AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

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Economic evaluation of clinical quality registries

Final report

Monash University and Health Outcomes Australia have prepared this report on behalf of the Australian Commission on Safety and Quality in Health Care.

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Level 5, 255 Elizabeth Street, Sydney NSW 2001

Phone: (02) 9126 3600
Fax: (02) 9126 3613

Email: mail@safetyandquality.gov.au
Website: www.safetyandquality.gov.au

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Preface

Clinical quality registries have attracted attention in Australia and internationally as a potential means of improving patient outcomes and the safety and quality of health care. However, historically, there has been relatively little work in Australia quantifying the value and benefits of clinical quality registries.

The Australian Commission on Safety and Quality in Health Care (the Commission) engaged Health Outcomes Australia, through Monash University, to evaluate the economic impact of five selected clinical quality registries in Australia. The Australian Government Department of Health provided funding for the study, with part of the work also funded by the Victorian Department of Health and Human Services.

The purpose of this preface, which is the work of the Commission rather than the report's authors, is to provide an overview of the project and how the findings may be used in future.

Key points

The study assesses the cost-effectiveness of five Australian clinical quality registries. Using a conservative methodology, it shows that Australian clinical quality registries have delivered significant value for money when correctly implemented and sufficiently mature.

The key findings of the study are:

- Each of the five clinical quality registries improved clinical practice at a relatively low cost, leading to a significant net positive return on investment.
- The return on investment varied between clinical quality registries, with benefit-to-cost ratios ranging from 2:1 to 7:1.
- The minimum expected benefit-to-cost ratio would be 4:1 if full national coverage were achieved by all five clinical quality registries.

While the analysis shows the potential economic benefit of clinical quality registries, the study notes that not every clinical quality registry will be cost-effective. Problems such as low coverage, inadequate reporting and inadequate collection of information about patient outcomes will limit the effect of some clinical quality registries, and their value to the health system.

The report also finds it is likely there are substantially more individual practitioner, cultural and system-level benefits that flow from the registries than are captured by the study, given the study's focus on financial benefits and costs under very conservative assumptions.

Conclusion

The Commission worked closely with the authors and sees this work as a valuable addition to the available literature on the benefits of clinical quality registries.

The findings from the five case studies included in the analysis provide evidence of the potential value of clinical quality registries, and represent the first time this sort of analysis has been conducted in the Australian context.

This report will be used to support the development of a national policy context for clinical quality registries.

Economic evaluation of clinical quality registries

Australian Commission on Safety and Quality in Health Care

Monash University and Health Outcomes Australia

Contents

Executive summary

This study aimed to provide an objective economic basis to support future registry investment, and develop and articulate a methodology for other registries to assess their impact and cost-effectiveness.

The study focussed on financial costs and benefits and found significant net positive returns on investment for each of the registries under very conservative assumptions of attribution. Substantial benefits were measured reflecting improvements to clinical practice and outcomes over time. These included enhanced survival, improvements in quality of life and avoided costs of treatment or hospital stay.

Because the study focussed on financial benefits and costs under very conservative assumptions, there are substantially more individual practitioner, cultural and system level benefits than the evaluation captures.

The registries had benefits including enhanced survival for patients, improvements in quality of life and avoided costs of treatment or hospital stay. There are broader clinical quality registry functions that drive continuous improvement and maintenance of safety and standards.

- The link between registries and clinical trials allows rapid translation of research into practice (most of the registries are associated with clinical trial groups where evaluation of clinical problems within the Australian health care system are investigated).
- As Australia moves towards re-certification of practitioners, registry data, particularly where it assesses patient outcomes, will be increasingly important in ensuring quality of care delivered by individual practitioners and their teams; clinical quality registries help deliver quality assurance of the clinical teams that are contributing to the data sets.
- The action of a clinical team contributing to a registry results in a substantial contribution to standardisation of care, with additional benefits around team collaboration, sharing of information and team communication.

The study conservatively evaluated five registries that have had a measurable influence on clinical practice. The analyses focussed on a selection of indicators within each registry (based mainly on data availability) not the complete set of indicators measured by each registry. The evaluations should be viewed as case studies showing that registries, when correctly implemented and sufficiently mature, have delivered significant value for money.

There is likely to have been considerable clinical, societal and economic benefit driven by continuous improvement and changes in practices motivated by registry data and functions. However, the study presents only incremental benefits that can be attributed independently to each registry, rather than other influences on practice, such as guidelines, novel therapies or newly published trials.

Not every registry will be cost effective. Problems of low coverage, inadequate feedback and constrained outcome measures still limit the impact of many registries.

An internal rate of return of between 23-52% was measured in the Victorian Prostate Cancer Registry (Victorian PCR), Victorian State Trauma Registry (VSTR), Australia & New Zealand Intensive Care Adult Patient Database (ANZICS APD), Australia and New Zealand Dialysis and Transplantation (ANZDATA) Registry, and the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). This finding persists under a range of

assumptions on the value of a life year, and even though some potential benefits remain unmeasured. Typically, registry costs were under $1 million a year for operation, including set-up costs, but with varying scope of coverage.

Evaluating the stand-alone impact of a registry is challenging, as there is generally no comparable data on outcomes amongst non-registry participants. By selecting suitable control groups, the study isolated and quantified the incremental benefits of particular registry activities, in particular unit-level feedback, (e.g. feedback of clinical indicators through the Victorian PCR and ANZDATA) individual clinician level feedback (e.g. on surgical revision rate for AOANJRR) and active structured outlier identification and reporting (e.g. Case Review Group feedback for VSTR and the Outlier Management Program for ANZICS APD).

A brief summary of the findings are shown in Table 1 below. More details on the evaluation and results are in the main body of this report and its appendices.

Table 1: Summary results of the evaluation of five selected clinical quality registries[1]

Registry	Net benefit	Benefit to cost ratio	Summary of method
Victorian Prostate Cancer Registry (Victorian PCR)	$2.4 million	2:1	Economic value is measured through reduction in positive surgical margin rate and reduced active intervention in low risk patients. Period of analysis was five years, from registry inception and subsequent coverage of a threshold of hospitals, to latest available data.
Victorian State Trauma Registry (VSTR)	$30 million	6:1	Economic value is measured through reduction in in-hospital mortality and average length of stay. Period of analysis was nine years, from date of full patient coverage to most recent available data.
Australia and New Zealand Intensive Care Adult Patient Database (ANZICS APD)	$26 million	4:1	Economic value is measured through the reduction in ICU mortality and average length of stay. Period of analysis was 14 years, from earliest to most recent available published and verified data.
Australia and New Zealand Dialysis and Transplantation Database (ANZDATA)	$49 million	7:1	Economic value is measured through reduction in dialysis mortality, transplant graft loss and incidence of peritonitis. Period of analysis was 10 years from earliest available to most recent published data.

[1] Summaries of the case studies are presented in Appendix A

Registry	Net benefit	Benefit to cost ratio	Summary of method
Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR)	$53 million	5:1	Economic value is measured through reduction in revision burden in hip and knee replacement surgery. Period of analysis was 13 years, from date of full national coverage to most recent published data. Supplementary analyses for this case study showed a range of potential benefit of up to $143 million based on well-known vignettes demonstrating a reduction in use of specific hip and knee devices identified through the registry as having an unusually high rate of requiring revision surgery. Beyond these individual examples of specific devices, the overall benefit measured by the registry over time was more than $600 million when the hip and knee surgery revision rate over time in Australia was compared to international benchmarks.

The findings above were extrapolated to estimate the indicative potential benefit achieved with full national coverage – that is, with participation of the entire eligible clinical population nationally. The main assumptions in this are of a commensurate increase in benefits with an increase in the number of patients covered, and a crude estimate of the proportion of fixed and variable costs of registry operation.[2] Results are presented in Table 2, below.

[2] Based on 30% variable (data collection and analysis) 70% fixed costs; as indicated in the Victorian PCR. Benefits calculated at single patient level are multiplied based on percentage coverage in the eligible national population.

Table 2: Extrapolation of the findings to estimate the indicative potential benefit achieved with full national coverage

Registry	Current national coverage	Current benefits	Current costs	Current BCR	Extrap-olated benefits	Extrap-olated costs	Extrap-olated BCR
Victorian PCR	11%	$5.2m	$2.7m	2:1	$44m	$8.9m	5:1
VSTR*	25%	$36m	$6.5m	6:1	$147m	$12m	12:1
ANZICS	80%	$36m	$9.8m	4:1	$45m	$11m	4:1
ANZDATA**	100%	$58m	$8.8m	7:1	$58m	$8.8m	7:1
AOANJRR**	100%	$65m	$13m	5:1	$65m	$13m	5:1

BCR = benefit: cost ratio; current = current evaluation (gross benefits); extrapolated = extrapolation to full national coverage
*crude estimate. Likely overestimate due to assumption of starting from zero coverage in other states. In reality, there is some existing coverage with different definitions of “major trauma”
** Extrapolated benefits are equal to current benefits due to current national coverage

The crude extrapolation analysis shows that, if full national patient coverage is achieved, where not currently present, there is likely to be a minimum expected benefit to cost ratio of 4 to 1.

An additional analysis performed on the AOANJRR case study demonstrates wider benefits. The study examined additional improvement in surgeons that logged in to view their individual outcomes feedback compared to those that did not. The reduction in use of one hip and one knee device class identified by the registry suggests an additional benefit of $78 million compared to the international benchmarks. Over the time Australia experienced a decline in burden of revision in hip and knee arthroplasty, the revision rate has increased in the US, which does not have a full national registry, and the UK, which has a less effective national registry. As Australia avoided a similar increase, and experienced a reduction in the revision burden, if the reduction alone were to be attributed to the AOANJRR, it would be equivalent to a benefit of $618 million from 1999 to 2014.

Conclusions

Registries, when sufficiently funded and operated effectively, improve the value of healthcare delivery at a relatively low cost. By increasing the availability and use of process and outcomes data, investment in registries is likely to deliver strong economic returns on investment.

Sustainability of funding and resourcing are ongoing challenges for many registries. These challenges often prevent registries from achieving the scale required to make full use of the data they have collected in order to generate reliable reports, influence clinical practice and improve patient outcomes. Relatively small injections of funding to aggregate and boost existing efforts are likely to be highly cost-effective (e.g. expanding a registry’s coverage from state to national). In addition to a likely economic return on investment, benefits to funders include the receipt of reliable performance data on health outcomes.

Registry impact is apparent where timely and reliable feedback (reporting) of health outcomes data is provided to clinicians. Registry impact (and in turn, funding) is likely to improve where reporting includes health system managers and payers.

Background and objectives

Project background

CQRs provide information to identify benchmarks, significant outcome variance, and inform improvements in healthcare quality. Well-designed CQRs are an increasingly important component of clinical practice and health system monitoring. The provision of timely, relevant and reliable feedback on patient care to clinicians drives improvements in healthcare quality. Improved reporting of registry information on the appropriateness and effectiveness of care is likely to improve adherence to evidence-based practice and clinical outcomes.

National registries have the added advantage of scaled central functions and ability to track variation in outcomes at multiple levels.

In July 2015, the Department of Health and the Commission contracted Monash University and Health Outcomes Australia to help provide further evidence of the economic value of high priority CQRs, through case studies examining the value created by five existing registries in Australia. This report is the result of work undertaken as part of a broader suite of projects to enhance knowledge of the use and value of CQRs.

The Commission developed the Framework for Australian Clinical Quality Registries in collaboration with states and territories and expert registry groups.[3] The framework was endorsed by the Australian health minister's advisory council (AHMAC) in March 2014. The framework describes a mechanism by which jurisdictions can authorise and secure patient record-level data, within high-priority clinical domains, to measure, monitor and report on the appropriateness and effectiveness of health care. The Commission is working with the Department of Health and with states and territories to identify these high priority clinical domains.

The Department of Health is investing in CQRs. It has funded the AOANJRR since its foundation in 1998. The recent Review of Medicines and Medical Devices recommended, "all high-risk implantable devices are included in a registry that is compliant with the requirements for registries established by the Australian Commission on Safety and Quality in Health Care."[4] In addition, the Department of Health has reviewed opportunities for investment in registries in Australia; and is currently funding expert groups to establish CQRs for cardiac implants, breast devices and cancer screening.

This is occurring in the context of work being done by clinicians and clinical specialty groups to build and operate CQRs. An actively maintained list of CQRs is maintained by Monash University, in association with the Commission and the National Health and Medical Research Council (NHMRC).[5] An informal Registries Special Interest Group is co-ordinated by Monash University, and their webpage contains numerous resources related to registries.[6]

[3] Australian Commission on Safety and Quality in Health Care, Framework for Australian clinical quality registries [PDF 363 KB]. Sydney. ACSQHC, March 2014.
[4] Sansom. LS, Delatte. W, Horvath. J, Review of Medicines and Medical Devices Regulation [PDF 3.1 MB], 2015.
[5] Available from the Monash Clinical Registries webpage
[6] Available from the Registry Special Interest Group webpage

Objectives of this report

The project was guided by a Steering Committee representing the Commission, Monash University, the Victorian Department of Health and Human Services and the Department of Health, with results discussed and the final report shaped with input from the group.

The objectives of the project were two-fold:

- Provide an objective economic basis to support future registry investment
- Develop and articulate a methodology for other registries to assess their impact and cost-effectiveness

Perspectives on the impact of Clinical Quality Registries

This project is restricted to an economic evaluation of a subset of information repositories known as CQRs. Excluded from the evaluation are epidemiological registries that focus on tracking the incidence and prevalence of specific diseases or conditions; and product registries that monitor the performance and safety of devices, drugs or products.

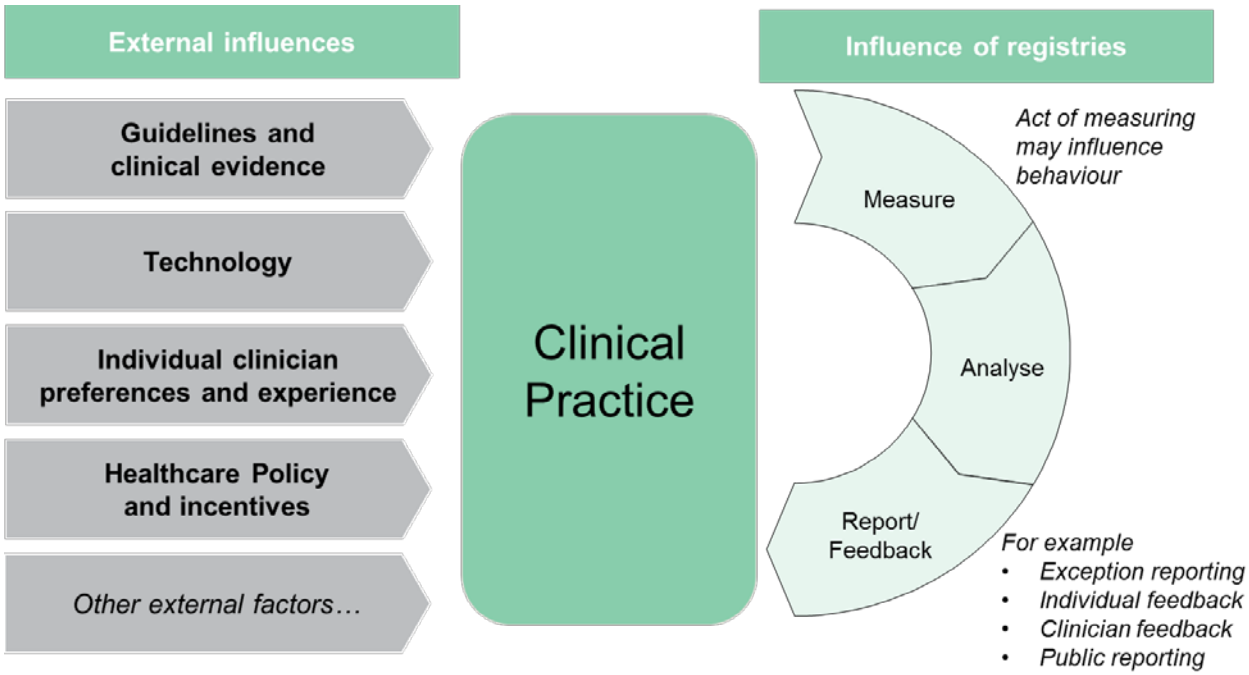
CQRs are defined by the Commission's Framework as "organisations that systematically monitor the quality (appropriateness and effectiveness) of health care, within specific clinical domains, by routinely collecting, analysing and reporting health-related information. The information is used to identify benchmarks, significant outcome variance, and inform improvements in healthcare quality."[7]

A salient, defining feature of a CQR is the inclusion of a process of feedback to clinicians regarding their results. This is a fundamental determinant of impact on clinical practice.[8] The specific mechanism and operational details of the feedback process vary with, among other factors, registry maturity, the nature of information collected, and preferences of participants. Ideally, this feedback loop should be timely and sufficiently detailed to allow clinicians to identify and understand the causes of variation and outlying performance, therefore enabling correction of sub-optimal practices where appropriate.

CQRs are one component of the broader clinical 'learning system'. They co-exist with healthcare policy, regulation and guidelines, as well as research and clinical trials, individual clinician preferences, technology and a host of other factors (see Figure 1). Evaluating the impact of registries therefore involves controlling for these confounding factors and attempting to isolate and evaluate the changes due to the registry.[9]

[7] Australian Commission on Safety and Quality in Health Care, Framework for Australian clinical quality registries [PDF 363 KB]. Sydney. ACSQHC, March 2014.
[8] Larsson, S From Concept to Reality, Putting Value-Based Health Care into Practice in Sweden November 2010
[9] Further background information is presented in support slides 1-4

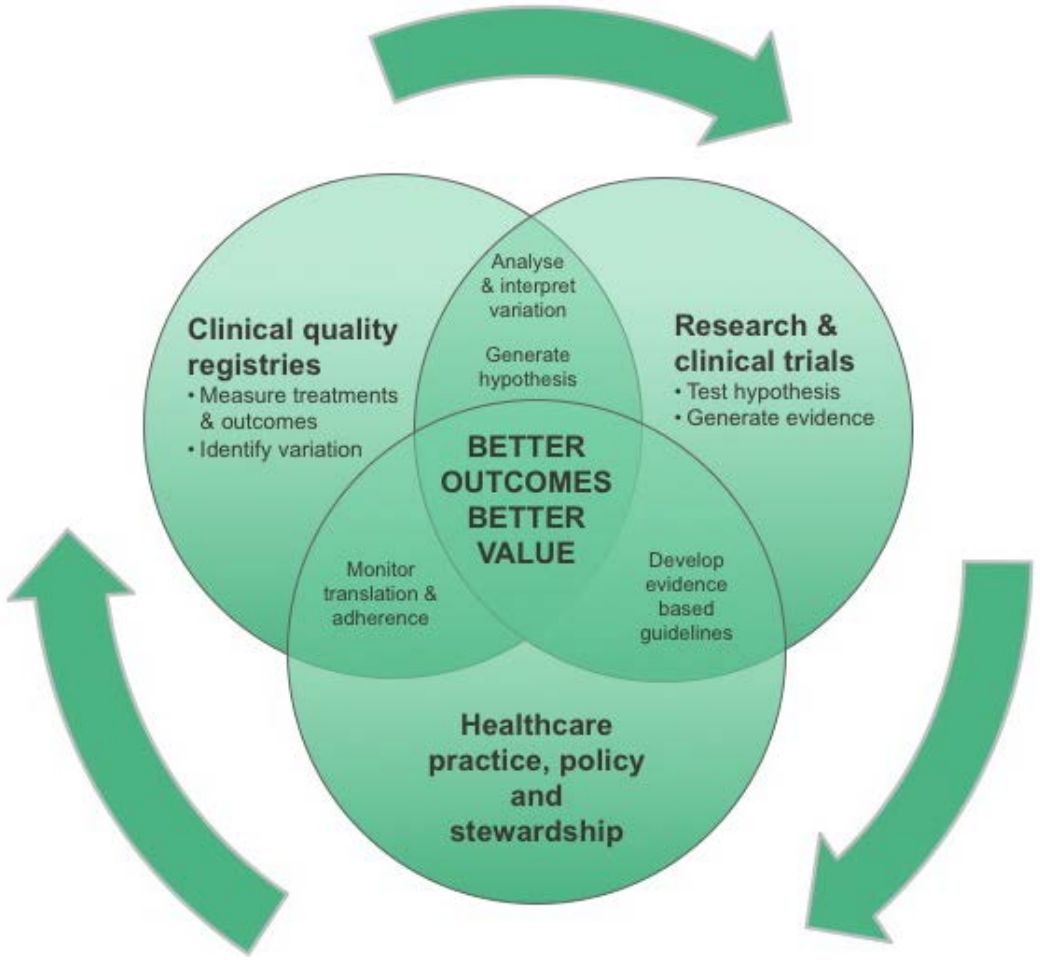
Figure 1: The position of registries within the broader clinical system



While registries can affect clinical practice on their own, there are synergies between the different components of the clinical system that magnify individual contributions and serve to deliver benefits and reduce costs. In a well-functioning, self-improving system, each of these influence and complement each other (as depicted in Figure 2).

