

ROYAL AUSTRALASIAN COLLEGE OF SURGEONS



Patron H.R.H. The Prince of Wales

National Trauma Registry Consortium

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Professor Chris Baggoley
Chief Executive Officer
Australian Commission on Safety and Quality in Health Care
GPO Box 5480
SYDNEY NSW 2001

Dear Professor Baggoley

Re Australian Clinical Quality Registries

I would like to thank you for the opportunity to comment on the draft operating standards and technical design for Australian Clinical Quality Registries. The documents have been distributed to the members of the Trauma Systems Performance Improvement and Registries Sub-Committee of the Royal Australasian College of Surgeons (RACS) and the members of the Steering Committee of the National Trauma Registry Consortium (NTRC) for their comments and suggestions.

National Trauma Registry Consortium:

The NTRC was developed as an initiative of the national Trauma Committee of the RACS via its Trauma Systems Performance Improvement and Registries Sub-Committee in 2003. The initiative was supported by and developed within the Centre of National Research on Disability and Rehabilitation Medicine (CONROD), a research centre within the School of Medicine, University of Queensland. CONROD has been the major funding source for the whole project, employing a research officer until this year. CONROD has provided \$30,000 per year for the project from 2003 to mid-2008, but the support from that body has actually been much greater per year than that amount. Funding has also been received from the Australasian Trauma Society (ATS), the Institute of Trauma Injury Management (ITIM) of New South Wales and the RACS. With the resignation of the NTRC Project Officer from CONROD, the administrative duties are now performed solely by the secretariat for the RACS Trauma Systems Performance and Registries Sub-Committee. The Director of CONROD has indicated that that body will assist with the preparation of the next NTRC report for the year 2006.

The Project Officer (Ms Tamzyn Davey) is still involved (1 day per week) in a study on *International Benchmarking Outcomes* with Professor Rod McClure, Professor Phil Schluter and Dr Kate Cameron, and as such remains an integral part of the NTRC programme.

At the beginning of the project, agreements were developed between the RACS and the University of Queensland for CONROD to act as the secretariat for the NTRC. Two agreements were signed. The NTRC has had a very loose governance arrangement. I have allowed this situation to continue as our reports are purely de-identified aggregate data, already available in the public domain. As we move towards a national trauma registry, this situation must alter and an appropriate governance structure must be developed. A draft document with a proposed governance structure is attached. This document has received general acceptance from the members of the NTRC Steering Committee.

We have had very good support from registries in Australia and New Zealand, witnessed by the increasing contribution of data to the reports.

We have established good international relationships with the National Trauma Data Base (USA), Canadian Trauma Registry, German Trauma Registry and the United Arab Emirates Registry. There is increasing support to develop an international trauma registry for benchmarking. Australian and New Zealand registries are eager now to benchmark their performance against national and international standards.

Our funding has been extremely limited, and without the support of CONROD we could not have achieved what we have. There has been much *pro bono* work as well.

We have been meeting with the Commission now for three (3) years, and what initially appeared very promising for us has now been delayed. This is no doubt due to changes in office bearers and the change in direction of the Commission. The philosophy behind the development of this draft is very important for the establishment of clinical registries, and as such is welcome. However, the delays from our contact with the Commission have not helped our quest for support.

We welcome the call for pilot projects. We have a draft minimum data set (MDS) developed, and will have preliminary results from our benchmarking studies available later in the year.

A national trauma registry will have a minimum data set with a data dictionary, primary data collection, appropriate data protection and agreed benchmarking. The ability of a hospital to benchmark its performance with an individual patient against the national profile is critical to the project. This quality assurance activity is the predominant role of a national trauma registry.

Many studies have shown unacceptable rates of preventable and potentially preventable deaths in injured patients. A national trauma registry should provide the benchmark data to assess improvements in care. However, as systems improve, and as the rates fall, outcomes other than death should be addressed; again to monitor the effect of both the system and the provider's care. Such outcomes might include quality of life at six months.

Draft Guidelines for the Establishment and Management of Clinical Registries:

In the Executive Summary - Data Collection, points 1-29 are all generally acceptable.

