated that, on average, 58 injuries were equivalent to one fatality given the severity of the injuries considered. The results of these analyses are summarized in Exhibit 3, which indicates that the sum of the weighted injuries and fatalities averted ranged from 57 to 101 equivalent fatalities.

Exhibit 3 ANNUAL QUANTIFIED BENEFITS OF NHTSA'S CHILD RESTRAINT RULE			
Type of Anchor	**Endpoint**	**Avoided Incidence (cases/year)**	**Equivalent Fatalities (undiscounted)**
Options permitted in final rule:			
Rigid restraint attachment/ Rigid vehicle anchor	Lives saved Injuries prevented **Total**	36 – 47 1,231-2,893 **N/A**	36 – 47 21 - 50 **57 – 97**
Non-rigid restraint attachment/ Rigid vehicle anchor	Lives saved Injuries prevented **Total**	36 – 50 1,235-2,929 **N/A**	36 – 50 21 - 50 **57 – 101**
Option not permitted in final rule:			
Non-rigid restraint attachment/ Non-rigid vehicle anchor	Lives saved Injuries prevented **Total**	36 – 50 1,235-2,929 **N/A**	36 – 50 21 - 50 **57 – 101**
Source: NHTSA (1999), p. i, Table S-1, p. 49, Table 17. Note: Detail does not add to total due to rounding.			

This exhibit suggests that the three attachment systems considered led to similar ranges of benefits. The options allowed under the final rule, a rigid vehicle anchor with rigid or non-rigid restraint attachments, would avert from 36 to 50 deaths and from 1,231 to 2,929 injuries annually. The rejected option, which includes non-rigid vehicle and restraint attachments, would avert the same range of deaths and injuries. When injuries were converted to equivalent fatalities and added to lives saved, the undiscounted results ranged from 57 to 101 equivalent fatalities.

NHTSA then estimated the cost-effectiveness of the final rule by dividing the compliance costs by the equivalent fatalities reported above. The results of this calculation indicated that the undiscounted costs per equivalent life saved ranged from $1.5 to $2.7 million. NHTSA also reported the sensitivity of the benefits estimates to the assumptions made regarding the effectiveness of the requirements, including assessment of the potential effects of locking seatbelts on correct usage rates.

In addition, NHTSA presented sensitivity analyses that discounted the estimates of equivalent fatalities at different rates then recalculated the cost-effectiveness estimates. The costs of the rule are incurred immediately (i.e., in the year in which the vehicle or car restraint is purchased) whereas the benefits accrue over a longer time period (i.e., over the years in which the vehicle or car restraint is used). The discount rates applied included 2, 4, 7, and 10 percent.

At the time that the analysis was completed, OMB recommended application of a 7 percent rate; if discounted at this rate, the costs per ELS range from $2.1 to $3.7 million.[10]

In this analysis, NHTSA did not report a total dollar value for all of the injuries and fatalities averted by the rule, and hence did not calculate net benefits (benefits minus costs). In more recent analyses, NHTSA has used the estimates of the dollar value of injuries and fatalities (from its ELS calculations; i.e., updated versions of the estimates provided in Exhibit 2) to determine the value of net benefits.

[10] More recent OMB guidance requires that agencies report results undiscounted and discounted at seven and three percent rates (OMB 2003).

SECTION 3.0: CASE STUDY APPROACH

To apply different approaches for estimating the HRQL and longevity impacts of averting crash-related injuries to children, we relied on injury data for a sample of 22 restrained children provided by NHTSA. We applied the EQ-5D and HUI-2 indices by asking medical experts to determine the attribute descriptions that best matched the likely impacts of each injury. For the QWB and FCI indices, we relied on data from assessments completed by other researchers. Below, we discuss the injury data used, and then describe the approaches for applying each index.[11] Additional information on each index is provided in Appendix A.

3.1 Injury Descriptions

The first step in the case study analysis involved developing injury descriptions that could be scored under the alternative HRQL approaches. As discussed in the prior section, the NHTSA analysis of the 1999 child restraints rule included only very broad classifications of injuries based on the extent of incapacitation or threat to life. Because our analysis required descriptive information on individual injuries, we instead relied on data from NHTSA's National Automotive Sampling System, Crashworthiness Data System (NASS-CDS). This system includes data on 22 sample cases that involved injuries to children in child restraints over the 1999-2003 time period.[12] We supplemented these data as needed with other information sources, in particular to determine the duration of the injuries and their impacts on life expectancy.

We relied on the NASS-CDS data because they were the only easily accessible source of detailed information on injuries to restrained children according to NHTSA staff. However, the standard error associated with extrapolation from this small subset of the NHTSA sample is likely to be extremely large.[13] Hence while these data are useful for providing insights into the differences between alternative HRQL approaches, they should not be used to draw conclusions about the impact of eliminating injuries to restrained children. Our analysis therefore should be considered hypothetical, and is not comparable to the results of NHTSA's 1999 child restraints analysis.

The injuries reported for these 22 cases are provided in Exhibit 4 below. The exhibit indicates the sample weight, or multiplier, that is applied to the values for each sample case to extrapolate to the national population. These weights vary because the sample was stratified by geographic area, police jurisdiction, and crash characteristics (NHTSA 2002). In addition, the exhibit indicates the status of the child immediately after the accident; i.e., whether he or she was killed, hospitalized, or transported for treatment then released. For each case, the exhibit also indicates the individual injuries incurred. The final column reports the Abbreviated Injury Scale (AIS) classification for the case, which represents the ranking of injury severity in terms of the

[11] Phaedra Corso and Xiangming Fang of the Centers for Disease Control (CDC) and Prevention conducted the expert assignment process for the EQ-5D and HUI-2 and worked with the researchers to acquire the QWB and FCI estimates. They also provided substantial assistance in developing the spreadsheets and drafting this case study.

[12] Data provided by Jim Simons, NHTSA, on December 7, 2004.

[13] Email from Nancy Bondy, NHTSA, to Lisa Robinson, January 18, 2005.

threat to life.[14] If more than one injury occurs, NHTSA categorizes the case under the highest AIS score; i.e., by the most life-threatening injury or Maximum AIS (MAIS). For the nonfatal multiple injury cases, we mark the injury NHTSA reports as the MAIS with an asterisk (*) in the injury description column.

Exhibit 4

CRASH-RELATED INJURIES TO RESTRAINED CHILDREN, AGES 0 - 6 (1999-2003)

Case Number	Weighting Factor	Injury Description	MAIS
1	***21.29***	***Non-fatal (hospitalized)*** a. Blunt, traumatic abdominal injury b. Vault skull fracture NFS*****	***2***
2	***54.34***	***Fatal*** a. Humerous fracture open/displaced/ comminuted b. Vault skull fracture comminuted	***3***
3	***18.81***	***Non-fatal (hospitalized)*** a. Cerebrum contusions - multiple NFS***** b. Cerebrum subarachnoid hemorrhage c. Vault skull fracture closed	***3***
4	***411.33***	***Non-fatal (hospitalized)*** a. Vault skull fracture NFS	***2***
5	***85.65***	***Fatal*** a. Head crush b. Lung contusion bilateral with or without hemo-/pneumothorax c. Rib cage fracture >3 ribs on one side and <4 ribs on either side d. Tibia fracture NFS	***6***
6	***3.41***	***Fatal*** a. Brain stem injury involving hemorrhage b. Vault skull fracture complex: (openb with loss of brain tissue) c. Cerebrum hematoma/hemorrhage NFS - extra axial d. Cerebrum hematoma/hemorrhage subdural NFS e. Subclavian vein laceration NFS f. Cerebrum subarachnoid hemorrhage g. Vault skull fracture comminuted	***5***
7	***124.43***	***Non-fatal (hospitalized)*** a. Cerebrum hematoma/hemorrhage epidural or extradural small bilateral***** b. Vault skull fracture complex: (openb with loss of brain tissue) c. Cerebrum hematoma/hemorrhage subdural small d. Unconscious post resuscitation on admission or initial observation at Scene (GCS <9) appropriate movements with painful stimulit no matter e. Cerebrum contusion multiple, at least one on each side small f. Cerebrum subarachnoid hemorrhage	***5***

[14] A score of "0" indicates that there were no injuries, whereas a score of "6" indicates that the injury was likely to be immediately fatal; intermediate scores of 1 through 5 indicate injuries of increasing severity. Cases with injuries categorized only as "0" or "1" are excluded from this analysis because they are not expected to noticeably impact the HRQL.

Exhibit 4 CRASH-RELATED INJURIES TO RESTRAINED CHILDREN, AGES 0 - 6 (1999-2003)			
Case Number	**Weighting Factor**	**Injury Description**	**MAIS**
8	***8.39***	***Non-fatal (transported and released)*** a. Lethargic, stuporous, obtunded post resuscitation on admission or initial observation at scene (GCS 9-14) NFS	***2***
9	***50.12***	***Non-fatal (hospitalized)*** a. Unconscious post resusciation on admission or initial observation at scene (GCS <9) inappropriate movements no matter length of unconsciousness***** b. Lung contusion bilateral with or without hemo-/pneumothorax c. Cervical spine cord contusion incomplete cord syndrome with dislocation d. Spleen laceration moderate (OIS Grade III)	***5***
10	***8.24***	***Non-fatal (transported and released)*** a. Tibia fracture shaft	***2***
11	***37.29***	***Non-fatal (hospitalized)*** a. Cerebrum contusion single small***** b. Orbit fracture open/displaced/comminuted c. Vault skull fracture closed	***3***
12	***75.56***	***Non-fatal (hospitalized)*** a. Awake post resuscitation on admission or initial observation at scene (GCS 15) prior unconsciousness, but length of time NFS	***2***
13	***16.03***	***Fatal*** a. Cerebrum hematoma/hemorrhage epidural or extradural small b. Cerebrum hematoma/hemorrhage subdural small c. Cerebrum brain swelling/edema NFS d. Cerebrum subarachnoid hemorrhage e. Base (basilar) skull fracture NFS f. Vault skull fracture comminuted g. Vault skull fracture closed	***4***
14	***145.31***	***Non-fatal (transported and released)*** a. Leg or ankle fracture NFS	***2***
15	***1***	***Non-fatal (hospitalized)*** a. Clavicle fracture (OIS Grade I or II)	***2***
16	***128.9***	***Non-fatal (hospitalized)*** a. Unconscious post resuscitation on admission or initial observation at scene (GCS <9) appropriate movements with painful stimulit no matter***** b. Cerebrum subarachnoid hemorrhage	***4***
17	***61.87***	***Non-fatal (transported and released)*** a. Clavicle fracture (OIS Grade I or II)	***2***
18	***85.65***	***Non-fatal (hospitalized)*** a. Base (basilar) skull fracture NFS***** b. Orbit fracture NFS	***3***
19	***1***	***Fatal*** a. Thoracic spine cord laceration incomplete cord syndrome with fracture b. Lung contusion bilateral with or without hemo-/pneumothorax c. Cerebrum hematoma/hemorrhage subdural NFS c. Jejunum-ileum laceration perforation (OIS Grade III) f. Cerebrum subarachnoid hemorrhage g. Cervical spine dislocation h. Humerus fracture NFS	***5***

Exhibit 4 CRASH-RELATED INJURIES TO RESTRAINED CHILDREN, AGES 0 - 6 (1999-2003)			
Case Number	**Weighting Factor**	**Injury Description**	**MAIS**
20	***7.75***	***Non-fatal (hospitalized)*** a. Femur fracture NFS***** b. Pelvis fracture NFS	***3***
21	***382.64***	***Non-fatal (hospitalized)*** a. Maxilla fracture NFS	***2***
22	***23.03***	***Non-fatal (hospitalized)*** a. Awake post resuscitation on admission or initial observation at scene (GCS 15) amnesia	***2***
Source: NASS-CDS data provided by Jim Simons, NHTSA, December 7, 2004. Notes: Injury descriptions are transferred verbatim from the NHTSA file without editing. NFS = Not further specified; GCS = Glasgow Coma Scale; OIS = Organ Injury Scale. ***** indicates MAIS injury for multiple injury cases that are not immediately fatal. Case 11 included two MAIS 2 injuries; we identify the first (injury 11a) as the MAIS because it generally results in larger HRQL decrements.			

