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Complete List of Authors:	Vaikuntam, Bharat Phani; University of Sydney Sydney Medical School, Northern Clinical School; John Walsh Centre for Rehabilitation Research, Kolling Institute Middleton, James; University of Sydney Sydney Medical School, Northern Clinical School; John Walsh Centre for Rehabilitation Research, Kolling Institute McElduff , Patrick ; Health Policy Analysis Pty Ltd Pearse, Jim; Health Policy Analysis Pty Ltd Walsh, John; University of Sydney Sydney Medical School, Northern Clinical School; John Walsh Centre for Rehabilitation Research, Kolling Institute Cameron, Ian; University of Sydney, Sydney Medical School - Northern; John Walsh Centre for Rehabilitation Research, Kolling Institute Sharwood, Lisa; Kolling Institute; University of Sydney
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Assessing the impact of care pathways on potentially preventable complications and costs for spinal trauma patients: protocol for a data linkage study using cohort study and administrative data.

Vaikuntam BP[1,2*], Middleton JW[1,2,4], McElduff P[3], Pearce J[3], Walsh J[1,2], Cameron ID[1,2], Sharwood LN[1,2]

[*]corresponding author

[1]Sydney Medical School, Northern; University of Sydney, Sydney, Australia

[2]John Walsh Centre for Rehabilitation Research; Kolling Institute, Sydney, Australia

[3]Health Policy Analysis, Sydney, Australia

[4]NSW State-wide Spinal Cord Injury Service; Agency for Clinical Innovation, Sydney, Australia

Corresponding author: Vaikuntam Bharat Phani

Email: bvai6198@uni.sydney.edu.au

Telephone: +61 411820726

Postal Address: [2]John Walsh Centre for Rehabilitation Research, Kolling Institute, Royal North Shore Hospital, Sydney, NSW 2065 Australia

Author 2: Middleton James Walter

Email: james.middleton@sydney.edu.au

Institutional Address: [1]Sydney Medical School, Northern; University of Sydney, Sydney, Australia.

[2]John Walsh Centre for Rehabilitation Research; Kolling Institute, Sydney, Australia.

[4]NSW State-wide Spinal Cord Injury Service; Agency for Clinical Innovation, Sydney, Australia

Author 3: McElduff Patrick

Email: pmcelduff@healthpolicy.com.au

Institutional Address: [3]Health Policy Analysis, Sydney, Australia

Author 4: Pearse Jim

Email: JPearse@healthpolicy.com.au

Institutional Address: [3]Health Policy Analysis, Sydney, Australia

Author 5: Walsh John

Email: magoo.actuarial@gmail.com

Institutional Address: [1]Sydney Medical School, Northern; University of Sydney, Sydney, Australia.

[2]John Walsh Centre for Rehabilitation Research; Kolling Institute, Sydney, Australia.

Author 6: Cameron Ian David

Email: ian.cameron@sydney.edu.au

Institutional Address: [1]Sydney Medical School, Northern; University of Sydney, Sydney, Australia.

[2]John Walsh Centre for Rehabilitation Research; Kolling Institute, Sydney, Australia.

Author 7: Sharwood Lisa Nicole

Email: lisa.sharwood@sydney.edu.au

Institutional Address: [1]Sydney Medical School, Northern; University of Sydney, Sydney, Australia.

[2]John Walsh Centre for Rehabilitation Research; Kolling Institute, Sydney, Australia.

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ABSTRACT

Introduction Traumatic spinal cord injuries have significant consequences both for the injured individual and the healthcare system, usually resulting in life-long disability. Evidence has shown that timely medical and surgical interventions can lead to better patient outcomes with implicit cost savings. Potentially preventable secondary complications are therefore indicators of the effectiveness of acute care following traumatic injury. The extent to which policy and clinical variation within the healthcare service impact on outcomes and acute care costs for patients with traumatic spinal cord injury (TSCI) in Australia is not well described.

Methods and Analysis A comprehensive dataset will be formed using record linkage to combine patient health and administrative records from seven minimum data collections (including costs), with an existing dataset of patients with acute TSCI (Access to Care Study), for the time period June 2013-June 2016. This person-level dataset will be analysed to estimate the acute care treatment costs of traumatic spinal cord injury in New South Wales, extrapolated nationally. Subgroup analyses will describe the associated costs of secondary complications and regression analysis will identify drivers of higher treatment costs. Mapping patient care and health service pathways of these patients will enable measurement of deviations from best-practice care standards and cost-effectiveness analyses of the different pathways.

Ethics and dissemination Ethics approval has been obtained from the New South Wales Population and Health Services Research Ethics Committee. Dissemination strategies include peer-reviewed publications in scientific journals and conference presentations to enable translation of study findings to clinical and policy audiences.

ARTICLE SUMMARY

Article Focus

- This article reports the protocol of a data linkage study assessing the impact of care pathways on potentially preventable complications and costs for patients with acute TSCI.
- This study will quantify the financial costs of deviation from best practice standards and identify a cost-effective best-practice clinical pathway for patients with TSCI.

Strengths and limitations

- The effective use of the Centre for Health Record's capacity to link to additional datasets that are not routinely part of the administrative data collections enables a richer subset of data within which to examine the costs and care provided for patients with TSCI in the state of New South Wales, Australia.
- The use of New South Wales Activity Based Funding District and Network Return Data is a novel strategy to capture the true costs of treatment for patients with TSCI in acute care settings at the hospital level.
- The costs are limited to the perspective of the healthcare provider with direct social care costs and indirect costs from loss of productivity to patients or care givers not included, and thereby underestimates the financial impact of TSCI to the society as a whole.