In such a system, registries generate data that support improvements in the safety and quality of care, and support health services research. Clinical trials inform the development of clinical guidelines, and (the adherence to which can be subsequently measured by registries). The findings of both inform improvements in health practice, policy and regulation.

Figure 2: A self-improving synergistic health-care system[10]



As an illustration of all of the above points, the New York Cardiac Registry provides an example of an established registry where the impact on clinical practice, clinical research and healthcare policy has been evaluated and published. A summary is provided in support slides 5-7, and for further details, see the summary written by Hannan *et al.*[11]

[10] Australian Clinical Trials Alliance submission to Senate Select Committee on Health [PDF 900 KB], 2014

[11] Hannan et al, Journal of the American College of Cardiology, Vol 59, No. 25, 2012

Approach and methodology

Overview of registries selected

This project evaluated a selected sample of CQRs of sufficient maturity, where evidence of change in clinical practice and outcomes was available and attributable to registry activity, and where the economic value of that change is measureable.

Registries were shortlisted for inclusion based on meeting the principles set out in the Commission's Framework of Clinical Quality Registries. Selected registries track and measure indicators that are considered the most important and relevant for the clinical specialty.

Given the project timelines, the study only included those registries available to participate within the duration of the project, and where data was available in the specified period.

Table 3: Registries selected for study and indicators they collect

Registry	Hosted by	Evidence of impact
Victorian PCR	Monash University	• Prostate cancer research international active surveillance (PRIAS) guideline compliance resulting in lower rates of unnecessary intervention • Positive need surgical margin reduction - better survival and avoided for secondary therapy • Earlier treatment
VSTR	Monash University	• Reduced in-hospital mortality • Reduced average length of stay • Better longer term functional outcomes
ANZICS APD	ANZICS	• ICU Standardised Mortality Rates • Adverse events – (e.g. central line infection rates) • Rates of re-admission • Length of stay in ICU • Sepsis
ANZDATA	Royal Adelaide Hospital	• Graft failure rate reduction over time • Mortality • Reduced rates of complications (e.g. peritonitis rates) • Changes in practices (e.g. shunt timing)
AOANJRR	University of Adelaide	• Reduction in arthroplasty revision rates • Early recall/removal from market of poorly performing prosthetic devices used in joint replacement surgery

This selection of CQRs represents a variety of conditions, host institutions, influences on clinical practice and operational periods with registry establishment ranging from the late 1970s to 2009.

Methodology for evaluation of economic impact

A four-stage process was followed to assess the net economic impact attributed to the registry:[12]

1. Assessing changes in clinical outcomes and treatment costs
2. Adjusting for confounding influences by comparing against a control group
3. Conversion to economic value
4. Measuring against registry costs.

1. Assessing changes in clinical outcomes and treatment costs

Benefits to patient outcomes are based on indicators measured by the registries. In some cases, the registry directly measures patient outcomes such as mortality or morbidity. In other cases, the registry measures indicators of clinical practice (e.g. adherence to guidelines and protocol such as those for avoiding intervention in low-risk prostate cancer patients or transfer and triage of major trauma patients) which were then combined with measured outcomes data or data from published literature to infer clinical outcomes. Direct costs of treatment are based on average actual costs using average cost of care data detailed in the national hospital cost data collection published by the Independent Hospital Pricing Authority (IHPA) in both public and private hospitals. The analysis focuses on a sub-selection of indicators, based on current and historic data availability, among the variety of indicators measured by each registry.

2. Adjusting for confounding influences by comparing against a control group

To assess the benefit attributed to the operation of the registry (as opposed to benefits merely measured by the registry), data was sought from control groups where key indicators have been recorded, but where there has been differential (or no) application of the registry. Identifying this group and adjusting for potentially confounding factors was the most challenging part of this project, and the greatest limitation to isolating the true value of a registry.

In each case study, a definitive point in time was selected where a change in registry activity was evident; for example, the addition of new hospitals, the commencement of structured feedback to outliers, or a change in type or delivery method of feedback. This reference point was used to compare clinical outcomes, either before and after the change or between groups. In this way, groups of clinicians or hospitals that were affected by the change(s), and groups that were not were able to be identified. The latter groups were used as controls, attempting to account for external events that may have delivered improvements to clinical outcomes independent of the registry. This is a conservative calculation, as none of the improvement in the control group is attributed to the registry in this way.

Only incremental gains, following changes in registry activity, are calculated and included. These gains are scaled down to represent the proportion of patients affected.

[12] Further details on evaluation methodology are presented in support slides 8-9.

For example, where a registry commences a process of individual hospital level feedback to hospitals with poorer mortality rates in 2011 and data up to 2013 is available and accessible:

Only the hospitals that receive such feedback are included in this economic evaluation, and only the clinical impact observed after the commencement of feedback (2011-13) is calculated. The study then attributed to the registry, the percentage of this impact that is not likely to have occurred incidentally, (as measured through the control group), or indeed if the affected hospitals continued at their own natural rate of improvement observed before 2011 (as measured through historic data).

The analysis therefore assesses whether a single, decisive registry activity that is not evenly distributed across all participants (e.g. feedback) has produced incremental economic value beyond any value that would be predicted to occur incidentally or independent of the registry.

The resulting attribution of economic value is very conservative. There is likely to have been considerable clinical, societal and economic benefit prior, post and concurrent to the study's narrow analysis. These benefits will have been partly driven by changes in practices and guidelines motivated by registry data, and the act of collecting data for registries. The purpose of this analysis, however was to evaluate stringently attributable economic value.

In addition to quantitative data from registries and published papers, a limited number of qualitative interviews with clinicians, data managers and topic experts involved with the registry were conducted, in order to understand both the changes that take place on the ground as a result of registry feedback, as well as the broader context of changes to guidelines, policies, technology and other external factors that occurred during the periods under evaluation.

3. Conversion to economic value

Economic value in this analysis comprises changes to treatment costs and changes to life expectancy or quality of life. The evaluation is a retrospective analysis of the net present value of benefits to date in these two areas. Avoided treatment costs are largely taken from the IHPA resources on Australian refined diagnosis related groups (ARDRG) data.[13]

There are a number of ways to value improvements to life expectancy and quality of life. Established and recommended methodologies were used where possible. In particular, the value of statistical life year guidance[14] from the Office of Best Practice Regulation (OBPR) was used as the basis for valuation of extended and/or improved quality life years. Where there are substantial impairments to the quality of life associated with an outcome (e.g. undergoing dialysis, or experiencing side effects of surgery such as incontinence), a quality of life adjustment has been applied using health state utility/disease burden weightings taken from recognised sources (including the Australian Institute of Health and Welfare or the World Health Organization). All figures are in 2014 dollars. Values over $10 million are rounded to the nearest million for presentation purposes.

A 3% per annum discount rate was applied on all costs and benefits in the analyses to reflect private future time preferences.[15] [16]

[13] Further information on ARDRG costing is available at on the IHPA website
[14] December 2014, Best Practice Regulation Guidance Note Value of statistical life [PDF 130 KB]
[15] Page 13 in Harrison M, Valuing the future: the social discount rate in cost-benefit analysis [PDF 726 KB], Visiting Researcher Paper, Productivity Commission, Canberra, 2010.
[16] In economics, time preference (or time discounting, delay discounting, temporal discounting) is the relative valuation placed on a good at an earlier date compared with its valuation at a later date

4. Measuring against registry costs

Costs include establishment, maintenance and operational costs, and both the central registry operations (e.g. data collection, cleaning, analysis and publications) as well as peripheral data collection costs. These have been sourced from the registries, and are included in the totals regardless of which group pays for them (e.g. hospital or central registry).[17]

[17] Registry cost data is presented in support slides 28, 49, 68 and 87.

Results of the economic evaluation of five case studies

Table 4: Results of the economic evaluation

Registry	Period of analysis	Gross attributed benefit: total	Costs avoided	QALYs preserved	Registry costs	Benefit to cost ratio[18]	Internal rate of return[19]
Victorian PCR	2009-13	$5.2m	$1.4m	$3.8m	$2.7m	2:1	52%
VSTR	2005-13	$36m	$1.2m	$35m	$6.5m	6:1	51%
ANZICS APD	2000-13	$36m	$32m	$4m	$9.8m	4:1	23%
ANZDATA	2004-13	$58m	$14m	$44m	$8.8m	7:1	48%
AOA NJRR	≤2002-14	$65m	$36m	$29m	$13m	5:1	25%

QALYs = quality adjusted life years

The Victorian PCR showed a net benefit of $2.4 million from inception (2009) to most recently available data (2013). Economic value is measured through reduction in positive surgical margin rates after radical prostatectomy and reduced active intervention in low risk patients. Attribution of benefits was achieved by comparing outcomes for units that were early contributors to the registry to those that were later contributors.

The VSTR showed a net benefit of $30 million from full coverage (2005) to most recently available data (2013). Economic value was measured through reduction in in-hospital mortality and average length of stay. Attribution of benefits was achieved by comparing the rate of improvement at a system level after the introduction of structured feedback, between hospitals in receipt of this feedback due to individual outlier cases, and those that were not.

The ANZIC APD showed a net benefit of $26 million in the period of available data (2000-2013). Economic value was measured through the reduction in intensive care unit (ICU) mortality and average length of stay. Attribution of benefit was achieved by comparing the rate of improvement of the standardised mortality ratio in units identified as outliers before and after the introduction of structured feedback to outlier units.

[18] The benefit to cost ratio is used as a measure of return on investment. It is a ratio of the calculated, registry attributed monetary benefits, relative to registry costs as reported by the registries themselves.

[19] The internal rate of return is used as a measure of return on investment. It is the rate of return at which the net present value of all benefit (cash) flows from calculated registry benefits is equal to zero. It therefore represents the discount rate at which the investment breaks even and the present value of all future benefit flows is equal to the initial investment.

The ANZDATA showed a net benefit of $49 million over the period of available data (2004-2013). Economic value was measured through the reduction in dialysis mortality, transplant graft loss and incidence of peritonitis. Attribution of benefits was achieved by comparing the rate of improvement at hospitals that accessed registry feedback to those that did not.

The AOANJRR showed a net benefit of $53 million over the period of analysed data (≤2002-2014). Economic value was measured through the reduction in rate of revision in hip and knee replacement surgery (arthroplasty). Attribution of benefit was achieved by comparing the rate of improvement in revision surgery amongst surgeons who accessed their individual outcomes data through registry feedback, to those who did not.[20] Supplementary analyses for this case study showed a range of potential benefit of up to $143 million based on vignette studies on reduction in use of specific well-known hip and knee devices. These were identified through the registry as having an unusually high rate of requiring revision surgery. Beyond these individual examples of specific devices, the overall benefit measured by the registry over time was more than $600 million when the hip and knee surgery revision rate over time in Australia was compared to international benchmarks.

Limitations of the approach

The most significant limitation of this study was the availability of suitable alternative data sources to control for confounding factors that may have influenced patient outcomes independent to the registry. The study was therefore limited to an evaluation of aspects within the registries themselves.

In this respect and for others, the study has been very conservative in its assumptions. For example, costs have been included over a longer time frame than the benefits measured, and included whole registry operation costs, even where only a smaller set of sites may have been affected by the benefits. Additionally, sensitivity analysis also confirmed the results are robust to a reasonable range of valuation assumptions.

In the longer-term, the registries themselves may provide the data necessary to refine some of the assumptions made, for example, the use of long-term survival rates for prostate cancer patients would replace the assumptions made from positive surgical margin (PSM) rate reduction due to the registry.

There are a number of areas where, given more time, further investigation would be valuable. For example, instructive assessments could be undertaken on 12-month mortality and re-admission of trauma patients, functional and quality of life outcomes of trauma and ICU patients post-discharge, costs of inter-current illness in patients with preserved renal transplant grafts and mortality risk and ongoing quality of life impairment in patients undergoing arthroplasty revision. Nevertheless, for the purposes of this paper the findings are significant, and are of sufficient depth and breadth to answer the questions posed in this evaluation.

Opportunities to expand coverage

With the exception of ANZDATA registry and AOANJRR, the evaluated registries operate below full national patient coverage. The Victorian PCR covers approximately 75% of Victorian incident cases and over the last few years has facilitated similar registry commencement in other states, such as South Australia and New South Wales. The

[20] Supplementary analyses were performed on the AOANJRR case study to quantify some of the benefit that is overlooked in the attribution analysis (specifically within the control group and in the period of time not covered in the analysis.). These are described in the case study appendix and support slides 115-119.

ANZICS APD registry covers approximately 80% of ICU patients across Australia. VSTR covers all major trauma cases in the state of Victoria.

Some broad assumptions have been applied in order to extrapolate the notional benefit from increasing geographic coverage.

Benefits – benefits are expected to scale in line with coverage, as more patients are covered by the registry and affected by it. There may be additional benefits from covering more sites, as measured variation within a larger population achieves higher statistical power and significance.

Costs – peripheral costs (e.g. data collection) are expected and some costs of analyses would also scale in line with coverage; while there may be some synergies in expanding, e.g. to hospitals within a single network; there may also be additional barriers for more remote sites. Benefits of scale are most relevant in central registry operations: as long as existing infrastructure can support expansion, then the increase in central staffing costs for quality, audit and analysis is typically the same. The Victorian PCR anticipated a 30% variable cost component for its current expansion plans. Accordingly, a similar relationship has been applied for cost increases in scaling the other two registries.

Table 5: Extrapolation of benefit to costs ratios based on full national coverage

Registry	Current national coverage	Current benefits	Current costs	Current BCR	Extrap-olated benefits	Extrap-olated costs	Extrap-olated BCR
Victorian PCR	11%	$5.2m	$2.7m	2:1	$44m	$8.9m	5:1
VSTR*	25%	$36m	$6.5m	6:1	$147m	$12m	12:1
ANZICS	80%	$36m	$9.8m	4:1	$45m	$11m	4:1
ANZDATA**	100%	$58m	$8.8m	7:1	$58m	$8.8m	7:1
AOANJRR**	100%	$65m	$13m	5:1	$65m	$13m	5:1

BCR = benefit:cost ratio; current = current evaluation (gross benefits); extrapolated = extrapolation to full national coverage
*crude estimate due to different definitions of “major trauma” in different jurisdictions and broad assumption of starting from zero coverage in other states when in reality there is some existing coverage.
ANZDATA Registry and AOANJRR are considered to have existing full national coverage.
** Extrapolated benefits are equal to current benefits due to current national coverage

The crude extrapolation analysis shows that, if full national patient coverage is achieved where not currently the case, there is likely to be a minimum expected benefit to cost ratio of 4 to 1.

Conclusions

This project has demonstrated that the five Australian CQRs assessed have improved the value of health care delivery and delivered benefits well in excess of costs, even where conservative assumptions have been taken and only a limited portion of benefits have been considered (due to data and control group availability). They have done this at a relatively low cost, e.g. typically less than one million dollars per annum, for an overall return of 2-7 times investment costs.

The study observed that there were a number of challenges faced by the registries evaluated:

- Common challenges in funding and sustainability. While there are a range of funding models and funding bodies – governments, academic institutions, private sector and charities - resourcing remains a challenge. Staff shortages in particular, are well documented. Cross subsidies from host institutions and time donated by staff are much valued and ensure core registry functions are preserved. However, such limitations can undermine the timeliness, amount and quality of feedback provided, and constrain the ability to extract value from data collected.
- Importance of maintaining data quality. This includes appropriate governance, accountability for data collection at the point of healthcare delivery, as well as central auditing and quality control, which are essential to ensure that clinicians have trust in, and can act upon, registry feedback.

There were opportunities to expand coverage in three of the registries investigated, and expected commensurate improvement in returns from the preliminary crude scale-up analysis.

A consistent theme in the evaluation has been the importance of providing feedback to clinicians, jurisdictions, policy makers, and others, to influence clinical practice. Where this has been enhanced, for example through introducing site-level reports, outlier management or case-review, there has consistently been a demonstrated improvement in outcomes and associated benefit for patients.

Appendix A – Case study summaries

Victorian Prostate Cancer Registry

For the period 2009 to 2013, an economic benefit of almost $5.2 million is attributed to the presence of the Victorian PCR. Costs for this period amounted to $2.7 million, resulting in a net benefit of $2.4 million.

Appendix A, table 1: Results of the Victorian PCR case study

Period of analysis	Gross attributed benefit	Registry costs	Internal rate of return	Benefit to cost ratio	Extrapolated benefit to cost ratio[21]
2009-2013	$5.2m	$2.7m	52%	2:1	5:1

The Victorian PCR was established in 2009 with three initial contributing metropolitan hospitals. The registry now contains 33 contributing hospitals across the state with funding through Cancer Australia, the Victorian Department of Health and Movember foundation. The registry funds include data collection costs.

New contributing hospitals were added periodically until the end of 2012. Since 2013, the registry has covered circa 75% of incident cases, equivalent to 10,000 men over the five-year period of analysis, 2009-2013.

The registry has measured improvements in several clinical quality indicators. Two indicators were selected for further evaluation, based on availability of data and evidence of demonstrable change over recent years.

1. **Reduction in PSM rate:** Patients with a PSM following radical prostatectomy (surgical removal of the prostate) show cancer cells extending beyond the edge of the resected margin. Many of these patients require secondary therapy, with additional cost and impact on quality of life. There is also a greater risk of disease progression and mortality.[22]

2. **Fewer active interventions in patients deemed at low risk of disease progression (PRIAS intervention)[23]:** Patients who meet criteria for being at low risk of disease progression are not recommended to receive active treatment. Such treatment is not deemed to offer any mortality or quality of life benefit. Avoiding active treatment in this low risk cohort benefits from fewer costly unnecessary procedures and incremental improvements in quality of life associated with avoidance of side effects from these interventions.

[21] Predicted benefits if the registry achieved 100% national coverage from current 75% state coverage. Based on 30% of costs being variable and benefits directly proportionate to percentage coverage.