Point 5 is very important. Australian and New Zealand registries are increasingly moving to Collector (US based), which has a data dictionary. This might be the basis for our registry data base if more local registries move to it.

Point 6 is significant when a trauma registry needs to collect operative data. Using the hospital-based data system will allow collection of operative data more simply than tediously checking through the hospital notes by a trauma registry nurse.

Points 13-23 are appropriately detailed and very important, as are points 26-28.

With respect to point 29, an important role for the Commission would be to provide direction in securing recurrent funding for appropriate registries.

The indicators as detailed on page 12 – process, outcome and structure –are all components of a trauma registry: eg process – time to placement of an endotracheal tube, time to operating room; outcome – results following evacuation of an extra-dural haematoma; structure – number of inter-hospital transfers, delays in availability of suitable transport platforms.

A National Trauma Registry would not take over the role of data collection at state and jurisdictional level. The organisational cost would be prohibitive. This is still seen as the role of the state and jurisdictional health authorities. If such a body did not want their data included in a national data set, then the state or jurisdiction would be excluded from the national picture. It would of course be regrettable.

Chapter 5 (pages 17-19) is a very sound analysis of the role of clinical registries. The last paragraph on page 19 should be highlighted – there are no identifying systems for developed registries and no national standards for funding applications.

Chapter 6 – Attributes of Clinical Registries – pages 20-26 – is good and attributes 1-6 detailed on page 20 would be integral to a national trauma registry. The emphasis on a core minimum data set is critical. Too much data is difficult, and causes registries to drop out. Other data may be added later if needed.

Most trauma registries at the moment collect their data from the hospital records on paper, and then transfer it to a web based data entry system. Clearly the minimum data set for a national trauma registry must be limited, and part of what current registries collect. This will allow the component part of the national trauma registry minimum data set in the participating registries record to be sent to the national data bank at one touch, once primary data transfer has ethical approval.

The statement on page 22 is extremely significant for a trauma registry – viz “The manual component of data collection is currently the major limiting step in establishing new registries, and explains why it is feasible to contemplate new registries for only a limited number of conditions where differences in quality can have major impacts on quality of life or cost”. Clearly, trauma is one of those.

The challenge “to identify the epidemiologically sound variables that have a fundamental impact on outcomes and an easily accessible to data collectors” (page 25) is noted and fully endorsed.

Chapter 7 – Data Collection (pages 27-36) – is again very detailed and appears complete. Timeliness is important and a substantial difficulty in a trauma registry. In an ideal national trauma registry with appropriate benchmarking, a hospital should be able to access its performance on an individual patient after the complete data has been entered, as quickly as possible, therefore comparing its management with national benchmarks – eg prior to its next trauma review committee meeting. Obviously a registry or hospital contributing data to a national trauma registry should have access for benchmarking only to the data from their own unit. This process is fundamental.

With respect to data definitions, most current registries use the ones they have developed. With movement to Collector, this could alter. This might progress international comparisons.

The ability for registries at state and jurisdictional level to interact with administration data has been noted and supported.

The development of an individual healthcare identifier (page 31) will vastly improve trauma data bases – eg linking pre-hospital and in-hospital care, identifying several admissions or multiple hospital admissions etc.

The summary on page 36 is comprehensive and appears complete.

With respect to data elements (Chapter 8, pages 37-43), the approval of the National Trauma Registry Consortium has been to involve clinicians, epidemiologists, information technologists, medical statistics experts and the trauma registry staff – ie the data collectors. All those elements are essential. Clinicians might desire a certain piece of data, but the trauma registry staff can identify how practical it is to collect it accurately.

It is obvious that at a national trauma registry the IT expertise must be available to develop the data production and safety processes. The comment (page 42) that it can be up to six months or so for outcomes in major trauma to be assessed is fully supported.

Chapters 9 and 10 – Risk Adjustment and Data Security – emphasise the need for a national trauma registry to have IT and statistical support.

With respect to Chapter 11, a national trauma registry must ensure that participating registries have this contract (11.2) in place. It is essential that reports are produced on a strict timeline (page 54).