INTRODUCTION

Traumatic spinal cord injury (TSCI) is a devastating injury, most often being life-altering and causing life-long disability. The ongoing physical, mental and economic consequences of this type of injury have substantial effects on patients and their families. The equally enduring economic responsibilities on the health care service fall similarly on personal health insurance, as well as disability and injury insurance providers. The cost of spinal cord injury in Australia was last estimated at $2 billion annually in 2008 [1]; consumer price indexation adjusts this to $2.38 billion in 2017 [2]. The majority (79%) of all new spinal cord injury cases reported to specialist Spinal Cord Injury Units (SCIU) are attributable to trauma and as such, the burden of TSCI on the Australian health care system is high [3]. Improvements in pre-hospital and early trauma care have seen improved survival rates after severe traumatic injury [4], shifting a greater morbidity burden to life-time injury. As this continues the long-term costs of ongoing disability associated with severe injury will also rise.

The incidence of TSCI in Australia is reported between 15.0 – 32.3 cases per million population per year, with an estimated prevalence of 10,000 - 20,000 Australians living with an SCI [5-7]. Very high treatment costs for patients with TSCI in an acute care setting have been described in the international context [8 9]; however, updated evaluation of treatment costs for patients with TSCI in Australia are needed. It is vital to contextualise these costs in the present day configuration of acute care settings and specialist services. This picture must be completed with exploration and clarification of the drivers of higher treatment costs, and in particular, any measurable association with clinical variation in the care of patients with TSCI. The prevalence

and cost of potentially preventable complications for patients with TSCI needs exploration in the Australian healthcare setting, in order to drive health service improvement nationally.

Evidence has shown that failure to provide care according to specific guidelines in a timely manner for the patient with TSCI, can directly affect both patient outcomes and the costs of rehabilitation and treatment [10 11]. During the immediate post-injury phase, patients with TSCI are at high risk of secondary neurological damage related to neural tissue oedema, increased cord compression, altered blood flow and reduced tissue perfusion, which can lead to permanent neurological degeneration. Timely medical and surgical interventions can prevent or reduce the extent of secondary neurological injury and lead to better patient outcomes with implicit cost savings [12 13]. It is further well described that specific acute care protocols must be followed to avoid preventable secondary complications such as pressure injuries, urinary tract or respiratory infections, which may otherwise severely hamper long term recovery and outcomes.

Significant variations in policy and practice may exist among health care providers based on differences in perceptions of precisely what constitutes 'best-practice' specialist care, including referral patterns to specialist centres and the timing of surgical intervention [14]. However, there is little evidence on the extent to which variations in clinical practice and institutional performance in Australia affect patient outcomes and acute care costs, and further, are amenable to change. This has been identified as a priority by the Australian Institute for Health and Welfare [15].

This study will examine a data linkage cohort of patients 16 years of age or older, who sustained acute TSCI in the Australian state of New South Wales (NSW) between 01 June 2013 and 03 Jan 2016 with the following primary aims:

1. To accurately quantify the acute care costs for patients with TSCI across NSW, and explore health service pathway and clinical practice variations potentially attributable to higher cost hospitalisations.
2. To describe the incidence of potentially preventable complications in patients with acute TSCI and the associated incremental healthcare costs.
3. To benchmark actual patient pathways and care against the best-practice standards previously defined using a modified e-Delphi process and other sources, quantifying financial costs associated with deviation of care from these standards.
4. To estimate and compare the cost-effectiveness of treatment pathway options, and construct an efficiency measure for comparison.

Understanding the costs and health service drivers associated with potentially preventable complications should clarify the investment potential in the construction and implementation of a cost-effective 'best-practice' clinical pathway for patients with TSCI. Communication of these findings will therefore aim to drive change on a national scale.

METHODS AND ANALYSIS

The Access to Care study [7] is a cohort study of 202 patients with TSCI, documenting early care protocols and transport decisions from the scene of injury to definitive diagnosis and specialised treatment. Recruitment occurred from June 2013 to January 2016. The NSW Admitted Patient Data Collection (APDC) will be used to identify and extract TSCI patient records from all separations from NSW public hospitals, based on specific TSCI related International Classification of Diseases and Related Health Problems, 10th Version, Australian Modification (ICD-10 AM) codes (Appendix 1) in their diagnosis codes. Data linkage will be undertaken by

the NSW Centre for Health Record Linkage(CHeReL), linking the Access to Care study dataset with the APDC.

The NSW APDC contains demographic and hospitalisation data for every inpatient admission to any public hospital in NSW. These records will be then linked by the CHeReL, with the following administrative patient datasets using a combination of deterministic and probabilistic methods;

- NSW Emergency Department Data Collection (EDDC) which contains data on presentations to emergency departments in most public hospitals in NSW;
- NSW Ambulance data collection which contains information from the Computer Aided Dispatch (CAD) system and patient health records;
- NSW Registry of Births, Deaths and Marriages Data which records information for deaths occurring in NSW; and the NSW Cause of Death files;
- NSW Activity Based Funding District and Network Return (NSW-DNR) Data Collection on individual patient cost and health service activity data to ensure all cases were included prior to case identification.

The CHeReL uses probabilistic record linkage techniques to link the patient identifiers from the APDC to the other datasets using a best practice protocol for preserving the patient privacy. Linked patient health care records will include pre-hospital and acute care administrative data collections and death records, as well as cost data collections to provide a comprehensive dataset. The final record linked dataset will be analysed to identify the first hospital admission for a patient satisfying the criteria for a TSCI (hereafter called the index admission), providing details of comorbidities, inpatient complications and unplanned readmissions within the study

period to address the study objectives. The index admission will be considered the first to have one of the identified ICD-10-AM codes for TSCI in an acute separation (see Appendix 1); such admissions will most likely have an immediately preceding NSW Ambulance retrieval and transfer record.

