Scoping study to enhance spinal cord injury data connectivity within Australia and internationally

Phase II Report: Business Plan

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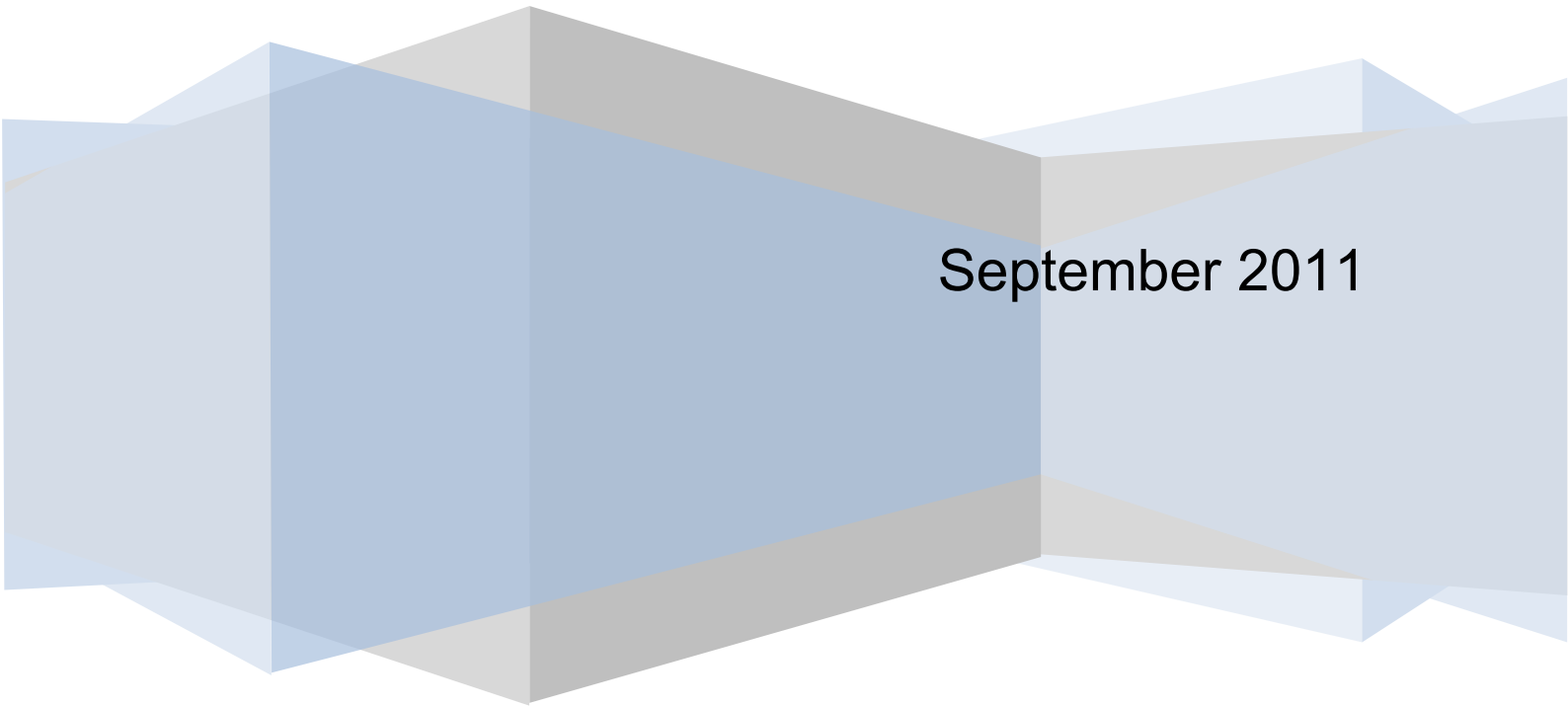

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LIST OF ABBREVIATIONS

ACSQHC	Australian Commission on Safety and Quality in Health Care
AIHW	Australian Institute of Health and Welfare
AROC	Australian Rehabilitation Outcomes Centre
ASCIR	Australian Spinal Cord Injury Register
DEPM	Department of Epidemiology & Preventive Medicine
DoHA	Department of Health and Ageing
NISU	National Injury Surveillance Unit
SCI	Spinal cord injury
SCID	Spinal Cord Injury Database (NSW)
SCIN	Spinal Cord Injury Network
SSCIS	State Spinal Cord Injury Service (NSW)

