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Prioritised National Clinical Quality Registry Project Business Case

Australian Spine Registry

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EXECUTIVE SUMMARY

The Australian Spine Registry national pilot has been developed by the Spine Society of Australia in conjunction with Monash University, with limited funding from key stakeholder groups. Completed in October 2020, the ASR Pilot represents the first step towards building a national spine surgery registry.

Limited recruitment is currently ongoing, however, the registry's ability to expand is constrained due lack of funding and funding uncertainty.

The SSA has developed this pilot registry to align with the ACQSHC Framework and to fulfil the prioritisation criteria for developing CQRs.

The ASR is seeking funding to support the development of Stage 2 – National Rollout of the Australian Spine Registry. This business case describes the steps taken in Stage 1 to plan, develop, implement and evaluate the ASR operating model and outlines the vision and strategy for Stage 2 to achieve national coverage.

The key messages of this business case are:

	Link / Pg
➢ Spine surgery is complex and the cost of spine surgery often significant. Costs are dependent on the complexity of the surgery, the person's age and their associated comorbidities.	17
➢ It is also well established that spine surgery, especially complex spine surgery, is increasing. The primary demographic for spine surgery is people between the ages of 60 – 80 and it is well reported that this group suffers more associated comorbidities and undergoes more complex surgery. This age group is disproportionately increasing in the Australian population.	22 94
➢ Clinical registries have been introduced at a state or national level in Australia. They have become one of the most clinically valued tools for quality improvement. ➢ The Australian Spine Registry was established in 2016 by the Spine Society of Australia in conjunction with Monash University. Patient recruitment and data collection commenced on 15 January 2018. ➢ Funded through small industry grants, the ASR developed a pilot program which was successfully completed in October 2020. At the completion of the pilot, the registry had recruited 2037 patients, had established ethics and governance approvals across 16 hospital sites across Australia and had 14 actively participating surgeons. The data completion for both patients and surgeons was greater than 80%. This data collection compliance is consistent with obtaining statistically relevant information.	41

	Link / Pg
➢ The registry collects data of all spine surgery patients at participating sites. It minimizes paper-based data collection through a web-based data collection software package which incorporates post-operative questionnaires collection via email. ➢ The ASR, through this pilot, successfully demonstrated that patient surgical and outcome data can be independently monitored, collected and analysed using both private practice and public hospital patients. It has shown that collecting spine surgery data is achievable. ➢ The ASR plans to automate statistical analysis of the database providing real time information to surgeons and to also to allow ad hoc reporting to all stakeholders. ➢ The ASR will facilitate surgeon and hospital benchmarking and assist surgeons with CPD and credentialling requirements. ➢ The registry has generated considerable interest in public and private hospitals across Australia and internationally. Three major public hospitals and up to 9 spine surgeons have recently been recruited into the registry, almost doubling the current surgeon count. This demonstrates that there is considerable clinical interest in the registry.	51 62
➢ Currently there is no equivalent program being utilized in Australia which monitors the quality and value of spine surgery. Cochrane and other systematic reviews have noted difficulties in conducting randomized controlled trials in spine surgery. ➢ This has led to practice variation as documented by The Australian Atlas of Healthcare Variation. ➢ The Atlas advocated in the 2015[1], 2017[2] and 2021[3] editions that it was important to develop and support the Australian Spine Registry to collect data on patient outcomes and support audit and peer review. ➢ In the 2021[3] edition it is recommended that surgeons participate in the Australian Spine Registry.	30 Appendix 9
➢ This business case puts forward the advantages for establishing a sustainable long term funding model for the ASR and the long-term benefits that the registry will have for all stakeholders and the value that it will provide in spine surgery care. ➢ Reliance on short term industry grants is administratively extremely inefficient and inadequate to provide the human resources and logistical support for the ASR expansion. In addition, surgeons need to be confident that the ASR will be ongoing and that their data contributions will not disappear due to funding insecurity.	62 85

GLOSSARY OF ABBREVIATIONS AND TERMS

Abbreviation	Description
ACDF	Anterior cervical discectomy and fusion, or anterior cervical decompression and fusion
ACHI	Australian Classification of Health Interventions
ACSQHC	Australian Commission on Safety and Quality in Health Care
ADR	Artificial disk replacement
AIHW	Australian Institute of Health and Welfare
ALIF	Anterior lumbar interbody fusion
AOA	Australian Orthopaedic Association
AOANJRR	Australian Orthopaedic Association National Joint Replacement Registry
AR-DRG	Australian refined diagnostic related group
ASD	Adult scoliosis deformity
ASR	Australian Spine Registry
BOD	Burden of disease (measures include DALY, HALE, HRQoL, QALY, YLL, YLD)
BPP	Back pain and problems
CQR	Clinical quality registry
CUSOM	Cumulative summation method
DALY	Disability adjusted life years (DALY=YLL+YLD)
DEPM	Department of Epidemiology and Preventative Medicine, Monash University
DLIF	Direct (lateral approach) lumbar interbody fusion
DRG	Diagnostic related group
EMR	Electronic medical record
EQ5D	EuroQoL Five Dimensions Questionnaire
HALE	Health adjusted life years (expected number of years in good health)
HIS	Health information services
HRQoL	Health Related Quality of Life
KEOPS	Data management tool designed and constructed for spine specialists
LBP	Lower back pain
LE	Expected life years for a given age cohort at birth
MBS	Medicare benefits schedule
MSAC	Medical Services Advisory Committee
NDI	Neck Disability Index
NESB	Non-English-Speaking Background
NHCDC	National hospital cost data collection
NSA	Neurosurgical Society of Australasia
ODI	Oswestry Disability Index
PBS	Pharmaceutical benefits scheme
PLAC	Prostheses List Advisory Committee
PLIF	Posterior lumbar interbody fusion
PROMs	Patient Reported Outcome Measures

Abbreviation	Description
QALY	Quality adjusted life years
RSU	Registry Sciences Unit, Department of Epidemiology and Preventative Medicine, Monash University
SSA	Spine Society of Australia
TGA	Therapeutic Goods Administration
THA	Total hip arthroplasty
THK	Total knee arthroplasty
TLIF	Transforaminal lumbar interbody fusion
VLAD	Variable Life Adjusted Displays
XLIF	Extreme (lateral approach) lumbar interbody fusion
YLD	Years of life lived with disability
YLL	Years of life lost due to premature death

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INTRODUCTION

The Australian Spine Registry is an initiative of the Spine Society of Australia in conjunction with Monash University. The registry has recently completed a pilot and is now looking to further expand the registry. Development of the Australian Spine Registry (ASR) will facilitate:

- collection of prospective pre- and post-operative patient reported outcome measures (PROMs)
- surveillance of spine surgery procedures.
- surveillance of implanted prostheses, and
- collection of longitudinal health outcome data for the entire population undergoing spine surgery.

Collected patient level data will enable monitoring and reporting on the quality (appropriateness and effectiveness) of patient care and outcomes. The data set will also permit identification of clinical variation, risk-adjusted and benchmarked against agreed clinical quality indicators. This data will provide valuable feedback to surgeons, hospitals and other healthcare services, be a catalyst for spine surgery related research, and inform and drive measurable changes and improvements to national spine surgery practice, which will deliver savings to the healthcare system over coming decades.

A clinician led spine registry (with expert support from data custodians) will have the capacity to adopt a more creative and granular view of other data sets and identify potential data sources for healthcare system linkage, integration and interoperability.

Outcome data reported by the registry will be made available to participating stakeholders - consumers, clinicians, hospitals, clinical colleges, insurers, medical device companies, healthcare organisations /managers, jurisdictional health departments, policy makers, researchers and funders.

Sustainably funded and resourced, the ASR will be a catalyst for continuous improvement in all aspects of spine surgery clinical practice and patient care.

Section 1:

Background

BACKGROUND

1.1 Problem - Spine Surgery's Data

The Australian community spends over $1 billion on spine surgery every year. With an ageing population and other factors at play, this figure is projected to grow by more than 20% over the next decade.[1] However, there is limited oversight or measurement of the effectiveness of spine surgery, whether it delivers clinical efficacy and optimal patient outcomes, or the extent to which it delivers value to consumers and the healthcare system.

The Australian healthcare system is awash with more data than ever before. However, it lacks the essential information of clinical and patient outcomes data which is necessary to monitor and evaluate clinical practice and patient care. In addition, it lacks proper linkage and integration in many areas. This hinders surgical activity and financial monitoring at a broad system-level.

Without outcome data it is impossible to bring about change and improvements to achieve more value-based, patient-centred care.

The main reasons for the paucity of spine surgery data are threefold:

- Spine surgery is diverse, complex, and does not have readily obtained outcome metrics, such as death, amputation or arthroplasty revision. It is thus heavily dependent on data from patient reported outcome measures (PROMS) questionnaires, which makes spine registry administration costly and burdensome if dependent on traditional paper and phone methods.
- To date there has been no single, independent, nationally collaborative entity with broad coverage and surgeon support which collects, analyses and reports on validated patient outcome measures to assess the extent to which spine surgery improves pain, disability, and quality of life.
- There has been no guaranteed long term, sustainable funding to establish an entity to do this work.

Data should be the basis for informed decision-making, planning, accountability, and quality assurance. It could impact on every aspect of quality clinical care for spine surgery patients. In the absence of accurate, reliable, real-world data on spine surgery interventions, it is impossible to accurately track, monitor and measure clinical practice and patient care, and identify opportunities for change and improvements.

Without the infrastructural capability to collect and analyse clinical and patient data, variations in clinical practice and patient outcomes will remain largely unscrutinised and unexplained. The effectiveness of spine surgery healthcare expenditure to deliver value-based care will therefore remain unexamined.

The ASR fills this gap in patient outcome data.

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[1] Estimate based on demographic projections, (ABS Population Projections, Australia 2017-2066), historical hospital separations data (ACSQHC analysis. Data drawn from the Admitted Patient Care National Minimum Data Set (APC NMDS), 2011-12 to 2018-19, Australian Institute of Health and Welfare 2019.), and APRA data on growth in spine surgery prostheses. (APRA Statistics. Private health insurance prostheses report. December 2020. Released 23 February 2021)

1.2 Opportunity – ‘good, fast, cost-effective’

Rarely are changes ‘good, fast and cheap’. However relative to other alternatives, clinical registries are good in terms of their impact, fast if they are appropriately and sustainably resourced and properly implemented, and cost-effective in terms of the modest outlay required to operate.

Current research and the ASR pilot study support the proposition that a national spine registry is possible and will render improvements in clinical outcomes, patient sequelae and quality of life, and provide significant economic benefits.[4] Over the last three decades, hundreds of clinical registries around the world have demonstrated capacity to significantly influence clinical practice, healthcare quality and safety, and patient outcomes. [5]

It is well documented that registries are a cost-effective means to directly impact healthcare delivery and healthcare costs across a wide spectrum of clinical domains. Recent analysis of the economic benefits of five Australian registries, based on full national coverage, estimated a benefit to cost ratio of between 4-12 times, and tens of millions of dollars in wider savings and benefits to the community. [6]

1.3 Solution - Filling the Data Gap

A well designed, properly implemented, professionally supported, and adequately funded clinical quality registry (CQR) for spine surgery is the most appropriate mechanism to fill the information void concerning spine surgery. It can produce vast amounts of valuable data for clinical, patient, research and health policy purposes.[2] A relatively small outlay of funding to support the ASR will yield measurable results for improving clinical practice and patient outcomes.

1.4 Australian Spine Registry

In 2016, the Spine Society of Australia took the bold initiative to develop a two-year pilot of the Australian Spine Registry. It was launched in 2018 and the pilot was completed in October 2020.

The registry, recruiting patients from private surgeons and public hospitals, uses web-based software for demographic, diagnosis, surgical data and PROMs. It uses both disease specific ODI and NDI questionnaires and a general health quality of life questionnaire (EQ-5D-3L). The questionnaires are administered pre-operatively and at 6, 12 and 24 months post operatively.[3]

Demographic data is entered by administrative staff at either the private practice or the public hospital whilst diagnosis and surgical data is entered by the surgeon. Folllow-up post operatively is conducted by registry operations staff through Monash University.

The registry uses a modified form of the KEOPs software platform which uses an extensive drop-down menu set which minimizes the need for free text. It also allows for simple customisation.

Whilst spine surgery is diverse, the KEOPs software allows for data extraction and analysis of defined diagnostic and surgical cohorts.

It has successfully demonstrated proof of concept, and operational capability. A robust, viable ASR model is now ready for national rollout.

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[2] For example, the latest published report of the AOANJRR (ASR’s companion orthopaedic joint registry), contained over 400 pages of detailed data and analysis. (Reference - AOANJRR Annual Report, 2020)

[3] https://www.spineregistry.org.au

Section 2:

Government Framework

GOVERNMENT FRAMEWORKS

1.5 Clinical Quality Registries Framework

The Commonwealth Government has long-held an ambition to develop clinical registries to facilitate data-driven, evidence-based healthcare that is patient-centred and value-based. Under the aegis of the Australian Commission on Quality and Safety in Health Care (ACSQHC), it is building a comprehensive national framework for development of CQRs across the healthcare system. [7] [8] [9] [10]

In 2010, Health Ministers endorsed the Commission's tested and validated *Operating Principles and Technical Standards for Clinical Quality Registries* [11] 'to facilitate efficiencies in the development of national CQR infrastructure and to promote best practice design, development, operation and security'. In response to a request by the Australian Health Ministers' Advisory Council (AHMAC) to develop national health information arrangements for CQRs, the Commission, with advice from jurisdictions and CQR experts, produced the *Framework for Australian Clinical Quality Registries* in 2014.[12]

1.6 National CQR Strategy

The Framework incorporates the endorsed Strategic and Operating Principles and Technical Standards for CQRs. In 2016, the Commission developed a Prioritised List of Clinical Domains for Clinical Quality Registry Development and undertook an Economic Evaluation of Clinical Quality Registries.[6] Further to this work, the Commission is reviewing and updating the Framework to incorporate guidance on governance arrangements for CQRs to support CQR development in these prioritised domains in which musculoskeletal conditions were considered a high priority. [13] In addition, the recently released 2021 Atlas of Clinical Variation supported the need for a spine registry. [3]

In February 2021 the Commonwealth Department of Health (the Department), released the *National Clinical Quality Registry and Virtual Registry Strategy: A National Strategy for Clinical Quality Registries and Virtual Registries 2020-2030*. [14] The National Strategy aims to optimise the contribution of CQRs to a self-improving healthcare system, and to maximise returns on CQR investment.

The National Strategy supports the Framework to 'consider ways to provide a nationally consistent approach to the selection, funding, implementation, management and performance of CQRs to improve health outcomes. Stage 1 of this initiative will investigate and demonstrate the practical application of the National Strategy to CQR development and implementation. Stage 2 involves implementing the plan for national rollout of the registry.

1.7 Proposed Federal Data Sharing Arrangements

The Australian Government and research governance bodies have also recognised the potential efficiencies that could be achieved through optimised data sharing arrangements between Accredited Data Authorities under the Five-Safes Framework. [15] If the governance and data management requirements of CQRs were deemed to be suitably managed under such data-sharing arrangements, this may achieve significant savings in the cost and time required to establish CQRs, safely manage ethical considerations and facilitate data-linkage to realise the potential benefits.

The National Strategy identifies the opportunities and challenges to applying data-sharing arrangements to CQRs in its vision for data linkage, interoperability and integration. Stage 1 includes the development of a project plan and considers registry governance and operating principles, national health information arrangements and national technical arrangements including operational management, data collection, data hosting, data analysis and reporting

Section 3:
Current Situation

CURRENT SITUATION

1.8 Burden of Disease Associated with Spine Problems

1.8.1 Back Pain, Neck Pain and Spine Problems

Burden of disease measures the impact of living with illness and injury and dying prematurely.

Disease burden of (chronic/degenerative) spine problems is usually identified and inferred symptomatically by the presence of pain. The most widely reported indicators for chronic spinal problems are:

(i) *low back pain* (LBP),
(ii) *back pain and problems* (BPP), including associated leg pain, [4] or
(iii) *neck pain* (NP) in the cervical spine region, with/without pain to the arms.

The level of disease burden is driven by three main factors:

- population growth,
- population ageing,
- changes in the amount of disease/injury.

Disease burden associated with spine problems can be modified by improved diagnosis and treatment and the management of co-morbidities. [16] As there is almost no mortality from spine problems, the disease burden primarily relates to years of life lost from living with disability (YLD).

1.8.2 Global Burden of Disease (BOD)

Back pain has a significant impact on the global population.[17 18] Back pain is the world's leading cause of non-fatal disease burden, or life years lived with a chronic disability (YLD).[19 17 20] This is due to the toll on individuals in terms of pain, illness, disability, and economic loss, and also the cost to the community via healthcare system expenditure, workforce participation, lost productivity and other economic harm.[19 17 20] In the last 25 years the burden from LBP has doubled, affecting more than 540 million people worldwide, and with an ageing global population, the prevalence of spine problems is increasing.[20] (see Figure 1)

Neck pain, considered as a separate disease burden, ranks fourth in terms of YLD.[21] It also is the cause of considerable pain, disability, and economic cost. Globally, between 1990 and 2017 the prevalence of neck pain increased by 76%.[22] The major influence on the epidemiology of cervical pathology in upper-middle income countries, including Australia, is ageing population with associated development of degenerative disorders.[23]

The associations of backpain and neck pain are multifactorial and include bio-physical, socio-economic, demographic, psychological, and genetic factors, as well as the patients other comorbidities. However, clear causal pathways are yet to be established.[18]

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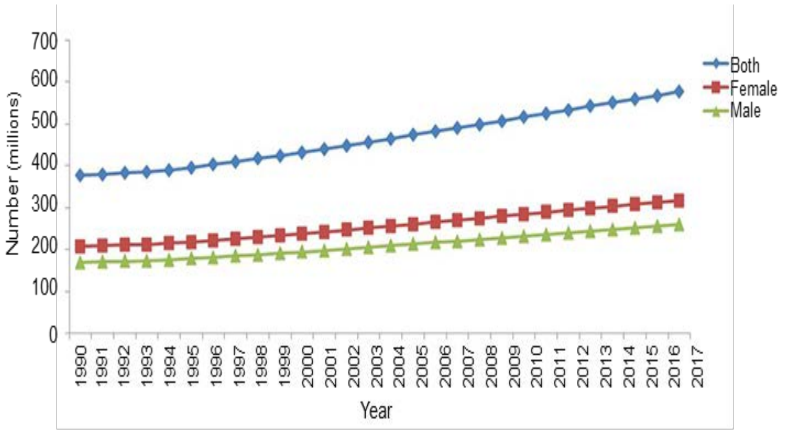
[4] AIHW defines 'Back problems' as "a range of conditions related to the bones, joints, connective tissue, muscles and nerves of the back. These conditions can affect the neck (cervical spine), upper back (thoracic spine) and lower back (lumbar spine) as well as the sacrum and tailbone (coccyx). They include disc disorders (such as herniated discs or disc degeneration), sciatica and curvature of the spine (scoliosis), and back pain/problems not elsewhere classified." Back problems associated with another condition, such as osteoporosis or arthritis are not included in data. For this reason, the total prevalence of back problems is likely to be underestimated. (Source: https://www.aihw.gov.au/reports/chronic-musculoskeletal-conditions/back-problems/contents/what-are-back-problems)

Figure 1. *Estimated global prevalence of people with low back pain from 1990 to 2017.*



Source: Wu A, March L, Zheng X, et al. Global low back pain prevalence and years lived with disability from 1990 to 2017: estimates from the Global Burden of Disease Study 2017. Annals of Translational Medicine. 2020, 8(6):299-299.