Analysis Plan

The study aims are expanded in the following paragraphs.

1. *To accurately quantify the acute care costs for patients with TSCI across NSW, and explore health service pathway and clinical practice variations potentially attributable to higher cost hospitalisations.*

Data on resource use will be collected using the NSW-DNR data and Australian Refined Diagnostic Related Group (AR-DRG) codes recorded in the APDC and EDDC for each episode of care for patients with TSCI. Sub-categorisations within the NSW-DNR include employee related costs, costs of visiting medical officers, other operating expenses, professional indemnity charges, hospital finance costs, depreciation and amortisation, payments to affiliated health organisations and grant and subsidy costs.

A Generalized Linear Model (GLM) regression with a log link and gamma error term will be performed on the costs to determine independent predictors of acute care costs. Variables for the severity of the injury such as the ICD 10th revision-based Injury Severity Scores (ICISS), Charlson Co-morbidity Index and the level of injury (cervical, thoracic or lumbar regions) will be included in the model to adjust for the heterogeneity between the patients. Sensitivity analysis will be used to account for the excess costs incurred by co-morbidities not attributable to TSCI; decreasing costs by percentage figure relative to the presence of co-morbidities at the time

of the TSCI. Variation in activity-based costs will be explored to highlight areas of resource use that require further investigation, similar to research conducted recently across the NSW Trauma Service, using this approach [16].

2. To describe the incidence of potentially preventable complications in patients with acute TSCI and the associated incremental healthcare costs.

Potentially preventable complications (such as pressure ulcers or urinary tract infections) related to the TSCI and within the index admission will be identified within the ICD-10-AM codes, pre-defined according to published data [17] and listed in Appendix 2. Subsequent re-admissions from the index admission and within the study period will be scrutinised to determine any ongoing injury sequalae including potentially preventable complications. Readmissions within 30 days from first acute discharge will be principally identified as unplanned readmissions. The cost of these secondary complications will be estimated using the NSW DNR data and AR-DRG codes recorded for each episode of care.

3. To benchmark actual patient pathways and care against the best-practice standards previously defined through a modified e-Delphi process and other sources, quantifying financial costs associated with deviation of care from these standards.

The patient clinical care pathway will be mapped from the scene of injury to definitive care, incorporating numbers of hospital transfers, hospital specific factors describing healthcare utilisation, length of stay, hospital level and their location. This mapping will be compared with the best-practice care standards defined by the modified e-Delphi process[18] and current state based guidelines for the management of major trauma, to determine the clinical pathway components reflecting optimal timing and care. This comparison will permit factors potentially associated with unwarranted clinical variation for patients with TSCI to be identified.

A gap driver analysis will aim to identify drivers of cost and clinical pathway differences and will consider factors including delayed and/or multiple transfers, delays in timing of surgery, lack of admission to specialist TSCI services and the occurrence of secondary complications. A range of controllable and uncontrollable factors will be measured against the best practice standards. Multilevel regression analysis will be performed to determine patient-level, and hospital-level factors associated with cost variability.

4. *To estimate and compare the cost-effectiveness of treatment pathway options, and propose a cost-effective clinical pathway*

Decision-analytic modelling will be used to build a cost-effective clinical pathway closely emulating the best-practice standards. A decision tree will be modelled based on the observed hospital costs, admissions, readmissions, mortality and complications data from the linked health records, Australian life tables, previously mapped care pathways, incidence rates and previously published literature. Total resource use calculated will include the costs for admissions, complications, emergency department visits, surgery, readmissions and diagnostic services, and will be estimated for the analysis and presented in Australian dollars. Relevant internal validity measures will be undertaken to affirm the validity of the model [19]. A cost-effectiveness analysis will be conducted to compare the proposed/modelled care pathway against the current care practices identified in the record linked data, from the perspective of the healthcare provider. The model will utilize the study population and the study settings described above over a period of 12 months post-injury for the evaluation. Service utilisation data attached to each unique health record will be extracted and analysed based on the relevance of AR-DRG codes to the ICD-10 codes of interest. Cost weights associated with each AR-DRG will be adjusted for differences for each financial year during the entire study period. All cost data will be inflated or deflated as

required using the published health deflators and a discount rate of 5% will be used in the evaluation. The Quality Adjusted Life Years (QALYs) for each treatment arm for the modelling will be derived from follow up interview self-reports from the patients in the nested Access to Care study, combined with estimates from similarly published literature.

These utility measures will be subject to probabilistic sensitivity analysis along with other key parameters in the model over a wide range based on clinical judgement and existing literature. The incremental cost effectiveness ratios (ICERs) will be estimated to compare the interventions using the expected costs and effects from the decision analytic modelling exercise. A cost-effectiveness (CE) plane will be used to plot the ICER and the uncertainty will be represented by confidence ellipses, which are a two dimensional representation of the confidence intervals [20].

All the data analyses will be conducted using Stata software (version 15.0 STATA Corporation, College Station, TX, USA) and the decision analytic modelling will be conducted using the Treeage Pro software (2017 Version R2).

Patient and public involvement

The study will use de-identified record linked health data and will not involve any patients or public for this study.