Although the NHTSA data set indicates the actual age and gender of each child, none of the four approaches we used provided "with injury" HRQL estimates that differed by age or gender. For simplicity, we therefore assumed that the average age of the affected children was three years, and that they reflect the same gender distribution as the general population of the same age.[15] In reality, injuries to a newborn could have quite different effects than would the same injury for a three or six year old; these differences are not captured in our HRQL assessment.

Throughout this analysis, we treat these injuries as if they occur in a single year, rather than as spread out over a five year period. While we use discounting to reflect the time value of averting the future HRQL impacts associated with an injury that occurs in the current year, we do not discount to reflect the different years of incidence in the NASS-CDS database. This approach does not affect our comparisons across alternative HRQL indices (because they are all based on the same timing assumptions), but means that the total number of projected injuries (and estimates of resulting QALY losses) is higher than would be expected in a single year based on this data source. Hence these totals should not be compared to cost estimates calculated on an annual basis.

As indicated by the sample weights in Exhibit 4, these 22 sample cases represented 1,752 cases nationally over the five year period addressed. Five of the 22 sampled cases (representing 160 cases nationally) were immediately fatal. For the remaining 17 sampled cases (1,592 nationally), the NHTSA data only indicate the initial treatment (hospitalized or transported for treatment then released). Because the data do not indicate the overall duration of the injuries, we estimated the time period over which HRQL is affected as part of our case study analysis.

[15] As of the year 2000, the population age 0 to 5 was 51 percent male and 49 percent female (Census, 2004).

In addition, the NASS-CDS data do not address the life expectancy of these children with or without the injuries. Such data are, however, incorporated into NHTSA's ELS estimates (described in Section 2.0) based on detailed life tables, taking into account the probability of surviving to each age conditional on having survived to the previous age.[16] We followed a similar approach in this case study.

Our approach for assessing life expectancy with and without the injuries varied depending on the scenario. In the absence of the injuries, we assumed that all of the affected children would live an average life span, and used U.S. life tables for the year 2000 to estimate population average conditional survival rates for each year of age (CDC 2002) as illustrated in Appendix B. In the "with injury" case, we assumed that the injuries would not affect life expectancy in 15 of the 17 cases that are not immediately fatal. In the remaining two nonfatal cases (in combination representing 175 cases nationally), we expected that the injuries would ultimately reduce life expectancy; these include the traumatic brain injury in case number 7, and the spinal cord injury in case number 9, as listed in Exhibit 4 above.

For these two cases, we assessed the reduction in life expectancy based on data from recent studies.[17] For the brain injury, we used a study by Harrison-Felix et al. (2004) that tracks individuals with traumatic brain injuries in the U.S., age 16 and over, for up to 13 years. The researchers note that these injuries reduce overall life expectancy by seven years when compared to population averages, and that individuals with these injuries are, on average, two times more likely to die than comparable individuals of the same age in the general population. Harrison-Felix et al. indicate that this average may overstate increased mortality for those injured at an early age because the extent of increased mortality appears to rise with age at injury. However, we use this factor of two in the case study in the absence of estimates that are more specific to the age and type of injury for the affected sample case.

For the spinal injury, we relied on data from a study by Frankel et al. (1998) that tracks individuals with spinal cord injuries in Great Britain over a 50 year period. This study reports standardized mortality ratios (SMRs) for different injury severities, age groups, and time periods. (SMRs represent the ratio of deaths in the injured population to deaths in the general population.) Because changes in medical treatment over time are likely to affect these mortality rates, we use the data for the most recent injury years reported (1973 to 1990), for the injury category that appears most similar to the injury included in our dataset.[18] We also average death rates across age groups rather than using data only for those injured at the youngest age reported (0 to 30 years), because the death rates among this younger age group are so small that the resulting estimates are highly uncertain. For the injury group that appears most similar to the injury described in our dataset, this approach yields an average SMR of 4.36.[19]

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[16] Phone conversation between Ted Miller and Lisa Robinson, March 2, 2005.

[17] These studies were selected by Phaedra Corso and Xiangming Fang of CDC and NHTSA consultant Ted Miller. (Email from Xiangming Fang, CDC, to Lisa Robinson, February 8, 2005; phone conversation between Ted Miller and Lisa Robinson, March 4, 2005.)

[18] Injury group based on phone conversation between Ted Miller and Lisa Robinson, March 4, 2005.

[19] SMR selected based on review of Frankel et al. (1998) by Emmett Keeler and Dennis Fryback, April 13, 2005.

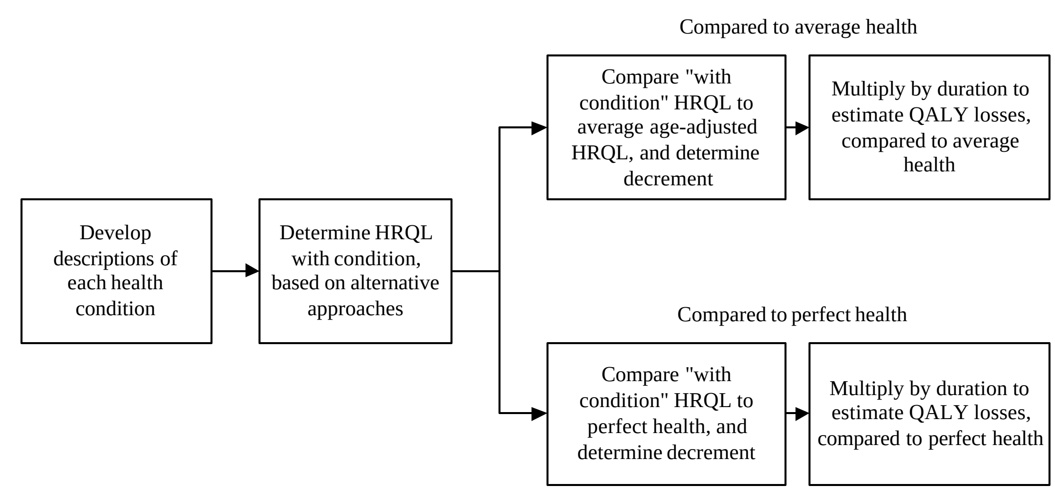
In summary, when calculating conditional survival rates, we adjust the age-specific general population mortality rates by a factor of 2.0 for the brain injury, and 4.36 for the spinal injury. An example of these calculations is provided in Appendix B.

3.2 EQ-5D and HUI-2 Analysis

For the EQ-5D and HUI-2 indices, we asked medical experts to identify the domain attributes that best characterize the impacts of each injury.[20,21] (These domain attributes reflect the different aspects of HRQL considered under each index, and are provided in Appendix A.) We asked the experts to assign the attributes to each injury individually, and in combination for the multiple injury cases, for the acute, rehabilitation, and long-term phases. We also asked the experts to estimate the duration of each phase. We then used the standard weights from the community surveys associated with each index to value these attributes, and compared the resulting HRQL with the injury to HRQL without the injury. Finally, we multiplied this decrement by its duration to determine the quality adjusted life year (QALY) losses attributable to the injury. This process is illustrated in Exhibit 5, and discussed in more detail below.

Exhibit 5

STEPS IN EQ-5D AND HUI-2 HRQL ASSESSMENT



[20] We relied on medical experts rather than patients due to the limited time and resources available for this analysis.
[21] We chose the HUI-2 rather than the HUI-3 because it was originally designed to assess HRQL for a group of pediatric cancer patients and the preference weights were based on a community survey of parents of minor children. The HUI-2 also includes consideration of fertility, which could be affected by permanent disability in some cases.

3.2.1 Expert Assignment

To identify experts to participate in this process, we worked through the case study team's professional contacts. We identified five experts, including a general pediatrician, an orthopedist, a pediatric trauma specialist, an emergency medicine doctor and medical officer, and a senior scientist.[22] The experts are listed in Exhibit 6 below.

Exhibit 6

MEDICAL EXPERTS

1. Carmen Brauer, M.D., Harvard School of Public Health
2. Kristine Campbell, M.D., Children's Hospital of Pittsburgh
3. Tim Davis, M.D., Centers for Disease Control and Prevention
4. Arlene Greenspan, Ph.D., Centers for Disease Control and Prevention
5. David Mooney, M.D., Children's Hospital, Boston

Members of the case study team contacted each expert by phone to describe the project and determine whether the expert was interested and available to participate. We then sent a package of materials to each expert that included a cover letter providing detailed instructions, sheets defining the attributes within each domain for each index, and tables containing the injury descriptions (from Exhibit 4) that included space to fill in the relevant attribute levels for each domain of each index. The experts were asked to assess the attributes for each injury individually, and for all the injuries combined, for each case. These attributes were identified separately for the acute, rehabilitation, and long term phases of the injury, as defined in the instructions to the experts. A copy of the cover letter sent to each expert appears below. The domain attributes are provided in Appendix A to this report.

Exhibit 7

INSTRUCTIONS SENT TO MEDICAL EXPERTS

December 18, 2004

Dear Expert Panelist,

Thank you for helping the National Center for Injury Prevention and Control develop a case study for the IOM's *Committee to Evaluate Measures of Health Benefits for Environmental, Health, and Safety Regulations*. We have been charged with converting a previous cost-effectiveness analysis (CEA) developed by the National Highway and Traffic Safety Administration (NHTSA) on a child restraint rule into a revised CEA that uses a different metric to value health.

As such, we are trying to value certain injuries impacted by the proposed rule. The first step in this process is categorizing each injury by attribute-level for the domains of health identified by the Health Utilities Index (HUI) and the EQ-5D. The HUI (defined in Table 1) and the EQ-5D (defined in Table 2) are classification systems designed to describe health status for a particular disease or injury. The HUI is comprised of 7 domains of health (sensation, mobility, emotion, cognition, self-care, pain, and fertility), with 3–5 attribute levels

[22] We selected these experts based largely on the extent and relevance of their medical expertise and their willingness to participate in this assessment on short notice. Ideally, we would have considered other criteria such as including a broader range of subspecialties and geographic locations, since these considerations are likely to affect the characteristics of the patients seen and conditions examined.

Exhibit 7

INSTRUCTIONS SENT TO MEDICAL EXPERTS

within each domain. The EQ-5D is comprised of 5 domains of health (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), with 3 attribute levels within each domain.

For this task, we are asking you, as our panel of experts in trauma, surgery, or pediatrics, to classify the injuries impacted by the NHTSA rule into the HUI domains and attributes of health, and then again into the EQ-5D domains and attributes of health. From your classifications, we will then be able to separately apply the HUI or EQ-5D quality of life weights (on a scale from 0 to 1, where 0 is death and 1 is perfect health) associated with each overall score. The weights for each classification were obtained from a community-based sample and have been tested for validity and reliability. This will allow us to assess the loss in health-related quality of life for each injury based on two different classification systems.

The injuries that we need classified are those preventable by the child restraint rule, that is, injuries affecting children aged 0–6 years. They are categorized by AIS—or, Abbreviated Injury Scale, which describes the severity of an injury on a scale of 0 (no threat to life) to 6 (virtually unsurvivable). For this exercise, we are asking you to only classify injuries that have AIS scores from 2–5.

Please use Tables 3 and 4 to classify the injuries based on the HUI.
Table 3 (Excel file: Table3_expert_panel.xls) is comprised of 3 worksheets. The first worksheet (labeled Acute QOL on the tab at the bottom of the page) should be used to assess the duration and quality of life classification for the acute phase of each injury listed in column 2. For example, the acute phase could include resuscitation, operative procedures, and intensive care.

The second worksheet in Table 3 (labeled Rehabilitation QOL on the tab at the bottom of the page) should be used to assess the duration and quality of life classification for the rehabilitation phase of each injury listed in column 2. For example, the rehabilitation phase could include the processes undertaken to restore as much of functional capacities (based on each domain of health) as possible.

