Australian Government
Repatriation Medical Authority

REPATRIATION MEDICAL AUTHORITY

STATEMENT OF REASONS

RE: DECISION NOT TO MAKE STATEMENTS OF PRINCIPLES FOR POSTCONCUSSION SYNDROME

PART I INTRODUCTION

1. The Repatriation Medical Authority (the Authority) has decided to revoke and reissue Statements of Principles in respect of physical injury due to munitions discharge under subsections 196B (2) and (8) or (3) and (8) of the *Veterans' Entitlements Act 1986* (the Act), following notice of an investigation into physical injury due to munitions discharge gazetted on 30 June 2010 in the *Commonwealth of Australia Gazette*.

2. The Authority has decided to make Statements of Principles under subsections 196B (2) or (3) of the Act in respect of concussion and moderate to severe traumatic brain injury, following notice of an investigation into traumatic brain injury gazetted on 14 December 2011 in the *Commonwealth of Australia Gazette*.

3. The Authority has decided not to make Statements of Principles under subsections 196B (2) or (3) of the Act in respect of postconcussion syndrome, following notice of an investigation into postconcussion syndrome gazetted on 9 May 2012 in the *Commonwealth of Australia Gazette*.

4. The Authority declares that postconcussion syndrome is not a disease or injury for the purposes of the Act and hence is not a condition for which a Statement of Principles could be determined.

PART II BACKGROUND TO THE INVESTIGATION

5. In June 2010 the Authority, acting on its own initiative, notified its intention to carry out an investigation concerning physical injury due to munitions discharge, in accordance with s.196G(1) of the Act. An investigation notice was placed in the *Commonwealth of Australia Gazette* on 30 June 2010.

6. In December 2011 the Authority, acting on its own initiative, notified an investigation to ascertain if Statements of Principles concerning traumatic brain injury (TBI) could be determined, in accordance with s.196G(1) of the Act. An investigation notice was placed in the *Commonwealth of Australia Gazette* on 14 December 2011.

7. In April 2012 the Authority, acting on its own initiative, notified an investigation to ascertain if Statements of Principles concerning postconcussion syndrome could be determined, in accordance with s.196G(1) of the Act. This investigation was conducted in conjunction with the investigation in respect of TBI. An investigation notice was placed in the *Commonwealth of Australia Gazette* on 9 May 2012.

8. These investigations were undertaken as part of a comprehensive review of matters relating to TBI.

PART III SUBMISSIONS RECEIVED BY THE AUTHORITY PURSUANT TO SECTION 196F

9. Following notification of its investigation, the Authority received five submissions from persons or organisations eligible to make submissions pursuant to s.196F of the Act as follows:

(a) A submission dated 14 March 2012 from a senior representative of an ex-service organisation. The submission consisted of a range of documents, including reports, fact sheets, book titles, published articles and lists of references. The material was reviewed and information that appeared likely to be relevant sound medical-scientific evidence was obtained for the purposes of the investigation.

(b) A letter dated March 2012 from the Surgeon General Australian Defence Force, providing statistics on numbers of cases of TBI in the Defence Forces.

(c) A letter dated 30 March 2012 from the President of the Repatriation Commission. The letter stated that there would be an examination of current practices for claims relating to TBI and mild traumatic brain injury (MTBI).

(d) A letter dated 25 June 2012 from the President of the Repatriation Commission, providing the information promised in the letter of 30 March.

(e) A letter dated 25 July 2012 from a veteran concerning symptoms experienced after exposure to artillery fire.

PART IV EVIDENCE/INFORMATION AVAILABLE TO THE REPATRIATION MEDICAL AUTHORITY

10. The following information was available to the Authority.

(a) Submissions and correspondence as detailed in Part III above.