1.8.3 Australian Morbidity

In Australia, out of the 25 disease groups causing greatest disease burden (disability adjusted life years - DALY), *back pain and problems* (BPP) ranks second only to coronary heart disease, and in terms of years lived with disability (YLD) ranks number one.[24] People living with chronic spine problems represent 8.1% of the nation's total non-fatal disease burden, and 4.1% of the total burden of disease. In 2017-18, an estimated 4 million Australians or 16% of the total population had back problems, of whom 38% were moderately to significantly restricted in their daily activities (e.g. mobility, communication or self-care). [25] It rates highest among people aged 65–74 years, [26] with this cohort accounting for almost a quarter of all hospitalisations for BPP. [27]

1.8.4 Comorbidities

Spinal problems often occur with other comorbidities and share common risk factors that may interact to determine the health status of individuals. Based on self-reported data, in 2017-18 an estimated 2.5 million Australians over the age of 45 years had back problems. For selected conditions,[5] 28.4% of this group had at least one other chronic condition, and 46.0% two or more chronic conditions. [28] Among this cohort the most common comorbidities were arthritis (48%), mental and behavioural conditions (34%), asthma (17%), and heart, stroke and vascular disease (16%). [29]

1.8.5 Impact on Individuals

Back problems often lead to poorer quality of life, psychological distress, bodily pain and disability. Close to half of the population over 18 years of age reporting back problems, experience moderate to very severe pain, and/or moderate to very high levels of psychological distress. Compared to those without back problems, people with back problems are 1.8 and 2.4 times as likely to rate their health as fair (16.2%) or poor (6.5%) respectively.[28] Insufficient physical activity (60%), obesity (40%) and smoking (18%) are the most prevalent risk factors associated with back pain. [29]

1.8.6 Economic Impact

Whilst estimates vary, the cost of back problems to the Australia community is considerable. In 2015-16, BPP cost the Australian healthcare system $2.86 billion, representing 23% of disease expenditure on musculoskeletal conditions, and 2.4% of total health expenditure. [30,31]

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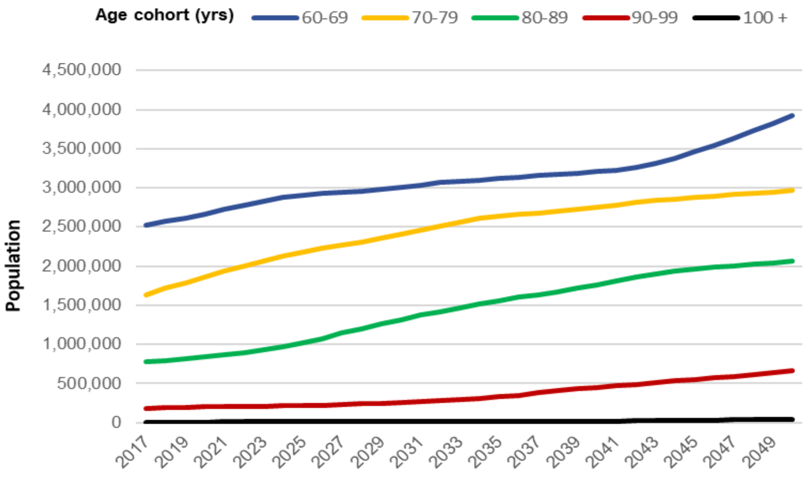
[5] The selected conditions are: arthritis, mental and behavioural conditions, asthma, heart, stroke and vascular disease (HSVD), osteoporosis, diabetes, chronic obstructive pulmonary disease (COPD), cancer, and chronic kidney disease.

Australia now spends $4.8 billion per year on management of low back pain. Back pain reduces Australia's GDP by AU$3.2 billion per annum and is the most common condition keeping older Australians (aged 45-64) out of the workforce.[32] Spinal injury claims make up 17.8% of workers compensation claims in Australia.[6]

1.8.7 Hospitalisations

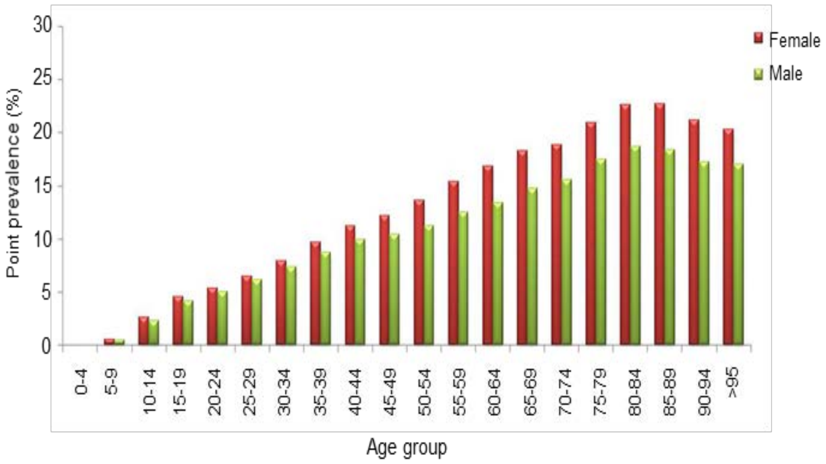
From 2008-09 to 2017-18 hospitalisations for back problems as the principal diagnosis increased by 64%, with 180,818 people being hospitalised for back problems in 2017–18. The main reasons for hospital admission were lower back pain (27%), lumbar and intervertebral disc disorders with radiculopathy (10%) and spinal stenosis (8.6%). More females experience back problems than males and have higher rates of hospitalisation (802/100,000 compared with 657/100,000). Beyond 65 years of age hospitalisation rates for spine problems increase significantly.[33] (Figure 2 and Figure 3)

Figure 2. Projected population growth for major spine surgery cohorts 2017-2050



Source: ABS, Population Projections, Australia 2017-2066: Population Projections By Age, Australia 2017-2066

Figure 3. The age-specific prevalence of low back pain in 2017, by gender.



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[6] https://www.safeworkaustralia.gov.au/sites/default/files/2021-01/Australian%20Workers%20%20Compensation%20Statistics%202018-19p%20FINAL_2.pdf

Source: Wu A, March L, Zheng X, et al. Global low back pain prevalence and years lived with disability from 1990 to 2017: estimates from the Global Burden of Disease Study 2017. *Annals of Translational Medicine.* 2020, 8(6):299-299.

1.8.8 Trends

Not only is life expectancy (LE) increasing, but years of life lived in full health, are also extending. [34] [7]

The cohort of post-war baby boomers will cause an increase in the size and proportion of older age groups over the next two decades. This will lead to an increase in the prevalence of spine problems, and consequent disease burden and healthcare expenditure. The age-group where spine surgery is most frequently performed (60-79 years), is growing faster than the general population and relative to any other cohort. [see Appendix 1: Effect of post-war Baby Boomers on ageing population, comorbidities and spine surgery (separations, procedures and MBS numbers)]

Furthermore, older Australians generally are remaining more active over later years, working longer, and travelling more than preceding generations. As health consumers are often better educated, more aware of advances in medical care, and less inclined to endure long term painful and disabling spinal conditions into their later years. They see surgery as an increasingly viable option for spine problems.

Advances in anaesthesia, surgical techniques and training, perioperative care, implantable prostheses, and medical technologies, now allow increasingly more complex procedures on older patients than were previously possible.[35] These factors combined with an ageing population, will mean that rates of spine surgery are expected to continue to grow rapidly. The resultant increases in costs and the limited health care budget compound the need for accurate data to allow studies of long-term outcomes and economic evaluations to determine efficacy and cost-effectiveness.[6]

1.9 Spine Surgery Clinical Domain

1.9.1 Spine Surgery

In general, spine surgery is undertaken with the following basic aims:

- realignment of the spine to correct spinal deformity,
- removal of material compressing neural structures,
- stabilisation of local instabilities and fractures.

Surgery can be performed at any level of the spine from the base of the skull to the coccyx.

Spine surgery has an ancient history, but modern procedures based on detailed neurological examination developed through the late nineteenth and twentieth centuries. The introduction of computerized tomography (CT) scanning, magnetic resonance imaging (MRI) and intraoperative microscopes in the 1970s brought significant advances. These have expanded the field of spine surgery with the potential for reduced complications and improved patient outcomes.

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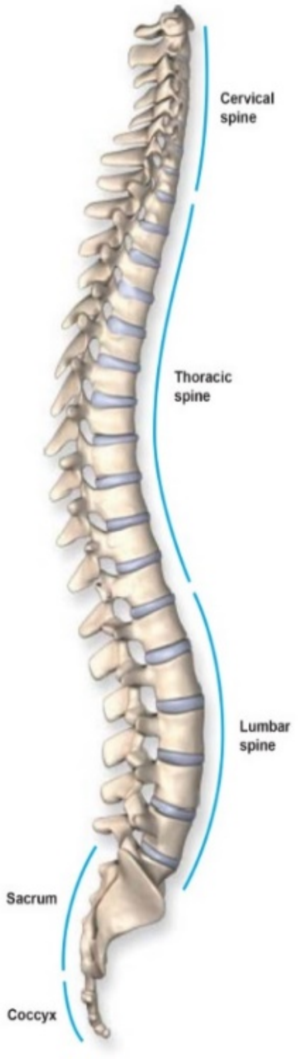
[7] Measured by HALE – Health Adjusted Life Expectancy or QALY – Quality Adjusted Life Years



In the last 10-20 years, further advances in imaging, surgical techniques, implant technology, neurophysiological monitoring, spinal navigation and perioperative care, have made many different options available in spine surgery.

Spine surgery techniques now range from relatively simple decompressive and stabilising procedures to complex surgery, including vertebral reconstruction and deformity correction surgery.

Significant literature concerning long term function and patient satisfaction is limited [36] Numerous examples exist where initial clinical trials have reported efficacy but follow up investigations in independent studies fail to demonstrate a significant long-term effect [37], pointing to the importance of ongoing post-market analysis by independent researchers. There is a need for the regular, routine collection of validated long-term outcome measures, including quality of life, and not just length of stay and short-term process measures which are the present standard in government and insurer databases. [37]

1.9.2 Spine Surgery Data

Spine surgery is usually the last resort in the treatment of back problems, and while surgery is not necessary or suitable for everyone with spine problems, approximately 60,000 Australians undergo spine surgery every year,[8] [9] close to a third of all hospitalisations for BPP.[10] In 2018-19 there were 57,539 spine procedures performed in hospitals, an increase of 16% over the previous seven years. Based on historical NHCDC cost data and ACSQHC analysis, current expenditure for spine surgery is conservatively estimated at over $1 billion per annum. [38]

Figure 4. *The human spine*

From 2017- 2066 it is projected that the Australian population will double, however the over 65 years cohort will increase by 168%.[39] (Figure 5) By this time there will be in excess of 10 million people over 65 years comprising more than 20% of the population. (Figure 6)

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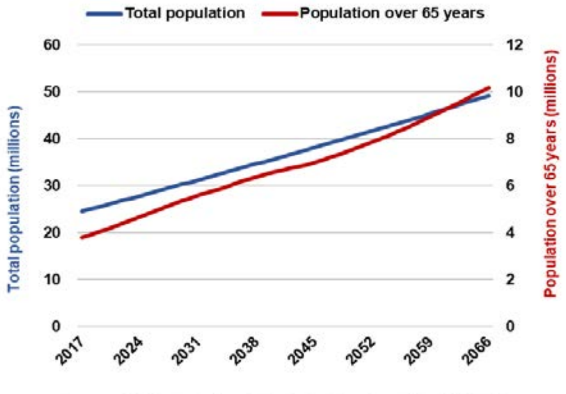
[8] AIHW. National Hospital Morbidity Database *(NHMD)*Australian Morbidity Database. Admitted patient care 2018.

[9] Based on 57,539 Australians undergoing spine surgery in 2018, and average increase of 2% per annum.

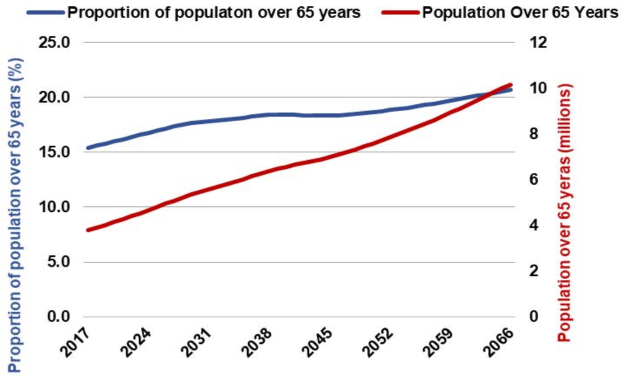
[10] Based on 180,818 hospitalisations for BPP and 57,539 patients undergoing spine surgery in 2018.

Figure 5. *Projected Australian population over 65 years and total population over time, 2020-2066*



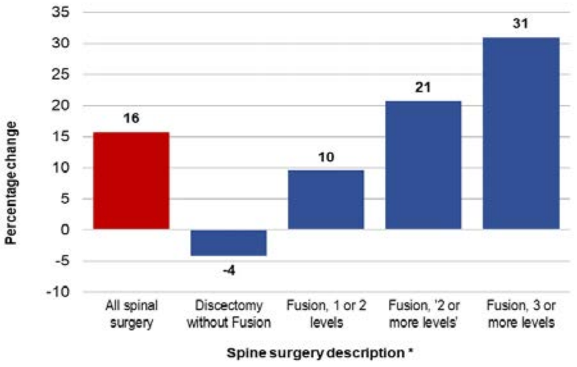
Source: ABS, Dataset: Population Projections, Australia, 2017-2066

Figure 6. *Projected Australian population over 65 years and as a proportion of total population over time*



Source: ABS, Dataset: Population Projections, Australia, 2017-2066

Figure 7. *Change (%) in spinal surgery numbers, 2011-12 to 2018-19 (separations by complexity of surgery)*



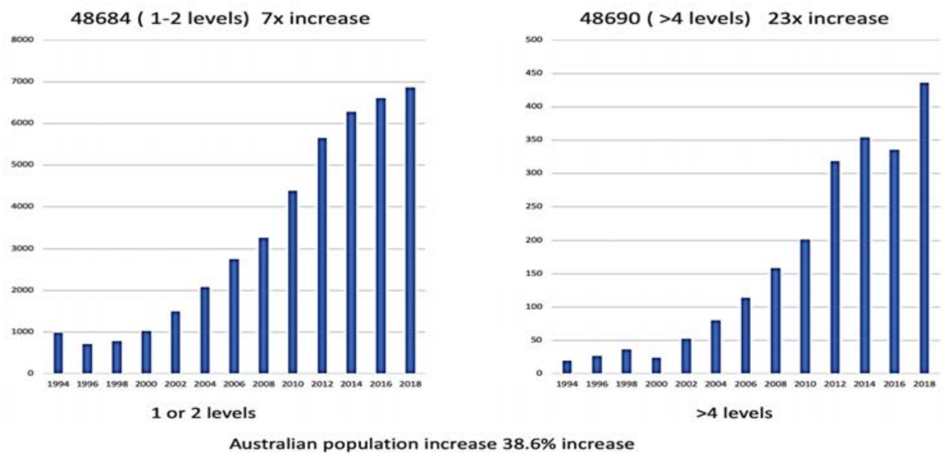
* Based on ACHI codes for spinal surgery, 10th edition
Source: AIHW. Procedures data cubes. Cat. no. WEB 216. Canberra: AIHW. Viewed 12 October 2020, https://www.aihw.gov.au/reports/hospitals/procedures-data-cubes

Based on previous AIHW data, spine surgery is projected to grow by more than 20%[11] over the next decade. Based on a number of data sources, the rate of complex surgery is increasing at a faster rate compared to simpler spine procedure categories.[40] [12]

Spine surgery, especially fusion, has been recognised as one of the most expensive interventions amongst clinical diseases, conditions and disorders.[38]

- Whilst the average total cost of a single level discectomy is approximately $6,000, more complex surgery for adult scoliosis may cost around $160,000, even without complications.[13]
- AIHW data shows the rate of complex spine surgery (Level >3), which has a higher implantable device cost component, and higher rates of complications,[41] is growing faster, compared to other spine procedures categories.[40] [14]
- MBS data indicate that from 1994 to 2018 more complex spinal fusion surgery (Item # 48690, >4 levels) increased by a factor of 23x, whereas simple spinal fusion (Item # 48684, 1-2 levels) increased by a factor of about 7x. Over the same period the total population increased by 38.6%. [41] (Figure 8 and Figure 9)
- MBS data (1993 -2018) shows that surgery using internal fixation occurs more frequently in older age groups. This means that spine internal fixation usage is sensitive to demographic changes (Figure 11).

Figure 8. *Comparison of complex spinal fusion procedures 1994-2018**



1 or 2 levels:	SPINE, segmental internal fixation of, other than for scoliosis, being a service associated with a service to which any one of items 48642 to 48675 applies - 1 or 2 levels
>4 levels:	SPINE, segmental internal fixation of, other than for scoliosis, being a service associated with a service to which items 48642 to 48675 apply - more than 4 levels

* Data for 2018 is between Jan – Oct as the MBS coding system changed November 1, 2018.

Source: MBS billing data: http://medicarestatistics.humanservices.gov.au/statistics/mbs_item.jsp

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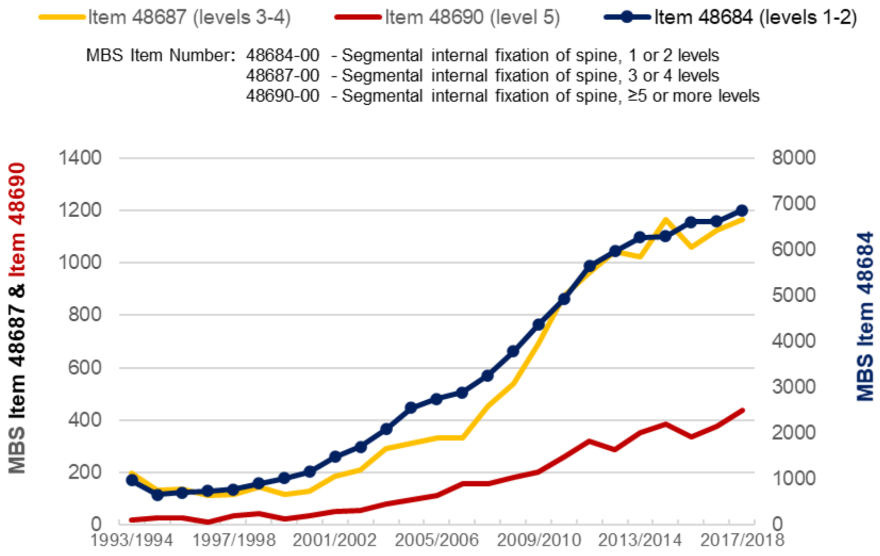
[11] See Footnote #1. Extrapolation from 2012-18 spine procedure numbers, reflecting continuation of average annual growth rate of 2% over that period. Excludes any allowance for baby boomer bubble coming in next two decades.

[12] AIHW data does not differentiate beyond 3 level fusion whereas MBS billing data provides levels 1-5.

[13] Healthcare industry source estimates.

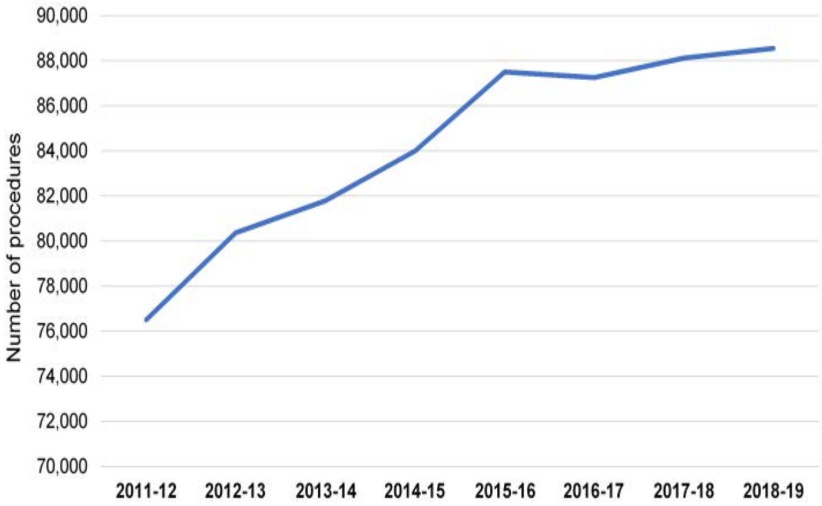
[14] AIHW data does not differentiate beyond 3 level fusion whereas MBS billing data provides levels 1->4.

Figure 9. *Complex spine surgery - spinal fusion levels 1-2, 3-4 and ≥5 1993/94 to 2017/18*



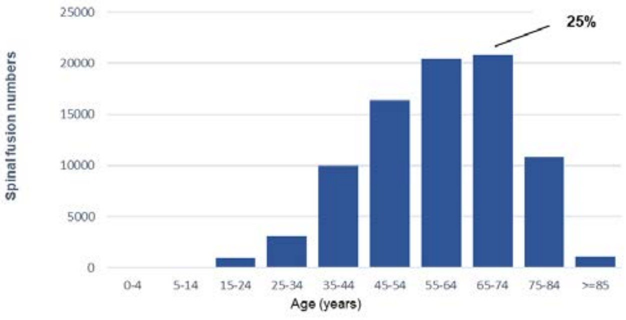
Source: AIHW - MBS billing data (processed billing requests)

Figure 10. *Spinal surgery procedures in public and private hospitals, 2011-12 to 2018-19*



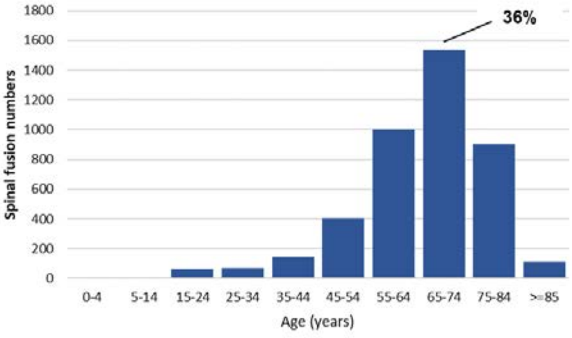
Source: Australian Institute of Health and Welfare 2019. Procedures data cubes. Cat. no. WEB 216. Canberra: AIHW. Viewed 12 October 2020, https://www.aihw.gov.au/reports/hospitals/procedures-***data-cubes***

Figure 11. Item 48684 (fusion 1-2 levels) x patient age 1993-2021



Source: MBS_Data_1931901451.8 www.health.gov.au

Figure 12. Item 48690 (fusion > 4 levels) x patient age 1993-2021



Source: MBS_Data_1931810757.1 www.health.gov.au

Adult spinal deformity (ASD) covers a broad spectrum of abnormal lumbar and thoraco-lumbar curvatures of the spine presenting in adulthood, and prevalence and incidence is increasing in the ageing population. ASD causes high levels of functional disability due to severe back and leg pain. It has a significant impact on health-related quality of life compared with other chronic conditions and creates substantial societal disease burden.

