

Recommendations for Changes to the Definition of Catastrophic Impairment

Final Report of the Catastrophic Impairment Expert Panel to the Superintendent

April 8, 2011

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1. EXECUTIVE SUMMARY

In the first phase of its mandate, the Expert Panel reviewed the definition of catastrophic impairment in the Statutory Accident Benefits Schedule and made recommendations to the Superintendent of the Financial Services Commission of Ontario on changes to the definition. The Expert Panel's recommendations aim to ensure that individuals who are most seriously injured in traffic accidents receive appropriate treatment. The Expert Panel developed its recommendations by giving precedence to scientific evidence and judgment. The Expert Panel made recommendations for significant changes at two levels: accuracy and fairness of the determination.

First, the Expert Panel revised the definition to improve its accuracy, relevance and clarity. Consequently, we recommend that assessment systems with acceptable validity, reliability and predictive ability be included (when available) as a criterion to determine the presence of catastrophic impairment. Specifically, the Expert Panel recommends that the American Spinal Injury Association (ASIA) classification be used to assist with the determination of catastrophic impairment subsequent to spinal cord injury. We recommend that the Extended Glasgow Outcome Scale (GOS-E) be used to assist with the determination of catastrophic impairment subsequent to traumatic brain injury in adults and that the Spinal Cord Independence Measure be used to assist with the measurement of catastrophic impairment associated with ambulation dysfunction. Finally, the Expert Panel recommends that the Global Assessment of Functioning (GAF) be used to assist with the determination of catastrophic impairment subsequent to psychiatric disorders. We believe that these assessment systems, particularly when combined with clinical anchors, will considerably compensate for long-recognized ambiguities and limitations found within the AMA Guides, 4th Edition.

The Expert Panel considered various methods for the rating of multi-system physical impairments. However, we found that the guidelines and rating systems used in other jurisdictions or the revised methodologies presented in more recent editions of the AMA Guides do not offer any benefits over continued reliance on the 4th edition.

The Expert Panel did not find that combining physical and mental/behavioural conditions can be achieved in a valid and reliable way with the currently available methods of impairment cross-rating. Moreover, the Expert Panel did not find sufficient evidence that combined impairment ratings are more clinically meaningful than using separate criteria. While 55% physical impairment establishes paraplegia as a prime example of catastrophic impairment, we did not find evidence for an equivalent threshold when physical and mental/behavioral impairments are combined. The Panel had difficulty understanding how combinations of physical impairments and psychological conditions that independently do not meet the criteria outlined in the revised version of 2(e) and 2(f) could be equated to a severe injury to the brain or, spinal cord or to blindness. Further investigation of this area is needed. Specifically defining a clinically comparable combined psycho-physical whole person impairment threshold that corresponds to the currently accepted physical threshold is needed. Therefore, until further scientific evidence is gained, we recommend that separate criteria and methods of evaluation be used for the determination of catastrophic impairment and that physical and psychiatric impairments not be combined for the purpose of catastrophic determination.

Second, the Expert Panel aimed to improve the fairness of the process of determination for catastrophic impairment. The Expert Panel believes that fairness will be improved if Insured Persons with catastrophic impairments receive benefits without undue delay and if the final determination of catastrophic impairment agrees with the natural history of the condition. Therefore, the Expert Panel recommends that a designation of interim catastrophic impairment status (hereafter referred to as the interim status) be allowed for Insured adults with traumatic brain injuries and for those with major physical impairments who unequivocally require intensive and prolonged rehabilitation. The purpose of the interim status is to ensure that these individuals have access to the rehabilitation services that are necessary to maximize their chance of achieving a lower final impairment level, and potentially that is less than catastrophic.

In summary, the Expert Panel proposes solutions to improve the determination of catastrophic impairment for Ontarians injured in traffic collisions by relying on the current scientific evidence and scientific judgment. We believe that that the integration of scientific knowledge to clinical expertise will benefit Ontarians and our automobile insurance system.

2. INTRODUCTION

2.1 Mandate of the Panel

The Catastrophic Impairment Expert Panel (hereafter referred to as the Panel) was mandated to review the definition of “catastrophic impairment” located in the Statutory Accident Benefits Schedule (SABS) and make recommendations to the Superintendent of the Financial Services Commission of Ontario (FSCO) on changes to the definition to ensure that the most seriously injured accident victims are treated appropriately (Phase I). The Panel members (hereafter referred to as the Members) will also make recommendations regarding the training, qualifications and experience of assessors who conduct catastrophic impairment assessments under the SABS (Phase II). The current report focuses on recommended changes to the definition of catastrophic impairment (Phase I).

2.2 The Expert Panel

2.2.1 Chair of the Panel:

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2.3 Objectives

The objectives of the Panel are to:

- 2.3.1 Identify ambiguities and gaps in the current SABS definition of “catastrophic impairment” in order to reflect emerging scientific knowledge and judgment.
- 2.3.2 Identify the required training, qualifications and experience of assessors who conduct catastrophic impairment assessments under the SABS.
- 2.3.3 Make recommendations for changes to the definition of catastrophic impairment and assessor qualifications.
- 2.3.4 Review and comment on such matters as requested by the Superintendent.

The Panel did not review or comment on issues unrelated to the SABS definition of catastrophic impairment. Issues deemed to fall outside of the mandate included the \$2000 cap on assessments; expenses covered within the assessment cap; and benefits under the SABS available to claimants deemed to have a catastrophic impairment.

2.4 Current Definition and Interpretation of Catastrophic Impairment

The following definition and interpretation of catastrophic impairment is a direct citation from the “Insurance Act, ONTARIO REGULATION 34/10, STATUTORY ACCIDENT BENEFITS SCHEDULE - EFFECTIVE SEPTEMBER 1, 2010”. A full version of the regulations can be found at

http://www.e-laws.gov.on.ca/html/regs/english/elaws_regs_100034_e.htm.

Definitions and interpretation

3.(1) In this Regulation,

"accident" means an incident in which the use or operation of an automobile directly causes an impairment or directly causes damage to any prescription eyewear, denture, hearing aid, prosthesis or other medical or dental device; ("accident")

"impairment" means a loss or abnormality of a psychological, physiological or anatomical structure or function;

(2) For the purposes of this Regulation, a catastrophic impairment caused by an accident is,

(a) paraplegia or quadriplegia;

(b) the amputation of an arm or leg or another impairment causing the total and permanent loss of use of an arm or a leg;

(c) the total loss of vision in both eyes;

(d) subject to subsection (4), brain impairment that results in,

(i) a score of 9 or less on the Glasgow Coma Scale, as published in Jennett, B. and Teasdale, G., Management of Head Injuries, Contemporary Neurology Series, Volume 20, F.A. Davis Company, Philadelphia, 1981⁵¹, according to a test administered within a reasonable period of time after the accident by a person trained for that purpose, or

(ii) a score of 2 (vegetative) or 3 (severe disability) on the Glasgow Outcome Scale, as published in Jennett, B. and Bond, M., Assessment of Outcome After Severe Brain Damage, Lancet i:480, 1975⁴⁹, according to a test administered more than six months after the accident by a person trained for that purpose;

(e) subject to subsections (4), (5) and (6), an impairment or combination of impairments that, in accordance with the American Medical Association's Guides to the Evaluation of Permanent Impairment, 4th edition, 1993⁵, results in 55 per cent or more impairment of the whole person; or

(f) subject to subsections (4), (5) and (6), an impairment that, in accordance with the American Medical Association's Guides to the Evaluation of Permanent Impairment, 4th edition, 1993, results in a class 4 impairment (marked impairment) or class 5 impairment (extreme impairment) due to mental or behavioural disorder.⁵ O. Reg. 34/10, s. 3 (2).

(3) Subsection (4) applies if an insured person is under the age of 16 years at the time of the accident and none of the Glasgow Coma Scale, the Glasgow Outcome Scale or the American Medical Association's Guides to the Evaluation of Permanent Impairment, 4th edition, 1993, referred to in clause (2) (d), (e) or (f) can be applied by reason of the age of the insured person.⁵ O. Reg. 34/10, s. 3 (3).

(4) For the purposes of clauses (2) (d), (e) and (f), an impairment sustained in an accident by an insured person described in subsection (3) that can reasonably be believed

to be a catastrophic impairment shall be deemed to be the impairment that is most analogous to the impairment referred to in clause (2) (d), (e) or (f), after taking into consideration the developmental implications of the impairment. O. Reg. 34/10, s. 3 (4).

(5) Clauses (2) (e) and (f) do not apply in respect of an insured person who sustains an impairment as a result of an accident unless,

- (a) a physician or, in the case of an impairment that is only a brain impairment, either a physician or a neuropsychologist states in writing that the insured person's condition is unlikely to cease to be a catastrophic impairment; or
- (b) two years have elapsed since the accident. O. Reg. 289/10, s. 1 (2).

(6) For the purpose of clauses (2) (e) and (f), an impairment that is sustained by an insured person but is not listed in the American Medical Association's Guides to the Evaluation of Permanent Impairment, 4th edition, 1993 is deemed to be the impairment that is listed in that document and that is most analogous to the impairment sustained by the insured person.⁵ O. Reg. 34/10, s. 3 (6).

Determination of catastrophic impairment

45. (1) An insured person who sustains an impairment as a result of an accident may apply to the insurer for a determination of whether the impairment is a catastrophic impairment. O. Reg. 34/10, s. 45 (1).

(2) The following rules apply with respect to an application under subsection (1):

- 1. An assessment or examination in connection with a determination of catastrophic impairment shall be conducted only by a physician but the physician may be assisted by such other regulated health professionals as he or she may reasonably require.
- 2. Despite paragraph 1, if the impairment is a brain impairment only, the assessment or examination may be conducted by a neuropsychologist who may be assisted by such other regulated health professionals as he or she may reasonably require.
- 3. If a Guideline specifies conditions, restrictions or limits with respect to the determination of whether an impairment is a catastrophic impairment, the determination must be made in accordance with those conditions, restrictions and limits. O. Reg. 34/10, s. 45 (2); O. Reg. 289/10, s. 5.

(3) Within 10 business days after receiving an application under subsection (1) prepared and signed by the person who conducted the assessment or examination under subsection (2), the insurer shall give the insured person,

- (a) a notice stating that the insurer has determined that the impairment is a catastrophic impairment; or
- (b) a notice stating that the insurer has determined that the impairment is not a catastrophic impairment and specifying the medical and any other reasons for the insurer's decision and, if the insurer requires an examination under section 44 relating to whether the impairment is a catastrophic impairment, so advising the insured person. O. Reg. 34/10, s. 45 (3).

(4) If an application is made under this section not more than 104 weeks after the accident and, immediately before the application was made, the insured person was receiving attendant care benefits,

- (a) the insurer shall continue to pay attendant care benefits to the insured person during the period before the insurer makes a determination under this section; and
- (b) the amount of the attendant care benefits for the period referred to in clause (a) shall be determined on the assumption that the insured person's impairment is a catastrophic impairment. O. Reg. 34/10, s. 45 (4).

(5) Within 10 business days after receiving the report of an examination under section 44, the insurer shall,

- (a) give a copy of the report to the insured person and to the person who prepared the application under this section; and
- (b) provide the insured person with a notice stating that the insurer has determined that the impairment is a catastrophic impairment or is not a catastrophic impairment and setting out the medical and any other reasons for the insurer's determination. O. Reg. 34/10, s. 45 (5).

(6) If an insured person is determined to have sustained a catastrophic impairment as a result of an accident, the insured person is entitled to payment of all expenses incurred before the date of the determination and to which the insured person would otherwise be entitled to payment under this Regulation by virtue of having sustained a catastrophic impairment. O. Reg. 34/10, s. 45 (6).

3. METHODOLOGY

The project is being conducted in two phases. In Phase I (current phase of the project), the Panel reviewed the current SABS definition of catastrophic impairment and made recommendations for changes to the definition of catastrophic impairment. In Phase II, the Panel will identify the required training, qualifications and experience of assessors who conduct catastrophic impairment assessments under the SABS and make recommendations for changes to the definition of catastrophic impairment and assessor qualifications.

3.1 Guiding Principle

As outlined in Objective 2.3.1, the Panel has been asked to base its deliberation and develop its recommendations on emerging scientific knowledge and judgment. The work of the Panel gave precedence to valid and reliable scientific evidence. In the absence of valid and reliable scientific evidence, the Panel informed its deliberation and developed its recommendations based on the best practices used in other Canadian and international jurisdictions. Finally, if both scientific evidence and best practices were not available, the Panel relied on expert opinions to inform its work. The Chair reserved the right to seek opinions from individuals outside of the Panel to inform the work of the Panel.

3.2 Disclosures of Conflicts of Interest

The work conducted by the Panel was carried out in a rigorous, transparent and unbiased manner. Therefore, at the first Panel meeting, the Members (including the Chair) were asked to openly disclose any conflicts of interest they may have with their involvement in this project. The disclosed conflicts of interest are included in Appendix 14.

The definition of Conflict of Interest endorsed by the International Committee of Medical Journal Editors was used:

Conflict of interest exists when an author (or the author's institution), reviewer, or editor has financial or personal relationships that inappropriately influence (bias) his or her actions (such relationships are also known as dual commitments, competing interests, or competing loyalties). These relationships vary from being negligible to having great potential for influencing judgment. Not all relationships represent true conflict of interest. On the other hand, the potential for conflict of interest can exist regardless of whether an individual believes that the relationship affects his or her scientific judgment. Financial relationships (such as employment, consultancies, stock ownership, honoraria, and paid expert testimony) are the most easily identifiable conflicts of interest and the most likely to undermine the credibility of the journal, the authors, and of science itself. However, conflicts can occur for other reasons, such as personal relationships, academic competition, and intellectual passion.

For the purpose of the Catastrophic Impairment Expert Panel, the terms “journal, author, reviewer or editor” in the above definition are replaced by “Chair or Expert Panel member”.

3.3 Baseline survey of Expert Panel Members

Prior to the first meeting of the Panel, the Members were asked to respond to an anonymous electronic questionnaire to determine:

- 3.3.1 Level of agreement with the guiding principle (described in section 3.1 of the methodology);
- 3.3.2 Individual understanding of the meaning of catastrophic impairment;
- 3.3.3 Level of agreement with the current definition of catastrophic impairment; and
- 3.3.4 Recommendations for improvement of the SABS definition of “catastrophic impairment.”

Where applicable, the Members were invited to support their answers and recommendations with the best available scientific evidence.

3.4 Identify ambiguities and gaps in the current SABS definition of “catastrophic impairment” in order to reflect emerging scientific knowledge and judgment

- 3.4.1 The Panel conducted non-systematic reviews of the recent scientific literature to identify “ambiguities and gaps” in the current SABS definition of “catastrophic impairment.” A systematic review of the literature was not possible given the resources and timeline available to the Panel. A search of Pubmed from 2000-2010

was conducted to identify research articles that specifically address the reliability, validity and predictive ability of the:

- 3.4.1.1 Glasgow Coma Scale;
- 3.4.1.2 Glasgow Outcome Scale;
- 3.4.1.3 American Medical Association's Guides to the Evaluation of Permanent Impairment.

Based on the Panel's recommendations, additional literature searches were conducted to examine the reliability and validity of the American Spinal Injury Association classification of spinal cord injury (ASIA), the Global Assessment of Functioning (GAF) and the King's Outcome Scale for Childhood Head Injury (KOSCHI). The relevant literature was presented to the Panel in order to guide their decisions concerning incorporation of these measures (Appendix 12).

The articles were reviewed by the Chair and his staff. To be included in the review, articles must have included original data and must have been judged to be scientifically valid by the Chair. Opinion papers, editorials, letter to the editor, case reports, case-series, textbook chapters without original data, basic science papers and narrative reviews of the literature were not considered. Summaries of the evidence were presented to the Panel to inform their deliberation.

Finally, PubMed was searched for alternative methods which could be used to define and determine catastrophic impairment. The result of this search was presented to the Panel to inform their deliberation.

- 3.4.2 The Panel conducted a non-systematic search of laws and regulations used in other jurisdictions to define "catastrophic impairment", "permanent impairment", and "permanent disability".
- 3.4.3 Potential gaps and ambiguities in the current SABS definition were also investigated by eliciting the opinions of the Members.

3.5 Development of recommendations for changing the definition and determination of catastrophic impairment

The Panel used a modified Delphi methodology to develop recommendations on changes to the definition and determination of catastrophic impairment. The Panel baseline survey, the literature review and the best practices from other jurisdictions serve as the foundation for the development of recommendations. The Panel also determined the feasibility of implementing the recommendations to the Ontario automobile insurance system.

The agreement of the Panel on the proposed recommendations and their suggestions for improvement were sought through electronic surveys. The results of the surveys were analyzed by the Chair and used to determine whether or not consensus was reached. Consensus was deemed to have been reached when 75% of the Panel (6/8 members) agreed with a recommendation. The Panel meetings were used to discuss the results of the

surveys and to refine the recommendations. When consensus was not reached, modified recommendations were submitted to the Panel in a second or third survey. The “round 2 or round 3” recommendations were based on the feedback received in the previous surveys and from the discussions of the Panel.

4. PROPOSED REVISIONS to the SABS – CATASTROPHIC IMPAIRMENT DEFINITIONS

In the initial stage of its deliberations, the Panel discussed the meaning of “catastrophic impairment.” In summary, the Panel agreed that a catastrophic impairment is an extremely serious impairment or combination of impairments that is expected to be permanent and which severely impacts an individual's ability to function independently. It was the opinion of the Panel that catastrophic impairment is not a medical entity; rather, it is a legal entity which defines a point along the medical spectrum of impairment severity (Appendix 1, Survey 1).

The Panel agreed that, except for 2 (d) i, all current SABS definitions required significant revisions. The Panel voted to eliminate 2 (d) i: brain impairment that results in “a score of 9 or less on the Glasgow Coma Scale, as published in Jennett, B. and Teasdale, G., Management of Head Injuries, Contemporary Neurology Series, Volume 20, F.A. Davis Company, Philadelphia, 1981, according to a test administered within a reasonable period of time after the accident by a person trained for that purpose” (Appendix 2, Survey 2).⁵¹ It is the opinion of the Panel that this definition ought to be eliminated because of the questionable ability of the GCS to predict the long term outcomes associated with respect to catastrophic impairment (Appendix 12, section 3). An alternative is proposed below in section 4.1.6.

4.1 Definitions

4.1.1 Adult versus paediatric definitions

The definitions proposed below apply to all age groups unless specified. For the purpose of these definitions, an adult is anyone 18 years of age or older. The following definitions 2 (a) (section 4.1.3), 2 (b) (section 4.1.4) and 2 (c) (section 4.1.5) apply to all age groups. The Panel recognized the long-term developmental implications of traumatic brain injuries in the paediatric population (<18 years old) and proposed a definition (definition 3, section 4.1.10) that is specific to this age group. Given the complexity of the issues, and the time constraints, the Panel determined that it was unable to adequately address adaptations to definitions 2 (e) (section 4.1.7) and 2 (f) (section 4.1.8) for the paediatric population. The Panel recognizes that adapting these definitions to the paediatric population is a priority and recommends that an Expert Paediatric Working Group be convened to address this issue as soon as possible. In the interim, the Panel recommends that the determination of catastrophic impairment for individuals younger than 18 years of age who sustain an impairment that is not covered by definitions 2 (a), 2 (b), 2 (c) or 3 be done by seeking the closest analogy using definitions 2 (e) and 2 (f) as well as the other adult definitions.

4.1.2 Interim catastrophic impairment status

The Panel recommends that an interim catastrophic impairment status be created for patients whose impairments specifically meet or exceed the criteria outlined under definition 2(d)

(section 4.1.6), 2 (e) (section 4.1.7). The purpose of the interim catastrophic impairment status is to ensure that these insured individuals have access to the rehabilitation services that are necessary to improve their health and maximize their chances of achieving a final impairment level that is less than catastrophic. The Panel also believes that a designation of interim catastrophic impairment status is necessary to balance access to higher level of funding necessary for early rehabilitation with the need to minimize the risk of patients being permanently designated as catastrophically impaired when there is a reasonable chance that they will cease to be catastrophically impaired.

4.1.3 2 (a) – Paraplegia/ Tetraplegia

Proposed revision:

2. For the purposes of this Regulation, a catastrophic impairment caused by an accident is,

2(a) paraplegia or tetraplegia that meets the following criteria i and ii, and either iii or iv:

- i. The Insured Person is currently participating in, or has completed a period of, in-patient spinal cord injury rehabilitation in a public rehabilitation hospital; and
- ii. The neurological recovery is such that the permanent ASIA Grade can be determined with reasonable medical certainty according to the American Spinal Injury Association Standards (*Marino RJ et al. ASIA Neurological Standards Committee 2002. International standards for neurological classification of spinal cord injury. J Spinal Cord Med 2003; 26(Suppl 1): S50–S56*)⁶² and
- iii. The permanent ASIA Grade is A, B, or C or,
- iv. The permanent ASIA Grade is or will be D provided that the insured has a permanent inability to walk independently as defined by scores 0–3 on the Spinal Cord Independence Measure item 12 (indoor mobility, ability to walk <10 m) (*Catz A, Itzkovich M, Tesio L, et al. A multicenter international study on the spinal cord independence measure, version III: Rasch psychometric validation. Spinal Cord 2007; 45: 275–91*) and/or requires urological surgical diversion, an implanted device, or intermittent or constant catheterization in order to manage the residual neuro-urological impairment.¹²

Rationale for revision of 2 (a):

The scientific knowledge about the diagnostic classification of spinal cord injuries has grown in the past 15 years (Appendix 12, section 4). The American Spinal Injury Association (ASIA) classification of spinal cord injury has become the standard in medical practice. The ASIA system classifies patients in five mutually exclusive severity categories that range from complete (Grade A) to normal (Grade E).

The Panel recommends that the ASIA system be used for the determination of catastrophic impairment secondary to spinal cord injuries. Our review of the recent literature suggests that its reliability and validity is adequate.^{33;63;70} The ability of the ASIA system to predict the ambulatory capacity of patients with spinal cord injuries provides a useful system for tracking the evolution of these injuries in the first year after the trauma.⁹⁴

The recent scientific literature suggests that the majority of Grade D patients will be able to ambulate independently one year after the injury.⁹⁴ It was the consensus opinion of the Panel that those patients with Grade E, and those patients with Grade D injuries who successfully recover their ability to ambulate independently, are not catastrophically impaired. This led the Panel to initially question whether a suitable threshold for catastrophic impairment should be set at ASIA Grade C, thus excluding all ASIA Grade D and E patients.

While the overall reliability of the ASIA classification is adequate, the Panel recognized that differentiating between the two motor incomplete categories (Grades C and D) may be associated with unacceptable levels of error and inconsistency. Moreover, the Panel was also concerned that some patients with Grade D spinal cord injuries will not be able to ambulate for appreciable distances without substantial reliance on assistive devices and/or will not be able to manage their neurogenic viscera solely by means of medication or routine. Therefore, the Panel recommends that the determination with respect to patients with spinal cord injury should focus on the spectrum of mobility and neuro-urological impairments found within Grade D. The Panel recommends that the threshold mobility impairment should be a permanent inability to walk independently as defined by scores 0–3 on the Spinal Cord Independence Measure item 12 (indoor mobility, ability to walk <10 m) and the threshold urological impairment should be a requirement for urological surgical diversion, an implanted device, or intermittent or constant catheterization in order to manage the residual neuro-urological impairment.¹²

Individuals injured in traffic collisions may suffer from transient paralysis (also known as spinal shock). By definition, transient paralysis is an acute condition associated with favorable outcomes. The Panel agreed that transient paralysis is not a catastrophic impairment and that the determination of ASIA grade must not be made until the neurological recovery is such that the permanent ASIA Grade can be determined with reasonable medical certainty.

Finally, the Panel strongly supports the use of the ASIA classification for the purpose of catastrophic impairment determination because it is commonly used in routine spinal cord injury care, it requires the use of a standardized examination protocol and removes some of the subjectivity and other limitations associated with the use of the related sections of the AMA Guides. This system provides a more structured formula to rate impairment, and can be expected to both increase inter-rater reliability and more effectively identify the catastrophically impaired spinal cord injured patient.⁶²

4.1.4 2 (b) - Severe impairment of ambulatory mobility

Proposed revision:

2. For the purposes of this Regulation, a catastrophic impairment caused by an accident is,

2 (b) Severe impairment of ambulatory mobility, as determined in accordance with the following criteria:

- i. Trans-tibial or higher amputation of one limb, or
- ii. Severe and permanent alteration of prior structure and function involving one or both lower limbs as a result of which:

- a. The Insured Person is currently participating in, or has completed a period of in-patient rehabilitation in a public rehabilitation facility, and
- b. It can be reasonably determined that the Insured Person has or will have a permanent inability to walk independently and instead requires at least bilateral ambulatory assistive devices [mobility impairment equivalent to that defined by scores 0–3 on the Spinal Cord Independence Measure item 12 (indoor mobility, ability to walk <10 m) (*Catz A, Itzkovich M, Tesio L, et al. A multicenter international study on the spinal cord independence measure, version III: Rasch psychometric validation. Spinal Cord 2007; 45: 275–91*).¹²

Rationale for revision of 2(b):

The Panel recommends significant changes to definition 2 (b). These changes were motivated by three realities. First, the Panel found no scientific evidence to assist its deliberation on the determination of catastrophic impairment secondary to severe physical injuries. Second, the current definition does not accurately describe the range of injuries that can lead to catastrophic impairment. The current definition focuses on amputations and does not include other injuries such as burns or crush injuries. Third, the definition offers no specific criterion for the determination of catastrophic impairment.

The Panel relied on its clinical expertise and scientific judgment to revise definition 2 (b). The Panel has concluded that separate definitions are needed to determine the presence of catastrophic impairment related to the upper limb versus the lower limb. We recommend that the AMA Guides be used for the determination of catastrophic impairment related to upper extremity injury.⁵ The Panel found that any extensive impairment to an upper extremity would result in 55% or more whole person impairment (WPI) and can therefore be determined using the revised 2e definition (see section 4.1.7).

However, the Panel proposes a different approach for patients with a catastrophic impairment related to ambulatory mobility. While Section 2 of Chapter 3 of the AMA Guides 4th edition offers a detailed assessment methodology, if injury is confined to the lower extremities the final rating does not permit a determination of catastrophic impairment.⁵ This is true for all amputations. In fact, the highest score for a severe impairment such as a hip disarticulation is only 40% WPI. Moreover, even two below knee amputations (or similar injuries) do not result in an impairment of 55% WPI. This is very problematic given the lifetime costs associated with the purchase, maintenance and replacement of one or more prosthetic limbs, as well as the obviously serious challenges to independence that can arise. Rather than recommending a scoring adjustment (which would have no scientific justification given the structure of the AMA guides), we recommend that catastrophic impairment related to ambulatory mobility be determined according to the revised definition 2 (b) presented above.⁵

4.1.5 2 (c) - Blindness

Proposed revision:

2. For the purposes of this Regulation, a catastrophic impairment caused by an accident is,

2 (c). Legal blindness in both eyes due to structural damage to the visual system. Non-organic visual loss (hysterical blindness) is excluded from this definition.

Rationale for revisions of 2 (c):

The Panel agreed that only minor clarifications to the definition were needed. Non-organic visual loss was excluded from this definition because it is not associated with actual physical damage to the visual system.

4.1.6 2 (d) – Traumatic Brain Injury in Adults

Proposed revision:

Two proposed definitions have been developed. The first would apply in the event that the Government accepts the Panel's recommendation to implement interim catastrophic impairment status. The second definition is to be used in the event that the interim status is not implemented.

4.1.6.1 If Interim Catastrophic Impairment Status is Approved

2. For the purposes of this Regulation, a catastrophic impairment caused by an accident is,

2d: Traumatic Brain Injury in Adults (18 years of age or older):

- i. An Insured is granted an interim catastrophic impairment status when accepted for admission to a program of inpatient neurological rehabilitation at a recognized neurological rehabilitation center (List of facilities to be published in a Superintendent Guideline).
- ii. Catastrophic impairment, based upon an evaluation that has been in accordance with published guidelines for a structured GOS-E assessment (*Jennett, B. and Bond, M., Assessment of Outcome After Severe Brain Damage, Lancet i:480, 1975*)⁴⁹, to be:
 - a) Vegetative (VS) after 3 months or
 - b) Severe Disability Upper (SD+) or Severe Disability Lower (SD -) after 6 months, or Moderate Disability Lower (MD-) after one year due to documented brain impairment, provided that the determination has been preceded by a period of inpatient neurological rehabilitation in a recognized rehabilitation center (List of facilities to be published in a Superintendent Guideline).

4.1.6.2 If Interim Catastrophic Impairment Status is not Approved

2d: Traumatic Brain Injury in Adults (18 years of age or older):

The impairment is deemed to be catastrophic, when determined in accordance with published guidelines for a structured GOS-E assessment (*Jennett, B. and Bond, M., Assessment of Outcome After Severe Brain Damage, Lancet i:480, 1975*)⁴⁹, is:

- i. Vegetative (VS) after 3 months, or
- ii. Severe Disability Upper (SD+) or Severe Disability Lower (SD-) after 6 months, or
- iii. Moderate Disability Lower (MD-) after 1 year, provided that the determination has been preceded by a period of inpatient neurological rehabilitation in a recognized

rehabilitation center (List of facilities to be published in a Superintendent Guideline)

Rationale for revisions of 2 (d):

The Panel recommends the use of the Extended Glasgow Outcome Scale (GOS-E) for the determination of catastrophic impairment secondary to brain injury in adults. The GOS-E has strong psychometric properties and it is particularly reliable when a structured interview, standard scoring algorithm and a quality control system are used to monitor its administration and scoring (Appendix 12, section 2).

The GOS-E allows the grading of traumatic brain injuries into one of eight categories that range from death to good recovery. The Panel set the threshold for catastrophic impairment status at Moderate Disability Lower (MD-), as we find that the Moderate Disability Lower (MD-) category best approximates the Severe Disability level that is in use with the GOS under the current SABS. However, the Panel recognized that this finding, made in isolation, might be problematic and consequently stipulated that any finding other than Vegetative must be associated with a preceding period of inpatient neurological rehabilitation. In combination, these features will increase the sensitivity and specificity of the determination, and reduce any variability which might arise from reliance upon the GOSE definitions, when discriminating Moderate (Lower) from lesser levels of impairment. The requirement of a preceding period of inpatient rehabilitation also ensures that the patient has been exposed to and has engaged in an appropriate level of expert rehabilitation before a determination is made. Finally, precluding final assessment of the patient with Moderate Disability Lower (MD-), until one year after onset ensures that the condition has stabilized or is close to a final plateau and that the probability of further recovery to less than the Moderate Disability (Lower) level is unlikely.⁵⁰

The natural history of traumatic head injury suggests that a significant proportion of patients with initially moderate or severe levels of disability will improve during the year following their injury. However, these patients will require substantial rehabilitation during this period to optimize their recovery. Therefore, we recommend that an interim catastrophic impairment status be created to allow these patients to access the necessary level of medical and rehabilitation care.

4.1.7 2 (e) – Other Physical Impairments (not covered by 2(a), 2 (b), 2 (c) or 2 (d))

Proposed definition:

2. For the purposes of this Regulation, a catastrophic impairment caused by an accident is,

2 (e): A physical impairment or combination of physical impairments that, in accordance with the *American Medical Association's Guides to the Evaluation of Permanent Impairment, 4th edition 1993*, (GEPI-4), results in a physical impairment rating of 55 per cent whole person impairment (WPI).

- i. Unless covered by specific rating guidelines within relevant Sections of Chapters 3-13 of GEPI-4, all impairments relatable to non-psychiatric symptoms and syndromes (e.g. functional somatic syndromes, chronic pain syndromes, chronic fatigue syndromes, fibromyalgia syndrome, etc.) that arise from the accident are to be understood to have been incorporated into the weighting of the GEPI-4 physical impairment ratings set out in Chapters 3 – 13.⁵
- ii. With the exception of traumatic brain injury impairments, mental and/or behavioural impairments are excluded from the rating of physical impairments.
- iii. Definition 2(e), including subsections i and ii, cannot be used for a determination of catastrophic impairment until two years after the accident, unless at least three months after the accident, there is a traumatic physical impairment rating of at least 55% WPI and there is no reasonable expectation of improvement to less than 55% WPI.

If Interim Catastrophic Impairment Status is Approved

- iv. Interim catastrophic impairment status is deemed to apply to any patient whose traumatic physical impairment rating is at least 55% WPI, when that determination is made at least three months after the accident date.
- v. Interim catastrophic impairment status ceases to exist as soon as a final determination has been made, in accordance with subsection iii, and in any event no later than two years after onset.