[22] Evans. S, Millar, J, Positive Surgical Margins: rate, contributing factors and impact on further treatment

[23] Prostate Cancer Research International Active Surveillance (PRIAS). Further details in support slide 16.

From 2009 to 2013, the Victorian PCR measured a 12% reduction in PSM rate compared to 2010 baseline.[24] This is equivalent to 219 fewer patients with a PSM following radical prostatectomy, 56 fewer patients requiring secondary treatment and 11 fewer predicted deaths.

In the same period, the registry measured a 21% reduction in the rate of active intervention in low risk patients. This is equivalent to 91 avoided unnecessary treatments and 13.3 saved quality adjusted life years through incremental reduction in treatment side effects.

To determine the influence of the Victorian PCR on the observed changes to PSM and PRIAS intervention rates, rates of improvement were compared in early contributing hospitals (i.e. since 2009) to later contributors (2010 onwards). The rate of improvement observed in later contributors was used as a proxy for the effect of any changes that were occurring in practices and outcomes outside of the registry's influence (over the time they were not contributing to the registry).

The rate of improvement in both indicators was demonstrably greater in early registry contributing hospitals compared to later contributors. The mode of treatment was observed to have been constant over the period and changes to surgical practice are assumed to affect all hospitals uniformly. These therefore do not confound the results.

Only the incremental improvement in early contributing hospitals, which exceeded the improvement measured at later contributors, is attributed to the registry. This results in the following impact being attributed to the registry[25]

- fifty-nine (of 219) fewer patients with a PSM following radical prostatectomy with 15 (of 56) fewer men requiring secondary treatment and three (of 11) fewer deaths.
- sixty-six (of 91) fewer low risk patients receiving unnecessary active treatment and 9.1 (of 13.3) saved quality adjusted life years.

According to clinician opinion, the Victorian PCR influenced changes in clinical practice through a number of specific levers. Following receipt of benchmarking and annual reports from the registry, senior clinicians started to present key clinical quality indicators in grand round and multi-disciplinary team meetings. This raised greater awareness of quality performance (i.e. relating to PSM rate) and best practice guidelines (i.e. adherence to PRIAS treatment guidelines). As a further result of benchmarking reports, greater senior surgical oversight was commenced to supervise radical prostatectomies in instances where surgical registrars were performing the procedure.

Victorian State Trauma Registry

For the period 2005 to 2013, an economic benefit of over $36 million was attributed to structured outlier feedback from the VSTR. Costs for this period amounted to $6.5 million, resulting in a net benefit of $30 million. Calculations were based on improvements in two quality indicators.

[24] 2010 was chosen as the baseline year due to insufficient volume of data prior to this point. pT2 patient group.

[25] Compared to 2010 baseline. Further details on the unit level impact of an avoided Positive Surgical Margin, or unnecessary treatment in Low risk PRIAS patient is presented in the tables in support slides 22, 23, 26, and 27

Appendix A, table 2: results of the VSTR case study

Period of analysis	Gross attributed benefit	Registry costs	Internal rate of return	Benefit to cost ratio	Extrapolated benefit to cost ratio
2005-2013	$36m	$6.5m	51%	6:1	12:1

The VSTR was established in 2001 following the 1999 Ministerial Review of Trauma Emergency Services (ROTES). ROTES led to the formation of an integrated system of care for patients sustaining major trauma in Victoria (Victorian state trauma system).[26] Three thousand eligible patients were included in 2013-14. Funding is provided by the Victorian Department of Health and Human Services, and Transport Accident Commission. Data collection costs are met by a mixture of registry and health services.

Full coverage was achieved in 2005, and full maturity of feedback was considered to be achieved from 2011. Since 2011, the registry has provided structured outlier feedback directly to health services and jurisdictional governance bodies through its case review group.

The VSTR monitors and evaluates performance of the Victorian state trauma system, and collects data on all major trauma cases in Victoria across all phases of trauma care. This includes data from 138 health services containing two adult and one paediatric major trauma services and staged care through regional and metropolitan health services

The registry collects a broad range of data on patient and event demographics, including; clinical management, mode and severity of injury, in-hospital mortality, length of stay and long term functional outcomes. Two key indicators were included in the analysis due to availability of data of sufficient duration, and demonstrable evidence of change.

1. **Reduction in average length of stay (ALOS):** Longer lengths of stay are associated with increased cost on a straightforward cost per bed day basis.[27]

2. **Reduction in the rate of in-hospital mortality:** Reduction in deaths of major trauma patients beyond any predicted decrease that would be expected due to case-mix changes or external factors. Avoided mortalities result in quality adjusted life year benefits from the years of life preserved.[28]

From 2005 to 2013, the Victorian State Trauma Registry measured a 23% reduction in ALOS from 8.7 to 6.7 days. This is equivalent to over 16 000 trauma bed days saved compared to 2005 baseline rate.[29]

In the same period, the registry measured a reduction in relative risk of mortality from 1 to 0.7 in all major trauma patients, adjusted for age, modality of injury and injury severity. This is equivalent to 366 prevented mortalities compared to 2005 baseline rate.

[26] More details on registry background are presented in support slides 32-34
[27] Cost of an average major trauma bed day provided by the funding analytics branch Emergency and Trauma Services, Department of Human Services Victoria $3236.
[28] Preserved years of life were calculated based on registry data on age of mortality and demographics.
[29] For injury severity score (ISS) > 12 patients, representing approximately 80% of the total patient cohort.

The VSTR influences outcomes at individual hospitals through the collection, analysis and feedback of data. The 2011 inception of the case review group outlier feedback process was selected as the definitive timeline event to compare improvements in outcomes pre and post provision of this structured feedback to outlier units.

The case review group was formed to improve safety and quality of all major trauma care by reviewing patient journeys and management. The case review group reviews cases at metropolitan and regional services that may fall outside major trauma guidelines. Health services are informed when cases are identified as part of a whole of system quality analysis. As the trauma system is integrated, with inter-hospital transfer and staged patient triage, outcomes at major trauma services will be affected by the triage and transfer patterns of cases subsequently reviewed by the case review group; and the changes implemented at hospitals that have had cases reviewed in this way. A whole of system level approach was adopted in the analysis that included outcomes from the major trauma services. In 2013-14, the case review group reviewed 173 major trauma cases.

Rate of improvement in ALOS and mortality rates were compared in hospitals that received additional structured feedback through the case review group (case review group hospitals) versus those hospitals that did not (non- case review group hospitals).[30]

Only the increased rate of improvement in the case review group hospitals, which exceeded the rate of improvement measured across the non-case review group hospitals, is attributed to the registry. The attributed benefit was further scaled down to the proportion of patients receiving treatment at case review group feedback recipient hospitals.[31]

- four hundred and fifty-eight fewer bed days compared to 2005 baseline (16 000 in total cohort).
- thirty-one (366 in total cohort) fewer deaths compared to 2005 baseline

According to clinician opinion, the VSTR influenced hospitals to use existing clinical governance mechanisms to review patient management. Changes implemented as a result of structured feedback from the case review group included earlier liaison of regional trauma service with Adult Retrieval Victoria, and providing retrieval coordination and joint assessment of clinical management and transfer needs. Earlier consultation, and thus more efficient coordination with major trauma service hospitals, was also commenced.

Australia and New Zealand Intensive Care Society Adult Patient Database

For the period 2000 to 2013, an economic benefit of over $36 million is attributed to the ANZICS APD's outlier management program. Costs for the period 2000 to 2013 amounted to $9.8 million, resulting in a net benefit of $26 million. Economic benefit is based on improvements in ICU length of stay, and ICU mortality.

[30] A whole of system approach was used by comparing the total cohort (including major trauma services) with and without the case review group affected cohort included. Further details on this approach are found on support slides 41-43

[31] Attributed benefits are discounted 3% to the year of realisation and are net of inpatient rehabilitation costs.

Appendix A, table 3: Results of the ANZICS APD case study

Period of analysis	Gross attributed benefit	Registry costs	Internal rate of return	Benefit to cost ratio	Extrapolated benefit to cost ratio
2000-2013	$36m	$9.8m	23%	4:1	4:1

The ANZICS APD was established in the early 1990s as part of a broader set of four linked clinical quality registries.[32] Registry costs are assimilated in to the ANZICS central financial budget. Data collection costs are met by participating ICUs.[33]

Participation in the registry is recognised as a clinical performance indicator for hospitals by the Australian Council on Healthcare Standards. Feedback of registry data and analysis occurs through quarterly and annual reports distributed through the ANZICS Centre for Outcomes and Resource Evaluation (CORE) Portal. There are 160 contributing units across Australia and New Zealand with an estimated 80% overall incident coverage. Admissions amount to about 100 000 per annum in Australia alone. Only Australian ICUs are evaluated in this report.

The ANZICS APD influences clinical outcomes by providing quarterly and annual reports enabling ICUs to analyse performance against risk-adjusted benchmarks. Since 2008/2009 a process of additional, structured outlier feedback has occurred.

Two quality indicators measured by the ANZIC APD are in the scope of analysis in this report due to data availability and evidence of demonstrable change in clinical practice and outcomes.

1. **Reduction in ICU ALOS:** Longer lengths of stay in ICU are associated with increased cost on a cost per bed-day basis.[34]

2. **Reduction in standardised mortality rate (SMR):** Reduction in deaths of ICU patients beyond any predicted decrease that would be expected as a result of case mix changes. Avoided mortalities result in quality adjusted life year benefits from the years of life preserved.[35]

From 2000 to 2013, the ANZICS APD measured a 16% reduction in ICU length of stay from 3.8 to 3.2 days. This is equivalent to over 360 000 ICU bed days across participating units based on 2000 benchmark rate.

In the same period, the registry measured a reduction in standardised mortality ratio from 1.09 to 0.69. This is equivalent to 36 000 fewer ICU deaths compared to 2000 baseline. [36]

The registry's outlier management program (OMP) identifies outlier units based on having poorer standardised mortality rate than average. Where an ICU is identified in quarterly

[32] Adult Patient Database (APD), Paediatric Intensive Care (ANZPICR), Critical Care Resources (CCR), Central Line Associated Bloodstream Infection (CLABSI)
[33] Costs table and further background information is presented in support slide 68
[34] Cost of Care Standards 2010 NSW Ministry of Health (3% pa inflation rate applied on 2009/10 figures) $4,300
[35] For the purpose of this analysis, each avoided mortality was projected to preserve one year of life. Bohensky JCC.
[36] Comorbidity adjusted based on Acute Physiology and Chronic Health Evaluation III (APACHE III) filters.

benchmarking as having an SMR above the 99% confidence interval, a structured program of notification and analysis is undertaken. If an outlier is determined through the OMP to be a 'true' outlier, i.e. poor SMR is not explained by data quality issues, case mix adjustment or false elevation, a detailed review of processes of care is undertaken. This process engages the Unit director, jurisdictional governance body or health department and clinician members of the Outlier Working Group.[37]

To determine the proportion of the measured changes in ALOS and SMR that can be attributed to the registry, rates of improvement at outlier hospitals were compared before and after inception of the outlier management program. Hospitals were grouped depending on if they were ever identified as an outlier or not. Outlier hospitals were further separated by the year of being identified, as this would determine if they had received the additional structured feedback of the outlier management program. Only hospitals that were outliers after 2009 (late outlier group) received structured feedback and additional analysis from the outlier management program. These hospitals were compared against pre-2009 outliers (early outlier group) having not received additional outlier management program feedback. In this evaluation, the counterfactual improvement observed over time in hospitals that had never been an outlier (inlier group) was used as the baseline.

Only the incremental improvement in ALOS and standardised mortality ratio in the late outlier group, that occurred after the outlier management program started in 2009, and exceeded the rate of improvement seen in the early outlier group in the same time period, was attributable to the registry. (ALOS and standardised mortality ratio improvement was also observed in this group before 2009, so only the additional improvement observed after the outlier management program started, was ultimately attributed to the registry.)

- 10 500 (of 360 000 overall) fewer ICU bed days in the late outlier group of hospitals in the period 2009-2013 compared to 2000 rate.
- thirty (of 36 000 overall) fewer ICU mortalities in the late outlier group of hospitals in the period 2009-2013 compared to 2000 SMR.

According to clinician opinion, the ANZICS APD influenced changes in clinical practice through a number of levers. Changes implemented at ICU level as a result of outlier management program feedback include; provision of venous thromboembolism prophylaxis, greater unit-level scrutiny on time to admission and inter-hospital transfer, increased focus on avoiding after-hours or weekend discharge, presence of a pharmacist on ICU ward rounds to enable oversight of medication management and greater supervision of less experienced clinical team members.

Australia and New Zealand Dialysis and Transplantation Registry

For the period 2004 to 2013, an economic benefit of $58 million is attributed to hospital level feedback from the ANZDATA registry. Costs for the period amounted to $8.8 million, resulting in a net benefit of $49 million. Economic benefit is based on improvements in rates of risk adjusted dialysis mortality, transplant graft loss and peritonitis.

[37] Further details on the ANZICS APD outlier management program, including schematic representation of processes, are included in support slides 54 and 55.

Appendix A, table 4: Results of the ANZDATA case study

Period of analysis	Gross attributed benefit	Registry costs	Internal rate of return	Benefit to cost ratio	Extrapolated benefit to cost ratio
2004-2013	$58m	$8.8m	48%	7:1	NA

The ANZDATA Registry was established in the late 1970s to register all patients receiving renal replacement therapy, where the intention was to treat long term (i.e. in patients where renal function was not expected to recover).

All renal units across Australia and New Zealand provide data to the registry, including transplanting, dialysis and satellite dialysis units. The registry compiles data on incidence and prevalence of end stage kidney disease, treatment (haemodialysis, peritoneal dialysis, and transplant) complications (including dialysis technique failure and transplant graft loss) and mortality. There were over 21 000 patients recorded in the registry as of the end of 2013.

Registry costs are met by the Australian Organ and Tissue Donation and Transplantation Authority (AOTDTA), with contributions from the New Zealand Ministry of Health, Kidney Health Australia and the Australia & New Zealand Society of Nephrology. Funding from these sources support the organ donor registry and living kidney donor registry in addition to the ANZDATA Registry. Data collection costs are met by individual renal units.

The registry influences clinical outcomes by providing quarterly reports specific to individual renal unit activity (dialysis key performance indicators, dialysis outcomes, transplant care, and transplant surgery). Annual consolidated reports are also provided to all hospitals and made publicly available through the registry website. Since 2011, renal units have used unique log-in credentials to access hospital level reports through the ANZDATA Registry secure online portal.

Three quality indicators measured by the registry are in the scope of analysis in this report due to data availability and evidence of demonstrable change in outcomes over time.

1. **Dialysis mortality rate:** Reduction in actual deaths of patients receiving renal replacement therapy through dialysis (haemodialysis and peritoneal dialysis) in all settings. Avoided mortalities result in quality adjusted life year benefits. There are additional ongoing costs of care, which are deducted from this benefit.

2. **Transplant graft loss:** Reduction in number of transplant grafts that fail after 90 days, resulting in the patient needing to commence/recommence renal replacement therapy through dialysis. Avoided graft losses result in economic benefit through avoided dialysis costs and incremental gains in quality of life. There are additional costs of ongoing transplant graft care (immunosuppression and follow up) which are deducted from the benefit.

3. **Peritonitis rate**: Reduction in the incidence of infection of the peritoneum leading to hospitalisation, in patients that undergo renal replacement therapy through peritoneal dialysis. Reducing the incidence of peritonitis results in economic benefit through avoided treatment costs and incremental improvements in quality of life.

From 2004 to 2014, the ANZDATA registry measured a 15% reduction dialysis mortality rate. This is equivalent to 1156 fewer deaths based on 2004 benchmark rate.

In the same period, the registry measured a 39% reduction in transplant graft loss rate. This is equivalent to 606 fewer transplant grafts lost compared to 2004 baseline. Peritonitis rates in this period reduced by 40%, resulting in 2573 fewer infections compared to baseline.

To determine the proportion of the measured changes in the three aforementioned indicators that can be attributed to the registry, rates of improvement at hospitals that accessed registry feedback reports were compared to hospitals that did not access reports (or accessed them significantly fewer times than others). Hospitals in the latter group are a proxy for the counterfactual improvement in outcomes independent of the registry. Only benefits in the period 2011 to 2013 are included in the analysis, as this corresponds to the period where access to registry feedback can be tracked and measured using (de-identified) portal login data.

Only the incremental improvement in outcomes in the group of hospitals that accessed unit level feedback, which exceeds the rate of improvement observed in those hospitals that did not, is attributed to the registry. Benefits are scaled to the number of patients receiving treatment at these hospitals.

- one hundred and ninety-six (of 770 overall) fewer dialysis mortalities in the hospitals that accessed registry feedback in the period 2011-2013 compared to 2004 rate.
- seventy-six (of 322 overall) fewer transplant grafts lost in the hospitals that accessed registry feedback in the period 2011-2013 compared to 2004 rate.
- three hundred and seven (of 1646 overall) fewer incidences of peritonitis hospitalisations in the hospitals that accessed registry feedback in the period 2011-2013 compared to 2004 rate.

According to clinician opinion, the ANZDATA registry influenced changes in clinical practice through a number of specific levers. Following receipt of registry feedback, senior clinicians revised supportive care procedures around dialysis treatment to prevent failures and complications. Some of the specific steps taken included improved provision of patient education to first time dialysis patients, development of a structured approach for management of dialysis exit site infections and prophylactic antibiotic use to prevent infections in new peritoneal dialysis patients.

Provision of real-time access to data has been identified as both a challenge and opportunity by renal physicians.

Australian Orthopaedic Association National Joint Replacement Registry

For the period 1999 to 2014, economic benefit of over $65 million is attributed to the AOANJRR. Costs for the period amounted to under $13 million, resulting in a net benefit of $53 million. Economic benefit is based on improvements in rates of revision of hip and knee replacements in osteoarthritis. The range expressed in the results is due to supplementary analyses of two well-documented examples of registry influence that were quantified in addition to the standard attribution analysis followed elsewhere.

Appendix A, table 5: Results of the AOANJRR case study

Period of analysis	Gross attributed benefit	Registry costs	Internal rate of return	Benefit to cost ratio	Extrapolated benefit to cost ratio
≤2002-2014	$65m to $143m	$13m	25 to 78%	5:1 to 11:1	NA

The AOANJRR was established in 1999 to define, improve and maintain the quality of care of individuals receiving joint replacement surgery.

Hip and knee replacement data collection started with nine hospitals in South Australia, with staged implementation across states and territories occurring up to 2002. Data on interventions from 1999 to 2002 were consolidated to form the baseline for comparison. All hospitals that perform joint replacement surgery in Australia provide data to the registry, giving the registry full national coverage. While data collection is voluntary, there is 100% eligible hospital compliance, equivalent to around 300 hospitals providing data for 8000 joint replacement procedures per month.

Registry costs are met by the Department of Health. Data collection costs are met by individual hospitals who appoint a data collection coordinator. A third of total costs are associated with data entry and analysis for feedback and reporting. The AOANJRR was declared a federal Quality Assurance Activity (FQAA) in 1999. This declaration, renewed every five years since, permits the collection of data at the individual patient and health care provider level without per-time consent, but prohibits its disclosure. The Australian government introduced legislation in 2009 that enabled cost recovery through a levy paid by device manufacturers. In 2013/14, this amounted to $2.162 million.

The registry influences clinical outcomes by providing publicly available annual and supplementary reports. Since 2009/10, individual surgeon data is also provided through a secure online facility. An additional resource is the provision of ad hoc reports (245 in 2014) as requested by industry, individual surgeons, hospitals, academic institutions, government and government agencies.