In the United States hospitalizations for ASD increased 2.5-fold over the previous decade to 2016.[42] A spine registry reporting patient outcome measures (HRQoL, function, PROMs) will play an important role in demonstrating the efficacy and value of such treatments, and will enable improvements to clinical guidelines, facilitate further research, and enable patients to be more actively involved in management of their own disease.

1.9.3 Spine Surgery Prostheses

Of the $1 billion dollars spent on spine surgery every year, the protheses component is over $250 million.[15] (Figure 13) The two categories of prostheses are:

i. devices - implantable metal or synthetic devices such as pedicle screws and rods used to stabilise the spine in spinal fusions, and

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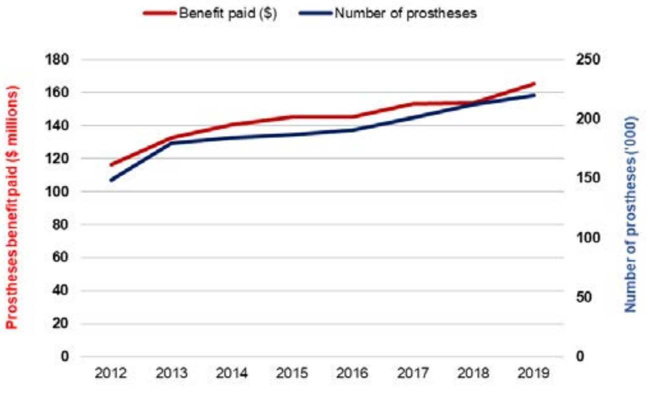
[15] Industry sources conservatively estimate $160m from PHI benefit refunds, plus non-surgical prostheses of approximately $90m.

ii. biologics - developed from biological sources, including bone grafting augmentation, stem cell therapies, and bone morphogenetic protein (BMP) used to promote bone and tissue growth.

However, there is currently no effective means of monitoring device performance or cost. The usage and price of medical devices is highly regulated. It is subject to an evidence-based approvals process by the Therapeutic Goods Administration (TGA), the Prostheses List Advisory Committee (PLAC) and the Medical Schedule Advisory Committee (MSAC), as well as government purchasing and procurement policies.

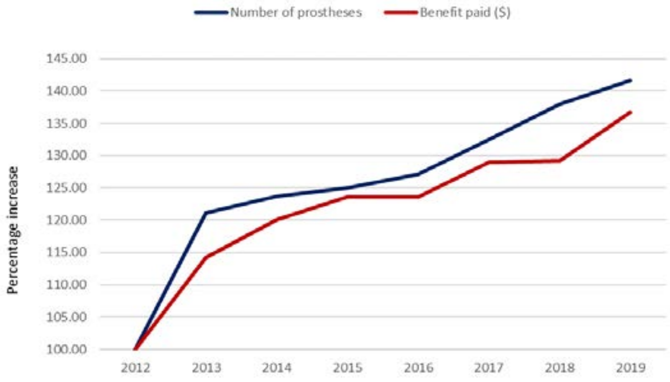
However, from 2012-2020, prostheses spend for privately insured patients grew by 37%, and volume grew by 42%, more than double the rate of increase in spine surgery (see Figure 14) The Australian market remains stable, but prostheses costs continue to be a concern. and this trend is likely to continue.[43] This is consistent with the MBS data (1993 – 2018) for the item numbers related to spine internal fixation.

Figure 13. *PHI funded spinal prostheses by volume and benefit ($) paid 2012-2019*



Source: APRA Statistics. Private health insurance prostheses report. December 2020 (released 23 February 2021)

Figure 14. *PHI funded spinal prostheses- percentage change in number and benefit ($) paid 2012-2019**



Source: APRA Statistics. Private health insurance prostheses report. December 2020 (released 23 February 2021)

*(2012 = Index 100)

1.9.4 Domain-Specific Challenges for Spine Surgery

Spine surgery is complex, costly and varied,[16] and is subject to a number of domain-specific challenges. Despite all the medical advances, higher rates of spine surgery admissions and procedures, and increasing complexity of procedures and operations, outcomes are uncertain, with disparities and differences in outcomes unexplained. There is a lack of aligned real-world, evidence-based data to understand the effectiveness and efficacy of spine surgery, and the extent to which it actually benefits the patient.

(1) Workforce Dynamics

Spine surgery in Australia is performed both by neurosurgeons and orthopaedic surgeons. They are represented by the NSA (Neurosurgical Society of Australasia), the Australian Orthopaedic Association (AOA), and the Spine Society of Australia (SSA).

The SSA comprises of neurosurgeons, orthopaedic surgeons, physical therapists and basic researchers. It has a current membership of 128 surgeons.

Between 2005 and 2019 the total number of neurosurgeons grew by 220%, from 119 to 262. Over the same period the Australian population increased by 25%. As the majority of spine surgery is discretionary, the increase in surgeon numbers, may in itself be a driver of increased surgical numbers.

Registry data on clinical practice and patient outcomes would facilitate more careful, evidence-based monitoring and auditing of professional practice.

(2) Economics

Increasing costs put the value of spine surgery under scrutiny. Accurate data is one of the most basic tools needed to profile, and inevitably, justify expenditure on spine surgery amongst competing healthcare priorities. Without such data, it is not possible to understand the benefits of one surgery type over another, or the appropriateness of surgical interventions. Nor is it possible to monitor and compare different devices, assess impacts of new developments in techniques and prostheses, and prepare and appropriately train the clinical workforce. This data can be collected using a registry. Leading health authorities are now recognising that unique scientific, clinical and social insights can be collected through clinical quality spine registries.

1.9.5 Clinical Variation in Spine Surgery

Clinical variation in the rate of spine surgeries may occur across regions, between cultural groups, or by gender, and may be influenced by clinician diagnostic and treatment approaches, patient preferences, surgeon location, and according to socio-economic and insurance status. [2] Variation can be expected where it is a response to patient needs and treatment options. However, the first step to understanding underlying reasons for unexplained and unwarranted variation is quality data.

The Australian Atlas of Healthcare Variation (the Atlas), published by the Commission, has identified lumbar spine surgery as an area of significant interest, with notable differences in rates of clinical intervention [1] [2]. Relevant findings of variation, clinical commentary and recommendations are summarised in Table 1.

When examined across local areas, lumbar surgery admissions ranged from 36 - 173 per 100,000 people (compared to the average of 96 per 100,000). The number of admissions was 4.8 times higher in the area with the highest rate compared to the area with the lowest rate, raising questions

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[16] There are more than 60 separate procedures listed on the Australian Medical Benefits Schedule.

about underlying patterns of disease, equity and access, diagnosis, treatment options and appropriateness of interventions.[1] The reported variation for lumbar spinal decompression and lumbar spinal fusion were 5.2 and 6.9 times respectively. The reasons for variation were indeterminate, and it could not be determined how much of the observed variation was unwarranted. The Atlas report highlighted the absence of routine collection of clinical information on spine surgery that would permit more detailed understanding. [2]

Table 1. Key Findings on Clinical Variation in Spine Surgery[17]

Procedure Investigated	Data (1)	Variation (2)	Clinical Commentary	Recommendations
2015 **Lumbar spine surgery** (3)	2010–11 to 2012–13 17,000 hospital admissions for lumbar spine surgery	**4.8 times** Range = 36:173 per 100,000 hospital admissions.	• Limited evidence to support lumbar spine fusion surgery for painful degenerative back conditions. • Outcomes for patients who receive these interventions are unknown. • Despite increasing rate of fusion surgery, insufficient evidence is available to support its use for painful degenerative back conditions. • No obvious explanation exists for higher admission rates in regional centres compared to major cities. • It is not possible to state how much variation is unwarranted. • Reasons for higher rates in regional centres intra and interstate are not known.	• State and territory health departments consider mechanisms to improve coding, analytics and collection of outcome data on lumbar spine surgery in adults. • The Commission promotes the collection of patient-reported outcome measures for lumbar spine surgery.
2017 **Lumbar spinal decompression** (4) (5)	2012-2014 44,169 hospital admissions for lumbar spinal decompression.	**5.2 times** Range = 30 to 156 per 100,000 hospital admissions.	Possible reasons for variation, (although none was proven): • Wide variation in use of a surgical procedure may reflect lack of agreement on its indications. • 'Indication creep' and differing clinician views of the value of the operation in new patient populations. e.g. Broadened usage of spinal fusion surgery from treatment of spinal fractures and deformities to include degenerative spine disorders. • Lack of agreement on indications for specific spinal procedures. Where clinical efficacy is not proven beyond specific small patient populations, substantial variation raises the likelihood that rates are too high in some areas.	• A pilot trial of a multi-site Australian Spine Registry, to be undertaken by the Spine Society of Australia and Monash University, that will provide an online database of patient-reported and clinical outcomes.
2017 **Lumbar spinal fusion** (4)	2012-2014 14,746 hospital admissions for lumbar spinal fusion	**6.9 times** Range = 10 to 69 per 100,000 hospital admissions	• Where evidence is unclear: - the priority is to determine whether there are subgroups of patients more likely to benefit from the procedure. Ideally by routine collection of pre- and post-operative PROMs - need to ensure patients understand the evidence about the likelihood of risks and benefits of the procedure. Requires more patient information, education to improve health literacy and high-quality tools for shared decision-making to support better, more informed patient choices about care. • Concern expressed regarding differing clinical views about the value of lumbar spinal fusion operations (both with/without decompression) for degenerative disease. Some systematic reviews highlight lack of high-quality evidence regarding patient benefits of these surgeries.	• Spine Society of Australia to work in consultation with ACSQHC to develop a business case to establish nation-wide coverage of the ASR

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[17] (Source: The Australian Atlas of Healthcare Variation 2015, and 2017, ACSQHC)

Procedure Investigated	Data (1)	Variation (2)	Clinical Commentary	Recommendations
2021 **Lumbar spinal decompression** (4) (5)	2015–2018, 43,185 hospitalisations	**7.7 times** Range = 34 - 126 per 100,000 people	Possible reasons for variation as discussed in the Atlas: • Clinical decision making: High or low rates of spinal decompression in some areas may be related to differences between clinicians in interpretation of the available evidence about the effectiveness of spinal decompression and differing clinical beliefs about the likelihood of benefits and complications of this type of spinal surgery for some groups of patients. • Patients' expectations: Patients' expectations about the need for spinal surgery to deal with chronic low back pain may drive variation. These expectations may be affected by psychosocial factors, such as dependence on alcohol or other drugs, depression and job loss.	• High-quality research and outcome monitoring ○ Undertake high-quality research to resolve uncertainties about benefit. ○ **Ensure resourcing to support widespread use of the Australian Spine Registry.** ○ Develop agreed measures for audit.
2021 **Lumbar spinal fusion** (4)	2015-2018 14,608 hospital admissions for lumbar spinal fusion	**12.4 times** Range = from 7 to 87 per 100,000 people	• Access to services: lack of access to affordable and accessible alternatives to surgery, such as physiotherapy with cognitive behavioural therapy, multidisciplinary back pain assessment clinics and pain clinics. • Workforce issues: Workforce factors may influence the overall rates of spinal surgery and geographic variation in rates.	

(1) Spine surgery hospital admissions, National Hospital Morbidity Database, AIHW.
(2) Comparison between highest and lowest rates per area (SA3)
(3) Refers to any type of surgery in the lumbar spine or lower back. Most admissions for back surgery are for people aged 45 years and over. Two common procedures are decompression and fusion.
(4) Excludes procedures for recent injury or related to past injury
(5) Includes laminectomy and discectomy

Source: [1,3,44]

Understanding the variation in spine surgery across Australia is a priority, a proposition endorsed by the Commission's recommendation for the setting up of a spine registry by SSA, to collect clinical and patient reported data. This will contribute to more equitable access to better value health care, as well as address matters of quality and efficiency improvement.[45]

The Commission also recommended, subsequent to running a pilot and publishing results, the development of a business case to implement the ASR nationally. With the pilot now concluded, the ASR now needs to expand the number of participating surgeons, hospitals and patients in order to further understand and analyse variation in treatment and outcomes. (See Appendix 2: Investigation of clinical variation in spine surgery – research opportunities)

1.9.6 Researching Clinical Variation

Research into the study of surgical variance is difficult. Randomized clinical trials (RCT) for surgery suffer from recruitment difficulties, study group heterogeneity, possible volunteer bias and study group crossover. Sometimes they are simply infeasible to conduct for ethical or practical reasons. Innovative methodologies using registry outcome data have been increasingly employed to overcome the difficulties of RCTs. The use of PROMs data allows variances to be explored between surgeons, hospitals, implants and patient cohorts. [46]

Despite the many advances, spine surgery suffers from a lack of diagnostic clarity, differing treatments and surgical interventions, and considerable variation in clinical and patient outcomes. The emergence of "failed back surgery syndrome (FBSS)," [47] or alternatively, "postsurgical spine syndrome", [48] is indicative of the complexity and mix of underlying conditions, diagnoses, patient factors and treatment pathways for spine surgery. [49] Multiple spine surgeries are often the option of diminishing returns for a diverse, heterogeneous group of patients. [50] [48] One study found that just over half of the patients undergoing spine surgery for degenerative disease gained little or no benefit from the surgery, even after multiple operations. [51] Variability of diagnostic and surgical algorithms make spine problems and surgical interventions difficult to standardize. Internationally, the need for a more standardized approach to spine registry methodology has also been recognized. [42]

These problems and limitations make comparison and generalizability of research studies problematic. Comparison of the results from other countries/populations, with different healthcare systems, and spine registries with differing approaches/methodologies, should be approached with caution. [18]

An ageing population and the increasing prevalence of chronic degenerative conditions amenable to surgical intervention, will likely require greater rationing of healthcare dollars, and potentially stricter prioritising of clinical domains and surgical interventions. Total hip (THA) and total knee arthroplasty (TKA) for example, are widely accepted as cost-effective and improve patient functioning and quality of life. In Australia, the AOANJR Registry has vigorously advanced the development of data and research in this regard. However, compared with other surgical domains, spine surgery interventions to treat deformity and degenerative conditions, comparatively, remain far less supported by Australian data and research. Pragmatically, a spine registry is the most appropriate vehicle to collect, analyse and promulgate essential data for such purposes, and to provide an evidence-base for benchmarking quality of patient outcomes, clinical efficacy, and economic justification.

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[18] There is recognition of the need to agree a more standardised approach to data collection and analysis to allow national and international collaboration and benchmarking.

1.10 Spine Surgery – A Priority Clinical Domain for CQR Development

Based on a set of *threshold* and *prioritisation criteria*, the Commission developed a list of high priority clinical domains suitable for clinical quality registry development. [38]

Musculoskeletal disorders, which included spinal surgery, ranked #2 amongst the top 20 highest priority clinical domains. Spine surgery has been designated by the ACSQHC as a *high priority clinical domain* for development of a registry. [38]

Detailed analysis determined that spine surgery has a high cost to the healthcare system, creates a high burden of disease in the community, and was considered a priority for quality improvement by stakeholders. [38] Table 2 sets out how the clinical domain of spine surgery satisfies the Commission's criteria for high priority CQR development.

In addition, Table 3 details ASR's compliance with the Commission's CQR frameworks and operating principles. By dint of its successful Stage 1 Pilot, the ASR has demonstrated each requirement, or is planning to do so in Stage 2 – National Rollout, thereby confirming its high priority status, and CQR alignment and capability.

Table 2. ASR fulfilment of CQR Framework prioritisation criteria

	Criteria	Spine surgery fulfilment of criteria
1.	**Clinical relevance**	
1.1	There are serious consequences for the patient associated with poor quality care for the clinical condition or with poor quality of the device or procedure.	• Back pain and problems ranks third in terms of DALY (11.84%), and first in terms of non-fatal burden of disease (YLD) in Australia. An ageing population will experience a growing disease burden associated with spine problems. The inevitable increase in spine surgery reinforces the need to minimise poor quality care and healthcare costs. A spine registry offers the most cost-effective way of achieving collection of longitudinal, risk-adjusted health outcome data on the appropriateness and effectiveness of spine surgery interventions. See **1.8 Burden of Disease Associated with Spine Problems** and **1.9.2 Spine Surgery Data**
1.2	An evidence-based, well executed sequence of care improves patient outcomes for the clinical condition.	• Notwithstanding variation in some clinical and patient outcomes, there is longstanding evidence in the literature that spine surgery interventions improve patient health and well-being. These characteristics make spine surgery a suitable domain for the collection of longitudinal patient and clinical outcomes data to evaluate the efficacy of surgical treatments. See **1.9.1 Spine Surgery**
1.3	Unwarranted variation from this sequence of care can be identified and addressed.	• Currently, system-wide data does not allow sufficiently detailed analysis at the clinical and patient level to permit better understanding of existing, and potentially, unknown or unacknowledged variations in clinical outcomes. A spine registry will collect clinical and patient reported outcomes data permitting more forensic examination of spine surgery and patient outcomes, improved monitoring, and provide the basis for addressing a range of clinical and patient care issues. The ASR Pilot has already demonstrated this capability. • The frequency and range of patient spine problems and underlying conditions, the variable and discretionary nature of most treatments, and inherent knowledge imbalance mean it is relatively easy to generate surgeries. Individual surgeon audits will provide direct feedback on performance, benchmarking with surgeon cohorts, identification of outliers in order to address safety and quality issues, and opportunities for poor performing surgeons to improve clinical performance with training and mentoring. • In addition, hospital audits will allow comparison of one hospital with another, and to identify surgical versus patient care problems, and variations. • Minimising unwarranted variation also requires hospitals to implement more rigorous scope of practice guidelines to assist in determining what surgeons can do within their realm of expertise, and to ensure surgeons have proper training to perform procedures and complex surgery.

	Criteria	Spine surgery fulfilment of criteria
		• One of the potential causes of variation is the number of surgeons. Workforce evaluation is currently undertaken for neurosurgeon and orthopaedic specialties, but none has addressed spine surgery. Registry data will assist this process. • Detailed spine registry data will help address safety, quality and performance issues, minimise practice variability and inadequate credentialing, and ensure deployment of appropriately skilled surgeons with spine surgical expertise. See **1.9.5 Clinical Variation in Spine Surgery**
1.4	The condition, device or procedure of interest is associated with a high cost to the health system.	• Spine problems, consequent spine surgery and use of implantable devices result in high cost to the healthcare system. Musculoskeletal disorders represent 12.83% of total healthcare expenditure (NHCDC, 2012-2013). Total cost of spine problems (non-surgical and surgical) stands at over $4 billion. Spine surgery costs the community in excess of $1 billion annually in healthcare costs, representing over 20% of total musculoskeletal healthcare expenditure. • Spine surgery is the second costliest area of surgery after heart surgery, ranging from $6,000 for routine discectomy up to $160,000 for complex ASD. Not only is spine surgery expenditure expected to grow by more than 20% over the next decade, but within the case mix, complex surgery is increasing at a faster rate than less complex interventions. • The prostheses component of total spine surgery is estimated at $250 million. From 2012-2019, prostheses expenditure for privately insured patients grew by 42%,[19] and this trend is expected to continue. ASR will be able to effectively monitor spine surgery trends and costs. It will also the have capacity to conduct post-market surveillance of spine surgery prostheses, and track this currently unmonitored expenditure to identify device usage, performance and cost, and promote treatment options that yield better, and more cost-effective outcomes. • Use of intensive care in post-operative management of spine surgery patients has increased. The extent to which this very costly care option is related to factors such increased patient comorbidities, patients having spine surgery at an older age, or increased surgical complexity is not known. ASR data will facilitate a better understanding of patient and clinical drivers, and potential ways of reducing intensive care use, without compromising patient outcomes. It will provide a potential information source for identifying and responding to inappropriate care or inefficient use of limited resources. See **1.9.2 Spine Surgery Data**

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[19] APRA PHI Prostheses Report. June 2020 (released 18 August 2020): prostheses 197,408, benefits paid $145,206,550.