Chapter 12 – Organisation and Governance – is generally supported, although meeting numbers of steering and management committees may vary depending on the needs of the registry. A draft of a national trauma registry governance structure is attached. The role of leadership is critical to the success, direction and quality assurance of the registry.

For a clinical registry such as a national trauma registry, the Chair should be a clinician with current hands-on experience in the appropriate field (or at least very recent experience). For the national trauma registry that would ideally be someone from the RACS or Australian College of Emergency Medicine (ACEM), a clinician of national standing. Representation from the funding body (page 58) is important. It is agreed that the body responsible for the governance should be a legal entity (page 56). The points in the summary (page 62) are supported, especially that custodianship of data must be explicit in contracts between the funding body and the state and territory registries.

The concluding chapters (13 – Ethics and Privacy, 14 – Information Output, 15 – Resources and Funds) are adequate. It would assist greatly if the Commission could, as a matter of priority, provide information on potential sources of funds.

Draft Architecture Overview – Clinical Registries – Version 2 – 8/05/2008:

This document does make valid points, especially in Sections 3 and 4 - Guiding Principles and Infrastructure; however, the document is repetitive after study of the first document – viz Guidelines for the Establishment and Management of Clinical Registries – and could be condensed into a mere effective concise statement. The long term architecture version should perhaps be a separate document, as it is visionary. The concept of a single point access (page 23) appears at the moment unrealistic.

Standards Map:

The technical aspects of the Standards Map are beyond the scope of this review.

Conclusion:

The Guidelines for the Establishment and Management of Clinical Registries is an excellent document, detailed and comprehensive, and covers virtually all aspects. The thrust and direction of the document appears satisfactory. With the caveats mentioned above, the document on Architecture Overview is also very sound and appropriate in its direction.

On behalf of the National Trauma Registry Consortium, I would like to thank the Commission for the opportunity to comment on the documents.