The third worksheet in Table 3 (labeled Permanent QOL on the tab at the bottom of the page) should be used to assess the duration and quality of life classification for the long-term, or permanent phase, of each injury listed in column 2. The permanent phase is intended to evaluate the reintegration of injury patients into society, and how a disability might impact lifetime quality of life. If the injury does not result in permanent disability, then you would classify each domain of health at its most optimum attribute level.

Here is an example of how you might classify a femur fracture for all 3 phases (acute, rehabilitation, and permanent) of the injury:
Acute QOL

Duration: 1 month
Sensation: 1–Ability to see, hear, and speak normally for age
Mobility: 4–Requires the help of another person to walk or get around and requires mechanical equipment as well.
Emotion: 1–Generally happy and free from worry.
Cognition: 1–Learns and remembers school work normally for age.
Self-care: 3–Requires mechanical equipment to eat, bathe, dress, or use the toilet independently.
Pain: 3–Frequent pain. Discomfort relieved by oral medicines with occasional disruption of normal activities.
Fertility: 1–Able to have children with a fertile spouse.

Rehabilitation QOL

Duration: 5 months
Sensation: 1–Ability to see, hear, and speak normally for age
Mobility: 3–Requires mechanical equipment (such as canes, crutches, braces, or wheelchair) to walk or get around independently.
Emotion: 1–Generally happy and free from worry.
Cognition: 1–Learns and remembers school work normally for age.
Self-care: 2–Eats, bathes, dresses, or uses the toilet independently with difficulty
Pain: 2–Occasional pain. Discomfort relieved by oral medicines with occasional disruption of normal activities.
Fertility: 1–Able to have children with a fertile spouse.

Permanent QOL

Sensation: 1–Ability to see, hear, and speak normally for age
Mobility: 1–Able to walk, bend, lift, jump, and run normally for age.
Emotion: 1–Generally happy and free from worry.
Cognition: 1–Learns and remembers school work normally for age.
Self-care: 1–Eats, bathes, dresses, and uses the toilet normally for age.
Pain: 1–Free of pain and discomfort.
Fertility: 1–Able to have children with a fertile spouse.

Exhibit 7

INSTRUCTIONS SENT TO MEDICAL EXPERTS

For Table 4 (Excel file: Table4_expert_panel.xls), please assign the same type of information (i.e., for each phase of injury – acute, rehabilitation, and permanent) for 12 sample cases where a child restraint failure occurred, which resulted in multiple injuries that should be considered simultaneously.

Please use Tables 5 and 6 to classify the injuries based on the EQ -5D
Following the same approach for classifying injuries based on the HUI, please use Table 5 (Excel file: Table5_expert_panel.xls) to classify individual injuries based on the EQ-5D and Table 6 (Excel file: Table6_expert_panel.xls) to classify the 12 sample cases that resulted in multiple injuries based on the EQ-5D. As before, the first worksheet (labeled Acute QOL on the tab at the bottom of the page) in Table 5 and Table 6 should be used to assess the duration and quality of life classification for the acute phase of each injury listed in column 2. The second worksheet in Table 5 and Table 6 (labeled Rehabilitation QOL on the tab at the bottom of the page) should be used to assess the duration and quality of life classification for the rehabilitation phase of each injury listed in column 2. And the third worksheet in Table 5 and Table 6 (labeled Permanent QOL on the tab at the bottom of the page) should be used to assess the duration and quality of life classification for the long-term, or permanent phase, of each injury listed in column 2.

Once you have completed Worksheets 1–3 for Tables 3, 4, 5, and 6 in their entirety, please return them to Xiangming Fang at ddz6@cdc.gov or by fax at 770 488-1011 by **December 30, 2004**.

Again, thank you very much for your time and for contributing your invaluable expertise to the development of this case study. We expect to have a draft version of the case study completed by April 2005 and we will be glad to send you a copy at that time. If you have any questions about this project or about this specific task, please do not hesitate to contact me.

Sincerely,

Phaedra S. Corso, Ph.D.
Senior Health Economist
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention

The expert assignment was complex and time consuming. Each expert was asked to assess a total of 52 injury scenarios, including the 40 individual injuries listed in Exhibit 4 and the effects of all injuries combined for the 12 multiple injury cases. The injury scenarios included all cases that were potentially survivable (i.e., had a MAIS score of less than 6); the experts were not told whether the injuries resulted in fatality. (We adjusted the data to reflect fatalities after it was received from the experts.) The assessment covered three phases (acute, rehabilitation, and long term). The EQ-5D includes five domains and the HUI-2 includes seven, which means that each expert provided 1,872 separate attribute scores (52 injuries * 3 phases * 12 domains) as well as 104 duration estimates for the acute and rehabilitation stages (52 injuries * 2 phases). We did not request duration estimates for the long-term phase, which we assume covered the remainder of the individual's lifespan. The experts comments on this process are provided in Section 5.1.

Once we received the completed tables from the experts, we incorporated them into a spreadsheet model used to assess the HRQL impacts associated with the injuries, as discussed in more detail below.[23] In addition, the Committee commissioned a statistical analysis of the results

[23] These spreadsheets were initially developed by Phaedra Corso and Xiangming Fang of CDC, then refined and expanded by Committee consultant Robert Black. Jon Walker of NHTSA and Xiangming Fang and Bill Rhoads of CDC assisted us in checking the resulting calculations.

(Mason, 2005), the findings of which are summarized in Section 5 below. This analysis considered the variation in scores across experts, both within the context of each individual index (i.e., the EQ-5D or HUI-2) and across the two indices, as well as the extent to which the two indices led to consistent estimates of QALY losses.

The results of the expert assignment process allow us to compare the results under the two indices based on a common approach. However, the process we followed was more abbreviated than generally desirable in regulatory contexts, due to goals of this case study and the limited time and resources available to the Committee. For example, we did not work with the experts to ensure that they had a thorough or common understanding of the materials describing the injuries, the domain attributes, or the task itself. In addition, we did not attempt to resolve any inconsistencies either within the responses of an individual expert or across the responses from different experts, and in some cases used simplifying assumptions when an expert's response was incomplete.[24]

3.2.2 HRQL with Injury

The domain attributes identified through the expert judgment process discussed above provide descriptive information on the HRQL impacts of the health condition; for example, the extent to which the condition limits mobility. To determine the value of these attributes (i.e., individuals' relative ranking of these effects, or their willingness to trade-off perfect health against these impacts), we weighted the attributes using the standard estimates of community preferences associated with each index. This weighting process places the values on a scale anchored at zero and one, where zero corresponds to death and one corresponds to perfect or optimal health.[25] Specifically, for the EQ-5D, these weights were derived from a representative U.S. national sample, based on time trade-off research (Shaw et al., 2005).[26] For the HUI-2, the attributes were weighted using a multiattribute utility function based on a community sample of Canadian residents (Torrance et. al, 1996, Table 8, page 716).

As discussed below, we compared the resulting values to both age-adjusted average health and perfect health. For perfect health, the comparison is straightforward; we simply use the estimates from the experts for each injury, valued using the approaches noted above. For the comparison to average health, the calculation is more complex. Many researchers believe that individuals responding to these sorts of questionnaires implicitly compare the condition to perfect health, rather than to average health for an individual of a given age. The case study team

[24] One expert did not provide estimates of duration; we do not include this expert's responses in our results. (We expected that duration would be correlated somewhat with the domain attributes selected, assuming that the experts were reporting HRQL averaged over each phase.) Some experts also did not assess fertility impacts under the HUI, and we conservatively assumed that the attribute values would be "1" (i.e., no affect on fertility). Also, we used the same duration estimates in both the EQ-5D and HUI-2 analyses in those cases where an expert reported different durations for the same health effect under the different indices.
[25] Values less than zero are possible in cases where the multiple attributes are assigned at the most impaired level.
[26] Dr. William Lawrence, Agency for Healthcare Research and Quality (AHRQ), provided the spreadsheet used to apply these weights.

discussed several approaches for anchoring the expert responses in average age-adjusted health; e.g., by providing information on the domain attributes likely to be associated with typical health at selected years of age. However, we determined that these approaches were too complex to implement in the sort of simple expert judgment process used for this case study.

Instead, we used a proportional adjustment when comparing average population health to "with injury" HRQL.[27] (A different approach was used for the QWB patient data, as discussed in Section 3.3 below.) More specifically, when comparing the crash-related injuries to average health, we first calculated the percentage of perfect health represented by the result for the injury. For example, if "with injury" HRQL is 0.8, we assume that it is 80 percent of perfect health (which is valued at 1.0). We then multiply this percentage by the mean population HRQL for the same age, then use the adjusted result in our analysis. For example, if the "initial" HRQL score for a particular injury is 0.8 and the average population HRQL is 0.9 for the same age, the "adjusted" HRQL score for that injury (in comparison to average health) would be 0.72 (0.8 * 0.9). Under our sensitivity analysis, where the comparison is to perfect health rather than to average age-adjusted health, we simply use the initial value of 0.8 to represent HRQL with the injury. This is equivalent to assuming that each expert was comparing the injury to perfect health, and, if they had instead compared to age-adjusted average health, the estimate of HRQL with the injury would reflect the same proportionate reduction. While this is a somewhat imperfect adjustment, it was the most pragmatic option in the context of this case study.

3.2.3 HRQL Without Injury

As noted above, in our base case analysis (i.e., our best estimates), we compare the HRQL values for these injuries to the average HRQL for individuals of the same age. In sensitivity analysis, we also compare the "with injury" HRQL estimates to a value of 1.0. This latter comparison is equivalent to assuming that, in the absence of the crash-related injuries, the affected individuals would be in perfect health throughout their lifetimes.

The age-adjusted estimates of average population health use the same community weights as discussed above for the "with injury" assessment, and are based on unpublished analyses from the following sources. (We include the QWB in the below list so that the results for average population health can be easily compared to the results for the other indices; detailed information on our approach for applying the QWB is provided later in Section 3.3.)[28]

- EQ-5D: Dr. William Lawrence, Agency for Healthcare Research and Quality (AHRQ), provided estimates of average HRQL by age and gender, based on 2001 data from the Medical Expenditure Panel Survey (MEPS). These data represent roughly 19,000 – 20,000 surveys provided by 22,500 eligible respondents. Estimates were provided by gender and age, divided into 10-year age groups beginning with ages 20-29 and ending at ages 80-89.[29]

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[27] This approach is based on a suggestion from Judy Wagner and discussions with Dennis Fryback, Alan Garber, Marthe Gold, and Emmett Keeler.
[28] Updated values for the EQ-5D and QWB are available in Hamner et al., forthcoming.
[29] Email from William Lawrence to Wilhelmine Miller, November 9, 2004.

- HUI-2: Average HRQL estimates by age and sex were provided for the HUI-3 by Barbara Altman, National Center for Health Statistics (NCHS), based on data from the Joint U.S.-Canada Survey of Health, 2002-2003, representing a U.S. sample of roughly 5,000 individuals. Estimates were provided by gender and age, divided into 10-year age groups from ages 20-29 to ages 70-79, as well as the 80-85 age group.[30] We use these HUI-3 results for the HUI-2 because the researchers expect that general population averages will be similar across the two HUI versions.[31]

- QWB: John Anderson, University of California – San Diego, provided estimates of average HRQL by age and gender, divided into 10-year age groups beginning with ages 20-29 and ending at ages 80-89, based on U.S. National Health Interview Survey data for the year 2001.[32]

In Exhibit 8, we provide the estimates of "without injury" health used in this analysis for selected ages, for males and females combined. (Again, we include the QWB as well as the EQ-5D and HUI for ease of comparison.) We weighted the gender-specific values for each index by the proportion of males and females of each age in the U.S. general population as of the year 2000, to determine population averages (Census 2004). The exhibit reports the values for only a few ages for illustrative purposes; the case study calculations use the full range of age-specific estimates provided. The source documents provide information on the confidence intervals associated with the gender-specific estimates; information on the uncertainty associated with each generic instrument and its set of community weights is provided in the documentation for each index.