	Criteria	ASR fulfilment of criteria
2.	**Feasibility**	
2.1	The clinical condition is suited to CQR data collection.	- The Pilot has shown it is possible to capture patient and clinical data for analysis and reporting for a clearly defined population i.e. the entire national population of patients undergoing spine surgery. - Internationally, there are at least 25 spine registries operating in 14 countries across Europe, Canada, US and the UK. [52] These registries have been established and/or supported by spine surgeons to monitor the outcomes of spinal procedures, and collect data to better understand procedures, techniques, and patient experience and quality of life. See **1.11.1 Clinical Registries** and **1.11.2 Spine Registries**
2.1.1	The relevant clinical population can be captured.	- There are no identifiable barriers to patient engagement with the registry. Subject to privacy, security and opt-in/out permissions, patient data will be collected and entered by the patient's treating surgeon and practice staff into customised KEOPS software. The ASR Pilot recorded very high levels (over 80%) of patient engagement and enrolment in registry data collection. - At present, spine surgery patient administrative information is captured in clinical practice data bases by treating public and private hospitals (e.g. admissions and separations), and PHIs (insured members). This offers the potential for data linkage.
2.1.2	The clinical condition or event is able to be systematically recognised.	- Spine problems have a range of well-defined diagnoses and treatment pathways, with spine surgery a recognised treatment option for a range of indications and disorders.
2.2	There is clinician support for the CQR (or the proposed CQR).	- A committed and skilled clinical leadership group from the Spine Society of Australia has been actively involved in advancing development of the ASR over the last decade. They have been instrumental in promoting registry benefits and garnering broad-based clinician support. This is essential for (voluntary) clinician participation in data collection, and engagement in quality improvement activities resulting from data analysis and reporting. The Pilot has demonstrated that where clinicians have a sense of ownership of the registry, and are fully 'invested' in the process, their engagement, commitment and participation is stronger. Trust in the quality of data, motivation of participants, supportive organisational and cultural factors, as well as positive 'outcome' expectancy', will provide the basis for strong surgeon participation, and willingness to engage in the feedback process. [53] See **Appendix 3: SSA Letter of Support**

	Criteria	ASR fulfilment of criteria
2.	**Feasibility**	
		• Maintaining consistency and quality of care requires clinician engagement. Traditional top-down approaches to mandating change have been shown not to work. ASR will generate data to indicate how procedures and patient care could be improved. Individual surgeons can look at their performance against others (benchmarking best practice). For example, in the case of degenerative spondylolisthesis there are certain cases which can be treated with decompression alone. • It is anticipated that ASR collected data will provide the means to clarify the best treatment options. • Spine surgeons are a relatively small sub-specialty, organizationally bound together by their clinical representative bodies, the Spine Society of Australia and the Neurosurgical Society of Australasia. These organizations have already been working collaboratively for many years. • The musculoskeletal domain has been active in registry establishment across various DRGs. The AOANJRR is a notable example of how a well-supported and funded clinical registry can be a vehicle for change, providing real-world evidence and alternatives, without which the chances of changing joint surgery practices, would be unlikely. Since the AOANJRR is owned by AOA it has great (fact-based) integrity. It is not driven by external stakeholder or shareholder agendas, such as governments opting for the cheapest treatments, or industry promoting the most expensive (profitable) prostheses. • Similarly, the ASR is owned and keenly supported by the SSA, has a strong patient and clinical focus, and has also maintained a broad and positively disposed stakeholder base.
2.3	The governance requirements for a successful CQR are in place.	• Strong emphasis has been placed on establishing the appropriate registry governance structures, systems and processes to: ➢ provide formal governance structures to enable strategic focus, planning of priorities, and oversight and management of resources ➢ collect, protect and share data privately and securely ➢ address outliers or unexplained variance ➢ provide mechanisms to ensure quality of care issues are effectively addressed • Necessary governance to ensure operational effectiveness, efficiency and accountability have been established under the Stage 1 Pilot, with additional measures to be instituted in Stage 2 National Rollout. • ASR governance structures (Steering Committee, Data & Research Committee, User Group, Stakeholder Group, management roles and responsibilities, and Stage 2 project governance) are detailed in

	Criteria	ASR fulfilment of criteria
2.	**Feasibility**	
		- **Stage 2 – Governance and Management** Framework, **Section 1.35 Project Governance.**
2.4	The information requirements for a successful CQR are in place.	- Potential sample and selection bias will be minimised as the entire population of spine surgery patients will be captured. Segmentation of the spine surgeon population for registry participation will ensure a representative surgeon sample is maintained until all spine surgeons have the opportunity to participate. It will also minimise potential case-mix bias so data can reliably be benchmarked as early as possible in rollout. Surgeon participation is projected to reach a target minimum of 50% in 5 years, and 90% by 2030, with close to complete coverage over time as registry participation becomes the norm. Patient (opt-in) enrolment rates are expected to be a minimum of 80% (achieved during the Pilot). Longitudinal patient survey completion rates benchmarked during the Pilot are anticipated to increase as survey methods, administration and follow-up processes change and improve over time, and registry-related tasks become embedded in daily spine surgery practice activities. Pilot data suggest non-compliance appears to have little effect on data quality. - Necessary data infrastructure is in place and managed by Monash University, the registry custodian. (See **7. Stage 1 – ASR Pilot** and **8. Stage 2 – National Rollout** for details.)
2.4.1	An entire population with a chronic condition or disease, or who have undergone an acute event can be captured.	- The entire population of patients undergoing spine surgery procedures, currently 60,000, can be captured.
2.4.2	There is a suitable data source.	- PROMs data will be collected pre- and post-operatively from spine surgery patients utilising a range of patient self-administered questionnaires, including ODI, NDI, and EQ5D™. These survey instruments are proven and established, and widely used (valid and reliable). The ASR Pilot has demonstrated a high rate (over 80%) of patient questionnaire completion.
2.4.3	Clinically meaningful performance indicators can be defined.	- Key performance indicators have been identified with reference to clinical practice and expertise, SSA, other Australian clinical registries, and international spine registries. Performance measures are comprehensive and relate to key elements of the patient's journey and experience, and healthcare pathways associated with clinical, perioperative, and post-operative care.
2.4.4	There is potential for reliable risk adjustment.	- Comorbidities add complexity to diagnosis and treatment of patient spine problems. They may create additional risks for patients undergoing spine surgery, and have a significant influence on clinical and patient outcomes.

	Criteria	ASR fulfilment of criteria
2.	**Feasibility**	
		• Risk adjustment is part of ASR's standard procedure. Comorbidity data has been collected during the Pilot. This process is being expanded and refined for national rollout with the addition of other comorbidity data including obesity, smoking, osteoporosis, and mental health problems. Collection of comorbidity data from surgeons is challenging due to inconsistent collection practices. We are examining alternative sources of information e.g. PBS data and hospital EMR data to improve data consistency and quality. (Hospitals receive higher incentives for managing patients with comorbidities so are likely to have more accurate records.) Better data linkages and integration will assist.
2.5	There are sufficient resources available for the sustainable operation of the CQR.	• No. The core registry infrastructure is in place and the foundational work has been completed in Stage 1- Pilot. Funding to enable full implementation is now required for Stage 2. Current funding arrangements are not sustainable.

Table 3. Assessment of ASR's alignment with CQR frameworks and operational principles

Clinical Quality Registry Attribute		ASR compliance with CQR principle				
		Complies	Partially Complies	Plan to comply in future	Do not plan to comply	Comment
Core Attribute						
1	Collect data with clear & defined purpose	✓				
2	Contains a core minimum data-set		✓	✓		Data set will be refined according to data point relevance and collection compliance as the registry evolves.
3	Collect epidemiologically sound data elements	✓				
4	Uniformly collect data - i.e. Level 2(1)	✓				
5	Outcome measure taken at time of clinical stabilisation	✓				
6	Burden of cost/data collection against loss to follow-up	✓				
7	Data collected from eligible population	✓				
Data collection						
8	Data capture enhances health care and not a burden	✓				
9	Data capture is done close to time of care	✓				
10	Uniformly collect data & easily accessible	✓				
11	Standard definitions, specifications used to collect data	✓				
12	Data dictionary is established		✓			Data Dictionary partially compliant to the CQR requirements due to ASR software platform being commercial IP.
13	Existing data sources are utilised for data collection		✓	✓		Plan to develop data linkages based on ongoing resourcing
14	Record linkage is available	✓				Record linkage is available on the software platform however currently not used because of storage constraints.
Data elements						
15	Identifying information is collected	✓				
16	Process of care measures are collected (PROMs etc)	✓				
17	Outcome measures assessed with objective measures	✓				
Risk adjustment						
18	Collect objective reliable covariates for risk adjustment	✓				
Data security						
19	Secure access, transfer and messaging	✓				
20	Secure data storage	✓				
21	Authentication and institutional policies followed	✓				
Ensuring data quality						
22	Ascertainment - percentage of eligible patients	✓				
23	Robust quality control plan	✓				
24	Data checked in a sample of cases (e.g. practice/site audits)	✓				
25	Built in data management processes	✓				
26	Reports provided in strict timeline and funded	✓				
Organisation and governance						
27	Accountable formalised governance	✓				
28	Manage contingencies from data analysis with policy	✓		✓		Further policies to be developed
Data custodianship						
29	Data custodianship must be explicit	✓				
30	Access & reporting policies are available	✓				
31	Third party access approved by Steering Committee	✓				
Ethics and privacy						
32	IEC must be obtained to establish registry	✓				
33	Personnel must be familiar with ethical conduct	✓				
34	Participants must be informed about data use	✓				
35	IEC approval must be sought for projects	✓				
Information output						
36	Data used for best practice/benchmarking performance	✓				
37	Reporting on risk adjustment outcome analysis			✓		Will be developed as the volume of data in the database increases.
38	Verify data collected through peer review	✓				
39	Ad hoc data analysis to monitor clinical findings	✓				
40	Annual reporting	✓				
41	Documented procedures for outlier reporting			✓		Will be developed as the volume of data in the database increases.
Resources and funds						
42	Resources and funds (adequate, appropriate, sustainable)	✓				Depends on current business case application. To date funding has been ad hoc, uncertain, and time-consuming.

Reference: After Simmonds, Frances, Jones, Lauren, Berger, Monique, Tazelaar-Molinia, Jodie, and Zhang, Ming, "Australian clinical quality registries project for ACS&QHC: final report" (2009). Australian Health Services Research Institute. 494. https://ro.uow.edu.au/ahsri/494

1.11 Registry Value - Quality, Safety and Improvement in Patient Care

1.11.1 Clinical Registries

Where clinical registries have been introduced at a state or national level in Australia, they have become one of the most clinically valued tools for quality improvement. [54]

A proven strategy to reduce variation and improve care is to measure and compare it using high quality clinical data which is respected by clinicians. This has been successfully tested in a range of clinical areas including in the management of surgery (e.g. trauma [55], cardiac surgery [56], transplantation [57], and breast surgery [58]) and in the medical management of patients (e.g. stroke care [59], cardiac care [60], dialysis [57] and cancer care [61]).

Clinical registries have emerged as being a feasible way to capture “real world” care across large patient populations[62] and provide the most effective means of collecting high quality data. The Australian Commission on Safety and Quality in Health Care has advocated development of clinical registries.

Registries improve quality of care by:

- providing credible risk adjusted data which engages the common desire of clinical teams to improve,
- arming clinicians with information about how their outcomes benchmark with others, both locally and (sometimes) overseas,
- providing the ability to identify and investigate variation in clinical practice and outcomes, and,
- providing an early warning if quality deteriorates.

In addition to being important tools in improving quality of care, clinical registries provide unparalleled ability to track how innovation translates into longer term outcomes in the ‘real world’ [63,64]. For example, new devices or surgical techniques may be demonstrated in limited populations but data is seldom available demonstrating long-term outcomes in a more general patient population.

1.11.2 Spine Surgery Registries

There is now recognition by authorities that unique clinical insights can be gained by large scale registries [65]. There are at least 25 prospective spine surgery registries in fourteen countries currently running throughout Europe, North America, United Kingdom, two of which collect information at an international level [52]. In Australia, however, there is no national spine surgery registry. The Spine Society of Australia (SSA), founded in 1990, is a multidisciplinary organisation with both orthopedic and neurosurgical members, and is the driver for establishing Australia’s first national spine surgery registry.

1.11.3 Registry Research Opportunities, Benefits and Translational Impacts

The registry will provide significant opportunities for surgeons to benchmark their performance and undertake research.

In addition to the financial and broader economic benefits of registries, there are significant individual practitioner benefits and research benefits. There is clear evidence around the world regarding the impact registries have on research in the clinical domains in which they operate, including driving continuous improvement in patient care, and maintaining quality, safety and standards. [66] One of the key outcomes of spine surgery registries is to allow national and international benchmarking and to make sure that spine care is value-based.

The capacity for registries to act as a catalyst for the development and proliferation of research and related activities is illustrated in Figure 15 showing registry publications, presentations and ad hoc report activity for three registries.

The positive impact of the AOANJRR's launch on research publications, conference posters, ad hoc reports, and presentations in a variety of fora is both dramatic and highly significant. This pattern of providing strong stimulus for research is also evident in other spine registries in Europe, Canada and USA. The ASR will be collecting information from both public and private patients. This will enable comparison with the other overseas registries, enable refinement of the data set and data collection, allow evaluation of outcomes and benchmarking for specific spine surgery procedures

Research findings from the ASR will enable comparison of similarities and differences in outcomes for the Australian populations with other countries and healthcare systems, and facilitate greater understanding in spine surgery variation nationally and internationally. Table 4 below lists three longstanding international spine registries and their scope of operation, with whom it is anticipated the ASR will forge strong relationships.

The ASR will provide fundamental infrastructure, oversight, guidance and support for those undertaking spine-related research. In 2021, the ASR will establish the Research and Data Governance Committee, which will be instrumental in ensuring registry data, analysis and reporting is accessible and used appropriately for targeted research purposes.

It is no coincidence that few research papers in spine surgery come from Australia. The ASR will provide a platform for nested and independent research, including clinical trials, and observational and longitudinal studies. It will provide major impetus and opportunities for attracting and retaining researchers in spine surgery related fields, and amplify the benefits that flow from an active and invigorated clinical and scientific research community focused on spine surgery.

Table 4. International Spine Registries

Registry	Location	Scope of Operation
SweSpine **(Swedish Spine Registry)**	**Sweden**	Sweden currently has a world-leading spine surgery registry that covers the entire spinal column, with more than 125,000 index operations entered in the registry, especially concerning degenerative disorders. Since 2013, 10,000 new surgeries are added each year.
CSORN **(Canadian Spine Registry)**	**Canada**	The CSORN dataset includes primary data collection, abstracted medical chart information, patient history and outcomes (pain, function, disability and quality-of-life). As of December 2018, the Network had 12,381 enrolments consisting of 9,738 that have had surgery.[20]
EuroSpine Spine Tango Registry	**International**	Spine Tango (ST) is an international spine registry that documents the effectiveness and safety of spine care, treatment techniques and technologies through EUROSPINE's unified registry approach to generate a (collective) evidence base for prevention, treatment effectiveness, patient safety, and best practice. The Spine Tango registry contains the following data (approximate numbers) from 19 countries and 72 centres: • 113,000 surgery cases • 79,000 clinician follow-ups • 268,000 patient self-assessments (COMI) • 208,000 other outcome measures (e.g. ODI)

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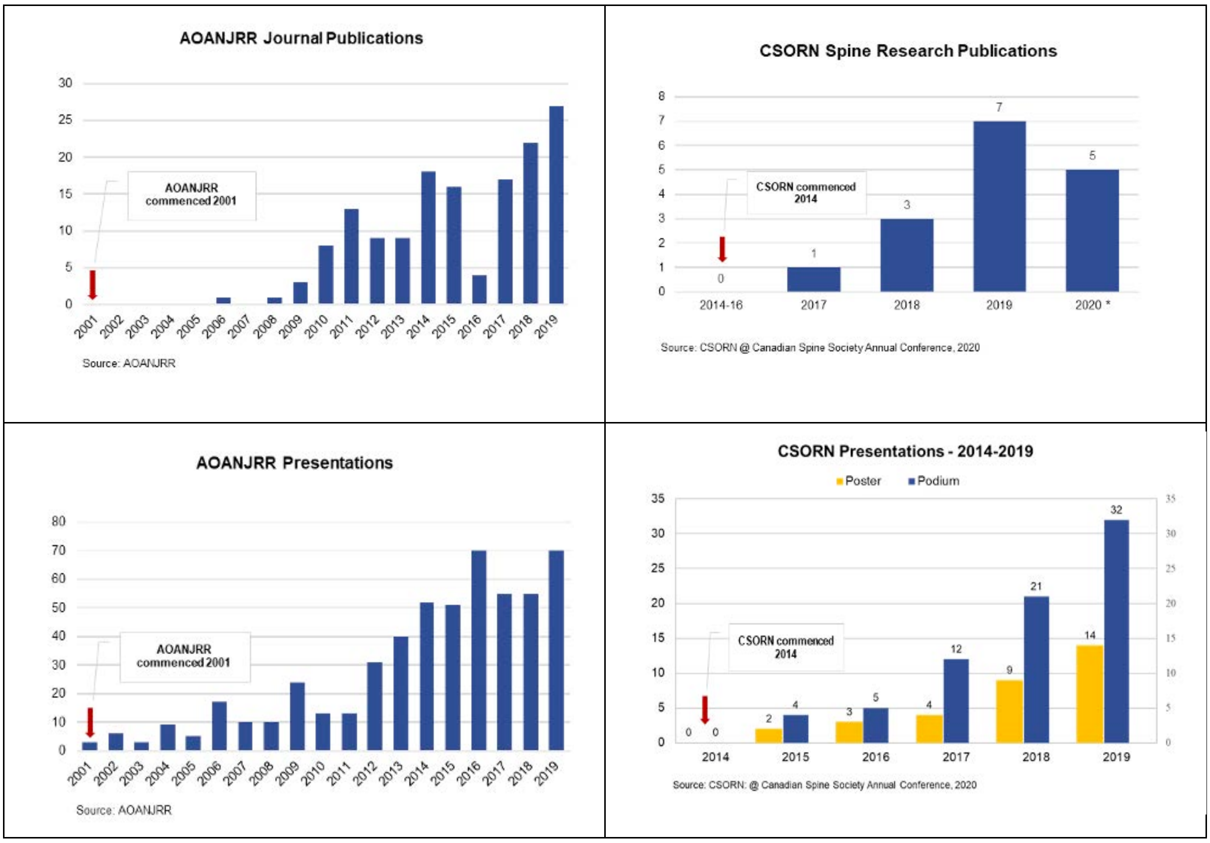
[20] CANADIAN SPINE OUTCOMES AND RESEARCH NETWORK (CSORN): 2018 Annual Report

Figure 15. Impact of registries as a catalyst for scientific research and communication

AOANJRR - Australian Orthopaedic Association National Joint Replacement Registry
CSORN - Canadian Spine Outcomes and Research Network



1.11.4 Economic Evaluation of CQRs (Value, Variability, Benefits and Costs)

Registries generate value in several ways by helping to deliver:

- more effective clinical and patient outcomes (e.g. improved/reduced pain, function, and patient quality of life),
- more efficient patient care (e.g. reduced infections, complications, revisions), and
- more appropriate patient care (e.g. compliance with clinical guidelines and standards, identification of variation and outliers).

This value can be captured in economic terms. [4] Variability in patient outcomes is costly from an individual's health, quality of life, and financial perspectives. It is also costly at the population, healthcare system, and societal levels. To curb the cost curve and improve the value of spine surgery requires observation of clinical practice and patient outcomes in real world settings and evaluating benefits (and costs) of observed changes, allowing for confounding factors. [51]

The ASR will assist the process of driving value-based care and more effective allocation of resources. Armed with nation-wide prospective patient and clinical data, it will have the necessary statistical power to accurately identify low value and high value contributors to spine care and evaluate the real value spine surgery delivers at the individual patient and population levels. These may differ widely.

1.11.5 Return on Investment (ROI)

More concerted efforts to refine the approach to understanding and quantifying the (direct and indirect) economic and other benefits generated by clinical quality registries are yielding better results

Understanding the benefits of clinical registries is challenging,[6] [67] including:

- Variation in registry models and approaches to data collection and usage, [68]
- inconsistencies in the economic evaluative tools [5] used and their application, [69]
- defining the boundaries of registry activity within a complex healthcare ecosystem, amidst other improvement initiatives,
- quantifying the impact of that activity.[70] [71]

Nevertheless, most studies undertaken have reported a positive economic benefit from registry activity. A recent study by the Commission assessing the economic impact of five Australian CQRs concluded that each of the registries improved clinical practice at a relatively low cost, and provided a significant net positive return, with benefit to cost ratios ranging from 2:1 to 7:1. With full national coverage, a minimum benefit to cost ratio of 4:1 could be expected. A systematic review examining existing evidence of cost-effectiveness or cost-benefit of CQRs also confirmed that CQRs can be cost-effective and lead to significant returns on investment. [6]

The ASR will be established within a best-practice CQR framework designed to improve quality and safety of clinical and patient care, maximise patient outcomes, and amplify economic impacts and benefits at patient, population and community levels. Economic evaluation of ASR's impact and activity will be an area for future analysis.

Section 4:
ASR Business Care

1.12 Project Alignment

Development of the Australian Spine Registry is underpinned by the principles provided in the Commission's Framework. Data will contribute to quality reporting on treatments, interventions and patient outcomes to participating clinicians, hospitals, jurisdictional health departments, consumers and funding bodies. The registry will be developed as a staged process, in-line with the Framework, the National Strategy and proposed data sharing arrangements.