(b) A literature search conducted on PubMed in December 2011 using the search terms "mild traumatic brain injury" and "traumatic brain injury": mild[All Fields] AND ("brain injuries"[MeSH Terms] OR ("brain"[All Fields] AND "injuries"[All Fields]) OR "brain injuries"[All Fields] OR ("traumatic"[All Fields] AND "brain"[All Fields] AND "injury"[All Fields]) OR "traumatic brain injury"[All Fields]. The search was updated in March 2012 to identify any further recent relevant articles. A further search using the term "postconcussion syndrome" identified similar articles to those identified in the search above. Articles were selected based on relevance, study quality, reliability and journal authority. In particular, recent reviews and meta-analyses were sought. The above search was supplemented by specific searches for "traumatic brain injury" or "postconcussion syndrome" and various factors of interest, internet searches, manual searches of reference lists and extracts from relevant sections of textbooks or reports.

(c) Medical or scientific publications as set out in the bibliography attached hereto.

(d) A briefing paper prepared for presentation to the Authority by a research officer of the Secretariat.

PART V DISEASE AND INJURY

11. The Authority determines Statements of Principles where there is sound medical scientific evidence that, "a particular kind of injury, disease or death" is relevantly related to service[1].

12. Section 5D of the Act defines disease and injury relevantly as follows:

> ***disease*** means:
>
> (a) any physical or mental ailment, disorder, defect or morbid condition (whether of sudden onset or gradual development); or
>
> (b) the recurrence of such an ailment, disorder, defect or morbid condition;
>
> but does not include:
>
> (c) the aggravation of such an ailment, disorder, defect or morbid condition; or
>
> (d) a temporary departure from:
>
> (i) the normal physiological state; or
>
> (ii) the accepted ranges of physiological or biochemical measures;
>
> that results from normal physiological stress (for example, the effect of exercise on blood pressure) or the temporary effect of extraneous agents (for example, alcohol on blood cholesterol levels);
>
> [and]
>
> ***injury*** means any physical or mental injury (including the recurrence of a physical or mental injury) but does not include:
>
> (a) a disease; or
>
> (b) the aggravation of a physical or mental injury.

13. The proper meaning of what constitutes a disease or injury for the purposes of determining a Statement of Principles under the Act is to be determined by the Authority. In considering these terms, the Authority had regard to ordinary dictionary definitions, medical dictionaries, and its expert knowledge. In determining whether a condition is a disease as defined, the Authority is entitled to have regard to the connotations of the word 'disease' as used and understood in its ordinary meaning.[2]

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[1] See s196B(2) & (3) of the Act.

[2] *Comcare v Mooi* (1996) 42 ALD 495.

14. Being familiar with the ordinary English meanings of the terms that are used in section 5D, the Authority considered whether postconcussion syndrome was "a particular kind of injury, disease or death" within the ordinary meaning of those terms.

15. In particular the Authority applied the ordinary meaning of those terms to its consideration of whether postconcussion syndrome is a disease. It also relied upon its expert medical knowledge and had regard to internationally agreed concepts in considering whether postconcussion syndrome may represent a disease state.

PART VI REASONS FOR THE DECISION

16. The sound medical-scientific evidence available to the Authority led to the following considerations.

Traumatic Brain Injury

17. TBI can be classified as mild, moderate or severe and also as closed or penetrating. Most (70-90%) brain injuries are mild.[3] The terms "mild traumatic brain injury" and "concussion" are generally used interchangeably. Like moderate and severe traumatic brain injury, concussion is an acute injury. Causes of TBI include falls, motor vehicle collisions, assault and blast exposure.

Definition of mild traumatic brain injury

18. The literature uses a wide range of definitions for MTBI, commonly involving a combination of the following: Glasgow Coma Scale score of varying cut-off levels, loss of consciousness (unspecified or varying length), post-traumatic amnesia (unspecified or varying length), absence or presence of neurological findings or seizures or skull fractures, and normal imaging.

19. Standardised definitions of MTBI have recently been developed and are being used in newer research. Two common definitions are as follows.

Australian Defence Force - MTBI

20. The Australian Defence Force[4] defines MTBI as normal structural imaging, with at least one of the following:

(a) loss of consciousness from 0 to 30 minutes;

(b) alteration of consciousness from a moment up to 24 hours;

(c) post-traumatic amnesia up to 24 hours; or

(d) a Glasgow Coma Scale score of 13 to 15.