Rationale for revisions of 2 (e):

The Panel reviewed the literature on the validity and reliability of the AMA Guides and found very little scientific literature to support of their use for the determination of catastrophic impairment (Appendix 12, section 1). Moreover, we found no literature supporting the use of a 55% WPI threshold as a cut-point for catastrophic impairment status. However, we note that 55% WPI is the score given to paraplegia, which the Panel agreed was a reasonable exemplar of the catastrophically impaired accident victim. The Panel's literature review suggests that the reliability of the AMA Guides is moderate at best in patients with either low back pain or major trauma (Appendix 12, section 1).⁵ There is evidence that AMA Guides has adequate construct validity in patients with upper extremity injuries and fractures of the lower limb (Appendix 12, section 1).^{66;67;69;95}

The Panel was unable to identify an alternative impairment rating system for physical impairments not covered under definitions 2 (a), 2 (b), 2 (c) or 2 (d). The Panel found no convincing scientific or clinical evidence that earlier or later editions of the AMA Guides offered substantial advantages over the 4th edition. Therefore, based on our collective clinical experience and the scarce available literature on its reliability and validity, we recommend that Chapters 3-13 of the AMA Guides 4th edition be used for the determination of catastrophic impairment

status in patients with physical impairments not covered under definitions 2 (a), 2 (b), 2 (c) or 2 (d).⁵

The Panel recommends that interim status be instituted for individuals who meet the 55% WPI threshold three months or more after the accident. The Panel was aware that patients whose physical impairments are initially of catastrophic severity may not reach their final rehabilitative plateau for many months or even years. Of necessity, therefore, an accurate determination of final outcome should not be made before two years unless there is an unambiguous prognosis. While a two year delay increases the likelihood of accurately identifying patients with permanent catastrophic impairment, it also may preclude timely access to catastrophic impairment benefits. The Panel believes that the interim status will provide the necessary resources to those who need prolonged and substantial rehabilitations services and assistance with re-integration into the community. These services should improve the probability of a catastrophically impaired Insured to make a significant recovery, perhaps to a non-catastrophic impairment level. The goal of instituting interim status is to provide extended access to rehabilitative and attendant care services and thus promote maximal medical recovery, for patients at high risk of a permanent catastrophic impairment.

The Panel agreed that physical and mental or behavioural impairments cannot be combined in any consistent manner using the AMA Guides 4th Edition.⁵ The impairment rating systems for physical and mental/behavioural impairment are not compatible and cannot be combined. Moreover, the Panel found no scientific evidence supporting the reliability and validity of mental/behavioural impairment ratings using the AMA Guides (Chapter 14).⁵ The Panel had difficulty understanding how combinations of physical impairments and psychological conditions that independently do not meet the criteria outlined in the revised version of 2(e) and 2(f) could be equated to a severe injury to the brain or, spinal cord or to blindness. The Panel also had difficulty understanding that combining impairments is a simple additive process. Finally, the Panel did not have the resources to conduct a comprehensive literature review to determine whether a valid and reliable method of combining physical and psychological impairments exists. Research is also needed into identifying the most appropriate threshold WPI score(s) for various psychophysical combinations.

4.1.8 2 (f) – Psychiatric Impairment

Proposed definition:

2. For the purposes of this Regulation, a catastrophic impairment caused by an accident is,

2(f) psychiatric impairment that meets the following criteria:

- i. The post-traumatic psychiatric impairment(s) must arise as a direct result of one or more of the following disorders, when diagnosed in accordance with DSM IV TR criteria: (a) Major Depressive Disorder, (b) Post Traumatic Stress Disorder, (c) a Psychotic Disorder, or (d) such other disorder(s) as may be published within a Superintendent Guideline.

- ii. Impairments due to pain are excluded other than with respect to the extent to which they prolong or contribute to the duration or severity of the psychiatric disorders which may be considered under Criterion (i).
- iii. Any impairment or impairments arising from traumatic brain injury must be evaluated using Section 2(d) or 2(e) rather than this Section.
- iv. Severe impairment(s) are consistent with a Global Assessment of Functioning (GAF) score of 40 or less, after exclusion of all physical and environmental limitations.¹
- v. For the purposes of determining whether the impairment is sufficiently severe as to be consistent to Criterion (iv) - a GAF score of 40 or less - at minimum there must be demonstrable and persuasive evidence that the impairment(s) very seriously compromise independence and psychosocial functioning, such that the Insured Person clearly requires substantial mental health care and support services. In determining the demonstrability and persuasiveness of the evidence, the following generally recognized indicia are relevant:
 - a. Institutionalization;
 - b. Repeated hospitalizations, where the goal and duration are directly related to the provision of treatment of severe psychiatric impairment;
 - c. Appropriate interventions and/or psychopharmacological medications such as: ECT, mood stabilizer medication, neuroleptic medications and/or such other medications that are primarily indicated for the treatment of severe psychiatric disorders;
 - d. Determination of loss of competence to manage finances and property, or Treatment Decisions, or for the care of dependents;
 - e. Monitoring through scheduled in-person psychiatric follow-up reviews at a frequency equivalent to at least once per month.
 - f. Regular and frequent supervision and direction by community-based mental health services, using community funded mental health professionals to ensure proper hygiene, nutrition, compliance with prescribed medication and/or other forms of psychiatric therapeutic interventions, and safety for self or others.

Rationale for revisions of 2 (f):

As stated above, the Panel found no scientific evidence supporting the reliability and validity of mental/behavioural impairment ratings using the AMA Guides 4th Edition (Chapter 14).⁵ Moreover, the Panel noted that Chapter 14 does not specifically address psychological impairment. Rather, it relies heavily of the functional limitations experienced by a patient (in four complex spheres of life) to derive its ratings. Furthermore, the Panel did not find a valid and reliable assessment tool to measure overall psychiatric impairment. The Panel consulted two psychiatrists (Drs. William Gnam and Ram Veluri) to obtain their expert clinical opinion on how to define catastrophic psychiatric impairment.

The Panel recommends that the Superintendent assemble an independent panel of experts to develop a comprehensive list of disorders to be included under criteria 2(f) i. We recommend that the definition must incorporate the Global Assessment of Functioning Scale (GAF) as one of the necessary criteria (Appendix 12, section 4).¹ The GAF has good reliability and face

validity.^{80;84;96} The Panel selected a GAF cut-point of 40 as a threshold for catastrophic impairment because it likely captures individuals with severe psychiatric impairment, whose capacity for living safely within the community is tenuous in the absence of substantial mental health support services.

4.1.9 Clause 6

The Panel unanimously agreed that this definition was to be eliminated because of the redundancy with 2(e).

4.1.10 3 – Traumatic Brain Injury in Children

Proposed definition:

3. Paediatric Traumatic Brain Injury (prior to age 18)^a

- i. A child who sustains a traumatic brain injury is automatically deemed to have sustained a catastrophic impairment automatically provided that either one of the following criteria (a or b) is met on the basis of traumatic brain injury sustained in the accident in question:
 - a. In-patient admission to a Level I trauma centre with positive findings on CT/MRI scan indicating intracranial pathology that is the result of the accident, including but not limited to intracranial contusions or haemorrhages, diffuse axonal injury, cerebral edema, midline shift, or pneumocephaly; or
 - b. Inpatient admission to a publically funded rehabilitation facility (i.e. an Ontario Association of Children Rehabilitation Facility or equivalent) for a program of brain injury rehabilitation or Ontario Association of Children Rehab Facilities);

Paediatric catastrophic impairment on the basis of traumatic brain injury is any one of the following criteria:

- ii. At any time after the first 3 months, the child's level of neurological function does not exceed the KOSCHI Category of Vegetative (*Crouchman M et al., A practical outcome scale for paediatric head injury. Archives of Disease in Childhood. 2001; 84:1204*)¹⁸: The child is breathing spontaneously and may have sleep/wake cycles. He may have non-purposeful or reflex movements of limbs or eyes. There is no evidence of ability to communicate verbally or non-verbally or to respond to commands.
- iii. At any time after the first 6 months, the child's level of function does not exceed the KOSCHI Category of Severe (*Crouchman M et al., A practical outcome scale for paediatric head injury. Archives of Disease in Childhood. 2001; 84:1204*)¹⁸: (1) The child is at least intermittently able to move part of the body/eyes to command or make purposeful spontaneous movements; for example, a confused child pulling at nasogastric tube, lashing out at caregivers, or rolling over in bed. (2) May be fully conscious and able to communicate but not yet able to carry out any self care activities such as feeding. (3) Severe Impairment implies a continuing high level of dependency, but the child can assist in daily activities; for

example, can feed self or walk with assistance or help to place items of clothing. (4) Such a child is fully conscious but may still have a degree of post-traumatic amnesia.

- iv. At any time after the first 9 months^b, the child's level of function remains seriously altered such that the child is for the most part not age appropriately independent and requires supervision/actual help for physical, cognitive and/or behavioural impairments for the majority of his/her waking day.

Rationale for revisions of 3:

The final outcome for a brain injured child may not become apparent for years or even decades after injury (i.e. in the case of the very young child). The Panel was aware of the inadvisability of substantially delaying a final determination of catastrophic impairment in children, on the sole basis of achieving reasonable certainty of outcome. The Panel weighed the arguments in favour of and against creating a set of criteria of unknown reliability and validity that would permit an early determination

The Panel noted that a long period of waiting for a final determination could impose medically unnecessary stressors on parents and families already challenged with coping with a child suffering from a serious traumatic brain injury. Notwithstanding the above, the Panel was also aware that false positive determinations of catastrophic impairment were not in the best interest of the child, or a reasonable burden for the Insurer.

The Panel noted that certain objective markers of serious acute traumatic brain injury are correlated to poor outcome. Such markers are also indicative of a need for extended use of rehabilitation resources, in order to reduce the eventual impairment. The Panel concluded that the problems associated with a false-positive determination through early identification of catastrophic impairment were far outweighed by the benefits to all catastrophically impaired children and their families.

In particular, the Panel noted that radiological features of serious brain injury, in association with admission to a Level I hospital are good clinical predictors of a prolonged recovery and poor outcome. Similarly, given the careful screening of patients at paediatric rehabilitation centers, it is believed that admission for brain injury rehabilitation is a sensitive and specific indicator of high risk of poor outcome. Using these criteria for an automatic determination of catastrophic impairment will provide injured children access to early and necessary health care.

The Panel acknowledges that the underlying premise, that use of these criteria for automatic determination will be highly advantageous and have a limited and acceptable 'downside', is an assumption that must be tested, and the results monitored for a period of time.

For those children who do not fall within the automatic determination criteria, an early determination based upon clinical status would still be important. The natural course of the condition suggests that most improvement occurs early. A child who is still Vegetative at 3 months or still Severe at 6 months, is very unlikely to ever recover to an independent level of function. Similarly, it is the opinion of the Panel that children showing serious impairments and

disabilities including a significant delay in maturation despite at least 9 months of recovery have a poor prognosis. The cut-point of nine months was arbitrarily selected by the Panel and it is important to note that a later cut-point would further reduce the likelihood of a false positive determination.

Having set out criteria for automatic determination, the Panel then focused on determinations that would require direct or chart-based clinical evaluations. The Panel agreed that the standard tools used to evaluate traumatic brain injury in adults (e.g., Glasgow Coma Scale and Glasgow outcome Scale, and the AMA Guides) are not appropriate for head injuries in children.

The Panel considered recommending the King's Outcome Scale for Childhood Head Injury (KOSCHI), a modified GOS adapted to children. However, the scientific evidence on the psychometric properties of the KOSCHI is preliminary and does not support its use as the sole basis of determination at this time. The data supporting its construct validity is preliminary and its inter-examiner reliability is poor to moderate.^{11;18} The Panel also observed that the reviewed studies on the reliability of the KOSCHI used examiners that were either inexperienced clinicians or examiners who would not be involved in making a determination of catastrophic impairment in Ontario.^{11;18} Therefore, the Panel recommends that an inter-examiner reliability study be conducted with experienced paediatric neurologists and rehabilitation medicine specialists in Ontario.

The Panel recommends that (until the results of an inter-examiner reliability study are available) the Vegetative and Severe Categories of KOSCHI be used, with the time thresholds of 3 months and 6 months respectively. The Panel felt that the Moderate Category of KOSCHI could not be used without modification because it may be liable to misclassification of children. The Panel therefore drew on its clinical expertise and experience to modify the Moderate KOSCHI category.

As for those few children with subtle injuries that will become serious sources of impairment only with the fullness of time, meaning a delayed manifestation sometimes spanning decades in the case of infants whose impairments of cognition, emotion or behavioural regulation may not fully express themselves until late teen years, optimally the direct paediatric evaluative route should remain available, along with the adult criteria pertaining to traumatic brain injury, until age 21. However this is a question of policy and outside the Panel's direct mandate.

4.1.11 Challenges to be resolved

The Panel met several challenges throughout the course of its deliberations. In the section below, the Panel describes these challenges and makes recommendations on how to address them.

i. Combining physical and psychological impairment: The Panel did not have the resources to conduct a comprehensive review of the literature to determine whether valid and reliable methods of combining physical and psychological impairments exist. The Panel recommends that the Superintendent convenes an Expert Panel of clinicians and scientists to systematically

review the literature and determine whether a valid and reliable methodology is available to rate and combine physical and psychological impairment ratings.

ii. Method to rate physical and psychiatric impairments in the paediatric population: The Panel made recommendations for the determination of physical (2(e)) and psychiatric (2(f)) impairments in adults. However, we could not indentify a clinically and scientifically sound method to accomplish the same in the paediatric population. Therefore, the Panel recommends that the Superintendent convene a Paediatric Expert Panel of clinicians and scientists to examine and recommend a valid and reliable method of assessment for the paediatric population.

iii. Classification of traumatic Head Injury in the paediatric population: As mentioned in section 4.1.10, the Panel considered recommending the King's Outcome Scale for Childhood Head Injury (KOSCHI), a modified GOS adapted to children. However, the scientific evidence on the psychometric properties of the KOSCHI is preliminary and does not support its use as the sole basis of determination at this time. The Panel recommends that an inter-examiner reliability study be conducted with experienced clinicians in Ontario. The Panel also recommends that the Superintendent re-evaluates definition 3, once the results of the study are available.

iv. Premorbidity and Age: A significant minority of the population involved in car accidents have prior chronic illnesses and impairments; the same is true of senior citizens. The Panel notes that these persons may be particularly vulnerable to the effects of injury, leading to loss of capacity to remain independent within the home or otherwise enjoy a reasonable quality of life. The Panel acknowledges the need to address the question of premorbid vulnerability from illness or aging. The Panel recommends that the Superintendent considers the development of an additional criterion or means of adjustment to an existing criterion, to address special circumstances in which significant but sub-catastrophic threshold impairments arising from car accident injuries, when superimposed on prior and significant impairment from chronic illness and/or age-related health conditions, create disproportionately adverse outcomes.

5. Acknowledgements

The Panel is indebted to Dr. Heather Shearer for the extraordinary rigor of her work and her exceptional commitment to the Panel. The Chair also thanks Drs. Maja Stupar and Craig Jacobs for their invaluable assistance with the literature review.

We also thank Drs. William Gnam and Ram Veluri for their assistance in the development definition 2(f).

Finally, the Panel thanks Sivan Raz and Willie Handler for their administrative support and technical knowledge of the current SABS.

^a The Panel notes that brain maturation may continue through to a child's 21st birthday. Consequently, impairment of higher centres of the brain such as the Executive functions of social integration, insight, judgment, goal setting and behavioural integration may not be effectively discernible from typical features of the immature teenage brain

prior to that time. Hence, the Panel believes that there is a reasonable scientific basis for a 21st birthday cut-off for the paediatric traumatic brain injury criterion.

^b By structuring the definition as we have, we make it possible for the Superintendent or a subsequent paediatric working panel to elect a different cut-off date for definition iii, such as 9 months or 12 months.

Appendix 1

BASELINE - SURVEY 1

A.1 Baseline Survey

The purpose of the baseline survey was to understand the views and beliefs of the Expert Panel with regards to the current definition of catastrophic impairment. The Expert Panel was contacted on December 5, 2010. Panel members were asked to complete the survey within 5 days of receipt. The results were discussed at the first meeting of the Expert Panel on December 10, 2010. Both quantitative and qualitative responses were collected using the electronic survey. Panel members were asked to rate their level of agreement with a statement on a five point Likert scale with options ranging from strongly agree to strongly disagree. Panel Members were asked “Please explain why you agree or disagree with the above statement”. These qualitative responses were grouped according to response on the Likert scale question. The results of survey 1 are presented below.

A.1.1 Question 1. Do you agree with the following guiding principle statement regarding the Expert Panel's work?

“The panel is being asked to base its deliberation and develop its recommendations on emerging scientific knowledge and judgment. Therefore, the work of the expert panel will give precedence to valid and reliable scientific evidence. In the absence of valid and reliable scientific evidence, the panel will inform its deliberation and develop its recommendations based on the “best practices” used in other Canadian and International jurisdictions. Finally, if both scientific evidence and best practices are not available, the panel will rely on expert opinions to inform its work. The chair reserves the right to seek opinions from individuals outside of the expert panel to inform the work of the panel.”

The Expert Panel reached consensus with 100% of members supporting the guiding principle.

A.1.2 Question 2. As an expert clinician or scientist, please describe what 'catastrophic impairment' means to you.

In summary, the Expert Panel described a catastrophic impairment as an extreme physical or psychological impairment that is expected to be permanent and severely impact an individual's ability to function independently and be financially independent. It is the opinion of the Panel that catastrophic impairment is not a medical concept; it is a legal concept.

A.1.3 Question 3. The current definition of “catastrophic impairment” includes paraplegia or quadriplegia. Do you agree that an individual who is injured in a traffic collision and becomes paraplegic or quadriplegic is catastrophically impaired?

The Expert Panel reached consensus (75%) and agreed that paraplegia or quadriplegia are catastrophic impairments.

A.1.7 Question 4. The current definition of “catastrophic impairment” includes the amputation of an arm or leg or another impairment causing the total and permanent loss of use of an arm or a leg. Do you agree that an individual who is injured in a traffic collision and suffers arm or leg amputation or another impairment causing the total and permanent loss of use of an arm or a leg is catastrophically impaired?

The Expert Panel reached consensus (75%) and agreed that the amputation of an arm or leg or another impairment causing the total and permanent loss of use of an arm or a leg is a catastrophic impairment.

A.1.7 Question 5. The current definition of “catastrophic impairment” includes the total loss of vision in both eyes. Do you agree that an individual who is injured in a traffic collision and becomes completely blind in both eyes is catastrophically impaired?

The Expert Panel reached consensus (75%) and agreed that the total loss of vision in both eyes is a catastrophic impairment.

A.1.6 Question 6. The current definition of “catastrophic impairment” includes a brain impairment that results in a score of 9 or less on the Glasgow Coma Scale (as published in Jennett, B. and Teasdale, G., Management of Head Injuries, Contemporary Neurology Series, Volume 20, F.A. Davis Company, Philadelphia, 1981), according to a test administered within a reasonable period of time after the accident by a person trained for that purpose. Do you agree that an individual who is injured in a traffic collision and has a score of a score of 9 or less on the Glasgow Coma Scale as administered by a trained professional within a reasonable period of time after the accident is catastrophically impaired?

The Expert Panel did not reach consensus on whether a Glasgow Coma Scale of 9 or less is a useful measure of catastrophic impairment related to a brain injury. In fact, the Panel was evenly split between the levels of agreement.

A.1.7 Question 7. The current definition of “catastrophic impairment” includes a brain impairment that results in a score of 2 (vegetative) or 3 (severe disability) on the Glasgow Outcome Scale, (as published in Jennett, B. and Bond, M., Assessment of Outcome After Severe Brain Damage, Lancet i:480, 1975,) according to a test administered more than six months after the accident by a person trained for that purpose. Do you agree that an individual who is injured in a traffic collision and has a score of 2 (vegetative) or 3 (severe disability) on the Glasgow Outcome Scale is catastrophically impaired (according to a test administered more than six months after the accident by a person trained for that purpose)?

The Expert Panel did not reach consensus on whether a Glasgow Outcome Scale a score of 2 (vegetative) or 3 (severe disability) is a useful measure of catastrophic impairment related to

a brain injury. As with the Glasgow Come Scale, the Panel was evenly split between the levels of agreement.

A.1.8 Question 8. The current definition of “catastrophic impairment” includes an impairment or combination of impairments that, in accordance with the American Medical Association's (AMA) Guides to the Evaluation of Permanent Impairment, 4th edition, 1993, results in 55 per cent or more impairment of the whole person. Do you agree that an individual who is injured in a traffic collision and has a score of 55% or more is catastrophically impaired (according the AMA's Guides to the Evaluation of Permanent Impairment, 4th edition, 1993)?

The Expert Panel did not reach consensus on whether the American Medical Association's (AMA) Guides to the Evaluation of Permanent Impairment, 4th edition, 1993 (55 per cent or more impairment) is a useful measure of catastrophic impairment related to a brain injury.

A.1.9 Question 9. The current definition of “catastrophic impairment” includes an impairment that, in accordance with the American Medical Association's Guides to the Evaluation of Permanent Impairment, 4th edition, 1993, results in a class 4 impairment (marked impairment) or class 5 impairment (extreme impairment) due to mental or behavioural disorder. Do you agree that an individual who is injured in a traffic collision and has a class 4 impairment (marked impairment) or class 5 impairment (extreme impairment) due to mental or behavioural disorder is catastrophically impaired (according the AMA's Guides to the Evaluation of Permanent Impairment, 4th edition, 1993)?

The Expert Panel did not reach consensus on whether the American Medical Association's (AMA) Guides to the Evaluation of Permanent Impairment, 4th edition, 1993 (class 4 impairment (marked impairment) or class 5 impairment (extreme impairment) due to mental or behavioural disorder) is a useful measure of catastrophic impairment related to a brain injury.

A.1.10 Question 10. The current definition of “catastrophic impairment” states that if an injured individual is under the age of 16 years at the time of the accident and none of the Glasgow Coma Scale, the Glasgow Outcome Scale or the American Medical Association's Guides to the Evaluation of Permanent Impairment, 4th edition, 1993, referred to above can be applied by reason of the age of the insured person then the definition presented in Questions 6-9 apply to an insured person who is under the age of 16 years. Do you agree that the definitions of catastrophic impairment presented in Questions 6-9 (GCS, GOS, AMA Guides 4th Edition) apply to an insured person who is under the age of 16?

The Expert Panel did not reach consensus on whether the definitions presented in questions 6-9 apply to an insured person who is under the age of 16. The Panel was evenly split in their levels of agreement.

A.1.12 Question 11. The current definition of “catastrophic impairment” states that the American Medical Association's Guides to the Evaluation of Permanent Impairment, 4th edition, 1993 do not apply in respect of an insured person who sustains an impairment as a

result of an accident unless, a physician or, in the case of an impairment that is only a brain impairment, either a physician or a neuropsychologist states in writing that the insured person's condition is unlikely to cease to be a catastrophic impairment; or two years have elapsed since the accident. Do you agree with the definition of catastrophic impairment presented above?

The Expert Panel did not reach consensus on whether the American Medical Association's (AMA) Guides to the Evaluation of Permanent Impairment, 4th edition, 1993 do not apply in respect of an insured person who has reached maximum medical improvement or two years have elapsed since the accident as a useful measure of catastrophic impairment related to a brain injury.

A.1.12 Question 12. The current definition of “catastrophic impairment” states that an impairment that is sustained by an insured person but is not listed in the American Medical Association's Guides to the Evaluation of Permanent Impairment, 4th edition, 1993 is deemed to be the impairment that is listed in that document and that is most analogous to the impairment sustained by the insured person. Do you agree with the definition of catastrophic impairment presented above?

The Expert Panel did not reach consensus on whether the American Medical Association's (AMA) Guides to the Evaluation of Permanent Impairment, 4th edition, 1993 definition of catastrophic impairment listed in the document is analogous to the sustained impairment as a useful measure of catastrophic impairment related to a brain injury.

A.1.13 Question 13. Please provide any recommendations for improvement to the operational definition of catastrophic impairment. Support your recommendation with scientific evidence if it is available. This question only required qualitative responses, which can be found in below.

The Expert Panel noted that the current SABS definition of catastrophic impairment needs to be revised to improve the accuracy of the determination, the timing of the determination and clarifying issues related to causation.

RESPONSES TO SURVEY 1:

QUESTION 1

Do you agree with the following guiding principle statement regarding the Expert Panel's work?

“The panel is being asked to base its deliberation and develop its recommendations on emerging scientific knowledge and judgment. Therefore, the work of the expert panel will give precedence to valid and reliable scientific evidence. In the absence of valid and reliable scientific evidence, the panel will inform its deliberation and develop its recommendations based on the “best practices” used in other Canadian and International jurisdictions. Finally, if both scientific evidence and best practices are not available, the panel will rely on expert opinions to inform its

work. The chair reserves the right to seek opinions from individuals outside of the expert panel to inform the work of the panel.”

Please explain why you agree or disagree with the above statement.

Answer Options & Responses:

Strongly Agree: (4/8 responses)

Agree: (4/8 responses)

Neither Agree nor Disagree: (0/8 responses)

Disagree: (0/8 responses)

Strongly Disagree: (0/8 responses)

QUESTION 2

As an expert clinician or scientist, please describe what does 'catastrophic impairment' means to you.

QUESTION 3

The current definition of “catastrophic impairment” includes paraplegia or quadriplegia. Do you agree that an individual who is injured in a traffic collision and becomes paraplegic or quadriplegic is catastrophically impaired?

Please explain why you agree or disagree with the above statement.

Answer Options & Responses:

Strongly Agree: (6/8 responses)

Agree: (0/8 responses)

Neither Agree nor Disagree: (2/8 responses)

Disagree: (0/8 responses)

Strongly Disagree: (0/8 responses)

QUESTION 4

The current definition of “catastrophic impairment” includes the amputation of an arm or leg or another impairment causing the total and permanent loss of use of an arm or a leg.

Do you agree that an individual who is injured in a traffic collision and suffers arm or leg amputation or another impairment causing the total and permanent loss of use of an arm or a leg is catastrophically impaired?

Please explain why you agree or disagree with the above statement.

Answer Options & Responses:

Strongly Agree: (4/8 responses)

Agree: (2/8 responses)

Neither Agree nor Disagree: (1/8 responses)

Disagree: (1/8 responses)

Strongly Disagree: (0/8 responses)

QUESTION 5

The current definition of “catastrophic impairment” includes the total loss of vision in both eyes. Do you agree that an individual who is injured in a traffic collision and becomes completely blind in both eyes is catastrophically impaired?
Please explain why you agree or disagree with the above statement.

Answer Options & Responses:

Strongly Agree: (5/8 responses)

Agree: (2/8 responses)

Neither Agree nor Disagree: (1/8 responses)

Disagree: (0/8 responses)

Strongly Disagree: (0/8 responses)

QUESTION 6

The current definition of “catastrophic impairment” includes a brain impairment that results in a score of 9 or less on the Glasgow Coma Scale (as published in Jennett, B. and Teasdale, G., Management of Head Injuries, Contemporary Neurology Series, Volume 20, F.A. Davis Company, Philadelphia, 1981), according to a test administered within a reasonable period of time after the accident by a person trained for that purpose.

Do you agree that an individual who is injured in a traffic collision and has a score of a score of 9 or less on the Glasgow Coma Scale as administered by a trained professional within a reasonable period of time after the accident is catastrophically impaired?

Please explain why you agree or disagree with the above statement.

Answer Options & Responses:

Strongly Agree: (2/8 responses)

Agree: (1/8 responses)

Neither Agree nor Disagree: (2/8 responses)

Disagree: (2/8 responses)

Strongly Disagree: (1/8 responses)

QUESTION 7

The current definition of “catastrophic impairment” includes a brain impairment that results in a score of 2 (vegetative) or 3 (severe disability) on the Glasgow Outcome Scale, (as published in Jennett, B. and Bond, M., Assessment of Outcome After Severe Brain Damage, Lancet i:480, 1975,) according to a test administered more than six months after the accident by a person trained for that purpose.

Do you agree that an individual who is injured in a traffic collision and has a score of 2 (vegetative) or 3 (severe disability) on the Glasgow Outcome Scale is catastrophically impaired (according to a test administered more than six months after the accident by a person trained for that purpose)?

Please explain why you agree or disagree with the above statement.

Answer Options & Responses:

Strongly Agree: (1/8 responses)

Agree: (2/8 responses)

Neither Agree nor Disagree: (2/8 responses)

Disagree: (1/8 responses)

Strongly Disagree: (2/8 responses)

QUESTION 8

The current definition of “catastrophic impairment” includes an impairment or combination of impairments that, in accordance with the American Medical Association's (AMA) Guides to the Evaluation of Permanent Impairment, 4th edition, 1993, results in 55 per cent or more impairment of the whole person.

Do you agree that an individual who is injured in a traffic collision and has a score of 55% or more is catastrophically impaired (according the AMA's Guides to the Evaluation of Permanent Impairment, 4th edition, 1993)?

Please explain why you agree or disagree with the above statement.

Answer Options & Responses:

Strongly Agree: (1/8 responses)

Agree: (2/8 responses)

Neither Agree nor Disagree: (4/8 responses)

Disagree: (1/8 responses)

Strongly Disagree: (0/8 responses)

QUESTION 9

The current definition of “catastrophic impairment” includes an impairment that, in accordance with the American Medical Association's Guides to the Evaluation of Permanent Impairment, 4th edition, 1993, results in a class 4 impairment (marked impairment) or class 5 impairment (extreme impairment) due to mental or behavioural disorder.

Do you agree that an individual who is injured in a traffic collision and has a class 4 impairment (marked impairment) or class 5 impairment (extreme impairment) due to mental or behavioural disorder is catastrophically impaired (according the AMA's Guides to the Evaluation of Permanent Impairment, 4th edition, 1993)?

Please explain why you agree or disagree with the above statement.

Answer Options & Responses:

Strongly Agree: (1/8 responses)

Agree: (2/8 responses)

Neither Agree nor Disagree: (4/8 responses)

Disagree: (1/8 responses)

Strongly Disagree: (0/8 responses)

QUESTION 10

The current definition of “catastrophic impairment” states that if an injured individual is under the age of 16 years at the time of the accident and none of the Glasgow Coma Scale, the Glasgow Outcome Scale or the American Medical Association's Guides to the Evaluation of Permanent Impairment, 4th edition, 1993, referred to above can be applied by reason of the age of the insured person then the definition presented in Questions 6-9 apply to an insured person who is under the age of 16 years.

Do you agree that the definitions of catastrophic impairment presented in Questions 6-9 apply to an insured person who is under the age of 16?

Please explain why you agree or disagree with the above statement.

Answer Options & Responses:

Strongly Agree: (0/8 responses)

Agree: (3/8 responses)

Neither Agree nor Disagree: (1/8 responses)

Disagree: (1/8 responses)

Strongly Disagree: (2/8 responses)

QUESTION 11

The current definition of “catastrophic impairment” states that the American Medical Association's Guides to the Evaluation of Permanent Impairment, 4th edition, 1993 do not apply in respect of an insured person who sustains an impairment as a result of an accident unless, a physician or, in the case of an impairment that is only a brain impairment, either a physician or a neuropsychologist states in writing that the insured person's condition is unlikely to cease to be a catastrophic impairment; or two years have elapsed since the accident.

Do you agree with the definition of catastrophic impairment presented above?

Please explain why you agree or disagree with the above statement.

Answer Options & Responses:

Strongly Agree: (0/8 responses)

Agree: (2/8 responses)

Neither Agree nor Disagree: (2/8 responses)

Disagree: (3/8 responses)

Strongly Disagree: (1/8 responses)

QUESTION 12

The current definition of “catastrophic impairment” states that an impairment that is sustained by an insured person but is not listed in the American Medical Association's Guides to the Evaluation of Permanent Impairment, 4th edition, 1993 is deemed to be the impairment that is listed in that document and that is most analogous to the impairment sustained by the insured person.

Do you agree with the definition of catastrophic impairment presented above?

Please explain why you agree or disagree with the above statement.

Answer Options & Responses:

Strongly Agree: (1/8 responses)

Agree: (1/8 responses)

Neither Agree nor Disagree: (2/8 responses)

Disagree: (2/8 responses)

Strongly Disagree: (2/8 responses)

QUESTION 13

Please provide any recommendations for improvement to the operational definition of catastrophic impairment. Support your recommendation with scientific evidence if it is available.

Appendix 2

DEFINITIONS - SURVEY 2

At the first meeting of the Expert Panel, it was recommended that deliberations be conducted with a “top down” approach to determine if any of the current SABS definitions of catastrophic impairment are inadequate and should be eliminated. Therefore, a second survey was designed to seek the Expert Panel’s opinion on whether the current definitions of catastrophic impairment need to be eliminated, revised or kept intact. The second survey was e-mailed to the Expert Panel on December 16, 2010 and to return it by January 5, 2011. Panel Members were reminded to recommend a “replacement criteria/method of determination” if they believed that one of the existing criteria should be eliminated.

Both quantitative and qualitative responses were collected using the electronic survey. Quantitative responses were recorded using a choice of three options of (1)“Yes, it is adequate and does not require revision”; (2)“Yes, it is adequate but it requires revision”; and (3)“No, it is not adequate and should be eliminated”. If option (1) was chosen, Panel Members were asked to continue to the next survey question. If either option (2) or (3) were chosen, Panel Members were asked to proceed to the text box below the question and “Please suggest evidence-based revisions to the definition”. The level of consensus among the Expert Panel is presented below. The results of Survey 2 are located below.

A.2.1 Question 1.

The current definition of “catastrophic impairment” includes paraplegia or quadriplegia. Do you think this definition should be eliminated, revised or kept intact? Please select the most appropriate answer from the drop down menu.