A separate online facility is available for orthopaedic companies to monitor their own prostheses, as well as Australian (and international) regulatory bodies to monitor the outcomes of prostheses used in Australia. The data obtained through both online facilities (for individual surgeons and devices) are updated daily and are over 90% complete within six weeks of the procedure date.

The registry collects a defined minimum data set that enables outcomes to be determined based on patient characteristics, prosthesis type and features, method of prosthesis fixation and surgical technique used. Three principle metrics are tracked: prosthesis revision rate, identification of poorly performing prostheses, and mortality. The latter is achieved through data linkage with national mortality data. The first two are in the scope of this evaluation.

1. **Prosthesis revision rate:** Reduction in the proportion of joint replacement procedures that require subsequent revision. Revision surgery leads to additional treatment costs, associated side effects of surgery and poorer quality of life related outcomes.

2. **Identification of poorly performing prostheses**: Identification of prostheses that have a higher than expected revision rate compared to others in the same class. The registry coordinates with the government and Therapeutic Goods Administration (TGA) on

identified prostheses. This enables decisions to be made relating to licensing and remuneration, or where required, removal of prostheses from the Australian market.

From 1999/02 to 2014, the AOANJRR registry measured a 23% reduction burden of revision (annual proportion of procedures that are revisions of previous arthroplasties) and 14% reduction in knee replacement revision burden. This is equivalent to almost 6500 fewer hip and 3900 knee revision procedures. In the same period, the revision rate increased in these two procedures in two countries with ostensibly less effective registries, the United States and United Kingdom. Accordingly, if the full reduction in revision burden were to be attributed to the AOANJRR, this would be equivalent to a benefit of $618m.

In keeping with the other case studies, to determine the proportion of the measured changes in burden of revision in hip and knee replacement that can be attributed to a specific registry function, rates of improvement in surgeons that accessed their individual outcomes data were compared against those that did not. Surgeons in the latter group are a proxy for the counterfactual improvement in outcomes independent of the registry. Only benefits in the period 2010 to 2014 are included in the analysis, when individual surgeon outcomes data was available.

Only the incremental improvement in outcomes in the group of surgeons that accessed individual outcomes feedback, which exceeds the rate of improvement observed in those surgeons that did not, is attributed to the registry (compared to 1999-2002 baseline.) Benefits are scaled to the number of patients treated in each group.

- 629 (of 6486 overall) fewer hip replacement revision procedures in the period 2010-2014
- 534 (of 3863 overall) fewer knee replacement revision procedures the in period 2010-2014

The AOANJRR case study is particularly challenging in the attribution of benefits through a case control analysis. The registry publishes broadly and influences remuneration, licensing and availability of prostheses on the Australian device market. Two key examples were analysed to quantify some of the missing benefit from the described attribution analysis: reduction in use of large head metal on metal hip prostheses and reduction in uni-compartmental knee replacements.

According to clinician opinion, the registry influenced changes in clinical practice through levers at government, hospital and clinician levels. Following receipt of registry feedback clinicians were able to select prostheses with demonstrably better outcomes. Some hospitals mandated use of such prostheses. Governments and regulators were able to make informed licensing and remuneration decisions, including withdrawal of poorly performing prostheses from the market.

Appendix B – Case study details

Victorian Prostate Cancer Registry

Introduction

Prostate Cancer is the most commonly diagnosed cancer in Australia with close to 20 000 new cases diagnosed per annum from 2009. The age-standardised incidence of the disease has increased over time; from 79 new cases per 100 000 males in 1982 to 194 per 100 000 in 2009. This increase is expected to continue, reaching 25 000 new cases per year in 2020 primarily owing to changes in diagnostic practice, greater uptake of testing and population ageing.

Though mortality rates are decreasing, with 5-year survival following diagnosis now higher than 90%, prostate cancer is the fourth leading cause of mortality in Australian males.[38] A preliminary 2013 study by the Hunter Medical Research Institute estimated that the overall economic burden of the disease amounted to $1.4 billion in 2012.[39] Health care costs were estimated to account for $444 million of this figure, with the remainder being attributed to lost wellbeing, side effects from treatment and the equivalent of lost QALYs from premature death and disability. [40]

The Victorian PCR was established as the first prostate cancer clinical quality registry in Australia, through funding by a Cancer Australia priority driven collaborative cancer research scheme. The registry commenced with three metropolitan hospitals initially contributing data in 2009. Subsequent funding support provided by Cancer Australia and the Victorian Department of Health has seen the registry expand across additional sites. From 2013, a total of thirty-three hospitals have been actively contributing to the registry with approximately 75 percent of incident cases covered. In Victoria, this amounts to close to 10,000 males over the five year period from 2009 to 2013 (Appendix B, Figure 1).

[38] 1 Australian Institute of Health and Welfare (AIHW) 2013. Prostate cancer in Australia. Cancer series no. 79
[39] Hunter Medical Research Institute, 'Economists uncovering the cost of prostate cancer', 2013
[40] PWC. A Review and Costing Study into Radiotherapy Services September 2013 Final Report to the IHPA

Appendix B, Figure 1: Participation in Victorian PCR

Source Victorian PCR 5-year report (published 2015 Monash University)

Appendix B, Table 1: Summary of Victorian PCR

Category	Content
Establishment	Founded in 2009 and has grown to 33 sites
Patient coverage	Prostate cancer, opt-out (<3% opt-out rate), 75% coverage of Victorian incident cases
Managed by	Monash University
Funding sources	Government (federal and state), cancer organisations (e.g. Cancer Australia, Movember Foundation)
Principal metrics	Mortality, morbidity, surgical outcomes, patterns of care (and variations thereof), PROMS related to quality of life and disease impact
Analysis	Quality control, data cleaning and auditing conducted by program staff, cross-checks against admin data. Risk-adjustments
Feedback processes	11 indicators are fed back to hospitals and urologists every 6 months through benchmarking reports. Annual report released to public

Approach Used

The approach used in the economic analysis for the Victorian PCR follows the methodology described in 'Approach and methodology' in this report. A schematic model was adopted to evaluate two clinical indicators measured by the registry where a demonstrable change in practice or outcomes can be identified.

1. PSM rate

Where radical prostatectomy is the primary treatment and subsequent pathology reports show unequivocally that the tumour has extended resected tissue. PSMs have been independently associated with disease progression and mortality. The measure predicts the need for secondary therapies and their associated side effects. Accordingly, a reduction in PSM rate is associated with improved patient morbidity and mortality outcomes, as well as a reduction in the costs of secondary therapies. Surgeon experience, technique and volume of surgery undertaken at the treating centre are all factors that impact overall PSM rate.

The assumptions of the PSM rate indicator were:

- As baseline disease state is a predictor of PSM rate, only organ confined intermediate risk (pT2) patients are included in this analysis.[41]
- PSM rate is associated with increased secondary therapy and risk of mortality.[42]
- Rates of surgical intervention in this patient group is constant over time.

[41] Registry data and Manuscript: Sampurno, F, Earnest, A, Evans, S. et.al The Victorian Prostate Cancer Registry (2009-2012) Improvements in clinical quality indicators

[42] A range of studies consider PSM mortality rate in univariate analysis from 4-18% (e.g. Wright, J., Jurol 2010).

- Changes in guidelines and practices occur uniformly across all participating units.[43]

2. Adherence with PRIAS

The PRIAS protocol applies to patients with a low risk of disease progression. For these patients active intervention (referred to here as PRIAS Intervention), whether surgical or through radiotherapy, is not deemed to offer additional prognostic or quality of life benefit compared to active surveillance. The protocol was developed to preserve quality of life in cases where invasive treatment is not indicated and Active Surveillance is more appropriate. Better adherence with the protocol avoids both the cost and adverse patient effect of unnecessary invasive procedures.[44]

The assumptions of the PRIAS rate indicator were:

- Quality of Life decrements for urinary, bowel and sexual bother of 0.15, 0.15 and 0.195.[45]
- Patient reported quality of life outcomes taken from registry records at 12 and 24 months post diagnosis.
- Eligible patients met low risk classification standards (i.e. clinical stage T1/T2, prostate specific antigen less than or equal to 10ng/ml, Gleason score of less than or equal to 6, one or two positive biopsy cores and active treatment within 12 months of diagnosis). The latter ensures that patients with multiple biopsies, who initially met low risk classification but later progressed to higher risk, are omitted from the analysis.
- Expert opinion suggests that measured changes in practice due to registry feedback will occur with a delay due to the time required to collect, analyse, feedback and act on reported outcomes. The time period from collecting prostate cancer outcomes data to seeing actionable changes in clinical practice is likely to be around one year. There will be a delay in measuring and reporting the results of these changes on clinical quality indicators.[46]

Results

Total benefits attributed to the presence of the registry amount to $5.2 million from the period 2009 to 2013. The period of analysis corresponds to the year of registry inception, to the year of most recently available published data. Costs for the equivalent period totalled $2.7 million, resulting in a $2.4 million net benefit over the five-year period of analysis. This is shown in Appendix B, Figure 2.

Appendix B, Table 2: Results of the Victorian PCR case study

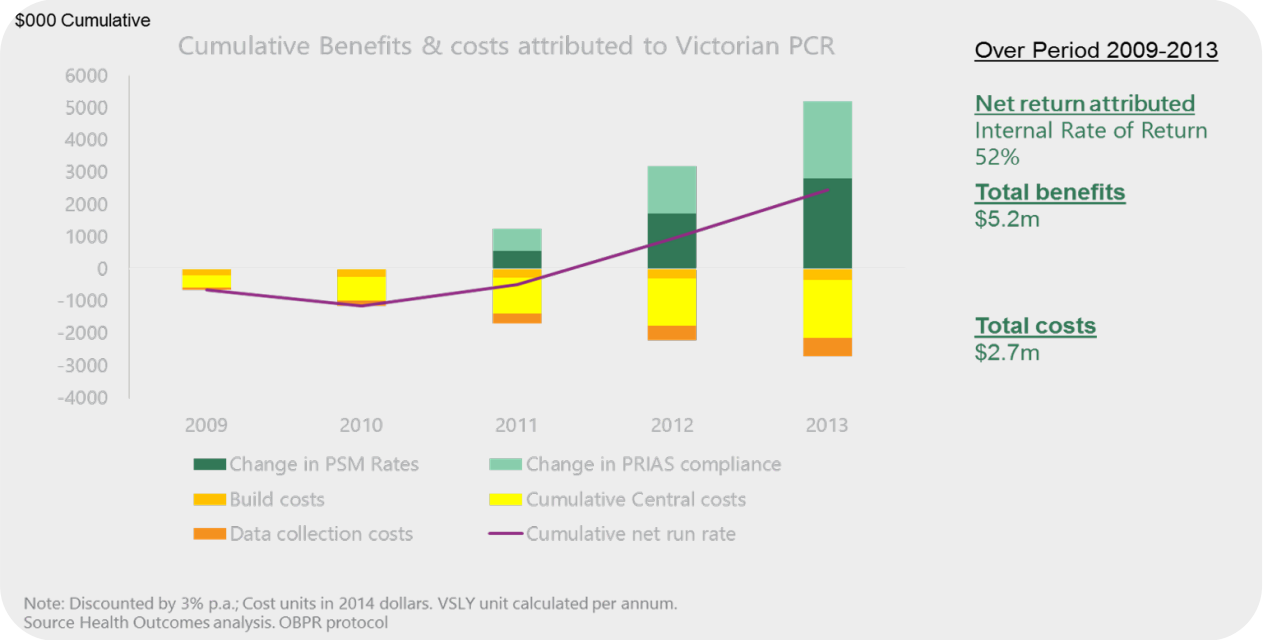
Period of analysis	Gross attributed benefit	Registry costs	Internal rate of return	Benefit to cost ratio
2009-2013	$5.2m	$2.7m	52%	2:1

[43] Registry timespan and key events support slide 14
[44] Further details on PRIAS guidelines presented in support slides 16 and 18
[45] Disease weights taken from WHO global burden of disease study 2010 and AIHW disease impairment data
[46] Expert opinion and interviews with registry chief investigators.

For the purpose of this evaluation, the baseline rate for PSM and rate of PRIAS intervention is 2010. This is due to inadequate sample size before to this point with three initial contributing hospitals providing data. Outcomes data from 2010 onwards represents greater validity to facilitate a meaningful assessment of improvements in the two clinical indicators. Attributed benefits can therefore only be realised from 2011 onwards, due to the time required for the system to enact, measure and report changes in practice and outcomes.

However, registry costs are considered to accrue from the registry's inception in 2009. This ensures that the evaluation captures the initial set up costs, and cumulative costs of measuring and reporting outcomes prior to the realisation of any resultant benefit. The rationale for this conservative approach is that the registry requires this upfront investment to build capacity and data volume, to form benchmarks against which subsequent performance will be measured. Even in the period where no economic benefit is quantifiable, expert opinion suggests that data collection and reporting facilitates maintenance of clinical standards and continuous improvement.[47] Funding is provided by government and charity. Data collection costs are met by the registry. Costs are broken down as central (data management and overheads) and peripheral (data collection and reporting) and presented in support slide 28.

Appendix B, Figure 2: Cumulative costs and attributed benefits of the Victorian PCR



Economic benefit in the period of analysis was equally driven by a reduction in both indicator rates. Reduction in Positive Surgical Margin Rates resulted in a $2.8 million Gross benefit. This can be further broken down to $0.5 million in avoided secondary treatment and $2.3 million in QALY benefits from avoided mortality.

Reduction in the rate of low risk patients undergoing active treatment, contrary to the recommendations of PRIAS guidelines, results in an overall registry attributable benefit of $2.4 million. This can be further broken down to $0.9 million in avoided unnecessary treatment costs and $1.5 million in economic benefit associated with improved quality of life. The former being net of the additional costs of active surveillance (periodic biopsy and follow up) as the alternative sequence of care in eligible patients.

[47] Expert opinion – interviews with stakeholders and registry chief investigators, Steering Committee feedback

Appendix B, Table 3: gross benefit by indicator Victorian PCR

Clinical indicator	Measure of economic impact	Gross benefit	Percentage of total
Positive Surgical Margin Rate	Avoided Secondary Treatment	$0.5m	8%
Positive Surgical Margin Rate	Reduced mortality (QALY)	$2.3m	44%
PRIAS Rate (active intervention in low risk cases where it is not indicated)	Avoided Unnecessary Procedures	$0.9m	18%
PRIAS Rate (active intervention in low risk cases where it is not indicated)	Quality of Life (QALY)	$1.5m	30%

Changes in practice influenced by the registry

Interviews of clinical stakeholders have identified the key changes implemented at individual hospital sites as a result of receiving feedback and benchmark reports from the registry. Of particular note is the impact of bi-annual and annual reports that enable units to compare clinical outcome performance against risk-adjusted averages across the state.

Registry feedback in this form has been effective in identifying variations in outcomes between hospitals, and has resulted in clinicians making changes in patterns of care to address these. In practice, there has been greater open discussion within multidisciplinary team meetings and grand round events, on quality indicators such as positive surgical margins and PRIAS intervention rates. Greater internal scrutiny and awareness of such outcomes measures are considered to have had a positive effect on their improvements over time.

Other significant changes in practice have occurred as a result of feedback reports from the registry. These include greater senior oversight of surgical procedures, with more routine supervision by consultants during radical prostatectomy. Changes in practice such as this are considered by experts to have had a direct effect on reduction on PSM rate.[48]

Attribution of Benefits to the Victorian Prostate Cancer Registry

Gross benefits measured by the registry: The Victorian PCR measured a continuous improvement in positive surgical margins in pT2 organ confined patients from the 2010 baseline rate to 2013. This was equivalent to 219 fewer patients with a PSM following radical prostatectomy, 56 fewer patients requiring consequent secondary treatment and a projected 11 fewer deaths from subsequent higher risk of mortality over the five-year period.

In the same period, the registry measured a reduction in rate of active intervention in low risk (PRIAS) criteria patients' equivalent to 91 avoided unnecessary treatments and 13.3 quality adjusted life years through an incremental reduction in side effects of invasive treatment compared to active surveillance.[49]

[48] Interviews with registry investigators and independent experts (Urologists, Surgeons).
[49] More details presented in support slides 21-27

A proportion of the gross observed benefit is attributable to the Victorian PCR. The residual improvement may be explained by changes in practice that occurred independent to the presence of the registry, such as advances in technology and enhancements in surgical procedures.

Benefits attribution

In the Victorian PCR case study, the rates of improvement in PSM and PRIAS patient active treatment were compared between hospitals that were early contributors to the registry and those that commenced data provision later.

Victorian PCR data demonstrated that the year on year rate of improvement in PSM rate and PRIAS intervention was demonstrably greater in the early contributing hospitals versus those hospitals that joined the registry later. The difference in rate of improvement between the two groups each year was attributed to the Victorian PCR as an incremental benefit of contributing data to, and receiving feedback from the registry.

Further details on the steps involved in the attribution of benefits can be found in support slides 19, 20 and 24. The overall approach is summarised in this section.

Measure

Rate of improvement in PSM and rate of improvement in active intervention in PRIAS patients. For both clinical indicators, improvement is equivalent to a reduction in rate. Because the rates of improvement are being analysed, variation in starting point between groups does not undermine findings.

Case and Control Group

Early registry contributor hospitals (case) compared to later registry contributor hospitals (control).

Early contributors are defined as those hospitals that commenced data provision from 2009, and have had the benefit of reporting to and receiving biannual and annual feedback from the registry from this date. Later contributors joined the registry at periodic intervals from this date to the end of 2012. In practice, the composition of cohorts for comparison depended on the incidence number of eligible cases available for analysis. Comparison groups were selected such that case volume and facility type (metropolitan, public/private) could be closely matched. For the P indicator, outcomes for the entire hospital cohort were compared with early contributors included (case) versus excluded (control). For the PRIAS rate indicator, outcomes data for the three early registry contributors alone was compared to data from subsequent registry contributors. Data in both cases was adjusted for case mix.

The goal is to quantify the improvement that would occur in both of the measured indicators independent of the registry and deduct this from total benefit observed in registry contributors.

In the absence of reported PSM and PRIAS intervention rates for hospitals that are not contributors to the registry, hospitals with later contribution act as a proxy to represent counterfactual changes independent of the registry (whilst they are not contributing to the registry). It is expected that the hospitals that contributed data from 2009 would have improved rates in both indicators in 2010. Late contributors are periodically added to the cohort from 2010 to 2012, and it is expected that each subsequent addition of a new hospital would slow the rate of improvement in this group compared to the early contributors. An underlying assumption here is that improvements as a result of registry feedback will occur with a delay. This is due to the time taken to collect, process, analyse data and then provide

feedback. A further delay occurs as this feedback is acted upon in hospitals, and new outcomes are produced and measured by the registry.

When the registry receives new contributing hospitals, this slows the rate of improvement in the late contributor group. This happened in 2011 and again in 2012 when more new hospitals commenced contribution. Each new contributor will not have previously had the benefit of the registry's feedback. Early adopters will show continuous improvement due to receipt of feedback since inception. No new hospitals joined the registry in 2013 and with this, it would be expected that gradually the rates of improvement would converge. As the period of analysis is up to 2013, this predicted observation is beyond the scope of this analysis.

Only the incremental difference in rate between the two groups is attributed to the registry. The approach is displayed graphically in support slide 20.

Opportunities to expand the evaluation

Long-term follow up data beyond 24 months is not available at the time of evaluation.