ETHICS AND DISSEMINATION

Ethics approval has been obtained from the NSW Population and Health Services Research Ethics Committee. The Access to Care study database contains 202 patients who have consented to access to their medical records, this dataset was identified for the purpose of record linkage and returned de-identified. Dissemination of research findings to key stakeholders is envisaged through peer reviewed publications in scientific journals, conference proceedings and

collaborator meetings. The study is ideally placed to establish standards, reduce costs with potential for research translation across the state of NSW.

DISCUSSION

The long-term impact of TSCI on our health care system is significant and ongoing. Deficits in clinical policy and practice can significantly impact the extent of long term disability and resultant quality of life for patients with TSCI, thereby escalating personal and health care system economic costs. Identification of specific deficits in system performance will facilitate application of targeted improvement strategies, aiming for greater efficiency of our services, focused resource use, highest standard of practice and consequently optimal outcomes. This study is ideally placed to establish standards, reduce costs and translate evidence back to the bedside.

A particular challenge envisaged in this study is the mapping of patient pathways, which may reveal many routes with multiple interactions within the healthcare system. Many individual routes can be defined based on the initial diagnosis, geographical location and the transition pathway. However, to be useful for the analysis, these pathways will need to be aggregated into a manageable number of broader pathways guided primarily by existing policy directives to pre-hospital and acute care services. Particular limitations are envisaged with the study design; firstly, the costs are limited to the acute care episode, and direct social care costs or indirect costs from loss of productivity to patients or caregivers are not included. This therefore underestimates the financial impact of TSCI to society as a whole. Despite all the efforts to accurately describe all cost elements of acute care, the possibility of some resources not being captured cannot be excluded. However, we anticipate this aspect at least to be uniform across all subgroups or

pathways and not significantly affect the research findings as most of the resources will be accounted for in the costing exercise.

This study proposes to describe the costs of acute care, including those identified as attributable to potentially preventable complications. Care pathway deviations from best practice will be described, such as delayed surgery or delayed admission to SCIU for patients with TSCI. Importantly, we aim to quantify the degree to which variation in clinical practice and institutional performance impacts on patient outcomes and acute care costs and is amenable to change. These findings are likely to have significant clinical consequences for the patient, cost implications for the health service [21] and offers significant potential to make amenable recommendations for improvement.

List of abbreviations

APDC - NSW admitted patient data collection

AR-DRG - Australian refined diagnostic related group

EDDC - NSW emergency department data collection

ICD-10-AM - International classification of diseases – tenth revision, Australian modification

ICER - Incremental cost effectiveness ratio

NSW - New South Wales

QALY – Quality adjusted life years

SCI - Spinal cord injury

SCIU – Spinal cord injury unit

TSCI - Traumatic spinal cord injury

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DECLARATIONS

Ethics: Ethics approval for this study has been grant NSW Population & Health Services Research Ethics Committee on 17 August 2016 (AU RED REF: HREC/16/CIPHS/19).

Availability of data and materials: The data used in this protocol cannot be shared with any other researchers unless approved by the relevant data custodians at the Centre for Health Record Linkage.

Contributorship statement: LNS is the principal investigator for this funded study and was principally responsible for the conception and design of this study and the acquisition of the record linkage data. JWM and JW provided substantial intellectual content during the study design. JWM is the principal investigator for the Access to Care study. LNS is the principal investigator for the Delphi process project. BPV wrote the first draft of the manuscript and co-ordinated commentary and review for subsequent revisions. All authors contributed to the critical review and approval of the final manuscript.

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Competing interests: The authors declare that they have no competing interests.

APPENDIX 1

The dataset combined all patients for whom one of the following ICD-10-AM (International Classification of Diseases – Tenth Revision, Australian Modification) codes have been identified in any separation, and in any position of the diagnostic code list within the NSW Admitted Patient Data Collection (APDC):

S12, S12.0, S12.1, S12.2, S12.21, S12.22, S12.23, S12.24, S12.25, S12.7, S12.8, S12.9, S13.1, S13.10, S13.11, S13.12, S13.13, S13.14, S13.15, S13.16, S13.17, S13.18, S13.2, S13.3, S14.0, S14.10, S14.11, S14.12, S14.13, S14.70, S14.71, S14.72, S14.73, S14.74, S14.75, S14.76, S14.77, S14.78, S22.0, S22.00, S22.01, S22.02, S22.03, S22.04, S22.05, S22.06, S22.1, S24.0, S24.1, S24.10, S24.11, S24.12, S24.7, S24.70, S24.71, S24.72, S24.73, S24.74, S24.75, S24.76, S24.77, S32, S32.0, S32.00, S32.01, S32.02, S32.03, S32.04, S32.05, S34.0, S34.1, S34.3, S34.70, S34.71, S34.72, S34.73, S34.74, S34.75, S34.76, T06.0, T06.1, T09.3.