[30] Email from Barbara Altman to Wilhelmine Miller, January 7, 2004.
[31] Email exchange between David Feeny and Wilhelmine Miller, January 11, 2005.
[32] Email from Janel Hanmer to Lisa Robinson, April 21, 2005.

Exhibit 8 **HRQL IN THE ABSENCE OF CRASH-RELATED INJURIES**				
	Age 20	**Age 40**	**Age 60**	**Age 80**
Mean Population Index Value (base case)				
EQ-5D	0.921	0.875	0.825	0.746
HUI-2	0.908	0.880	0.822	0.694
QWB	0.822	0.800	0.737	0.651
Perfect Health (sensitivity analysis)				
All indices	1.0	1.0	1.0	1.0
Notes: Estimates are preliminary; see Hamner et al. (forthcoming) for updated EQ-5D and QWB estimates. See sources below for information on the confidence intervals related to each of these estimates. Additional uncertainty related to the generic instruments and valuation surveys is discussed in the documents describing their development. Sources: EQ-5D: Unpublished analysis by William Lawrence, November 9, 2004 HUI-2: Unpublished HUI-3 analysis by Barbara Altman, January 7, 2005. QWB: Unpublished analysis by John Anderson, April 21, 2005.				

As is evident from the exhibit, the estimates of average population health vary across the indices. This variation reflects several factors, including the differences in: (1) the data sources used to assess health attributes; (2) the sources of community weights used to value these attributes; and (3) the indices themselves. Which index leads to higher estimates of average HRQL varies by age, although the EQ-5D values are often greater than the HUI estimates (especially for the youngest and oldest age groups illustrated) and the QWB generally results in the lowest values. As expected, average HRQL declines with age under all three indices.

These analyses are missing average population health estimates for the very young and the very old. We assumed that average health could be approximated by perfect health (1.0) for ages 0 to 9, and that the value from age 10 to 19 would be the mid-point between perfect health and the values estimated for ages 20 to 29. For elderly individuals, we assumed that HRQL would remain constant throughout their remaining life span at the value reported for the eldest age group.

In this case study, using these average health assumptions for children means that the HRQL impacts will be the same in the years immediately following the injury regardless of whether the comparison is to perfect or average health. The acute and rehabilitation phases of the injuries generally last less than a year, which means that the comparison is to a value of 1.0 under both scenarios for all cases (we assume an average age at incidence of 3). The values will differ under the average and perfect health scenarios, however, for those injuries with long term impacts, because average health declines with age.

3.3 QWB and FCI Analyses

For the remaining two indices, we relied on existing research rather than the expert judgment process discussed above. This section provides background information on these other approaches, as well as references for more detailed information on the underlying research. For both indices, we rely on adult data due to the lack of values for children; the implications of this approach are discussed in Section 5.0.

3.3.1 Holbrook et al. QWB Values

Our QWB analysis is based on data from the Trauma Recovery Project provided by Troy Holbrook of the University of California, San Diego. The researchers involved in this project tracked 1,408 trauma patients from four San Diego hospitals between December 1, 1993 and September 1, 1996 (Holbrook et al., 1999). The patients enrolled in the study were age 18 or older, had Glasgow Coma Scores (GCSs) on admission of 12 or greater, and completed hospital stays lasting 24 hours or more.[33] The researchers evaluated patient status prior to discharge as well as at six, 12, and 18 months after discharge, administering the QWB to assess HRQL impacts and a variety of other instruments to assess functional impacts and psychological effects. (See Appendix B for the QWB domains and attribute descriptions.) The results were weighted using the QWB scoring algorithm reported in Kaplan and Anderson (1988), which was based on a general population valuation survey of adults in San Diego, California conducted in the late 1970s.

For this case study, Holbrook provided QWB values organized by body region and AIS score for the 821 adults for whom AIS data were available.[34] The data included values for each of the four time periods at which patient status was assessed, including mean, standard deviation, minimum, and maximum values. In addition, the number of patients surveyed were reported for each variable. Holbrook also provided data for 273 adolescents that included six, 12, 18, and 24 month follow-up scores.[35] However, because the adolescent sample size was quite small for many of the body region/AIS combinations considered (ranging from 0 to 36 cases), we used the adult data in our analysis of lifetime impacts, and then compared it to the adolescent data for each body region/AIS combination considered.

The case study team matched the adult QWB data with the body regions and AIS scores for each individual injury for the 22 cases in our data set.[36] We then used the score for the injury identified as the MAIS to assess the HRQL impacts. Data are not available on the extent to which surveyed individuals had co-occurring injuries (in addition to the MAIS) similar to those incurred in the multiple injury cases in our sample. As under the other indices, in our

[33] In contrast, four of the 17 nonfatal sample in our database were not hospitalized, and two had GCS scores less than nine (lower GCS scores indicate worse injuries).
[34] Email from Troy Holbrook to Phaedra Corso, January 21, 2005.
[35] Email from Troy Holbrook to Phaedra Corso, January 18, 2005.
[36] Because the NASS-CDS dataset indicates the AIS for each injury but provides incomplete information on body region in some cases, Carmen Brauer assisted Phaedra Corso and Xiangming Fang in determining the appropriate body region for each injury.

spreadsheets we assigned "with injury" values of zero for all of the cases identified as immediately fatal.

We applied the Holbrook pre-discharge weights to the hospitalization period for those nonfatal cases that were identified as hospitalized in the NASS-CDS dataset (we did not apply the pre-discharge values to cases that were transported then released). We then applied the Holbrook six month values from discharge (or injury date, if not hospitalized) to six months, the 12 month values from six to 12 months, and the 18 month values from 12 months through the remaining lifespan. In the QWB analysis, we used the same approach to assess life expectancy with and without injury as used in the EQ-5D and HUI-2 analyses, discussed in previously in Section 3.1 and illustrated in Appendix B.

For those cases that were hospitalized, we estimated the hospital length of stay based on data for children from the Kid Inpatient Database from the Healthcare Cost and Utilization project (see:.http://www.hcup-us.ahrq.gov.HCUPnet.asp).[37] These data are organized by age group and principal diagnoses, reflecting the nature of the injury and body region affected. For the injuries identified in the NASS-CDS dataset, the average length of stay ranged from roughly two to18 days, with a mean value of about five days.

As with the other indices, we compared the QWB results both to perfect health (a value of 1.0) and to average age-adjusted health to determine the impact of the injury. The QWB population averages for each age were presented earlier in Exhibit 8, and in general result in lower values than the estimates for the EQ-5D and HUI.

Comparing the "with injury" values to these estimates of age-adjusted average population health is complicated because the Holbrook QWB data reflect all aspects of a patient's health, not only the impacts of the injury, and address adults. This differs from EQ-5D and HUI-2 assessment, where we asked the experts to consider only the attributes associated with each injury for children age 0 to 6. The patients surveyed in the QWB analysis are likely to be in poorer health on average than the children addressed in this case study due to age-related factors apart from the effects of the injury of concern.

It was not possible to fully adjust for the differences between the adult population surveyed in the Holbrook QWB analysis and the injuries to children considered in this case study. However, we followed a two step process in applying these estimates to at least partially account for these differences. First, we compared the QWB results for each injury and time period to the estimate of average health for a 36 year old (i.e., the average age of the QWB sample), and determined the "with injury" HRQL as a percentage of the average HRQL for that age. We then applied this percentage reduction to the HRQL estimates for all ages as relevant.[38]

For example, if the QWB results for the injury were 0.7 and the average health for a 36 year old was 0.8, we assumed that HRQL with injury was 87.5 percent of average health

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[37] The length of stay research was conducted by Wilhelmine Miller and Ryan Palugod, February 10, 2005. Although NHTSA also collects data on the length of hospital stays, this information was not included in the dataset used for this analysis.
[38] This approach was suggested by Emmett Keeler.

(0.7/0.8=0.875) regardless of the age at incidence. This approach is equivalent to assuming that the proportionate reduction in HRQL is the same for every age, and differs from the approach used for the EQ-5D and HUI-2, where we assumed the experts' comparisons were to perfect health (a value of 1.0). We did not make a similar adjustment to the Holbrook QWB results when comparing to perfect health; the decrement would be the same in each year when compared to a constant value of 1.0. Thus, in this latter comparison, we are overstating the impacts of the injury both because the values reflect HRQL decrements other than those related to the injury itself and because the affected individuals are not likely to be in otherwise perfect health throughout their lifetimes.

3.3.2 MacKenzie et al. FCI Values

For the FCI, we relied on on-going work by Ellen MacKenzie of Johns Hopkins University and others (MacKenzie and Segui-Gomez, 2004). This index is being developed to provide a preference-based HRQL measure that is linked to the AIS scale used in NHTSA analyses (see Section 2.0). However, the FCI is intended to address only certain aspects of HRQL, focusing on the impacts of traumatic injuries on functional status. This index has not yet been widely validated or used.

The FCI researchers used a modified Delphi process to work with 12 experts to assign descriptive levels to each injury identified under the AIS system; the domains and descriptive levels are provided in Appendix A.[39] The resulting estimates reflect the impact of individual injuries; FCI estimates have not been developed for population average age-adjusted health. The experts assumed that the affected individuals were between 18 and 54 years of age, and were told to assign scores that reflected the level of impairment likely to be experienced by 80 percent of the affected individuals. These scores indicate the individuals' probable status at 12 months post-injury, and are expected to reflect the long term limitations on functioning (if any) associated with the injury. The domain attributes were weighted based on the preferences of a small, structured U.S. sample of 114 individuals, including clinical experts, blue and white collar workers, college students, and persons with functional limitations (Mackenzie et al. 1996). This weighting used a visual analog scale, which the researchers then converted to standard gamble equivalents (Segui-Gomez, undated).

For this case study, MacKenzie provided predicted 12-month FCI scores based on the AIS descriptions for each injury contained in our database.[40] For most of the nonfatal injuries, the scores indicated that the individual would have returned to normal functioning at the 12 month mark; values indicating functional limitations were provided for only five of the 17 sampled cases with nonfatal injuries. MacKenzie reported FCI values for each individual injury in each of these five cases. In addition, for the multiple injury cases, MacKenzie provided "all injury" values that reflect the worst score in each domain across all of the injuries incurred. We use these all-injury values in our comparisons for the multiple injury cases in our dataset.

[39] Email from Ellen MacKenzie to Wilhelmine Miller and Phaedra Corso, March 16, 2005.

[40] Emails from Ellen MacKenzie to Wilhelmine Miller and Phaedra Corso, February 2, 2005 and March 16, 2005.

Because this index is still under development and only 12-month values were available, we did not assess lifetime impacts using the FCI. Instead, we compared the 12-month FCI values to the values for the same time under the EQ-5D, HUI-2, and QWB. For each index, we used values that reflect comparison to perfect health (a value of 1.0), because average population values are not available for the FCI.

SECTION 4.0: RESULTS OF CASE STUDY ANALYSIS

In the following sections, we first report the estimates of HRQL associated with each injury that result when we use the expert assignment process for the EQ-5D and HUI-2 and the results of previous research for the QWB and FCI. We then add in consideration of the duration of the impacts, and provide the estimates of total QALY losses under the EQ-5D, HUI-2 and QWB. We do not assess QALY losses under the FCI because HRQL results are available only for a single point in time.

4.1 EQ-5D and HUI-2 HRQL Results

As discussed in Section 3.2, we asked medical experts to determine the duration and attribute descriptions that best match the likely impacts of each of the injuries assessed in this case study under two generic HRQL indices, the EQ-5D and HUI-2. Detailed results were provided by four of these experts; the fifth provided incomplete data and hence is not included in our calculations.[41]

Below, we summarize the HRQL estimates for each case under each index considered by the four experts. We first calculated the results for each individual expert, then determined the median HRQL across the four experts (we report median rather than mean values due to the small number of experts involved).[42] As discussed above, these estimates reflect the attribute levels weighted to reflect community preferences, on a scale where 1.0 corresponds to perfect health and zero corresponds to death. Hence the "with injury" weighted HRQL value for fatal cases is "zero" under each index. We assume that these estimates implicitly reflect comparison to perfect health; the effect of instead comparing to average age-adjusted health is discussed later in this section. Exhibit 10 summarizes the results for the EQ-5D; the following exhibit addresses the HUI-2.