The evaluation treats public and private units equally. The relative impact of feedback on early versus late contributors may be confounded by the practice of clinicians performing surgery at multiple sites. Registry data suggests this is true for around 30% of clinicians who typically operate across public and private sites. Multiple site of practice could be converted to an independent variable and examined within a statistical model in future analysis.

The analysis does not include the long-term likelihood of PRIAS criteria patients requiring active treatment due to no longer meeting low risk criteria. Expert opinion suggests this is likely to apply to 20-30% of initial low risk patients. Longer follow is required to quantify impact on the analysis.

There may be a difference in outcomes for patients who are diagnosed in a contributing hospital but receive treatment elsewhere. This data could be obtained from the registry in future analyses.

The early and late adopter groups for each indicator were defined based on coarse existing spate registry analyses for each indicator. This should be refined in future analyses using the dates that individual hospitals started providing data to the registry. In this way, the groups shall be the same for each indicator compared.

QALY benefits of survival are based on estimated median (projected) age of mortality taken from the registry. A longer period of registry operation will provide a more accurate estimation.

Sensitivity analysis can be found on support slides 29-30.

Victorian State Trauma Registry

Introduction

Trauma in Australia and New Zealand is a leading cause of mortality in the first four decades of life. Injury related deaths have declined in the last twenty years. However they continue to represent a significant burden on health resources and long-term patient outcomes. The identification and management of seriously injured patients requires a coordinated approach

comprised of pre-hospital management, emergency management, and definitive care at an appropriate location.[50]

The VSTR was established in 2001 following the 1999 Ministerial Review of Trauma Emergency Services (ROTES). ROTES led to the formation of an integrated system of care for patients sustaining major trauma in Victoria (Victorian state trauma system).[51] The VSTR monitors and evaluates performance of the Victorian state trauma system. It collects data on all major trauma cases in Victoria across all phases of trauma care from 138 health services comprising; two adult and one paediatric major trauma services and staged care through regional and metropolitan health services.

Full coverage was achieved in 2005 following completion of ethics procedures at contributing hospitals. Full maturity of feedback was considered to be achieved from 2011 following the inception of structured outlier feedback directly to health services through the case review group (CRG).[52] 3,000 eligible patients were covered by the registry in 2013-14.

Appendix B, Figure 3: Participation in VSTR

Source Victorian State Trauma System and Registry 2014 Summary Report

[50] Kate A Curtis, Rebecca J Mitchell et. al Injury trends and mortality in adult patients with major trauma in New South Wales. Med J Aust 2012; 197 (4): 233-237

[51] Further details on registry background and definition of major trauma are presented in support slides 32-34

[52] CRG reviews cases transferred to a non-MTS, receiving definitive care at a non-MTS or a time critical transfer that took longer than 6 hours. Further on the case review group are presented in support slide 36.

Appendix B, Table 4: Summary of VSTR

Category	Content
Establishment	Established in 2001 following review of Trauma and Emergency Services in Victoria
Patient coverage	State wide coverage of all major trauma patients in Victoria, full coverage achieved from 2005 and outlier feedback maturity from 2011
Managed by	Victorian State Trauma Outcomes Registry Monitoring Group (VSTORM) based at Monash University
Funding sources	Department of Health and Human Services (DHHS) Victoria and Transport Accident Commission (TAC)
Principal metrics	System process metrics such as triage and transfer, discharge destination, mortality, length of stay, long term functional outcomes
Analysis	Quality control, monitoring and evaluation of Victorian State Trauma System. Identification and feedback to outlying units
Feedback processes	Annual report, quarterly reports (to health services and DHHS) and structured feedback through Case Review Group which meets 3 times a year

Approach Used

The approach used in the economic analysis for the Victorian State Trauma Registry follows the methodology described in 'Approach and methodology' in this report. A schematic model was adopted to evaluate the clinical indicators measured by the registry where a demonstrable change in practice or outcomes can be identified. Two key clinical quality indicators were identified for analysis.

1. Reduction in Average Length of Stay (ALOS)

Longer lengths of stay are associated with increased cost on a straightforward cost per bed day basis. Accordingly, a reduction in average length of stay is associated with a reduction in health care costs.[53]

The main assumptions and considerations for the ALOS were:

- Only patients with an injury severity score greater than 12 (ISS>12) are isolated in this analysis as the trend in reduced ALOS is most pronounced in this group.
- External factors (changes in safety legislation and technology etc.) will affect hospitals uniformly.
- Major changes in guidelines mainly occurred pre or post the period of analysis. Those that affect the evaluated period will affect all hospitals uniformly.[54]
- Changes in guidelines and practices occur uniformly across all participating units.

[53] Cost of an average Major Trauma Bed Day provided by the funding analytics branch Emergency and Trauma Services, Department of Human Services Victoria $3,236.

[54] Timeline of significant events in Victorian Major Trauma Registry is presented in support slide 39

2. Reduction in the rate of in-hospital mortality

The registry measures the actual deaths of major trauma patients compared against any predicted changes in the rate of occurrence that would be expected due to case mix changes or external factors (e.g. bush fires). Avoided mortalities result in quality adjusted life year benefits from the years of life preserved. There are ongoing costs associated with reduced mortality, including costs of follow up care and rehabilitation. Some of these were factored in to this analysis where data was available.[55]

The main assumptions and considerations for in-hospital mortality were:

- All major trauma patients included in the analysis –adjusted for age, mode of injury, severity
- Broad pattern of discharge destination has not changed demonstrably in the last 3-5 years. Only follow up costs relating to subsequent in-patient rehabilitation were accessible and included in the analysis.[56]
- Changes in guidelines and practices occur uniformly across all parts of the trauma system.
- Median age of mortality is taken from registry data to calculate years of life saved from ABS life expectancy data.[57]
- Follow up 12-month mortality data and longer-term functional outcomes are not available at the time of analysis.

Results

Total benefits attributed to the presence of the registry amount to $36 million from the period 2005 to 2013. The period of analysis corresponds to the year of full registry coverage to the year of most recently available data. Costs for the equivalent period totalled $6.5 million, resulting in a $30 million Net benefit. This is shown in Appendix B, Figure 4.

Appendix B, Table 5: Results of the VSTR case study

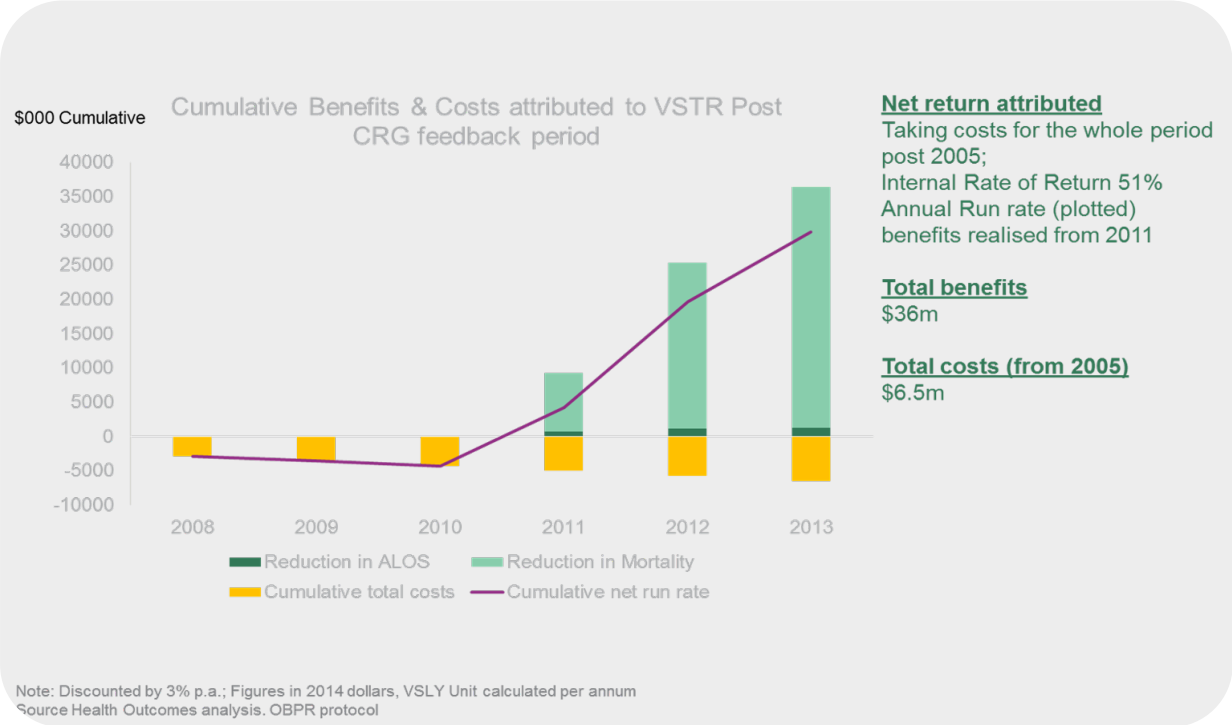
Period of analysis	Gross attributed benefit	Registry costs	Internal rate of return	Benefit to cost ratio
2005-2013	$36m	$6.5m	51%	6:1

For the purpose of this evaluation the baseline rate for average length of stay and standardised in-hospital mortality is the year of full coverage; 2005 and costs are accrued from this year. Registry attributed benefits are only realised after health service outlier feedback from the CRG commenced in 2011.[58] The rationale for this conservative approach is that the registry requires advanced investment to build capacity and data volume in order to form benchmarks against which subsequent performance will be measured. Even in the period where no economic benefit is quantifiable in this evaluation, expert opinion suggests that data collection and reporting activity facilitates both the maintenance of clinical

[55] Preserved years of life were calculated based on registry data on age of mortality and demographics.
[56] Registry data and Australian Rehabilitation Outcomes Centre annual report 2014
[57] Australian Bureau of Statistics data tables March 2011 cat. no. 4102.0
[58] The process of attribution of benefits to the post CRG period is explained further in support slides 41-43

standards and continuous improvement.[59] Funding is provided by the Victorian Department of Health and Human Services, and Transport Accident Commission. Data collection costs are met through individual health service and through the registry itself. Costs are expressed as central (data management and overheads) and peripheral (data collection and reporting) in support slide 49.

Appendix B, Figure 4: Cumulative costs and attributed benefits of the VSTR



Economic benefit in the period of analysis was driven by a reduction in standardised in-hospital mortality of major trauma patients. Registry attributed benefits from reduced mortality amounted to a $39 million, as calculated based on registry data on median age of mortality and proportion of patients discharged to in-patient rehabilitation.[60] The costs of likely in-patient rehabilitation are deducted from benefits figures presented in this analysis.[61]

Appendix B, Table 6: gross benefit by indicator, VTSR

Clinical indicator	Measure of economic impact	Gross benefit	Percentage of total
Reduction in ALOS	Avoided treatment (service) costs	$1.2m	3%
Reduction in standardised in-hospital mortality	QALY	$35m	97%

[59] Expert opinion – interviews with stakeholders.
[60] Quality of Life benefit was calculated using years of life saved based on Australian Bureau of Statistics (ABS) life tables for male gender, as the more conservative estimate.
[61] Average costs of in-patient rehabilitation as presented by Australian Rehabilitation Outcomes Centre (AROC) annual report 2014 based on average number of bed days for any in-patient rehabilitation patient.

Changes in practice influenced by the registry

Interviews of clinical stakeholders have identified key changes implemented as a result of receiving feedback from the registry.

VSTR feedback has influenced hospitals to use existing clinical governance mechanisms to review patient management, particularly with regard to care coordination and patient transfer to receive definitive care at a major trauma service.

Changes implemented specifically as a result of structured feedback from the CRG included earlier liaison of regional and metropolitan trauma hospitals with Adult Retrieval Victoria (ARV) for joint assessment of clinical management, need for transfer and retrieval coordination.[62] Earlier consultation, and thus more efficient coordination, with major trauma service hospitals was also commenced for patients determined to require transfer.

Attribution of benefits to Victorian State Trauma Registry outlier feedback through the CRG

Gross benefits measured by the registry: The VTSR measured a reduction in ALOS for trauma patients (ISS>12) from the 2005 baseline rate to 2013. This was equivalent to more than 16 000 fewer trauma bed days compared to baseline rate.

In the same period, the registry measured a reduction in crude mortality rate for all major trauma patients equivalent to 366 fewer mortalities compared to 2005 baseline mortality rate.[63]

A proportion of the gross observed benefit is attributable to the VSTR. The residual improvement may be explained by changes in practice that occurred independent to the presence of the registry, such as advances in traffic safety, work/home safety and enhancements in clinical procedures.

In the VSTR analysis, the rates of improvement in average length of stay and in-hospital mortality were compared before and after the inception of structured outlier feedback through the CRG. Structured additional feedback to outliers commenced in 2011. The rate of year on year improvement in both indicators was greater after 2011 compared to before this year. Only cases that are identified as potentially having not been managed in accordance with major trauma guidelines are reviewed by the CRG. As such, not all hospitals will have received outlier feedback through this registry function in the period of analysis. Accordingly, two groups were defined to determine the incremental benefit of the registry's case review group function: CGR Hospitals and non-CRG Hospitals.[64] The rate of improvement in both indicators was fastest in the CRG Hospital group, and particularly in the period after 2011. The incremental improvement (after 2011 and compared to the non-CRG group) was attributed to the registry.

The overall approach for the attribution of benefits to this registry function are summarised in this section with further information available in the support slides.

[62] Adult Retrieval Victoria (AVR) is a state-wide contact and coordination service for major trauma advice, adult critical care advice, critical care bed access and retrieval of adult critical care patients

[63] More details are presented in support slides 45-48.

[64] Major Trauma Service Hospitals do not receive feedback from the Case Review Group but their outcomes are affected by this registry function due to the integrated nature of the Victorian State Trauma System.

Measure

In order to isolate benefits that can be clearly attributed to the presence of the registry, an analysis has been conducted of the rate of improvement in average length of stay (ALOS) as a trauma patient and risk adjusted mortality, before and after the introduction of the CRG structured feedback process.

Case and control group

The Victorian state trauma system is an integrated system. Due to the nature of staged patient care in regional and metropolitan trauma hospitals, inter-hospital transfer for definitive care, dedicated centres for neurosurgery, spinal injury and microsurgery; it would not be legitimate to compare individual hospital units against each other or omit outcomes data from the major trauma service hospitals in the analysis. For example, if a metropolitan hospital receives feedback from the CRG and improves its performance in transferring critically ill patients to major trauma service, there is a possibility that the resulting case mix change would result in a greater proportion of frail and elderly patients remain at the metropolitan hospital, with comparatively higher rates of morbidity and mortality, whereas the definitive care outcomes at the major trauma service hospital would likely improve due to more timely triage and transfer through the system.

A system level approach is therefore adopted to the control/attribution of benefits in this analysis

During the timeframe of 2005-2013, there is a clear distinction in the analyses and feedback provided to potential outlier metropolitan and regional centres before and after 2011 when the CRG commenced formal feedback.

The study compared system performance before and after the CRG health service feedback function commenced. The overall improvement within the same time-frame for the system was used as a benchmark, without the hospitals that received feedback from the CRG. The two comparison groups were:

1. CRG hospitals: All hospitals within the VSTR, including those that have received feedback from the CRG over the period 2011-2013/4 including outcomes in this period from major trauma services. Benefit findings were scaled down to the proportion of patients that have been admitted to a unit that received CRG feedback.

2. Non-CRG hospitals: All hospitals within the VSTR minus any unit that received additional CRG feedback.

The additional improvement in the CRG group, after the commencement of CRG feedback in 2011, was attributed to the registry's feedback, after deducting any benefit that would have occurred if this group kept improving outcomes at the rate observed before 2011.

Opportunities to expand the analysis

The analysis does not factor in long term improvements in patient functional outcomes due to data availability. Registry data in this area could be included in future economic evaluation around productivity.

Rehabilitation costs are approximated based on registry data on discharge to in-patient rehabilitation and published reports on mean in-patient rehabilitation length of stay. Ambulatory rehabilitation costs and detailed analysis of rehabilitation services offered specifically to major trauma patients was beyond the scope of this evaluation.

Evaluation of the costs of trauma patient discharged to in-patient services other than rehabilitation was beyond the scope of this evaluation.

Avoided mortality is based on the lower bound (male) from ABS life tables. Further granularity can be achieved by examining registry data on major trauma gender demographics. Years of survival are not impaired by disease weight in this analysis due to data availability on long-term quality of life outcomes. Future registry data may facilitate this. If each QALY reduced by 35% for ongoing impairment there would still be a gross QALY $24m benefit.

12-month mortality and readmission could be added to future analyses by linkage to Victorian births, deaths and marriages data. This was not feasible in the timescale of this analysis.

Sensitivity analysis can be found on support slide 50.

Australia and New Zealand Intensive Care Society Adult Patient Database

Introduction

Intensive care refers to the specialist treatment provided to patients who are acutely unwell and require critical medical care. Care provided in ICUs is through multi-disciplinary teams and typically covers diverse areas of clinical specialty including burns, trauma, sepsis, overdose, respiratory failure, organ transplant, and post-operative care (spinal surgery, cardiothoracic surgery). There were over 100 000 ICU admissions in Australia in 2013/14 across approximately 160 ICUs (adult and paediatric). ICU bed availability varies between states and territories.

The ANZIC APD was established in 1992 as a bi-national registry run by the Centre for Outcome and Resource Evaluation. It is part of a broader set of 4 linked CQRs that benchmark performance and analyse outcomes at ICUs across Australia and New Zealand.

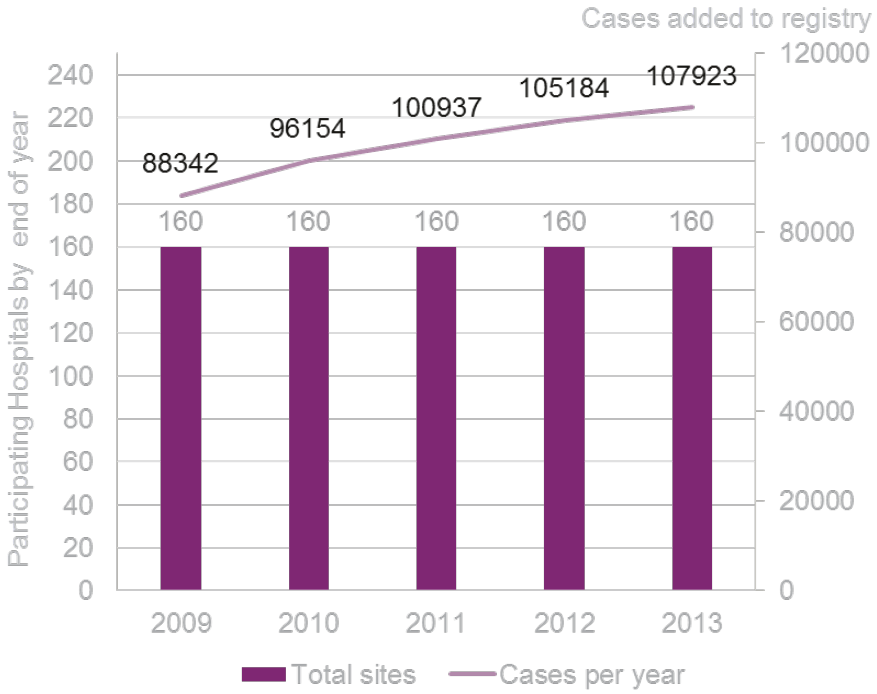
1. Adult Patient Database
2. ANZICS Paediatric Intensive Care
3. Critical Care Resources
4. Central Line Associated Bloodstream Infection

There are currently approximately 160 contributing units across Australia with an estimated 80% to 85% coverage of incident cases.[65] The APD registry collects data on standardised mortality, average length of ICU stay, and complications (sepsis, central line infections etc.)