APPENDIX 2

List of complications and ICD 10 codes

Complication	ICD 10 codes
Urinary tract infection	N30, N39
Hydronephrosis, hydro-ureter	N13
Other disorders of bladder	N31
Urethritis	N34, N37
Haematuria	R31
Other urinary complication	N99.8, N99.9
Decubitus ulcers (pressure ulcer)	L89
Pneumonitis due to solids and liquids	J69
Tracheostomy complication	J95.0
Urinary retention/incontinence	R33, R32, N39.4, N39.3
Pneumonia, pulmonary collapse	J12, J14, J15, J17, J18, J98.1
Pleurisy	R09.1, J86.9, J86.0, J90
Respiratory failure	J96.9, J96.0, J96.1

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Complete List of Authors:	Vaikuntam, Bharat Phani; University of Sydney Sydney Medical School, Northern Clinical School; John Walsh Centre for Rehabilitation Research, Kolling Institute Middleton, James; University of Sydney Sydney Medical School, Northern Clinical School; John Walsh Centre for Rehabilitation Research, Kolling Institute McElduff , Patrick ; Health Policy Analysis Pty Ltd Pearse, Jim; Health Policy Analysis Pty Ltd Walsh, John; University of Sydney Sydney Medical School, Northern Clinical School; John Walsh Centre for Rehabilitation Research, Kolling Institute Cameron, Ian; University of Sydney, Sydney Medical School - Northern; John Walsh Centre for Rehabilitation Research, Kolling Institute Sharwood, Lisa; Kolling Institute; University of Sydney
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Vaikuntam BP[1,2*], Middleton JW[1,2,4], McElduff P[3], Pearse J[3], Walsh J[1,2], Cameron ID[1,2], Sharwood LN[1,2]

[*]corresponding author

[1]Sydney Medical School, Northern; University of Sydney, Sydney, Australia

[2]John Walsh Centre for Rehabilitation Research; Kolling Institute, Sydney, Australia

[3]Health Policy Analysis, Sydney, Australia

[4]NSW State-wide Spinal Cord Injury Service; Agency for Clinical Innovation, Sydney, Australia

Corresponding author: Vaikuntam Bharat Phani

Email: bvai6198@uni.sydney.edu.au

Telephone: +61 411820726

Postal Address: [2]John Walsh Centre for Rehabilitation Research, Kolling Institute, Royal North Shore Hospital, Sydney, NSW 2065 Australia

Author 2: Middleton James Walter

Email: james.middleton@sydney.edu.au

Institutional Address: [1]Sydney Medical School, Northern; University of Sydney, Sydney, Australia.

[2]John Walsh Centre for Rehabilitation Research; Kolling Institute, Sydney, Australia.

[4]NSW State-wide Spinal Cord Injury Service; Agency for Clinical Innovation, Sydney, Australia

Author 3: McElduff Patrick

Email: pmcelduff@healthpolicy.com.au

Institutional Address: [3]Health Policy Analysis, Sydney, Australia

Author 4: Pearse Jim

Email: JPearse@healthpolicy.com.au

Institutional Address: [3]Health Policy Analysis, Sydney, Australia

Author 5: Walsh John

Email: magoo.actuarial@gmail.com

Institutional Address: [1]Sydney Medical School, Northern; University of Sydney, Sydney, Australia.

[2]John Walsh Centre for Rehabilitation Research; Kolling Institute, Sydney, Australia.

Author 6: Cameron Ian Douglas

Email: ian.cameron@sydney.edu.au

Institutional Address: [1]Sydney Medical School, Northern; University of Sydney, Sydney, Australia.

[2]John Walsh Centre for Rehabilitation Research; Kolling Institute, Sydney, Australia.

Author 7: Sharwood Lisa Nicole

Email: lisa.sharwood@sydney.edu.au

Institutional Address: [1]Sydney Medical School, Northern; University of Sydney, Sydney, Australia.

[2]John Walsh Centre for Rehabilitation Research; Kolling Institute, Sydney, Australia.

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Introduction Traumatic spinal cord injuries have significant consequences both for the injured individual and the healthcare system, usually resulting in life-long disability. Evidence has shown that timely medical and surgical interventions can lead to better patient outcomes with implicit cost savings. Potentially preventable secondary complications are therefore indicators of the effectiveness of acute care following traumatic injury. The extent to which policy and clinical variation within the healthcare service impact on outcomes and acute care costs for patients with traumatic spinal cord injury (TSCI) in Australia is not well described.

Methods and Analysis A comprehensive dataset will be formed using record linkage to combine patient health and administrative records from seven minimum data collections (including costs), with an existing dataset of patients with acute TSCI (Access to Care Study), for the time period June 2013-June 2016. This person-level dataset will be analysed to estimate the acute care treatment costs of traumatic spinal cord injury in New South Wales, extrapolated nationally. Subgroup analyses will describe the associated costs of secondary complications and regression analysis will identify drivers of higher treatment costs. Mapping patient care and health service pathways of these patients will enable measurement of deviations from best-practice care standards and cost-effectiveness analyses of the different pathways.

Ethics and dissemination Ethics approval has been obtained from the New South Wales Population and Health Services Research Ethics Committee. Dissemination strategies include peer-reviewed publications in scientific journals and conference presentations to enable translation of study findings to clinical and policy audiences.

ARTICLE SUMMARY

Article Focus

- This article reports the protocol of a data linkage study assessing the impact of care pathways on potentially preventable complications and costs for patients with acute TSCI.
- This study will quantify the financial costs of deviation from best practice standards and identify a cost-effective best-practice clinical pathway for patients with TSCI.

Strengths and limitations

- The effective use of the Centre for Health Record's capacity to link to additional datasets that are not routinely part of the administrative data collections enables a richer subset of data within which to examine the costs and care provided for patients with TSCI in the state of New South Wales, Australia.
- The use of New South Wales Activity Based Funding District and Network Return Data is a novel strategy to capture the true costs of treatment for patients with TSCI in acute care settings at the hospital level.
- The costs are limited to the perspective of the healthcare provider with direct social care costs and indirect costs from loss of productivity to patients or care givers not included, and thereby underestimates the financial impact of TSCI to the society as a whole.