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[41]One expert felt unqualified to assess duration, so we excluded this experts' scores rather than using a default assumption due to concerns about the correlation between domain scores and duration estimates. For the remaining experts, missing attribute values were conservatively scored as a "1" (no decrement), which may lead us to understate the impact of the injuries in some cases.

[42] See Appendix C for analysis of the variation across experts.

Exhibit 10 HRQL WITH INJURY: EQ-5D (median, compared to perfect health)					
Case Number	**Number of Injuries**	**MAIS**	**Quality of Life with Injury**		
			Acute Phase	**Rehabilitation Phase**	**Long-Term**
1	2	2	0.262	0.788	1.000
2	2	3 (fatal)	0.000	0.000	0.000
3	3	3	0.278	0.597	0.800
4	1	2	0.792	0.822	1.000
5	4	6 (fatal)	0.000	0.000	0.000
6	7	5 (fatal)	0.000	0.000	0.000
7	6	5	0.004	0.331	0.316
8	1	2	0.464	0.796	0.922
9	4	5	(0.109)	0.272	0.387
10	1	2	0.598	0.733	1.000
11	3	3	0.597	0.643	0.835
12	1	2	1.000	1.000	1.000
13	7	4 (fatal)	0.000	0.000	0.000
14	1	2	0.598	0.733	1.000
15	1	2	0.748	0.788	1.000
16	2	4	0.039	0.505	0.775
17	1	2	0.748	0.788	1.000
18	2	3	0.638	0.792	1.000
19	7	5 (fatal)	0.000	0.000	0.000
20	2	3	0.084	0.357	1.000
21	1	2	0.782	0.798	1.000
22	1	2	1.000	1.000	1.000

Notes:
Values reflect HRQL with the injury; not the decrement from normal health.
See Exhibit 4 for detailed information on the injuries incurred in each case.
For fatal cases, "with injury" HRQL is zero.
Values in parenthesis are negative, reflecting the weighted value of attributes assessed at their lowest levels (e.g., "severe" limitations).

The EQ-5D results in the exhibit show many of the expected trends. The estimates indicate that HRQL of the injured individuals generally improves over time; i.e., in most cases the HRQL in the rehabilitation phase is generally better than in the acute phase, and the long-term phase shows additional improvements. Two of the injuries are so minor that HRQL is unaffected under this index, as shown by the values of "1.0" for cases 12 and 22. (As indicated in Appendix B, the EQ-5D provides three choices within each domain, representing no, moderate, or severe limitations.) For 11 of the 17 nonfatal injuries, the HRQL impacts are short-lived, with a return to normal health in the final phase, as designated by the values of 1.0 in the long-term column.

Exhibit 11

HRQL WITH INJURY: HUI-2
(median, compared to perfect health)

Case Number	Number of Injuries	MAIS	Quality of Life with Injury		
			Acute Phase	Rehabilitation Phase	Long-Term
1	2	2	0.298	0.714	1.000
2	2	3 (fatal)	0.000	0.000	0.000
3	3	3	0.187	0.551	0.912
4	1	2	0.800	0.905	1.000
5	4	6 (fatal)	0.000	0.000	0.000
6	7	5 (fatal)	0.000	0.000	0.000
7	6	5	0.029	0.339	0.392
8	1	2	0.307	0.765	0.938
9	4	5	0.008	0.385	0.415
10	1	2	0.708	0.752	1.000
11	3	3	0.432	0.799	0.958
12	1	2	0.732	1.000	1.000
13	7	4 (fatal)	0.000	0.000	0.000
14	1	2	0.708	0.832	1.000
15	1	2	0.788	0.922	1.000
16	2	4	0.129	0.516	0.822
17	1	2	0.788	0.922	1.000
18	2	3	0.635	0.968	1.000
19	7	5 (fatal)	0.000	0.000	0.000
20	2	3	0.266	0.495	1.000
21	1	2	0.814	0.953	1.000
22	1	2	0.732	1.000	1.000

Notes:
Values reflect HRQL with the injury; not the decrement from normal health.
See Exhibit 4 for detailed information on the injuries incurred in each case.
For fatal cases, “with injury” HRQL is zero.
Values in parenthesis are negative, reflecting the weighted value of attributes assessed at their lowest levels (e.g., “severe” limitations).

Application of the HUI-2 results in different values than the EQ-5D, but shows many of the same patterns. The estimates indicate that the HRQL of the injured individuals consistently improves over time. Under the HUI (which has more domains and attribute values than the EQ-5D), all of the nonfatal injuries have some affect on HRQL in the acute phase. For 11 of the 17 nonfatal injury cases, the HRQL impacts are short-lived with an eventual return to normal health.[43]

4.2 QWB HRQL Results

As discussed in Section 3.3, the QWB analysis differs from the EQ-5D and HUI-2 analyses in several important respects. We transfer HRQL estimates from research conducted by Troy Holbrook on adult injuries, reported pre-discharge and for follow-ups at six, 12, and 18 months. These estimates reflect all aspects of health (not just the results of the injury), and were reported by body region affected and AIS score rather than for individual injuries. We matched these results with the body regions and AIS scores for each injury listed in Exhibit 4. For multiple injury cases, we used the QWB results for the injury identified as most life-threatening; i.e., the injury identified as the MAIS.[44] Exhibit 12 provides the HRQL scores for each time period for each case in our database.

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[43] The six cases identified as lacking long-term effects are identical in the median results across the two indices. However, the assessments by the individual experts varied; they identified from three to seven of the cases as having long-term effects.

[44] Because the Holbrook data address trauma from a variety of causes, not just car crash injuries to restrained children, the co-occurring injuries are likely to differ from those included in our dataset.

Exhibit 12 HRQL WITH INJURY: QWB (median, compared to perfect health)						
Case Number	**Number of Injuries**	**MAIS**	**Quality of Life with Injury**			
			At Discharge	**6 months**	**12 months**	**18 months**
1	2	2	0.384	0.641	0.675	0.686
2	2	3 (fatal)	0.000	0.000	0.000	0.000
3	3	3	0.392	0.620	0.673	0.677
4	1	2	0.384	0.641	0.675	0.686
5	4	6 (fatal)	0.000	0.000	0.000	0.000
6	7	5 (fatal)	0.000	0.000	0.000	0.000
7	6	5	0.384	0.670	0.721	0.712
8	1	2	N/A	0.641	0.675	0.686
9	4	5	0.384	0.671	0.721	0.712
10	1	2	N/A	0.621	0.667	0.673
11	3	3	0.392	0.620	0.673	0.677
12	1	2	0.384	0.641	0.675	0.686
13	7	4 (fatal)	0.000	0.000	0.000	0.000
14	1	2	N/A	0.621	0.667	0.673
15	1	2	0.404	0.657	0.722	0.700
16	2	4	0.402	0.627	0.657	0.699
17	1	2	N/A	0.657	0.722	0.700
18	2	3	0.392	0.620	0.673	0.677
19	7	5 (fatal)	0.000	0.000	0.000	0.000
20	2	3	0.389	0.591	0.630	0.651
21	1	2	0.391	0.628	0.687	0.714
22	1	2	0.384	0.641	0.675	0.686

Notes:
N/A indicates that the child was not hospitalized.
Values are for adults, and reflect all aspects of HRQL, not only those associated with the injury.
Values reflect HRQL with the injury; not the decrement from normal health.
See Exhibit 4 for detailed information on the injuries incurred in each case.
For fatal cases, “with injury” HRQL is zero.

Inspection of these estimates suggests that they generally appear more uniform than the estimates for the other indices (see Exhibits 10 and 11).[45] However, it is difficult to separate the variation that can be attributed to the use of a different index from the variation that results from

[45] In the EQ-5D and HUI-2 expert assignments, in combination the acute and rehabilitation periods generally last less than a year (with an average of about two months). However, the duration of the acute and rehabilitation phases varied across injuries and across experts.

the use of different data. These differences include the effects of injury severity, the use of broad classifications, and the inclusion of unrelated co-morbidities.

- The Holbrook QWB data considers hospitalized patients with relatively high GCS scores, whereas the NASS-CDS data include a few cases that were not hospitalized as well as a few cases with more severe injuries (i.e., lower GCS scores).

- The QWB data also use more aggregate categories (i.e., classification by body part and AIS rather than individual injuries) than provided in the expert assignment of the EQ-5D and HUI-2 attributes.

- The QWB estimates address impacts on adults rather than children, and include aspects of health that are unrelated to the injury (e.g., related to aging). In addition, the QWB data are for patients with injuries from a variety of causes (not only those associated with vehicle crashes), and may include co-occurring injuries that follow a different pattern than in the crash-related cases included in our dataset.

Over time, the exhibit indicates that HRQL estimates improve as expected as patients recover from the injuries.

For the QWB, Holbrook provided adolescent as well as adult values. We used the adult values in the above analysis because of the small size of the adolescent sample. Below, we compare the adolescent and adult values for those body regions/AIS categories included in our database for nonfatal MAIS injuries. As suggested by the exhibit, most of the MAIS injuries for restrained children are classified as head-neck injuries; a few affect other body regions. We include the standard deviations and sample sizes for each estimate in this exhibit.

Exhibit 13

COMPARISON OF QWB ADULT AND ADOLESCENT VALUES FOR NONFATAL MAIS INJURIES

Body Region	AIS	Time period	Adult Values			Adolescent Values		
			Sample Size	Mean	Standard Deviation	Sample Size	Mean	Standard Deviation
Head/Neck	2	pre-discharge	174	0.384	0.043	N/A	N/A	N/A
		6 months	144	0.641	0.127	36	0.736	0.090
		12 months	141	0.675	0.137	35	0.742	0.078
		18 months	131	0.686	0.121	35	0.746	0.094
		24 months	N/A	N/A	N/A	31	0.754	0.095
	3	pre-discharge	70	0.392	0.029	N/A	N/A	N/A
		6 months	59	0.620	0.111	36	0.735	0.094
		12 months	57	0.672	0.120	33	0.770	0.113
		18 months	47	0.677	0.130	35	0.782	0.115
		24 months	N/A	N/A	N/A	35	0.775	0.120
	5	pre-discharge	5	0.384	0.012	N/A	N/A	N/A
		6 months	2	0.671	0.043	3	0.680	0.078
		12 months	3	0.721	0.068	3	0.721	0.066
		18 months	3	0.712	0.045	3	0.697	0.038
		24 months	N/A	N/A	N/A	3	0.671	0.047
Face	2	pre-discharge	44	0.390	0.047	N/A	N/A	N/A
		6 months	34	0.628	0.108	18	0.700	0.075
		12 months	38	0.687	0.109	16	0.743	0.089
		18 months	34	0.714	0.120	17	0.744	0.057
		24 months	N/A	N/A	N/A	16	0.733	0.085
Chest	2	pre-discharge	48	0.404	0.036	N/A	N/A	N/A
		6 months	39	0.657	0.118	7	0.734	0.063
		12 months	35	0.722	0.121	8	0.723	0.068
		18 months	36	0.700	0.109	8	0.734	0.076
		24 months	N/A	N/A	N/A	7	0.757	0.046
Extremities/ Pelvis	2	pre-discharge	161	0.394	0.032	N/A	N/A	N/A
		6 months	131	0.621	0.107	40	0.737	0.114
		12 months	133	0.667	0.121	39	0.755	0.096
		18 months	128	0.673	0.122	39	0.758	0.081
		24 months	N/A	N/A	N/A	41	0.768	0.104
	3	pre-discharge	179	0.389	0.028	N/A	N/A	N/A
		6 months	160	0.591	0.113	37	0.688	0.093
		12 months	148	0.630	0.132	31	0.769	0.114
		18 months	127	0.651	0.121	35	0.777	0.095
		24 months	N/A	N/A	N/A	29	0.765	0.088

Sources:
Data provided by Troy Holbrook on January 18 and 21, 2005.
Note:
N/A indicates time periods for which data were not reported in the respective data set.