The Expert Panel reached consensus (100%) that the definition of “catastrophic impairment” which includes paraplegia or quadriplegia is adequate but it requires revision.

A.2.2 Question 2.

The current definition of “catastrophic impairment” includes the amputation of an arm or leg or another impairment causing the total and permanent loss of use of an arm or a leg. Do you think this definition should be eliminated, revised or kept intact? Please select the most appropriate answer from the drop down menu.

The Expert Panel agreed (100%) that the definition of “catastrophic impairment” which includes the amputation of an arm or leg or another impairment causing the total and permanent loss of use of an arm or a leg was adequate. However, the Panel recommends that the definition requires revisions.

A.2.3 Question 3.

The current definition of “catastrophic impairment” includes the total loss of vision in both eyes. Do you think this definition should be eliminated, revised or kept intact? Please select the most appropriate answer from the drop down menu.

The Expert Panel reached consensus (87.5%) that definition of “catastrophic impairment” which includes the total loss of vision in both eyes is adequate but it required revision.

A.2.4 Question 4.

The current definition of “catastrophic impairment” includes a brain impairment that results in a score of 9 or less on the Glasgow Coma Scale (as published in Jennett, B. and Teasdale, G., Management of Head Injuries, Contemporary Neurology Series, Volume 20, F.A. Davis Company, Philadelphia, 1981), according to a test administered within a reasonable period of time after the accident by a person trained for that purpose.

Do you think this definition should be eliminated, revised or kept intact? Please select the most appropriate answer from the drop down menu.

The Expert Panel reached consensus (75%) that the use of the Glasgow Coma Scale as a measure of catastrophic impairment was not adequate and should be eliminated.

A.2.5 Question 5.

The current definition of “catastrophic impairment” includes a brain impairment that results in a score of 2 (vegetative) or 3 (severe disability) on the Glasgow Outcome Scale, as published in Jennett, B. and Bond, M., Assessment of Outcome After Severe Brain Damage, Lancet i:480, 1975, according to a test administered more than six months after the accident by a person trained for that purpose.

Do you think this definition should be eliminated, revised or kept intact? Please select the most appropriate answer from the drop down menu.

The Expert Panel did agree that the definition of “catastrophic impairment” which includes a brain impairment that results in a score of 2 (vegetative) or 3 (severe disability) on the Glasgow Outcome Scale was adequate (87.5%). A majority of Panel Members stated that the definition requires revisions.

A.2.6 Question 6.

The current definition of “catastrophic impairment” includes an impairment or combination of impairments that, in accordance with the American Medical Association's Guides to the Evaluation of Permanent Impairment, 4th edition, 1993, results in 55 per cent or more impairment of the whole person.

Do you think this definition should be eliminated, revised or kept intact? Please select the most appropriate answer from the drop down menu.

The Expert Panel reached consensus that the American Medical Association's Guides to the Evaluation of Permanent Impairment, 4th edition, 1993, results in 55 per cent or more impairment of the whole person should be kept. However, the Panel indicated that the definition requires revisions.

A.2.7 Question 7.

The current definition of “catastrophic impairment” includes an impairment that, in accordance with the American Medical Association's Guides to the Evaluation of Permanent Impairment,

4th edition, 1993, results in a class 4 impairment (marked impairment) or class 5 impairment (extreme impairment) due to mental or behavioural disorder.

Do you think this definition should be eliminated, revised or kept intact? Please select the most appropriate answer from the drop down menu.

The Expert Panel did not reach consensus on whether to keep, revise, or eliminate the definition of catastrophic impairment which results in a class 4 impairment (marked impairment) or class 5 impairment (extreme impairment) due to mental or behavioural disorder. The definition was discussed at the Expert Panel meeting that took place on February 10, 2011.

A.2.8 Question 8.

The current definition of “catastrophic impairment” states that if an injured individual is under the age of 16 years at the time of the accident and none of the Glasgow Coma Scale, the Glasgow Outcome Scale or the American Medical Association's *Guides to the Evaluation of Permanent Impairment*, 4th edition, 1993, referred to above can be applied by reason of the age of the insured person then the definition presented in Questions 7-11 apply to an insured person who is under the age of 16 years.

Do you think this definition should be eliminated, revised or kept intact? Please select the most appropriate answer from the drop down menu.

The Expert Panel did not reach consensus of whether the current definition of catastrophic impairment using the Glasgow Coma Scale, Glasgow Outcome Scale, 55% whole person impairment and class 4 impairment or class 5 impairment due to mental or behavioural disorder be applied to an injured individual under the age of 16 years should be kept intact, revised, or eliminated. This definition will be discussed at an upcoming meeting of the Panel.

A.2.9 Question 9.

The current definition of “catastrophic impairment” states that the American Medical Association's *Guides to the Evaluation of Permanent Impairment*, 4th edition, 1993 do not apply in respect of an insured person who sustains an impairment as a result of an accident unless, a physician or, in the case of an impairment that is only a brain impairment, either a physician or a neuropsychologist states in writing that the insured person's condition is unlikely to cease to be a catastrophic impairment; or two years have elapsed since the accident.

Do you think this definition should be eliminated, revised or kept intact? Please select the most appropriate answer from the drop down menu.

The Expert Panel reached consensus (85.7%) that the current definition of catastrophic impairment with respect to an insured person who has reached maximum medical improvement or two years have elapsed since the accident should be kept. However, Panel Members also indicated that the definition needs to be revised.

A.2.10 Question 10.

The current definition of “catastrophic impairment” states that an impairment that is sustained by an insured person but is not listed in the American Medical Association's *Guides to the Evaluation of Permanent Impairment*, 4th edition, 1993 is deemed to be the impairment that is

listed in that document and that is most analogous to the impairment sustained by the insured person.

Do you think this definition should be eliminated, revised or kept intact? Please select the most appropriate answer from the drop down menu.

The Expert Panel did not reach consensus on whether the American Medical Association's (AMA) Guides to the Evaluation of Permanent Impairment, 4th edition, 1993 definition of catastrophic impairment listed in the document is analogous to the sustained impairment should be eliminated, revised or kept intact. In fact, the Panel was equally split between revising the definition and eliminating it. This definition will be discussed at an upcoming meeting of the Panel.

RESPONSES TO SURVEY 2

QUESTION 1

The current definition of “catastrophic impairment” includes paraplegia or quadriplegia. Do you believe this definition should be eliminated, revised or kept intact?

Answer Options & Responses:

Yes, it is adequate as is and it does not require revision: (0/8 responses)

Yes, it is adequate but it requires revisions: (8/8 responses)

No, it is not adequate and should be eliminated: (0/8 responses)

QUESTION 2

The current definition of “catastrophic impairment” includes the amputation of an arm or leg or another impairment causing the total and permanent loss of use of an arm or a leg. Do you believe this definition should be eliminated, revised or kept intact?

Answer Options & Responses:

Yes, it is adequate as is and it does not require revision: (3/8 responses)

Yes, it is adequate but it requires revisions: (5/8 responses)

No, it is not adequate and should be eliminated: (0/8 responses)

QUESTION 3

The current definition of “catastrophic impairment” includes the total loss of vision in both eyes. Do you believe this definition should be eliminated, revised or kept intact?

Answer Options & Responses:

Yes, it is adequate as is and it does not require revision: (1/8 responses)

Yes, it is adequate but it requires revisions: (7/8 responses)

No, it is not adequate and should be eliminated: (0/8 responses)

QUESTION 4

The current definition of “catastrophic impairment” includes a brain impairment that results in a score of 9 or less on the Glasgow Coma Scale (as published in Jennett, B. and Teasdale, G., Management of Head Injuries, Contemporary Neurology Series, Volume 20, F.A. Davis Company, Philadelphia, 1981), according to a test administered within a reasonable period of time after the accident by a person trained for that purpose. Do you believe this definition should be eliminated, revised or kept intact?

Answer Options & Responses:

Yes, it is adequate as is and it does not require revision: (0/8 responses)

Yes, it is adequate but it requires revisions: (2/8 responses)

No, it is not adequate and should be eliminated: (6/8 responses)

QUESTION 5

The current definition of “catastrophic impairment” includes a brain impairment that results in a score of 2 (vegetative) or 3 (severe disability) on the Glasgow Outcome Scale, as published in Jennett, B. and Bond, M., Assessment of Outcome After Severe Brain Damage, Lancet i:480, 1975, according to a test administered more than six months after the accident by a person trained for that purpose. Do you believe this definition should be eliminated, revised or kept intact?

Answer Options & Responses:

Yes, it is adequate as is and it does not require revision: (2/8 responses)

Yes, it is adequate but it requires revisions: (5/8 responses)

No, it is not adequate and should be eliminated: (1/8 responses)

QUESTION 6

The current definition of “catastrophic impairment” includes an impairment or combination of impairments that, in accordance with the American Medical Association's Guides to the Evaluation of Permanent Impairment, 4th edition, 1993, results in 55 per cent or more impairment of the whole person. Do you believe this definition should be eliminated, revised, or kept intact?

Answer Options & Responses:

Yes, it is adequate as is and it does not require revision: (2/8 responses)

Yes, it is adequate but it requires revisions: (4/8 responses)

No, it is not adequate and should be eliminated: (1/8 responses)

QUESTION 7

The current definition of “catastrophic impairment” includes an impairment that, in accordance with the American Medical Association's Guides to the Evaluation of Permanent Impairment, 4th edition, 1993, results in a class 4 impairment (marked impairment) or class 5 impairment (extreme impairment) due to mental or behavioural disorder. Do you believe this definition should be eliminated, revised or kept intact?

Answer Options & Responses:

Yes, it is adequate as is and it does not require revision: (1/8 responses)

Yes, it is adequate but it requires revisions: (4/8 responses)

No, it is not adequate and should be eliminated: (2/8 responses)

QUESTION 8

The current definition of “catastrophic impairment” states that if an injured individual is under the age of 16 years at the time of the accident and none of the Glasgow Coma Scale, the Glasgow Outcome Scale or the American Medical Association's Guides to the Evaluation of Permanent Impairment, 4th edition, 1993, referred to above can be applied by reason of the age of the insured person then the definition presented Questions 4-8 apply to an insured person who is under the age of 16 years. Do you believe this definition should be eliminated, revised or kept intact?

Answer Options & Responses:

Yes, it is adequate as is and it does not require revision: (1/8 responses)

Yes, it is adequate but it requires revisions: (2/8 responses)

No, it is not adequate and should be eliminated: (5/8 responses)

QUESTION 9

The current definition of “catastrophic impairment” states that the American Medical Association's Guides to the Evaluation of Permanent Impairment, 4th edition, 1993 do not apply in respect of an insured person who sustains an impairment as a result of an accident unless, a physician or, in the case of an impairment that is only a brain impairment, either a physician or a neuropsychologist states in writing that the insured person's condition is unlikely to cease to be a catastrophic impairment; or two years have elapsed since the accident. Do you believe this definition should be eliminated, revised or kept intact?

Answer Options & Responses:

Yes, it is adequate as is and it does not require revision: (2/8 responses)

Yes, it is adequate but it requires revisions: (4/8 responses)

No, it is not adequate and should be eliminated: (1/8 responses)

QUESTION 10

The current definition of “catastrophic impairment” states that an impairment that is sustained by an insured person but is not listed in the American Medical Association's Guides to the Evaluation of Permanent Impairment, 4th edition, 1993 is deemed to be the impairment that is listed in that document and that is most analogous to the impairment sustained by the insured person. Do you believe this definition should be eliminated, revised or kept intact?

Answer Options & Responses:

Yes, it is adequate as is and it does not require revision: (0/8 responses)

Yes, it is adequate but it requires revisions: (4/8 responses)

No, it is not adequate and should be eliminated: (4/8 responses)

Appendix 3

SURVEY 3 - Proposed revisions to subsection 2(e)

Round 1 Subgroup revisions for subsections 2 (e) and (f)

In order to develop recommendations for amendments to portions of the existing definition of catastrophic impairment the Expert Panel was divided into two subgroups. Subgroup 1 is charged with making initial recommendations for the following definitions: 2 (b). Amputation; 2 (d). Glasgow Coma Scale; 2 (e). AMA Guides 4th Edition (55% WPI); Maximum medical improvement (5); and the Analogy clause (6). Subgroup 2 is charged with making recommendations for: 2 (a) Paraplegia/quadruplegia; 2 (c) Loss of vision; 2 (d) Glasgow Outcome Scale; 2 (f) AMA Guides 4th Edition (mental/behavioral); 3 & 4 Pediatric.

The Expert Panel follows a Delphi methodology. Thus, each subgroup was asked to make recommendations for changes to portions of the definition. This was done using an electronic survey. Both Subgroups were emailed a link to Survey Monkey on January 24, 2011. Panel Members were asked to complete the survey by day end of January 25, 2011. Subgroup 1 was asked to make recommendations for changes to sub-section 2 (e) and Subgroup 2 reviewed sub-section 2 (f). The suggestions for each sub-section were incorporated where possible. The revised definitions were emailed to the Subgroups in Survey 4.

The Panel members were asked whether or not they agreed with the revised definition. Panel Members that disagreed were asked to suggest revisions to be used in the next round of revisions. The responses to these surveys are presented below.

Subgroup 1.

For the purposes of this Regulation, a catastrophic impairment caused by an accident is,...

Proposed revision:

2(e) subject to subsections (4), (5) and (6), an impairment or combination of impairments caused by the accident that, in accordance with the American Medical Association's *Guides to the Evaluation of Permanent Impairment*, 4th edition, 1993, results in a physical impairment rating of 55 per cent or more of the whole person.

Subgroup 1 did not reach consensus on the propose revision. In summary, Subgroup members indicated that the definition needed to be more specific in regards to: (1) the exclusion of mental/behavioural disorders; (2) pre-existing conditions should be considered in the rating of impairment when augmented by the injury; and (3) the timing of determination needs to be clarified when there is no likelihood of improvement, or the condition is very likely to deteriorate.

Subgroup 2.

For the purposes of this Regulation, a catastrophic impairment caused by an accident is,...

Proposed revision:

2 (f) subject to subsections (4), (5) and (6), an impairment caused by the accident that, in accordance with the American Medical Association's *Guides to the Evaluation of Permanent Impairment*, 4th edition, 1993, results in a class 4 impairment (marked impairment) or class 5 impairment (extreme impairment) due to mental or behavioral disorder.

Subgroup 2 was split between agreeing (3/5) and disagreeing (2/5) with the proposed definition. In summary, Subgroup 2 recommended that following specific criteria be incorporated: (1) only pain disorders with psychogenic features may be considered; (2) change the wording to "caused by or augmented by" the accident to account for pre-existing conditions worsened by the injury; (3) the definition needs to include clear markers of psychiatric impairment; and (4) remove the wording "caused by the accident" in the proposed definition.

RESPONSES TO SURVEY 3

1. Current definition

For the purposes of this Regulation, a catastrophic impairment caused by an accident is,...

2(e) subject to subsections (4), (5) and (6), an impairment or combination of impairments that, in accordance with the American Medical Association's *Guides to the Evaluation of Permanent Impairment*, 4th edition, 1993, results in 55 per cent or more impairment of the whole person

2. Issues to consider

- i. The Expert Panel recommended revising the current definition (2(e)).
- ii. The scientific evidence suggests that the AMA guides have a moderate level of reliability for conditions low back pain and major trauma. However, great variations in rating exist between raters for lumbar spine radiculopathy, radial neuropathy and total hip replacement. Weak to moderate evidence for the validity of the AMA guides for the rating of upper and lower extremity fractures.
- iii. Should physical and psychological impairment ratings be combined? The Guides do not allow for physical and psychological impairments to be combined.
- iv. Apportionment: To what extent is the impairment attributable to the accident? Do we need to specify in the revision that the final rating needs to be adjusting for any pre-existing impairment;
- v. Pain without organic origin is not ratable by the guides. The 4th edition does not provide a rating for pain.

Proposed Revision

2(e) subject to subsections (4), (5) and (6), an impairment or combination of impairments **caused by the accident** that, in accordance with the American Medical Association's *Guides to the Evaluation of Permanent Impairment*, 4th edition, 1993, results in a **physical** impairment rating of 55 per cent or more of the whole person

Do you agree with this definition?

If you do not agree, please suggest revisions in the space below.

Answers & Responses:

Yes: (2/4 responses)

No: (2/4 responses)

Proposed revisions to subsection 2(f):

1. Current definition

For the purposes of this Regulation, a catastrophic impairment caused by an accident is,

...

2 (f) subject to subsections (4), (5) and (6), an impairment that, in accordance with the American Medical Association's *Guides to the Evaluation of Permanent Impairment*, 4th edition, 1993, results in a class 4 impairment (marked impairment) or class 5 impairment (extreme impairment) due to mental or behavioral disorder.

2. Issues to consider

- i. The Expert Panel recommended revising the current definition (2(f)).
- ii. The scientific evidence suggests that the AMA guides have a moderate level of reliability for conditions low back pain and major trauma. However, great variations in rating exist between raters for lumbar spine radiculopathy, radial neuropathy and total hip replacement. Weak to moderate evidence for the validity of the AMA guides for the rating of upper and lower extremity fractures.
- iii. Should physical and psychological impairment ratings be combined? The Guides do not allow for physical and psychological impairments to be combined.
- iv. Apportionment: To what extent is the impairment attributable to the accident? Do we need to specify in the revision that the final rating needs to be adjusting for any pre-existing impairment;
- v. Pain without organic origin is not ratable by the guides. The 4th edition does not provide a rating for pain.

Proposed Revision

2 (f) subject to subsections (4), (5) and (6), an impairment **caused by the accident** that, in accordance with the American Medical Association's *Guides to the Evaluation of Permanent Impairment*, 4th edition, 1993, results in a class 4 impairment (marked impairment) or class 5 impairment (extreme impairment) due to mental or behavioral disorder.

Do you agree with this definition?

If you do not agree, please suggest revisions in the space below.

Answers & Responses:

Yes: (3/5 responses)

No: (2/5 responses)

Appendix 4

SURVEY 4 - Proposed revisions to subsection 2(e) – second revision

Round 2 Subgroup revisions for subsection 2 (e) and (f)

The purpose of Survey 4 was to have Panel Members vote on the revisions of sub-sections 2 (e) and 2(f) that followed Survey 3. Thus, both Subgroups were provided an opportunity for a second round of revisions to sub-sections 2 (e) and 2 (f) using a Survey Monkey questionnaire. The revised version of 2 (e) was emailed to Subgroup 1 on February 3rd, 2011. The recommendations were incorporated where possible and the revised definition was emailed to the entire Panel for review as Survey 5.

Subgroup 2 was emailed the revised version of 2 (f) on February 5th, 2011. The recommendations were incorporated where possible and the revised definition was presented at the Expert Panel meeting on February 10th, 2011 for discussion.

This round of surveys had the same format as Survey 3. The responses to Survey 4 are presented below.

Subgroup One:

For the purposes of this Regulation, a catastrophic impairment caused by an accident is,...

Proposed revision:

2(e) subject to subsections (4), (5) and (6), an impairment or combination of impairments caused by or augmented by the accident that, in accordance with the American Medical Association's *Guides to the Evaluation of Permanent Impairment*, 4th edition, 1993, results in a physical impairment rating of 55 per cent whole person impairment (WPI).

A provisional catastrophic impairment status may be established no sooner than six months after the accident. A final catastrophic impairment determination may be established no earlier than two years since the accident.

The catastrophic impairment decision must indicate that there is no reasonable probability of improvement to less than 55%; if there is a rating of 55% impairment or more, and the person is deteriorating or very likely to deteriorate, a catastrophic impairment decision should be made (without having to wait for stabilization).

Do you agree with this definition?

Members of Subgroup 1 reached consensus (75%) that the revised definition was adequate. The Subgroup further recommended that the definition explicitly exclude mental and behavioural disorders and pain disorders from 2 (e).

Subgroup Two:

For the purposes of this Regulation, a catastrophic impairment caused by an accident is,...

Proposed revision:

2 (f) subject to subsections (4), (5) and (6), an impairment caused by or augmented by the accident that, in accordance with the American Medical Association's *Guides to the Evaluation of Permanent Impairment*, 4th edition, 1993, results in a class 4 impairment (marked impairment) or class 5 impairment (extreme impairment) due to mental or behavioral disorder.

A provisional catastrophic impairment status may be established no sooner than six months after the accident. A final catastrophic impairment determination may be established no earlier than two years since the accident.

The catastrophic impairment decision must indicate that there is no reasonable probability of improvement to less than a class 4 impairment (marked impairment) due to mental or behavioral disorder, and the person is deteriorating or very likely to deteriorate, a catastrophic impairment decision should be made (without having to wait for stabilization).

Do you agree with this definition?

Subgroup 2 did not reach consensus on this revised version of 2 (f). Members of Subgroup 2 recommended the following revisions: (1) with regards to chronic pain, only pain disorders of psychogenic nature should be considered; (2) clear psychiatric markers need to be included for the determination of catastrophic impairment; (3) review the proposed timing of determination to ensure adequate funding; (4) remove the wording "caused by the accident" in the proposed definition.

The revised version of 2 (f) described above was extensively discussed at the February 10, 2011 meeting of the Expert Panel. The Panel discussed the validity, reliability and predictive accuracy of Chapter 14 of the AMA Guides 4th edition. Given the lack of scientific support for its validity, reliability and predictive accuracy, the Expert Panel agreed that Chapter 14 of the AMA Guides 4th Editions should no longer be used for the determination of catastrophic impairment related to mental/behavioral disorders. The Panel agreed that the determination of catastrophic impairment related to mental/behavioral disorders must be based on clearly defined psychiatric markers of severe psychiatric illness that may develop following a traffic collision. An alternative definition was proposed by Dr. Arthur Ameis. Dr. Côté asked Dr. Ameis to consult with his psychiatric colleagues to develop a definition that would satisfy the medical threshold for catastrophic impairment related to mental disorders that follow a traffic collision. Dr. Ameis consulted two psychiatrists (Drs. William Gnam and Ram Veluri) to develop 2 (f). The consultation led to the development of revised definition presented below:

2(f) subject to subsections (4), (5) and (6), an impairment that is associated with a severe post-traumatic psychiatric illness and meets the following criteria

- (i) [Causation and Diagnostic criteria]: for the purposes of determination of catastrophic psychiatric impairment, the impairment must arise as a direct result of one or more of

the following : (a) Major Depressive Disorder, (b) Post Traumatic Stress Disorder, or (c) such other conditions as may be published within the Guideline

- (ii) [Severity criteria]: The determination must cite indicia of severe mental illness generally accepted by psychiatrists as markedly compromising independence and psychosocial functioning, including those published within the Guideline. For the purposes of determining impairment and severity, physical (or environmental) limitations are to be excluded; for the purposes of this determination all forms of pain issues are to be considered to be encompassed within the overall psychiatric conditions
- (iii) [Determination guidelines]: The evaluation of causation, diagnosis and severity must be made by a psychiatrist designated by the Superintendent for that purpose, and must adhere to generally accepted psychiatric standards for such determinations as well as to guidelines published within a Guideline as set out for this purpose.
- (iv) [Provisional Determination]: a provisional rather than final determination may be made when, in the opinion of the designated psychiatrist, the insured has not been provided with and/or has not completed a reasonable number of trials of appropriate treatment. Guidelines regarding extended funding after a provisional determination is made will be set out in the Guidelines.

Superintendent Guidelines for evaluation of 2(f) psychiatric illness as a result of the accident in question

A determination must be made by a psychiatrist, on the basis of a preponderance of evidence of severity, citing a Requirement for generally accepted indicia of management of severe psychiatric impairment, including where possible those indicia set out below:

- I: Institutionalization
- II: One or more of the following forms of intervention
 - (a) Repeated hospitalizations of substantial duration necessitated by a need for psychiatric treatment
 - (b) ECT
 - (c) Mood stabilizers, Anti-Psychotic and/or other major psychiatric medications
- III: Ongoing supervision and direction by public health agencies providing community support systems including psychiatric medical and nursing services and other forms of monitoring and support in order for the individual to remain within the community (i.e. CCAC, ACT teams)
- IV: Psychiatric determination of loss of competence for Property or Treatment Decision Making
- V: Requirement for involvement of CAS

- VI: Requirement for daily supervision and direction to ensure proper hygiene, nutrition, medication and other forms of psychiatric therapeutic compliance, and safety for self or others
- VII: Requirement for monitoring by a psychiatrist through scheduled reviews at a frequency equivalent to at least once per month

RESPONSES TO SURVEY 4

Proposed Revision

For the purposes of this Regulation, a catastrophic impairment caused by an accident is,

...

2(e) subject to subsections (4), (5) and (6), an impairment or combination of impairments caused by or augmented by the accident that, in accordance with the American Medical Association's *Guides to the Evaluation of Permanent Impairment*, 4th edition, 1993, results in a physical impairment rating of 55 per cent whole person impairment (WPI).

A provisional catastrophic impairment status may be established no sooner than six months after the accident. A final catastrophic impairment determination may be established no earlier than two years since the accident.

The catastrophic impairment decision must indicate that there is no reasonable probability of improvement to less than 55%; if there is a rating of 55% impairment or more, and the person is deteriorating or very likely to deteriorate, a catastrophic impairment decision should be made (without having to wait for stabilization).

Do you agree with this definition?

If you do not agree, please suggest revisions in the space below.

Answers & Responses:

Yes: (3/4 responses)

No: (1/4 responses)

Proposed revisions to subsection 2(f) – second revision:

Proposed Revision

For the purposes of this Regulation, a catastrophic impairment caused by an accident is,

...

2 (f) subject to subsections (4), (5) and (6), an impairment caused by or augmented by the accident that, in accordance with the American Medical Association's *Guides to the Evaluation of Permanent Impairment*, 4th edition, 1993, results in a class 4 impairment (marked impairment) or class 5 impairment (extreme impairment) due to mental or behavioral disorder.

A provisional catastrophic impairment status may be established no sooner than six months after the accident. A final catastrophic impairment determination may be established no earlier than two years since the accident.

The catastrophic impairment decision must indicate that there is no reasonable probability of improvement to less than a class 4 impairment (marked impairment) due to mental or behavioral disorder, and the person is deteriorating or very likely to deteriorate, a catastrophic impairment decision should be made (without having to wait for stabilization).

Do you agree with this definition?

If you do not agree, please suggest revisions in the space below.

Answers & Responses:

Yes: (2/5 responses)

No: (3/5 responses)

Appendix 5

Survey 5 - Proposed revisions to subsection 2(e)

The recommendations submitted by Subgroup 1 in Survey 4 were used to revise sub-section 2 (e). The revised version of 2 (e) was emailed to the entire Expert Panel on February 8th, 2011. The group members were asked to respond by day end on February 9th, 2011. The responses are presented below.

Proposed Revision

For the purposes of this Regulation, a catastrophic impairment caused by an accident is,

...

2(e) subject to subsections (4), (5) and (6), an impairment or combination of impairments caused by or augmented by the accident that, in accordance with the American Medical Association's Guides to the Evaluation of Permanent Impairment, 4th edition, 1993, results in a physical impairment rating of 55 per cent whole person impairment (WPI). A physical impairment excludes pain-related impairments not covered in relevant chapters of the American Medical Association's Guides to the Evaluation of Permanent Impairment, 4th edition. A physical impairment also excludes mental and behavioral impairments.

A provisional catastrophic impairment status may be established no sooner than six months after the accident. A final catastrophic impairment determination may be established no earlier than two years since the accident.

The catastrophic impairment decision must indicate that there is no reasonable probability of improvement to less than 55%; if there is a rating of 55% impairment or more, and the person is deteriorating or very likely to deteriorate, a catastrophic impairment decision should be made (without having to wait for stabilization).

Do you agree with this definition?

The Expert Panel did not reach consensus with this round of full Panel voting. Panel members had very detailed recommendations. The relevant recommendations led to the development of 2(e) which was tested in Survey 6.

RESPONSES TO SURVEY 5

Full Panel Vote

Proposed Revision

For the purposes of this Regulation, a catastrophic impairment caused by an accident is,

...

2(e) subject to subsections (4), (5) and (6), an impairment or combination of impairments caused by or augmented by the accident that, in accordance with the American Medical Association's Guides to the Evaluation of Permanent Impairment, 4th edition, 1993, results in a physical impairment rating of 55 per cent whole person impairment (WPI). A physical impairment excludes pain-related impairments not covered in relevant chapters of the American Medical

Association's Guides to the Evaluation of Permanent Impairment, 4th edition. A physical impairment also excludes mental and behavioral impairments.

A provisional catastrophic impairment status may be established no sooner than six months after the accident. A final catastrophic impairment determination may be established no earlier than two years since the accident.

The catastrophic impairment decision must indicate that there is no reasonable probability of improvement to less than 55%; if there is a rating of 55% impairment or more, and the person is deteriorating or very likely to deteriorate, a catastrophic impairment decision should be made (without having to wait for stabilization).

Do you agree with this definition?

If you do not agree, please suggest revisions in the space below.

Answers & Responses:

Yes: (3/8 responses)

No: (5/8 responses)

Appendix 6

SURVEY 6 - Proposed revisions to subsection 2(e) and 2(f)

In Survey 6, the Expert Panel was asked to vote on the revised version of 2(e) and 2(f). The entire Panel was asked for their votes and recommendations on February 18, 2011. The group members were asked to respond by noon, February 22, 2011. The responses are presented below.

Proposed Revision of 2 (e)

For the purposes of this Regulation, a catastrophic impairment caused by an accident is,...

An impairment or combination of physical impairments that, in accordance with the American Medical Association's Guides to the Evaluation of Permanent Impairment, 4th edition, 1993, results in a traumatic physical impairment rating of 55 per cent whole person impairment (WPI). For rating traumatic physical impairment, functional somatic syndromes, chronic pain syndromes, and other pain-related impairments must be excluded unless covered by specific rating guidelines within relevant chapters of the American Medical Association's Guides to the Evaluation of Permanent Impairment, 4th edition (Chapters 3-13). With the exception of traumatic neuropsychiatric impairments, mental and/or behavioural impairments are excluded from the rating of physical impairments.

A provisional or final catastrophic impairment determination each require that there is a current physical impairment rating of 55% or more and that there is no probability of improvement to less than 55%.

A provisional catastrophic impairment status may be established no sooner than six months after the accident. A final catastrophic impairment determination may be established no earlier than two years after the accident, unless the condition is deteriorating, or expected to deteriorate, and there is no probability of eventual improvement to less than 55%.

The Expert Panel did reach consensus (75%) with this round of full Panel voting. Panel members had very detailed recommendations as well as requesting some minor wording changes. The relevant recommendations led to the revision of some wording. A vote was taken at the Panel meeting on February 24, 2011 for approval of the newly changed definition. The Expert Panel did reach consensus (87.5%) and the revised version was adopted. Please find below the final revised version of 2 (e):

For the purposes of this Regulation, a catastrophic impairment caused by an accident is,...

A physical impairment or combination of physical impairments that, in accordance with the American Medical Association's Guides to the Evaluation of Permanent Impairment, 4th edition, 1993, results in a physical impairment rating of 55 per cent whole person impairment (WPI). Unless covered by specific rating guidelines within relevant Sections of Chapters 3-13 of GEPI-4, all impairments relatable to non-psychiatric symptoms and syndromes (e.g. functional somatic syndromes, chronic pain syndromes, chronic fatigue syndromes,

Fibromyalgia Syndrome, etc.) that arise from the accident are to be understood to have been incorporated into the GEPI-4 physical impairment ratings set out in Chapters 3 – 13. With the exception of traumatic brain injury impairments, mental and/or behavioural impairments are excluded from the rating of physical impairments.

A provisional or final catastrophic impairment determination each require that there is a current physical impairment rating of 55% WPI or more and that there is no probability of improvement to less than 55% WPI.

A provisional catastrophic impairment status may be established no sooner than three months after the accident. A final catastrophic impairment determination may be established no earlier than two years after the accident, unless the condition is deteriorating, or expected to deteriorate, and it is unlikely to improve to less than 55% WPI.

Proposed Revision of 2 (f):

2(f) subject to subsections (4), (5) and (6), an impairment that is associated with a severe post-traumatic psychiatric illness and meets the following criteria

(i) [Causation and Diagnostic criteria]: for the purposes of determination of catastrophic psychiatric impairment, the impairment must arise as a direct result of one or more of the following : (a) Major Depressive Disorder, (b) Post Traumatic Stress Disorder, or (c) such other conditions as may be published within the Guideline

(ii) [Severity criteria]: The determination must cite indicia of severe mental illness generally accepted by psychiatrists as markedly compromising independence and psychosocial functioning, including those published within the Guideline. For the purposes of determining impairment and severity, physical (or environmental) limitations are to be excluded; for the purposes of this determination all forms of pain issues are to be considered to be encompassed within the overall psychiatric conditions

(iii) [Determination guidelines]: The evaluation of causation, diagnosis and severity must be made by a psychiatrist designated by the Superintendent for that purpose, and must adhere to generally accepted psychiatric standards for such determinations as well as to guidelines published within a Guideline as set out for this purpose.

(iv) [Provisional Determination]: a provisional rather than final determination may be made when, in the opinion of the designated psychiatrist, the insured has not been provided with and/or has not completed a reasonable number of trials of appropriate treatment. Guidelines regarding extended funding after a provisional determination is made will be set out in the Guidelines.