Feedback has occurred through quarterly and annual reports that enable units to analyse performance against benchmarked averages. Since 2008/9, individual outlier units have received additional structured analysis and feedback through the registry's outlier management program (OMP).[66]

[65] Registry stakeholder interview and grey literature.
[66] Outlier status is determined by standardised mortality ratio (SMR). If SMR is above 99% confidence intervals for the bi-national cohort, the OMP program is initiated. Further details in support slides 54-55

Appendix B, Figure 5: Participation in ANZICS APD



Source ANZICS Core website and grey literature

Appendix B, Table 7: Summary of ANZICS APD

Category	Content
Establishment	In operation since 1992, bi-national registry forming part of a broader set of 4 linked clinical quality registries
Patient coverage	Intensive care units across Australia and New Zealand (c80% coverage), now covering 160 units
Managed by	ANZICS CORE
Funding sources	Federal governments and Queensland private units
Principal metrics	Standardised mortality, ICU length of stay, central line infection rates
Analysis	Quality control, benchmarking, evaluation of resourcing
Feedback processes	Quarterly and annual reports with unit level and consolidated outcomes data. Accessed through self log-in to CORE portal. Additional structured feedback provided to outlier units

Approach used

The approach used in the economic analysis for the ANZICS APD registry follows the methodology described described in ‘Approach and methodology’ in this report. A schematic model was adopted to evaluate the clinical indicators measured by the registry where a

demonstrable change in practice or outcomes can be identified. Two key clinical indicators were identified for analysis.

1. Reduction in ALOS in ICU

Longer lengths of stay are associated with increased cost on a straightforward cost per bed day basis. Length of stay can be influenced by age, comorbidity, diagnosis amongst other factors. A reduction in average length of stay in ICU is associated with a reduction in health care costs.[67]

The main assumptions and considerations for ALOS were:

- ALOS in median bed days for ICU stay only. Data on discharge destination was not available for this analysis.
- Only patients aged 16 and over are included in the analysis, risk standardised for age, comorbidity and principle diagnosis.
- Data was censored for readmissions in the same episode.
- Changes in guidelines and practices occur uniformly across all participating units in the period of analysis.[68]

2. Reduction in the rate of ICU SMR

The registry measures the actual deaths of ICU patients compared against any predicted changes in the rate of occurrence that would be expected due to case mix changes. The ratio of observed and predicted deaths is referred to as the SMR. SMR was measured and any reduction therein over time converted to avoided mortalities. Avoided mortalities result in quality adjusted life year benefits from the years of life preserved.

The main assumptions and considerations for ICU SMR were:

- All adult ICU patients included in the analysis – adjusted for age, mode of injury, severity.
- Changes in guidelines and practices occur uniformly across all Intensive Care Units.
- Each avoided mortality is deemed to preserve one year of life.[69]
- Predicted mortality is used to standardise the effect of case mix etc. based on the Acute Physiology, age and Chronic Health Evaluation (APACHE) III-J mortality prediction model.
- Follow up mortality data and longer-term functional outcomes are not available at the time of analysis.

Results

Total benefits attributed to the presence of the registry amount to $36 million from the period 2000 to 2013. The period of analysis corresponds to the period of available data. Costs for the equivalent period totalled $9.8 million, resulting in a $26 million net benefit. This is shown in Appendix B, Figure 6.

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[67] Cost of an average ICU bed day taken from registry grey literature and cost index data from New South Wales Department of Health [PDF 1.3 MB] $4,500 per day

[68] Support slide 59 contains further details on key events associated to the timeline of analysis.

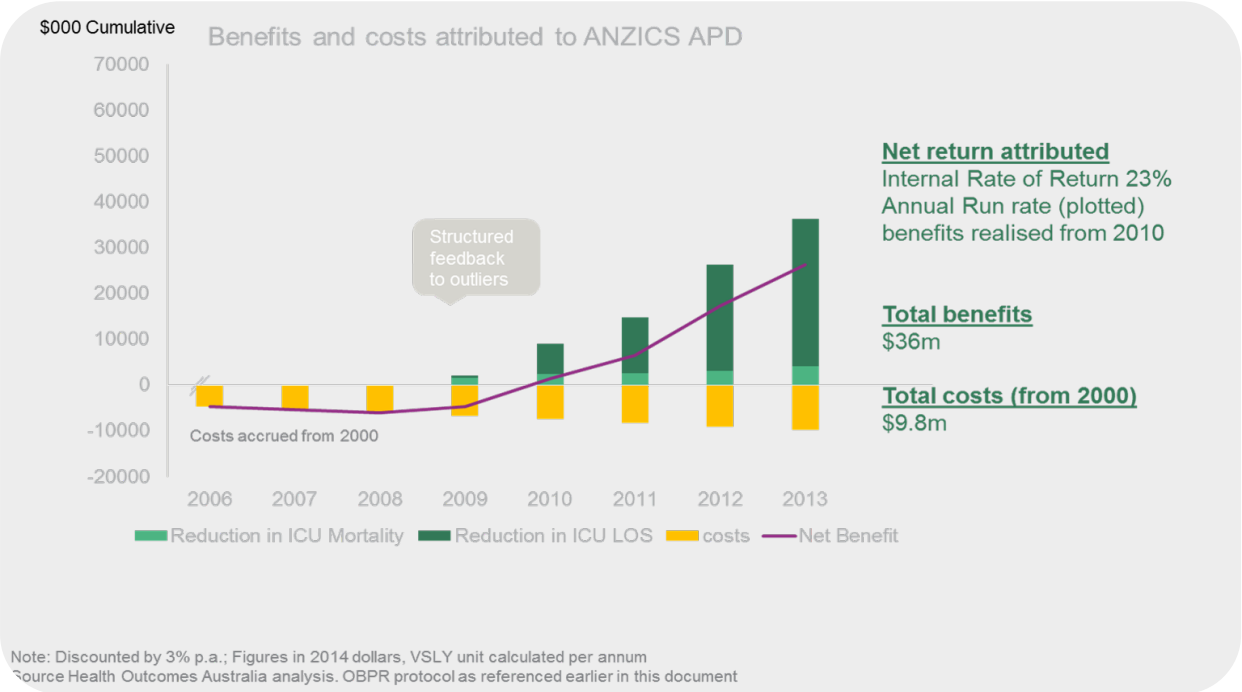
[69] There is a paucity of evidence around long-term survival of ICU patients. Research is underway using data from Tasmanian ICUs. Early analysis from this study suggests that survival is largely age dependent, with 3-year survival in the median age group at 50%. The Bohensky JCC 2012 study quoted 80% survival at 180 days. Expert opinion is 1-year survival is a fair/conservative estimate for the purpose of this analysis.

Appendix B, Table 8: Results of the ANZICS APD case study

Period of analysis	Gross attributed benefit	Registry costs	Internal rate of return	Benefit to cost ratio
2000-2013	$36m	$9.8m	23%	4:1

For the purpose of this evaluation, the baseline rate for average length of ICU stay and standardised ICU mortality is the year of earliest available data, 2000. Costs are accrued from this year. Registry attributed benefits are only realised after structured outlier feedback through the OMP commenced in 2009.[70] The rationale for this conservative approach is that the registry requires advanced investment to build capacity and data volume in order to form benchmarks against which subsequent performance will be measured and outlier ICUs will be reliably identified. Even in the period where no economic benefit is quantifiable in this evaluation, expert opinion suggests that data collection and reporting activity facilitates both the maintenance of clinical standards and continuous improvement.[71] Funding is provided by federal governments, with data collection costs met by individual ICUs as a cost of regular business operation. Costs for this registry are difficult to break down at central and peripheral level because they form part of the central ANZICS budget. The period of operation of the registry has also made it challenging to identify initial set-up costs. Further information on ANZICS APD costs are presented in support slide 68.

Appendix B, Figure 6: Cumulative costs and attributed benefits of the ANZICS APD registry



Economic benefit in the period of analysis was driven by a reduction in ICU average length of stay. Registry attributed benefits from reduced length of stay amounted to $32 million,

[70] The process of attribution of benefits to the post OMP period is explained further in support slides 60-61

[71] Expert opinion – interviews with stakeholders RG to update

with reduced ICU mortality in the same period resulting in economic benefit of $4 million (after discounting).

Appendix B, Table 9: gross benefit by indicator ANZICS APD

Clinical indicator	Measure of economic impact	Gross benefit	Percentage of total
Reduction in ALOS	Avoided treatment (service) costs	$32m	89%
Reduction in standardised ICU hospital mortality	QALY	$4m	11%

Changes in Practice influenced by the registry

Interviews with clinical stakeholders have identified key changes implemented as a result of receiving feedback from the registry.

ANZICS APD feedback has encouraged process-oriented checklists and more formal tracking of processes thought to be good practices. Changes implemented at ICU level broadly fall under resource and access, and clinical practice.

Resource and Access

The presence of a pharmacist on ICU ward rounds was encouraged to enable swifter and more appropriate oversight of medicines management.

Greater unit level scrutiny on access issues such as time to admission and inter-hospital transfer

Drawing attention to after-hours and weekend discharge and seeking to avoid these where possible.

Promoting availability of medical emergency teams to respond to critically ill patients outside of ICU

Greater senior medical staff (Consultant Intensive Care Physicians) supervision of less experienced doctors.

Clinical Practice

Provision of Venous Thromboembolism Prophylaxis

Attribution of benefits to the ANZICS APD

Gross benefits measured by the registry: The ANZICS APD registry measured a continuous improvement in ALOS in ICU from the 2000 baseline rate to 2013. This is equivalent to 360,000 fewer ICU bed days compared to year 2000 rate.

In the same period, there was a continuous reduction in standardised mortality ratio equivalent to more than 36,000 fewer mortalities compared to 2000 baseline standardised mortality rate.[72]

[72] Further details are presented in support slides 62-65.

A proportion of the gross observed benefit is attributable to the ANZICS APD registry. The residual improvement may be explained by changes in practice that occurred independent to the presence of the registry, such as advances in technology, medication, other clinical level improvements or resourcing.

In the ANZICS APD case study, the rates of improvement in ICU average length of stay and ICU standardised mortality were compared before and after the 2009 commencement of structured outlier feedback through the OMP.

The rate of year on year improvement in both indicators was greater after 2009 compared to before this year for all ICUs. Only ICUs that are identified as "true" outliers based on their SMR are provided additional OMP structured analysis and feedback.[73] As such, only outliers that were defined after 2009 will have received OMP feedback. Outliers before this time will have been able to track their own performance through benchmarking reports and may have addressed issues with performance. Accordingly, two groups were defined to determine the incremental benefit of the registry's OMP function: late outlier ICU hospitals and early outlier ICU hospitals.[74] The rate of improvement in both indicators was fastest in the late outlier group, and in the period after 2009. The incremental improvement (compared to pre-2009, and the early outlier group) was attributed to the registry.

The overall approach for the attribution of benefits to this registry function are summarised in this section with further information available in the support slides.

Measure

In order to isolate benefits that can be clearly attributed to the presence of the registry, an analysis was conducted of the rate of improvement in average length of stay in ICU and risk adjusted mortality, before and after the introduction of the outlier management program structured feedback.

Case and Control Group

During the timeframe of 2000-2013, there is a clear distinction in the analyses and feedback provided to outlier ICUs before and after 2009 when the OMP commenced formal structured feedback.

To determine the proportion of the measured changes in ALOS and SMR that can be attributed to the registry, rates of improvement at outlier hospitals were compared before and after inception of the OMP. The two comparison groups were:

1. Late outliers – Hospitals that were outliers after 2009. These hospitals received OMP feedback through the ICU director, jurisdictional governance body/health department and clinician members of an outlier working group.

2. Early Outliers – Hospitals that did not received additional OMP feedback. SMR has at some point before 2009 met the definition of "outlier" but as the OMP has not commenced structured feedback until this date, no additional analysis and feedback took place.

[73] A "true" outlier is one who's SMR is poorer than cohort 99% confidence interval and cannot be explained by case mix, data quality or reporting adjustments.

[74] Units that have never been an outlier will not have received additional structured OMP feedback at any point, and will not have been identifiable as a stand out (poor) performer in benchmarking reports. Outcomes from these "inliers" were used as the baseline rate to benchmark outlier performance in both the case and control ICUs.

The additional improvement in the late outlier group, after the commencement of OMP feedback in 2009, was attributed to the registry's feedback, after deducting any benefit that would have occurred if this group kept improving outcomes at the rate observed before 2009.

Opportunities to expand the analysis

Longer term functional outcomes and disability free survival data was not available at the time of analysis. Some of this data can be obtained through data linkage for future evaluation.

Long-term survival data was not available at the time of the analysis. The majority of the benefit quantified in this case study comes from reduction in average length of stay in ICU, and not from SMR. It is therefore not expected to be of material significance for the scope of this analysis.

Destination of discharge data was not available at the time of analysis. This data can be extracted from the registry for future evaluation to deduct clinical follow up costs from quantified benefits.

ICU performance and impact on economic benefits could be compared with activity data from the Critical Care Resources database to determine the economic impact of patterns of care. Of particular interest are after hours and weekend discharge, staff and bed resourcing, refused referrals across and between all groups of ICUs (metropolitan, regional, public private etc.).

Sensitivity analysis can be found on support slides 66-67.

Australia and New Zealand Dialysis and Transplantation Registry

Introduction

Dialysis and transplantation, together referred to as renal replacement therapy (RRT), are used to treat end-stage kidney disease (ESKD). ESKD is the most severe form of chronic kidney disease (Stage 5 kidney disease/renal failure) and represents a significant burden on the Australian healthcare system. Dialysis alone contributes to approximately 15 per cent of all hospitalisations in Australia.[75] A 2010 analysis of the projected economic impact of ESKD in Australia to 2020, estimated the present value cumulative cost of RRT for all prevalent cases to be between $11.3 and $12.3 billion (based on population incidence projections and annualised treatment costs).[76]

ESRD is associated with a number of other chronic diseases, including cardiovascular disease and diabetes and is both a significant detriment to patient quality of life, and contributor to mortality in Australia. Over 50 people die every day with kidney related disease. [77]

ANZDATA was founded in the late 1970s to register all patients receiving renal replacement therapy, where the intention is to treat long term (renal function is not expected to recover). All renal units, including transplanting, dialysis and satellite dialysis units, across Australia

[75] AIHW – Dialysis and Kidney Transplantation in Australia 1991-2010 More details on ESKD in support slide 74
[76] Kidney Health Australia – The Economic Impact of End-Stage Kidney Disease in Australia Projections to 2020
[77] ABS data presented by Kidney Health Australia

and New Zealand provide data to the registry. The registry compiles data on incidence and prevalence of end stage kidney disease, treatment (haemodialysis, peritoneal dialysis, transplant), complications (including dialysis technique failure and transplant graft loss) and mortality. In 2013 there were more than 21 000 prevalent ESKD patients reported by the registry.[78]

Appendix B, Figure 7: Participation in ANZDATA registry

Source ANZDATA Annual Report 2014

[78] ANZDATA annual report 2014

Appendix B, Table 10: Summary of ANZDATA registry

Category	Content
Establishment	Founded in late 1970s
Patient coverage	All renal units providing details on renal replacement patients in Australia and New Zealand, including transplanting units, satellite haemodialysis units
Managed by	ANZDATA – Royal Adelaide Hospital
Funding sources	Australian Organ and Tissue Authority, New Zealand Ministry of Health, Kidney Health Australia
Principal metrics	RRT mortality specific to modality of treatment, RRT complications (peritonitis, dialysis technique failure), comorbidities
Analysis	Quality control, data parsing registry staff
Feedback processes	Quarterly unit level benchmarking reports, annual report – public disclosure of site level outcomes. Key performance indicators produced quarterly in addition regarding haemodialysis access and peritonitis. Access through online self log-in since 2011

Approach used

The approach used in the economic analysis for the ANZDATA registry follows the methodology described described in 'Approach and methodology' in this report. A schematic model was adopted to evaluate the clinical indicators measured by the registry where a demonstrable change in practice or outcomes can be identified (see support slides). Three key clinical indicators were identified for analysis.

1. Reduction in dialysis mortality

The registry measures the number of patients who die while receiving RRT through dialysis (haemodialysis and peritoneal). Avoided mortalities result in QALY benefits from the years of life preserved.

The main assumptions and considerations for reduction in dialysis mortality were:

- Years of life preserved are calculated based on registry data on average treatment duration. Death is adjusted for time on treatment and assumed to occur within the first year of dialysis. As such, the full mean duration of dialysis is considered to be preserved in an avoided mortality.[79]
- Each avoided mortality results in ongoing costs of dialysis for surviving patients. Similar to point 1, the full mean period of 4.5 years is considered as the period in which there will be additional cost.
- Ongoing dialysis results in disease weight impairment (quality adjustment) to each life year saved. For the purpose of preserved life, the lower bound of referenced disease

[79] Mean period of dialysis taken from registry data as 4.5 years as quoted in Senthuran, S. MJA 2008 188 292-295 [PDF 232 KB]

weights is used in this analysis (0.603 value of a statistical year (VSLY) preserved per avoided mortality).[80]

- Conservative estimate of proportion of vascular re-access procedures was adopted. For this analysis, it was assumed that all avoided mortalities would result in one additional vascular access procedure.
- Changes in guidelines and practices occur uniformly across all participating units in the period of analysis.[81]

2. Reduction in renal transplant graft loss rate

The registry measures the actual number of renal transplant grafts lost due to failure of function.[82] Preserved grafts lead to benefits from avoided subsequent dialysis and initial surgical access (for haemodialysis patients). There are also incremental improvements in quality of life for patients with a surviving graft versus those on dialysis for RRT.

The main assumptions and considerations for reduction in renal transplant graft loss rate were:

- Assumes graft loss leads to a lifetime on dialysis as alternative renal replacement therapy. In reality, some patients receive subsequent grafts. This is addressed in the sensitivity analysis.
- The median survival with a functioning transplant graft is 11 years as quoted in registry data and expert opinion.
- Costs of average year on dialysis is the mean based on proportion of patients receiving RRT through haemodialysis and peritoneal dialysis (in all settings), as reported in the registry annual report 2014.
- Benefits are reduced by the ongoing costs of immunosuppression and medical follow up required for patients with a functioning renal transplant.[83]

3. Reduction in incidence/rates of peritonitis

The registry measures the incident number of peritonitis cases for patients receiving RRT through peritoneal dialysis. Reduction in the rate of peritoneal infections results in economic benefits associated with reduced costs of treatment. There are additional incremental quality of life benefits to patients from avoiding incidences of peritonitis.

The main assumptions and considerations for reduction in incidence/rates of peritonitis were:

- Only the proportion of patients that have a hospital admission as part of their episode of peritonitis are included in the evaluation. This is estimated at 69% from risk adjusted registry data.
- The overall cost of dialysis used in this evaluation is not affected by a change from peritoneal to haemodialysis as a mean dialysis annual cost unit is used. The proportion of patients that switch to permanent haemodialysis following infection is estimated at 16% from risk adjusted registry data.