The adult values show a lower "with injury" HRQL, as expected given than the QWB assessment addresses all aspects of health; adolescents are likely to be in better health on average. These data support the conclusion that applying the adult QWB values directly to younger persons will overstate the HRQL decrements. As discussed earlier, we implement a simple adjustment in our comparisons of the injury values to average health to at least partially address these effects.

4.3 FCI HRQL Results

The FCI differs from the other indices in that it only provides values for 12 months after injury, focuses on functional capacity rather than on a more comprehensive measure of HRQL, and is still in the initial stages of development. For this case study, we compare the 12 month values under the FCI to the 12 month values for the other three indices, rather than using it to assess lifetime effects. We focus on the five injuries that are identified in the FCI dataset as affecting functioning at the 12 month mark.[46] Under the FCI, the remaining 12 nonfatal injury cases are expected to fully recover to normal functioning by the one year mark.

Exhibit 14

COMPARISON OF 12 MONTH VALUES ACROSS INDICES

IOM Case Number	MAIS	Quality of Life with Injury at 12 Months			
		FCI	**EQ-5D**	**HUI-2**	**QWB**
3	3	0.863	0.800	0.912	0.673
7	5	0.662	0.316	0.392	0.721
9	5	0.597	0.387	0.415	0.721
10	2	0.915	1.000	1.000	0.667
16	4	0.677	0.775	0.822	0.657

Source:
FCI data from Ellen MacKenzie provided on February 2 and March 16, 2005.
See text for sources for other indices.
Notes:
Indices reflect the impact of the injuries only, except for the QWB which includes other factors that affect HRQL.
Includes only those nonfatal cases with HRQL estimates less than 1.0 at 12 months according to the FCI data.
Values reflect HRQL with the injury (compared to perfect health); not the decrement.
See Exhibit 4 for detailed information on the injuries incurred in each case.

The estimates vary in the extent to which they appear consistent across indices. This variation may reflect a number of differences between the indices themselves as well as the data sources and methods used in the analyses. The FCI attributes were determined from a more extensive expert elicitation process than either the EQ-5D or HUI-2 attributes, and the QWB is based on patient surveys. The FCI and QWB attributes are based on adult injuries, while the EQ-5D and HUI-2 reflect injuries to children. The preference weights used for the FCI are also based on a smaller community sample than the weights for the other indices, and in all cases the weights are based on injuries to adults rather than children. Finally, the lower QWB values result because the assessment considered all HRQL limitations for the adults surveyed, not just the effects of the injury.

[46] The median results from the expert assignment suggest that six cases would have long-term effects; the five in Exhibit 18 plus case number 8.

4.4 EQ-5D, HUI-2, and QWB Estimates of QALY Losses

The next step in the analysis involves estimating the losses in HRQL and longevity that could be avoided over time if all of these injuries were averted by a hypothetical regulation. This step includes: (1) determining the decrement from "without injury" HRQL for each phase of each injury; (2) multiplying the decrement by duration and summing across the phases for each injury, to estimate the QALY losses; and (3) multiplying these per case values by the sample weights from Exhibit 4 to estimate total losses nationally.

Exhibit 15 provides the estimates of total QALY losses for our base case scenario, where we assume that HRQL in the absence of the injury would equal the population average for individuals in the same age group, and apply both seven and three percent discount rates in determining the present value of future year impacts.[47] As discussed earlier, we assume that all of the injuries occur in a single year, and use discounting only to adjust the future year impacts for those injuries with long term effects. We use average population HRQL in developing our base case estimates because it provides the most realistic assessment of the impacts of the injuries over time.[48] We repeat the weighting factors from Exhibit 4; in the exhibit below, the results for each case have been multiplied by these sample weights to estimate the total national impacts of these injuries.

[47] The use of these discount rates reflects current OMB guidance for regulatory analysis (OMB 2003).

[48] These comparisons involve different adjustments. As discussed in Section 3.2, for the expert assignment of the EQ-5D and HUI-2 attributes, we assume that the assignment implicitly involved comparison to perfect health (a value of 1.0), and that the decrement from average health would represent the same proportional reduction. As discussed in Section 3.3, for the QWB, we calculate the decrement from average health for the average age of the patient sample, then apply the same proportional adjustment across all ages.

Exhibit 15 TOTAL QALY LOSSES COMPARED TO AVERAGE AGE-ADJUSTED HEALTH								
			Case Study Expert Assignment (median)				Holbrook QWB Patient Data (median)	
			EQ-5D		HUI-2			
Case Number	**Sample Weight**	**MAIS**	3 percent discount rate	7 percent discount rate	3 percent discount rate	7 percent discount rate	3 percent discount rate	7 percent discount rate
1	21.29	2	1.6	1.6	2.2	2.2	98	53
2	54.34	3 (fatal)	1,517	783	1,511	780	1,421	748
3	18.81	3	105	55	47	25	91	50
4	411.33	2	7.5	7.5	11	11	1,886	1,027
5	85.65	6 (fatal)	2,392	1,235	2,381	1,230	2,240	1,180
6	3.41	5 (fatal)	95	49	95	49	89	47
7	124.43	5	2,437	1,237	2,178	1,100	556	269
8	8.39	2	18	9.6	15	7.7	38	21
9	50.12	5	925	458	881	432	277	119
10	8.24	2	0.3	0.3	0.3	0.3	41	22
11	37.29	3	172	89	46	25	181	99
12	75.56	2	0.002	0.002	0.1	0.1	347	189
13	16.03	4 (fatal)	448	231	446	230	419	221
14	145.31	2	6.3	6.3	5.0	5.0	724	393
15	1	2	0.03	0.03	0.02	0.02	4.1	2.3
16	128.9	4	824	431	650	341	543	299
17	61.87	2	2.0	2.0	1.1	1.1	256	140
18	85.65	3	2.6	2.6	1.4	1.4	416	226
19	1	5 (fatal)	28	14	28	14	26	14
20	7.75	3	1.2	1.2	1.1	1.1	44	24
21	382.64	2	15	15	5.5	5.5	1,431	791
22	23.03	2	0.00	0.00	0.00	0.00	106	58
		Total	8,998	4,629	8,305	4,263	11,236	5,992

Notes:
Assumes that, in the absence of injury, health status would equal the average for the U.S. population in the same age group.
Represents HRQL decrement per case for each phase multiplied by duration and sample weight.
Detail may not add to total due to rounding.

The exhibit indicates that the estimates of total QALY decrements are relatively similar across the EQ-5D and HUI-2, although in total the values under the HUI-2 are somewhat lower than the totals for the EQ-5D. For these two indices, the largest values are associated with those fatal cases and severe injuries with the largest sample weights, reflecting their comparatively high per case values and the sometimes sizable number of cases represented nationally. Several cases have very small values, usually because they reflect injuries with only short-term impacts. Identical results occur under both the three and seven percent discount rate for the injuries cases where the impacts are limited to the first year; the choice of discount rate affects those injuries with longer term impacts.

The total QALY losses under the QWB are somewhat higher than the results for the EQ-5D and HUI-2, due to a number of differences in the data used in the assessments as well as the differences inherent in each index. These differences are discussed in detail in Sections 3.2.3, 3.3.1, and 4.2 above. As with the other indices, the largest QWB values are often associated with those fatal cases that with the greatest sample weights. However, some of the more minor (e.g., MAIS 2) injuries also have relatively large QWB values, which are magnified in cases where the sample weights are large. The QWB data were provided for broad injury categories and reflect only hospitalized adult patients with Glascow Coma Scale (GCS) scores of 12 and greater, whereas the data used in the EQ-5D and HUI-2 assessment are for individual injuries, include children who were not hospitalized, and reflect a wider range of GCS classifications (see Exhibit 4). These differences between the two data sets may explain at least in part why the QWB estimates of the QALY losses associated with particular cases differ from the estimates under the other two indices. Relying on patient, rather than expert, estimates of HRQL impacts may also account for some of these differences.

Discounting the long term impacts at a three percent rate, rather than at seven percent, increases the present value of the totals, as expected. It does not affect the values for the short-term effects because we do not discount the first year values. (In most cases, the experts' estimates of the duration of the acute and rehabilitation periods combined is less than one year; on average, these phases total about two months). Larger differences occur for the long term impacts, because the three percent rate increases the contribution of future year effects to the total present value by discounting them by a smaller amount. Undiscounted, the different approaches lead to estimated losses of 21,000 to 27,000 QALYs.

Of these totals, 160 of the cases nationally are immediately fatal. These cases lead to losses of 12,000 life years if undiscounted, or 4,800 life years if discounted at three percent, and 2,400 life years if discounted at seven percent. (These life year estimates are not adjusted for HRQL.)

In the calculation of QALY losses, negative HRQL values can result in losses that are greater than the duration of the condition. Negative values occur in cases where the attributes in multiple domains are assigned levels indicating the most severe impairments. For example, HRQL is negative for the acute phase of case 9 (a severe spinal cord injury) under the EQ-5D (see Exhibit 10). At the age of incidence (age 3), we assume that average HRQL without the injury is 1.0, and find that the HRQL with the illness is *negative* 0.109, for a *decrement* of 1.109 from average health. For this injury, the median of the experts' estimate of duration was 30 days for the acute phase. If we multiply this duration estimate by the HRQL decrement (1.109*30 days), the result is a loss of 33 quality adjusted life days, exceeding actual duration.

Exhibit 16 provides the estimates for our sensitivity analysis, where we assume perfect health in the absence of the injury. This comparison is likely to overstate the actual impact of the averting these injuries because the affected individuals are not likely to be in perfect health throughout their life span in the absence of the injury. However, we include this perfect health comparison since it is often found in the literature.

Exhibit 16

SENSITIVITY ANALYSIS OF QALY LOSSES COMPARED TO AVERAGE OR PERFECT HEALTH

Scenario	Discount Rate	Case Study Expert Assignment (median)		Holbrook QWB Results (median)
		EQ-5D	HUI-2	
Total QALY losses compared to *average* age-adjusted health	3 percent	8,998	8,305	11,236
	7 percent	4,629	4,263	5,992
Total QALY losses compared to *perfect* health	3 percent	9,717	9,040	19,862
	7 percent	4,832	4,469	9,822

Note:
See Section 3.0 for information on the analytic approach used to develop these comparisons.

This exhibit indicates that comparison to perfect health (a value of 1.0) rather than average health increases the estimates of QALY losses across the different approaches, as expected. However, the overall results show similar patterns to the results reported in Exhibit 15. The difference between average health and perfect health scenarios is moderated by the fact that we assume that HRQL is 1.0 for the young children considered in this analysis under both the average health and perfect health scenarios. Average HRQL decreases with age (see Exhibit 8), and hence the use of the average population health scenario has the largest impact on the results for those injuries with life long effects. Again, the present value of the results decreases when discounted at seven rather than three percent, as expected.

SECTION 5.0: LIMITATIONS

This case study was prepared as a learning exercise for the IOM Committee to Evaluate Measures of Health Benefits for Environmental, Health, and Safety Regulation, and as such lacks some of the detail and complexity that would be required in an actual regulatory analysis. Perhaps most importantly, current guidance (OMB 2003) requires substantial assessment of uncertainty, while this case study largely relies on mean or median estimates and includes only limited sensitivity analysis. The existing guidelines for regulatory analysis require agencies to discuss qualitatively the main uncertainties in the calculations and to use sensitivity analysis or formal probabilistic analysis to quantitatively assess uncertainty.[49] The OMB guidance also emphasizes the importance of providing information on impacts that cannot be quantified or that can be quantified in physical terms but not assigned a value. The Committee also did not assess the distribution of the effects of this regulation, which is required under the OMB guidelines and other administrative and legal authorities.