INTRODUCTION

Traumatic spinal cord injury (TSCI) is a devastating injury, most often being life-altering and causing life-long disability. The ongoing physical, mental and economic consequences of this type of injury have substantial effects on patients and their families. The equally enduring economic responsibilities on the health care service fall similarly on personal health insurance, as well as disability and injury insurance providers. The cost of spinal cord injury in Australia was last estimated at $2 billion annually in 2008 [1]; consumer price indexation adjusts this to $2.38 billion in 2017 [2]. The majority (79%) of all new spinal cord injury cases reported to specialist Spinal Cord Injury Units (SCIU) are attributable to trauma and as such, the burden of TSCI on the Australian health care system is high [3]. Improvements in pre-hospital and early trauma care have seen improved survival rates after severe traumatic injury [4], shifting a greater morbidity burden to life-time injury. As this continues the long-term costs of ongoing disability associated with severe injury will also rise.

The incidence of TSCI in Australia is reported between 15.0 – 32.3 cases per million population per year, with an estimated prevalence of 10,000 - 20,000 Australians living with an SCI [5-7]. Very high treatment costs for patients with TSCI in an acute care setting have been described in the international context [8 9]; however, updated evaluation of treatment costs for patients with TSCI in Australia are needed. It is vital to contextualise these costs in the present day configuration of acute care settings and specialist services. This picture must be completed with exploration and clarification of the drivers of higher treatment costs, and in particular, any measurable association with clinical variation in the care of patients with TSCI. The prevalence

and cost of potentially preventable complications for patients with TSCI needs exploration in the Australian healthcare setting, in order to drive health service improvement nationally.

Evidence has shown that failure to provide care according to specific guidelines in a timely manner for the patient with TSCI, can directly affect both patient outcomes and the costs of rehabilitation and treatment [10 11]. During the immediate post-injury phase, patients with TSCI are at high risk of secondary neurological damage related to neural tissue oedema, increased cord compression, altered blood flow and reduced tissue perfusion, which can lead to permanent neurological degeneration. Timely medical and surgical interventions can prevent or reduce the extent of secondary neurological injury and lead to better patient outcomes with implicit cost savings [12 13]. It is further well described that specific acute care protocols must be followed to avoid preventable secondary complications such as pressure injuries, urinary tract or respiratory infections, which may otherwise severely hamper long term recovery and outcomes.

Significant variations in policy and practice may exist among health care providers based on differences in perceptions of precisely what constitutes 'best-practice' specialist care, including referral patterns to specialist centres and the timing of surgical intervention [14]. However, there is little evidence on the extent to which variations in clinical practice and institutional performance in Australia affect patient outcomes and acute care costs, and further, are amenable to change. This has been identified as a priority by the Australian Institute for Health and Welfare [15].

This study will examine a data linkage cohort of patients 16 years of age or older, who sustained acute TSCI in the Australian state of New South Wales (NSW) between 01 June 2013 and 03 Jan 2016 with the following primary aims:

1. To accurately quantify the acute care costs for patients with TSCI across NSW, and explore health service pathway and clinical practice variations potentially attributable to higher cost hospitalisations.
2. To describe the incidence of potentially preventable complications in patients with acute TSCI and the associated incremental healthcare costs.
3. To benchmark actual patient pathways and care against the best-practice standards previously defined using a modified e-Delphi process and other sources, quantifying financial costs associated with deviation of care from these standards.
4. To estimate and compare the cost-effectiveness of treatment pathway options, and construct an efficiency measure for comparison.

Understanding the costs and health service drivers associated with potentially preventable complications should clarify the investment potential in the construction and implementation of a cost-effective 'best-practice' clinical pathway for patients with TSCI. Communication of these findings will therefore aim to drive change on a national scale.

METHODS AND ANALYSIS

The Access to Care study [7] is a cohort study of 202 patients with TSCI, documenting early care protocols and transport decisions from the scene of injury to definitive diagnosis and specialised treatment. Recruitment occurred from June 2013 to January 2016. The NSW Admitted Patient Data Collection (APDC) will be used to identify and extract TSCI patient records from all separations from NSW public hospitals, based on specific TSCI related International Classification of Diseases and Related Health Problems, 10th Version, Australian Modification (ICD-10 AM) codes (Appendix 1) in their diagnosis codes. Data linkage will be undertaken by

the NSW Centre for Health Record Linkage(CHeReL), linking the Access to Care study dataset with the APDC.

The NSW APDC contains demographic and hospitalisation data for every inpatient admission to any public hospital in NSW. These records will be then linked by the CHeReL, with the following administrative patient datasets using a combination of deterministic and probabilistic methods;

- NSW Emergency Department Data Collection (EDDC) which contains data on presentations to emergency departments in most public hospitals in NSW;
- NSW Ambulance data collection which contains information from the Computer Aided Dispatch (CAD) system and patient health records;
- NSW Registry of Births, Deaths and Marriages Data which records information for deaths occurring in NSW; and the NSW Cause of Death files;
- NSW Activity Based Funding District and Network Return (NSW-DNR) Data Collection on individual patient cost and health service activity data to ensure all cases were included prior to case identification.

The CHeReL uses probabilistic record linkage techniques to link the patient identifiers from the APDC to the other datasets using a best practice protocol for preserving the patient privacy. Linked patient health care records will include pre-hospital and acute care administrative data collections and death records, as well as cost data collections to provide a comprehensive dataset. The final record linked dataset will be analysed to identify the first hospital admission for a patient satisfying the criteria for a TSCI (hereafter called the index admission), providing details of comorbidities, inpatient complications and unplanned readmissions within the study

period to address the study objectives. The index admission will be considered the first to have one of the identified ICD-10-AM codes for TSCI in an acute separation (see Appendix 1); such admissions will most likely have an immediately preceding NSW Ambulance retrieval and transfer record.