Superintendent Guidelines for evaluation of 2(f) psychiatric illness as a result of the accident in question

A determination must be made by a psychiatrist, on the basis of a preponderance of evidence

of severity, citing a Requirement for generally accepted indicia of management of severe psychiatric impairment, including where possible those indicia set out below:

I: Institutionalization

II: One or more of the following forms of intervention

- (a) Repeated hospitalizations of substantial duration necessitated by a need for psychiatric treatment
- (b) ECT
- (c) Mood stabilizers, Anti-Psychotic and/or other major psychiatric medications

III: Ongoing supervision and direction by public health agencies providing community support systems including psychiatric medical and nursing services and other forms of monitoring and support in order for the individual to remain within the community (i.e. CCAC, ACT teams)

IV: Psychiatric determination of loss of competence for Property or Treatment Decision Making

V: Requirement for involvement of CAS

VI: Requirement for daily supervision and direction to ensure proper hygiene, nutrition, medication and other forms of psychiatric therapeutic compliance, and safety for self or others

VII: Requirement for monitoring by a psychiatrist through scheduled reviews at a frequency equivalent to at least once per month

The Expert Panel did not reach consensus with this round of full Panel voting, and was in fact split equally. Panel members had very detailed recommendations as well as requesting some wording changes. The relevant recommendations led to the development of a revised definition of 2(f) which was voted on by the full Panel in Survey 7.

RESPONSES TO SURVEY 6

Full Panel Vote

Proposed Revision for 2 (e):

For the purposes of this Regulation, a catastrophic impairment caused by an accident is,...

An impairment or combination of physical impairments that, in accordance with the American Medical Association's Guides to the Evaluation of Permanent Impairment, 4th edition, 1993, results in a traumatic physical impairment rating of 55 per cent whole person impairment (WPI). For rating traumatic physical impairment, functional somatic syndromes, chronic pain syndromes, and other pain-related impairments must be excluded unless covered by specific rating guidelines within relevant chapters of the American Medical Association's

Guides to the Evaluation of Permanent Impairment, 4th edition (Chapters 3-13). With the exception of traumatic neuropsychiatric impairments, mental and/or behavioural impairments are excluded from the rating of physical impairments.

A provisional or final catastrophic impairment determination each require that there is a current physical impairment rating of 55% or more and that there is no probability of improvement to less than 55%.

A provisional catastrophic impairment status may be established no sooner than six months after the accident. A final catastrophic impairment determination may be established no earlier than two years after the accident, unless the condition is deteriorating, or expected to deteriorate, and there is no probability of eventual improvement to less than 55%.

Do you agree with this definition?

If you do not agree, please suggest revisions in the space below.

Answers & Responses:

Yes: (6/8 responses)

No: (2/8 responses)

Proposed Revision for 2 (f):

2(f) subject to subsections (4), (5) and (6), an impairment that is associated with a severe post-traumatic psychiatric illness and meets the following criteria

- (v) [Causation and Diagnostic criteria]: for the purposes of determination of catastrophic psychiatric impairment, the impairment must arise as a direct result of one or more of the following : (a) Major Depressive Disorder, (b) Post Traumatic Stress Disorder, or (c) such other conditions as may be published within the Guideline
- (vi) [Severity criteria]: The determination must cite indicia of severe mental illness generally accepted by psychiatrists as markedly compromising independence and psychosocial functioning, including those published within the Guideline. For the purposes of determining impairment and severity, physical (or environmental) limitations are to be excluded; for the purposes of this determination all forms of pain issues are to be considered to be encompassed within the overall psychiatric conditions
- (vii) [Determination guidelines]: The evaluation of causation, diagnosis and severity must be made by a psychiatrist designated by the Superintendent for that purpose, and must adhere to generally accepted psychiatric standards for such determinations as well as to guidelines published within a Guideline as set out for this purpose..
- (viii)[Provisional Determination]: a provisional rather than final determination may be made when, in the opinion of the designated psychiatrist, the insured has not been provided with and/or has not completed a reasonable number of trials of appropriate treatment.

Guidelines regarding extended funding after a provisional determination is made will be set out in the Guidelines.

Superintendent Guidelines for evaluation of 2(f) psychiatric illness as a result of the accident in question

A determination must be made by a psychiatrist, on the basis of a preponderance of evidence of severity, citing a Requirement for generally accepted indicia of management of severe psychiatric impairment, including where possible those indicia set out below

I: Institutionalization

II: One or more of the following forms of intervention

(a) Repeated hospitalizations of substantial duration necessitated by a need for psychiatric treatment

(b) ECT

(c) Mood stabilizers, Anti-Psychotic and/or other major psychiatric medications

III: Ongoing supervision and direction by public health agencies providing community support systems including psychiatric medical and nursing services and other forms of monitoring and support in order for the individual to remain within the community (i.e. CCAC, ACT teams)

IV: Psychiatric determination of loss of competence for Property or Treatment Decision Making

V: Requirement for involvement of CAS

VI: Requirement for daily supervision and direction to ensure proper hygiene, nutrition, medication and other forms of psychiatric therapeutic compliance, and safety for self or others

VII: Requirement for monitoring by a psychiatrist through scheduled reviews at a frequency equivalent to at least once per month

Do you agree with this definition?

If you do not agree, please suggest revisions in the space below.

Answers & Responses:

Yes: (4/8 responses)

No: (4/8 responses)

Appendix 7

Survey 7 - Proposed revisions to subsection 2(f), (a), & (b)

In Survey 7, the Expert Panel was asked to vote on the revised version of 2 (f) described in section 4.1.8. They were also asked to vote on revised definitions of 2 (a) and (b). The entire Panel was asked for their votes and recommendations on March 7, 2011. The group members were asked to respond by noon, March 9, 2011. The results of the survey are presented below.

The Expert Panel did reach consensus (87.5%) with this round of full Panel voting for the proposed revision of 2 (f), as presented as the last revision provided in section 4.1.8. Panel members provided recommendations as well as requesting some wording changes. The relevant revisions were made during the March 10, 2011 Expert Panel meeting. The Panel then voted on the newly revised definition of 2 (f) and unanimous consensus was reached to accept the new definition. Please find below the final revised version of 2 (f):

2(f) subject to subsections (4), (5) and (6), Severe post-traumatic psychiatric impairment, as determined in accordance with a Superintendent's Guideline.

Superintendent Guideline for 2(f)

For the purposes of this determination, all of the following criteria must be met:

- vi. The post-traumatic psychiatric impairment(s) must arise as a direct result of one or more of the following disorders, when diagnosed in accordance with DSM IV TR criteria: (a) Major Depressive Disorder, (b) Post Traumatic Stress Disorder, (c) a Psychotic Disorder, (d) such other disorder(s) as may be published within the Guideline.
- vii. Impairments due to pain are excluded other than with respect to the extent to which they prolong or contribute to the severity of the psychiatric disorders which may be considered under Criterion (i).
- viii. Any impairments arising secondary to traumatic brain injury are excluded.
- ix. Severe impairment(s) are consistent with a Global Assessment of Functioning (GAF) (REF – DSM 4 TR) score of 40 or less, after exclusion of all physical and environmental limitations.
- x. For the purposes of determining whether the impairment is sufficiently severe as to be consistent to Criterion (iv) - a GAF score of 40 or less - at minimum there must be demonstrable and persuasive evidence that the impairment(s) very seriously compromise independence and psychosocial functioning, such that the Insured Person clearly requires substantial mental health care and support services. In determining the demonstrability and persuasiveness of the evidence, the following generally recognized indicia are relevant in determining the demonstrability and persuasiveness of the evidence:
 1. Institutionalization;
 2. Repeated hospitalizations, where the goal and duration are directly related to the provision of treatment of severe psychiatric impairment;

3. Appropriate interventions and/or psychopharmacological medications such as: ECT, mood stabilizer medication, neuroleptic medications and/or such other medications that are primarily indicated for the treatment of severe psychiatric disorders;
4. Determination of loss of competence to manage finances and property, or Treatment Decisions, or for the care of dependents;
5. Monitoring through scheduled in-person psychiatric follow-up reviews at a frequency equivalent to at least once per month.
6. Regular and frequent supervision and direction by community-based mental health services, using community funded mental health professionals to ensure proper hygiene, nutrition, compliance with prescribed medication and/or other forms of psychiatric therapeutic interventions, and safety for self or others.

The definition for 2 (a) was also presented in Survey 7:

Proposed Revision of 2 (a):

(2) For the purposes of this Regulation, a catastrophic impairment caused by an accident is,

(a) paraplegia or quadriplegia that results in a class A (no motor or sensory function is preserved in the sacral segments S4-S5), B (sensory but not motor function is preserved below the neurological level and includes the sacral segments S4-S5) or C (motor function is preserved below the neurological level, and more than half of key muscles below the neurological level have a muscle grade less than 3 or more) impairment according to the American Spinal Injury Association Standards (Marino RJ et al. ASIA Neurological Standards Committee 2002. International standards for neurological classification of spinal cord injury. J Spinal Cord Med 2003; 26(Suppl 1): S50–S56.)

The Expert Panel did reach consensus (75%) with this round of full Panel voting for the proposed revision of 2 (a). Panel members provided recommendations as well as requesting some wording changes. The relevant revisions were discussed during the March 10, 2011 Expert Panel meeting and the revised definition was emailed to the Expert Panel via Survey 8.

The revised definition for 2 (b) was presented to the Panel in Survey 7. Please find below the revised version of 2 (b).

Proposed Revision of 2 (b):

(2) For the purposes of this Regulation, a catastrophic impairment caused by an accident is,

Severe impairment of anatomy, strength, range of motion, and/or sensation in any extremity in accordance with a Superintendent's Guideline

Guideline:

In order for a severe traumatic limb impairment to be considered a catastrophic impairment, the following criteria must be met:

1. Substantial rehabilitation therapy has been required, including a period of admission to a public rehabilitation hospital AND one of the following:
 - a. Amputation of one lower extremity at a transtibial or higher level
 - b. Post-traumatic impairments of upper extremity function arising from extensive or critical structural damage and/or amputation, and which, other than through reliance upon a functional prosthetic device, results in the total and permanent loss of use of the extremity for all instrumental and personal activities of daily life.

The Expert Panel did reach consensus (75%) with this round of full Panel voting for this definition. Despite this, Panel members provided valuable feedback and recommendations which directed revisions to the definition. The revised definition for 2 (b) was voted on by Expert Panel members in Survey 9.

RESPONSES TO SURVEY 7

Full Panel Vote

QUESTION 1 – 2 (f)

Proposed Revision

2(f): subject to subsections (4), (5) and (6), Severe post-traumatic psychiatric impairment, as determined in accordance with a Superintendent's Guideline.

Superintendent Guideline for 2(f)

For the purposes of this determination, all of the following criteria must be met:

- (i) The post-traumatic psychiatric impairment(s) must arise as a direct result of one or more of the following Axis I disorders, when diagnosed in accordance with DSM IV TR criteria: (a) Major Depressive Disorder, (b) Post Traumatic Stress Disorder, (c) a Psychotic Disorder, (d) such other disorder(s) as may be published within an Appendix to this Guideline.
- (ii) Impairments due to pain are excluded other than with respect to the extent to which they prolong or contribute to the severity of the psychiatric disorders which may be considered under Criterion (i).
- (iii) Any impairments arising secondary to traumatic brain injury are excluded.
- (iv) Severe impairment(s) are consistent with a Global Assessment of Functioning (GAF) score of 40 or less, after exclusion of all physical and environmental limitations.
- (v) For the purposes of determining whether the impairment is sufficiently severe as to be consistent to Criterion (iv) - a GAF score of 40 or less - at minimum there must be demonstrable and persuasive evidence that the impairment(s) very seriously compromise independence and psychosocial functioning, such that the Insured Person clearly requires

substantial mental health care and support services. In determining the demonstrability and persuasiveness of the evidence, preference should be given to citing generally recognized indicia of severe psychiatric impairment such as:

1. Institutionalization
2. Repeated hospitalizations, where the goal and duration are directly related to the provision of treatment of severe psychiatric impairment;
3. Appropriate interventions and/or psychopharmacological medications such as: ECT, mood stabilizer medication, neuroleptic medications and/or such other medications that are primarily indicated for the treatment of severe psychiatric disorders.
4. Determination of loss of competence to manage finances and property, or Treatment Decisions, or for the care of dependents.
5. Monitoring through scheduled in-person psychiatric follow-up reviews at a frequency equivalent to at least once per month.
6. Regular and frequent supervision and direction by community-based mental health services, using community funded mental health professionals to ensure proper hygiene, nutrition, compliance with prescribed medication and/or other forms of psychiatric therapeutic interventions, and safety for self or others.

Do you agree with this definition?

If you do not agree, please suggest revisions in the space below

Answer Options & Responses:

Yes: (7/8 responses)

No: (1/8 responses)

QUESTION 2 - 2 (a)

Proposed Revision

(2) For the purposes of this Regulation, a catastrophic impairment caused by an accident is,

(a) paraplegia or quadriplegia that results in a class A (no motor or sensory function is preserved in the sacral segments S4-S5), B (sensory but not motor function is preserved below the neurological level and includes the sacral segments S4-S5) or C (motor function is preserved below the neurological level, and more than half of key muscles below the neurological level have a muscle grade less than 3 or more) impairment according to the American Spinal Injury Association Standards (Marino RJ et al. ASIA Neurological Standards Committee 2002. International standards for neurological classification of spinal cord injury. J Spinal Cord Med 2003; 26(Suppl 1): S50–S56.)

Do you agree with this definition?

If you do not agree, please suggest revisions in the space below

Answer Options & Responses:

Yes: (6/8 responses)

No: (2/8 responses)

QUESTION 3 – 2 (b)

Proposed Revision

(2) For the purposes of this Regulation, a catastrophic impairment caused by an accident is,

Severe impairment of anatomy, strength, range of motion, and/or sensation in any extremity in accordance with a Superintendent's Guideline

Guideline:

In order for a severe traumatic limb impairment to be considered a catastrophic impairment, the following criteria must be met:

1. Substantial rehabilitation therapy has been required, including a period of admission to a public rehabilitation hospital AND one of the following:
 - a. Amputation of one lower extremity at a transtibial or higher level
 - b. Post-traumatic impairments of upper extremity function arising from extensive or critical structural damage and/or amputation, and which, other than through reliance upon a functional prosthetic device, results in the total and permanent loss of use of the extremity for all instrumental and personal activities of daily life.

Do you agree with this definition?

If you do not agree, please suggest revisions in the space below

Answer Options & Responses:

Yes: (6/8 responses)

No: (2/8 responses)

Appendix 8

Survey 8 - Proposed revisions to subsection 2(a)

In Survey 8, the Expert Panel was asked to vote on the revised version of 2 (a). The suggested revisions to the definition were made during the March 10, 2011 Expert Panel meeting. The entire Panel was asked for their votes and recommendations on March 11, 2011. The group members were asked to respond as soon as possible. The responses to the revision of definition 2 (a) are presented below. Please find below the revised definition for 2 (a):

Proposed Definition of 2 (a):

(2) For the purposes of this Regulation, a catastrophic impairment caused by an accident is,

(2a) paraplegia or quadriplegia that meets the following three criteria:

- i. The Insured Person is currently participating in, or has completed a period of, in-patient rehabilitation in a public rehabilitation hospital;
- ii. The neurological recovery is such that the permanent ASIA Grade can be determined with reasonable medical certainty.
- iii. The permanent ASIA Grade is or will be A, B, C or D when determined according to the American Spinal Injury Association Standards (Marino RJ et al. ASIA Neurological Standards Committee 2002. International standards for neurological classification of spinal cord injury. J Spinal Cord Med 2003; 26(Suppl 1): S50–S56).

The Expert Panel did reach consensus (87.5%) with this round of full Panel voting for the proposed revision of 2 (a). One wording recommendation was made which was adopted into the final definition. This was to substitute the term “quadriplegia” with the more current term “tetraplegia”. Therefore, the final revised and accepted version of 2 (a) is:

2(a) For the purposes of this Regulation, a catastrophic impairment caused by an accident is, (2a) paraplegia or tetraplegia that meets the following three criteria: i. The Insured Person is currently participating in, or has completed a period of, in-patient rehabilitation in a public rehabilitation hospital; ii. The neurological recovery is such that the permanent ASIA Grade can be determined with reasonable medical certainty. iii. The permanent ASIA Grade is or will be A, B, C or D when determined according to the American Spinal Injury Association Standards (Marino RJ et al. ASIA Neurological Standards Committee 2002. International standards for neurological classification of spinal cord injury. J Spinal Cord Med 2003; 26(Suppl 1): S50–S56).

RESPONSES TO SURVEY 8

Full Panel Vote

Proposed Revision

(2) For the purposes of this Regulation, a catastrophic impairment caused by an accident is,

(2a) paraplegia or quadriplegia that meets the following three criteria:

- i The Insured Person is currently participating in, or has completed a period of, in-patient rehabilitation in a public rehabilitation hospital;
- ii The neurological recovery is such that the permanent ASIA Grade can be determined with reasonable medical certainty.
- iii The permanent ASIA Grade is or will be A, B, C or D when determined according to the American Spinal Injury Association Standards (Marino RJ et al. ASIA Neurological Standards Committee 2002. International standards for neurological classification of spinal cord injury. J Spinal Cord Med 2003; 26(Suppl 1): S50–S56).

Do you agree with this definition?

If you do not agree, please suggest revisions in the space below

Answer Options & Responses:

Yes: (7/8 responses)

No: (1/8 responses)

Appendix 9

Survey 9 - Proposed revisions to subsection 2(b)

In Survey 9, the Expert Panel was asked to vote on the revised version of 2 (b). The entire Panel was asked for their votes and recommendations on March 16th, 2011. The group members were asked to respond as soon as possible. The responses to the proposed revision of definition 2 (b) are presented below.

The Panel did reach unanimous consensus with this round of voting. One Panel member raised some concerns over some of the wording in the definition and this was address at the March 24th, 2011 Expert Panel meeting. These concerns were reviewed amongst Panel Members and it was decided that the proposed definition would be accepted as stated in Survey 9. Please find below the final revised and accepted definition for 2 (b):

2 (b): For the purposes of this Regulation, a catastrophic impairment caused by an accident is,

Impairment of ambulatory mobility, as determined in accordance with the following criteria:

1. Trans-tibial or higher amputation of one limb OR
2. Severe and permanent alteration of prior structure and function involving one or both lower limbs such that:
 - (a) The insured person is currently participating in, or has completed a period of in-patient rehabilitation in a public rehabilitation facility AND
 - (b) The Insured Person has a permanent and constant requirement for bilateral ambulatory assistive devices for mobility (i.e. two crutches, two canes, or a walker).

RESPONSES TO SURVEY 9

Full Panel Vote

Proposed Revision

2 (b): For the purposes of this Regulation, a catastrophic impairment caused by an accident is,

Impairment of ambulatory mobility, as determined in accordance with the following criteria:

1. Trans-tibial or higher amputation of one limb OR
2. Severe and permanent alteration of prior structure and function involving one or both lower limbs such that:
 - (a) The insured person is currently participating in, or has completed a period of in-patient rehabilitation in a public rehabilitation facility AND
 - (b) The Insured Person has a permanent and constant requirement for bilateral ambulatory assistive devices for mobility (i.e. two crutches, two canes, or a walker).

Do you agree with this definition?

If you do not agree, please suggest revisions in the space below

Answer Options & Responses:

Yes: (8/8 responses)

No: (0/8 responses)

Appendix 10

Survey 10 - Proposed revisions to paediatric traumatic brain injury definition and 2(a) & 2(b) for those under 18 years of age

In Survey 10, the Expert Panel was asked to vote on the revised version of the paediatric traumatic brain injury definition and subsections 2(a) and 2(b) as they refer to the paediatric population. The entire Panel was asked for their votes and recommendations on March 24th, 2011. The group members were asked to respond as soon as possible. The responses to the proposed revision of definition are presented below.

The Panel did reach consensus (87.5%) with this round of voting for the TBI definition. Panel members raised some concerns over some of the wording in the definition and this was addressed at the March 31st, 2011 Expert Panel meeting. These concerns were reviewed amongst Panel Members and revisions were made to the definition.

The Panel did reach consensus (87.5%) with this round of voting accepting that definitions 2(a) and 2(b), as created for the adult population, were suitable for the paediatric population. Panel members raised some concerns over some of the wording in the definition and this was addressed at the March 31st, 2011 Expert Panel meeting. Based on one of the Panel Member's request to review a recently published scientific article on the ASIA criteria, modifications to these definitions were made.

RESPONSES TO SURVEY 10

Full Panel Vote

Proposed Revision

3: Paediatric Traumatic Brain Injury

A child up to the age of 18 years who suffers a traumatic brain injury is deemed to have a catastrophic impairment if the following criteria are all met:

- i. Admission to a Level I trauma centre or treatment facility for paediatrics (including or equivalent to The Hospital for Sick Children, Children's Hospital of Eastern Ontario, Children's Hospital of Western Ontario, Kingston General Hospital, Chedoke McMaster Children's Hospital); and
- ii. Positive findings on CT/MRI scan indicating intracranial pathology that is the result of the accident are noted (including but not limited to contusions, intracranial haemorrhages, diffuse axonal injury, cerebral edema, midline shift, depressed skull fractures, pneumocephaly)

Alternate route to Catastrophic Determination:

For those children who were not admitted to hospital (such as described in 3(i)), they may be assessed at 6 months or more post trauma; and if they meet the following criteria they are

deemed to be catastrophically impaired. The Insured suffers from one of the following three levels of impairments

1) Vegetative

The child is breathing spontaneously and may have sleep/wake cycles. He may have non-purposeful or reflex movements of limbs or eyes. There is no evidence of ability to communicate verbally or non-verbally or to respond to commands.

2) Severe disability

(a) The child is at least intermittently able to move part of the body/eyes to command or make purposeful spontaneous movements; for example, confused child pulling at nasogastric tube, lashing out at carers, rolling over in bed. May be fully conscious and able to communicate but not yet able to carry out any self care activities such as feeding

(b) Implies a continuing high level of dependency, but the child can assist in daily activities; for example, can feed self or walk with assistance or help to place items of clothing. Such a child is fully conscious but may still have a degree of post-traumatic amnesia.

3) Moderate disability

(a) The child is mostly independent but needs a degree of supervision/actual help for physical or behavioural problems. Such a child has overt problems; for example, 12 year old with moderate hemiplegia and dyspraxia insecure on stairs or needing help with dressing.

(b) The child is age appropriately independent but has residual problems with learning/behaviour or neurological sequelae affecting function. He probably should have special needs assistance but his special needs may not have been recognized/met.

(A recommendation will be made to the superintendent that the definition be re-evaluated in 18 months once a study has been conducted to determine the reliability of the KOSCHI scale as an instrument to grade as a tool for diagnosis.)

Do you agree with this definition?

If you do not agree, please suggest revisions in the space below

Answer Options & Responses:

Yes: (7/8 responses)

No: (1/8 responses)

QUESTION 2

PROPOSED DEFINITION

Paediatric Definitions for sections 2(a) & 2(b):

Do you agree that sections 2 (a) & (b) used for the adult population also apply to the paediatric population?

(2) For the purposes of this Regulation, a catastrophic impairment caused by an accident is,

2 (a): paraplegia or quadriplegia that meets the following three criteria:

- i. The Insured Person is currently participating in, or has completed a period of, in-patient rehabilitation in a public rehabilitation hospital;
- ii. The neurological recovery is such that the permanent ASIA Grade can be determined with reasonable medical certainty.
- iii. The permanent ASIA Grade is or will be A, B, C or D when determined according to the American Spinal Injury Association Standards (Marino RJ et al. ASIA Neurological Standards Committee 2002. International standards for neurological classification of spinal cord injury. J Spinal Cord Med 2003; 26(Suppl 1): S50–S56).

2 (b): Impairment of ambulatory mobility, as determined in accordance with the following criteria:

1. Trans-tibial or higher amputation of one limb OR
2. Severe and permanent alteration of prior structure and function involving one or both lower limbs such that:
 - (a) The insured person is currently participating in, or has completed a period of in-patient rehabilitation in a public rehabilitation facility AND
 - (b) The Insured Person has a permanent and constant requirement for bilateral ambulatory assistive devices for mobility (i.e. two crutches, two canes, or a walker).

Do you agree with this definition?

If you do not agree, please suggest revisions in the space below

Answer Options & Responses:

Yes: (7/8 responses)

No: (1/8 responses)

Appendix 11

Survey 11 - Proposed revisions to 2 (d) based on the allocation of interim benefits

In Survey 11, the Expert Panel was asked to vote on the revised version of 2 (d). Although this definition had been previously voted on and consensus was reached, the Panel felt this definition needed to be revised to address if interim benefits were or were not allocated. The entire Panel was asked for their votes and recommendations on March 29th, 2011. The group members were asked to respond as soon as possible. The responses to the proposed revision of definition are presented below.

The Panel did reach consensus (75%) with this round of voting for both versions of 2 (d), with or without interim benefits. Panel members provided valuable feedback and raised some concerns over some of the wording in the definition. This was addressed at the March 31st, 2011 Expert Panel meeting and revisions were made to the definitions. Please find below the final revised and accepted definitions for 2 (d), with and without interim benefits:

2d: Traumatic Brain Injury in Adults (18 years of age or older) If Interim Benefits are Approved

1. A determinative GOSE evaluation and rating performed in strict accordance with guidelines for a structured assessment (reference) by an evaluator with appropriate scope of practice and experience which results in a finding of:

- a) A GOS-E rating of Vegetative at any time on or after 3 months OR
- b) The Insured has either been admitted to, or has been accepted by and is awaiting inpatient admission to a recognized rehabilitation center (list of facilities) for neurological rehabilitation and has a GOS-E rating of Moderate Disability (Lower) on or after 1 year

2. An Insured whose traumatic brain impairment is not sufficiently severe to meet Clause 1 and has other significant traumatic physical impairments is not precluded from a determination under (e), with the TBI rated in accordance with Chapter 4.

3. An Insured has either been admitted to, or has been accepted by and is awaiting inpatient admission to, a recognized rehabilitation center (list of facilities) for neurological rehabilitation whose level of functioning does not exceed a GOSE rating of Moderate Disability (Lower) during a period commencing after 3 months may apply for interim status.

2d: Traumatic Brain Injury in Adults (18 years of age or older) If Interim Benefits are Not Approved

1. Provided that the determinative GOSE evaluation and rating has been made in strict accordance with guidelines for a structured assessment (reference) by an evaluator with appropriate scope of practice and experience, Catastrophic Impairment is:

- a) A GOS-E rating of Vegetative at any time on or after 3 months OR
 - b) A GOS-E rating of Severe at any time on or after 6 months OR
 - c) The Insured has either been admitted to, or has been accepted by and is awaiting inpatient admission to a recognized rehabilitation center (list of facilities) for neurological rehabilitation and has a GOS-E rating of Moderate Disability (Lower) at any time on or after 1 years
2. An Insured whose traumatic brain impairment is not sufficiently severe to meet Clause 1 and has other significant traumatic physical impairments is not precluded from a determination under (e), with the TBI rated in accordance with Chapter 4.

QUESTION 1 – 2(d) with interim benefits

PROPOSED DEFINITION

Intro: If Interim Benefits are approved then we need a three pronged approach for:

- (a) early identification of potential CAT
- (b) unequivocal CAT
- (c) final determination at or beyond likely MRR

2(d): Traumatic Brain Injury in Adults (18 years of age or older)

1. A determinative GOSE evaluation and rating performed in strict accordance with guidelines for a structured assessment (reference) by an evaluator with appropriate scope of practice and experience which results in a finding of:

- a) A GOS-E rating of Vegetative at any time on or after 3 months OR
 - b) The Insured has either been admitted to, or has been accepted by and is awaiting inpatient admission to a recognized rehabilitation center (list of facilities) for neurological rehabilitation and has a GOS-E rating of Moderate Disability (Lower) on or after 1 year
2. An Insured whose traumatic brain impairment is not sufficiently severe to meet Clause 1 and has other significant traumatic physical impairments is not precluded from a determination under (e), with the TBI rated in accordance with Chapter 4.
3. An Insured has either been admitted to, or has been accepted by and is awaiting inpatient admission to, a recognized rehabilitation center (list of facilities) for neurological rehabilitation whose level of functioning does not exceed a GOSE rating of Moderate Disability (Lower) during a period commencing after 3 months may apply for interim status.

Do you agree with this definition?

If you do not agree, please suggest revisions in the space below

Answer Options & Responses:

Yes: (6/8 responses)

No: (2/8 responses)

QUESTION 2 – 2(d) without interim benefits

PROPOSED DEFINITION

Intro: If Interim Benefits are Not Approved then we need a two stage process for:

- (1) early identification of very bad outcome
- (2) timely identification of poor outcome Definition 2d: Traumatic Brain Injury in Adults (18 years of age or older)

1. Provided that the determinative GOSE evaluation and rating has been made in strict accordance with guidelines for a structured assessment (reference) by an evaluator with appropriate scope of practice and experience, Catastrophic Impairment is:

- a) A GOS-E rating of Vegetative at any time on or after 3 months OR
- b) The Insured has either been admitted to, or has been accepted by and is awaiting inpatient admission to a recognized rehabilitation center (list of facilities) for neurological rehabilitation and has a GOS-E rating of Moderate Disability (Lower) at any time on or after 1 years

2. An Insured whose traumatic brain impairment is not sufficiently severe to meet Clause 1 and has other significant traumatic physical impairments is not precluded from a determination under (e), with the TBI rated in accordance with Chapter 4.

Do you agree with this definition?

If you do not agree, please suggest revisions in the space below

Answer Options & Responses:

Yes: (6/8 responses)

No: (2/8 responses)

Appendix 12

LITERATURE REVIEW

12.1 AMA Guides

Purpose of the Literature Review

The purpose of the review is to determine the reliability and validity (face, construct and predictive) of the AMA Guides impairment ratings. The review focused on the 4th, 5th and 6th edition of the AMA Guides. The results of the review will be submitted to the Catastrophic Impairment Expert Panel to inform their deliberation of the AMA Guides.

Methodology

We conducted a review of the recent literature. The title and abstract of the articles was screened for relevance by Pierre Côté. The relevant articles were critically appraised by Maja Stupar using a modified version of the QUADAS instrument.⁹⁸

Search Strategy

We searched Pubmed from January 2000 to December 2010. The search strategy included the following key terms: ‘AMA Guides’ combined with ‘prognos*’, ‘predict*’, ‘reliab*’ and ‘valid*’. A separate search was performed using ‘AMA Guide*’ with an ‘AND’ connector combined with the MeSH term ‘Reproducibility of Results’. Finally, a search with key term ‘AMA Guide*’ was combined using an ‘AND’ connector with ‘(valid* OR reliab* OR predict* OR prognos*)’. The reference lists of the selected articles were reviewed for other potentially relevant articles. Finally, the ‘Find Similar’ option in Pubmed was used to select further relevant articles using the most recent relevant result.

Pubmed Search Strategy

AMA guides predict*
 AMA guides prognos*
 AMA guides reliab*
 AMA guides valid*
 AMA guide AND Reproducibility of Results[MeSH]
 AMA guide AND (valid* OR reliab* OR predict* OR prognos*)

A similar search was performed in the EMBASE Medline database using MeSH terms ‘Guideline’, ‘Practice Guideline’, ‘American Medical Association’, ‘Practice Guidelines as Topic’, and ‘Reproducibility of Results’. The MeSH terms were combined with the keywords ‘guide*’, ‘AMA guide*’ and (valid* or reliab* or prognos* or predict*). No additional articles were obtained from the EMBASE search compared to the Pubmed search.

EMBASE Medline Search Strategy

AMA guidelines psychometrics
 (Search on validity and reliability of the use of AMA guidelines)
 1. exp American Medical Association/
 2. guide*.mp.

3. exp Guideline/ or exp Practice Guideline/
4. 2 or 3
5. exp Practice Guidelines as Topic/
6. AMA guide*.mp.
7. 1 and 4
8. 1 and 5
9. 4 and 6
10. exp "Reproducibility of Results"/
11. 7 and 10
12. 8 and 10
13. 9 and 10
14. (valid* or reliab* or predict* or prognos*).mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
15. 7 and 14
16. 8 and 14
17. 9 and 14
18. limit 15 to (english language and humans and yr="2000 -Current")
19. limit 16 to (english language and humans and yr="2000 -Current")
20. limit 17 to (english language and humans and yr="2000 -Current")

We also searched Google Scholar for articles relevant to the topic using terms ‘AMA Guides’, ‘reliability’ and ‘validity’.

Results

Search Results

The Pubmed search yielded 114 results. One hundred and five (105) articles were not relevant and excluded from the review. Therefore, nine articles were critically appraised for methodological quality using the QUADAS tool.^{30;37;67;69;71;72;75;82;83} Following the critical appraisal, four articles were deemed scientifically admissible^{30;67;69;75} (Table 1) and five were excluded (Table 2). Two were excluded because they lacked quantitative results^{82;83} and two because they were not relevant to our mandate (these two articles did not evaluate AMA impairment ratings but instead the actual methods used to obtain the ratings)^{71;72}. Finally, one article was excluded because it was most likely using AMA guides prior to the fourth edition.³⁷ No additional articles were obtained from the EMBASE search. Two articles were obtained using Google Scholar.^{66;95}

Reliability of the AMA Guides

Three articles addressed the reliability of the AMA Guides. One article evaluated the reliability of the 5th and 6th edition of the AMA Guides, one evaluated the reliability of the 4th edition and the other assessed consistency in impairment ratings.