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[3] Holm L, Cassidy JD, Carroll LJ, Borg J (2005). Summary of the WHO Collaborating Centre for Neurotrauma Task Force on mild traumatic brain injury. J Rehabil Med, 37: 137-41.

[4] Department of Defence (2012) Health Directive 293, Management of Mild Traumatic Brain Injury in Australian Defence Force Members, 7 February 2012.

World Health Organisation

21. The WHO Task force definition[5] states that:

> "MTBI is an acute brain injury resulting from mechanical energy to the head from external physical forces.
>
> Operational criteria for clinical identification include:
>
> (i) 1 or more of the following: confusion or disorientation, loss of consciousness for 30 minutes or less, post-traumatic amnesia for less than 24 hours, and/or other transient neurological abnormalities such as focal signs, seizure, and intracranial lesion not requiring surgery; and
>
> (ii) Glasgow Coma Scale score of 13–15 after 30 minutes post-injury or later upon presentation for health care.
>
> These manifestations of MTBI must not be due to drugs, alcohol, medications, caused by other injuries or treatment for other injuries (e.g. systemic injuries, facial injuries or intubation), caused by other problems (e.g. psychological trauma, language barrier or coexisting medical conditions) or caused by penetrating craniocerebral injury."

Short term effects of MTBI

22. Symptoms experienced immediately after a MTBI can include confusion, disorientation, slowed thinking, difficulty concentrating, loss of memory, weakness, dizziness, loss of balance, blurred vision, drowsiness, feeling foggy, sensitivity to noise, irritability, headache and nausea.[6] [7]

Reversible cognitive deficits

23. Paper-based and computer-based neuropsychological tests have been used to assess the effects of concussion in military and civilian populations.

24. A meta-analysis revealed no residual neuropsychological impairment on the basis of such tests by 3 months after a non-sports related concussion using data from unselected or prospective samples.[8] A meta-analysis on concussion in sport demonstrated recovery after a concussion within 7 days.[9] Reversibility of cognitive

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[5] Carroll LJ, Cassidy JD, Holm L, Kraus J, Coronado VG (2004). Methodological issues and research recommendations for mild traumatic brain injury: the WHO Collaborating Centre Task Force on mild traumatic brain injury. J Rehabil Med, Suppl 43: 113-25.

[6] Ponsford J, Cameron P, Fitzgerald M, Grant M, Mikocka-Walus A. (2011) Long-term outcomes after uncomplicated mild traumatic brain injury: a comparison with trauma controls. J Neurotrauma. 2011 Jun;28(6):937-46.

[7] Department of Defense and Department of Veterans Affairs (2008). "Traumatic Brain Injury Task Force". Available at: http://www.cdc.gov/nchs/data/icd9/Sep08TBI.pdf. Accessed 12-12-11.

[8] Belanger HG, Curtiss G, Demery JA, Lebowitz BK, Vanderploeg RD. (2005) Factors moderating neuropsychological outcomes following mild traumatic brain injury: a meta-analysis. J Int Neuropsychol Soc. May;11(3):215-27.

[9] Belanger HG, Vanderploeg RD. (2005) The neuropsychological impact of sports-related concussion: a meta-analysis. J Int Neuropsychol Soc. Jul;11(4):345-57.

deficits was demonstrated in a US military group within the first 5 to 10 days post injury.[10]

25. Although the mechanism of primary blast injury may be distinct from other mechanisms of injury, those with blast injury do not differ from those with other causes of MTBI in results of neuropsychological testing.[11]

Recovery from symptoms

26. A WHO review concluded that, "there is consistent and methodologically sound evidence that children's prognosis after MTBI is good, with resolution of MTBI-specific symptoms within 2 or 3 months after MTBI and little evidence of residual cognitive, behavioural or academic deficits…For adults, cognitive deficits and symptoms after MTBI are common in the acute stage, and the majority of studies report recovery for most within 3 to 12 months."[12]

Multiple concussions

27. There have been concerns about greater effects from multiple concussions, but studies of athletes have found no difference in neuropsychological test results in those with multiple concussions compared to single concussions.[13] [14]

Findings of studies of longer term health outcomes following MTBI

Symptoms following MTBI

28. A number of studies have examined the possibility that there may be health consequences of MTBI beyond the immediate period of the injury, including a range of symptoms.