In this section, we briefly discuss the sources of uncertainty most directly related to our application of the four HRQL approaches. We first discuss the comments received from the experts involved in the assignment of the EQ-5D and HUI-2 attribute levels, and then discuss other key areas of uncertainty that affect the application of these two indices and our QWB and FCI analysis.

5.1 Comments from Experts Involved in the HRQL Assignment[50]

As described in Section 3.2.1, the expert judgment process used to determine the domain attributes for each injury under the EQ-5D and HUI-2 was both time-consuming and challenging. Below, we summarize some of the expert's key observations on the process, provided in informal communications with the case study team.

The experts varied in their estimates of duration and several indicated that assessing the duration of the injury phases was challenging, in particular for those lacking extensive medical training or clinical experience. An alternative would be to use estimates from the research literature (similar to the approach used in the IOM Committee's other case studies), or to ask experts with relevant experience to assess HRQL at pre-specified intervals (e.g., at three, six, 12, and 18 months post-injury). These approaches would have eased the burden of the assessment process, both in terms of its cognitive demands and the amount of time required.

In addition, the experts received relatively little descriptive information about the injuries. The tables we provided indicated the AIS score for single injuries but not for multiple injuries. This lack of severity data for the multiple injury scenarios made the assessment process more difficult for these cases. More information about the exact injury location, size (e.g., of a hemorrhage), and timing (e.g., coma duration) would have been helpful as well. The experts

[49] As of January, 2005, formal probabilistic analysis was required for all rules with impacts that exceed $1 billion annually; this requirement would not include the child restraints rule that is the subject of this case study because its impacts are well below this threshold.
[50] Based on information provided informally to Phaedra Corso by the participating experts.

were also told to assume that the injuries affected children age zero to six, but the effects of injury can be quite different for children at different points within this age range. Hence providing more specific data on age at injury could have eased the determination of the relevant attributes.

The experts also recognized that their area of specialization, experience, and practice affected their perspective on the attribute levels likely to be associated with the different injuries. Several observed that a well-rounded panel would be necessary to provide an accurate classification of health. Such a panel would include physicians who are familiar with the immediate injuries and states of health (emergency physicians, trauma surgeons), and those that are familiar with long-term health outcomes specific to injuries (pediatricians, rehabilitation specialists).

In addition, the experts had several comments related to the attribute scales provided for each index. First, they noted that the scales do not provide enough variation within each domain to adequately describe some injuries, and that additional, finer distinctions are needed. For example, the self-care dimension of the EQ-5D includes “1- I have no problems with self care,” and “2- I have some problems washing or dressing myself, ” whereas some injuries would be best described as “some problems feeding myself or using the toilet.”

A second observation regarding the attribute scales related to their applicability to children. The experts noted that the scales are not always relevant for children of the ages addressed in this case study. For example, attributes 3 and 4 in the self-care domain of the HUI-2 (see Appendix A) are not appropriately consecutive; few children under the age of three years use the toilet “independently,” and most would require the “help of another person” before requiring mechanical equipment. Similarly, the experts had trouble determining how to address fertility for these young children, and in some cases did not provide attribute scores for this domain.

Third, using the attribute scales to assess the long-term effects of injuries incurred in childhood is difficult. While a large part of this difficulty relates to the need for more health science research on the actual impacts of injuries over time, the indices themselves were difficult to apply in these cases. An individual injured as a child will have a different perspective on what constitutes “usual activity” than would an individual injured as an adult. Hence one expert noted that there may not be the same perceived loss in HRQL for the child compared to an adult who sustains the same injury. Thus this expert did not include decrements in permanent HRQL for the “usual activities” domain unless the injury could potentially make the child unemployable or permanently disabled. (We are uncertain whether other experts followed this same logic.) More generally, some experts found it challenging to predict future levels of HRQL, especially for certain domains such as those measuring psychological or social well-being.

As noted earlier, due to time and resource constraints, the case study team followed an expert elicitation process that was less extensive than often recommended. Some of the problems noted above could be addressed by more closely following the practices advocated in the literature on preferred practices. An improved process could involve, for example, pretesting the materials before sending them out; providing additional instruction to ensure that the experts had a thorough and common understanding of the injuries, domain attributes, and the task itself; working with each expert to develop an understanding of the rationale for any missing or inconsistent responses; and using a more formal approach to address inconsistencies across the experts.

5.2 Implications of Key Uncertainties

This analysis is subject to a number of uncertainties in addition to the limitations of the expert assignment process. Many of these uncertainties relate to the data sources used, including the information on injuries to children provided in the NASS-CDS data, the construction and weighting of the individual generic indices, and the characteristics of the QWB and FCI research. The limitations and uncertainties associated with each of these data sources are discussed in the references provided in this case study. In particular, because the NASS-CDS sample was designed for purposes other than predicting injuries to restrained children and contains few examples of such injuries, extrapolating from these data is likely to yield highly uncertain estimates.

Below, we focus on the key uncertainties in the analyses conducted by the case study team and the implications for our comparison of the results across the indices. We are uncertain about the direction or magnitude of the bias resulting from these considerations; more research would be needed to determine the significance of these effects.

In reviewing the results of this case study, we found that the major sources of uncertainty appear to relate to the use of adult values for children. The expert assignment of the attributes under the EQ-5D and the HUI-2 explicitly addressed children ages zero to six, but the community weights applied to these attributes were for adults. The QWB and FCI data and values address adults only. NHTSA's ELS approach faces similar challenges, because it is based on data on injuries in all crashes regardless of whether an adult or child is affected, rather than on the specific injuries to children averted by its rule.

The use of adult values is often necessitated by the limitations in the available data but raises difficult practical and ethical questions. The pragmatic concerns relate largely to the nature of the injuries' impacts. The physical impact on children may vary significantly from the impact on adults; for example, children may recover more quickly and HRQL effects will differ because they are engaged in different types of activities. In addition, many of the domain attributes in the generic indices relate to activities not normally undertaken by small children. Injuries to children can also significantly affect the HRQL of caregivers, including their ability to engage in normal activities as well as their emotional and social well-being. These types of impacts were not taken into account in our analysis.

The ethical questions revolve around issues regarding whose values should be considered. Young children are generally not able to respond to survey questions describing the effects of their injuries, and the responses of their parents or medical experts may differ from self-reported data. In addition, the value placed on these attributes or HRQL decrements may vary depending on whether they are estimated from the perspective of the child, parent, or broader community.

A number of other uncertainties relate to the particular methods used to assess QALY losses in this case study. The previous section discussed generally some of the issues raised by the experts involved in assigning EQ-5D and HUI-2 attributes to each case. The Committee also commissioned a statistical analysis of the variation in the expert's assignments and in their estimates of duration (Mason 2005), as noted earlier. This analysis found that, although there were differences across the attribute levels assigned by different experts, the extent of the differences was not dependent on whether the EQ-5D or HUI-2 was used. When the expert data was used to estimate QALY losses, the major differences across the results were due to the variation in the expert's estimates of duration.

As discussed in more detail in Sections 3.3 and 4.0, our approach for applying the QWB and FCI research also reflects some limitations. In the case of the QWB, these limitations result from the use of values based on general categorization of injuries from all causes, as well as from the use of adult values that reflect all aspects of HRQL. For the FCI, data were available for only a single point in time, and the approach is still undergoing development.

In addition, the case study required comparing the "with condition" HRQL values to "without condition" values under both average and perfect health scenarios. Creating these comparisons required making assumptions about which scenario was the basis for the "with condition" values and then adjusting these values as needed. This adjustment process, and the assumptions that underlie it, adds another source of uncertainty.

In sum, this case study provided the Committee with important information regarding the data available for regulatory analysis and the difficulties inherent in applying generic indices to injuries to children. Some of these difficulties can be addressed by using more sophisticated analytic approaches; e.g., by improving the expert elicitation process. Others would require more primary research; for example to develop values more directly applicable to children.

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APPENDIX A: DOMAIN AND ATTRIBUTE DESCRIPTIONS FOR EACH INDEX

Exhibit A-1 EQ-5D HEALTH STATUS CLASSIFICATION SYSTEM		
Domain	**Attribute Level**	**Description**
MOBILITY	1	I have no problems in walking about
	2	I have some problems in walking about
	3	I am confined to bed
SELF-CARE	1	I have no problems with self-care
	2	I have some problems washing or dressing myself
	3	I am unable to wash or dress myself
USUAL ACTIVITIES	1	I have no problems with performing my usual activities (e.g., work, study, housework, family or leisure activities)
	2	I have some problems with performing my usual activities
	3	I am unable to perform my usual activities
PAIN / DISCOMFORT	1	I have no pain or discomfort
	2	I have moderate pain or discomfort
	3	I have extreme pain or discomfort
ANXIETY / DEPRESSION	1	I am not anxious or depressed
	2	I am moderately anxious or depressed
	3	I am extremely anxious or depressed

Exhibit A-2
HEALTH UTILITIES INDEX MARK 2 (HUI-2) HEALTH STATUS CLASSIFICATION SYSTEM

Domain	Attribute Level	Description
SENSATION	1	Able to see, hear, and speak normally for age.
	2	Requires equipment to see or hear or speak.
	3	Sees, hears, or speaks with limitations even with equipment.
	4	Blind, deaf, or mute.
MOBILITY	1	Able to walk, bend, lift, jump, and run normally for age.
	2	Walks, bends, lifts, jumps, or runs with some limitations but does not require help.
	3	Requires mechanical equipment (such as canes, crutches, braces, or wheelchair) to walk or get around independently.
	4	Requires the help of another person to walk or get around and requires mechanical equipment as well.
	5	Unable to control or use arms and legs.
EMOTION	1	Generally happy and free from worry.
	2	Occasionally fretful, angry, irritable, anxious, depressed, or suffering "night terrors".
	3	Often fretful, angry, irritable, anxious, depressed, or suffering "night terrors".
	4	Almost always fretful, angry, irritable, anxious, depressed.
	5	Extremely fretful, angry, irritable, anxious, or depressed usually requiring hospitalization or psychiatric institutional care.
COGNITIVE	1	Learns and remembers school work normally for age.
	2	Learns and remembers school work more slowly than classmates as judged by parents and/or teachers.
	3	Learns and remembers very slowly and usually requires special educational assistance.
	4	Unable to learn and remember.
SELF-CARE	1	Eats, bathes, dresses, and uses the toilet normally for age
	2	Eats, bathes, dresses, or uses the toilet independently with difficulty.
	3	Requires mechanical equipment to eat, bathe, dress, or use the toilet independently.
	4	Requires the help of another person to eat, bathe, dress, or use the toilet.
PAIN	1	Free of pain and discomfort.
	2	Occasional pain. Discomfort relieved by non-prescription drugs or self-control activity without disruption of normal activities.
	3	Frequent pain. Discomfort relieved by oral medicines with occasional disruption of normal activities.
	4	Frequent pain; frequent disruption of normal activities. Discomfort requires prescription narcotics for relief.
	5	Severe pain. Pain not relieved by drugs and constantly disrupts normal activities.
FERTILITY	1	Able to have children with a fertile spouse.
	2	Difficulty in having children with a fertile spouse.
	3	Unable to have children with a fertile spouse.