Frost et al. assessed the inter-rater reliability of AMA 5th and 6th edition Guides impairment ratings (Table 1).³⁰ The sample of raters included six occupational medicine residents and two 4th year medical students. Twenty mock cases of low back pain were provided to the raters. The raters were instructed to rate impairment based on either the 5th and 6th edition AMA Guides.

The case summaries describe the injury event, acute clinical findings, laboratory tests, medical interventions, the clinical course of the case and the history and physical examination at 'maximal medical improvement'. The authors report that inter-rater reliability was better among raters using the 5th edition of the AMA Guides (ICC=0.724; 95% CI 0.560-0.863) than among raters using the 6th edition (ICC=0.650; 95% CI 0.450-0.820). The 4th edition AMA Guides were not assessed in this study.

Marshall et al. developed and performed a validation study of an impairment questionnaire (IQ) in survivors of major trauma using the 4th edition AMA Guides.⁶⁶ The authors studied a convenience sample of 43 patients recruited from two trauma centers in Ontario, Canada. The study participants had sustained trauma within one year of the start of the study and were included if the ISS was greater than 12, age was at least 18 yrs, and patients were admitted to hospital for at least 24 hrs. Exclusion criteria were inability to communicate in English, significant aphasia, pregnancy, severe head injury (Glasgow Coma Scale score < 9) and paraplegia or tetraplegia.

The authors assessed inter-rater and intra-rater reliability of the AMA Guides ratings. The ratings were performed independently by three different physicians (two trauma surgeons and one specialist in physical medicine and rehabilitation). The inter-rater reliability was reported as a Pearson correlation. The inter-rater reliability was $r=0.69$ (95% CI 0.23-0.90) between two physician ratings at the Ottawa Trauma Centre and $r=0.90$ (95% CI 0.69-0.97) at the London Trauma Centre for participants who reported their trauma to have occurred longer than 6 months prior to the commencement of the study. The intra-rater reliability was reported as intra-class correlation coefficient of ICC= 0.62 (95% CI 0.39-0.79). In a sub-sample of 26 participants who sustained their injury more than 6 month prior to the study, the two-week test-retest reliability was $r=0.89$ ($p<0.001$). A limitation of this study is the use of Pearson's r correlation coefficient to estimate the inter-examiner and test –retest reliability. Pearson's r tends to overestimate the true reliability compared to the intra-class correlation coefficient.

Patel et al. conducted a cross-sectional study to determine the variability of US physiatrists' rating of permanent partial impairment using clinical vignettes (Table 1).⁷⁵ Two hundred physiatrists were randomly selected from the membership directory of the American Academy of Physical Medicine and Rehabilitation. Fifty two out of 163 eligible physiatrists responded to the survey. The physiatrists were asked to provide a diagnosis, an impairment rating and document how they derived at their rating. Three clinical vignettes were used: 1) lumbar radiculopathy; 2) fracture of the humerus with residual radial nerve neuropathy; and 3) intertrochanteric femoral fracture/total hip replacement.

The impairment ratings ranged 0-14% for the lumbar radiculopathy case. The range in ratings was 3-60% for the radial neuropathy case and 8-100% for the total hip replacement case. No consistent associations were found between the ratings and geographical location, years in practice or type of practice. Responders used various sources to derive the impairment ratings. These included the 3rd, 4th and 5th editions of the AMA guides, state guides and clinical impression. Although this article did not specifically address ratings based on the AMA Guides, the 4th and 5th editions of the AMA guides were most commonly cited as the sources used to arrive at the ratings.

Validity of the AMA Guides

Four articles evaluated the construct validity of the AMA Guides. No articles evaluated the predictive validity of the AMA Guides. All of the studies evaluated the validity of the 4th edition AMA guides by assessing their correlation to other measures of function and patient-reported outcomes.^{67,69}

Mink van der Molen et al. correlated the baseline Hand Injury Severity Scores (HISS) with follow-up AMA guides (4th edition) impairment ratings in patients older than 15 years who were admitted to hospital with acute upper extremity injuries (distal to the carpal bones) and treated on the day of injury in the department of plastic and reconstructive surgery (Table 1).⁶⁹ Correlations between the AMA guides and an early version of the Dutch translation of the full Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire (completed six months after the injury) were also computed. A sample of 110 patients were enrolled, but complete data analysis was performed on 71 patients. Responders were on average more severely injured than non-respondents.

The authors reported strong correlations between baseline HISS scores and AMA impairment ratings. The Spearman's rank correlation was 0.81 ($p < 0.001$) for each of the hand, the upper extremity and the total body AMA impairment. The 59 scores available for the DASH demonstrated that the DASH correlated weakly with AMA impairment ratings (Spearman's rank correlation=0.29-0.41; $p < 0.05$) [please refer to table 4 of the original article for detailed correlations]. The authors also found that time off work ($n=61$) had a moderate correlation with AMA impairment ratings for the hand ($r=0.68$; $p < 0.001$), upper extremity ($r=0.63$; $p < 0.001$) and total body impairment ($r=0.65$; $p < 0.001$).

McCarthy et al published a prospective validation study with a 1-year follow-up on 302 participants between the ages of 18 and 64 years who were admitted to one of three level-I trauma centers in the US with a lower extremity fracture.⁶⁷ The authors correlated 4th edition AMA Guides impairment ratings with clinical functional performance measures assessed by physical therapists and with the Sickness Impact Profile (SIP). The AMA ratings, the functional measures and the SIP were measured one-year after the injury. The functional performance measures included lower extremity range of motion, muscle strength, and the ability to perform five different functional tasks. Physical therapists conducted the assessment of functional performance as well as impairment even though it is common for a physician to perform an evaluation of impairment.

At follow-up, a moderate correlation was found with AMA impairment ratings for both the functional performance measure (Pearson correlation coefficient=0.57; 95% CI 0.49-0.60) and the SIP (Pearson correlation coefficient=0.55; 95% CI 0.47-0.63). Correlations were highest when measures of impairment were based on strength rather than on range of motion. The relationship between the impairment rating and function (as observed by an examiner and as reported by the patient) was not influenced by the location of the fracture or the receipt of disability compensation.

It is not clear whether the AMA ratings and functional assessment performance were measured independently. Moreover, the validity and reliability of the functional assessment measures are not known.

Van Oosterom et al. reported the validity of the 4th edition AMA Guides ratings by comparing it to the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire in patients with severe hand trauma. Seventy eight patients with unilateral multiple phalangeal fractures treated surgically in the Academic Hospital Rotterdam (now Erasmus Medical Centre) between July 1987 and July 1997 with a minimum follow-up period of 2 years were included in the study. Overall, the authors did not find that the DASH questionnaire was correlated with the AMA ratings. No correlation was found for the DASH function module and the AMA hand impairment rating ($r=0.09$; $p=0.42$). Weak partial correlation coefficients were reported between the DASH function module and the AMA arm ratings ($r=0.35$; $p=0.002$) and with the AMA total body ($r=0.34$; $p=0.003$). There was a weak correlation between AMA arm ratings and the DASH work score ($r=0.24$; $p=0.045$). These results emphasize the clear distinction between impairment and disability in patients with hand injuries.

Table 1. AMA Guides- Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Validity	Reliability	Predictive Value
Forst L et al, 2010 ³⁰	Inter-rater reliability among 6 occupational medicine residents and 2 fourth-year medical students for the impairment ratings of the 5th and 6th editions of the AMA guides	20 mock cases of low back pain from summaries that were found on the internet and in medical texts	Low back pain case summaries described an injury event, acute findings, laboratory tests, medical interventions, clinical course and the history and physical examination at the time of 'maximal medical improvement'	n/a	ICC=0.629 (95% CI 0.465-0.795) among all raters, not controlling for version; ICC=0.724 (95% CI 0.56-0.863) among fifth edition raters only; ICC=0.650 (95% CI 0.450-0.820) among sixth edition raters only; ICC=0.770 (95% CI 0.506-0.902) average ratings of fifth vs average ratings of sixth	n/a
Marshall SC et al, 2007 ⁶⁶	Reliability multicentre, prospective study of a convenience sample with major trauma to evaluate a self-administered questionnaire of impairment (the IQ) developed based on the 4th ed AMA Guides	43 volunteer participants (19 females, 24 males) who had sustained major trauma within 1 year of study commencement recruited from two trauma centers in Ontario, Canada.	Participants were eligible if they were older than 18 years, their Injury Severity Score (ISS) was greater than 12 and they were admitted to the hospital for at least 24 hours. They were excluded if they were not able to communicate in English, if they had significant aphasia, were pregnant, had a severe head injury (Glasgow Coma Scale <9) or were paraplegic or tetraplegic.		Inter-rater reliability between 2 physicians determining impairment based on 4th ed AMA guides on participants with trauma >6months before study: r=0.69 (95% CI 0.23-0.90) at Ottawa Trauma Centre; r=0.90 (95% CI 0.69-0.97) at the London Trauma Centre; Intra-rater reliability for all 3 raters within participants with injury >6months before study start was Intraclass correlation coefficient=0.62 (95% CI 0.39-0.79); Test-retest reliability of the IQ in 26 participants with no change over two weeks was r=0.89 (p<0.001)	n/a

Table 1. AMA Guides- Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Validity	Reliability	Predictive Value
McCarthy ML et al, 1998 ⁶⁷	Prospective validation study correlating functional performance measures and patient-reported outcomes to AMA guides (4th edition) impairment rating at one year follow-up	302 participants who had a fracture of the lower extremity who were admitted to one of three level-I trauma centers in the USA recruited between May 1990 and December 1991	Patients between 18 and 64 years of age admitted to one of three level-I trauma centers with unilateral fracture of the acetabulum, femur, tibia, talus, calcaneus, or forefoot; excluded if had an isolated phalangeal or metatarsal fracture, could not speak English, had a major neurological injury, a concomitant injury of the upper extremity that precluded the use of crutches at the time of discharge, had received definite orthopaedic treatment before arrival at the trauma center or had previously been diagnosed with a psychiatric illness	At 1 year, Pearson correlation coefficient=0.57 (.49-0.60) between AMA guides impairment rating and a functional performance measure; Pearson correlation coefficient=0.55 (0.47-0.63) between AMA rating and patient reported measure (Sickness Impact Profile)	n/a	n/a
Mink van der Molen AB et al, 2003 ⁶⁹	Validation cohort study comparing hand injury severity (HISS) scores calculated by one of the authors at baseline (using hand injury charts filled out by a resident on call at the time of admission, typed operative reports, available x-rays and pictures taken during operation) to self-completed DASH scores and AMA (4th ed) impairment ratings 6 months post-injury	110 patients over 15 years of age who underwent a surgical procedure between July 1998 and July 1999 at the Department of Plastic and Reconstructive Surgery (Rotterdam, Netherlands) for a 'fresh' upper extremity injury distal to the carpal bones (complete data analyzed on 71 participants, 59 of which completed the DASH)	Recent upper extremity injuries distal to the carpal bones undergoing surgery	Spearman's rank correlation = 0.81 (p<0.001) between HISS score and AMA impairment rating for each hand, the upper extremity and AMA total body impairment (using 0 scores for other body parts); Spearman's rank=0.29-0.41 (p<0.05) between DASH and AMA impairment (n=59; Table 4); time off work (n=61) correlated with AMA hand impairment [0.68 (p<0.001)], with AMA upper extremity impairment [0.63 (p<0.001)] and with AMA total body impairment [0.65 (p<0.001)]	n/a	n/a

Table 1. AMA Guides- Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Validity	Reliability	Predictive Value
Patel B et al, 2003 ⁷⁵	Cross-sectional study of physiatrists' ratings of permanent partial impairment across the USA	52 US physiatrists (out of 200) responded to a survey with 3 clinical vignettes for which they were asked to provide a diagnosis, an impairment rating and how the impairment rating was obtained	3 clinical vignettes (2 of which were obtained from the AAPM&R Disability Evaluation Program handbook) with the first being a case of radiculopathy, the second a case of radial neuropathy and the third a case for total hip replacement	Such a wide range of ratings suggests a lack of validity	The range of impairment values were 0-14% for radiculopathy, 3-60% for radial neuropathy and 8-100% for total hip replacement; responses did not correlate with region, years of experience or type of practice except in the first case where there was a trend of younger respondents giving lower ratings; respondents used different sources for obtaining their results with 5th than 4th edition of the AMA guides being the most common	Predictive value would be affected by lack of validity and reliability of developing ratings
van Oosterom FJT et al, 2007 ⁹⁵	Validation study comparing the functional module of the DASH to the AMA Guides ratings in patients with phalangeal fractures	78 patients with 228 fractures were enrolled from the Academic Hospital Rotterdam from July 1987 to July 1997 with an average of 3 fractures per patient	Patients with multiple phalangeal fractures within the same hand treated surgically in the Academic Hospital Rotterdam (now Erasmus Medical Centre) between July 1987 and July 1997 with a minimum follow-up period of 2 years	Pearson correlation between AMA Impairment Ratings and DASH function module was low even after controlling for comorbidities and the follow-up time; No correlation for the hand DASH score ($r=0.09;p=0.42$); Weak partial correlation coefficients for the hand ($r=0.35;p=0.002$) and total body ($r=0.34;p=0.003$) DASH function module scores and the work DASH score ($r=0.24;p=0.045$)	n/a	n/a

Table 2. AMA GUIDELINES - 4TH Ed. – Excluded Articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Validity	Reliability	Predictive Value
Gloss DC et al, 1982 ³⁷	Cross-sectional validity and inter-rater reliability study	118 patients (96 male; 22 female) treated surgically by a hand surgeon and/or plastic surgeon for an injury or disease condition affecting one hand	Patients 9-80 years of age treated surgically by a hand surgeon and/or plastic surgeon for an injury or disease condition affecting one hand	Product moment correlation between hand impairment and finger dexterity test ($r=-0.528$; $p<0.01$), hand dynamometer test ($r=-0.198$; $p>0.01$), tapping test ($r=-0.331$; $p<0.01$), placing test ($r=0.487$; $p<0.01$), displacing test ($r=0.534$; $p<0.01$), one-hand test ($r=0.582$; $p<0.01$), two-hand test ($r=0.598$; $p<0.01$)	Inter-rater correlation (Cronbach's alpha?)=0.75	n/a
Nattrass CL et al, 1999 ⁷¹	Cross-sectional validation study	34 subjects (21 women; 13 men) from an outpatient department in a Rehabilitation Medicine Unit in Melbourne, Australia	Participants between 20 and 65 years of age with chronic low back with or without leg pain of at least 6 months; participants excluded if had cervical or thoracic involvement or any acute muscle spasm	n/a	Range of Motion measured using dual inclinometer: Pearson's $r=0.12-0.38$ with the Wadell Disability Index; Pearson's $r=0.22-0.38$ with Oswestry Disability Index; Pearson's $r=0.35-0.54$ with Waddell Physical Impairment Scale	n/a

Table 2. AMA GUIDELINES - 4TH Ed. – Excluded Articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Validity	Reliability	Predictive Value
Nitschke JE et al, 1999 ⁷²	Repeated measures design for intra and inter-rater reliability study over 1 week	34 subjects (21 women; 13 men) from an outpatient department in a Rehabilitation Medicine Unit in Melbourne, Australia	Participants between 20 and 65 years of age with chronic low back or leg pain of at least 6 months; participants excluded if had cervical or thoracic involvement or any acute muscle spasm	n/a	Inter-rater ICC=0.13-0.52 for dual inclinometer ROM measure (4th ed AMA Guides) with best values for flexion followed by extension and lateral flexion; Intra-rater ICC=0.70-0.90 with best values for flexion and right lateral flexion, worst for extension	n/a
Rondinelli RD, 2009 ⁸²	Narrative review; suggests to validate individual scales used in AMA	n/a	n/a	no quantitative results	no quantitative results	no quantitative results

Table 2. AMA GUIDELINES - 4TH Ed. – Excluded Articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Validity	Reliability	Predictive Value
Ryu SG et al, 2009 ⁸³	Qualitative comparison of the Korean Academy of Medical Sciences Guideline for rating the impairment in Mental and Behavioural Disorders with the 6th edition AMA Guides	none; qualitative analysis of differences between the two guidelines	none; qualitative analysis of differences between the two guidelines	n/a	n/a	n/a

12.2 Glasgow Outcome Scale

Purpose of the Literature Review

The purpose of the review is to determine the reliability and validity (face, construct and predictive) of the Glasgow Outcome Scale (GOS). The results of the review will be submitted to the Catastrophic Impairment Expert Panel to inform their deliberation of the Glasgow Outcome Scale.

Methodology

We conducted a review of the recent literature. The title and abstract of the articles were screened for relevance by Drs. Craig Jacobs and Pierre Côté. The relevant articles were critically appraised by Craig Jacobs using the SIGN instrument for cohort studies and a modified version of the QUADAS instrument for validity and reliability studies.^{2;98}

Search Strategy

We searched Pubmed from January 2000 to December 2010. The search strategy included the following key terms: MeSH term 'glasgow outcome scale' combined using an 'AND' connector with '(valid* OR reliab* OR predict* OR prognos*)'. Limits activated included 'Humans', 'English', and 'Published in the last 10 years'. The reference lists of the selected articles were reviewed for other potentially relevant articles.

Pubmed Search Strategy

Glasgow outcome scale [MESH] AND (valid* OR reliab* OR predict* OR prognos*).

Results

Search Results

The Pubmed search yielded 337 results. Three hundred twenty five (325) articles were not relevant and excluded from the review. Dr. J. David Cassidy, one of the Catastrophic Impairment Expert Panel members provided an additional six articles. One additional article was selected for review from the reference lists of the previously identified articles and one newly published article that was emailed from Pubmed was included. Therefore, a total of 20 articles were critically appraised for methodological quality.

Following the critical appraisal, nine articles were deemed scientifically admissible^{46;54;59;68;78;79;90;99;100} (Table 1) and eleven were excluded.^{6;13;21;26;57;60;77;87;88;92;101} The articles were excluded for the following reasons: narrative reviews^{88;92}; no blinding of assessor^{57;77}; significant loss to follow-up^{57;87}; inadequate reporting of results¹³ (we contacted the corresponding author of the article for clarification-no response was obtained); not relevant to the review⁶⁰; selection bias and no validation of translated questionnaires²¹; small cell size in multivariable regression leading to poor precision of estimates⁶; and incorrect scoring of GOS.²⁶

Reliability of the Glasgow Outcome Scale

Four articles addressed the reliability of the Glasgow Outcome Scale. One study addressed inter-rater reliability of an alternative method to determine GOSE scores (adding a quality control system).⁵⁹ One study addressed the reliability in-person and telephone structured interviews for the GOS and GOSE.⁷⁸ One study addressed the reliability of postal questionnaires for the GOS.⁹⁹ Finally, one study addressed the inter-rater reliability of the GOS and GOSE using structured interviews.¹⁰⁰

Lu et al. (2010) studied the inter-rater reliability study of the 6-month GOSE outcome using a new GOSE rating system in a sample of six cases that covered the range of GOSE outcomes.⁵⁹ The new method used three strategies to improve the ratings: (1) a quality-control system with a central reviewer, (2) an algorithm to compute the GOS score, and (3) use questions to distinguish between the upper and lower categories of a specific GOS score to arrive at the GOSE score. The reliability of the new method was compared to a variant of the new method (no quality control) and to the conventional method of computing the GOSE. The inter-rater reliability was $k_w=0.97$ (95% CI 0.91, 1.00) for the new method; $k_w=0.79$ (95% CI 0.69, 0.89) for the new method without quality control; and $k_w=0.70$; 95% CI 0.60, 0.81 for the conventional method (Table 1) The authors conclude that the new method reduces inter-rater variations.⁵⁹ The improvement in the reliability can be attributed the use of a quality control system.

Pettigrew et al. (2003) conducted a test-retest and inter-rater reliability study of structured in-person and telephone interviews for the GOS and GOSE.⁷⁸ For the test-retest reliability study, 30 head-injured participants were first interviewed in person and then re-interviewed a few days later by telephone by the same rater. For the inter-rater reliability, 56 head-injured participants were interviewed by telephone and then in person up to 1 month later by a different person who was blinded to the previous interview. The test-retest reliability statistics were $k_w=0.92$ (95% CI .57–1.00) for both GOS and GOSE. Weighted kappa for the interrater reliability study were $k_w=0.85$ (95% CI .59–1.00) for the GOS and $k_w=0.84$ (95% CI .58–1.00) for the GOSE (Table 1). The authors conclude that structured interviews for the GOS and GOSE are reliable even when using two different methods of contact (in-person and telephone). They also conclude that that inter-rater reliability is high using structured interviews through two different methods of data collection.⁷⁸

Wilson et al., (2002) studied the test-retest reliability of a postal questionnaire version of the GOS and the GOSE.⁹⁹ The study included participants with a diagnosis of head-injury for whom a 6-month GOS score was available. Participants were randomly allocated to either be part of a test-retest study of the postal questionnaire (two week interval), or to answer questions through a telephone interview. The questionnaire was completed by the person with a head injury or by a proxy. Patients received either the GOS or GOSE. Of the 174 participants who completed the initial questionnaire 141 (81%) responded to the second one. The mean interval between completion of the first and second questionnaires for the mailed test-retest study was 14.7 days for the GOS and 14.4 days for the GOSE. In the telephone study, the mean interval between the telephone interview and completion of the postal questionnaire was 5.7 days for the GOS and 6.4 days for the GOSE. The authors do not state whether the telephone interview and scoring of the postal questionnaire were performed by different individuals. The test-retest reliability was $k_w=0.94$ (95% CI 0.60-1.00) for the GOS questionnaire and $k_w=0.98$ (95% CI

0.66-1.00) for the GOSE. For the comparison with the telephone interview, $k_w = 0.67$ (95% CI = 0.35–1.00) for the GOS and $k_w = 0.92$ (95% CI 0.59–1.00) for the GOSE (Table 1). The authors conclude that there is good test-retest reliability as well as good agreement between postal questionnaires and telephone interviews.⁹⁹ However, the reliability of the GOSE is more stable across methods of administration.

Wilson et al., (1998) conducted an inter-rater reliability study of the GOS and GOSE using structured interviews.¹⁰⁰ Fifty head-injured participants were recruited from a regional neurosurgical unit and were interviewed between 5-17 months post-injury by a research psychologist and then by one of two research nurses. Interviews occurred in person on the same day using a structured GOSE questionnaire. The weighted kappa was $k_w = 0.89$ for the GOS and $k_w = 0.85$ for the GOSE. The authors concluded that the assessment of the GOS and GOSE using standard interviews is practical and reliable. (The structured interview with explanations as well as accompanying notes and definition of terms are provided as appendices.)¹⁰⁰

In summary, the evidence suggests that both the GOS and the GOSE are reliable measures. One study strongly supports the use of quality control to improve reliability and reduce the inter-rater variability in the GOSE scoring.

Face/Construct validity of the Glasgow Outcome Scale

Three cohort studies provide information on the construct validity of the Glasgow Outcome Scale. One study investigated the association between clinical predictors and poor outcome (measured with the GOS).^{54;90} The second study correlated the GOS/GOSE with the Functional Status Evaluation (FSE).⁴⁶ Finally, we included a study of the predictors of recovery (measured with a modified GOS) in a cohort of young children.⁷⁹

Thornhill et al., (2000) conducted a large prospective hospital-based cohort study of head-injured patients (aged 14 years or older) in Glasgow.⁹⁰ Participants ($n=2962$) were enrolled at five hospitals over a one year period and were followed for one year. Baseline data was collected through chart reviews. Follow-up status was measured through telephone interviews or postal questionnaires one year after the injury. Severity of injury was determined by GCS score at baseline (13-15 = mild, 9-12 = moderate, 3-8 = severe). The outcome was determined with the GOS. All severe and moderately injured participants were followed for one year and a random sample of the mild-injured group was followed for one year. Overall follow-up rate was 71%, ranging between 71-73% for the three groups. The incidence of disability from head-injury is reported at one year. Independent predictors of poor outcome (death or disability) were reported using multivariate logistic regression for the mild-injury group. The incidence of head-injured patients with severe or moderate disability at one year was 154 per 100,000 population (95% CI: 138-169). Disability (severe or moderate GOS scores) at one year was present in 51% of mild head injury participants, 54% of moderate head injury participants, and 78% of severe head injury participants. Predictors of death or disability (moderate disability on the GOS or worse) at one-year in the mild injured group are: >40 years of age (OR=1.80, CI 1.11 to 2.91), pre-existing physical limitations (OR= 2.24, CI 1.33 – 3.86), and a history of brain illness (OR=2.07, CI 1.33 – 3.21).⁹⁰ This study supports the validity of the GOS because it is associated with those with a worse risk profile at baseline. It also suggests that the status of patients changes over a one year period.

Hudak et al., (2005) conducted a cohort study of head injury patients to measure the correlation between the GOSE and the Functional Status Evaluation (FSE). Participants (n=177) with head injuries had both the FSE and the GOSE administered at six and twelve months post-injury. The FSE measures outcome in 10 domains including personal care, ambulation, major activity involving work or school, home management, leisure and recreation, travel, social integration, standard of living, financial independence and executive functioning. The FSE was administered through a structured interview whereas the GOSE was administered by self-administered questionnaire. Linear regression was used to determine the correlation between FSE and GOSE scores. The authors report a strong correlation between the two outcome measures ($r=-0.83$, $R^2=0.70$). GOSE was moderately correlated with ICU stay ($r=-0.44$) and hospital stay ($r=-0.44$).⁴⁶ This study supports the construct validity of the GOSE as a measure of functional status.

Prasad et al. (2002) studied the predictors of recovery from traumatic brain injury in a cohort of 60 children less than six years of age who sustained either inflicted or noninflicted traumatic brain injury. The outcome was measured three and 12 months post-injury with a modified version of the GOS. *“Good outcome referred to the return to age-appropriate or preinjury levels of functioning and the return to full-time classes with no special education services. Moderate disability was assigned based on: (1) a significant reduction in cognitive functioning from estimated premorbid levels; (2) motor deficits including hemiparesis interfering with activities of daily living; (3) referral to outpatient rehabilitation therapies, and (4) attending special education or resource classes. Severe disability was assigned if (1) cognitive functioning was in the deficient range, (2) severe motor deficits were present, such as lack of age appropriate postural control or ambulation, and/or (3) there was referral for inpatient rehabilitation. The criteria for persistent vegetative state were unchanged and reflected total dependence for daily care. For the purposes of this study, moderate disability, severe disability and persistent vegetative state were classified as ‘poor outcome’.”*⁷⁹

Regression analysis suggests that the modified Glasgow Coma Scale score, the duration of impaired consciousness and the number of intracranial lesions visualized on CT/MRI accounted for a significant amount of the variance in the Glasgow Outcome Scale (GOS) 3- and 12-month evaluations. Inflicted brain injury adversely affected the GOS. Age at injury and the Injury Severity Score were not associated with GOS scores at follow-up. It is important to note that this was a small study and the final selection of variables in the model was likely influenced by the power of the study.⁷⁹

In summary, the evidence supports that the GOS and GOSE have good face validity. Although we only retrieved three studies, the reviewed literature suggests that the GOS and GOSE have adequate construct validity.

Predictive validity of the Glasgow Outcome Scale

Two studies addressed the predictive validity of the Glasgow Outcome Scale.

King et al., (2005) conducted a study to measure the association between demographic and clinical variables (including the 3-month GOS) and the GOS measured at 12-months post-injury.⁵⁴ A total of 159 participants with severe closed traumatic head injury ($GCS \leq 8$) were enrolled at the University of Pittsburgh Medical Center. No participants were lost to follow-up. Three participants died. The GOS was dichotomized into good outcome (GOS 4-5) or poor

outcome (GOS 1-3). Multivariate logistic regression was used to assess the relationship of the variables with a poor GOS at 12-months. The GOS score at 3-months was the best predictor of a poor outcome (OR = 15.22, $p < 0.001$). Presence of prolonged hypotension, diffuse axonal injury and fixed/dilated pupils on admission also predicted the outcome (Table 1). Probabilities of poor outcome were then generated for each GOS score (adjusting for the other significant predictors of poor outcome in the model). A GOS score of 2 at 3-months had an adjusted risk of 89.4% for a poor outcome at 12-months. A GOS score of 5 at 3-months had an adjusted risk of 0.11% for a poor outcome at 12-months. The authors conclude that the 3-month GOS score is a powerful predictor of long-term outcome in patients with severe traumatic brain injury.⁵⁴

Miller et al., (2005) studied the association between the GOS score measured within three months and patient's outcome 15 months post-injury.¹⁰ One hundred and twenty-one participants with traumatic brain injury were enrolled at 7 military or Department of Veterans Affairs hospitals in the US. Injury severity was classified by length of loss of consciousness; those who lost consciousness for more than 24 hours were deemed severely injured. The majority of the study participants were young, male, employed, active military personnel. 88% of patients with a GOS of 5 at baseline retained a score of 5 at 15 months post-injury, with the remainder having a GOS of 4 at 15 months. Two thirds (66.7%) of those participants with a GOS score of 4 at baseline improved to a score 5 at 15 months with the remainder still at a GOS 4 at 15 months. Forty percent of those with a GOS score of 3 at baseline improved to a score of 5 at 15 months, 50 percent improved to a score of 4 at 15 months, and 10 percent remained at a score of 3.⁶⁸

The authors report that the injury severity at baseline did not seem to affect the likelihood of improved GOS score at 15 months since 59% of severely injured participants with a baseline GOS score of 3 or 4 increased to a score of 5 at 15 months. Also, 54.5% of non-severely injured participants with a baseline GOS score of 3 or 4 increased their score to a 5 at 15 months.⁶⁸

In summary, the reviewed evidence suggest that the GOS score measured three months after an injury is a strong predictor of the GOS score measured one year after the injury. The evidence also suggest that the status of head injury patients changes significantly over time and that an important proportion of patients improve within the first 12 to 15 months post-injury.

Table 1. Glasgow Outcome Scale- Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
Hudak et al, 2005 ⁴⁶	Prospective study. Comparison between FSE and GOS-E (both used as outcomes).	177 participants with TBI with FSE and GOS-E done at 6-12 months post-injury.	Brain injury requiring hospitalization confirmed either by presence of abnormal neuroimaging or altered mental status greater than 30 min.	n/a	Linear regression for correlation between FSE and GOS-E scores: $r = -0.83$, $r^2 = 0.70$. Spearman correlation for correlation between variables and outcome (no multivariate analysis done). Report moderate correlation between length of ICU stay (FSE: $r = 0.36$, $p = 0.001$; GOSE: $r = -0.44$, $p = 0.003$) and hospital stay (FSE: $r = 0.50$, $p = 0.001$; GOSE: $r = -0.44$, $p = 0.003$). Report smaller relationships between GCS and outcomes (FSE: $r = -0.18$, $p = 0.025$; GOSE: $r = 0.18$, $p = 0.014$). No difference for patients who went through craniotomy or not. No correlation between CT scan findings and GOSE. No correlation between Abbreviated Injury Scale and Injury Severity Scale and either GCS, FSE, or GOS-E.	n/a
King et al, 2005 ⁵⁴	Prospective cohort study examining association between GOS scores at 3 months with GOS at 12 months.	159 patients with severe, closed traumatic brain injury in level 1 trauma center.	Severe traumatic brain injury = GCS ≤ 8 . Open or penetrating wounds excluded. Patients dying prior to 3 month analysis excluded from analysis.	n/a	n/a	Association of predictor variables and poor outcome at 12 months: GOS at 3 months, OR = 15.2 (95% CI 5.3 - 45.6); Prolonged hypotension, OR = 3.7 (CI 1.0 - 13.7); Diffuse axonal injury, OR = 5.5 CI 2.0 - 15.6); Fixed and dilated pupils on admission, OR = 12.1 (1.2 - 118.2). Probability of poor outcome at 12

Table 1. Glasgow Outcome Scale- Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
						months after TBI is: 89.4% (CI = 85.7 – 93.2%) for GOS 2 at 3 months; 32.1% (CI = 27.0 – 37.3) for GOS 3 at 3 months; 5.0% (CI = 0.0 – 10.7%) for GOS 4 at 3 months; and 0.11% (95% CI: 0.0 – 0.14%) for GOS 5 at 3 months.
Lu et al, 2010 ⁵⁹	Inter-rater reliability study comparing a new alternate method of assessing GOSE and GOS scores with conventional structured interviews. Inter-rater reliability determined between an expert and untrained raters for each group.	32 raters from different trauma centers.	6 transcripts of structured outcome interview with patients used. Transcripts contained real patient data originating from previous studies. Covered the range of GOSE outcomes from lower severe disability to lower good recovery (as assigned by an expert).	GOSE: New alternative system: Overall agreement 97%, kw (weighted kappa) 0.97, 95% CI 0.91 - 1.00; Alternative system w/o central monitoring: Overall agreement 76%, kw=0.79, CI 0.69 - 0.89; Conventional structured interview: Overall agreement 63%, kw = 0.70, CI 0.60 - 0.81. GOS: Alternative method: Overall agreement 97%, kw= 0.95, CI 0.89 - 1.00; Alternative method w/o central monitoring: Overall agreement 83%, kw=0.81, CI 0.69 - 0.92, CI 0.69 - 0.92; Conventional structured interview: Overall agreement 83%, kw=0.76, CI 0.63 - 0.89.	n/a	n/a

Table 1. Glasgow Outcome Scale- Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
Miller et al, 2005 ⁶⁸	Prospective cohort. GOS measured w/in 3 months post-injury and at 15 months.	121 participants hospitalized for TBI in 7 military and Department of VA medical centers in US.	TBI with neuro evaluation w/in 3 months of injury, adult survivors of closed head injury with GOS score recorded during evaluation, LOC info available to classify injury by severity, and return for subsequent post-injury evaluations when GOS assessed.	n/a	n/a	88% of patients with GOS at 5 at baseline retained score of 5 at 15 months postinjury, with the remainder having a GOS of 4 at 15 months. 66.7% of those participants with a GOS score of 4 at baseline improved to a score 5 at 15 months with the remainder still at a GOS 4 at 15 months. 40% of those with a GOS score of 3 at baseline improved to a score of 5 at 15 months, 50 percent improved to a score of 4 at 15 months, and 10 percent remained at a score of 3. Injury severity did not seem to affect likelihood of improving GOS score at 15 months. 59% of severely injured participants with a baseline score of 3 or 4 increased to a score of 5 at 15 months; 54.5% of non-severely injured participants with a baseline score of 3 or 4 increased their score to a 5 at 15 months.