29. Commonly reported symptoms overlap with those of acute MTBI and include headache, dizziness, fatigue, irritability, difficulty in concentration and performing mental tasks, impairment of memory, insomnia, anxiety, depression, apathy and change in personality.

30. In a review of the long term consequences of traumatic brain injury, the Institute of Medicine (2009) concluded that there is evidence of an association between sustaining a TBI and the development of the above types of symptoms.[15]

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[10] Coldren RL, Russell ML, Parish RV, Dretsch M, Kelly MP. (2012) The ANAM lacks utility as a diagnostic or screening tool for concussion more than 10 days following injury. Mil Med. Feb;177(2):179-83

[11] Belanger HG, Kretzmer T, Yoash-Gantz R, Pickett T, Tupler LA. (2009) Cognitive sequelae of blast-related versus other mechanisms of brain trauma. J Int Neuropsychol Soc. Jan;15(1):1-8.

[12] Holm L, Cassidy JD, Carroll LJ, Borg J (2005). Summary of the WHO Collaborating Centre for Neurotrauma Task Force on mild traumatic brain injury. J Rehabil Med, 37: 137-41.

[13] Belanger HG, Spiegel E, Vanderploeg RD. (2010) Neuropsychological performance following a history of multiple self-reported concussions: a meta-analysis. J Int Neuropsychol Soc. Mar;16(2):262-7.

[14] Casson IR, Pellman EJ, Viano DC (2008). Concussion in the national football league: an overview for neurologists. Neurol Clin, 26: 217-41.

[15] Institute of Medicine (2009). Gulf War and Health. Long-Term Consequences of Traumatic Brain Injury, Volume 7. National Academy Press, Washington, D.C.

Use of the term "postconcussion syndrome"

31. A group of symptoms occurring after an MTBI has been collectively termed "postconcussion syndrome".

32. There is inconsistency in the definition and use of this term, with some clinicians and researchers using it to describe any combination of one or more symptoms experienced at any time point after an MTBI, while others use it to describe persistent complaints after an MTBI that individuals attribute to that injury event.[16]

ICD-10 and DSM-IV definitions

33. The authoritative manual on mental disorders, DSM-IV, has proposed a definition of “postconcussional disorder”, for research purposes only. This means that there is not yet a consensus amongst experts that an actual disorder exists.

34. ICD-10, the international system for disease classification, has included a definition of "postconcussional syndrome", although the accompanying guidelines indicate that this syndrome is not well defined as a disease.

35. A review by the WHO Collaborating Centre Task Force on MTBI[17] concluded that the proposed injury severity thresholds in DSM-IV and ICD-10 are not generally supported by the available research.

Research using the term "postconcussion syndrome"

36. Despite these methodological issues, researchers have investigated whether or not there are long term effects of MTBI using the ICD-10 or DSM-IV working definitions of “postconcussion syndrome”.

37. In two studies of healthy populations who had not experienced a traumatic brain injury, 59%[18] and 80%[19] of subjects respectively met symptom criteria for postconcussion syndrome.

38. In studies without comparison groups, a proportion of patients classified as having MTBI report that they experience somatic and cognitive symptoms (as opposed to objectively measured cognitive deficits) beyond the immediate period of the injury. Estimates of prevalence vary, but about 15 to 30% of people with MTBI report symptoms persisting beyond 3 months.[20]

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[16] Silver J, McAllister T, Yudofsky S (eds) (2011) Textbook of Traumatic Brain Injury, 2nd Edition, Chapter 15 Mild Brain injury, American Psychiatric Publishing Inc, Washington DC.

[17] Carroll LJ, Cassidy JD, Peloso PM, Borg J, et al (2004). Prognosis for mild traumatic brain injury: results of the WHO Collaborating Centre Task Force on mild traumatic brain injury. J Rehabil Med, Suppl 43: 84-105.

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[20] Hou R, Moss-Morris R, Peveler R, Mogg K, Bradley BP, Belli A. (2011) When a minor head injury results in enduring symptoms: a prospective investigation of risk factors for postconcussional syndrome after mild traumatic brain injury. J Neurol Neurosurg Psychiatry. Oct 25.