EXECUTIVE SUMMARY

Since the mid 1990's the Australian Spinal Cord Injury Register (ASCIR) has been the primary registry for recording incident cases of traumatic Spinal Cord Injury (SCI) in Australia. The ASCIR has been managed by the National Injury Surveillance Unit (NISU) at Flinders University and funded by the Australian Institute of Health and Welfare (AIHW) and the Department of Health and Ageing (DoHA). A funding crisis occurred in mid-2008 significantly impacting on the function and utility of the registry. Subsequent to this issue, the ASCIR underwent a comprehensive review in 2008 culminating in the release of a technical briefing paper in May 2010. Two key conclusions were evident from this review. Firstly, funding issues have resulted in a reduction in the ability of the NISU to adequately support the registry in its current form. Secondly, the ASCIR needs to be redesigned into a clinical quality registry.

The Department of Epidemiology and Preventive Medicine at Monash University (DEPM) was engaged by the Spinal Cord Injury Network (SCIN), the Australian Spinal Cord Injury Register (ASCIR) board and the National Injury Surveillance Unit (NISU) to undertake a scoping study to enhance spinal cord injury data connectivity within Australia and Internationally. This study included the development of a business plan for a redesigned ASCIR, including possible partnerships and funding models, and identifying potential ongoing funding sources.

In the scoping study three primary barriers for the continued role of the ASCIR were identified by the interview cohort. Firstly, all interviewees identified that an on-site data collector, and the financial resources to support this position, was necessary. While a number of units reported absorbing the cost of data collection by the unit, others identified this as a significant barrier to participation that warrants consideration in any external funding requests for the registry. Secondly, how the data is to be collected and the standardisation of the collection procedures was an identified issue. The need for clear data standards and linkage to alternative data sources, where applicable, to minimise resource required and streamline the process was expressed by the interviewees. Finally, 16 of the 18 interviewees expressed a need for a secure database with a web interface to assist in overcoming the previous two barriers.

INTRODUCTION

As reported in the technical briefing paper (O'Brien et al. 2010) the ASCIR reached a funding crisis in 2008 leading to limited data collection and processing. Subsequently, the AIHW provided funding to bring the registry up to date, but it was identified that most SIUs rely on self-funding to complete data collection.

The Phase I report produced by DEPM made the following recommendations:

i. A revised governance structure is required including representation from clinicians (medical and allied health), researchers and associated peak bodies (e.g. SCIN) ensuring appropriate regional representation and the appointment of an independent chairperson – [0-3 months].
ii. Establish an appropriately constituted Steering Committee to oversee the governance of the ASCIR, including the development of strategic direction and ensuring deliverables are met for the registry and funding bodies – [0-3 months].
iii. Convene an appropriately constituted Management Committee to manage day-to-day aspects of the registry and ensure data quality measures are reported regularly – [0-3 months].
iv. Terms of Reference for the Steering Committee and Management Committee need to be developed, including meeting schedules and membership policies – [0-3 months].
v. The data access policy needs to be reviewed and updated as necessary – [3-6 months].
vi. Identify data reporting procedures including peer review processes, feedback to SIUs and dissemination of findings to the wider public – [3-6 months].
vii. Provide a detailed and agreed policy on the use of the registry for research purposes and the publishing of data through peer-reviewed publications – [3-6 months].
viii. The ASCIR capture only adult traumatic SCI cases until the issues with case identification of paediatric and non-traumatic cases are resolved – [0-2 years].
ix. A non-traumatic SCI working party is established to develop the inclusion criteria, minimum dataset, case capture methods, and feasibility of data collection for this group – [6 months – 2 years].
x. A paediatric SCI working party is established to develop the inclusion criteria, minimum dataset, case capture methods, and feasibility of data collection for this group – [6 months – 2 years].

xi. Formation of a working party to revise the minimum dataset. The working party should include representatives from each SIU, a database specialist (to streamline database changes and compatibility), clinical quality registry methodological expertise, and regional representation. Consideration should also be given to including international representation on this working party to improve the potential for international comparison and benchmarking – [0-6 months].

xii. Develop a revised data collection form, data dictionary and documentation supporting a standardised approach to data collection methodology – [3-9 months].

xiii. Establish a training protocol for the collection of the revised minimum dataset using flexible approaches to accommodate the geographical challenges of the ASCIR (e.g. online tutorials, teleconferencing, etc.) – [6-9 months].