Table 1. Glasgow Outcome Scale- Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
Pettigrew et al, 2003 ⁷⁸	<p>Study 1: Test-retest (same rater, first in person, then phone).</p> <p>Study 2: Inter-rater reliability (different rater, first by telephone, then in person).</p>	<p>Study 1: 30 head injury participants.</p> <p>Study 2: 56 head injury participants.</p>	<p>Head injury not defined. Cases obtained from a study that examined apolipoprotein E genotype and recovery after head injury. GCS scores reported.</p>	<p>Study 1: GOSE - overall agreement 77%. κ (kappa) = 0.72 (CI 0.55 - 0.88). κ_w (weighted kappa) = 0.92 (CI 0.56-1.00). GOS - overall agreement = 90%. κ = 0.85 (CI 0.59 - 1.00); κ_w = 0.92 (CI 0.57 - 1.00).</p> <p>Study 2: GOSE - overall agreement = 71%. κ = 0.64 (CI 0.51 - 0.77). κ_w = 0.84 (CI 0.58 - 1.00). GOS - overall agreement = 86%. κ = 0.78 (CI 0.59 - 0.97); κ_w = 0.85 (CI 0.59 - 1.00).</p>	n/a	n/a
Prasad et al, 2001 ⁷⁹	Prospective cohort. GOS measured at baseline and 12 months.	Children aged 1 to 6 years hospitalized for inflicted (n=31) or non-inflicted (n=29) TBI in two children's hospitals in Texas, USA.	<p>Moderate TBI (GCS 9-12 or 13-15 with +ve neuroimaging on admission) and severe TBI (GCS 3-8), gestational age \geq32 weeks and age at injury < 6 years.</p> <p>GOS was modified for children.</p> <p>Severity Factor Score (SFS): Duration of impaired consciousness, lowest GCS score, and number of intracranial lesions on CT/MR imaging.</p>	n/a	Severity factor score (SFS) predicted level of recovery (e.g. a severity factor score 1 standard deviation (SD) above average (indicating high severity) predicts a 0.045 chance of good recovery. An SFS 1 SD below average (indicating low severity) predicted a 0.726 likelihood of good recovery.)	n/a

Table 1. Glasgow Outcome Scale- Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
Thornhill et al, 2000 ⁹⁰	Prospective cohort study. F/u with GOS at 1 year.	Five acute hospitals in Glasgow. 2962 participants with head injuries enrolled. Excluded those who lived outside Glasgow. Aimed to follow up all patients with severe or moderate head injuries and a random sample of patients with mild or unclassified head injury. F/u rate was 71% overall.	Patients admitted with head injury >14 yoa.	n/a	Factors independently associated with death or disability (GOS 1-4) in mild head-injured participants: >40 yoa (OR, 1.80, CI 1.11 - 2.91), pre-existing physical limitations (OR, 2.24, CI 1.33 - 3.86), history of brain illness (OR 2.07, CI 1.33 - 3.21).	n/a
Wilson et al, 2002 ⁹⁹	Reliability study of GOS and GOSE postal questionnaire. Test/retest for postal questionnaire and comparison between postal questionnaire and structured telephone interviews.	174 participants recruited from a head injury group from a previous study. 16 yoa or older, not currently in hospital or nursing home.	Previous admission to neurosurgical unit with dx of head injury.	Test/retest for postal questionnaire: 1. GOS kw (weighted kappa) = 0.94 (95%CI:0.60 - 1.00); 2. GOSE kw =0.98 (CI:0.66 - 1.00). Telephone interview vs. postal questionnaire: 1.GOS kw = 0.67 (CI: 0.35 - 1.00); 2. GOSE kw =0.92 (CI: 0.59 - 1.00).	n/a	n/a

Table 1. Glasgow Outcome Scale- Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
Wilson et al, 1998 ¹⁰⁰	Inter-rater reliability study of GOS and GOSE with structured interview guidelines.	50 patients (42M; 8F) recruited from regional neurosurgical unit.	No explicit case definition. Seems that inclusion was head injury with GCS<16. Participants recruited from "head injury admissions" at regional neurosurgical unit. 30% had GCS score of 3-8 (severe), 14% had GCS of 9-12(moderate), and 56% had GCS of 13-15 (mild). Restricted to conscious survivors.	Inter-rater reliability: Overall agreement 92% for GOS and 78% for GOSE. kw (weighted kappa) for GOS = 0.89 and GOSE = 0.85.	n/a	n/a

12.3 Glasgow Coma Scale – Literature Review

1. Purpose of the Literature Review

The purpose of the review is to determine the reliability and validity (face, construct and predictive) of the Glasgow Coma Scale (GCS). The results of the review will be submitted to the Catastrophic Impairment Expert Panel to inform their deliberation of the Glasgow Coma Scale.

2. Methodology

We conducted a review of the recent literature. The title and abstract of the articles was screened for relevance by Dr. Pierre Côté. The relevant articles were critically appraised by Drs. Heather Shearer, Craig Jacobs and Maja Stupar using a modified version of the QUADAS instrument for reliability and validity studies and the SIGN tool for predictive validity/cohort studies.^{2;98}

2.1 Search Strategy

A Medline (Pubmed) search was performed from January 2000 to December 2010. The search strategy included key terms (Glasgow coma scale [MESH]) AND (valid* OR reliab* OR predict* OR prognos*). References of selected articles were reviewed for other potentially relevant articles. Finally, the 'Find Similar' option in Pubmed was used to select further relevant articles using the most recent relevant result. The option to have any new articles with the term 'Glasgow Coma Scale' emailed to the reviewer was selected.

3. Results

3.1 Search Results

The Pubmed search yielded 1031 results. Because of the large number of articles, it was decided that only articles dated from January, 2007 to December 2010 would be reviewed. Again, references of selected articles were reviewed for other potentially relevant articles and five additional articles were selected. This limitation reduced the number of articles to 462. Following a title and abstract review for relevance to the topic of validity, reliability or predictive value of the Glasgow Coma Scale, 286 articles were excluded. An additional 14 articles dated prior to 2007 were selected for review based on references lists of selected articles. Of these remaining 190 articles, another 143 articles were excluded based on an abstract review for their relevance to the topic. Forty-seven complete articles were reviewed for quality using the QUADAS tool and to obtain quantitative results relevant to the topic. Twenty-one articles were included and 26 excluded from the final selection of forty-seven articles.

The reasons for the exclusion of 26 articles are provided below:

- Five studies did not address reliability, validity or predictive value of the GCS.^{8;10;19;53;73}
- Two review articles were narrative rather than systematic reviews.^{55;103}
- One article had a very low participation rate.⁹⁷
- One article provided no inclusion/exclusion criteria, used inappropriate statistical methodology, and did not blind the assessors.⁸⁹
- One article was excluded due to inappropriate analysis.⁸⁶
- One article had small cell sizes in multivariable regression which lead to imprecision of estimates.³⁴

- One article was excluded because the outcome measure was not administered properly but calculated retrospectively from file reviews.³¹
- One study had a high attrition rate, inappropriately controlled for confounders and did not report blinding of the measurements.⁷
- One study used inconsistent inclusion criteria and because it was not clear how the data was obtained (i.e. from a database, from assessment of hospital patients).²⁰
- One study used an outcome of questionable validity and reliability.²²
- One study used an outcome that was not clearly defined.⁵⁸
- One study was excluded due to insufficient reporting of statistical analysis.⁶⁴
- One study only reported frequency distribution and p-values were reported.⁵⁶
- One study did not report inclusion and exclusion criteria and did not blind examiners.⁵²
- One study only reported a bivariate analysis.⁶⁵

3.2 *Reliability of the Glasgow Coma Scale*

Nine studies addressed the inter-rater reliability of the Glasgow Coma Scale (Table 1).^{4;16;21;23;25;28;44;48;102}

3.2.1 Adult population

Akavipat⁴ studied the inter-rater reliability of the GCS using 8 trained assessors (2 expert clinicians, 2 expert nurses, 2 novice clinicians and 2 inexperienced nurses) in a sample of 64 newly admitted patients at a neurosurgical unit in Thailand. Patients were included if they were over 15 years of age, were newly admitted to the neurosurgical unit or suffered mental status alteration during admission. Patients who suffered mental status alteration because of anesthesia/sedative or neuromuscular blockers were excluded. Pairs of clinicians each assessed 16 patients. Inter-rater reliability for the GCS total scores was found to be high. Specifically, the ICC=0.97 (95% CI 0.91-0.99) for expert clinicians, ICC=0.90 (95% CI 0.71-0.96) for novice clinicians, ICC=0.95 (95% CI 0.87-0.98) for expert nurses and ICC=0.97 (95% CI 0.91-0.99) for inexperienced nurses (Table 1). A limitation of this paper is the poorly described sampling of patients. While 100 patients were assessed (41 awake, 44 drowsy, 9 stupor, 6 coma), only 64 were included in the analysis. The authors do not report the reasons for the exclusion of 38 patients. Selection bias cannot be ruled out in this study.

Davis et al. reported on the inter-rater reliability of the GCS between a physician and a paramedic in patients with traumatic brain injury (TBI) undergoing pre-hospital rapid sequence intubation (RSI).²¹ Eligible for the study were 412 adults with major trauma, a GCS of 3–8 and clinical suspicion of head trauma who were enrolled in the San Diego Paramedic RSI Trial. The inclusion criteria for the study were: 1) 18 years or older, 2) major trauma victim, 3) transport time of 10 minutes or greater to the trauma resuscitation suite, 4) suspected head injury by mechanism or physical examination, 5) GCS score 3–8, and 6) inability to intubate without RSI. They were excluded if there was a failure to achieve intravenous access or if cardiopulmonary resuscitation (CPR) was required before RSI. The authors report a kappa of 0.995. It is unclear whether the two raters were blinded from each others' ratings.

Ely et al. studied the inter-rater reliability study of the GCS in a prospective cohort study of adult patients admitted to the ICU of the Vanderbilt University Medical Center (tertiary-care, academic medical center).²⁵ Exclusion criteria were: a history of severe dementia, psychosis or neurologic disease; patient or family refusal; admission to the ICU after a daily cap of 10 study patients due to staffing limitations. Two critical care nurses independently rated 38 ICU patients. All assessments were conducted within four hours of each other. The weighted kappa for the GCS was 0.64 ($p < 0.001$).²⁵

Fischer et al. conducted an inter-rater reliability study of the GCS.²⁸ Two neurologists, eight ICU nurses, and four ICU physicians served as raters. The GCS was administered to 267 consecutive patients admitted to the ICU. Raters were blind to each other's ratings and the time interval was one-hour maximum between ratings. Weighted kappa statistics (95% CI) for overall inter-rater reliability were: total GCS $k_w = 0.61 (\pm 0.05)$; eye = 0.72 (± 0.06), motor = 0.74 (± 0.06), verbal = 0.78 (± 0.05). Weighted kappa values for neurologist-neurologist reliability were: total GCS $k_w = 0.67 (\pm 0.10)$; eye = 0.75 (± 0.12); motor = 0.79 (± 0.10); verbal = 0.78 (± 0.10). Weighted kappa values for neurologist-ICU staff interrater reliability were: total GCS $k_w = 0.56 (\pm 0.09)$, eye = 0.68 (± 0.10), motor = 0.68 (± 0.10), verbal = 0.70 (± 0.09). Weighted kappa values for ICU staff-ICU staff inter-rater reliability were: total GCS $k_w = 0.63 (\pm 0.08)$, eye = 0.74 (± 0.09), motor $k_w = 0.78 (\pm 0.09)$, verbal $k_w = 0.86 (\pm 0.07)$.²⁸

Heron et al. studied the inter-rater reliability study of the GCS in nurses.⁴⁴ A convenience sample of 75 nurses from a large metropolitan teaching hospital were included. The sample of raters included 15 nurses from each of five specialty areas were included: general intensive care unit (GICU), coronary care unit (CCU), emergency department (ED), post anaesthetic recovery room (PARR), and neurosurgical intensive care unit (NICU). Raters with less than 12 months experience were excluded. Six patients were selected from the NICU: One patient with GCS > 12, four between GCS 5-12, and one with GCS < 5. Patients older than 18 years old and admitted to hospital for at least 24 hours were included. The patients were videotaped and the nurses rated the GCS for each patient upon viewing the exam. All raters were blind to the other ratings. The following kappa scores were estimated from a bar graph as actual estimates were not reported. Total GCS score: All nurses $k = 0.57$, GICU $k = 0.56$, ER $k = 0.53$, PARR $k = 0.51$, NICU $k = 0.65$, CCU $k = 0.55$. Eye component: All nurses $k = 0.81$, GICU $k = 0.76$, ER $k = 0.78$, PARR $k = 0.82$, NICU $k = 0.65$, CCU $k = 0.55$. Verbal component: All nurses $k = 0.91$, GICU $k = 0.95$, ER $k = 0.92$, PARR $k = 0.79$, NICU $k = 0.95$, CCU $k = 0.95$. Motor component: All nurses $k = 0.65$, GICU $k = 0.62$, ER $k = 0.62$, PARR $k = 0.58$, NICU $k = 0.79$, CCU $k = 0.63$. Additionally, younger nurses and nurses who had undergraduate diplomas or degrees were more likely to obtain correct GCS scores (compared to two experts) than older nurses or those with specialty critical care training.⁴⁴

Iyer et al. conducted a prospective cohort study investigating the inter-rater reliability, validity and predictive validity of the GCS in critically ill patients.⁴⁸ Raters included 18 nurses, 10 fellows, and 5 consultants from ICU staff. A sample of 100 non-sedated or non-paralyzed patients with abnormal consciousness from the ICUs of Mayo Clinic's Saint Mary's Hospital were included in the study. The overall inter-rater reliability for the total GCS $k_w = 0.98$ (95% CI 0.98-0.99); verbal $k_w = 0.98$ (95% CI 0.97-0.98); motor $k_w = 0.97$ (95% CI 0.96-0.98); eye $k_w = 0.96$ (95% CI 0.95-0.97). The reliability stratified by types of raters was: fellow/fellow: total GCS $k_w = 0.96$, verbal $k_w = 0.84$, motor $k_w = 0.82$, eye $k_w = 1.00$; fellow/nurse: total GCS $k_w = 0.97$, verbal

$k_w=0.91$, motor $k_w=0.83$, eye $k_w=0.75$; Nurse/intensivist: total GCS $k_w=0.97$, verbal $k_w=0.61$, motor $k_w=0.89$, eye $k_w=0.59$; Fellow/intensivist: total GCS $k_w=0.99$, verbal $k_w=0.83$, motor $k_w=0.94$, eye $k_w=0.84$.⁴⁸

Wolf et al conducted a reliability study of the GCS in a sample of 80 patients with acute neurologic disease admitted to an intensive care unit.¹⁰² Twenty patients from each of the following four categories were included (alert, drowsy, stupor, coma). The raters included ten experienced neuroscience ICU nurses (minimum 2 years neuroscience experience), five inexperienced neuroscience ICU nurses and five ICU nurses with no neuroscience training. Patients were randomly assigned and scored by two nurses who were blinded to the other ratings and were unaware of the patient's diagnosis. The inter-rater reliability of the total GCS was $k_w=0.83$; (eye $k_w=0.85$; verbal $k_w=0.89$; and motor $k_w=0.74$) Reliability was slightly higher for experienced assessors.

3.2.2 Pediatric population

In a study by Cohen, the inter-rater reliability and predictive validity of the GCS was compared to the Full Outline of Unresponsiveness (FOUR) Score coma scale in a pediatric sample.¹⁶ Cohen used a convenience sample of 60 neuroscience patients, ages 2 to 18 years, recruited from the pediatric intensive care unit of Children's Hospital in the United States. The participants were classified by the principal investigator to one of four categories upon admission: alert ($n = 44$), drowsy ($n = 10$), stuporous ($n = 3$), or comatose ($n = 3$). Patients receiving sedatives and/or neuromuscular blocking agents were excluded. Poor outcome was determined using the Modified Rankin scale as a score 3-6 (3 = moderate disability, requiring some help, but able to walk without assistance; 4 = moderately severe disability, unable to walk without assistance and unable to attend to own bodily needs without assistance; 5 = severe disability, bedridden, incontinent and requiring constant nursing care and attention; and 6 = dead). The patients were assessed independently by two trained pediatric critical care nurses (35 nurse raters participated in the study). The inter-rater reliability of the GCS total score was $k_w=0.74$ (95% CI 0.59-0.87).

Durham et al. conducted an interrater reliability study of the GCS and the Children's Hospital of Philadelphia (CHOP) Infant Coma Scale in two series of children less than two years of age.²³ In the first series, 75 children (39M, 36F) were randomly selected from the Children's Hospital of Philadelphia. Patients were excluded if they were older than two years of age, sedated, used paralytic pharmacologic agents, and /or parental or nurse objection. The second series included 10 infants in ICU with traumatic brain injury and/or acute hypoxic-ischemic brain injury were enrolled. Six raters participated in the evaluation of the first series of patients: one neurosurgeon, three neurosurgical residents, a medical student and a trauma nurse specialist. The second series of patients were assessed by a critical care attending and a critical care fellow. The raters were blinded to each others scores. The inter-rater reliability for the neurosurgeon vs. neurosurgical resident were: eye $k=0.94$; motor $k=0.00$; and verbal $k=0.33$. The inter-rater reliability for the neurosurgical resident vs. medical student were: eye $k=1.00$; motor $k=0.33$; and verbal $k=0.24$. Finally, the inter-rater reliability coefficients for the neurosurgical resident vs. trauma nurse were: eye $k=0.86$; motor $k=0.30$; and verbal $k=0.45$. The inter-rater reliability coefficients for the second series of patients were: eye opening $k=1.00$; motor $k=0.40$; and verbal $k=0.54$.

In summary, the inter-rater reliability of the GCS varies greatly across studies of adults. Important variations are also reported in the three component scores (eye, motor and verbal) of the GCS. Similarly, the reliability coefficients for the component scores varied greatly in the pediatric population.

3.3 Face/Construct Validity of the Glasgow Coma Scale

Five studies addressed the face or construct validity of the GCS.^{4;14;25;40;48}

In the study by Akavipat⁴ (described above), the Spearman's rank correlation between the Full Outline of UnResponsiveness (FOUR) score and the GCS was 0.78 ($p < 0.01$).

Chierigato et al. assessed the face validity of the GCS by surveying 1334 Italian anesthetists. The authors stated that the GCS overlooks important clinical signs; the purpose of the study was to recommend clinical variables that in addition to the GCS would assist with the management of traumatic brain injury.¹⁴ The response rate to the questionnaire was 63%. Sixty-seven percent of respondents reported that the definition of TBI should include pupil reactivity to light and computer tomogram (CT) findings in addition to GCS scores.¹⁴

In the aforementioned paper by Ely et al. (section 3.2.1), the construct validity of the Richmond Agitation Sedation Scale (RASS) was correlated with the GCS.²⁵ Consecutive patients ($n=275$) receiving mechanical ventilation were enrolled. Patients were excluded if they had a history of psychosis or neurologic disease, were non-English speaking or deaf, were extubated or died before the nurses' screen, had been previously enrolled in the reliability study, or due to patient or family refusal. The GCS and the RASS were rated by different raters (1360 paired observations by neuropsychiatric experts). Spearman's correlation coefficient was calculated for association between RASS scores and GCS scores. The correlation was $r=0.91$, $p=0.001$. The odds ratio of having higher RASS scores with greater GCS scores was 1.39 ($p < 0.001$).²⁵

Guzel et al. investigated the correlation between neuron-specific enolase (NSE) levels and GCS scores in the early stages of TBI patients. NSE is an isoenzyme of enolase found almost exclusively in neuronal brain cell cytoplasm.⁴⁰ Damage to neuronal cells causes leakage of NSE into the bloodstream and can therefore be detected in the serum after traumatic injury. GCS scores and NSE samples were taken at 2 (N1), 24 (N2), and 48 (N3) hours after admission. The GCS scorer was blinded to NSE levels. Isolated head-injured patients were prospectively enrolled at ER and neurosurgery departments of a hospital in Turkey ($n=169$). Patients were excluded if they had: any major health issues such as diabetes, renal or cardiac failure, CNS diseases, and bleeding disorders prior to trauma; concomitant extracranial injury (i.e., pelvic or extremity fractures), intraabdominal, intrapleural or retroperitoneal hemorrhages, hepatic or splenic injuries, thorax or spinal cord damages, and alcohol intoxication. Patients who sustained injury more than 24 hours prior to admission or with a history of neurological and neuropsychiatric disorders or alcohol, drug, substance abuse and /or previous history of TBI were excluded. A negative correlation was found between NSE levels and corresponding GCS scores. Pearson's correlation coefficient (r) was used to determine correlation at each different time point. NSE 1 and GCS 1, $r=-0.438$ $p < 0.0001$; NSE2 and GCS2, $r=-0.529$ $p < 0.0001$; NSE3 and GCS3, $r=-0.547$ $p < 0.0001$. NSE levels were higher in those patients with GCS scores ≤ 8

compared to GCS scores >9. NSE1: For GCS≤8, mean NSE=101.57±83.60, for GCS>9, Mean NSE=44.4±41.80, p<0.0001. NSE2: For GCS≤8, Mean NSE=87.19±86.21, for GCS>9, Mean NSE=28.27±19.52, p<0.0001. NSE3: For GCS≤8, mean NSE=59.15±68.57, for GCS>9, Mean NSE=31.16±42.52, p<0.0001.⁴⁰

In the aforementioned study by Iyer et al, the Spearman correlation coefficients for GCS and FOUR score were high (P=0.98 (first rater) and P=0.92(second rater)).⁴⁸

In summary, there is good evidence that the GCS has adequate face and construct validity. The GCS is highly correlated to other measures such as the FOUR and RASS. It is also correlated with the neuron-specific enolase, a biological marker of brain injury.

3.4 Predictive Validity of the Glasgow Coma Scale

Twenty papers addressed the predictive validity of the GCS.^{15-17;21;24;27-29;35;36;38;39;45;47;48;61;74;76;91;102}

3.4.1 Adult population

Cho et al. assessed the predictive value of the Acute Physiology, Age, and Chronic Health Evaluation (APACHE) II and III and the Glasgow Coma Scale (GCS) scores to predict hospital mortality and functional outcome (Index of Independence in Activities of Daily Living) in patients with acute head injuries. The mean time to outcome assessment was 2.2 years (range: 1-3 years). Two hundred consecutive patients (14 years or older) from a neurosurgical intensive care unit at Taichung Veterans General Hospital (Taiwan) were recruited between September 1992 and December 1994. APACHE II and III and GCS were scored within 24 hours of being admitted to the hospital. APACHE II and III scores include the GCS. Early mortality was defined as death before the 14th day after admission. Late mortality was defined as death after the 15th day from admission. Using a cut-off point of 5, the GCS correctly predicted hospital mortality outcome for 81.9% of cases. The ROC curve was 0.86. The GCS was better at prediction early mortality (ROC area = 0.86) than late mortality (ROC area = 0.78). Using a cut-off point of 9 on the GCS yielded the best prediction for functional outcomes. The GCS correctly predicted severe morbidity in 60.7% of cases (ROC area = 0.73) Selection bias may have influenced the results of this study. The results of this study may be limited because only complete data was used in the analysis but the authors do not report if those excluded from analysis due to missing data differed in any way from participants. It is also not clear what the authors mean by 'non-selected' consecutive patients.¹⁵

In the aforementioned study by Davis et al. (section 3.2.1), the principal investigator debriefed paramedics upon arrival at the hospital to reconcile that the GCS scoring is done accurately.²¹ In assessing predictive ability, receiver-operator curve (ROC) analysis revealed a limited ability of GCS to predict the presence of severe TBI, injury severity, desaturation, aspiration, ICU length of stay, or ultimate survival (AUC 0.51-0.63). Predictive value of the GCS in survivors extubated and discharged from the ICU in 48 hours or less for survival was significant (OR 1.32, 95% CI 1.09 –1.61, p=0.005; adjusted for serum ethanol OR 1.37, 95% CI 1.11–1.69, p= 0.004) or the presence of severe TBI (OR 0.80, 95% CI 0.68–0.95, p= 0.009; adjusted for serum ethanol OR

0.79, 95% CI 0.66–0.94, $p=0.007$). The authors concluded that although a relationship between paramedic GCS and outcome exists, the ability to predict the severity of injury, airway-related complications, ICU length of stay, and overall survival is limited using that single variable (i.e. GCS).²¹

Eken et al. conducted a cohort study examining the ability of the GCS and the FOUR-score to predict three-month outcome.²⁴ Eligible patients were recruited from a tertiary care hospital emergency department if they met the following criteria: 1) older than 17 years of age; 2) altered consciousness after a trauma to the head; and 3) neurological complaints of lateralizing motor, and/or sensory deficits, dysarthria, dysphasia or facial asymmetry. Patients were excluded if they were intubated or given sedative or paralytic agents before they arrived at the ER. A total of 188 participants were enrolled. Three participants were lost to follow up at three months. Three outcome measures were used: 3-month mortality, hospital mortality, and 3-month Modified Rankin Scale (MRS). An unfavorable outcome was defined as either death or a low MRS (3-6). There was a moderate correlation between MRS at 3 months and the GCS ($r=-0.43$, $p<0.0001$). ROC curve analysis was used to predict the outcomes. For 3-month mortality, total GCS score area under the curve (AUC) = 0.73 (95% CI 0.66-0.79), eye score AUC= 0.65 (95% CI 0.57-0.72), motor score AUC= 0.68 (95% CI 0.61-0.75), verbal score AUC= 0.70 (95% CI 0.63-0.77). For hospital mortality, total GCS score AUC= 0.74 (95% CI 0.66-0.80), eye score AUC= 0.63 (95% CI 0.56-0.70), motor score AUC= 0.66 (95% CI 0.59-0.73), verbal score AUC= 0.71 (95% CI 0.63-0.77). For a Rankin Score of 3-6 (unfavourable outcome), the GCS total score AUC = 0.72 (95% CI 0.65 -0.78), eye score AUC = 0.62 (95% CI 0.55-0.69), motor score AUC = 0.65 (95% CI 0.58-0.72), verbal score AUC=0.72 (95% CI 0.65-0.78). The cut-off value for 3-month mortality prediction was 5 (positive likelihood ratio=11.7). Multivariable analysis performed showed an independent association of the GCS with 3-month mortality, OR=0.80 (95% CI 0.70-0.91).²⁴

Fabbri et al. conducted a prospective cohort study examining early predictors of unfavourable outcome in emergency room patients with moderate head injuries.²⁷ All patients ≥ 10 years with acute moderate head injury as defined by a GCS score of 9-13 and seen within 24 hours of trauma were enrolled in the study. Participants were excluded if they had severe hypotension caused by extra-cranial injuries ($n=8$), need for CPR ($n=5$), penetrating head injury ($n=2$), or the need for sedation for intubation before ER arrival ($n=14$). The outcome measure was GOS at 6 months an unfavourable outcome defined as dead, vegetative, or severe disability. A total of 309 participants were enrolled and 93.5% were successfully followed-up at 6 months. Variables included in the multivariable analysis were: sex, age, presence of any co-morbidity, GCS after ER stabilization, skull fracture, modified Marshall category, type of intracranial injury, ISS, coagulopathy, alcohol and/or drug intoxication, high-risk dynamics of injury, hypotension and hypoxia. After multivariate regression analysis, the six variables which predicted unfavourable outcome are (odds ratios with 95% CIs reported): basal skull fracture 8.9 (95% CI 2.5-31.3); subarachnoid haemorrhage 4.5 (95% CI 1.7-11.7); coagulopathy 4.5 (95% CI 1.4-14.9); subdural haematoma 3.0 (95% CI 1.1-8.6); Marshall category 1.8 (95% CI 1.3-2.5), and GCS score 0.6 (95% CI 0.4-0.8).²⁷

In the aforementioned study by Fischer et al, the predictive value of the GCS for 28-day mortality was also calculated.²⁸ The 28-day mortality was 13% in the study cohort. The AUC for the GCS was 0.78 (95% CI 0.68-0.87).²⁸

Foreman et al. conducted a prospective cohort study examining the predictive validity of the head abbreviated injury score (AIS), the injury severity score (ISS), and the Glasgow Coma Scale (GCS).²⁹ Subjects (n=410) with traumatic brain injury at an urban Level I trauma center were enrolled. Brain injuries were confirmed with imaging or a GCS score of less than 13 with the need for hospitalization. Exclusion criteria were: age < 13 years, preexisting history of intracranial tumor, stroke, epilepsy, MS, arteriovenous malformation, HIV encephalopathy, brain abscesses, Alzheimer's disease, Parkinson disease, or meningitis. Prisoners and homeless patients were also excluded. AIS, ISS, and GCS were measured on admission. The GOS-E was used to measure outcome at 12 months. The correlation between GOS-E and the GCS in the was $r_s = 0.227$, $p < 0.001$. The correlation between the AIS the GCS was $r_s = -0.262$, $p < 0.001$. The authors stratified the analysis by age and by injury severity. When stratifying by age, the correlations were stronger for patients ≤ 48 years in the univariate analysis (GCS with GOS-E for ≤ 48 yoa, $r_s = 0.300$, $p < 0.001$; head AIS with GCS $r_s = -0.375$, $p < 0.001$). When stratifying by injury severity, there was no statistically significant correlation between GCS with GOS-E or with GCS and AIS in the univariate analysis for either patients with mild to moderate injury or patients with severe injury. When excluding patients who were intoxicated, correlations improved (GCS and GOS-E correlation, $r_s = 0.391$, $p = 0.001$; GCS and head AIS correlation, $r_s = -0.327$, $p = 0.004$). The authors conclude that the GCS is weakly correlated with 12-month outcome.²⁹

Gill et al. (2005) examined whether using component scores of the GCS or simplified scores would impact on the predictive accuracy of the GCS. Data was collected from a trauma registry of patients evaluated at a US Level I trauma centre between 1990 to 2002. The sample included 8,432 individuals who were admitted to the trauma center and met the standard trauma alert criteria specified by the institution and the American College of Surgeons. Patients were excluded if the GCS was missing. The predictive accuracy of the various scoring methods was examined using ROC curves. Each of the three individual components (motor, verbal, eye) of the GCS had almost equal performance to the total GCS score in accurately predicting the clinical outcomes of emergency department intubation, neurosurgical intervention, clinically significant brain injury, and mortality (ROC Areas: ED Intubation: Total GCS ROC area=0.87; Eye=0.79; Verbal=0.85; Motor=0.83; Neurosurgical Intervention: Total GCS ROC=0.87; eye=0.85; verbal=0.87; motor=0.85; Brain Injury: Total GCS ROC=0.83; eye=0.78; verbal=0.82; motor=0.79; Mortality: Total GCS ROC: 0.91; eye=0.86; verbal=0.89; motor=0.89).³⁶

Gill et al. (2006) examined whether the individual components of the GCS or two 3-point simplified scores would reduce overall accuracy for predicting clinically important outcomes of head trauma compared with the total GCS score for the initial evaluation of traumatic brain injury.³⁵ A review of 7,233 patient records maintained in a trauma registry (noted above in Gill et al., 2005) was performed. Patients were excluded if the GCS score or its sub-component scores performed by out-of-hospital personnel pre-admission were missing. Predictive accuracy of all scoring methods was examined using ROC curves and 95% confidence intervals. The authors studied four outcomes: ED intubation; neurosurgical intervention; traumatic brain injury

and hospital mortality. Each of the three individual components of the GCS approached the performance of the total GCS score in accurately predicting the clinical outcomes of emergency department intubation, neurosurgical intervention, clinically significant brain injury, and mortality (ROC Areas: ED Intubation: Total GCS ROC area=0.83; Eye=0.77; Verbal=0.81; Motor=0.79; Neurosurg Intvx: Total GCS ROC=0.86; eye=0.83; verbal=0.85; motor=0.84; Brain Injury: Total GCS ROC=0.83; eye=0.78; verbal=0.82; motor=0.79; Mortality: Total GCS ROC: 0.89; eye=0.85; verbal=0.87; motor=0.88). Additionally, two 3-point simplified scores (simplified verbal score, simplified motor score) demonstrated similar test performance to the total GCS score for the prediction of the 4 clinically relevant TBI outcomes. In summary, the Total GCS and its five simplified neurological scales provide acceptable to good predictive accuracy for the occurrence of specific clinical conditions associated with acute TBI.³⁵