1.13 Purpose of the Business Case

The ASR national pilot has been developed by the Spine Society of Australia in conjunction with Monash University, with limited funding from key stakeholders. Completed in October 2020, the ASR Pilot represents the first step in a staged process.

The ASR pilot has been primarily funded by companies involved in the spine implant industry in Australia. The industry grants have been provided on a 1 – 2 year funding contract cycle. There have also been grants from the Spine Society of Australia, BUPA Foundation and the HCF Foundation. The HCF Foundation grant was awarded as part of a competitive grant process.

This has allowed a budget of approximately $150,000 per year which currently funds 0.9FTE, software and questionnaire licence costs and a service fee to Monash University as well as other ancillary costs. In addition, there has been very substantial pro bono contributions from all members of the ASR steering committee and clinical lead. The present funding model has allowed the pilot to demonstrate its aims however it is grossly inadequate to fund the next phase to national roll out. National roll-out will only be possible with a substantial increase in human resources and allowances for software improvements, data linkages, governance management, improved statistical analysis etc.

The SSA has built a pilot registry that aligns with the ACQSHC Framework and fulfils the prioritisation criteria for developing CQRs.

The ASR seeks funding to support the development of Stage 2 – National Rollout of the Australian Spine Registry. The business case outlines the steps taken in Stage 1 to plan, develop, implement and evaluate the ASR operating model. It then outlines the strategy and implementation plans for Stage 2 to achieve national coverage (See Stage 1- ASR Pilot, Sections 1.19 - 1.26 and Stage 2 – National Rollout, Sections 1.27 – 1.42.)

The Stage 2 project plan includes:

- ASR Strategic framework and roadmap
- Stakeholder analysis
- Strategic aims and operational objectives
- Project milestones and deliverables
- Governance and management
- Quality management
- Resourcing
- Budget
- Funding model options
- Outcome realisation
- Project review
- Risk management plan

This business case argues for a commitment of approximately $1m per annum over five years, to support national rollout of the Australian Spine Registry. It is an investment that will produce immediate benefits, as the pilot has already demonstrated. However, realisation of the full scope of benefits resulting from ASR's activities hinges on reaching threshold levels of clinician and patient participation to achieve sufficient (statistical) maturity. Stage 2 aims to achieve this objective.

As a result of the ASR Pilot's success there is growing enthusiasm and anticipation from clinicians and stakeholders to embrace national rollout of the registry without delay.

This business case demonstrates the ASR's leadership in preparing for a data-driven digital future, and its commitment to innovative approaches and practices in establishing a robust analytics capability to support spine surgery patients and clinicians.

1.14 Business Case Sponsor

Spine Society of Australia

1.15 Business Owner

Spine Society of Australia

1.16 Problem Statement

The Australian community spends over $1b on spine surgery every year. Inescapable forces of population demographics, ageing and associated advancing chronic and degenerative disease and comorbidities are significantly increasing the prevalence and national disease burden of spinal problems (characterised by BPP, LBP, NP), making it the number one cause of (non-fatal) years lived with disability. Spine problems have a huge impact on individuals' quality of life, healthcare expenditure, and other economic costs to the community.

Spine surgery, often the option of last resort for spine problems, will increase by over 20% in the next decade with more than 70,000 patients per annum undergoing surgery by 2030, adding a minimum $200 million to the healthcare budget. This will strain the present funding model and it is essential the spending is put to maximum benefit.

At present we have poorly linked data systems across all jurisdictions. This leads to a paucity of real-world, real time data on spine surgery to assist us in understanding or explaining patient outcomes, clinical outcomes, unexplained or unwarranted variations in surgical interventions. Better data would allow delivery of more cost-effective, patient-centric, clinician-lead, and value-based care to Australians. Without data most else is guesswork.

1.17 Assumptions and Constraints

A number of assumptions and constraints will affect ASR's capacity to implement Stage 2 and to realise expected benefits.

1.17.1 Assumptions

(1) Interest/support

- Continued interest in the outputs of the ASR for patients, clinicians and health authorities.
- Willingness of surgeons and patients to continue to embrace the voluntary nature of the ASR and ongoing commitment to data collection processes.

(2) Capability

- Continued leadership and support of the ASR by the SSA.
- Continued evolution of strong governance structures and quality management established by ASR in its pilot phase.
- Ongoing availability of Monash University services as custodian of the registry and provider of infrastructure and analytical support services.

(3) Clinical

- Continued availability of the current range of surgical treatments for back pain and problems, and spine deformities.

(4) Government policy directions and priorities

- Implementation of the National CQR Strategy and development of the ASR in accordance with this framework through ongoing dialogue with the Australian Government, the Commission, and stakeholders.
- Prioritisation of the ASR within the National Strategy.
- Ongoing development and investment in data sharing initiatives involving data linkage, interoperability and integration, which will assist growth and development of the ASR as these systems initiatives evolve and mature.
- It is assumed that development of a suitable registry funding model to provide a reliable and independent source of funding will be implemented. Feasibility of a cost-recovery model such as a levy on medical devices needs be part of these discussions.

1.17.2 Constraints

(1) Funding

- Funding decisions – lack of funding will kill this project. Short term funding and support sought from industry groups, private health insurers, SSA and Monash University has enabled development and completion of the Stage 1 Pilot. However, longer term funding, requires support from state and federal government bodies and industry, which the SSA will actively seek. Without ongoing sustainable funding, the ASR will:
    - be unable to capitalise on the significant investment and progress made in establishing the registry in Stage -1 Pilot,
    - struggle to achieve national coverage and reach sufficient data maturity to provide valid and reliable data for the full range of clinical, surveillance, and research purposes,
    - lack capacity to adequately communicate more broadly to stakeholders, or translate registry findings and research.

(2) Data quality and storage

- Poor data linkages with hospitals and other health data agencies and poor data quality would inhibit the ASR's data range and access, and impact analytics and outputs.
- Adequate database capacity on Monash University servers is required for growth and expansion.

(3) Hospitals and ethics

- Multiplicity of individual hospital governance requirements for ASR participation.
- Major administrative impost created by ethics governance and approvals. The process is onerous, burdensome, time-consuming and jurisdictionally disparate and disjointed.

(4) Legal issues

- Lack of clinician privacy and protection may inhibit surgeon participation. To build trust and confidence legislative protection from legal search would assist.

(5) Jurisdictional differences

- State-based differences concerning data collection e.g. WA requires opt-in rather than default 'consent' which will require time-consuming negotiation.

(6) Supporting legislation

- Currently there is a lack of registry-supporting legislation. It will require federal and state governments and jurisdictions to coordinate a 'registry-friendly' legal and administrative framework, for which the SSA and ASR will actively petition. If enacted, a supportive legal framework could overcome many of these hurdles.

1.18 Australian Spine Registry Aims

The Australian Spine Registry national rollout will capture information about all spine surgery patients nationally, with a particular focus on the assessment of quality of patient care and outcomes. It offers the potential to improve our understanding of current practice in spine surgery and reasons for variation in outcomes. This is critical to driving improvements in the management and care of patients requiring surgery.

The ASR aims to optimise quality of care and outcomes for spine surgery patients by:

1. Collecting and analysing patient-reported outcome measures to determine actual improvements in patients' clinical care experience and quality of life.
2. Determining the results and functional effectiveness of specific spine surgeries in a 'real world' setting with 'real world' data.
3. Identifying variability in treatment amongst individuals undergoing spine surgery and studying its causes and consequences.
4. Providing a tool for individual surgeons to complete audits of their spine surgery including the ability to benchmark themselves against their peers for common procedures.
5. Determining the degree of compliance (and reasons for non-compliance) with evidence-based guidelines for spine surgery.
6. Identifying factors that predict favourable and unfavourable surgical outcomes.
7. Monitoring trends in types of surgery.
8. Assist with device surveillance.
9. Providing an essential infrastructure and digital platform for all spine surgery research in Australia.
10. Providing the ability to track long term effects of innovations in spine surgery
11. Developing appropriate healthcare system data linkages, integration and interoperability to facilitate sharing of clinical information with appropriate healthcare agencies, to improve patient care and outcomes.[72]

The following (Sections 1.19 – 1.26) provides a summary of the work undertaken to plan, implement and evaluate the first stage development of the Australian Spine Registry, preparatory to proceeding to Stage 2 to scale activities nationally, the focus of this business case.

Section 5:
Stage 1 - ASR Pilot

STAGE 1 – ASR PILOT

The Spine Society of Australia, in conjunction with Monash University, initiated a pilot study to establish the Australian Spine Registry to determine the feasibility of a spine registry operating in Australia - a hybrid public-private healthcare system with well-established clinical specialties in spine surgery.

The project commenced in August 2016 with development and ethics approval of the ASR Protocol, which sets out the scope and detail of the pilot data collection study. Appointment of the Registry Coordinator, signing of a contract between SSA and Monash University to house the registry, and the first Steering Committee meeting, followed in 2017.[73]

1.19 Pilot Hypothesis

It was hypothesised that the ASR can monitor and report on outcomes of spine surgery which will serve to reduce variation in treatment and outcomes, and improve knowledge and management of spine surgery patients.[74]

1.20 Pilot Aims

Specific aims of the pilot were to:

1. Develop appropriate registry infrastructure, systems, processes, and governance,
2. Establish feasibility of data collection and accuracy, management processes, and software and data analysis capabilities,
3. Confirm acceptable levels of compliance,
4. Confirm costing of the project for future budgetary and planning purposes,
5. Establish and refine the minimum dataset,
6. Identify the total eligible population undergoing lumbar spinal surgery, and examine patient cohorts, and
7. Analyse and report on variation and clinical outcomes within the identified cohorts.

1.21 Pilot Implementation

Patient recruitment and data collection commenced on 15 January 2018. Currently, the Registry is collecting information regarding all spine surgery from 14 surgeons across 16 approved public and private hospital sites, in four states. This includes a cross-section of high, medium and low variance areas and collects data on all surgical patients at each participating site.

Clinical and patient-reported outcomes data were collected in order to evaluate the practicalities and efficacy of developing national registry infrastructure and operations. The pilot included data housing (within Monash University's Registry Sciences Unit), customisation of commercially available spine surgery software, (KEOPS), and collection, analysis and reporting of clinical and PROMs data. Assessing levels of stakeholder engagement and participation, particularly for practices, surgeons and patients was also central to the project.

The pilot reached its 2000 patient milestone on 1 October 2020. The ASR continues to operate in pilot mode, pending funding for national rollout. The pilot methodology is detailed in the approved ASR Protocol. [72]

1.22 Diagnostic and Data Collection Tools

KEOPS Software

KEOPS is a specialist spine surgery software application. It has many advantages including:

- diagnostic and clinical specificity (both patient and clinical data),
- ease of administrative, surgeon and patient use, and
- flexibility for future customisation.

Glassman Classification

KEOPS software has been customised to include the Glassman Classification, a diagnostic matrix with three primary elements commonly used in clinical decision-making: symptoms, structural pathology, and compressive pathology. This is used as a clinically relevant diagnostic schema to analyse registry cohorts.

Patient Reported Outcome Measures (PROMs)

Beyond the surgery specific data, patient reported outcome measures (PROMs) are collected pre- and post- operatively. They are critical to following patient progress and evaluating quality of care. Three validated and well accepted PROMs instruments are detailed in **Table 5**. [68]

Table 5. PROMs Instruments

Spine disease specific measures	
Oswestry Disability Index (ODI)	The most common and reliable PROM instrument. Used for assessment of low back pain and functional disability. [62 75]
Neck Disability Index (NDI)	Also referred to as the Vernon-Mior Disability Index. Used for acute or chronic disability of the neck to indicate severity of functional disability experienced by patients. [75-77]
General quality of life (QoL) measures	
EuroQol Five Dimensions (EQ5D™) questionnaire [75]	Standard measure of health status. [78] Shown to be valid and reliable for use in spine surgery and other medical disciplines. [79]

1.23 Statistical Methodology

Extraction, analysis and trending of the data during the pilot was conducted in the following manner:

(i) Identification of specific patient cohorts

Specific patient cohorts were identified through the registry database, and filters determined to permit construction of specific data extracts for real time download by the KEOPs software. This was a multi-functional task involving clinicians, researchers, and biostatisticians.

(ii) Generation of real time data extracts and analysis of the data

Real time data extraction functions are being developed and incorporated in the KEOPs database. Each patient cohort can then be extracted using specific measures including, but not limited to, demographics, PROMs, comorbidities, Glassman classification, surgeon, hospital, and location.

(iii) Statistical analysis and developing benchmarking frameworks

Specialist biostatisticians analysed the data using appropriate statistical techniques. Summary statistics for demographic, diagnostic and patient-reported outcome measures were carried out. Variables potentially impacting surgical outcomes were assessed.

As statistical processes appropriate to the registry continue to be developed and refined, and patient numbers grow, the ability to benchmark data and performance will increase. The statistical analysis plan will be reviewed annually by a biostatistician and changes to survey instruments and analytics made as required.

1.24 Key Findings and Conclusions

Results of the pilot study are detailed in *ASR Pilot (2018-20) - Outcomes and Evaluation.* In summary, the Stage 1- Pilot has established a viable operational model for the ASR and laid the foundations for proposed expansion Australia-wide in a Stage 2 – National Rollout.

During the pilot the ASR has also built awareness and momentum through publishing Annual Reports in 2018, 2019 and 2020, detailing registry activities, data analysis, and reporting. Over this period ASR has also presented at numerous conferences, contributed to publications, and constructed an informative website platform to build online presence to profile and to promulgate ASR information. (https://www.spineregistry.org.au/)

1.25 Observations and Success Factors

The ASR has adopted an innovative approach in many aspects of the pilot's development which has underwritten its success. Important elements include:

(i) Use of third-party software provider

Due to the complexities of spine surgery, and after a global search, ASR selected KEOPS, a spine surgery software program developed by an international software company, SMAIO. KEOPS is a web-based application with cloud data storage and high-level data security and encryption in place. It is a fully customisable data collection tool that can be adapted to any protocol.

The ability to customise KEOPS for Australian practices and its ease of use were key reasons for selection. The pilot has demonstrated its suitability for the registry purpose of data collection, extraction and analysis. It has demonstrated to be an effective, user-friendly solution.

Utilising an external software supplier has yielded an effective and mutually beneficial partnership. It has allowed ongoing feedback, and software changes, improvements and upgrades. Contractual arrangements provide ASR with maximum flexibility into the future, including the rights to acquire and further develop the KEOPS software application.

(ii) Direct data input by surgeons

The pilot has required development and embedding of new systems and processes into practice settings. This has been primarily driven by surgeons who undertake patient data input to ensure accuracy and compliance. With a completion rate of 89%, this represents significant generational and cultural change.[80]

(iii) Pre-operative PROMs

The ASR is the first registry under Monash Registry Sciences Unit to collect PROMs data pre-operatively (<3 months), as well as post-operatively (at 6, 12, and 24-months). Collection of real time data on patient reported outcomes is key to following patient progress and evaluating quality of care. It permits longitudinal study and analysis of spine surgery interventions and mapping of patient journeys. PROMs data collection is a crucial differentiator, providing direct feedback to surgeons, patients, and healthcare providers. It lies at the heart of ASR's support for more patient-centred, value-based care.

(iv) Participation rates

The following Table 6 confirms the viability of the registry in terms of patient and surgeon participation. Initially this was a concern given the voluntary nature of the registry model.

However, high response rates have been achieved because of strong buy-in from patients, surgeons and practice staff, and proactive support and follow-up from the ASR.

Table 6. ASR Pilot Participation Rates

	Patients (n= 2037)			Surgeons (n=15)	
	Enrolment in Pilot	**Pre-operative PROMs**	**Post-operative PROMs**	**Participation in pilot**	**Data Entry Compliance**
Participation/ Completion Rates	87%	84%	6 mth - 80% 12 mth - 83% 24 mth - 82%	100%	89%

(Source: ASR Annual Report 2020, Infographic, 31 Oct 2020)

Patient participation has been strong due to regular communication and streamlining processes for PROMs input. Adaptation of the method of data input will align with shifts in digital technology and patient preferences.

Pilot data indicate that voluntary participation by surgeons, where they understand the value of registry participation, will more likely be successful than mandatory compliance.

(v) Whole of practice data collection

Instituting ‘whole of practice’ data collection contrasts with the practice of other registries. This approach was implemented to:

- cast a wide net around an evolving minimum data set,
- enable participating surgeons to fulfil CPD practice audit requirements,
- permit comparison of different surgical techniques, for example, spondylolisthesis involving decompression, or decompression and fusion,
- simplify compliance for practices, and
- enable filtering across multiple data elements, offering scope for more refined and flexible analyses.

(vi) Data analysis

The pilot has demonstrated that it is possible to extract “clean” cohorts of patients from the database for analysis. It has also shown that surgeon PROMs questionnaire requirements can be customised without compromising the registry data set. An initial range of analyses and reports have been developed.

Data monitoring and interrogation will become more granular, sophisticated and efficient with expansion of the database. This will include refinement of data sets and improved comorbidity and complications inputs. These will assist the ability to risk-adjust.

(vii) Data integrity, accuracy and currency

It is possible, for a variety of reasons, that some patients may not be entered in the database. This may occur either by inadvertence, or potentially by ‘selective’ exclusion. To ensure maximum coverage of the eligible population of spine surgery patients, and to avoid possible “cherry-picking” of patients by surgeons entering data, procedures have been put in place to preserve data integrity and accuracy.

These measures include:

- random auditing of registry data against surgeon operating books,
- checking of hospital admissions against registry data entries,
- personal visits by the registry staff to practices, and
- practice audits.

Given the limited scale of the pilot this labour-intensive process was possible. However, as the database expands, linkages to hospital data, validating clinical practice records, and other auditing measures to ensure data integrity, accuracy and currency will require investment in software systems development to simplify and automate these processes.

(viii) Change management

The pilot has enhanced understanding of the strategies, training, support, and steps required to effectively implement new systems and processes into clinical practice settings. This will facilitate effective and streamlined national rollout.

Surgeons and their practices may be ‘the weakest link’ in the whole data collection process. However, pilot experience has demonstrated that the key to success lies in training and educating clinicians and practice staff in how the ASR works, and embedding and streamlining new systems and processes into ‘practice as usual’. There is a strong relationship between regular/routine communication and increased surgeon/practice staff compliance with data entry. Improvements have occurred as a result of regular comparative feedback to surgeons on data completeness and compliance.

1.26 ASR Pilot Outcomes

The Pilot represents Stage1 of a phased approach to the development of the ASR and provides ‘proof of concept’ in terms of governance, operations, and ‘real world’ data collection, analysis and reporting capabilities. This is demonstrated by the 2018 and 2019 ASR annual reports. [21] It has benchmarked patient participation, clinician acceptability, and stakeholder interest and engagement. Project costings have also provided a basis for Stage 2 budgetary and planning purposes.

The pilot has informed the strategy, necessary capabilities, benefits, and economic justification for proceeding to Stage 2 – National Rollout. It has confirmed the project scope and financial considerations in this business case for seeking funding to ensure the healthcare benefits of ASR can be fully realised in an appropriate timeframe.

Given the pilot’s success, the SSA is now well-placed to capitalise on the lessons learned from the initial phase of development. It is now equipped to build on strong interest and support amongst its membership. The Pilot has already generated significant momentum, trust and credibility.

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[21] ASR 2018 and 2019 Annual Reports https://www.spineregistry.org.au/news/

Section 6:
Stage 2 – National Rollout

STAGE 2 – NATIONAL ROLLOUT

National rollout of the ASR has been planned in accordance to the ASR's Strategic Plan 2020-2030 (the Plan), (see Appendix 4 – ASR Vision, Purpose and Values) and ACSQHC national CQR frameworks and guidelines. [12,14]

1.27 ASR Strategic Road Map – 10 Year Plan

The ASR Strategic Plan sets out the registry's pathway to national coverage and maturity.

Data analysis will identify and stimulate targeted, ongoing research and encourage industry engagement in order to improve evidence-based practices and patient outcomes.

The broad concept plan for ASR's development over the next decade, is shown in Australian Spine Registry Strategic Roadmap 2020-2030. (Figure 16) The strategic roadmap identifies six core phases of development, key milestones and growth targets for clinician participation and patient enrolments to achieve national coverage and statistical robustness.

The rollout will be done in a staged manner, as the pilot has demonstrated:

(i) The administrative difficulties inherent in obtaining ethics and governance approvals across jurisdictions and new public and private hospitals.
(ii) the need for thorough education of surgeon and their practice staff to maximize the chance for obtaining compliance with data collection.