[80] Source: World Health Organisation Global Burden of Disease Study 2010
[81] Support slide 73 contains further details on key events associated to the timeline of analysis.
[82] Renal Transplant Grafts may fail for a number of reasons. Refer to the ANZDATA annual report 2014 chapter 8
[83] Costs of care are derived from Howard, K., McDonald, S. et. al. The cost effectiveness of increasing kidney transplantation and home-based dialysis – Journal of Nephrology 2009, Haller, M. Nephrology Dialysis Transplant 2011 26: 2988-2995

- Quality of life impairments to patients with an acute episode of peritonitis is 0.053 as quoted in the World Health Organisation Global Burden of Disease study 2010.

Results

Total benefits attributed to the presence of the registry amount to $58 million from the period 2004 to 2013, the period of available data. Costs for the equivalent period totalled $8.8 million, resulting in a $49m net benefit. This is shown in Appendix B, Figure 8.

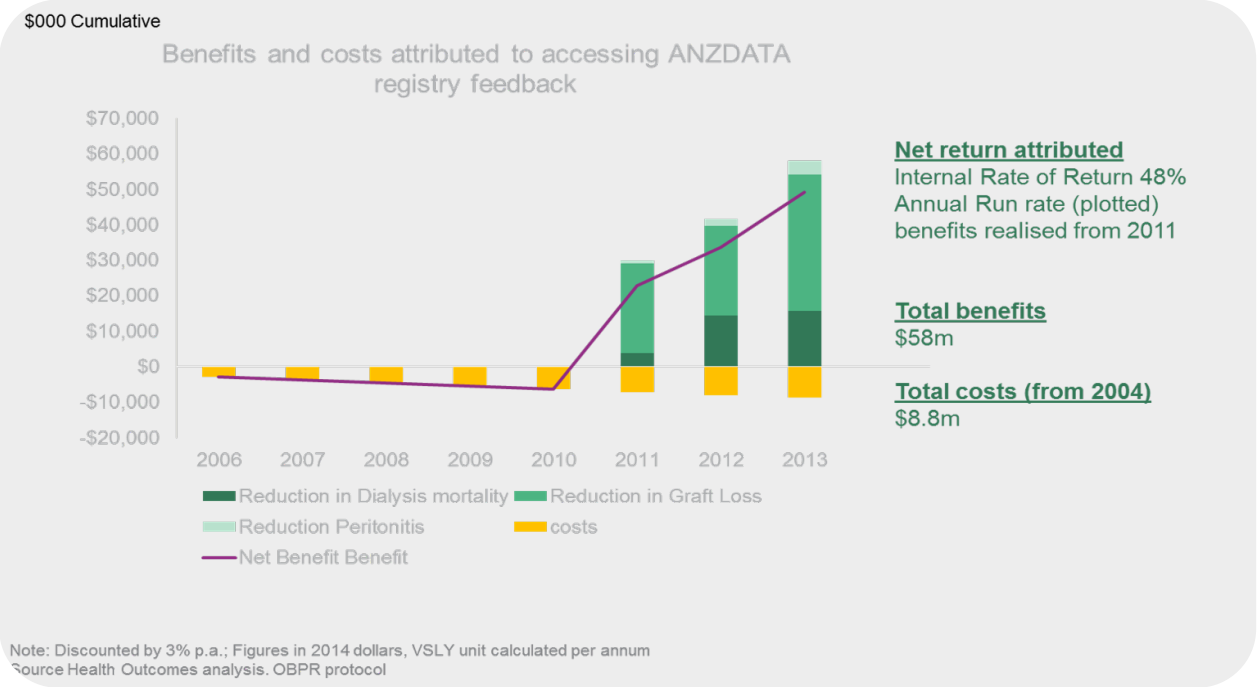
Appendix B, Table 11: Results of the ANZDATA registry case study

Period of Analysis	Gross attributed benefit	Registry Costs	Internal Rate of Return	Benefit to cost ratio
2004-2013	$58m	$8.8m	48%	7:1

For the purpose of this evaluation the baseline rate of dialysis mortality, graft loss and peritonitis rate was 2004. Costs are accrued from this year. Registry attributed benefits are only realised after 2011 when the registry changed the method of access to its benchmarking and feedback reports. Funding is provided by Federal Government, charity and Australian Organ and Tissue Authority, with data collection costs met by individual renal units as a cost of regular business. Costs for this registry are difficult to break down at central and peripheral level due to being part of the same funding source as the organ donor registry and living kidney donor registry. The period of operation of the registry has also made it challenging to identify initial set-up costs. Further information on ANZDATA costs is presented in support slide 87.

The rationale for accruing costs before the period of attributed benefits is that the registry requires advanced investment to build capacity and data volume to form benchmarks against which subsequent performance is measured. Feedback and reports where being provided prior to the change in the method of delivery in 2011. The subtle change in practice is simply used to determine a case and control for this analysis. In the period prior to attribution of benefit in this evaluation, significant improvements are seen in all three indicators that may have been due to the presence of the registry.

Appendix B, Figure 8: Cumulative costs and attributed benefits of the ANZDATA registry



Economic benefit in the period of analysis was driven by a reduction in dialysis mortality and transplant graft loss. Registry attributed benefits from reduced dialysis mortality amount to $16 million, with reduced transplant graft loss in the same period resulting in economic benefit of $39 million.

Appendix B, Table 12: Gross benefit by indicators, ANZDATA registry

Clinical indicator	Measure of economic impact	Gross benefit	Percentage of total
Dialysis mortality	Preserved QALY	$16m	28%
Transplant graft loss	Avoided treatment costs	$13m	22%
Transplant graft loss	QALY benefit	$26m	44%
Peritonitis incidence	Avoided treatment costs	$1.2m	2%
Peritonitis incidence	QALY benefit	$2.3m	4%

Changes in practice influenced by the registry

Interviews of clinical stakeholders have identified the key changes implemented at individual hospitals as a result of receiving feedback and benchmark reports from the registry.

Registry feedback has encouraged more candid discussion of quality indicators during multidisciplinary team meetings and grand rounds, making knowledge on indicators public to the clinical team and open to internal scrutiny.

Greater emphasis has been placed on supportive care around dialysis treatment to prevent technique failure and complications.

- Adequate patient education for first time dialysis patients.
- Improving training and capability for home based dialysis.
- Development of a structured approach for management of exit site infections
- Prophylactic antibiotic use to prevent infections in new peritoneal dialysis patients

Real time / timely access to data has been identified as being central to extracting maximum value from registry data assets.

Attribution of Benefits to the ANZDATA registry

Gross benefits measured by the registry: The ANZDATA registry measured a continuous improvement in risk adjusted dialysis deaths from 2004 baseline to 2013 equivalent to more than 360,000 fewer ICU bed Days.

In the same period, there was a 36% reduction in standardised mortality ratio. This is equivalent to more than 36,000 fewer mortalities compared to 2000 baseline standardised mortality rate.[84]

A proportion of the gross observed benefit is attributable to the ANZDATA registry. The residual improvement may be explained by changes in practice that occurred independent to the presence of the registry, such as advances in technology, medication, other clinical level improvements or resourcing.

In the ANZDATA case study, the rates of improvement in the three evaluated indicators were compared between hospitals that had accessed and downloaded registry feedback reports, and those that either had not, or had not done so frequently.

Registry feedback takes the form of quarterly unit level benchmarking reports, annual reports and since 2011, Key Performance Indicator Reports. From 2011, after an initial period of overlapping report delivery methods, the method for a hospital to access registry feedback was through a secure online registry portal. Each hospital was required independently to access feedback reports through unique login credentials. Reports could be viewed and downloaded in this manner, as well as requests being made to the registry. Individual hospital report access has been tracked over the last 12 months using each Australian hospital's unique login credentials.

The overall approach for the attribution of benefits to this registry function are summarised in this section with further information available in the support slides.

A significant assumption in this approach is that log-in/report access behaviour is consistent through the period of analysis 2011 to 2013 and matches the behaviour observed in the period of available login data (2014-5). This is considered to be a reasonable assumption as the reports and feedback being accessed in the period, correspond to outcomes data from 2008-2013. Any remaining variation in unit level report access behaviour is expected to be smoothed out at the consolidated, whole country level of analysis.

Measure

In order to isolate benefits that can be clearly attributed to the presence of the registry, the rate of improvement in three registry indicators has been analysed: dialysis mortality, graft loss and peritonitis rate, each risk adjusted for patent level risk factors.

[84] Further details are presented in support slides 78-80

Case and Control Group

In the period from 2011 to 2013, there is a clear distinction in frequency of access of registry feedback resources that are made available for each individual unit (and consolidated through the annual report).

To determine the proportion of the measured changes in dialysis mortality, graft loss and peritonitis rate that can be attributed to the registry, rates of improvement at hospitals that accessed registry feedback were compared to those that did not. Patient level variation between hospitals were adjusted through standardisation and risk adjustment in line with the key variables identified in registry annual and unit level reports. Some hospital level variables that cannot be controlled by individual units were also adjusted for in the analysis.[85]

1. Feedback Access Group: Hospitals that access registry feedback

2. Non-Feedback Access Group: Hospitals that did not access registry feedback (or were in the lowest quartile of access as defined depending on volume of complete data sets and balance of units in each group.

The additional improvement in the feedback access group after the change in feedback delivery method (2011) was attributed to accessing and acting upon the registry's feedback resources.

Opportunities to expand the analysis

Comprehensive data on inter-current illness (principally infection) in patients with a preserved graft was not available at the time of analysis. It is also not know what the change in this risk would be for patients who retain a functioning graft (compared to graft failure and switch to dialysis). This information may be available through the registry for future analysis.

The economic impact of enhanced risk of de-novo cancer and added risk of mortality in existing cancer cohort patients that preserve transplant grafts/increase time on dialysis is not quantifiable in the scope of this analysis. The relative carcinogenicity of the specific immunosuppressive agents or combinations of agents is not well understood. Further analysis could extend to incorporate this information.

Data on longer-term functional outcomes was not available at the time of analysis.

Due to timeliness of data access, alternative reporting and feedback functions have been developed in Victoria which may confound the results (with Victorian Units not logging in to access ANZDATA reports, but yet showing improved outcomes due to feedback from the Victorian Renal KPI project). An extended scope of analysis could factor in competing registry/data collection and reporting functions.

Sensitivity analysis can be found on support slides 88-90.

Australian Orthopaedic Association National Joint Replacement Registry

Introduction

Joint replacement (arthroplasty) is a commonly performed major surgical procedure that is highly effective in eliminating joint pain, correcting deformity and/or, restoring mobility. The

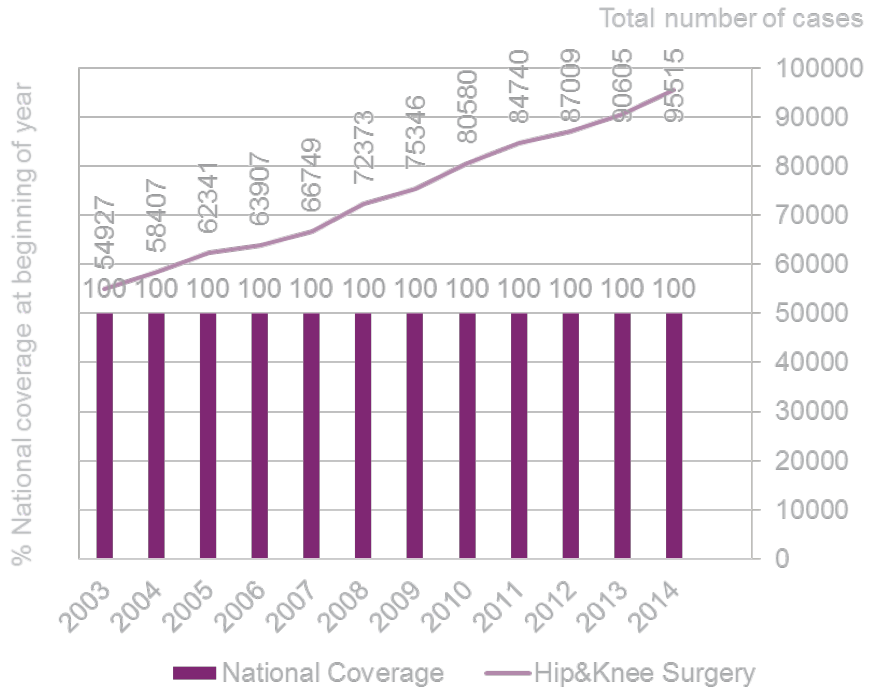
[85] For more details on the risk adjustments and variables of interest refer to the ANZDATA abridged Unit level reports for Transplant and Dialysis available through the registry website

replacement procedure removes damaged cartilage and bone from a joint and replaces it with a machine made device (prosthesis). The rate of joint replacement surgery is continuing to increase in Australia. Since 2003, the number of hip and knee replacement procedures has increased by 58.6% and 88.3% respectively to 2014. The overwhelming underlying cause of both procedures is osteoarthritis. There have been almost 1 million hip and knee replacements in Australia since 1999.[86]

Successful joint replacement is associated with significant improvement in quality of life. The majority of primary procedures lead to sustained improvement. A proportion however requires subsequent surgical revision, sometimes on more than one occasion. The associated side effects of the procedure are typically more pronounced upon revision.[87]

The AOANJRR was founded in 1999 to define, improve and maintain the quality of care of individuals receiving joint replacement surgery. Initially nine hospitals in South Australia contributed data on hip and knee replacement surgery, with full national coverage on these procedures being achieved by staged implementation through to 2003. Additional joints were included in the registry from 2008. The registry collects a defined minimum data set that enables outcomes to be determined based on patient characteristics, prosthesis type and features, method of prosthesis fixation and surgical technique used. All hospitals performing joint replacement surgery contribute data to the registry, with currently over 90,000 hip and knee replacements performed in Australia each year, in over 300 hospitals.

Appendix B, Figure 9: Participation in AOANJRR registry



Source Interview and AOANJRR 2015 Annual Report

[86] Australian Orthopaedic Association National Joint Replacement Registry Annual Report 2015
[87] Barrett, J. A., et. al. Rates and Outcomes of Primary and Revision Total Hip Replacement in the United States Medicare Population, Journal of Bone and Joint Surgery, 2003, Jan: 85 (1) 27-32

Appendix B, Table 13: Summary of AOANJRR registry

Category	Content
Establishment	Established in 1999 with Australian Department of Health funding
Patient coverage	Nationwide collection of all hip and knee replacement data from 2002 (full annual national data set thus from 2003). Full coverage achieved from 2002 following staged implementation across Australia
Managed by	University of Adelaide (Data Management and Analysis Centre – DMAC)
Funding sources	Australian Department of Health
Principal metrics	Rate of surgical revision, identification of prostheses with outlying rates thereof (also has linked mortality data)
Analysis	Quality control, monitoring and evaluation of prosthesis performance down to individual surgeon level, outlier device identification. Notification to regulator, clinicians, policy makers
Feedback processes	Annual report, ad hoc reporting of analyses, (to prosthetic device industry, government, clinicians, hospitals) presentation at scientific congress, real time individual clinician level reporting, outlier notification to industry, clinicians and regulator

Approach used

The approach used in the economic analysis for the AOANJRR registry follows the methodology described in 'Approach and methodology' in this report. A schematic model was adopted to evaluate the clinical indicators measured by the registry where a demonstrable change in practice or outcomes can be identified (support slide 98). The focus of the AOANJRR is on one principle metric: revision rate.

Revision is defined by the registry is any subsequent procedure following joint replacement, where a prosthesis is replaced, removed or inserted. The rate of revision is measured through a variety of statistical methods owing to the fact that different prostheses have varying expected survival lifespans.[88] In this analysis, the improvement in burden of revision over time, for two anatomical joint replacement types: hip and knee, has been evaluated. Selection of these joints was based on availability of a sufficient period of longitudinal national data to enable improvement over time to be meaningfully analysed.

The most significant cause of revision in both joint replacement procedures is aseptic loosening (close to 48% in hip replacements and 38% of knee replacements). This is where a localised inflammatory reaction is brought upon by the production of particles in the joint. These particles arise as a result of joint "wear." The subsequent inflammation results in bone loss around the prosthesis, leading to component loosening and pain. The type of prosthesis used, and its positioning affects the number of particles produced. Extent of use and time

[88] Further details can be found in the registry supplementary report on revision hip and knee arthroplasty [PDF 1.3 MB]

since implantation are also key determinants. These same factors also underlie the other significant causes of revision, such as dislocation and infection.[89]

1. Reduction in hip replacement surgery revision rate

The registry measures the number of patients who undergo hip replacement each year. When a procedure is revised, i.e. there are one or many subsequent procedures that involve the insertion, removal and/or replacement of a prosthesis or implant; these are recorded as incidences of revision.

Different prostheses have varying expected survival lifespans. As a joint replacement may need to be revised at any point in time, and typically not for a number of years, overall annual burden of revision is used to track improvements in outcomes over time. Burden of revision is a population cohort measure that expresses the proportion of procedures in a given year, that are revisions of previous joint replacements, regardless of when the initial procedure took place or which surgeon performed it. It is an internationally accepted unit to measure improvements over short to medium time frames and enables both internal and external comparison. (A simple calculation of number of revision procedures divided by number of overall arthroplasties of that joint type per year gives the annual burden of revision.)

Hip replacement revision surgery is associated with longer recovery and rehabilitation time compared to primary joint replacement. There are greater costs of treatment and marginal incremental increased risk of complications such as dislocation, pulmonary embolism and all-cause readmission. Accordingly, a reduction in revision rate is associated with improved patient morbidity as well as a reduction in costs of secondary/subsequent treatment. Patient demographics and type of prosthesis affect revision rate.

The main assumptions and considerations for hip replacement revision rate were:

- Each avoided revision surgery leads to preservation of quality of life and reduced associated costs of complications of surgery (e.g. risk of all cause readmission 10%, dislocation 8.4% Pulmonary Embolism (PE)/Deep Vein Thrombosis (DVT) 0.8%).[90] Costs are based on average ARDRG cost for the type of revision (major/minor) as observed through the registry.
- All revisions are included in the gross estimation of burden of revision (first, second, subsequent etc.). This enables us to factor in the economic impact of repeat revisions regardless of their number or date of primary joint replacement surgery.
- Quality of life impact is measured based on research on the disease utility values associated with hip replacement revision surgery. Incremental decrement for first revision is 0.12 is used.[91]
- A conservative estimate of two years of quality of life impact following revision surgery is used in this analysis based on similar studies on revision surgery in lower limb joint

[89] Further information relating to the underlying causes of revision surgery in joint replacement can be found in the registry Annual Report 2015.

[90] 90-day complications hip replacement: Barret, J., A. et. al. Rates and outcomes of primary and revision total hip replacement in the United States Medicare population. Journal of Bone and Joint Surgery 2003, Jan 85 (1) 27-32

[91] Quality of life disease utility value of 0.96 for successful first replacement and 0.84 for 1st revision Bozil et. al 2011 Health State Utility in patients with osteoarthritis of the hip and total hip arthroplasty.

replacement.[92] Actual duration of impact is not explicitly evaluated in referenced studies and is likely to be longer.

- At the time of analysis health state data and evidence on complications was only available for total hip replacement. This corresponds to roughly 73% of primary hip replacement procedures. Findings are scaled down accordingly. [93]
- Patient level factors, such as average age and gender distribution have stayed broadly constant over the period of analysis. This has been confirmed through registry data, as can be found in the annual reports.
- In order to control for changes in primary diagnosis leading to initial joint replacement, only osteoarthritis as primary cause is included in the analysis. This corresponds to roughly 89% of total hip replacements.
- Changes in guidelines and practices occur uniformly across surgeons in the period of analysis.[94]

2. Reduction in knee replacement surgery revision rate

The registry measures the number of patients who undergo knee replacement each year. When a procedure is revised, i.e. there are one or many subsequent procedures that involve the insertion, removal and/or replacement of a prosthesis or implant; these are recorded as incidences of revision. As with hip revision surgery, different prostheses have varying expected lifespans. Accordingly, overall annual burden of revision is used as the measure of surgery revision rate for year on year comparison.