Grmec et al (2001) assessed the value of three scoring systems for predicting the outcome of mortality in non-traumatic coma patients.³⁹ In a pre-hospital setting, both the Mainz Emergency Evaluation System (MEES) and the GCS were measured for each patient post-intervention. The Acute Physiology and Chronic Health Evaluation (APACHE II) score was recorded the day of admission. Data was collected from 286 consecutive patients, aged 16 and above, admitted to hospital for non-traumatic coma. The ROC curve was used to provide the predictive accuracy for mortality among all three scales. The AUC for the ROC was 0.86 for the APACHE II, 0.84 for the MEES, and 0.88 for the GCS. The authors concluded that the GCS score provides the best indicator of mortality in this patient group because of its simplicity, limited time to administer, and widespread use.³⁹

Hsiao et al. (2008) examined potential risk factors for mortality in blunt traumatic brain injury (TBI) patients seen in an emergency department (ED).⁴⁵ This chart review was performed on patients admitted to a tertiary care facility in Taiwan. Individuals with a CT scan and diagnosis of TBI in the ED and the need for intensive care were included in the review. A total of 204 TBI patients were admitted, with 48 being in the mortality group and the remaining 156 in the control group. Logistic regression was used to calculate the odds ratios for risk factors influencing death due to TBI. Death due to TBI was more likely in patients with a GCS score < 9 compared to those with a GCS score > 14 (OR=19.29, 95% CI=5.04, 73.82).⁴⁵

Husson et al, conducted a systematic review of determinants of 6-month functional outcome assessed within one month after moderate or severe TBI.⁴⁷ PubMed and PsychINFO were searched between 1995-2008. Two reviewers independently selected and quality assessed the articles. A best-evidence synthesis method was performed for prognostic factors assessed in two or more studies. Twenty-eight eight studies were accepted for the review. The authors found strong evidence for predicting poorer outcome at 6 months for: GCS score overall, GCS on admission to hospital score, the GCS motor score, midline shift on CT scan, subdural haematoma and pulsatility index. There was strong evidence of no association found for gender and intraventricular haemorrhage. There was inconclusive evidence for the prognostic value of GCS after resuscitation and field GCS scores.⁴⁷

In the aforementioned study by Iyer et al, for each 1-pt increase in total GCS score, there was an estimated 17% reduced odds of in-hospital mortality. For each 1-point increase in GCS score, there was an associated 18% reduction in odds of adverse neurological outcome (Rankin score of 3-6). These associations persisted after adjusting for age, sex and alertness. Predictive power with ROC curves: Area under curve for GCS=0.82 (for in-hospital mortality) and 0.76 for poor neuro outcome (Rankin 3-6).⁴⁸

Maguire et al conducted a systematic review of clinical prediction rules for CT use in head-injured children.⁶¹ Medline and Embase databases were searched. Eight clinical prediction rule studies were included out of 3357 titles/abstracts assessed. Studies were selected that included clinical prediction rules involving children aged 0-18 years with a history of head injury. Quality assessment of the articles was performed using a checklist of 14 items. Disagreement was resolved by discussion and consensus between three reviewers. Predictors of intracranial injury that were common to at least 6 rules were: GCS<15, mental status changes, evidence of skull fracture and scalp hematoma. Only studies incorporating the GCS are summarized here. A study by Dunning et al (2006) produced two rules and was the second highest methodologically scored study overall scoring 11 out of a possible 14 methodological points. The rule for children with any severity of trauma (n=22,772) had a rule-predicted CT frequency of 14%, a sensitivity of 0.98 (95% CI 0.96-1.00), a specificity of 0.87(95% CI 0.87-0.87), a NPV of 0.99 (95% CI 0.99-1.00) and a PPV of 0.09(0.08-0.10). The same study produced a rule for children with minor head injury (GCS≥13) (n=22,579). The rule-predicted CT frequency was 13%, sensitivity was 0.98 (95% CI 0.94-0.99), specificity 0.87(95% CI 0.87-0.88), NPV 0.99 (95% CI 0.99-1.00), and PPV 0.05 (95% CI 0.05-0.06). A study by Dalt et al (2006) produced a rule for children with any severity of trauma (n=3806). The rule-predicted CT frequency was 28%, sensitivity 1.00(0.82-1.00), sensitivity 0.73 (95% CI 0.71-0.74), NPV 1.00(95% CI 0.99-1.00) and PPV 0.021(95% CI 0.01-0.03). A study by Atabaki et al (2008) produced a rule for children with minor head injury (GCS≥13) (n=1000). The rule-predicted CT frequency was 54%, sensitivity 0.95(0.86-0.99), specificity 0.49(0.46-0.52), NPV 0.99 (95% CI 0.98-0.99), and PPV 0.12 (95% CI 0.09-0.15). It should be noted that both of these studies had a lower methodological quality score fulfilling 8 out of a possible 14 points.⁶¹

The MRT CRASH Trial Collaborators conducted a multinational, multicentre, prospective cohort study to develop prognostic models for death at 14 days and death or severe disability at 6 months post-TBI.⁷⁶ 10,008 head injured patients with a GCS score of 14 or less were enrolled. Participants were 16 years old or greater and within 8 hours of injury. 93% of participants were successfully followed up at 6 months. The outcome measures used were death at 14 days and death or severe disability as measured by the GOS at 6 months. Multivariable logistic regression was used to determine the independent association of prognostic variables with outcome. Prognostic variables studied were age, sex, cause of injury, time from injury to randomization, GCS score at randomization, pupil reactivity, results of CT, major extracranial injury, and level of income in the country. Two models were developed, one which contained only clinical and demographic variables and one which also contained CT results. Separate models were developed for low-middle and high income countries. Internal and external validity for the models was obtained. The relationship between the GCS and mortality at 14 days was linear and the relationship with 6 month outcome was similar. Age, GCS, pupil reactivity, and the presence

of major extracranial injury all predict poorer prognosis. The authors have developed a web based calculator using these models to calculate expected risk at death at 14 days or outcome at 6 months. This can be accessed at www.crash2.lshtm.ac.uk.⁷⁶

Oyetunji et al performed a cohort study comparing different parameters of physiologic injury assessment in their ability to predict in-hospital mortality after trauma.⁷⁴ 1,484,648 adult patients (at least 18 years of age) from the National Trauma Data Bank (NTDB version 7.0) were included. The measures tested included: Emergency department Revised Trauma Score (RTS), Emergency Department Systolic Blood Pressure (SBP); Shock (SBP less than 90 mm Hg); Emergency Department Glasgow Coma Scale-Total (GCS-T); Emergency Department Glasgow Coma Scale-Motor component only (GCS-M); SBP with GCS-T; SBP with GCS-M; Shock with GCS-T and Shock with GCS-M. Unadjusted results for GCS-total were AUC of 0.823 (95% CI 0.821-0.824). GCS-motor had an AUC of 0.840 (95% CI 0.838-0.842). There were more missing values for the RTS and much less for the variables of shock and SBP. GCS-total in combination with shock had a better AUC=0.841 (95% CI 0.840-0.843). GCS-motor in combination with shock or systemic blood pressure improved to 0.85. In the adjusted analysis (models were adjusted for gender, race, age, insurance status, anatomic injury severity, and mechanism of injury), RTS, GCS-M + Shock, and GCS-M + SBP all had an AUC between 0.94 and 0.95. A major limitation of this study is the large amount of missing data in the NTDB.⁷⁴

Tian et al. conducted a cohort study examining the incidence of posttraumatic cerebral infarction (PTCI) and predictive factors for the development of PTCI in patients with moderate or severe traumatic brain injury.⁹¹ Consecutive patients (n=657) admitted to the Shanghai Sixth People's Hospital with significant head trauma were considered for the study. They were excluded if they had open or penetrating wounds (n=89), a GCS score >12 (n=76), a history of hypertension or heart disease (n=49), a history of diabetes mellitus (n=31), if they died during the first 3 days post-admission (n=46), or if they had a prior cerebral infarction (n=13). In total 353 patients were enrolled. During the 3 month study period, 42(11.96%) patients developed posttraumatic cerebral infarction (PTCI): 31% in the first week, 43% in 2nd week, 14% in 3rd week, 7% in 4th week, and 5% between 1-3 months post-admission. Poor admission GCS (OR = 0.45; 95% CI 0.27-0.72), low systolic BP (OR = 0.35; 95% CI 0.17-0.71), decompression craniotomy (OR = 0.43; 95% CI 0.19-0.88), and brain herniation (OR = 0.41; 95% CI 0.20-0.86) were independently associated with PTCI.⁹¹

In the aforementioned paper by Wolf et al, using the Rankin Scale as outcome at 30 days post-admission, association with mortality was reported for both FOUR scale and GCS scores.¹⁰² The authors report that after adjusting for age, sex, alertness group, and diagnosis (traumatic vs non-traumatic), there is a reduction in odds of in-hospital mortality for each 1-point increase of the FOUR scale (OR=0.73, 95% CI = 0.56 – 0.95) and the GCS (OR = 0.56, 95% CI = 0.31-0.66).¹⁰²

3.4.2 Pediatric population

Courville et al performed a historical cohort study to develop a triaging tool to predict pediatric in-hospital mortality from data available soon after emergency department (ED) presentation.¹⁷ Data on 224,628 pediatric patients were obtained from the National Trauma Data Bank (NTDB) Version 6.2 which includes 1,465,729 patients admitted to US EDs from 2001 to 2005. Pediatric

patients were included if they were less than 18 years of age. Patients who did not have a hospital disposition status of either dead or alive or who were admitted more than one day after injury were excluded. Variables analyzed were (1) patient demographics, (2) Glasgow Coma Scale (GCS) values, (3) ED vital signs, (4) injury mechanism, and (5) number of days from trauma until admission. The authors reported that there was a 2.29% in-hospital mortality. Sixteen of 19 potential variables analyzed using the chi-square-assisted interaction detection (CHAID) model were associated with increased risk of in-hospital mortality. The most powerful variables of the CHAID model were low total GCS scores (i.e. 3) and systolic blood pressure (i.e. ≤ 98) in the ED. The CHAID model had an improved relative risk and a better combination of sensitivity and positive predictive value compared with GCS and systolic blood pressure in predicting mortality. Relative risk data was only provided for the CHAID model (training data: RR=79.09, 95% CI 73.5-85.1; testing data: RR=61.69, 95% CI 57.5-66.1). Positive predictive value was also only reported for the CHAID model (PV+ 58.2-61.5; PV- 99.1-99.2). The authors propose the use of a novel statistical technique (CHAID) that uses chi-squared testing for interaction detection in predicting mortality. The CHAID modeling seems to resemble decision analysis tree creation in assessing variables that could be predictive of outcome. The authors suggest that this analysis technique should be useful but needs to be further validated.¹⁷

In the study by Cohen described above (section 3.2.2), predictive value of the GCS was compared to that of the FOUR coma scale in predicting in-hospital mortality.¹⁶ Predictive value for in-hospital mortality was OR = 0.77 (95% CI 0.62-0.95) for the GCS. For poor outcome at the end of hospitalization, OR was 0.58 (95% CI 0.40-0.85). For in-hospital mortality, the area under the curve was 0.77 (95% CI 0.64-0.87). The differences in areas under the curve were not statistically significant between GCS and FOUR scores. Sensitivity and specificity were maximized for both the FOUR and the GCS at a score of 13 (FOUR sensitivity = 0.75, specificity = 0.86; GCS sensitivity = 0.75, specificity = 0.79). For poor outcome at the end of hospitalization, the area under the curve was 0.76 (95% CI 0.64-0.86) for GCS. Differences were not significant between GCS and FOUR scores. The results of this study may be limited because of the small sample size and the selection of the sample based on convenience. Finally, the outcome scale has been used in pediatric populations but there has no formal validation in this population.¹⁶

In a study examining functionality after head injury in adolescents, Goold et al. (2009) compared the GCS score to functional performance prior to hospital discharge.³⁸ Data was prospectively collected for all patients with TBI, aged 13-21 years, during a 10 year period at a US Level I trauma centre. The Occupational Therapy Head Injury Screen (OT HIMS) was a composite of the Galveston Orientation and Amnesia Test (GOAT) and the Cognisat. The purpose of the OT HIMS is to identify cognitive deficits in patients and provide education for patients on the impact of these on daily living. Two hundred and forty-eight individuals were administered the test. Correlation coefficients were calculated between the GCS and the GOAT and Cognisat. No correlation was noted between the GCS & the GOAT ($r=0.224$, $R^2=0.05$) or the GCS and the Cognisat ($R^2=0.093$). Additionally, the GCS score was not correlated with the scores of individuals who were discharged to rehabilitation facilities. Admission GCS did not predict the performance on OT HIMS after injury in this cohort of patients with adequate recovery to take the examination. One limitation is that patients who were not awake or did not have the functional ability to complete the OT HIMS were excluded. Thus, these results are only

applicable to those individuals who are functionally able to complete the examination, meaning that this study is not applicable to those with lower GCS scores.³⁸

Table 1. Glasgow Coma Scale - Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
Akavipat, 2009 ⁴	Cross-sectional inter-rater reliability, validity and feasibility study evaluating the newer Full Outline of UnResponsiveness (FOUR) to Glasgow Coma Scale (GCS); 6 assessors were used, 2 expert clinicians and 2 expert nurses, 2 novice clinicians and 2 inexperienced nurses	64 newly admitted patients at a neurosurgical unit in Thailand studied for each of the four stages of awake, drowsy, stuporous and comatose	Patients over 15 years of age who were newly admitted to the neurosurgical unit or suffered mental status alteration during admission were recruited except if they were affected by anesthesia or a sedative or neuromuscular blockers within 24 hours	Inter-rater reliability for the GCS total scores was high (n=16); ICC=0.97 (95% CI 0.91-0.99) for expert clinicians, 0.9 (0.71-0.96) for novice clinicians, 0.95 (0.87-0.98) for expert nurses and 0.97 (0.91-0.99) for inexperienced nurses; no significant difference was found between expert and novice clinicians/nurses; subscale reliability results in Table 2; Cronbach's alpha=0.85	Spearman's rank correlation between FOUR and GCS was 0.78 (p<0.01)	n/a

Table 1. Glasgow Coma Scale - Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
Chierigato A et al, 2010 ¹⁴	Survey study of anaesthetists (attending a course on neurotrauma throughout Italy) for their opinions on the weight of GCS ratings and other clinical variables in the assessment of traumatic brain injury with a focus on the first 24hrs after injury.	843 (63% response rate) anaesthetists responded to the survey between March and November 2005 out of 1334 who received the survey at the national courses on neurotrauma (7% of anaesthetists in Italy).	Anaesthetists recruited for the survey by distribution of the survey before the start of two nation-wide neurotrauma courses (9/12 courses on 'Severe Traumatic Brain Injury' and 8/12 courses on 'Neuroprotection in neuro-anaesthesia and neuro-intensive care'). Participants were asked to state their opinion, not what they thought were existing guidelines or accepted practice.	67% of the respondents believe that the definition of severe TBI should include, in addition to GCS scores, pupil reactivity to light and computer tomogram (CT) findings (the variables that guide Italian anaesthetists in TBI management). Most respondents (68.2%) administer sedation which allows prompt neurological evaluation and reliable GCS scoring. A minority of respondents (9.3%) withhold or antagonize sedation, delay tracheal intubation or allow patient-ventilator asynchrony.	n/a	n/a

Table 1. Glasgow Coma Scale - Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
Cho DY et al, 1997 ¹⁵	Cohort study assessing predictive value of 3 different scoring systems for head injury in a neurosurgical intensive care unit (NICU) for hospital mortality and functional outcome with a mean follow-up outcome assessment done 2.2yrs (1-3) after enrolment for surviving patients. The study compared the Acute Physiology, Age, and Chronic Health Evaluation (APACHE) II and III, and the Glasgow Coma Scale (GCS) scores.	200 consecutive patients with acute head injury and complete data were selected from an 8-bed NICU in a 1270-bed medical center in Taichung Veterans General Hospital (Taiwan).	Patients with acute head injury were recruited from a NICU in a Hospital in Taiwan from September 1992 to December 1994. Patients less than 14 years old were not included. APACHE II and III and GCS were scored on the day of admission (within 24hrs from entering the hospital). APACHE II and III scores include the GCS. Hospital mortality was defined as death before discharge from the hospital. Early mortality was defined as death before the 14th day after admission. Late mortality was defined as death after the 15th day from admission.	n/a	n/a	For prediction of hospital mortality, the best cut-off point was 5, the correct prediction outcome was 81.9%, the Youden index had the best cut-off point of 0.56 and the area under the ROC curve was 0.86 for the GCS (no statistical differences among APACHE III and II, and GCS). For the prediction of late mortality, APACHE III and II yield significantly better results in the area under the ROC curve, correct prediction and Youden index than those of GCS. Other physiological variables (AP III-GCS and AP IIGCS) play an important role in the prediction of late mortality in APACHE scores. For prediction of the functional outcome of surviving patients with acute head injury, the APACHE III yields the best results of correct prediction outcome, Youden index and the area under the ROC curve.

Table 1. Glasgow Coma Scale - Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
Cohen J, 2009 ¹⁶	Convenience cohort study including an inter-rater reliability assessment and a predictive value assessment of the GCS and the FOUR score in predicting in-hospital mortality and functional neurological outcome (morbidity) in pediatric patients.	Convenience sample of 60 pediatric patients were assessed by 2 nurses independently (from a total of 35 pediatric critical care nurse raters who participated in the study).	60 neuroscience patients, ages 2 to 18 years, were recruited from the pediatric intensive care unit of Children's Hospital in the United States. To assess the use of the GCS and the FOUR score on a variety of patients, the participants were assigned by the principal investigator to one of four categories upon admission: alert (n = 44), drowsy (n = 10), stuporous (n = 3), or comatose (n = 3), as previously defined by Ropper (1986). Patients from each of these categories were included in this study. Patients receiving sedatives and/or neuromuscular blocking agents were excluded. Poor outcome determined using the Modified Rankin scale as a score 3-6 with the following categorization: 0 = no symptoms; 1 = no significant disability despite symptoms, able to carry out all usual duties and activities; 2 = slight disability, unable to carry out all previous activities, but able to look after own affairs without assistance; 3 = moderate disability, requiring some help, but able to walk without assistance; 4 = moderately severe disability, unable to walk without assistance and unable to attend to own bodily needs without assistance; 5 = severe disability, bedridden,	n/a	Inter-rater reliability for the GCS total scores was weighted kappa=0.74 (95% CI 0.59-0.87); for the total FOUR score the weighted kappa was 0.95 (95% CI 0.91-0.99).	Predictive value of in-hospital mortality was OR=0.77 (0.62-0.95) for the GCS; for poor outcome at the end of hospitalization, OR=.58 (.40-.85) for the GCS. For in-hospital mortality, the area under the curve for the GCS was 0.77 (95% CI 0.64-0.87). The differences in areas under the curve were not statistically significant between GCS and FOUR scores. Sensitivity and specificity were maximized for both the FOUR and the GCS at a score of 13 (GCS sensitivity = .75, specificity = .79). For poor outcome at the end of hospitalization, the area under the curve for the GCS was .76 (95% CI = .64-.86). Differences were not significant between GCS and FOUR scores.

Table 1. Glasgow Coma Scale - Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
			incontinent and requiring constant nursing care and attention; and 6 = dead.			

Table 1. Glasgow Coma Scale - Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
Courville XF et al, 2009 ¹⁷	Retrospective cohort to develop a triaging tool to predict pediatric in-hospital mortality from data available soon after emergency department (ED) presentation.	Data on 224,628 pediatric patients were obtained from the National Trauma Data Bank (NTDB) Version 6.2 which includes 1,465,729 patients admitted to US EDs from 2001 to 2005.	Pediatric patients of less than 18 years of age. Patients who did not have a hospital disposition status of either dead or alive or who were admitted more than 1 day after injury were excluded. Variables analyzed were (1) patient demographics, (2) Glasgow Coma Scale (GCS) values, (3) ED vital signs, (4) injury mechanism, and (5) number of days from trauma until admission using the chi-square-assisted interaction detection (CHAID) model analysis.	n/a	n/a	There was a 2.29% in-hospital mortality. Sixteen of 19 potential variables analyzed were associated with increased risk of in-hospital mortality. The most powerful variables of the CHAID model were low total GCS scores (i.e. 3) and systolic blood pressure (i.e. <=98) in the ED. The CHAID model had an improved relative risk and a better combination of sensitivity and positive predictive value compared with GCS and systolic blood pressure in predicting mortality.

Table 1. Glasgow Coma Scale - Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
Davis DP et al, 2005 ²¹	Prospective cohort to explore the association between paramedic GCS and outcome in patients with traumatic brain injury (TBI) undergoing prehospital rapid sequence intubation (RSI). Follow-up period not reported.	412 adult major trauma victims with GCS 3–8 and clinical suspicion for head trauma enrolled to undergo succinylcholine-assisted intubation as part of the San Diego Paramedic RSI Trial.	The study enrolled adult major trauma victims with severe TBI as defined by: 1) apparent age 18 years or older, 2) major trauma victim as per county protocols, 3) transport time of 10 min or greater to the trauma resuscitation suite, 4) suspected head injury by mechanism or physical examination, 5) GCS score 3–8, and 6) inability to intubate without RSI. Subjects were excluded for failure to achieve intravenous access or if cardiopulmonary resuscitation (CPR) was required before RSI.	Inter-rater reliability between the principal investigator (physician) scoring immediately after patient delivery to hospital and the paramedic GCS scores in the field was high (kappa=0.995). The PI was debriefing paramedics upon patient delivery to check that the GCS scoring is appropriate so it does not appear that rater 2 was blinded to rater 1 scores.		Receiver-operator curve (ROC) analysis revealed a limited ability of GCS to predict the presence of severe TBI, injury severity, desaturation, aspiration, ICU length of stay, or ultimate survival (AUC 0.51-0.63). Predictive value of the GCS in survivors extubated and discharged from the ICU in 48h or less for survival was significant (OR 1.32, 95% CI 1.09 –1.61, p=0.005; adjusted for serum ethanol OR 1.37, 95% CI 1.11–1.69, p= 0.004) or the presence of severe TBI (OR 0.80, 95% CI 0.68–0.95, p= 0.009; adjusted OR 0.79, 95% CI 0.66–0.94, p= 0.007). Although a relationship between paramedic GCS and outcome exists, the ability to predict the severity of injury, airway-related complications, ICU length of stay, and overall survival is limited using this single variable.

Table 1. Glasgow Coma Scale - Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
Durham et al, 2000 ²³	Interrater reliability study of the GCS and CHOP Infant Coma Scale on hospitalized infants.	Patients: First series: 75 children (39M,36F). Second series: 10 infants in ICU. Raters: First series: 6 healthcare practitioners: neurosurgeon, 3 neurosurgical residents, a medical student and a trauma nurse specialist. Second series: a critical care attending and a critical care fellow.	First series: Randomly selected children from inpatient population. Excluded if greater than 2 years, sedated, paralytic pharmacologic agents used, or parental/nurse objection. Second series: Traumatic brain injury infants and/or acute hypoxicischemic brain injury under 2 yoa.	Group one (neurosurgeon vs neurosurgical resident)GCS eye 31.2%, $\kappa=0.94$; motor 28%, $\kappa=0.00$; verbal 56%, $\kappa=0.33$; Group 2(Neurosurgical resident vs medical student): GCS eye 100%, $\kappa=1.00$; motor 52%, $\kappa=0.33$; verbal 0%, $\kappa=0.24$; Group 3(neurosurgical resident vs trauma nurse) GCS eye 92%, $\kappa=0.86$; motor 48%, $\kappa=0.30$; verbal 64%, $\kappa=0.45$. Series 2 (ICU) GCS eye 100%, $\kappa=1.00$, motor 50%, $\kappa=0.40$, verbal 70%, $\kappa=0.54$	n/a	n/a

Table 1. Glasgow Coma Scale - Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
Eken et al, 2009 ²⁴	Prospective cohort study examining predictive validity of GCS and FOUR with 3-month mortality, in-hospital mortality and poor outcome using the Modified Rankin Scale.	Tertiary care hospital ED (Level IV trauma center). N=185	Included: All patients with head trauma and altered level of consciousness >17 yoa, neurological complaints of motor and/or sensory deficits, dysarthria, dysphasia, or facial asymmetry. Excluded: Intubated patients or those administered sedative or paralytic agents prior to arrival to ER.	n/a	n/a	Correlation between MRS at 3months and GCS: r=-0.43, p<0.0001. ROC curve analyses: For 3-month mortality, Total GCS AUC 0.726(95% CI 0.656-0.789), eye 0.646(0.573-0.715), motor 0.679(0.606-0.745), verbal 0.701(0.629-0.766); For Hospital mortality, Total GCS 0.735(0.655-0.797), eye 0.631(0.557-0.701), motor 0.662(0.589-0.730), verbal 0.705(0.634-0.770); For Rankin Score of 3-6 0.720(0.650-0.784), eye 0.620(0.546-0.690), motor 0.651(0.578-0.720), verbal 0.720(0.649-0.783). Cut off value for 3-month mortality prediction was 5 (positive likelihood ration=11.7). Multivariable analysis performed for association with 3-month mortality, GCS OR=0.796(95% CI 0.695-0.911; p=0.001).AUC for GCS in trauma patients only was 0.776 (p=0.0045; 95% CI 0.657-0.869). For non-traumatic patients only, AUC for GCS was 0.655(p=0.0026, CI:0.562-0.740).

Table 1. Glasgow Coma Scale - Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
Ely, EW et al, 2003 ²⁵	Prospective cohort interrater reliability and validity study	Reliability study: 2 critical care nurses, an intensivist, and a neuropsychiatric expert rated 38 ICU patients. Validity study: 275 mechanical ventilation patients enrolled. GCS and RASS rater by different raters – neuropsychiatric experts. (1360 paired observations).	Reliability study: Inclusion criteria: any adult admitted to the ICU; exclusion criteria: Hx of severe dementia, psychosis or neurologic disease, Patient or family refusal, admission to ICU after daily cap of 10 study patients (d/t staffing limitations). Validity study: consecutive patients receiving mechanical ventilation enrolled. Exclusion criteria: hx of psychosis or neurologic disease, non-english speaking or deaf, extubated or died before nurses' screen, previously enrolled in reliability study, or d/t patient or family refusal.	GCS weighted kappa=0.64, p<0.001	Construct validity: Spearman's correlation coefficient calculated for association between RASS score and GCS score.r=0.91, p,0.001. (Excellent correlation and discrimination). RASS also correlated with GCS over time (p<0.001) and odds ratio of having higher RASS scores with greater GCS scores was 1.39 (p<0.001).	n/a

Table 1. Glasgow Coma Scale - Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
Fabbri et al., 2007 ²⁷	Prospective cohort examining factors associated with unfavourable outcome (using GOS) in head injury patients with multivariable analysis.	ER of Forli, Italy. 309 participants enrolled consecutively.(91.4% of all moderate head injury patients).	Eligible: patients with acute moderate head injury, defined by GCS of 9-13, seen w/in 24 hours of trauma, age ≥10 years. Exclusion criteria: severe hypotension caused by extra-cranial injuries (8). Need for CPR(5), penetrating head injury(2), need for sedation for intubation before ER arrival(14).	n/a	n/a	Odds ratios with 95% CIs reported. Basal skull fracture 8.89(2.53-31.26) p<0.001; subarachnoid haemorrhage 4.5(1.73-11.73) p=0.002; coagulopathy 4.48(1.35-14.88) p=0.014; subdural haematoma 3.04(1.07-8.61) p=0.037; marshall category 1.82(1.33-2.50) p<0.001, GCS score 0.59(0.42-0.83) p<0.002. ROC curve using these predictive variables to predict outcome: accuracy =0.848±0.047, sensitivity: 95.6, specificity: 86.0%, PPV 99.1%, NPV 46.2%.

Table 1. Glasgow Coma Scale - Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
Fischer et al, 2010 ²⁸	Prospectively enrolled inter-rater reliability study of the GCS and the FOUR score. Also measured predictive values for the GCS and FOUR score using 28-day mortality as outcome.	ICU of the University Hospital of Basel, Switzerland. 267 prospectively enrolled patients (437 pair-wise ratings) for inter-rater reliability of ICU staff: 8 nurses and 4 physicians. Pair-wise ratings also measured in 100 of these participants by neurologists.	Inclusion: consecutive adult patients admitted to the ICU. Exclusion: unavailability of both neurologists or patient unwillingness to participate.	High degree of internal consistency for GCS: Cronbach's $\alpha=0.87$. Overall exact GCS agreement =71%. Interrater agreement for GCS, weighted kappa values with 95% CIs: Neurologist-neurologist: total GCS=0.67 (± 0.10), eye=0.75(± 0.12), motor=0.79(± 0.10), verbal=0.78(± 0.10); Neurologist-ICU staff: total=0.56(± 0.09), eye=0.68(± 0.10), motor=0.68(± 0.10), verbal=0.70(± 0.09); ICU staff-ICU staff: total= 0.63(± 0.08), eye=0.74(± 0.09), motor=0.78(± 0.09), verbal=0.86(± 0.07); Overall: total GCS = 0.61(± 0.05), eye=0.72(± 0.06), motor=0.74(± 0.06), verbal=0.78(± 0.05)	n/a	Area under the curve (AUC) for the receiver operating characteristic (ROC) curves for the GCS was 0.78 with a 95% confidence interval of 0.68-0.87. AUC of the ROC of the GCS-motor score for 28-day mortality was 0.75(95% CI 0.64-0.86).

Table 1. Glasgow Coma Scale - Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
Foreman et al, 2007 ²⁹	Prospective cohort measuring predictive validity of the AIS, ISS and GCS with GOS-E at 12 months.	Subjects recruited from neurosurgical service at an urban level 1 trauma center. 410 enrolled. F/u rate = 66%. No difference in age, GCS AIS, or length of stay baseline demographics between those lost to f/u. Difference in gender - more outcome information obtained from female participants.	Subjects with TBI. Brain injuries confirmed by presence of abnormal neuroimaging or a postresuscitation GCS score of less than 13. Mild injury = GCS 13-15 with abnormal CT. Mod injury = GCS score of 9-12. Severe injury = GCS of 3-8. Excluded: younger than 13 yoa, preexisting hx of intracranial tumor, stroke, epilepsy, MS, arteriovenous malformation, HIV encephalopathy, brain abscesses, Alzheimer's disease, Parkinson disease, or meningitis; prisoners and homeless patients (d/t difficulty with f/u).	n/a	n/a	Univariate correlation of GCS with GOS-E: Spearman's coefficient = -0.227, p < 0.001. For GCS with Head AIS, r = -0.262, p < 0.001. Multivariate analysis with GOS-E: GCS score and AIS, R = 0.275, p < 0.001; GCS score and ISS, R = 0.335, p < 0.001. Stratified analysis: GCS with GOS-E for ≤ 48 yoa, r = 0.300, p < 0.001; head AIS with GCS r = -0.375, p < 0.001. No significant correlation between outcome and any severity measure for patients > 48 yoa. Multivariate analysis with GOS-E stratified by age: GCS score and AIS for ≤ 48 yoa, R = 0.333, p < 0.001; GCS score and ISS, R = 0.404, p < 0.001. No statistically significant correlation between outcome and any severity measure for > 48 yoa. Stratification by injury severity: GCS > 8, GOS-E with GCS, r = 0.147, p < 0.057; GCS with AIS, r = -0.115, p < 0.137; for GCS ≤ 8, GOSE with GCS, r = 0.095, p < 0.344; for GCS with AIS, r = -0.019, p < 0.847; Multivariate GCS > 8, GCS and AIS with GOS-E, R = 0.176, p < 0.073; GCS and ISS with GOS-E, R = 0.231, p < 0.010;

Table 1. Glasgow Coma Scale - Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
						for GCS \leq 8, GCS and AIS with GOSE R=0.250, p<0.043; GCS and ISS with GOSE, R=0.341, p<0.002. When excluding intoxicated participants, GCS and head AIS correlation, r=-0.327, p=0.004; multivariate analysis of GCS and AIS with GOSE, R=0.451, p<0.001; GCS and ISS with GOSE, R=0.552, p<0.001.