xiv. ASCIR should adopt an opt-off method of consent to ensure complete case capture, minimise the potential for selection bias, and reduce administrative demands. Research sub-projects should seek individual ethics approvals as linked projects. While there is provision in the NHMRC National Statement on Ethical Conduct in Human Research for "unspecified" consent, the specific ethical issues for each project will need to be reviewed on a case-by-case basis – [0-3 months].

xv. Implementation of a secure database with web interface for data entry at site level – [0-6 months or on securing of funding].

xvi. Design system interfaces to allow data transfer from existing databases, and compatibility with other relevant registries – [0-6 months or on securing of funding].

xvii. Identify data quality assurance processes and build data audit and quality checks into the system to support the quality assurance protocols – [0-6 months or on securing of funding].

All of the recommendations are contingent on securing funding and the final three recommendations require dedicated and specialised funding.

CURRENT STRUCTURE

The National Injury Surveillance Unit (NISU) at Flinders University, funded by the Australian Institute of Health and Welfare (AIHW) and the Department of Health and Ageing (DoHA), has been the data management unit for the Australian Spinal Cord Injury Register (ASCIR). Data collection has included contributions from the Specialist Australian Spinal Cord Injury Units contributing information on incident cases of spinal cord injury.

The specialist units are identified in Table 1.

Table 1 – Australian Specialist Spinal Cord Injury Units

Spinal Cord Injury Units and hospitals	Location
South Australian Spinal Cord Injury Service – Royal Adelaide Hospital	Adelaide, South Australia
Queensland Spinal Cord Injuries Service – Princess Alexandra Hospital	Brisbane, Queensland
Sir Bedbrook Spinal Unit – Royal Perth Hospital	Perth, Western Australia
Victorian Spinal Cord Service – Austin Hospital	Melbourne, Victoria
Prince of Wales Hospital Spinal Cord Injury Service	Sydney, NSW
Royal North Shore Hospital Spinal Cord Injury Service	Sydney, NSW

FUTURE FUNDING

Funding has been identified as a key problem facing the ASCIR. In the Phase I report it was identified that future funding of the ASCIR should incorporate models based on expanded data collection procedures, the utilisation of a web-based system and a larger eligible population of cases.

There are only a few clinical quality registries that have established funding streams sufficient to ensure adequate registry coverage, sound operations and good governance (Phillips Fox, 2010). Adequate registry funding will cover the costs of infrastructure, data collection, data analysis and reporting while also allowing the registry to grow and demonstrate innovation (Phillips Fox, 2010). The core funding requirements of the ASCIR have been identified below.

Data Collection

On-site data collection is required at all sites. It is assumed that sites would be responsible for funding their own data collection and a cost estimate is included as additional costs in the funding table. Some sites reported that this cost could be absorbed by the health service; however other units have reported this as a significant barrier requiring external funding. The Project Manager would be responsible for coordinating the revision of the data collection form, data dictionary and other documentation. The costs of data collection would also include the development of a revised data collection form, data dictionary and documentation supporting a standardised approach to data collection methodology.

Training

A training protocol for the collection of the revised minimum dataset needs to be established which accommodates the geographic challenges of the ASCIR. A flexible approach would be required which would accommodate the individual needs of the units and the geographic challenges but would include options for training at individual sites, centralised training and electronic (web-based) training. Training would also be required for interviewers for outcome data collection (see outcomes below). Further training or refresher training in the use of coding may be required; however this would depend on the outcome of the core dataset revision.

Information Technology Platform

The need for implementation of a secure database with web interface for data entry at site level was identified in the Phase I report. This should include the design of a system interfaces to allow data transfer from existing databases, and compatibility with other relevant registries. This system must comply with the ACSQHC operating principles and technical standards for Australian clinical quality registries. There is also a need to identify data quality assurance processes and build data audit and quality checks into the system to support the quality assurance protocols. The cost of building a secure database with web interface has been estimated at approximately $60,000 which has been incorporated into core costs over two years and with ongoing maintenance by the part-time Database Manager.

Outcomes

It is recommended that the minimum dataset be extended to include additional clinical and outcomes data (including long-term follow-up). The cost of collection of this data has been included as an additional cost to be covered by the individual health services. The cost of collection of long term outcomes data at a single time point for 2,000 major trauma patients has been estimated at $30,000 AUD (Gabbe et al, 2010). It is estimated that there will be 300 traumatic spinal cord injury patients per year and 600 non-traumatic spinal cord injury patients per year. However, as the interviews are highly specific and nationwide the cost is now estimated to be $30 per hour and at least an hour per interview would be required so the cost would therefore be approximately $9,000 AUD per annum at a single time point for traumatic SCI only. Proposed timeframes for the collection of outcomes data are at one, two, and five years post injury and then every five years thereafter.