Analysis Plan

The study aims are expanded in the following paragraphs.

1. *To accurately quantify the acute care costs for patients with TSCI across NSW, and explore health service pathway and clinical practice variations potentially attributable to higher cost hospitalisations.*

Data on resource use will be collected using the NSW-DNR data and Australian Refined Diagnostic Related Group (AR-DRG) codes recorded in the APDC and EDDC for each episode of care for patients with TSCI. Sub-categorisations within the NSW-DNR include employee related costs, costs of visiting medical officers, other operating expenses, professional indemnity charges, hospital finance costs, depreciation and amortisation, payments to affiliated health organisations and grant and subsidy costs.

A Generalized Linear Model (GLM) regression with a log link and gamma error term will be performed on the costs to determine independent predictors of acute care costs. Variables for the severity of the injury such as the ICD 10th revision-based Injury Severity Scores (ICISS), Charlson Co-morbidity Index and the level of injury (cervical, thoracic or lumbar regions) will be included in the model to adjust for the heterogeneity between the patients. Sensitivity analysis will be used to account for the excess costs incurred by co-morbidities not attributable to TSCI; decreasing costs by percentage figure relative to the presence of co-morbidities at the time

of the TSCI. Variation in activity-based costs will be explored to highlight areas of resource use that require further investigation, similar to research conducted recently across the NSW Trauma Service, using this approach [16].

2. To describe the incidence of potentially preventable complications in patients with acute TSCI and the associated incremental healthcare costs.

Potentially preventable complications (such as pressure ulcers or urinary tract infections) related to the TSCI and within the index admission will be identified within the ICD-10-AM codes, pre-defined according to published data [17] and listed in Appendix 2. Subsequent re-admissions from the index admission and within the study period will be scrutinised to determine any ongoing injury sequalae including potentially preventable complications. Readmissions within 30 days from first acute discharge will be principally identified as unplanned readmissions. The cost of these secondary complications will be estimated using the NSW DNR data and AR-DRG codes recorded for each episode of care.

3. To benchmark actual patient pathways and care against the best-practice standards previously defined through a modified e-Delphi process and other sources, quantifying financial costs associated with deviation of care from these standards.

The patient clinical care pathway will be mapped from the scene of injury to definitive care, incorporating numbers of hospital transfers, hospital specific factors describing healthcare utilisation, length of stay, hospital level and their location. This mapping will be compared with the best-practice care standards defined by the modified e-Delphi process[18] and current state based guidelines for the management of major trauma, to determine the clinical pathway components reflecting optimal timing and care. This comparison will permit factors potentially associated with unwarranted clinical variation for patients with TSCI to be identified.

A gap driver analysis will aim to identify drivers of cost and clinical pathway differences and will consider factors including delayed and/or multiple transfers, delays in timing of surgery, lack of admission to specialist TSCI services and the occurrence of secondary complications. A range of controllable and uncontrollable factors will be measured against the best practice standards. Multilevel regression analysis will be performed to determine patient-level, and hospital-level factors associated with cost variability.

4. *To estimate and compare the cost-effectiveness of treatment pathway options, and propose a cost-effective clinical pathway*

Decision-analytic modelling will be used to build a cost-effective clinical pathway closely emulating the best-practice standards. A decision tree will be modelled based on the observed hospital costs, admissions, readmissions, mortality and complications data from the linked health records, Australian life tables, previously mapped care pathways, incidence rates and previously published literature. Total resource use calculated will include the costs for admissions, complications, emergency department visits, surgery, readmissions and diagnostic services, and will be estimated for the analysis and presented in Australian dollars. Relevant internal validity measures will be undertaken to affirm the validity of the model [19]. A cost-effectiveness analysis will be conducted to compare the proposed/modelled care pathway against the current care practices identified in the record linked data, from the perspective of the healthcare provider. The model will utilize the study population and the study settings described above over a period of 12 months post-injury for the evaluation. Service utilisation data attached to each unique health record will be extracted and analysed based on the relevance of AR-DRG codes to the ICD-10 codes of interest. Cost weights associated with each AR-DRG will be adjusted for differences for each financial year during the entire study period. All cost data will be inflated or deflated as

required using the published health deflators and a discount rate of 5% will be used in the evaluation. The Quality Adjusted Life Years (QALYs) for each treatment arm for the modelling will be derived from follow up interview self-reports from the patients in the nested Access to Care study, combined with estimates from similarly published literature.

These utility measures will be subject to probabilistic sensitivity analysis along with other key parameters in the model over a wide range based on clinical judgement and existing literature. The incremental cost effectiveness ratios (ICERs) will be estimated to compare the interventions using the expected costs and effects from the decision analytic modelling exercise. A cost-effectiveness (CE) plane will be used to plot the ICER and the uncertainty will be represented by confidence ellipses, which are a two dimensional representation of the confidence intervals [20].

All the data analyses will be conducted using Stata software (version 15.0 STATA Corporation, College Station, TX, USA) and the decision analytic modelling will be conducted using the Treeage Pro software (2017 Version R2).

Patient and public involvement

The study will use de-identified record linked health data and will not involve any patients or public for this study.

ETHICS AND DISSEMINATION

Ethics approval has been obtained from the NSW Population and Health Services Research Ethics Committee. The Access to Care study database contains 202 patients who have consented to access to their medical records, this dataset was identified for the purpose of record linkage and returned de-identified. Dissemination of research findings to key stakeholders is envisaged through peer reviewed publications in scientific journals, conference proceedings and

collaborator meetings. The study is ideally placed to establish standards, reduce costs with potential for research translation across the state of NSW.