39. More interpretable findings come from prospective studies which use comparison groups, especially those with comparison groups made up of subjects with trauma other than brain injuries. This type of study design accounts for background rates of symptoms and controls for the mental health related effects of trauma.

40. In a prospective cohort study of patients with MTBI compared to non-brain injured trauma controls, there was no significant difference between the groups in the proportion classified as having postconcussion syndrome, either acutely (within 14 days) or 3 months post injury.[21]

41. In another similarly designed prospective study, there were no significant differences between MTBI patients and trauma controls in overall reporting of post-concussive symptoms at 3 months post injury, nor in the proportion who met symptom criteria for postconcussion syndrome.[22]

42. In other words, the symptoms said to be characteristic of postconcussion syndrome were no more likely in those with MTBI than in those without.

Other methodological issues in studying long term effects of MTBI

43. Apart from definitional issues relating to the terms MTBI and postconcussion syndrome, research into long-term health outcomes following MTBI has faced various other methodological challenges.

Weakness in studies

44. Most studies in this field have major methodological weaknesses, in that they are retrospective rather than prospective in design, do not differentiate outcomes by timing of injury, do not use control groups, or do not adequately account for potential confounding by factors such as medication or psychological distress.

Multiple injuries

45. MTBI occurring in the context of war, and particularly MTBI due to blast, is often associated with multiple injuries to other structures, including sensory impairment due to facial trauma, pain and tinnitus. Multi-trauma patients, even in the absence of brain injury, have high rates of neurobehavioural symptoms (including memory difficulties, irritability, mood swings, amotivation and guilt) and lower rates of return to work.[23] Studies of the effects of MTBI must therefore control for the effects of other injuries.

46. Exposure to blast or other mechanisms of traumatic brain injury can cause both physiological and psychological trauma. These effects are hard to disentangle, both at the time of injury and subsequently.

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[21] Meares S, Shores EA, Taylor AJ, Batchelor J, et al (2011). The prospective course of postconcussion syndrome: the role of mild traumatic brain injury. Neuropsychology, 25(4): 454-65.

[22] Ponsford J, Cameron P, Fitzgerald M, Grant M, Mikocka-Walus A. (2011) Long-term outcomes after uncomplicated mild traumatic brain injury: a comparison with trauma controls. J Neurotrauma. 2011 Jun;28(6):937-46.

[23] French LM. 2010 Military traumatic brain injury: an examination of important differences. Ann N Y Acad Sci. Oct;1208:38-45.

No accepted objective measure

47. There is no accepted objective measure for the effects of MTBI. Functional imaging, biomarkers and electroencephalography are under investigation as ways to quantify TBI. Although these diagnostic modalities show some promise for assessment of severe TBI, they have not been validated for the diagnosis or monitoring of MTBI.

Symptoms may persist for other reasons

48. Several lines of evidence suggest that the symptoms associated with MTBI may occur and persist for reasons other than brain injury. Symptoms have been associated with a pre-injury depressive or anxiety disorder, acute post-traumatic stress, pain, female gender, other injuries and other exposures.[24] [25]

49. In a cross-sectional study of UK soldiers deployed to Iraq[26], symptoms and symptom severity were associated with self-reported exposure to blast whilst in a combat zone. However, the same symptoms were also associated with other in-theatre exposures such as potential exposure to depleted uranium and aiding the wounded.

50. The expectation that common sensations are signs of permanent brain damage can result in hypervigilance towards somatic symptoms and exaggerated concern about the meaning of sensations.[27] Screening may contribute to negative expectations, by bringing to attention a previous concussion and associating concussion with symptoms. In support of this, prospective studies have found that negative expectations can predict postconcussion symptoms.[28] [29]

Postconcussion symptoms overlap with PTSD

51. There is overlap between the symptoms of posttraumatic stress disorder and those of "postconcussion syndrome". Both are defined, in part, by the same events and the same self-reported symptoms. There is evidence from prospective and cross-sectional studies that PTSD accounts for a substantial component of symptom reporting.[30] [31] [32]

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[24] Carroll LJ, Cassidy JD, Peloso PM, Borg J, et al (2004). Prognosis for mild traumatic brain injury: results of the WHO Collaborating Centre Task Force on mild traumatic brain injury. J Rehabil Med, Suppl 43: 84-105.