Exhibit A-3

QUALITY OF WELL-BEING SCALE (QWB) HEALTH STATUS CLASSIFICATION SYSTEM

Domain	Attribute Level	Description
MOBILITY SCALE	5	No limitations for health reasons
	4	Did not drive a car, health related; did not ride in a car as usual for age (younger than 15 years), health related
	3	Did not use public transportation, health related
	2	Had or would have used more help than usual for age to use public transportation, health related
	1	In hospital, health related
PHYSICAL ACTIVITY SCALE	4	No limitations for health reasons
	3	In wheelchair, moved or controlled movement of wheelchair without help from someone else
	2	Had trouble or did not try to lift, stoop, bend over, or use stairs or inclines, health related; limped, used a cane, crutches, or walker, health related; had any other physical limitation in walking; or did not try to walk as far or as fast as others the same age are able, health related
	1	In wheelchair, did not move or control the movement of wheelchair without help from someone else, or in bed, chair, or couch for most or all of the day, health related
SOCIAL ACTIVITY SCALE	5	No limitations for health reasons
	4	Limited in other (e.g., recreational) role activity, health related
	3	Limited in major (primary) role activity, health related
	2	Performed no major role activity, health related, but did perform self-care activities
	1	Performed no major role activity, health related, and did not perform or had more help than usual in performance of one or more self-care activities, health related
SYMPTOM/ PROBLEM COMPLEX	23	Trouble sleeping; intoxication; problems with sexual interest or performance; or excessive worry
	22	No symptoms or problem
	21	Breathing smog or unpleasant air
	20	Wore glasses or contact lenses
	19	Taking medication or staying on a prescribed diet for health reasons
	18	Pain in ear, tooth, jaw, throat, lips, tongue; several missing or crooked permanent teeth-includes wearing bridges or false teeth; stuffy, runny nose; or any trouble hearing-includes wearing a hearing aid
	17	Overweight for age and height or skin defect of face, body, arms, or legs, such as scars, pimples, warts, bruises, or changes in color
	16	Pain or discomfort in one or both eyes (such as burning or itching) or any trouble seeing after correction
	15	Trouble talking, such as lisp, stuttering, hoarseness, or being unable to speak
	14	Burning or itching rash on large areas of face, body, arms, or legs
	13	Headache, or dizziness, or ringing in ears, or spells of feeling hot, or nervous or shaky

Exhibit A-3 QUALITY OF WELL-BEING SCALE (QWB) HEALTH STATUS CLASSIFICATION SYSTEM		
	12	Spells of feeling upset, being depressed, or of crying
	11	Cough, wheezing, or shortness of breath, with or without fever, chills, or aching all over
	10	General tiredness, weakness, or weight loss
	9	Sick or upset stomach, vomiting or loose bowel movement, with or without fever, chills, or aching all over
	8	Pain, burning, bleeding, itching, or other difficulty with rectum, bowel movements, or urination (passing water)
	7	Pain, stiffness, weakness, numbness, or other discomfort in chest, stomach (including hernia or rupture), side, neck, back, hips, or any joints or hands, feet, arms, or legs
	6	Any combination of one or more hands, feet, arms, or legs either missing, deformed (crooked), paralyzed (unable to move) or broken-includes wearing artificial limbs or braces
	5	Trouble learning, remembering, or thinking clearly
	4	Pain, bleeding, itching, or discharge (drainage) from sexual organs-does not include normal menstrual (monthly) bleeding
	3	Burn over large areas of face, body, arms, or legs
	2	Loss of consciousness such as seizure (fits), fainting, or coma (out cold or knocked out)
	1	Death

Exhibit A-4

FUNCTIONAL CAPACITY INDEX (VERSION 2.1) HEALTH STATUS CLASSIFICATION SYSTEM

Domain	Attribute Level	Description
EXCRETORY FUNCTION	A	No limitations: no accidents and no use of medication or devices.
	B	Moderate incontinence (bowel and bladder): accidents greater than once per week but not every day with or without use of medication or device (device does not include catheter or colostomy pouch).
	C2	Severe incontinence (bowel and bladder): accidents every day or continuous use of catheter or colostomy pouch.
EATING	A	No limitation: no limitations in chewing, swallowing or digesting food that require restrictions in diet or special preparation of foods.
	B	Minor to moderate limitation: restrictions in diet or special preparation of foods required
	C	Tube feeding and/or gastrostomy required.
SEXUAL FUNCTION	A	No limitations due to physical limitation.
	B	Some difficulty due to physical limitation.
	C	A lot of difficulty due to physical limitation: including not being able to do it at all.
AMBULATION (MAY INCLUDE LIMITATIONS DUE TO PAIN)	A	No limitations walking, running, walking briskly or standing for long periods: no limitations walking without help from another person or device and no limitations running or walking briskly or standing for long periods. (Device includes walking aids (e.g. can, crutch, walker) or prosthesis/orthosis.)
	B	Some limitations running or walking briskly or standing for long periods: no limitations walking without help from another person or device, but has some limitations running, walking briskly or standing for long periods. (Device includes walking aids (e.g. can, crutch, walker) or prosthesis/orthosis.)
	C1	Some limitations walking but independent (independent community ambulator): has some limitations walking but can walk at least 150 yards (length of city block) without help from another person or device. (Device includes walking aids (e.g. can, crutch, walker) or prosthesis/orthosis.)
	C2	Can walk long distances but only with device or help (community ambulator with assistance): has some limitations walking; can walk at least 150 yards (length of city block) but only with help from another person or device.(Device includes walking aids (e.g. can, crutch, walker) or prosthesis/orthosis.)
	D	Walking limited to short distances with or with out device or help (home ambulator): cannot walk 150 yards even with help or device, but can walk shorter distances (i.e. < 150 yards) with or without help from another person or device. (Device includes walking aids (e.g. can, crutch, walker) or prosthesis/orthosis.)
	E	Cannot walk at all: even short distances; requires wheelchair all the time to get around.
BENDING, STOOPING AND LIFTING (MAY INCLUDE LIMITATIONS DUE TO PAIN)	A	No difficulty bending, stooping, lifting and no difficulty lifting arms over head: no difficulty lifting and carrying weights up to 50 lbs (a small child); no difficulty lifting arms over head.
	B	Minor difficulty bending, stooping, lifting and/or difficulty lifting arms over head: had difficulty lifting and carrying 50 lbs (a small child), but can lift at least 10 lbs (a bag of groceries) with no or little difficulty and /or has difficulty lifting arms over head but can do it at least 5 times in a row.
	C	Major difficulty bending, stooping, lifting: has a lot of difficulty lifting and carrying at least 10 lbs (a bag of groceries), including not being able to do it at all; may or may not have difficulty lifting arms over head but can do it at least 5 times in a row.

Exhibit A-4

FUNCTIONAL CAPACITY INDEX (VERSION 2.1) HEALTH STATUS CLASSIFICATION SYSTEM

	D	Complete or near complete loss of upper body function: has difficulty lifting and carrying at least 10 lbs (a bag of groceries), including not being able to do it at all; has difficulty lifting arms over head at least 5 times in a row, including not being able to do it at all.
HAND AND WRIST FUNCTION (MAY INCLUDE LIMITATIONS DUE TO PAIN)	A	No limitations: no difficulty grasping and handling small or large objects with either hand; no difficulty twisting and turning doorknob or key with either hand
	B1	Minor difficulty in hand and/or wrist function – one hand: difficulty grasping and handling small objects with one hand but no difficulty with large objects and/or difficulty twisting and turning doorknob or key with one hand; may use special tool but does not require the help of another person.
	B2	Minor difficulty in hand and/or wrist function – both hands: difficulty grasping and handling small objects with both hands but no difficulty with large objects and/or difficulty twisting and turning doorknob or key with one or both hands; may use special tool but does not require the help of another person.
	C1	Major difficulty in hand function – one hand: difficulty grasping and handling large and small objects with one hand; may or may not have difficulty twisting and turning doorknob or key with one or both hands; may use special tool but does not require the help of another person
	C2	Major difficulty in hand function – both hands: difficulty grasping and handling large and small objects with both hands; may or may not have difficulty twisting and turning doorknob or key with one or both hands; may use special tool but does not require the help of another person.
	D	Near complete loss of hand function (including paralysis): difficulty grasping and handling large and small objects; requires the help of another person for some, but not all tasks necessary for daily living.
	E	Complete loss of function (including paralysis) in both hands: Difficulty grasping and handling large and small objects; requires the help of another person for all or nearly all tasks necessary for daily living.
SPEECH	A	No limitations.
	B	Minor limitations in everyday situations: can be understood by most everyone; may get stuck, stutter, stammer, slur.
	C	Major limitations: can only be understood by people who know person well.
	D	Cannot speak and/or be understood by others or requires voice box to speak.
HEARING	A	No limitations: no limitations hearing without hearing aid.
	B1	Minor difficulty hearing: with or without hearing aid has some difficulty hearing, but only when listening conditions are less than ideal.
	B2	Moderate difficulty: with or without hearing aid has difficulty hearing under everyday listening conditions.
	C	Profound to total loss of hearing; non-correctable: cannot hear even with the use of a hearing aid
VISION	A	No limitations: no difficulties reading small and large print, driving and going about daily activities with or without glasses/contacts.
	B	Minor or moderate limitations: minor or moderate difficulty reading small and large print, driving and going about daily activities with or without glasses/contacts.
	C	Severe limitations: severe difficulty reading small and large print, driving and going about daily activities with or without glasses/contacts; includes blind with light perception only.
	D	Blind without light perception.
COGNITIVE	A	No limitations.

Exhibit A-4 **FUNCTIONAL CAPACITY INDEX (VERSION 2.1) HEALTH STATUS CLASSIFICATION SYSTEM**		
FUNCTION	B	Minor limitations: minor difficulties with reasoning/solving problems, memory, concentration/thinking and/or attention; can live independently (i.e. does not require assistance with either ADL or IADL activities due to cognitive deficits).
	C	Moderate to severe limitations: moderate to severe difficulties with reasoning/solving problems, memory, concentration/thinking and/or attention; can live independently (i.e. does not require assistance with ADL activities) but (due to cognitive deficits) may need assistance with some IADL activities of daily living.
	D	Unconfined dependence: cannot live independently due to cognitive deficits but 24 hour supervision is not required
	E	Confined dependence: cannot live independently due to cognitive deficits; 24 hour supervision is required.
	F	Minimally response or vegetative state (VS): cannot respond to simple commands except possibly with eye movement

APPENDIX B: CALCULATION OF REDUCED LIFE EXPECTANCY

This appendix discusses our approach for using standardized mortality ratios (SMRs) to adjust life expectancy for those children who incur injuries that are anticipated to result in reduced life spans; i.e., severe traumatic brain injury and spinal cord injury. The Excel spreadsheet models used in this case study calculate population average conditional survival rates on an annual basis for each year of age, based on CDC estimates of the probability of dying between ages x and x+1 from the year 2000, referred to as q(x) in the CDC life tables (CDC 2002). We increase these death rates to reflect the impact of severe injuries on life expectancy, using an exponential approach. As discussed in Section 3.1, we apply an SMR of 2.0 for the traumatic brain injury and of 4.36 for the spinal cord injury, based on relevant studies. If d = the population average death rate, and s = the SMR, then this exponential approach uses the formula $1 - (1 - d)^s$ to calculate the "with injury" death rates.

This appendix provides two examples of the calculations using an SMR of 2.0: one for the year at incidence (when the probability of survival plus the probability of death equals 100 percent), and one for a future year (when the probability of survival plus the probability of death equals less than 100 percent because of the cumulative effect of the death rates in earlier years). Note that we use both the death and survival rates in our HRQL calculations, because we assume that deaths occur halfway through the year and hence the individual receives "half the QALY" for that year.

<u>Calculation for year 0 (age 3)</u>

Without condition population average annual death rate, year zero = 0.000243[a]
Without condition survival rate = 1 - 0.000243 = 0.999757

With condition *death* rate = $1- (1 - 0.000243)^{2.0} = 0.000486$
With condition *survival* rate = 1- 0.000486 = 0.999514

<u>Calculation for year 10 (age 13)</u>

Without condition population average annual death rate, year 10 = 0.000253[a]
Without condition survival rate, year 10 = 0.998055

With condition *death* rate = $1- (1 - 0.000253)^{2.0} = 0.000506$
With condition *survival* rate = survival rate for prior year * (1 – current year death rate) =
0.996617 * (1 - 0.000506) = 0.996113

[a.] from CDC life tables for 2000, assumes 3 = age at incidence