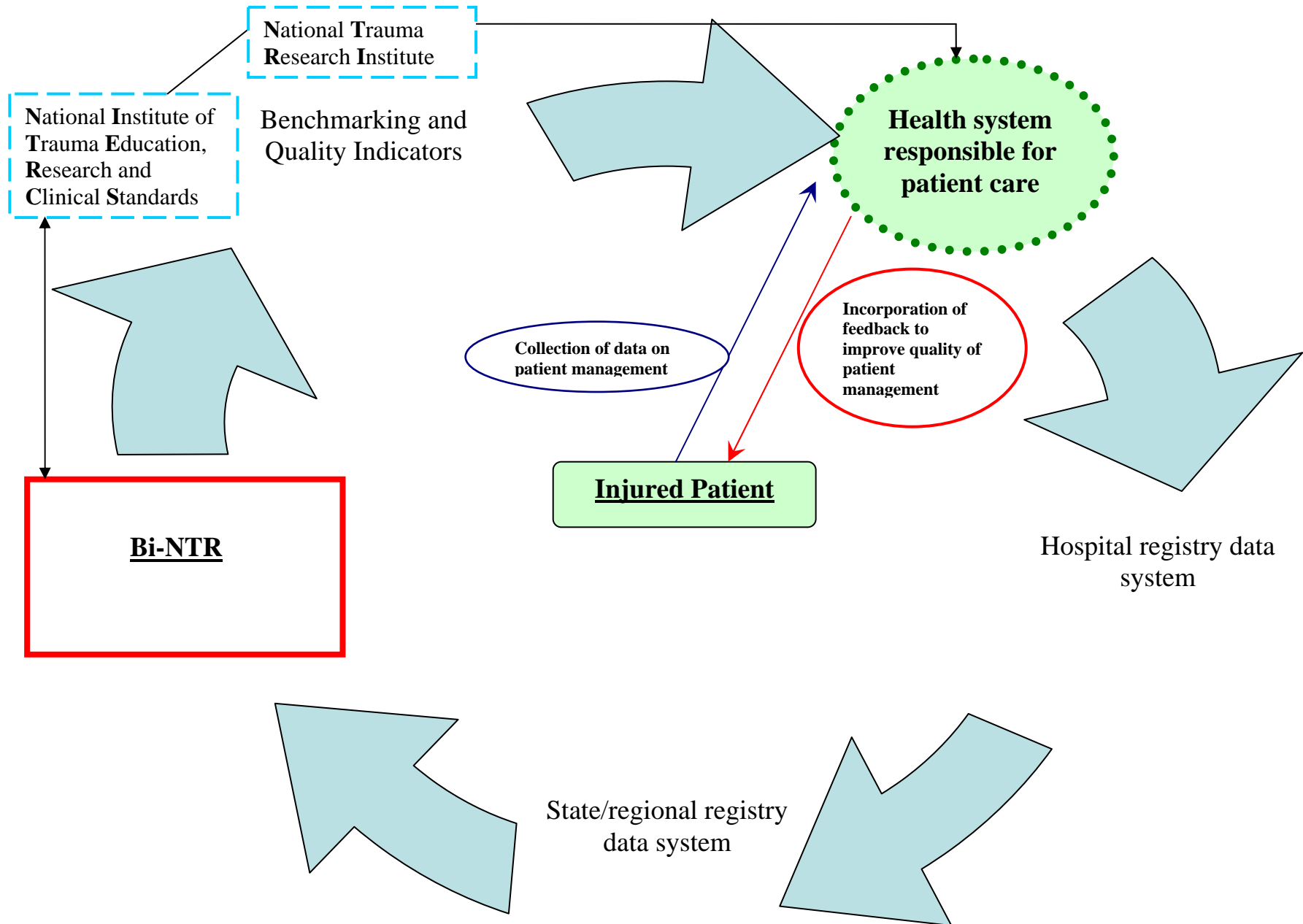
Yours sincerely



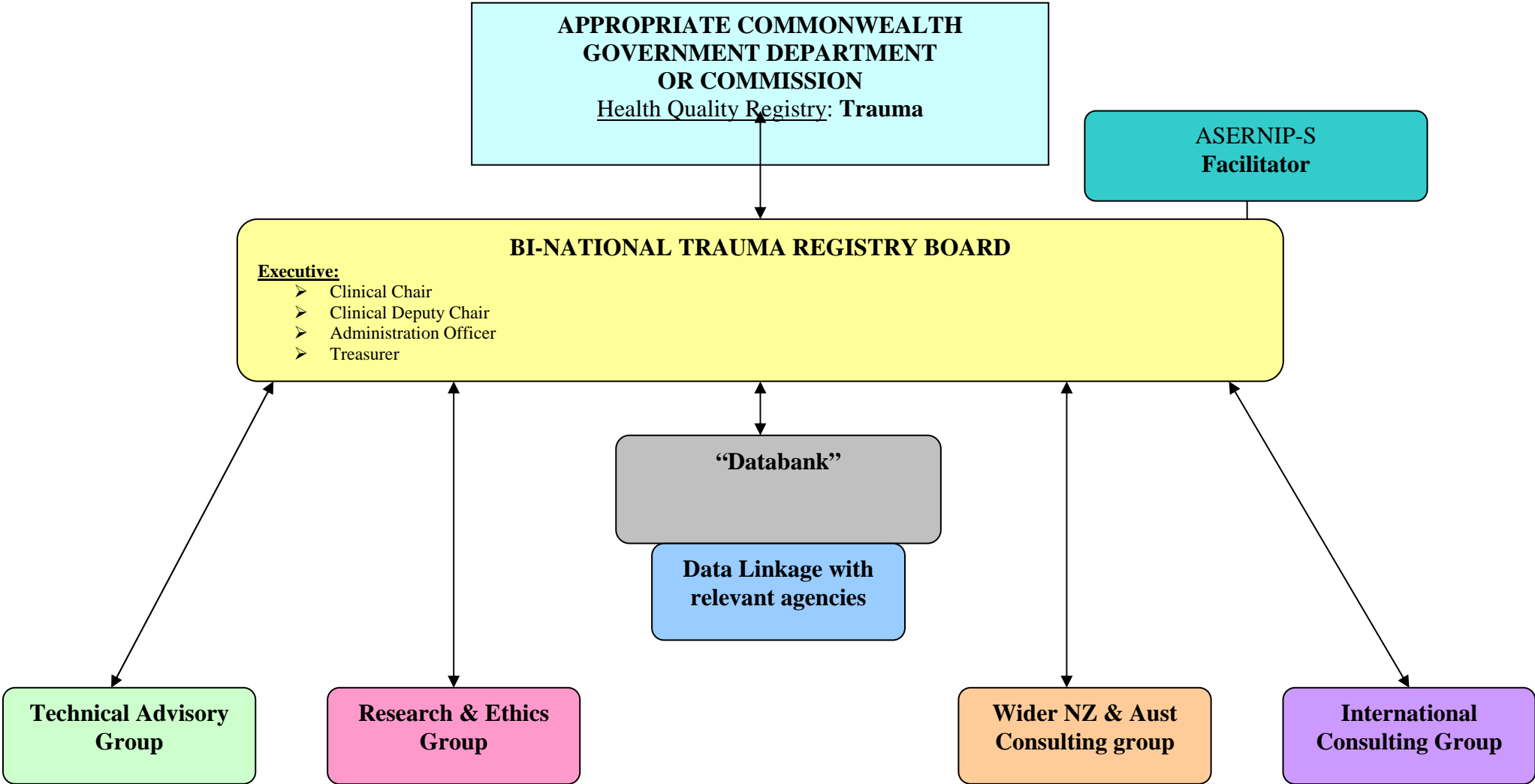
Cliff Pollard
Chair
National Trauma Registry Consortium