DISCUSSION

The long-term impact of TSCI on our health care system is significant and ongoing. Deficits in clinical policy and practice can significantly impact the extent of long term disability and resultant quality of life for patients with TSCI, thereby escalating personal and health care system economic costs. Identification of specific deficits in system performance will facilitate application of targeted improvement strategies, aiming for greater efficiency of our services, focused resource use, highest standard of practice and consequently optimal outcomes. This study is ideally placed to establish standards, reduce costs and translate evidence back to the bedside.

A particular challenge envisaged in this study is the mapping of patient pathways, which may reveal many routes with multiple interactions within the healthcare system. Many individual routes can be defined based on the initial diagnosis, geographical location and the transition pathway. However, to be useful for the analysis, these pathways will need to be aggregated into a manageable number of broader pathways guided primarily by existing policy directives to pre-hospital and acute care services. Particular limitations are envisaged with the study design; firstly, the costs are limited to the acute care episode, and direct social care costs or indirect costs from loss of productivity to patients or caregivers are not included. This therefore underestimates the financial impact of TSCI to society as a whole. Despite all the efforts to accurately describe all cost elements of acute care, the possibility of some resources not being captured cannot be excluded. However, we anticipate this aspect at least to be uniform across all subgroups or pathways and not significantly affect the research findings as most of the resources will be

accounted for in the costing exercise. Patients with major trauma will have other immediate healthcare needs in addition to spinal cord injury management and may follow a pathway best suited to patient needs rather than the best practice pathway. We anticipate adjusting for some of this variation by conducting a sensitivity analysis with a group of patients with an isolated spinal cord injury and including measures for patient injury severity, co-morbidity and multiple trauma in the analyses.

This study proposes to describe the costs of acute care, including those identified as attributable to potentially preventable complications. Care pathway deviations from best practice will be described, such as delayed surgery or delayed admission to SCIU for patients with TSCI. Importantly, we aim to quantify the degree to which variation in clinical practice and institutional performance impacts on patient outcomes and acute care costs and is amenable to change. These findings are likely to have significant clinical consequences for the patient, cost implications for the health service [21] and offers significant potential to make amenable recommendations for improvement.

List of abbreviations

APDC - NSW admitted patient data collection

AR-DRG - Australian refined diagnostic related group

EDDC - NSW emergency department data collection

ICD-10-AM - International classification of diseases – tenth revision, Australian modification

ICER - Incremental cost effectiveness ratio

NSW - New South Wales

QALY – Quality adjusted life years

SCI - Spinal cord injury

SCIU – Spinal cord injury unit

TSCI - Traumatic spinal cord injury

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DECLARATIONS

Ethics: Ethics approval for this study has been grant NSW Population & Health Services Research Ethics Committee on 17 August 2016 (AU RED REF: HREC/16/CIPHS/19).

Availability of data and materials: The data used in this protocol cannot be shared with any other researchers unless approved by the relevant data custodians at the Centre for Health Record Linkage.

Contributorship statement: LNS is the principal investigator for this funded study and was principally responsible for the conception and design of this study and the acquisition of the record linkage data. JWM, PM, JP, IDC and JW provided substantial intellectual content during the study design. JWM is the principal investigator for the Access to Care study. LNS is the principal investigator for the Delphi process project. BPV wrote the first draft of the manuscript and co-ordinated commentary and review for subsequent revisions. All authors contributed to the critical review and approval of the final manuscript.

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Competing interests: The authors declare that they have no competing interests.

APPENDIX 1

The dataset combined all patients for whom one of the following ICD-10-AM (International Classification of Diseases – Tenth Revision, Australian Modification) codes have been identified in any separation, and in any position of the diagnostic code list within the NSW Admitted Patient Data Collection (APDC):

S12, S12.0, S12.1, S12.2, S12.21, S12.22, S12.23, S12.24, S12.25, S12.7, S12.8, S12.9, S13.1, S13.10, S13.11, S13.12, S13.13, S13.14, S13.15, S13.16, S13.17, S13.18, S13.2, S13.3, S14.0, S14.10, S14.11, S14.12, S14.13, S14.70, S14.71, S14.72, S14.73, S14.74, S14.75, S14.76, S14.77, S14.78, S22.0, S22.00, S22.01, S22.02, S22.03, S22.04, S22.05, S22.06, S22.1, S24.0, S24.1, S24.10, S24.11, S24.12, S24.7, S24.70, S24.71, S24.72, S24.73, S24.74, S24.75, S24.76, S24.77, S32, S32.0, S32.00, S32.01, S32.02, S32.03, S32.04, S32.05, S34.0, S34.1, S34.3, S34.70, S34.71, S34.72, S34.73, S34.74, S34.75, S34.76, T06.0, T06.1, T09.3.

APPENDIX 2

List of complications and ICD 10 codes

Complication	ICD 10 codes
Urinary tract infection	N30, N39
Hydronephrosis, hydro-ureter	N13
Other disorders of bladder	N31
Urethritis	N34, N37
Haematuria	R31
Other urinary complication	N99.8, N99.9
Decubitus ulcers (pressure ulcer)	L89
Pneumonitis due to solids and liquids	J69
Tracheostomy complication	J95.0
Urinary retention/incontinence	R33, R32, N39.4, N39.3
Pneumonia, pulmonary collapse	J12, J14, J15, J17, J18, J98.1
Pleurisy	R09.1, J86.9, J86.0, J90
Respiratory failure	J96.9, J96.0, J96.1