1.28 Measuring ASR's Impact within Healthcare System

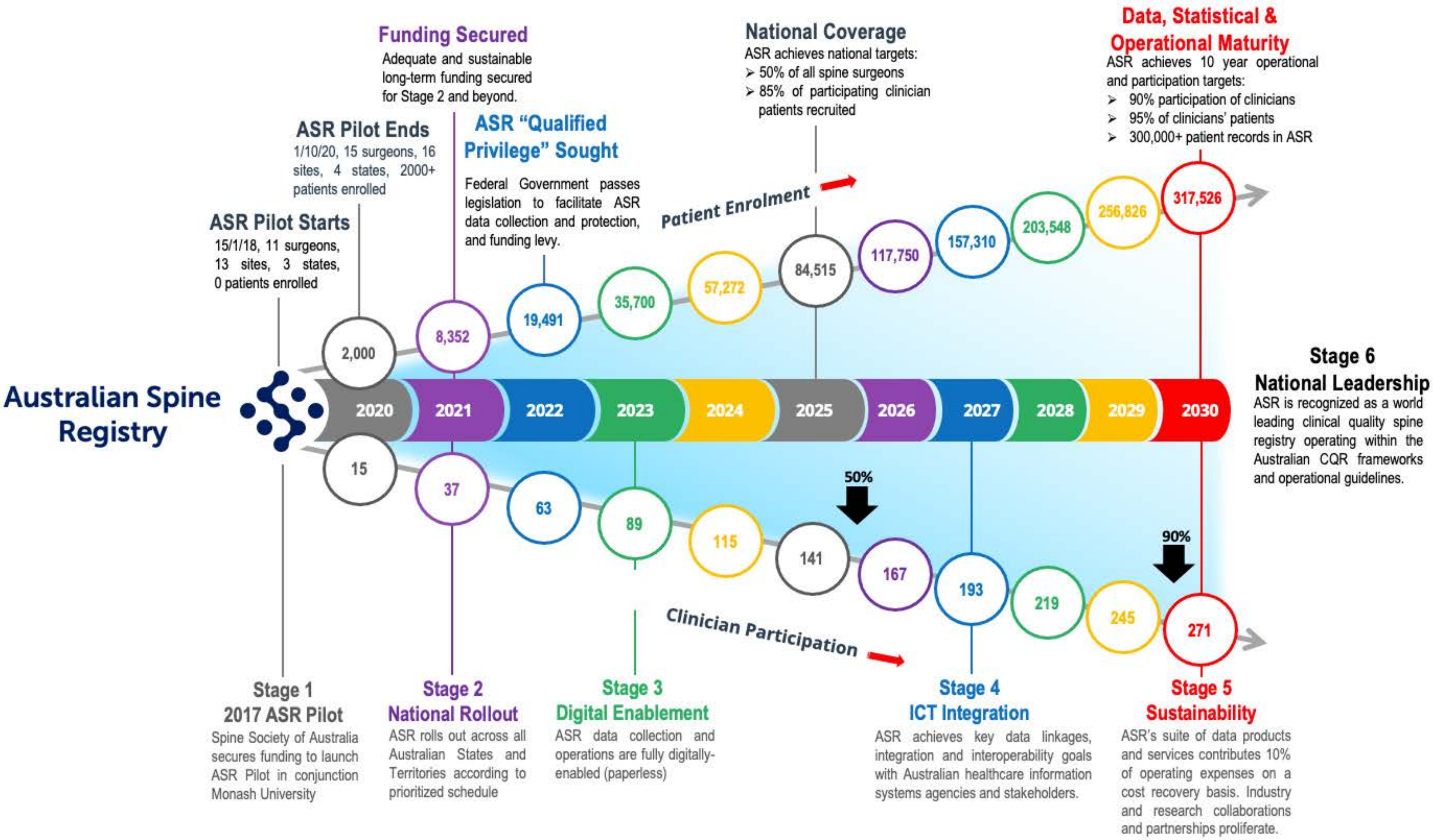
Currently there is no definitive study or model for measuring the impact of clinical registries, and therefore their accountability, within the healthcare system.

Ultimately, the ASR is concerned with improving quality of life for spine surgery patients. It is appropriate therefore that the ASR's operation and performance (like all CQRs) should be linked to broader healthcare system goals.

The feedback loop created by ASR activities occurs at the surgeon and patient level which is actionable and facilitates continuous change and improvement within the spine surgery care pathway. (Figure 17)

In context of overall healthcare system goals, the ASR will address a range of objectives, performance measures and expected benefits (health-related and economic) resulting from its operation over coming decades. (See Table 7: Australian Spine Registry Performance Framework.)

Figure 16. *Australian Spine Registry Strategic Roadmap 2020-2030*



ASR Pilot Starts
15/1/18, 11 surgeons, 13 sites, 3 states, 0 patients enrolled

ASR Pilot Ends
1/10/20, 15 surgeons, 16 sites, 4 states, 2000+ patients enrolled

Funding Secured
Adequate and sustainable long-term funding secured for Stage 2 and beyond.

ASR "Qualified Privilege" Sought
Federal Government passes legislation to facilitate ASR data collection and protection, and funding levy.

National Coverage
ASR achieves national targets:
- 50% of all spine surgeons
- 85% of participating clinician patients recruited

Data, Statistical & Operational Maturity
ASR achieves 10 year operational and participation targets:
- 90% participation of clinicians
- 95% of clinicians' patients
- 300,000+ patient records in ASR

Stage 6
National Leadership
ASR is recognized as a world leading clinical quality spine registry operating within the Australian CQR frameworks and operational guidelines.

Stage 1
2017 ASR Pilot
Spine Society of Australia secures funding to launch ASR Pilot in conjunction Monash University

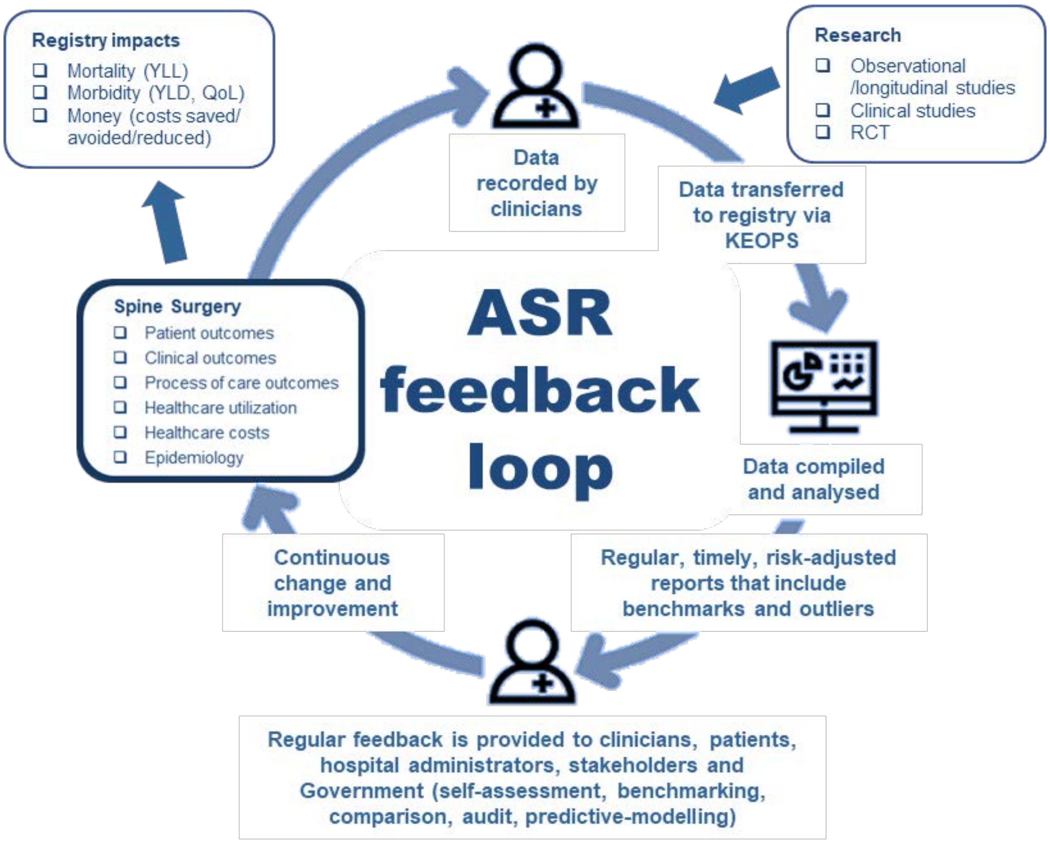
Stage 2
National Rollout
ASR rolls out across all Australian States and Territories according to prioritized schedule

Stage 3
Digital Enablement
ASR data collection and operations are fully digitally-enabled (paperless)

Stage 4
ICT Integration
ASR achieves key data linkages, integration and interoperability goals with Australian healthcare information systems agencies and stakeholders.

Stage 5
Sustainability
ASR's suite of data products and services contributes 10% of operating expenses on a cost recovery basis. Industry and research collaborations and partnerships proliferate.

Figure 17. ASR feedback loop drives continuous change and improvement in spine surgery



Reference: ACSQHC. Australian Commission on Safety and Quality in Health Care. Framework for Australian Clinical Quality Registries - 2014 Sydney (2014).

1.29 Critical Success Factors

1.29.1 ASR Frameworks and Platform

Successful establishment and development of the ASR depends on many factors, both internal and external. As part of its vision and strategic plan, ASR will work towards achieving key *enabling* and *resourcing* objectives, essential to providing a supportive environment and platform for registry activity and growth, including:

1.29.2 Enablers

- ASR Strategic Plan,
- Strong leadership and governance processes
- CQR National Strategy and Framework
- Sustainable funding model
- Streamlined ethics approval processes
- Supporting Commonwealth legislation (funding and qualified privilege)
- Strong stakeholder partnerships
- Data linkage, integration and interoperability
- Enhanced digital technologies (e.g. cloud, AI, big data, security).

1.29.3 Resourcing

- Sufficient, sustainable funding - $1.2m pa (over 5 years initially) as per Summary Budget – Table 15, and detailed ASR Budget in Appendix 7.

Table 7. Australian Spine Registry Performance Framework

Objective	Performance Measure/ KPIs	Benefit
Process of Care Outcomes e.g. perioperative care		
Improve quality and outcomes of perioperative patient care for spine surgery	Hospital measures Healthcare quality measures	Reduced healthcare costs: • unnecessary/ unwarranted • fewer hospital admissions • reduced hospital stays
Clinical Outcomes e.g. clinical efficacy, complications, revisions		
Improve value and efficacy of spine surgery Reduce poor clinical results and patient outcomes Reduce costs by eliminating unwarranted/ unexplained procedures	Appropriate risk-adjusted data analysis and reporting Clinical outcome measures (revisions, complications) Clinical variances (unexplained /unwarranted variations)	Improved patient assessment and outcome prediction Avoid unnecessary costs allowing resource reallocation. Greater equity and access to spine procedures by addressing clinical variations
Identify and drive improvements in evidence-based clinical best practice, and provide feedback and training for surgeons	Individual clinician benchmarking Clinical training	Improved evidence-based practice – independent feedback to surgeons Improved patient outcomes: • quality of life • increased confidence in spine surgery procedures
Patient Outcomes e.g. function, disability, quality of life		
Improve patient quality of life	Patient measures – PROMs, PREMs Data collected Actions taken for change/improvement	Improved function Reduced pain and disability Improved quality of life.
Healthcare Utilization e.g. separations, length of stay		
Increase equity and access to spine procedures by addressing clinical variations	Clinical variations (procedure, region, demographics)	Improved safety and standards

Objective	Performance Measure/ KPIs	Benefit
Healthcare Costs e.g. hospital, surgical, imaging, pathology etc		
Identify potential cost savings to community and healthcare system	Economic benefits measures: direct and indirect, cost savings, cost-benefit analysis, ROI, productivity	Reduced variances in spine surgery (outlier management)
Epidemiology e.g. patterns of health care – variations in treatment		
Understand the national burden of disease associated with spine problems	Population measures – burden of disease e.g. DALY, YLL, YLD, HALE, QALY	Better patient care
Registry Operations		
Efficient and effective clinical quality registry operations	Data quality and management KPIs Safety and quality benchmarks	Cost-effective data collection, analysis and reporting of spine surgery data to monitor safety and quality, and patient outcomes for spine surgery Provision of tailored reports to stakeholders nationally and internationally, including industry
Identify research opportunities and support targeted clinical research in spine surgery	Research outputs (projects, observational studies, clinical trials, publications) Translation measures International collaborations	Increased research into spine surgery Facilitation of targeted research into spine surgery Increased international clinical and research collaboration More effective and rapid translation of research outcomes

1.30 ASR Strategic and Operational Objectives

In accordance with the strategic road map, the ASR Strategic Plan addresses ten key areas of strategic and operational importance to develop the registry. They provide the framework for the Stage 2 - Project Plan for national rollout, as follows:

1. Data Collection
2. Monitoring
3. Governance
4. Innovation
5. Patient Centricity
6. Clinician Engagement
7. Research
8. Information Resources - Access and Dissemination
9. Stakeholder Engagement
10. Sustainability

Organisational and operational objectives for each core area of activity are detailed below.

1.30.1 Data Collection and Management

(1) Increase the size of the datasets collected through the national rollout (20-30 surgeons per year on commencement of secure funding source).

(2) Determine the sources and reliability of data on patient complications through hospital EMRs or other databases to improve the accuracy and completeness of complication data. To be initiated in the next two years with a five-year target for completion.

(3) Improve data linkages to extract more detailed and accurate information on patient comorbidities, including data mining of EMRs or PBS data.

(4) Extend the ASR eligible population to include data from trauma and paediatrics patients, and those from non-English speaking backgrounds. To be initiated in the next two years with a 2-3 year target for completion.

(5) Set up routine processes for analysing data accuracy. Governance framework to be initiated immediately and this will be an ongoing process.

(6) Undertake six-monthly reviews of data items to further refine the minimum dataset.

1.30.2 Monitoring, Analysis and Reporting

(1) Develop new, clean patient cohorts for analysis. Ongoing as patient numbers increase but aiming for one new cohort per 2 years.

(2) Develop systematic monitoring processes to identify benchmarks, significant variations in surgical interventions, and patient outcomes to monitor quality of healthcare. This would enable the development an automated statistical portal/dashboard for real time access by participating surgeons (2022).

(3) Develop a communication policy to ensure hospital and government departments are kept up to date and aware of the potential outputs of the ASR.

(4) As the database expands, there will be improvements in the statistical analysis in a manner that is relevant to each stakeholder group. This may include hospital reports, industry reports as requested. These reports would allow hospitals to analyse clinical variation in comparison to the national dataset. Set up the reporting infrastructure – 2022

(5) Improve the ability to risk adjust through researching the process and discussing with the relevant stakeholders. To be initiated in the next two years with a five-year target for completion.

1.30.3 Governance

(1) Review legal entities and develop governance and frameworks – policies, procedures and protocols, and operating rhythms for all ASR structures.

(2) Establish Research and Data Governance Committee to manage data requests (2021). Develop research strategy, polices, protocols, infrastructure and capabilities to provide a foundation on which nested and independent clinical intervention or other studies can be undertaken.

(3) Establish Stakeholder Advisory Committee and determine terms of reference.

(4) Establish ASR User Group and guidelines and determine terms of reference.

1.30.4 Innovation

Expand ITC and digital capabilities and expertise:

(1) Develop data linkages, integration and interoperability with other health related and government agencies within the national healthcare digital information system.

(2) Continue to monitor developments in spine and other clinical registries nationally and internationally, and trends and innovations in digital health.

(3) Explore collaborations with other clinical registries e.g. Victorian Trauma Registry, AOANJRR, and internationally – CSORN, Swespine.

(4) Develop digital enablement and automation features of data collection system – SMS, email, hand-held devices etc.

(5) Ongoing development and customisation of KEOPs software e.g. navigational improvements, development of ASR specific patient questionnaires via the KEOPs interface.

(6) Develop middleware/API to enable data transfer from practice management software to KEOPS.

1.30.5 Patient Centricity

(1) Optimize patient engagement and communications to maximise retention and PROMs completion rates.

(2) Continue to improve processes and enhance user-friendly interfaces for data collection via multiple channels to accommodate participating patient preferences.

(3) Translate patient communications to accommodate participants whose first language is not English.

(4) Nominate patient representatives for Steering Committee and Research and Data Governance Committee.

1.30.6 Clinician Engagement and Professional Development

Innovate value adding features and benefits for surgeons which can include:

(1) Simplification of ASR processes to maximise surgeon engagement and participation

(2) Endorsing ASR activities as part of the surgeon's CPD for AOA/SSA/NSA

(3) Assist surgeons with CPD certification

(4) Facilitation of surgeon credentialling within hospitals

(5) Processes and protocols to allow surgeons to interrogate their own data

(6) Protocols for the ASR to provide performance feedback and management

(7) Compliance feedback

(8) Clinician access to the database for research

(9) Benchmarking against the database

(10) Protocols for performance feedback and management

1.30.7 Research

(1) Establish Research and Data Governance Committee (see Governance)

(2) Increase collaboration with other international spine registries

(3) Continue to engage with Monash University to leverage their expertise

(4) Liaison with industry and other stakeholders in relation to registry research, analysis and reporting.

1.30.8 Information Resources - Access and Dissemination

(1) Maintain a rigorous program of publication

(2) Present at national and international conferences

(3) Expansion of the annual report

(4) Fee for service reporting to industry and other stakeholders e.g. regulators or industry requesting information concerning specific devices.

1.30.9 Stakeholder Engagement

(1) Establish Stakeholder Advisory Committee to ensure ongoing engagement and input from stakeholders (see Governance)

(2) Explore specific opportunities for collaborating in research

(3) Explore sponsorship with industry and stakeholders within the healthcare ecosystem.

1.30.10 Sustainability

(1) Obtain sufficient, secure long-term funding.

(2) Recruit appropriate expertise to support registry management and growth.

(3) Eliminate the burden of ethics and governance approvals through legislation.

(4) Increase surgeon involvement gradually 20-30 surgeons per year

(5) Achieve growth targets (patients and surgeons) to reach a viable threshold of statistical maturity and validity.

1.31 Challenges in Achieving Enrolment Targets

Many challenges have been met and lessons learned from the pilot.

The ASR has demonstrated the commitment, diligence and capability to deal with these challenges and risks in establishing registry activities, including:

- ongoing surgeon engagement and communication,
- ethics application and governance processes,
- surgeon and practice staff education and support,
- administrative support to fulfill compliance and audit objectives, and
- funding.

Unlike many registries commonly involving data mining of pre-existing databases and data sources, the ASR requires multiple collections of data directly involving patients and surgeons. Pre- and post-operative follow-up of PROMs is a distinguishing feature of the ASR, but the whole data collection process is more time-consuming, exacerbated by unharmonized jurisdictional ethics approval processes, and the need for ongoing education and training programs to ensure data entry compliance and integrity. This requires additional resourcing, beyond that of simpler (data-mining) registry models.

The primary driver of growth is surgeon interest. A balance of recruitment across geographies, jurisdictions, insurance status, and consideration of other variables will need to be considered to ensure recruitment is representative to minimise selection bias and data distortion. ASR's national rollout framework and prioritisation criteria for enrolment of surgeons is attached in Appendix 5.

1.32 Stakeholder Analysis

Throughout the development and implementation of the pilot ASR has undertaken extensive consultation with primary stakeholders. This includes patient feedback on collection of PROMs data, and in-depth clinician input on customisation of KEOPS software and development of data collection processes in practice settings.

The ASR Protocol[72] was written in collaboration with Monash University in consultation with the Spine Society of Australia, and with reference to current literature. It was reviewed by Melbourne Health Human Research Ethics Committee. Also ACQSHC CQR guidelines and frameworks informed the development of registry requirements specifications, design, security compliance and infrastructure. [12]. Advice and expertise on spine registry best practice has also been sought from leading national and international registry authorities.

The Pilot itself has confirmed patient participation, clinician acceptability, and strong stakeholder interest and engagement. In Stage 2 - National Rollout the broad range and depth of stakeholder engagement will continue to be facilitated through strategic stakeholder engagement initiatives, and governance structures including:

- Steering Committee
- Management Committee
- Research and Data Governance Committee
- Stakeholder Advisory Committee, and
- User Group

The Research and Data Governance Committee and Stakeholder Advisory Committee will be established in Stage 2. In addition, a range of ongoing consultations, liaison and communications with stakeholders beyond these forums are planned, including presentations, publications, seminars, conferences, newsletters, annual reports, regular updates and roundtables.

The following tables show the extent of ASR stakeholder liaison and consultation undertaken in development of the registry (Table 8), engagement strategies (Table 9), and the potential range of benefits accruing to stakeholder groups from registry activity. (Table 10)

Table 8. ASR Stakeholder Engagement

Stakeholder Group	Consulted prior to Stage 1-Pilot	Involved in Stage 1-Pilot	Consulted prior to business case submission	Continuing consultation in Stage 2 - National Rollout
Consumers/Patients	×	Via Pilot feedback	Via Pilot feedback	✓
Surgeons/Clinicians	✓	✓	✓	✓
Professional Colleges/ Associations (SSA, NSA, AOA)	✓	✓	✓	✓
Hospitals and Healthcare Managers (public & private)	✓	✓	✓	✓
Industry (medical device companies)	✓	✓	✓	✓
Industry Associations (MTAA)	✓	×	✓	✓
Health Insurers	✓	✓	✓	✓
Researchers, Universities, Research Institutes	✓	✓	✓	✓
Regulators (TGA, AHPRA, ACQSHC)	✓	×	✓	✓
Federal & State Governments, & Health Departments	✓	×	✓	✓

Table 9. ASR Stakeholder Analysis

Stakeholder Group	Impact Overview	Engagement Strategy
Consumers/ Patients	Consultation with patients regarding patient outcomes, use of PROMs survey instruments, consent and privacy provisions. Before and during the Pilot, consumers have indicated a strong interest in being involved in the ASR. Patient input into development and design of the PROMs data capture methodology and use of digital technology has been important.	It is proposed to have a member on the ASR Steering Committee in Stage 2. In particular, consumers with a personal experience to provide feedback on the development of the ASR.