Table 1. Glasgow Coma Scale - Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
Gill, 2005 ³⁶	Prospective cohort assessing the predictive accuracy of the GCS compared to any 1 of its 3 components or to a 3-pt motor or 3-pt verbal score for predicting clinically important outcomes after head trauma (ED intubation, neurosurgical intervention, clinically significant brain injury, and mortality during hospitalization)	8,432 patients of all ages (0-97 yoa) listed in a trauma registry who were evaluated at a level I trauma center between 1990-2002.	<p>Patients presenting to a Level I Trauma centre and who met standard trauma alert criteria as specified by the institution and in accordance with the American College of Surgeons. Patients were excluded if the eye, verbal or motor GCS components were missing from the registry.</p> <p>A priori differences in ROC curve area: <10%=lack clinical importance 10%-20%=possible clinical importance >20%=definite clinical importance</p>	n/a	n/a	<p>All differences between GCS & its components were less than 10%. The GCS eye component had the weakest predictive value. The simplified GCS motor and verbal scores had nearly the same test performance as the total GCS, with all differences less than 5%. ROC Areas: ED Intubation: Total GCS ROC area=0.865; Eye=0.787; Verbal=0.851; Motor=0.826. Neurosurg Intvx: Total GCS ROC=0.874; eye=0.849; verbal=0.869; motor=0.848. Brain Injury: Total GCS ROC=0.826; eye=0.780; verbal=0.823; motor=0.789 Mortality: Total GCS ROC: 0.906; eye=0.864; verbal=0.886; motor=0.894</p>

Table 1. Glasgow Coma Scale - Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
Gill, 2006 ³⁵	Prospective cohort assessing the predictive accuracy of the GCS reported by out-of hospital personnel compared to any 1 of its 3 components or to a 3-pt motor or 3-pt verbal score for predicting clinically important outcomes after head trauma (ED intubation, neurosurgical intervention, clinically significant brain injury, and mortality during hospitalization)	7,233 patients of all ages (0-97 yoa) listed in a trauma registry who were evaluated at a level I trauma center between 1990-2002.	GCS score of patients done by out-of-hospital personnel prior do admission to a Level I Trauma centre and who met standard trauma alert criteria as specified by the institution and in accordance with the American College of Surgeons. Patients were excluded if the out-of-hospital GCS or its components (eye, verbal or motor) were missing from the registry.	n/a	n/a	The five simplified neurological scales approached the performance of the total GCS for the prediction of four clinically relevant TBI outcomes. ROC Areas: ED Intubation: Total GCS ROC area=0.83; Eye=0.77; Verbal=0.81; Motor=0.79. Neurosurg Intvx: Total GCS ROC=0.86; eye=0.83; verbal=0.85; motor=0.84. Brain Injury: Total GCS ROC=0.83; eye=0.78; verbal=0.82; motor=0.79 Mortality: Total GCS ROC: 0.89; eye=0.85; verbal=0.87; motor=0.88
Goold et al., 2009 ³⁸	Prospective cohort study to determine the relationship between initial degree of head injury with subsequent cognitive function.	Data was collected from 248 patients, aged 13-21 years, admitted over a 10 year period to the Fletcher Allen Level I Trauma Center.	Patients admitted to a Level I trauma center. Patients had to be awake and have adequate physical function to complete the OT HIMS test, which was completed no sooner than 48 hrs prior to discharge. Patients < 13 years of age were not deemed to eligible to accurately complete the examination. Those who died before discharge, those who refused, and those whose parent's refused were not eligible.	n/a	n/a	No correlation was noted between the GCS & the GOAT (r=0.224, R ² =0.05) or the GCS and the Cognisat (R ² =0.093). Additionally, the GCS score was not correlated with the scores of individuals who were discharged to rehabilitation facilities. Admission GCS did not predict the performance on OT HIMS after injury in this cohort of patients with adequate recovery to take the

Table 1. Glasgow Coma Scale - Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
						examination.
Grmec et al., 2001 ³⁹	Prospective cohort examining the ability of the APACHE II, MEES, & GCS to predict mortality in nontraumatic coma patients.	286 consecutive patients hospitalized for non-traumatic coma between January 1996-October 1998. Subjects were 16-87 years old.	Patients with a GCS \leq 9 and a specific medical diagnosis of: hypoxic or ischaemic injury; focal cerebral injury; general cerebral injury; metabolic or septic encephalopathy; and drug induced coma or toxic injury, including drug overdose and coma persisting 24 hours after discontinuation of toxic substances.	n/a	n/a	The ROC curve was used to provide the predictive accuracy for mortality among all three scales. The AUC for the ROC was 0.86 for the APACHE II, 0.84 for the MEES, and 0.88 for the GCS. The differences between these ROC curves are not statistically significant

Table 1. Glasgow Coma Scale - Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
Guzel et al, 2008 ⁴⁰	Prospective cohort examining correlation between serum NSE levels and GCS scores in early stages of TBI.	169 (118F, 51M) patients prospectively enrolled at ER and neurosurgery departments of a hospital in Turkey.	Isolated head injury patients enrolled. Excluded: any patient with major health issues such as diabetes, renal or cardiac failure, CNS diseases, and bleeding disorders prior to trauma. Also excluded: patients with concomitant extracranial injury (i.e. pelvic or extremity fractures), intraabdominal, intrapleural or retroperitoneal hemorrhages, hepatic or splenic injuries, thorax or spinal cord damages, and alcohol intoxication. Patients who sustained injury more than 24 hours prior to admission or with a hx of neurological and neuropsychiatric disorders or alcohol, drug, substance abuse and /or previous hx of TBI were excluded.	n/a	Negative correlation between NSE levels and corresponding GCS scores. Pearson's correlation coefficient (r) used to determine correlation at 3 different points NSE 1 and GCS 1, r=-0.438 p<0.0001; NSE2 and GCS2, r=-0.529 p<0.0001; NSE3 and GCS3, r=-0.547 p<0.0001. NSE levels were higher in those patients with GCS scores ≤8 compared to GCS scores >9. NSE1: For GCS≤8, mean NSE=101.57±83.60, for GCS>9, Mean NSE=44.4±41.80, p<0.0001. NSE2: For GCS≤8, Mean NSE=87.19±86.21, for GCS>9, Mean NSE=28.27±19.52, p<0.0001. NSE3: For GCS≤8, mean NSE=59.15±68.57, for GCS>9, Mean NSE=31.16±42.52, p<0.0001.	n/a
Heron et al, 2001 ⁴⁴	Interrater reliability study using 6 videotaped patients with raters rating GCS while viewing video.	Raters: 75 RNs at a large metropolitan teaching hospital. 15 RNs from each of 5 specialty areas: general intensive care unit (GICU), coronary care unit (CCU), emergency department (ED), post anaesthetic recovery room (PARR), and neurosurgical intensive care unit	Patients: 6 patients selected from the NICU. One with GCS>12, four between GCS 5-12, and one with GCS<5. Patients >18 yoa and in hospital at least 24 hours prior to study.	Kappa scores estimated from a bar graph as actual scores were not reported. Total GCS score: All nurses κ=0.57, GICU κ=0.56, ER κ=0.53, PARR κ=0.51, NICU κ=0.65, CCU κ=0.55. Eye component: All nurses κ=0.81, GICU κ=0.76, ER κ=0.78, PARR κ=0.82, NICU κ=0.65, CCU κ=0.55. Verbal component: All nurses κ=0.91, GICU κ=0.95, ER κ=0.92, PARR κ=0.79, NICU κ=0.95, CCU κ=0.95. Motor component: All nurses κ=0.65,	n/a	n/a

Table 1. Glasgow Coma Scale - Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
		(NICU). Raters with less than 12 months experience excluded.		GICU $\kappa=0.62$, ER $\kappa=0.62$, PARR $\kappa=0.58$, NICU $\kappa=0.79$, CCU $\kappa=0.63$		
Hsiao et al., 2008 ⁴⁵	Retrospective chart review to assess risk factors predicting mortality in victims of blunt trauma brain injury in emergency departments.	204 patient records reviewed, all of whom had been admitted to the ICU at a tertiary care hospital in Taiwan between June 2004 – May, 2005. 48 of these patients died and the survivors were classified as the control group.	<p>Inclusion Criteria: Brain CT scan and diagnosis of TBI in the emergency department and the need for intensive care.</p> <p>Mortality Group: 48/204 patients who died in the ICU</p> <p>Control Group: 156/204 patients who were subsequently discharged from the ICU.</p>	n/a	n/a	Death due to TBI was more likely in patients with a GCS score < 9 compared to those with a GCS score > 14 (OR=19.29, 95% CI=5.04, 73.82). Additionally, age and skull fractures had increased risk for mortality (OR=1.04; 95%CI=1.01, 1.07. and OR=10.44; 95% CI=3.59, 30.38, respectively).

Table 1. Glasgow Coma Scale - Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
Husson et al, 2010 ⁴⁷	Systematic review of determinants, assessed within one month after moderate or severe TBI, of 6-month functional outcome.	Databases (pubMed and PsychINFO) searched between 1995-2008. 2 reviewers independently selected and quality assessed. Best-evidence synthesis method performed for prognostic factors assessed in 2 or more studies. 28 studies included, 27 high quality.	Selection criteria of studies: prospective cohort studies, determinants associated with functional outcome 6 months after moderate to severe traumatic brain injury in adult patients; determinants assessed within the first month post-injury.	n/a	n/a	Strong evidence for predicting outcome at 6 months for: GCS, GCS admission, motor score, midline shift on CT scan, subdural haematoma and pulsatility index. Strong evidence of no association found for gender and intraventricular haemorrhage.
Iyer et al, 2009 ⁴⁸	Prospective cohort studying interrater reliability, validity and predictive validity of the GCS and FOUR score scales in critically ill patients.	Raters: 18 nurses, 10 fellows, and 5 consultants from ICU staff. Patients: 100 patients from ICUs of Mayo clinic's Saint Mary's Hospital over a 1 year period.	Nonsedated or nonparalyzed patients admitted to ICUs with abnormal consciousness.	Cronbach α for GCS=0.87. Weighted kappas for GCS score: Overall total GCS weighted κ =0.98(0.98-0.99). Overall total Verbal GCS=0.98(0.97-0.98), Overall motor GCS =0.97(0.96-0.98). Overall eye GCS=0.96(0.95-0.97). Breakdown by raters: Fellow/fellow: total GCS=0.96, verbal=0.84, motor 0.82, eye 1.00. Fellow/nurse: total GCS=0.97, verbal=0.91, motor=0.83, eye=0.75. Nurse/intensivist: total GCS=0.97, verbal=0.61, motor=0.89, eye=0.59. Fellow/intensivist: total GCS=0.99, verbal=0.83, motor=0.94, eye=0.84.	Spearman correlation coefficients for GCS and FOUR score were P=0.98 (first rater) and P=0.92(second rater).	For each 1-pt increase in total GCS score an estimated 17% reduced odds of in-hospital mortality. For each 1-point increase in GCS score an associated 18% reduction in odds of adverse neuro outcome (Rankin9 score of 3-6). Associations persisted after adjusting for age, sex and alertness. Predictive power with ROC curves: Area under curve for GCS=0.82 (for in-hospital mortality) and 0.76 for poor neuro outcome (Rankin 3-6).

Table 1. Glasgow Coma Scale - Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
Maguire et al, 2009 ⁶¹	Systematic review of published clinical prediction rules for CT scan use for intracranial injury in children with head injury.	Medline and Embase searched. 8 clinical prediction rules identified out of 3357 titles/abstracts assessed.	Studies selected that included clinical prediction rules involving children aged 0-18 years with a hx of head injury. Quality assessed by a checklist of 14 items. Disagreement resolved by discussion and consensus between 3 reviewers.	n/a	n/a	4 rules accepted that included GCS in the prediction rules. For children with minor head injury (GCS≥13) two prediction rules accepted. For Atabaki et al: the rule-predicted CT frequency was 54%, sensitivity(95% CI)=0.95(0.86-0.99), specificity=0.49(0.46-0.52), NPV=0.99(0.98-0.99), PPV=0.12(0.09-0.15). For Dunning et al: Rule-predicted frequency was 13%, sensitivity=0.98(0.94-0.99), specificity=0.87(0.87-0.88), NPV=0.999(0.999-1.00), PPV=0.05(0.05-0.06).For children with any severity of trauma 2 rules were accepted. For Dalt et al: rule-predicted CT frequency=28%, sensitivity=1.00(0.82-1.00), specificity=-.73(0.71-0.74), NPV=1.00(0.998-1.00),PPV=0.021(0.01-0.032). For Dunning et al: Rule-predicted CT frequency was 14%, sensitivity =0.98(0.96-1.00), specificity=0.87(0.87-0.87), NPV=0.999(0.999-1.00), PPV=0.09(0.08-0.10).

Table 1. Glasgow Coma Scale - Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
MRT CRASH Trial Collaborators (Perel et al., 2008) ⁷⁶	Prospective cohort using multivariable logistic regression to develop and validate practical prognostic models for death at 14 days and for death or severe disability 6 months after TBI.	Multi-national, multi-centre trial. 10,005 participants enrolled. 7% loss to f/u at 6 months.	All head injured patients with a GCS of 14 or less that are 16 years old or greater, within 8 hours of injury. Excluded sedated patients and those patients whom corticosteroid therapy is clearly indicated or clearly not-indicated	n/a	n/a	Multivariable predictive model (without CT). Odds ratios reported with 95% CIs. For mortality at 14 days in high income countries(n=2294): Age(per 10 year increase after 40 years)=1.72(1.62-1.83); GCS(per decrease of each value of GCS)=1.24; Pupil reactivity: both=1, one=2.57(1.65-4.00), none=5.49(3.70-8.15); major extracranial injury=1.53(1.11-2.09). For mortality at 14 days in low-middle income countries(n=7412): age=1.47(1.40-1.54), GCS=1.39(1.35-1.42), pupil reactivity: one=1.91(1.53-2.39), none=3.92(3.14-4.90), major extracranial injury=1.15(0.99-1.34). For death or severe disability at 6 months in high income countries(n=2185): age=1.73(1.64-1.82), GCS=1.22(1.18-1.25), pupil reactivity: one=2.43(1.62-3.66), none=3.28(2.20-4.89), major extracranial injury=1.62(1.26-2.07). For death or severe disability at 6 months in low-middle income countries: age=1.70(1.63-1.77), GCS=1.42(1.39-1.45),

Table 1. Glasgow Coma Scale - Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
						<p>pupil reactivity: one=2.01(1.59-2.56), none=4.54(3.38-6.11), major extracranial injury=1.73(1.51-1.99). Additional models were created including CT scan findings. For mortality at 14 days in high income countries: age=1.73(1.62-1.84), GCS=1.18(1.12-1.23), one pupil reactive=2.00(1.25-3.20), no pupil reactive=4.00(2.58-6.20), major extracranial injury=1.53(1.10-2.13), CT findings: petechial hemorrhages=1.15(0.83-1.59), obliteration of 3rd ventricle or basal cisterns=4.46(2.97-6.68), subarachnoid bleed=1.48(1.09-2.02), midline shift=2.77(1.82-4.21), non-evacuated haematoma=2.06(1.49-2.84). For mortality at 14 days in low-middle income countries: age=1.46(1.39-1.54), GCS=1.27(1.24-1.31), one pupil reactive=1.45(1.14-1.86), no pupil reactive=3.12(2.46-3.97), major extracranial injury=1.08(0.91-1.28), CT findings: petechial haemorrhages=1.26(1.07-1.47), obliteration of 3rd</p>

Table 1. Glasgow Coma Scale - Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
						ventricle or basal cisterns=1.99(1.69-2.35), subarachnoid bleed=1.33(1.14-1.55), midline shift=1.78(1.44-2.21), non-evacuated haematoma=1.48(1.24-1.76). For death or severe disability at 6 months in high income countries (n=1955): age=1.73(1.63-1.83), GCS=1.18(1.14-1.22), one pupil reactive=2.12(1.39-3.24), no pupil reactive=2.83(1.84-4.35), major extracranial injury=1.55(1.20-1.99), CT findings: petechial hemorrhages=1.21(0.95-1.55), obliteration of 3rd ventricle or basal cisterns=2.21(1.49-3.30), subarachnoid bleed=1.62(1.26-2.08), midline shift=1.93(1.30-2.87), non-evacuated haematoma=1.72(1.33-2.22). For death or severe disability at 6 months in high low-middle income countries (n=5394): age=1.72(1.64-1.81), GCS=1.34(1.30-1.37), one pupil reactive=1.54(1.20-1.99), no pupil reactive=3.56(2.60-4.87), major extracranial injury=1.61(1.38-1.88), CT

Table 1. Glasgow Coma Scale - Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
						findings: petechial hemorrhages=1.49(1.29-1.73), obliteration of 3rd ventricle or basal cisterns=1.53(1.31-1.79), subarachnoid bleed=1.20(1.04-1.39), midline shift=1.86(1.48-2.32), non-evacuated haematoma=1.68(1.43-1.97).
Oyetunji et al, 2010 ⁷⁴	Retrospective cohort study comparing different parameters of physiologic injury assessment (Revised Trauma Score [RTS] compared to GCS, shock, systemic blood pressure [SBP]) in their ability to predict mortality after trauma.	1,484,648 adult patients from the National Trauma Data Bank (NTDB version 7.0) were studied. The measures tested included: Emergency department Revised Trauma Score (RTS), Emergency Department Systolic Blood Pressure (SBP); Shock (SBP less than 90 mm Hg); Emergency Department Glasgow Coma Scale-Total (GCS-T); Emergency Department Glasgow Coma Scale-Motor component only (GCS-M); SBP with	Adult patients (at least 18 years of age) in the NTDB were included. For purposes of this study, the conventional classifications of AUC were assumed, suggesting that an AUC less than 0.60 is poor, 0.70 to 0.79 is fair, 0.80 to 0.89 is good and greater than 0.90 is excellent discrimination	n/a	n/a	Unadjusted results for GCS-total were AUC of 0.823 (95% CI 0.821-0.824) with 267,952 missing values. GCS-motor had an AUC of 0.840 (95% CI 0.838-0.842) with 211,300 missing values. GCS-total in combination with shock had a better AUC=0.841 (95% CI 0.840-0.843). GCS-motor in combination with shock or systemic blood pressure improved to 0.85. In the adjusted analysis (models were adjusted for gender, race, age, insurance status, anatomic injury severity, and mechanism of injury), RTS, GCS-M + Shock, and GCS-M + SBP all had an AUC between 0.94 and 0.95.

Table 1. Glasgow Coma Scale - Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
		GCS-T; SBP with GCS-M; Shock with GCS-T and Shock with GCS-M.				
Tian et al, 2008 ⁹¹	Cohort study examining incidence and timing of PTCI in patients with moderate or severe head trauma and risk factors for the development of PTCI in these patients using logistic regression.	353 consecutive patients with moderate or severe head trauma retrospectively reviewed.	Patients admitted with significant head trauma included. Patients excluded if they had : 1. Open or penetrating wounds, 2. GCS >12, 3. Hx of hypertension or heart disease, 4. Hx of diabetes mellitus, 5. Death during first 3 days post-admission, 6. Prior cerebral infarction.	n/a	n/a	42(11.96%) patients developed posttraumatic cerebral infarction (PTCI). 31% in the first week, 43% in 2nd week, 14% in 3rd week, 7% in 4th week, and 5% between 1-3 months post-admission. Poor admission GCS (OR = 0.45; 95% CI 0.27-0.72), low systolic BP (OR = 0.35; CI 0.17-0.71), decompression craniotomy (OR = 0.43; CI 0.19-0.88), and brain herniation (OR = 0.41; CI 0.20-0.86) were independently associated with PTCI. Authors conclude that PTCI is a relatively common complication in patients with head trauma that develops early in the clinical course and the above factors are risk

Table 1. Glasgow Coma Scale - Accepted articles						
Author, Publication Year	Study Design	Setting & Subjects, Number (n) Enrolled	Case Definition	Reliability	Face/Construct Validity	Predictive Validity
						factors for PTCI in patients with moderate or severe traumatic brain injury.
Wolf et al, 2007 ¹⁰²	Prospective interrater reliability study. 20 nurses rated both the FOUR and the GCS. Participant order randomly assigned to nurses who were blinded to other ratings and not aware of the diagnosis of the patient.	80 (37 F; 43 M) patients with acute neurologic disease in an intensive care unit. 20 patients in each conscious category.	Patients aged 18 years and older admitted to a neuroscience ICU and patients seen in consultation and admitted to ICU within 24 hours of admission were included. Those on sedatives that could not be temporarily discontinued were excluded.	Overall kw (weighted kappa) FOUR score = 0.85; GCS=0.83. Cronbach α FOUR score = 0.95; GCS = 0.86. Overall kw for FOUR score with experienced nurses was 0.92, with 1 experienced and 1 inexperienced 0.83 and was 0.82 for 2 inexperienced nurses. GCS overall kw was 0.86 with experienced nurses, 0.81 for one experienced and one inexperienced and 0.83 for 2 inexperienced nurses.	n/a	For each 1-pt increase in FOUR score, there is a decreased odds of in-hospital mortality (OR=0.73, 95% CI = 0.56 - 0.95). For 1-pt increase in GCS score, there is a decreased odds of in-hospital mortality (OR = 0.45, 95% CI = 0.34 - 0.93).

12.4 Literature Reviews of Other Topics

ASIA Impairment Scale

Purpose of the Literature Review

The purpose of the review is to determine the reliability and validity (face, construct and predictive) of the ASIA (American Spine Injury Association) Impairment Scale. The results of the review were submitted to the Catastrophic Impairment Expert Panel to inform their deliberation of the impairment scale.

Methodology

We conducted a review of the recent literature. The title and abstract of the articles were screened for relevance by Pierre Côté and Heather Shearer. The relevant literature was examined to guide the Panel in their decisions to incorporate this measure into the revised definitions.

Search Strategy

A Medline (Pubmed) search was performed from January 2000 to December 2010. The search strategy included key terms (“ASIA impairment scale”) AND (valid* OR reliab* OR predict* OR prognos*) as well as ("ASIA impairment scale") AND (Reproducibility of Results[MeSH]). References of selected articles were reviewed for other potentially relevant articles. Finally, the ‘Find Similar’ option in Pubmed was used to select further relevant articles using the most recent relevant result. The option to have any new articles with the term ‘ASIA Impairment Scale’ emailed to the reviewer was selected.

Pubmed Search Strategy

(“ASIA Impairment scale”) AND (valid* OR reliab* OR predict* OR prognos*)
("ASIA impairment scale") AND (Reproducibility of Results[MeSH])

Results

Search Results

The Pubmed search yielded 36 results. Following a title and abstract review for relevance to the topic of validity, reliability or predictive value, 19 articles were excluded. A further review of titles and abstracts was performed by Pierre Côté. From the remaining 17 articles, 3 were deemed relevant and presented to the Panel.^{32;63;70} One additional article was presented to the Panel after its publication in March, 2011.⁹⁴

Global Assessment of Functioning (GAF)

Purpose of the Literature Review

The purpose of the review is to determine the reliability of the GAF (Global Assessment of Functioning). The results of the review were submitted to the Catastrophic Impairment Expert Panel to inform their deliberation of the scale.

Methodology

We conducted a review of the recent literature. The title and abstract of the articles were screened for relevance by Pierre Côté and Heather Shearer. The relevant literature was examined to guide the Panel in their decisions to incorporate this measure into the revised definition of 2 (f).

Search Strategy

A Medline (Pubmed) search was performed from January 2000 to December 2010. The search strategy included key terms ("global assessment of functioning") AND (reliab*). References of selected articles were reviewed for other potentially relevant articles. The option to have any new articles with the term 'global assessment of functioning' emailed to the reviewer was selected.

Pubmed Search Strategy

"global assessment of functioning" AND reliab*

Results

Search Results

The Pubmed search yielded 48 results. Following a title and abstract review for relevance to the topic of validity, reliability or predictive value, 17 articles were excluded. A further review of titles and abstracts was performed by Heather Shearer and Pierre Côté. From the remaining 12 articles, 4 were deemed relevant and presented to the Panel.^{80;81;84;96}

King's Outcome Scale for Childhood Head Injury (KOSCHI)

Purpose of the Literature Review

The purpose of the review is to determine the reliability and validity (face, construct and predictive) of the KOSCHI (King's Outcome Scale for Childhood Head Injury). The results of the review were submitted to the Catastrophic Impairment Expert Panel to inform their deliberation of the scale.

Methodology

We conducted a review of the recent literature. The title and abstract of the articles was screened for relevance by Pierre Côté and Heather Shearer. The relevant literature was examined to guide the Panel in their decisions to incorporate this measure into the revised definition of paediatric traumatic brain injury.

Search Strategy

A Medline (Pubmed) search was performed from January 2000 to December 2010. The search strategy included key terms (King's Outcome Scale for Childhood Head Injury) AND (reliab*), (KOSCHI) as well as (King's Outcome Scale for Childhood Head Injury). References of selected articles were reviewed for other potentially relevant articles. The option to have any new articles with the term 'King's Outcome Scale for Childhood Head Injury' emailed to the reviewer was selected.

Pubmed Search Strategy

(King's Outcome Scale for Childhood Head Injury) AND (reliab*)

KOSCHI

King's Outcome Scale for Childhood Head Injury

Results

Search Results

The Pubmed search yielded 10 results. Following a title and abstract review for relevance to the topic of validity, reliability or predictive value, 1 article was excluded. A further review of titles and abstracts was performed by Pierre Côté. From the remaining 9 articles, 8 were deemed relevant and presented to the Panel.^{3;9;11;18;41-43;85}

Appendix 13

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Appendix 14

DISCLOSURES OF CONFLICTS OF INTEREST

1. Arthur Ameis

1. Research grants:
None
2. Consultancy:
Multi-Disciplinary Assessment Centre
3. Honorarium (Monetary or Equivalent):
None
4. Honorarium (Non-Monetary):
Canadian Society of Medical Evaluators; Canadian Life and Health insurance Association; Osgoode Hall Law School; Ontario Trial Lawyers; Canadian Defense Lawyers

2. Linda Carroll

1. Research grants:
Past Sources of Research Funding: Jalan Pacific Inc (Brazil), Länsförsäkringar (Sweden), Canadian Chiropractic Protective Association, National Chiropractic Mutual Insurance Company, Insurance Bureau of Canada, Whiplash Commission (Sweden), Amgen, State Farm Inc., Alberta Heritage Foundation for Medical Research, WorkSafe BC, CIHR, Agency for Healthcare Research and Quality (USA), Royal Alexandra Hospital Foundation (Edmonton, AB), University Hospital Foundation Medical Research Competition (Edmonton, AB), National Health Research Development Program (NHRDP), Saskatchewan Government Insurance, Insurance Corporation of British Columbia, Société d'assurance automobile du Quebec, Trygg-Hansa Insurance Corporation, Sweden. I was also granted a five-year salary award as a Health Scholar from the Alberta Heritage Foundation for Medical Research.

Current Sources of Research Funding: Universities Occupational Safety and Health Education and Research Center (ERC), WorkSafe BC, Alberta Transportation Board: Traffic Safety, WCB Alberta, Alberta Heritage Foundation for Medical Research (7 - year Senior Health Scholar Award). I also have a seven-year salary award as a Senior Health Scholar from the Alberta Heritage Foundation for Medical Research (now Health Innovates – Alberta)

2. Consultancy:
Consultant Epidemiologist for Alberta Department of Finance (Insurance Branch).

3. J. David Cassidy

1. Research grants:
Danish Council for Independent Research (DK), Dickson Memorial Foundation, Canadian Institute of Health Research, Agency for Healthcare Research and Quality (USA), Alberta Provincial CIHR Training Program in Bone and Joint Health, Jalan Pacific Inc., Saskatchewan Health, Länsförsäkringar (SE), Insurance Bureau of Canada, Alberta Heritage Foundation for Medical Research, Ontario Workplace Safety and Board, Insurance Corporation of British Columbia, Société d'assurance automobile du Quebec, Who Collaborating Centre for Neurotrauma at Karolinska Institute (SE), AAFA Insurance (SE), Folksham Insurance (SE), Volvo Car Company (SE), National Chiropractic Mutual Insurance Company (USA), AVIVA Canada, Canadian Chiropractic Protective Association, Ontario Ministry of Health and Long Term Care, Ontario Neurotrauma Foundation, Chiropractors' Association of Saskatchewan, Canadian Orthopaedic Foundation, Foundation for Chiropractic Education and Research (USA) and Chiropractic Foundation for Spinal Research.
2. Consultancy:
Canadian Chiropractic Protective Association, Insurance Bureau of Canada, Attorney General of Nova Scotia, Connecticut Chiropractic Council.

3. Honorarium:
Canadian Chiropractic Protective Association, Program of Insurance Medicine and Medicolegal Expertise – University of Montreal, National Chiropractic Mutual Insurance Company, Trillium Health Centre Spine Institute, Danish Chiropractic Association, Canadian Society of Chiropractic Evaluators, University of Southern Denmark, Norwegian Society for Low Back Pain Research, Societé d'Assurance Automobile du Québec, Commission de la santé et de la sécurité du travail (Québec), Decatur Memorial Hospital (USA), Saskatchewan Government Insurance, Canadian Society of Medical Evaluators, University of Toronto Centre for Industrial Relations and Human Resources, Nordic Association of Traffic Medicine, World Federation of Chiropractic, Canadian Insurance Claims Managers Association, Swedish Society of Medicine, and Canadian Bar Association.

4. Pierre Côté

1. Research grants:
Canadian Institute of Health Research, Ontario Workplace Safety and Board, WorkSafe BC, Manitoba Workers' Compensation Board, National Chiropractic Mutual Insurance Company, AVIVA Canada, Canadian Chiropractic Protective Association, Ontario Ministry of Health and Long Term Care, Ontario Neurotrauma Foundation, Arthritis Society, Ontario Chiropractic Association, Chiropractic Foundation for Spinal Research, Foundation for Chiropractic Education and Research
2. Consultancy:
Canadian Chiropractic Protective Association, Insurance Bureau of Canada, Financial Services Commission of Ontario
3. Honorarium:
Association of Workers' compensation Board of Canada, Canadian Chiropractic Protective Association, Societé des Experts an Evaluation Medico-Légale du Québec, National Chiropractic Mutual Insurance Company, Trillium Health Centre Spine Institute, Institut Franco-Européen de Chiropratique, American College of Chiropractic Consultants, Canadian Life Insurance Medical Officers Association, Canadian Society of Chiropractic Evaluators, University of Southern Denmark, University of Bergen, Norwegian Society for Low Back Pain Research, College of the International Association of Industrial Boards Accidents and Commissions, Societé d'Assurance Automobile du Québec

5. Ron Kaplan

1. Research grants:
No research grants in over 15 years
2. Consultancy:
No consultancy
3. Honorarium:
Has received small gifts for modest amounts for speaking at various meetings.
4. Clinical Treatment and Assessment Practice:
- Clinical Treatment: Provides and directs assessment and treatment to patients in a variety of contexts including patients injured in auto accidents. Patients may self refer and are also referred by health professionals, lawyers, insurers.
 - Expert Assessments and Reports: Provides and directs psychological, neuropsychological and multi-disciplinary expert assessments in a variety of contexts including auto accident injuries. Referrals for expert assessments may be from plaintiff and defense counsel and insurers. Expert assessments address a number of questions including: diagnosis, prognosis, impairment level, disability, future care, impact on family relationships, etc. Provides testimony in arbitrations and court.
5. Voluntarily Positions:
- I am a member of a number of voluntary professional organizations.
 - Co- chair of the Ontario Psychological Association's auto insurance task force. The task force provides information to insurers, lawyers, government and the general public regarding psychological disorders as well as the role of psychological assessment and treatment. The task force also provides education to psychologists regarding the

appropriate application of SABS for provision services to patients with psychological impairments resulting from auto accidents. I receive no funds from my association for this work and pay my own expenses.

6. Michel Lacerte

1. Research grants: Not Applicable
2. Consultancy: Insurance Bureau of Canada, St. John's Rehab Hospital, WSIB, Multiple defense and plaintiff law firms and insurance companies (conducting independent medical examinations), Kaiser Aluminium, University of Western Ontario, Université de Montréal, Ca.
3. Honorarium: Canadian Life Insurance Medical Officers Association, Canadian Society of Medical Evaluators, Société des médecins experts du Québec, L'association des orthopédistes du Québec

7. Patrick Loisel

1. Research grants: Canadian Institute of Health Research, Institut de Recherche Robert Sauvé en Santé et Sécurité du Travail (Québec), Réseau de Recherche en Adaption Réadaptation du Québec
2. Consultancy : Workplace Safety and Insurance Board (Ontario)
3. Honorarium: University Health Network, Canadian Memorial Chiropractic College, Université de Sherbrooke, Reinsurance Group of America

8. Peter Rumney

I am a Paediatrician practicing solely in the field of acquired and traumatic brain injury rehabilitation for children and adolescents. My practice is in a hospital environment in an academic health sciences centre. I am paid through an alternative payment plan program from the Ministry of Health to deliver this care. I do medical legal evaluations for the patients that I have seen as my active patients. This means that I am primarily doing plaintiff medical legal reports. However, I do select reports for the Canadian Medical Protective Association and this is most often defence work.

My current research endeavours in the last five years have included a multi-centred study that is funded by the Ontario Neurotrauma Foundation. This study is looking at the factors that are helpful in supporting a successful reintegration for the child back into the community and school 2 – 5 years post trauma. I also have funding from the Health Innovation Fund to try and replicate and implement a Memory Link prosthesis clinic for adolescents here at the Holland Bloorview Kids Rehabilitation program. This is copying the Memory Link clinic from Baycrest Treatment Centre.