Governance

The formation of a strong governance structure is required with clearly defined policies for data access and reporting as well as adequate representation from all key stakeholders. This revised governance structure would include representation from clinicians (medical and allied health), researchers and associated peak bodies (e.g. SCIN) ensuring appropriate regional representation and the appointment of an independent chairperson. An appropriately constituted Steering Committee needs to be established to oversee the governance of the ASCIR, including the development of strategic direction and ensuring deliverables are met for the registry and funding bodies.

It is also recommended that an appropriately constituted Management Committee be convened to manage day-to-day aspects of the registry and ensure data quality measures are reported regularly. This would include the development of Terms of Reference for the Steering Committee and Management Committee, including meeting schedules and membership policies. It is recommended that the Management Committee meet on a monthly basis and the Steering Committee meets on a quarterly basis.

The ASCIR would be staffed by a part-time Project Manager with appropriate experience in the management of registries, a part-time Database Manager who would be responsible for implementing and maintaining a web-based database and Data Collectors who would be employed by the Health Services.

Reporting

The ASCIR, to date, has primarily reported epidemiological data as an annual report for the AIHW, site-specific reports, and a limited number of research outputs. It is recommended that a reporting schedule be established identifying content and including the production of quarterly and annual reports to identify trends and issues. Examples of content identified through the Phase I report could include items such as complication rates, treatment delivery and clinical outcomes. Development of reporting mechanisms would also include the ability to produce ad-hoc reports on local data and participate in aggregate reporting at a national level.

Ideally, the ASCIR would report on all cases and follow-up for traumatic and non-traumatic SCI across all age groups. However, while extension of the registry to the collection of non-traumatic and paediatric cases may not be possible initially, it should remain an aim of the ASCIR with working groups established to progress this extension.

The ASCIR would continue to play a role as a platform for future research projects as well as being able to record information capable of reporting on current and changing clinical practice. The registry would be used as a tool that could potentially inform health planning.

Key Personnel

A part-time Project Manager would be appointed and would have a critical role in the registry's function. The Project Manager would be responsible for the operational management of the ASCIR, including the organisation of the Steering and Reference Committees, meeting ethics requirements of the registry, ensuring documentation and training packages are up to date and contributing to the production of the quarterly and annual reports.

A Database Manager would be required to establish a web-based database and then maintain this database and respond to minor database problems. In addition this position would be responsible for generation of datasets for specific reports, requests and analyses, database training and contribution to the production of the quarterly and annual registry reports, including data completeness and additional quality reports as required.

Administrative costs are required to facilitate the Steering and Management committee meetings, complete other registry business and provide a forum for annual reporting of the registry findings to the spinal cord injury community. Administrative costs would also include general maintenance and the purchase of computers, printing and stationery, and teleconferencing costs.

The proposed budget shows the core registry costs anticipated for the operation of the ASCIR and salary costs are based on current Monash University salary rates. The additional registry costs for data collection and outcomes data collection at individual sites have been included separately for traumatic cases only and for traumatic and non-traumatic cases.

PROPOSED BUDGET

CORE REGISTRY COSTS		**Year 1**	**Year 2**
Project Manager	1 x 0.5 EFT @ $ 107,694 per annum including on-costs	$53,847	$53,846
Database Manager	1 x 0.2 EFT @ $107,694 per annum including on-costs initially, 0.4 EFT ongoing	$21,359	$43,078
Web-based Database	Cost of establishing web-based database	$30,000	$30,000
Governance and administrative costs	Travel, phone, training on site etc.	$5,000	$5,000
	Total (excluding GST)	**$110,206**	**$131,924**

ADDITIONAL REGISTRY COSTS (Traumatic cases only)		**Year 1**	**Year 2**
Data collection	$40 per case for 300 cases per year (estimate based on current data collection costs for other registries)	$12,000	$12,000
Outcomes data collection	$30 per hour for 300 cases per year	$9,000	$9,000
	Total (excluding GST)	**$21,000**	**$21,000**