Stakeholder Group	Impact Overview	Engagement Strategy
Surgeons/ Clinicians	Consent of surgeons to participate and provide data to achieve adequate data completion and accuracy rates. Ongoing consultation with surgeons regarding changes and improvements to data recording, input processes, and embedding systems and processes in clinical practice settings. Consultation regarding customisation of KEOPS software and refinement of minimum data sets.	The Steering Committee includes 3 orthopaedic spine surgeons and 2 neurosurgeons. It is proposed that this will continue beyond the pilot phase. Inclusion of a representative on the Steering Committee, and Research and Data Governance Committee. Consultation in ASR design, governance and reporting to minimise data-collection burden, optimise reporting function for clinicians reviewing their individual performance, and to support audit requirements. Promotion of ASR participation through policy, indemnity and credentialing incentives. Regular updates and feedback to surgeons to ensure relevance and appropriateness of registry activities in meeting their patient information and clinical data needs.
Specialist Colleges and Societies	SSA has been instrumental in establishing the ASR Pilot and continues to offer strong advocacy and support for participation of its members in the Registry.	Inclusion of representative on Steering Committee. Several members of the Steering Committee have been involved in executive roles in professional societies. As part of its Strategic Plan, SSA will implement initiatives to inform members about the ASR, and facilitate engagement across a range of media, forums, conferences, and publications, nationally and internationally.
Hospitals/ Healthcare Managers	Support participation in the ASR and provide data collection infrastructure and data linkages. Consultation on integration with credentialing and reporting requirements. Explore comorbidity and other data requirements and linkages.	At present, ASR engages with hospitals in three ways: 1. Negotiation of hospital agreements, 2. Negotiation of ethics approvals, 3. Through direct liaison with surgeons at the particular hospital. In the future, the ASR will establish a Stakeholder Advisory Committee in which hospitals could participate.
Industry (medical device companies)	Provide an avenue for industry to access data, previously unavailable, for post-market surveillance of implants.	Continue to provide industry with an understanding of the aims of the ASR. Provide industry with device specific reports on request. In the future, ASR will establish a Stakeholder Advisory Committee in which industry could participate.

Stakeholder Group	Impact Overview	Engagement Strategy
Insurers	Provide an avenue for insurers to access data, previously unavailable, concerning efficacy of spine surgery.	In the future, the ASR will establish a Stakeholder Advisory Committee in which PHI industry could participate.
Researchers, Universities, Research Institutes	Monash University is custodian of ASR infrastructure and data and provides necessary support and expertise as partner with SSA. We will facilitate participation of the research community in the ASR as a platform and catalyst for the full range of nested and independent research opportunities. This could be assisted by Monash University resources. Monash also facilitates publication of registry outputs. The Monash Registry Sciences Unit facilitates communication across different registry platforms and allows the sharing of new ideas and innovations in registry science. Where members of the academic staff are involved with government, via taskforces, committees etc, they are a conduit to the relevant government departments and key government experts and opinion leaders.	Monash University is currently represented on the Steering Committee and Management Committee. Moving forward Monash will also be represented on the Research and Data Governance Committee. Currently, the ASR Academic Lead is head of the Monash Registry Sciences Unit, and the Registry Coordinator has an Adjunct Researcher position at Monash to optimise communication. Continue to work closely with Monash University to take advantage of its CQR and data expertise, registry infrastructure and support. Work with other research organisations interested in spine research to identify research opportunities.
Regulators and Government Bodies (TGA, AHPRA, ACQSHC)	Over time, the registry may become a data resource, previously unavailable to regulators, for example in monitoring of Class 3 prostheses.	Moving forward ASR will establish a Stakeholder Advisory Committee in which regulator representatives could participate. Ongoing consultation and liaison with ACSQHC, TGA, Australian Digital Health Agency and others.
Governments and Health Departments	Initial Phase 1 Pilot completed. Funding is required to develop and implement Phase 2 National Rollout of the Registry. Support implementation of ACSQHC care pathways and credentialing pathways through endorsement and resourcing within jurisdictions. Assist with determining efficacy of care pathways via registry data analysis.	Inclusion of commonwealth and state jurisdictional representatives on the stakeholder advisory committee. Ongoing consultation regarding ASR design, governance, and implementation.

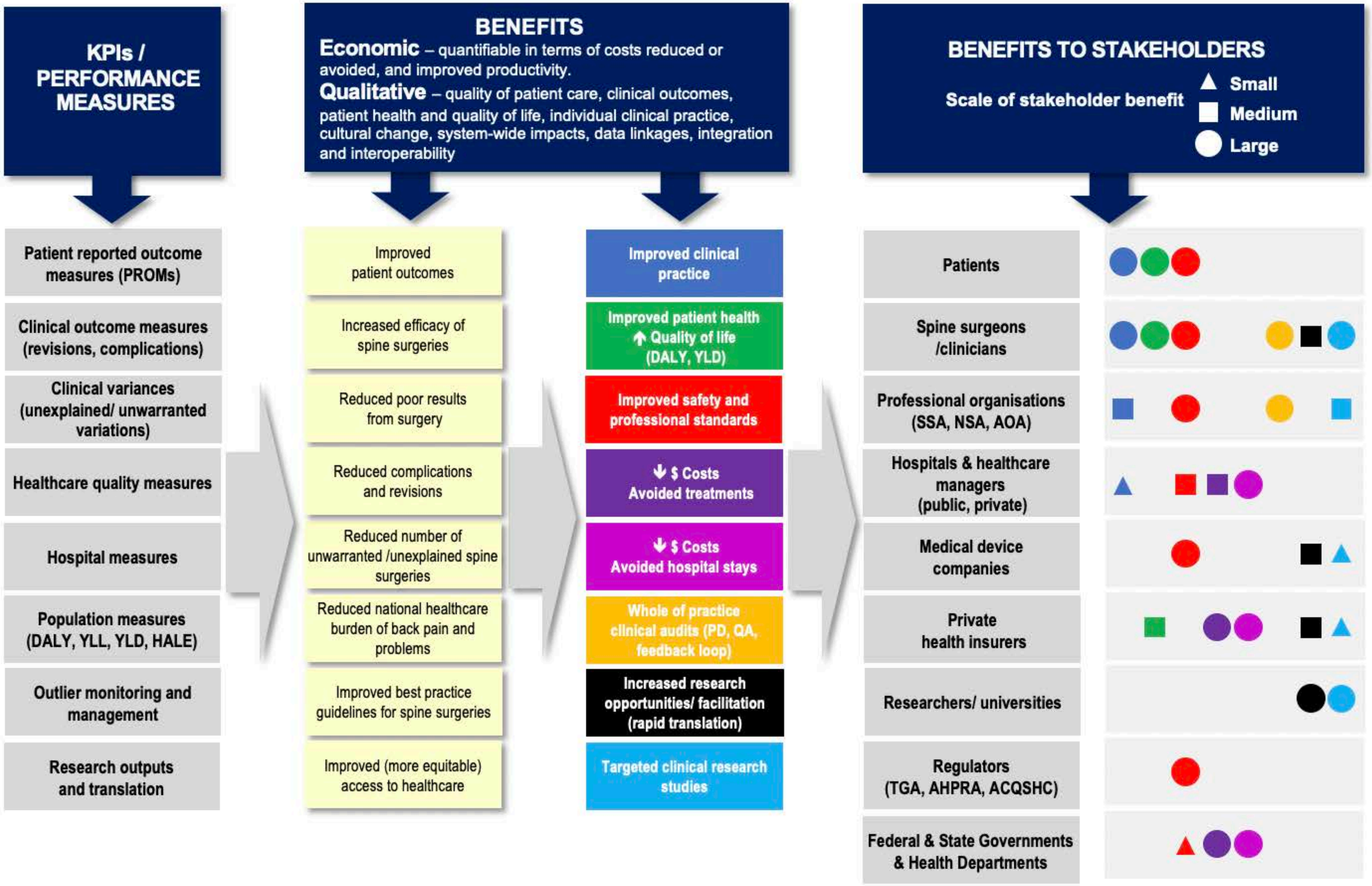
Table 10. ASR Stakeholder Benefits and Impact Analysis

Benefit		Stakeholder Group								
		Consumers	Surgeons	Colleges	Hospitals	Industry	Insurers	Researchers	Regulators	Governments and Health Departments
Quality of Life	Improved patient outcomes (PROMs)	●	●		○					
Clinical Efficacy	Improved clinical practice	●	●	●	●		●			
	Improved best practice guidelines for spine surgeries	●	●	●	●	◉	◉		●	●
	Reduced poor results from surgery	●	●		●	●	●			
	Reduced complications and revisions	●	●		●		●			
Safety and Quality	Reduced number of unwarranted/ unexplained spine surgeries	●	●	◉	◉		●	●	●	●
	Whole of practice clinical audits (PD, QA, feed-back loop)		●	●					●	●
	Device/ prostheses tracking and performance	●	●			●	●		●	●
	Improved safety and professional standards	●	●	●					●	●
Cost Savings	Reduced costs ($) - avoided treatments				●		●			●
	Reduced costs ($) - avoided hospital stays				●		●			●
Clinical Practice	Cultural change and system level benefits	●	●	●						
Research	Increased research opportunities/ facilitation/ collaboration (more rapid translation)		●	◉		●	○	●		
	Targeted clinical research studies (nested & independent)		●	◉		●	○	●		
Epidemiology	Improved population outcomes (DALY, YLD, YLL, HALE)	●	●				●			●
	Reduced national healthcare burden of back pain and problems						●			●
	Improved (more equitable) access to healthcare	●								●

Benefit Impact

● Significant ◉ Moderate ○ Some

Figure 18. Stakeholder Benefits Map



KPIs / PERFORMANCE MEASURES

- Patient reported outcome measures (PROMs)
- Clinical outcome measures (revisions, complications)
- Clinical variances (unexplained/ unwarranted variations)
- Healthcare quality measures
- Hospital measures
- Population measures (DALY, YLL, YLD, HALE)
- Outlier monitoring and management
- Research outputs and translation

BENEFITS

Economic – quantifiable in terms of costs reduced or avoided, and improved productivity.

Qualitative – quality of patient care, clinical outcomes, patient health and quality of life, individual clinical practice, cultural change, system-wide impacts, data linkages, integration and interoperability

- Improved patient outcomes
- Increased efficacy of spine surgeries
- Reduced poor results from surgery
- Reduced complications and revisions
- Reduced number of unwarranted /unexplained spine surgeries
- Reduced national healthcare burden of back pain and problems
- Improved best practice guidelines for spine surgeries
- Improved (more equitable) access to healthcare

- Improved clinical practice
- Improved patient health ↑ Quality of life (DALY, YLD)
- Improved safety and professional standards
- ↓ $ Costs Avoided treatments
- ↓ $ Costs Avoided hospital stays
- Whole of practice clinical audits (PD, QA, feedback loop)
- Increased research opportunities/ facilitation (rapid translation)
- Targeted clinical research studies

BENEFITS TO STAKEHOLDERS

Scale of stakeholder benefit ▲ Small ■ Medium ● Large

- Patients
- Spine surgeons /clinicians
- Professional organisations (SSA, NSA, AOA)
- Hospitals & healthcare managers (public, private)
- Medical device companies
- Private health insurers
- Researchers/ universities
- Regulators (TGA, AHPRA, ACQSHC)
- Federal & State Governments & Health Departments

1.33 Target outcomes

1. Stage 1 - ASR Pilot (completed)
2. Business Case - Stage 2 National Rollout (submitted)
3. Stage 2 - National Rollout (subject to funding)
4. Further stages in registry development - see Figure 16

1.34 Project Milestones and Budget: Stage 1 and Stage 2

Stage 1 project milestones and expenditure are summarised in Table 12 with a more detailed schedule included in Appendix 6.

A Stage 2 schedule of milestones, deliverables, timeframes and summary budget are set out in Table 13.

Table 11. Stage 2 national rollout targets for surgeon participation and patient enrolments, 2021-2030

	Year	Surgeons participating	Percentage of total surgeons (N=323)[2]	Total spine surgeries per year[3, 4]	Estimated patient enrolments[5]
Stage 1 Pilot	Y0 - 2020	15[1]	5	57,539	2,037
Stage 2 National Rollout	Y1 - 2021	37	8	59,265	8,352
	Y2 - 2022	63	20	61,043	19,491
	Y3 - 2023	89	27	62,874	35,700
	Y4 - 2024	115	35	64,761	57,272
	Y5 - 2025	141	43	66,703	84,515
10 Years	Y10 - 2030	271	90[6]	77,328	317,526

Assumptions

[1] Surgeons currently participating in pilot.

[2] Total number of surgeons remains constant over decade (N = n + additions - attrition).

[3] Total spine procedures 2018-19 (AIHW Hospital Separations, 2020).

[4] Total spine procedures increase 3% per annum.

[5] Patient enrolments are cumulative.

[6] 10% of surgeons remain non-participants.

Table 12. Project Milestones and Budget: Stage 1 Pilot

STAGE 1 – ASR PILOT			
Key Milestones	**Deliverable**	**Timeframe**	**Funding**
• Initial discussions between SSA and Monash University, February 2014 • Contract signed between SSA and KEOPS (software provider) 2014 • ASR Pilot Proposal and Protocol approved by SSA, April 2016 • Initial ethics approved (Lead HREC-NMA), August 2016 • Registry Coordinator appointed, February 2017 • Contract signed between SSA and Monash University (to agree data custodianship), February 2017 • Governance and operations established – Steering Committee convened, February 2017 • Pilot commenced, first patient enrolled, 13 surgeons, 15 January 2018 • Pilot concluded, 2037 patients, 31st October 2020 • Annual reports published 2018, 2019 • Evaluation of ASR Pilot, October 2020	• Pilot proposal • Pilot Protocol • Pilot Project Plan • Primary Ethics Submission and Approval • Site specific submissions and approvals (x13) • Contract with Monash University • Contract with SMAIO (KEOPS) • Licence agreements (paper and electronic) for all PROMs survey instruments • ASR registry communications package • (For a full list of Stage 1 deliverables for pilot launch see Appendix 6) • ASR Pilot Evaluation and Outcomes Report	Initiation and Planning phase: 2014-2018 Pilot phase: 2018-2020	Funding support • BUPA • De Puy-Synthes • HCF • Life Healthcare • Medtronic • Nuvasive • SSA • Stryker • Zimmer Biomet
SSA approves business case for national rollout of ASR	Business Case: ASR Stage 2 - National Rollout	March 2021	
		Sub-total (Stage 1 - 2016-2020)	**$638,000 ***

* Note: An additional $100,000 was paid by BUPA directly to Monash University for purposes of supporting the development of the ASR.

Table 13. Project Milestones and Budget: Stage 2 National Rollout

STAGE 2 – NATIONAL ROLLOUT			
Key Milestones	**Deliverable**	**Timeframe**	**Funding**
Project Management The ASR will rollout Stage 2 in line with a detailed project plan incorporating the following milestones and deliverables.	**Stage 2 National Rollout – Project Plan**	**2021**	
Implementation of National Rollout is based on the findings and experience of ASR Pilot and study evaluation, and in accordance with ASR Strategic Plan 2020-2030.	**Indicative Targets – 2021-2025** (See Table 11: Stage 2 Projections for details) • Surgeons participating - 43% • Estimated database - 65,000-70,000 patients • 14 surgeons currently participating in pilot. • 37 surgeons participating end Year 1 (8% of surgeon population) • 63 surgeons participating end Year 2 (20% of surgeon population) • 89 surgeons participating end Year 3 (27% of surgeon population) • 115 surgeons participating end Year 4 (35% of surgeon population) • 141 surgeons participating end Year 5 (43% of surgeon population)	2021-2025 2021 2022 2023 2024 Dec 2025	

STAGE 2 – NATIONAL ROLLOUT

Key Milestones	Deliverable	Timeframe	Funding
Data collection • Continue to implement data collection practices and protocols established in pilot phase. • Explore methods of improving patient and surgeon compliance. • Streamlining process to minimise administrative burden, working toward achieving fully digital data collection. • Examine other PROMs instruments for possible inclusion. • Explore options for developing linkages with other data bases (registries and healthcare information system agencies).	• • Data collection is 95% digitally enabled i.e. paperless by year end of 2023 • Maintain patient and surgeon data entry compliance above 90% • Feasibility plan evaluating data linkages with PBS, and other data bases by December 2021	Dec 2023 Dec 2021	
Data quality management including auditing • Active management of database and review of site data completeness and follow up with sites, in order to maximise data completeness and quality on a regular basis. • The registry recognises that as the number of surgeon participants grows, the burden of meaningful audits becomes an increasingly onerous administrative task. The issue of data linkage and integration between hospitals, surgeon practices (practice software e.g. Genie and KEOPS), and the ASR therefore is critical, in the future. Programmed data feeds, data-matching, and exceptions reporting will be explored to enable auditing procedures to be carried out in an effective, efficient and timely manner. • Determine feasibility of automating registry audit processes.	• Continue to implement data quality management practices and protocols established in pilot phase. • Surgeon practice audits - a target of 25% of new participating surgeon to be audited to ensure compliance with data entry requirements. • 7.5% of existing participating surgeons to be audited to ensure ongoing data completeness and accuracy. • Automated registry audit processes.	Ongoing Annual targets	
Stakeholder engagement and communication Stakeholder engagement will continue via a range of mechanisms, including:			

STAGE 2 – NATIONAL ROLLOUT			
Key Milestones	**Deliverable**	**Timeframe**	**Funding**
(1) Formal governance forums - Ongoing Steering Committee meetings including at least one fact-to-face annually. - Establishment and formalisation of charters for Research and Data Governance Committee, User Group, and Stakeholder Advisory Committee.	- Stakeholder Engagement Strategy - Governance structures, policies, procedures and operating rhythms.		
(2) Communications and presentations - Newsletters - Site visits and presentations - Presentations at group conferences and other forums, including government and safety and quality forums – podiums, posters and publications. - Patient-focused material on website - information, education and resources. - Industry/clinical group engagement seminars. - National ASR forums bringing together key stakeholders to discuss data collection, registry progress, changes and improvements, and research opportunities.	- ASR website, research papers and publications, conferences, seminars and other outputs.		
Database development - Development of data collection and management tools and ongoing IT support. - Examine feasibility of cloud-based servers. - Software program secured - KEOPS purchase negotiated.	- Improved data collection and management tools - Feasibility Report – migration to the cloud, cloud-based servers - Contract for purchase of KEOPS	Ongoing When required Y1	
Data analyses and reporting **(1) Data reporting** Continue annual data report and 6 monthly infographics reports and newsletters during Stage 2 rollout and beyond.	- Six monthly reports - Regular newsletters	As scheduled/ ongoing	

STAGE 2 – NATIONAL ROLLOUT

Key Milestones	**Deliverable**	**Timeframe**	**Funding**
(2) Site reports Hospital site specific reports can be provided to the hospital, on request, once minimum case load volumes per site are achieved (i.e. total cases for specific procedure cohorts reaches 50 cases per site). Following initial site report, annual reporting can be provided to monitor changes and improvements.	• Site specific reports	As requested	
(3) Surgeon reports Surgeon specific reports will be developed for individual feedback and peer group benchmarking. **(4) Expansion of data cohorts** • Patient cohorts and indications will be expanded to include paediatric, spinal trauma and NESB patients. • Extra procedure cohorts will be analysed as data becomes available.	• Surgeon specific reports • Expanded data cohorts	Y1 Y1 - spinal trauma Y1/2 - major NESB patient cohorts (initially Greek, Italian) >Y2 - other cohorts	
(5) Procedures Continue to refine reporting of procedures. The ASR is currently collecting data on all spine surgery (cervical, thoraco-lumbar, deformity). Due to the diversity of spine surgery, the registry has initially focussed on discectomy, anterior cervical discectomy and fusion (ACDF) and L4-L5 spondylolisthesis, with only the discectomy cohort yielding sufficient participant numbers during the pilot for accurate data analysis. Over time, as participant numbers grow, analysis will be extended to cover other procedure cohorts.	• Increased coverage of spine surgery procedure cohorts	Ongoing as database develops and matures	

STAGE 2 – NATIONAL ROLLOUT			
Key Milestones	**Deliverable**	**Timeframe**	**Funding**
(6) Device surveillance • Explore feasibility of device barcoding for tracking and surveillance. • Analysis of PROMs data concerning Class III devices as data becomes available.	• Feasibility Report • Class III data collection, analysis and reporting	Y1-2	
(7) Revisions monitoring Monitoring of revisions and complications is usually a reasonable indicator of success or otherwise of spine surgical intervention, and will continue to be refined.	• Revision data collection, analysis and reporting	Ongoing as database develops and matures	
The ability of the registry to monitor revisions will have limitations: • Lack of universal coverage of surgeons by the registry • Referral biases of surgeons involved in the surgery • Inadvisability of revisions for some patients due to general patient factors (frailty, comorbidities etc) • Inadvisability of surgical procedures due to specific surgical difficulties (e.g. risk of vascular injury with lumbar disc replacement) However, as a PROMs based registry, the ASR has the advantage of monitoring patient reported outcomes which are a relevant and accurate measure of the success of surgical intervention. This will be a significant development in monitoring potentially unwarranted or unexplained clinical variation.			
(8) Complications monitoring It has been acknowledged that the complications of spine surgery are usually under-reported.[81] Whilst surgeons have the capacity to record complications many may not be recorded as the complication: • Does not have any impact on clinical or patient outcomes,	• Complications data collection, analysis and reporting	Ongoing as database develops and matures	

STAGE 2 – NATIONAL ROLLOUT			
Key Milestones	**Deliverable**	**Timeframe**	**Funding**
- May occur after the initial data entries, which may not be revised or updated. Therefore, processes to establish data linkages with hospital EMRs will be explored in order to provide a more complete picture of peri-operative complications and adverse events.			
(9) Ad-hoc data request management The registry will produce a range of regular reports as well as responding to ad hoc data requests. The Research and Data Management Governance Committee will develop policies, procedures and protocols to manage all data requests, including ad hoc requests. This will minimise potential misuse of the data.	- Ad hoc data analysis and reports	As requested	
Using the internationally recognised Five-Safes disclosure risk management framework, ASR will apply safeguards that can be dialled up or down as appropriate depending on data sensitivity and privacy needs. Consistent risk management will help prevent data misuse or unintentional disclosure and ensure data privacy and security are maintained.			
Reporting requirements to funder The registry will continue to produce Annual Reports. As the registry data-base grows and matures the extent and depth of analysis and reporting will increase accordingly. Progress reports will be provided as required.	- Annual Reports	As scheduled	
Registry funding - assessment of cost-recovery funding model The registry pilot phase has been supported by individual time-limited grants, primarily from device manufacturers, with lesser amounts from private health insurers. This process has been very time-consuming and a significant administrative burden involving regular application, re-application, and contract negotiation. Leadership of this has been done on a pro-bono basis and is unsustainable into the future. It is essential therefore that an alternative funding model is instituted.	- Appropriate Federal Government funding for five years to achieve national rollout.		