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[27] Bryant R. (2011) Post-traumatic stress disorder vs traumatic brain injury. Dialogues Clin Neurosci.;13(3):251-62.

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[29] Whittaker R, Kemp S, House A. (2007) Illness perceptions and outcome in mild head injury: a longitudinal study. J Neurol Neurosurg Psychiatry. Jun;78(6):644-6.

[30] Wilk JE, Herrell RK, Wynn GH, Riviere LA, Hoge CW. (2012) Mild Traumatic Brain Injury (Concussion), Posttraumatic Stress Disorder, and Depression in U.S. Soldiers Involved in Combat Deployments: Association With Postdeployment Symptoms. Psychosom Med. Feb 24.

[31] Hoge CW, McGurk D, Thomas JL, Cox AL, Engel CC, Castro CA. (2008) Mild traumatic brain injury in U.S. Soldiers returning from Iraq. N Engl J Med. Jan 31;358(5):453-63.

Conclusions

52. While symptoms may be found long after MTBI in a proportion of cases, the sound medical-scientific evidence does not clearly establish "postconcussion syndrome" as a distinct disease entity.

Current relevant Statements of Principles

53. The Authority also had regard to the role of TBI as a factor in the existing Statements of Principles.

54. TBI is a factor in Statements of Principles for epileptic seizure, epilepsy, subdural haematoma, subarachnoid haemorrhage, deep vein thrombosis, cerebrovascular accident, Meniere's disease, anosmia, hypopituitarism, narcolepsy, Parkinson's disease, Alzheimer-type dementia, panic disorder, schizophrenia, dementia pugilistica, mood disorder due to a general medical condition with depressive features, anxiety disorder due to a general medical condition and mood disorder due to a general medical condition with manic or mixed features.

55. The level of severity of TBI is specified for each of these Statements of Principles.

56. MTBI is a factor in the Statements of Principles for epileptic seizure, epilepsy, subdural haematoma, cerebrovascular accident, hypopituitarism and anosmia. Repeated blows to the head (with or without concussion or loss of consciousness) are a factor in the Statements of Principles for dementia pugilistica.

57. The Statements of Principles that cover the consequences of exposure to a severe traumatic event (a category 1A or 1B stressor) such as might be associated with MTBI are: PTSD, acute stress disorder, depressive disorder, anxiety disorder, alcohol dependence and alcohol abuse, drug dependence and drug abuse, suicide and attempted suicide, schizophrenia, bipolar disorder, adjustment disorder, eating disorder, panic disorder and personality disorder.

58. The Authority concluded that diseases or injuries which arise as a result of a TBI are covered in these existing Statements of Principles.

PART VII DECISION

59. At its meeting on 7th August 2012 the Authority decided to make Statements of Principles in respect of concussion and moderate to severe traumatic brain injury. The Authority also revoked and reissued Statements of Principles concerning physical injury due to munitions discharge.

60. At the same meeting, the Authority decided not to make a Statement of Principles in respect of postconcussion syndrome for the purposes of subsection (2) or (3) of section 196B of the Act as the Authority concluded, for the reasons set out above, that:

[32] Polusny MA, Kehle SM, Nelson NW, Erbes CR, Arbisi PA, Thuras P. (2011) Longitudinal effects of mild traumatic brain injury and posttraumatic stress disorder comorbidity on postdeployment outcomes in national guard soldiers deployed to Iraq. Arch Gen Psychiatry. Jan;68(1):79-89.

(a) it is neither a "disease" within the meaning of section 5D of the Act nor a "particular kind of injury disease or death" such that the Authority could determine relevant Statements of Principles for it; and

(b) the Authority's current approach in determining TBI, MTBI and exposure to severe trauma as factors in identifiable diseases is consistent with the available sound medical-scientific evidence.

PART VIII BIBLIOGRAPHY

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