ADDITIONAL REGISTRY COSTS (Traumatic and non-traumatic cases))		**Year 1**	**Year 2**
Data collection	$40 per case for 900 cases per year (estimate based on current data collection costs for other registries)	$36,000	$36,000
Outcomes data collection	$30 per hour for 900 cases per year	$27,000	$27,000
	Total (excluding GST)	**$63,000**	**$63,000**

FUNDING OPTIONS

Existing funding models for clinical registries

There is currently no standard approach to the funding of clinical registries. Current registries in Australia operate under the following models:

- Private operation with a mixture of private and public funding (The ANZDATA registry);
- Private operation with Australian Government funding with cost recovery from device manufacturers (The Australian Orthopaedic Association (AOA) National Joint Replacement Registry (NJRR));
- Private operation with State Government funding (Paediatric Intensive Care Registry (ANZPIC));
- Australian Government operation and Australian Government funding (National Diabetes Registry);
- Private operation and private funding (Australian Cystic Fibrosis Data Registry);

Potential funding models for ASCIR

In order to ensure the sustainability of the ASCIR initially, core funding is required for approximately $110,000 with ongoing annual funding requirements of approximately $130,000. The individual state registries could apply for state government funding within their own jurisdiction as SCID has done in the past. It would also be a viable option for state registries to apply to philanthropic organisations as the Bi-National Burns Registry has successfully done. As the Registry is a National Registry funding from the Australian Government would be a possible option. It is envisaged that in the future, with the continued recognition of the importance of clinical registries, that the Australian Government will provide funding opportunities for clinical registries. However, there is no clear pathway to funding at present and ongoing monitoring of the situation will be required.

Private operation with Australian Government funding with cost recovery from device manufacturers is not an option for ASCIR as the registry is not associated with any particular device or procedure.

Rick Hansen Spinal Cord Injury Registry

In April 2010 The Queensland Premier announced that the Queensland Government would be providing $1 million to a Rick Hansen Spinal Cord Injury Registry site to be located in Brisbane. This has many benefits for the Queensland Spinal Cord Injury Registry as The Rick Hansen Spinal Cord Injury Registry has well established data collection procedures including a secure web-based data collection platform, already collects outcome dates at one, two, and five years post injury and then every five years thereafter. The registry is also in the process of developing an international dataset for collaboration with international partner registries

The Rick Hansen registry provides a possible opportunity for funding for the ASCIR and the advantages of utilising it include:

- An established core dataset which is extensive and covers many items requested by the clinicians interviewed (See Phase I report Appendices).
- An established and current technology infrastructure platform including top tier hosting.
- The provision of training and data collection protocols have been well established
- Reporting policies and procedures established and coordinated at a central location.
- Long-term follow-up protocols and data collection tools developed (1yr, 2yrs, 5 yrs and then every 5yrs).
- Incorporation of a multi-centre trial network.

While the above items are significant advantages for associating the ASCIR with the Rick Hansen Registry, there are a number of disadvantages that have been identified:

- The registry comprises only collection of acute and rehabilitation data collection for traumatic spinal cord injury.
- Must utilise their ethics processes (opt-in). This is contrary to our recommendation of an opt-off consent process as outlined in the Phase I report.
- Further in-depth review of data ownership and data control would be required prior to linking with this registry. It is unclear as to the level of individual unit control of their data within this registry.
- As most interviewees from the Phase I reporting process indicated that the inclusion of non-traumatic and paediatric cases are required to be incorporated into the registry, a separate Australian registry for these cases would still be required.

- Funding from the Rick Hansen Institute is for the site and not a data coordinator per se.

The opportunity that the Rick Hansen Institute presents is one that requires consideration by the ASCIR board and SCIN. The potential for sustainable funding must be considered in light of the needs of a registry that that must be robust for Australian requirements.

CONCLUSION

Based on the Phase I report and review this report has recognised the need for funding those areas identified to progress the ASCIR from an epidemiological registry to a clinical quality registry. It is clear that the revised ASCIR will require significant "buy-in" from all key stakeholder groups including specialist SIUs, researchers and funding bodies. ASCIR requires the development of a web-based registry, incorporating individual patient level data submission and data linkages with external systems.

FINAL RECOMMENDATIONS

- The ASCIR capture only adult traumatic SCI cases until the issues with case identification of paediatric and non-traumatic cases are resolved.
- The Rick Hansen Spinal Cord Registry is an excellent model but currently lacks the ability to capture paediatric and non-traumatic cases.
- State government, federal government and philanthropic organisations are viable funding options for ASCIR.

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