STAGE 2 – NATIONAL ROLLOUT			
Key Milestones	**Deliverable**	**Timeframe**	**Funding**
The availability of a significant amount of data in freely available annual reports will limit the scope for chargeable ad hoc reports. Therefore, the majority of ongoing funding will need to come from secure sources, namely government, in the short to medium term. In the longer term, Government may implement a cost-recovery funding model, for instance via a levy on device manufacturers or insurers. It should be noted in the aftermath of the COVID-19 crisis, device manufacturers and distributors will be much less enthusiastic than they have been to date, about discretionary spending, such as registry support.			
Resourcing for growth and expansion of ASR beyond the five-year plan for national rollout. This is dependent on development of a funding model to secure long term sustainable resourcing of the ASR (We are willing to contribute to this process.)	• National coverage with a target of 90% enrolment of all surgeons. See Figure 16: Strategic Road Map)		
Sub-total (Stage 2)			**$5,944,250**
Total (Stage 1 and 2)			**$6,582,250**

Section 7:

Stage 2 – Governance and Management Framework

STAGE 2 – GOVERNANCE AND MANAGEMENT FRAMEWORK

1.35 Project Governance

The Steering Committee commenced operation in 2016 with its first task being the initiation and planning of the Stage1- Pilot. The Management Committee and User Group were established at the start of the pilot. Stage 2 will see establishment of a Research & Data Governance Committee and a Stakeholder Advisory Group. The project will be managed by a Project Manager working with the ASR Manager and reporting into the Management Committee on operational matters, and ultimately accountable to the Steering Committee.

Table 14. Project Governance

Role	Name	Primary Responsibility / Expertise
Project Sponsor	Spine Society of Australia	Appointment of ASR Clinical Lead, and Steering Committee in accordance with the ASR Terms of Reference
Business Owner	Australian Spine Registry	Oversight of ASR and Stage 2 – National Rollout Project
Registry Custodian	Monash University	Manage ASR registry database – data storage, safety, security and provide analytical support services
Steering Committee	**Eight members**	Leadership and oversight of: ASR strategy, priorities, and performance Stage 2 – ASR National Rollout Project
	Michael Johnson	Clinical Lead and Chair Orthopaedic surgeon Previous President, SSA Chair, Spine MBS Clinical Committee Past Chair, AOA/NSA PFET Committee Past Chair of Professional Conduct and Standards, AOA
	Susannah Ahern	Academic Lead Professor (Practice) Divisional Co-Head, Clinical and Health Data Outcomes Innovation and Research (CHOIR) Head, Clinical Outcomes Data Reporting and Research Program (CORRP) (Formerly Registry Science and Research) Course Coordinator, Master Health Service Management/Master Health Administration Courses
	John Cunningham (OAM)	Orthopaedic surgeon Member, AOA/NSA PFET Committee
	Rob Kuru	Orthopaedic surgeon Member SSA Board, Vice-President SSA
	Kevin Seex	Neurosurgeon Clinical Associate Professor, Department of Clinical Medicine Macquarie University Treasurer, SSA

Role	Name	Primary Responsibility / Expertise
Steering Committee (cont'd)	John McNeil (AM)	Physician Emeritus Professor (former Head of School of Public Health & Preventative Medicine, Head of Department of Epidemiology and Preventative Medicine, Monash University)
	Ilana Ackerman	Associate Professor (Research), Public Health & Preventative Medicine, Monash University
	TBC	Patient/consumer representative
	Esther Apos	Registry Coordinator and Committee Secretary Adjunct Research Fellow, Monash University
Research & Data Governance Committee	TBC when committee is convened	Responsible for development of ASR research and data strategy, priorities, policies, procedures, protocols, privacy and security. Chair and Deputy Chair SSA - Orthopaedic surgeon SSA – Neurosurgeon Monash University Biostatistician Patient/consumer representative Registry Coordinator/Ethics
Stakeholder Advisory Group	Convenor SSA Monash University Medical device companies, MDM, MTAA Private health insurers/ PHA Public hospitals Private hospitals/APHA Consumer representative Government - DoH, DHHS Other registry groups with allied interests e.g. VOTOR, AOANJRR.	Provides input to ASR in meeting stakeholder data needs and innovation. Offers a forum for discussion and updating on ASR activities and initiatives. Canvases opportunities for improving data linkages, integration and interoperability.
User Group	Participating surgeons	Provides a forum for direct feedback from SSA members and practice staff to improve KEOPS usability, and data accuracy and compliance.

Project Team - ASR Resources		Primary Responsibility/Expertise
Management Committee	Chair of Steering Committee /Clinical Lead	Michael Johnson
	Academic Lead	Susannah Ahern
	Registry Manager	TBC
	Project Manager	TBC
Registry Manager	TBC	Responsible for overall management of registry. Reports to ASR Steering Committee
Project Manager	TBC	Responsible for Stage 2 - National Rollout Project. Reports to Registry Manager.
Research Officer/ Project Support	TBC	Undertakes research and related activities as directed by the Registry Manager. Assists the Project Manager as required.
Administration/ Research Assistant	TBC	Provides administration and support to the Registry Manager and Steering Committee. Assists the Project Manager as required.
Biostatistician	TBC	Provides data analytical capabilities to support ASR data collection, analysis and reporting requirements. Monash University
IT Support & Programming	Monash University	IT infrastructure and data security
	SMAIO	IT /programming and support

1.36 Quality Management

In 2017 the ASR Steering Committee engaged a Registry Coordinator (0.4EFT) to initiate and establish the Stage1 Pilot in accordance with the ASR Protocol and detailed project plans.

Similarly, the Stage 2 – National Rollout will be based on detailed workplans, timelines and reporting periods in accordance with the milestones in Table 13. The work plan will be developed according to a critical path management methodology. A Project Manager will be appointed to manage project implementation.

The program will be overseen by the Steering Committee. Any items in the work plan that are outstanding and risk delaying achievement of the milestone will be escalated to the Steering Committee to assess the impact and allocate resources where required to address barriers to completion of the item.

Any change in the project work plan requires approval by the Steering Committee (project owner), with ad hoc reporting to the SSA (project sponsor) to ensure ongoing guidance and support for the ASR.

1.37 Organisational Impact and Resourcing

The pilot has been stretched to achieve its objectives, with limited financial and human resources. Stage 2 National Rollout will require considerably more resources. Based on projected rollout the following resources will be required:

(1) Registry Manager

The Registry Coordinator position will be replaced by a full time, expanded Registry Manager role.

This role would be responsible for:

- Implementing strategic direction and planning as directed by the steering committee,
- Staff management and allocation of tasks,
- Staff liaison and support,
- Resource management,
- Budget oversight,
- Finance management,
- Updates to the steering committee,
- Communication and oversight of software development updates and continuous improvement including:
    - Exploring and identification of data linkages,
    - Data migration.
- Stakeholder engagement,
- Grant applications,
- Research opportunities both:
    - Registry generated,
    - External,
- Managing research projects,
- Publications
    - Annual report,
    - Newsletters,
    - Brochures,
    - Website,
    - Social media.
- Supervision of data analysis,

- Industry ad hoc reports,
- Liaising with other registries (national and international).

(2) Project Manager

The Project Manager is essential to coordinate and manage national rollout objectives.

This role would be responsible for:

- Site and surgeon onboarding and direct registry and general software support,
- Direct communication with hospitals and private practices,
- Completion of hospital specific contracts and ethics amendments/applications and ongoing ethics compliance/reporting,
- Coordination of governance arrangements and ongoing governance reporting,
- Feedback to surgeons for data compliance,
- Day to day communication with sites and surgeons to ensure registry operations are functioning,
- Day to day staff management and allocation of tasks.

(3) Research Officer/Project Support

The research officer/assistant will undertake research projects associated with ASR activities. Their roles and responsibilities will include:

- Identification of patients which require follow up (letters/phone calls)
- Follow up calls
- Data cleaning
- Data extraction and raw data analysis
- Liaises with KEOPs for updates
- Day to day running of communication activities as directed by the Registry Manager

(4) Administration Support

Administrative assistance has been essential to support the Registry Manager in undertaking pre-existing workload established during the pilot. This support role will assist all ASR staff and will be responsible for:

- registry materials (brochures, stationery, printing etc),
- Coordinating schedules and communications of the ASR manager and coordinator,
- document preparation and communications for meetings by the registry manager and clinical lead,
- coordinating travel arrangements,
- Assisting the research officer with follow up letters to patients and other mail outs as required,
- Manage communication/stakeholder database.

(5) Clinical Lead Support

Regular clinical support will be provided by the Clinical Lead in four areas:

- supporting national rollout,
- liaison with registry staff,
- liaison with surgeons,
- day to day clinical contact,
- research appraisal and facilitation.

(6) Academic Lead Support

Regular academic input (currently supplied by Monash) will be provided by the Academic Lead to:

- facilitate liaison between ASR and registry custodian (Monash),
- assist research appraisal and facilitation,
- ensure academic research oversight.

(7) Biostatistician/Data Analyst

ASR will leverage the expertise of the Monash Registry Sciences Unit by utilising inhouse data analysts who work across a range of local and international registries. This will be done on a contract basis as work demands.

(8) IT Support

Ongoing IT and programming support will be necessary for customisation of the KEOPS software program and development of data linkages, integration and interoperability. This will initially be done on a contract basis with SMAIO (the software vendor). It is envisaged that ASR will exercise its rights to purchase the software in the medium term, which will require a review of IT support.

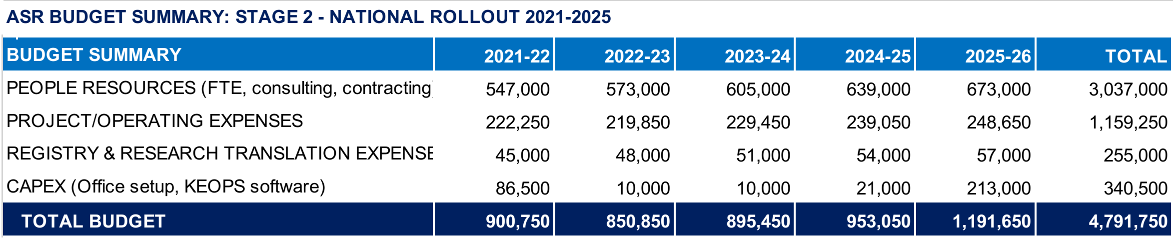
1.37.1 Leveraging Learnings from the Pilot

The Pilot has provided both proof of concept and capability, and an essential experience curve. Stage-2 will leverage the lessons learned and capitalise on the registry development expertise acquired during the Pilot, particularly by the incumbent Coordinator and Clinical Lead.

1.38 Budget

Table 15 summarises the financial resources required to implement Stage 2 - National Rollout. Figures are based on a detailed budgeting process, and reference to similar national registries. The budget is based on establishing the ASR as a standalone entity. Variations to the budget may be affected by alternative arrangements with hosting and academic partners. Full budget details are attached in Appendix 7.

Table 15. ASR Budget: Stage 2 – National Rollout 2021-2025



ASR BUDGET SUMMARY: STAGE 2 - NATIONAL ROLLOUT 2021-2025

BUDGET SUMMARY	2021-22	2022-23	2023-24	2024-25	2025-26	TOTAL
PEOPLE RESOURCES (FTE, consulting, contracting	547,000	573,000	605,000	639,000	673,000	3,037,000
PROJECT/OPERATING EXPENSES	222,250	219,850	229,450	239,050	248,650	1,159,250
REGISTRY & RESEARCH TRANSLATION EXPENSE	45,000	48,000	51,000	54,000	57,000	255,000
CAPEX (Office setup, KEOPS software)	86,500	10,000	10,000	21,000	213,000	340,500
TOTAL BUDGET	**900,750**	**850,850**	**895,450**	**953,050**	**1,191,650**	**4,791,750**

The budget provides for resourcing a Project Team as indicated above, (4FTE, contract/consulting services, and clinical and academic support), plus Stage 2 project/operating expenses, research translation costs, and initial capital expenditure necessary to establish a registry office and equip staff.

Professional representatives from the stakeholder groups will continue to provide in-kind support to contribute to the development of the ASR. The significant contribution of these representatives will continue to be recognised in publications and authorship on papers according to established guidelines. Consumer representatives will be recompensed for their meeting time as per agreed rates.

1.39 Funding Model

Clinical quality registries provide critical data for a range of healthcare stakeholders. Properly implemented, they catalyse research, support evidenced-base clinical practice, and underpin patient quality care. In the foreseeable future there is little likelihood of registries being self-sustaining.

It is therefore essential that funding is:

- **sufficient** to support and hasten growth and coverage in the drive to reach appropriate maturity and statistical viability.
- **appropriate** to meeting the needs of a growing organisation, financially capable of attracting the right people, and marshalling the resources necessary to meet its charter and vision, and
- **sustainable** to engage stakeholders and enlist clinicians who will need to be reassured that the investment of their time and efforts will be worthwhile and yield desired results.

It is clear, from the ASR pilot experience, that without proper funding for national rollout, relevant clinical data, and the associated economic benefits of the ASR, simply will not be realised.

It is essential that a long to medium term guaranteed funding source is required which should be at arms-length from stakeholders with a financial conflict of interest. It is the ASR's belief that the primary funder should be the Federal Government although some funding may be obtained from ad hoc industry reports.

Reliance on short term industry grants do not provide the financial security to maximise stakeholder engagement. Surgeons need to be confident that the ASR will be ongoing and that their data contributions will not disappear due to funding insecurity.

The government may elect to cost recover their funding contribution in a variety of ways.

Different models for funding registries have been considered. Table 16 illustrates one such model, involving a small levy on medical devices utilised in spine surgery. A Commonwealth levy of less than 0.5% over an initial five years, would provide a sufficient, appropriate and sustainable source of funding to ensure successful rollout and operation of the ASR. It could apply well into the future.

Other funding models could include a similar very small levy on private health insurers.

A bi-partisan approach with PHIs would further defray the level of contribution required to support the registry. Some registries are funded in this manner where the levy is generally accepted as a (minor) regulatory expense or cost of doing business.

Table 16. Illustrative Funding Model

FUNDING MODEL - MEDICAL DEVICE LEVY	2021-22	2022-23	2023-24	2024-25	2025-26	TOTAL ($)
Total ASR budget ($)	900,750	850,850	895,450	953,050	1,191,650	4,791,750
Annual medical device expenditure ($) (1) (2) (Implantable spine surgical devices)	250,000,000	257,500,000	265,225,000	273,181,750	281,377,203	1,327,283,953
DEVICE LEVY (%) REQUIRED TO FUND ASR	**0.36**	**0.33**	**0.34**	**0.35**	**0.42**	**0.36**

NOTES
1. APRA data indicates annual expenditure of $165m in 2019 for PHIs. Industry sources estimate total expenditure of $250m.
2. Assumes 3% annual growth in spine surgery device expenditure

1.40 Outcome Realisation

The Stage 1- Pilot has produced a viable model for patient and clinical data collection, analysis and reporting. Registry development has been supported by strong leadership and governance structures, project management discipline, and detailed protocols, as well as appropriate clinical and academic input and guidance. It has been enthusiastically endorsed by key stakeholders. Appropriate systems, processes, data security, customised software, and registry infrastructure are now in place and operational.

The Pilot Evaluation provides a high level of confidence that, with the establishment of these foundations, the ASR has a proven base on which to proceed to Stage 2 - National Rollout. The continuance of clear strategic intent, good governance and highly capable management, will ensure the full realisation of registry benefits through achieving Australia-wide coverage. Registry and research translational strategies and impacts identified in 1.11.3, further reinforce the likelihood of successful outcomes.

The partnership with Monash University provides ASR with access to the experience and expertise of the Registry Sciences Unit. This gives us further reassurance that the registry will be able to achieve its aims.

1.41 Post Project Review

A full review and evaluation of the Stage-1 Pilot has been completed. In Stage-2, the Project Manager will meet weekly with the Registry Manager, and provide monthly progress reports to the Management Committee, and quarterly updates to the Steering Committee. Reports will be structured as per the work plan milestones in Table 4. Incremental progress for each element will be documented in the following manner:

- Work carried out
- Barriers to completion
- Percentage complete
- Lessons learnt

An annual Project Status Report on Stage 2 National Rollout will be produced for the project's duration (five years), presented to the Steering Committee and incorporated in the ASR Annual Report. A copy of the Report will be forwarded to Australian Government Department of Health.

1.42 Risk Analysis

In managing risk, the ASR will undertake a range of activities that will enable it to respond to the impact of uncertainty on its objectives and activities. A risk management framework will be developed to enable ASR to respond to threats and opportunities as they arise, both externally and internally.

The Steering Committee will develop a Risk Management Strategy, and ensure appropriate policies, procedures, documents, processes, governance and resource capabilities are in place to manage risk, and support execution of ASR strategy, plans and projects. Risk management will be incorporated in the annual strategic planning process, and embedded in culture, policies and practices.

Initial ASR risk assessment identifies a number of risks requiring response and management. Priorities are listed in Appendix 8. Major risks to the operation and national expansion of the ASR are external factors, primarily associated with potential changes in national political policy and funding priorities. Most of the risks related to internal factors are common to other registries.

These risks will be eliminated, or minimised and effectively managed by strengthening the people and resource base of the registry with allocation of adequate, sustainable funding.

Section 8:
Summary

SUMMARY

Healthcare expenditure is continuing to outstrip national GDP. With an ageing population, it will be essential that we have the tools to balance the mounting challenge of healthcare resource allocations against the rising demand for spine surgery interventions. These are becoming increasingly more costly and complex.

An important question is ‘how can we minimise low value care, and maximise allocation of healthcare resources for maximum benefit of spine surgery patients’?

A clinical quality spine registry collecting data at the patient and clinical level will support robust analysis and research in spine surgery. This will assist consumers, surgeons, hospitals, industry and healthcare policy makers in navigating the resourcing challenges. The ASR is the most cost-effective solution to this problem.

Registry data will facilitate a granular and nuanced view of how to optimize the value of spine surgery. It will assist with assessing care pathways by identifying variance and focus on modifiable factors to achieve better patient outcomes.

The present system-derived data focuses on safety and process measures,[22] but does not provide actual outcome data at the patient and clinical level. This outcome data is essential to provide insights necessary to drive patient-centred, value-based care and reform.

The ASR will be at the forefront of delivering evidence to encourage spine surgical excellence, maximise patient outcomes, and drive change and improvement across the clinical domain of spine surgery. The ASR Pilot has provided unequivocal proof of concept and evidence of capability. We commend this business case for funding the Australian Spine Registry to launch a national rollout.

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[22] For example, data on claims, admissions, separations, DRGs or billing.

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Appendices

APPENDICES

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