Diagram of the Quality Feedback Loop

The injured patient is the central focus, with the Bi-NTR using injury data (fed down through the health system to the State- or hospital-based registry) and applying benchmarks and QI's which are then used to inform improved treatment of the patient



Outline of Proposed Governance Structure for the bi-National Trauma Registry – see explanatory diagram for a guide to group membership



Explanatory diagram with guide to group membership

APPROPRIATE COMMONWEALTH GOVERNMENT
DEPARTMENT OR COMMISSION
Health Quality Registry: TRAUMA

ASERNIP-S as a facilitator/interim governance body during development of business case phase and possibly beyond

Bi-National Trauma Registry Board

Executive with Chair (clinician from one of the professional bodies - to rotate every 2 years); **Deputy; full/part-time administration; Treasurer**

- Representative from Australian Commission on Safety and Quality in Health Care
- Representatives from professional bodies – RACS; ACEM; ATS; ANZICS; ANZBA; ACCCN; CENA and/or other appropriate body
- Representation from all participating registries in Australia and New Zealand as well as States and Territories where a registry is intended to be developed
- Council of Ambulance Authorities
- Consumer representative (from Consumers' Health Forum of Australia)
- NISU
- Australian Defence Force representatives
- Indigenous (both Australian & NZ) representation

Where appropriate, representatives from the Board may become members on the Wider Consulting Group and visa versa

Technical advisory group

- Bi-National Minimum Data Set
- Data quality
- Benchmarking and Performance indicators

“Data Bank” – Appropriate academic department – 3-5 yr performance based contract by tender

- Data management
- Data analysis
- Report writing &
- Dissemination
- Research

Research access advisory group-with representative from NH&MRC

- Approval to access data
- Ethics
- Research

Wider Consulting Group

- Representation from relevant professional bodies (who are not already included in the above agencies/committees):
 - Australian Orthopaedic Association;
 - ANZ College of Anaesthetics
 - Australian Faculty of Rehabilitation Medicine
 - The NZ Accident Compensation Corporation
- Interested expert clinicians and academics (who are not already included in the above agencies/committees)
- ANZ Association for the Surgery of Trauma (ANZAST)
- Neurosurgical Society of Australia (NSA)
- Divisional Group of Rural Surgery

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Data Linkage

- Prehospital/Emergency Service bodies
- Relevant insurance companies
- Workcover groups
- Police
- Transport authorities
- Coroner

International Consulting Group

- National Trauma Data Bank-USA
- Trauma Register of the German Society of Trauma Surgery
- Canadian National Trauma Registry