Knee replacement revision surgery is associated with longer recovery and rehabilitation time compared to primary joint replacement. There are greater costs of treatment and marginal increased risk of complications such as pulmonary embolism, deep vein thrombosis, pneumonia and other all-cause readmission (including for sepsis). Accordingly, a reduction in revision rate is associated with improved patient morbidity as well as a reduction in costs of secondary/subsequent treatment. Patient demographics and type of prosthesis affect revision rate.

The main assumptions and considerations for knee replacement revision rate were:

- Each avoided revision surgery leads to incremental preservation of quality of life and reduced associated costs of complications of surgery (e.g. risk of all cause readmission 3.9%, pulmonary embolism 0.16%, deep vein thrombosis (DVT) 2.02%, pneumonia 0.8%[95] Costs are based on average ARDRG data for the type of revision (major/minor) observed through the AOANJRR.
- All revisions are included in the gross estimation of burden of revision. This enables us to factor in the economic impact of repeat revisions regardless of their number or date of primary joint replacement surgery.

[92] Greidanus, N. V., (2007) Predictors of quality of life outcomes after revision total hip replacement. Journal of Bone and Joint Surgery; 89-B:1446-51.
[93] For further information on types of hip arthroplasty see support slide 95 and the Australian Orthopaedic Association National Joint Replacement Registry Annual Report 2015 [PDF 27.8 MB]
[94] Support slide 99 contains further details on key events associated to the timeline of analysis.
[95] Dieterich, J. (2014) Short Term Outcomes of Revision Total Knee Arthroplasty. Journal of Arthroplasty 29 2163–66

- Quality of life impact is measured based on research on the disease utility values associated with knee replacement revision surgery. Incremental decrement for first revision of 0.15 is used.[96]
- A conservative estimate of two years of quality of life impact following revision surgery is used in this analysis based on similar studies on revision surgery in lower limb replacement. Actual duration of impact is not explicitly evaluated in referenced studies and is likely to be longer.
- At the time of analysis health state data and evidence on complications was only available for total knee replacement. This corresponds to roughly 83% of primary knee replacement procedures.[97] Findings are scaled down accordingly.
- Patient level factors, such as average age and gender distribution have stayed broadly constant over the period of analysis. This has been confirmed through registry data.
- In order to control for changes in primary diagnosis leading to initial joint replacement, only osteoarthritis as primary cause is included in the analysis. This corresponds to roughly 98% of total knee replacements (primary total and uni-compartmental).
- Changes in guidelines and practices occur uniformly across all surgeons in the period of analysis.

Challenges

The economic evaluation for the AOANJRR is comparatively challenging for two main reasons:

1. Length of expected prosthesis survival

2. Broader impact on the health device market through the regulatory body; the TGA.

1. The registry has full national data coverage for hip and knee replacement surgery outcomes for twelve years. Joint replacements have a higher likelihood of failing/requiring revision the longer they are in place. For procedures performed in any given year, as more time passes, more revisions are likely to occur. This means for example, that in 2014, more revision procedures may be taking place on joint replacements that were initially performed in 2002 rather than those performed in 2013.

Joint prosthesis survival is typically long, which is one of the reasons that joint replacement is a successful treatment option. Almost half (47.5%) of the prosthesis combinations used for total conventional hip replacement (where primary diagnosis is osteoarthritis) have a 10 year cumulative percent revision[98] of less than 5%. Similarly almost one third of prosthesis combinations used in knee replacement procedures have a 10-year cumulative percent revision of less than 5%.

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[96] Slover, J.D., (2008) Impact of Hospital Volume on the Economic Value of Computer Navigation for Total Knee
Replacement. Journal of Bone and Joint Surgery Jul 1; 90(7): 1492–1500.

[97] For further information on types of knee arthroplasty see support slide 95 and the Australian Orthopaedic Association National Joint Replacement Registry Annual Report 2015 [PDF 27.8 MB]

[98] AOANJRR annual report 2015 Ten Year Prostheses Outcomes. Cumulative percent revision (CPR) is the survivorship probability of prostheses in joint replacements based on statistical analysis of the number of revisions until a measured time point and projections of experienced failure events over time. The latter is modelled using a survival curve (Kalan-Meier method) and censors for death. For further details on statistical methods used in this analysis and by the AOANJRR see the appendices to the Australian Orthopaedic Association National Joint Replacement Registry Annual Report 2015 [PDF 27.8 MB]

This means a sufficiently long period is required to analyse meaningfully change in revision rates over time and limits the analysis to revisions of hip and knee procedures only.

2. The registry also reports performance of prostheses to the Government and the national regulatory body, the TGA.[99]

The TGA uses registry data and feedback to issue device alerts and product recalls and provide safety information to the public. The Government also uses registry data to inform decisions about medical device reimbursement. Choices surgeons can make regarding prosthesis selection are impacted by reporting, as well as changes in licensing, reimbursement and subsequent market presence even when registry feedback does not go to them personally.

Other potential approaches to analysis

As detailed previously and reported in the support slides, attribution of benefits to the AOANJRR is challenging due to its broader role in influencing which prostheses are available for selection in the Australian device market. The registry publishes outcomes data broadly, both nationally and internationally.

For these reasons, a lower range of attributed benefit is presented, consistent with the other case studies in this report, which represents the additional benefit attributed to the process of providing individual outcomes feedback to individual surgeons. This happens over a specific period, 2010-2014.

Through the course of the evaluation, the registry has also provided data on a set of individual examples where the AOANJRR has directly influenced device availability on the Australian market. A higher range can therefore be shown, which quantifies some of the benefit that is not captured in the standard approach to attribution of benefits followed in this evaluation. This includes benefits that occurred before 2010 and benefits that have occurred in the control group of surgeons that did not access individual feedback but that were still attributable to the registry due to its broader influence on prostheses in the market.

Identification of device outliers

Analysing specific examples of identified device outliers (prosthetic devices with a higher than expected revision rate, as described in support slide 101) is possible in this evaluation due to the broadly published information on the sequence of events surrounding market withdrawal of certain devices, and influence of the Australian registry on influencing use of identified prostheses. Examples where utilisation of classes of prostheses has decreased in Australia were analysed. In one of these examples a specific type of prosthesis was withdrawn from the market altogether. These are not an exhaustive set of examples of where the registry has influenced change in clinical practice. Due to the nature of the analysis, a comparison with international data is inevitable to attribute benefit to the registry. An analysis of all of the examples in this way is beyond the scope of this evaluation so two main instances are presented to indicate the order of magnitude of the potential additional benefit yet to be quantified.

1. Large Head Metal on Metal Hip Prostheses

- There has been a reduction in use of large head metal on metal prostheses and withdrawal from the market of one particular variety of these, the Articular Surface Replacement (ASR) prosthesis marketed by DePuy Orthopaedics. It is broadly recognised, through the sequence of events surrounding the global market withdrawal of

[99] Further information on the TGA is presented on support slide 102.

the ASR prosthesis, and through independent citation, that the AOANJRR was instrumental in identifying the higher than expected revision rate in this device. It was the first registry to identify the ASR prosthesis as an outlier, following which the data was corroborated by the National Joint Registry for England, Wales Northern Ireland leading to the eventual voluntary global market withdrawal by the manufacturer. Further information on the registry's process of identification of device outliers is presented on support slide 101.

2. Uni-compartmental knee replacements

- Early identification of higher than expected revision rates has led to reduction in utilisation of this class of prosthesis relative to total knee replacement. This trend has not been observed internationally, with several OECD countries showing a steady usage of uni-compartmental knee replacements over time. In the United Kingdom for example, the percentage of primary knee replacements that are uni-compartmental increased 12.5% between 2003 and 2010, and has stayed above or equal to the 2003 rate through to 2014.

Benefits of avoided revisions calculated in these two examples are equivalent to $78 million.

There are likely to be many additional examples of reduced use of identified prosthesis, with varying economic impact. These were beyond the scope of this evaluation and include, amongst others:

- Resurfacing hip replacement and patient selection by gender
- Reduction in use of Austin-Moore type unipolar monoblock replacements in fractured neck of femur
- Reduction in use of exchangeable neck hip prostheses.

There have also been close to 60 products withdrawn completely from the Australian market over the period of the registry's activity, following outlier identification by the registry and subsequent coordination with the Therapeutic Goods Administration. In light of this, there is a further argument for attributing an even greater proportion of the avoided hip and knee replacement revisions measured over time, to the identification and feedback functions of the AOANJRR. This is only possible by comparing with international examples in countries where there is comparative clinical practice but relatively less effective registry coverage or function. This is beyond the scope of this evaluation, because coverage and function would need to be measured objectively, but an indication of the order of magnitude of effect is presented here:

International comparison

The annual burden of revision for hip and knee surgery from October 2005 to December 2010 in America increased 5.5% (14.6% to 15.4% and 9.1% to 9.6% respectively). In a similar period in Australia (December 2004 to December 2010) an 8% and 5.5% improvement was observed in revision burden in Hip and Knee arthroplasty respectively.

In the United Kingdom, cumulative percent revision for hip arthroplasty has increased each year from 2003 to 2009 in the first four years after primary joint replacement. Initial trends for more recent years suggest the year on year revision rate is getting progressively higher. A similar trend is observed in the first three years post-knee arthroplasty.

This has been put down to lack of restrictions on market entry for new devices in the United States, as well as a reduced impact of the registry to reduce selection of poorly performing prostheses through the steps described for the AOANJRR. In the United Kingdom registry,

lower coverage and clinician engagement are purported potential explanations for the inability of the registry to improve outcomes in a similar way to the AOANJRR in Australia.

Accordingly, if the full reduction in revision burden between 2003 and 2014 were to be attributed to the AOANJRR, this would be equivalent to a benefit of $361 million and $257 million for avoided hip and knee arthroplasty revisions respectively.

Results

Total benefits attributed to the presence of the registry amount to $65-143 million from the period 1999 to 2014, the full period of registry data for hip and knee replacement surgery. Registry costs for the equivalent period totalled $13 million, resulting in a $53 million to $131 million net benefit. This is shown in Appendix B, Figure 10.

Appendix B, Table 14: Results of the AOANJRR case study

Period of analysis	Gross attributed benefit	Registry costs	Internal rate of return	Benefit to cost ratio
≤2002-14	$65m to $143m	$13m	25 to 78%	5:1 to 11:1

For the purpose of this evaluation, the baseline rate of hip and knee revision rate was calculated using all available data from registry inception until full national coverage (1999-2002). It is deemed that the registry was able to exert national influence with state level outcomes data, whilst the phased national expansion occurred. This is made possible through the registry's role in informing the government and the regulatory body regarding the safety of prostheses available on the Australian market. As such, outcomes data from 1999 to 2002 was consolidated and used as the baseline for comparison.[100]

The prostheses available on the market were the same across the states, and data on outcomes related to individual prostheses was publicly available to surgeons irrespective of their location. On balance, it is expected that surgeons took an interest in, and were influenced by this revision data, even if the outcomes data did not relate specifically to their individual patients.[101]

The subsequent incremental benefit of providing such individual outcomes data (revision rates specific to individual surgeons) is the focus of this evaluation. The attributed benefits are therefore only realised after 2009/10 when the registry commenced individual surgeon level feedback by linking individual procedure outcomes to the surgeon performing primary arthroplasty.

In keeping with the other case studies, the attribution of benefits is to a specific additional function over a specific period of activity. This does not mean that there were no benefits realised prior to this period, indeed the international comparison highlights otherwise.[102]

In the period prior to attribution of benefit in this evaluation, significant improvements are seen in burden of revision.[103] Feedback on outcomes of joint replacement surgery was

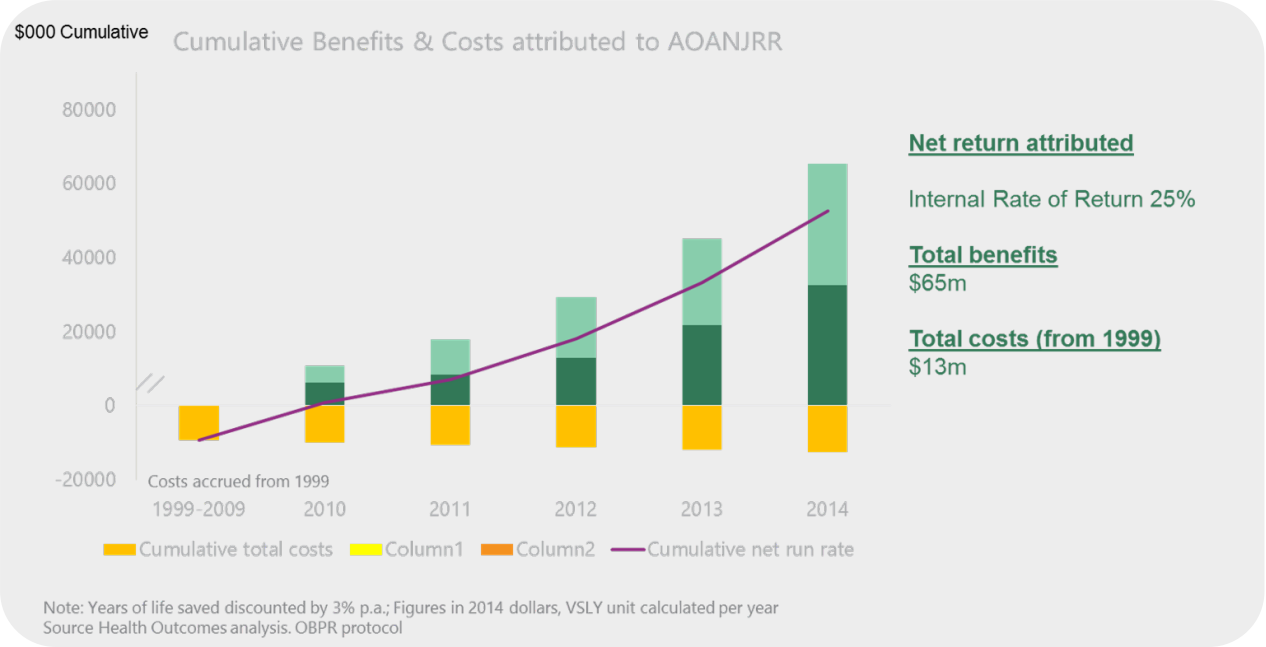
[100] Further information on TGA is available on support slide 102
[101] Interviews with registry stakeholders and subject experts.
[102] Support slides 103-104 revision rate changes over time in Australia, the United Kingdom and USA
[103] Support slides 110 and 114 present further information on the overall benefit measured by the registry

provided prior to the linkage to individual surgeons.[104] The subtle change in practice to is used to determine a case and control for this analysis and represents only a small proportion of the likely benefits attributable to the registry.

Funding is provided by Federal government, with costs recovered from the prosthetic device industry from 2008-9 onwards. Costs for data collection are met by individual hospitals through a designated data coordinator. Data transfer to the registry typically occurs in paper form. The most significant variable cost element to the registry is the subsequent data entry and analysis, representing a third of total registry costs. Further information on AOANJRR costs are presented in support slide 120.

In the economic analysis, costs are accrued from registry inception, before the period of attributed benefits. This is based on the theory that the registry requires advanced investment to build capacity and sufficient longitudinal data against which individual surgeon performance can be benchmarked.

Appendix B, Figure 10: Cumulative costs and attributed benefits of the AOANJRR at lower attributed benefit



Economic benefit in the period of analysis was driven by a reduction in treatment costs of revision surgery and its associated complications. Significant benefit was also achieved through preserved quality of life associated with avoided revision procedures. Registry attributed benefits from reduced hip replacement revision rate amounted to $32 million, and a reduced knee replacement revision benefit of $33 million.

[104] Timeline on registry events provides further background information on support slide 99

Appendix B, Table 15: Gross benefit by indicator AOANJRR

Clinical Indicator	Measure of Economic Impact	Gross Benefit	Percentage of Total
Hip replacement revision	Avoided treatment costs	$20-45m	32%
Hip replacement revision	QALY benefit	$12-26m	18%
Knee replacement revision	Avoided treatment costs	$15-33m	23%
Knee replacement revision	Quality of life benefit	$18-38m	27%

Changes in Practice influenced by the registry

Interviews with clinical stakeholders have identified the key changes implemented at individual hospitals as a result of receiving feedback and benchmark reports from the registry. Changes in outcomes occur through changes implemented at three levels. (Further information is found in support slide 100).

Individual clinician level

Changes implemented at the individual clinician level relate to selection of prostheses. Clinicians take a certain amount of pride in ensuring their results are favourable compared to their peers. They pay close attention to their individual data, available in as good as "real-time" for benchmarking purposes against that of peers, to ensure that prosthesis selection is optimal.[105] Examples mentioned of specific prostheses selection decisions facilitated by registry feedback and identification processes include; hip resurfacing in females, large head metal on metal hip replacements and uni-compartmental knee arthroplasty. The latter two are described further in support slides 116-119.

Hospital level

Hospital boards may audit their own data as provided by the registry and, as part of quality improvement initiatives, develop policy changes that prevent the use of identified higher than average rate of revision prostheses. In this way hospitals can mandate selection of better performing prostheses by their surgeons.

National level

Early identification of prostheses with a higher than expected rate of revision has led to the voluntary withdrawal of such prostheses by manufacturers. Less common, though also possible, is the mandated withdrawal from the market through the regulatory body.

Health departments use registry data to inform decisions about which medical devices to reimburse in the Australian market. Prostheses that demonstrate "Superior Clinical Performance" (<5% revision burden) are rebated at a higher rate for their class of prosthesis. This encourages positive selection of better performing prostheses.

Engagement with the AOANJRR is considered high. Participation is a quality of care activity and familiarisation and usage of the registry is integrated into surgical training and

[105] Qualitative analysis confirms that surgeons have very little ability to confound the overall results observed, by deliberately avoiding performing revision procedures. This is because the requirement to revise is most often due to catastrophic consequences predicted without revision. Typically only the very frail and elderly, or where revision would not improve symptoms whilst not increasing risk of catastrophe, provide surgeons with discretion to revise procedures or not.

continuous professional development (CPD). The registry has 100% data compliance from hospitals undertaking joint replacement, with less than 1% lost to follow up, and 93.3% of procedures can be linked to an individual surgeon performing a primary procedure as of 2015. Changes have recently been recommended to preclude the provision of CPD recognition to surgeons who do not participate with the registry (i.e. log in to view outcomes and discuss with 2 colleagues).

The Australian registry is regarded by clinicians to be leading source of information that influences global as well as national practice, as has been evidenced through its impact on the global market withdrawal of the ASR metal on metal hip prosthesis.

Attribution of Benefits to the AOA National Joint Replacement Registry

Gross benefits measured by the registry: The AOANJRR measured a continuous improvement in revision burden in hip and knee replacement surgery from the 1999-2002 baseline rate, to 2014. This was equivalent to 6486 fewer revisions of hip replacement procedures and 3863 fewer revisions of knee replacement procedures.[106]

For the purpose of this evaluation, a conservative approach is taken in line with the other case studies. The benefit attributed is for a specific function of the registry (individual feedback) over a specific period of time, and for a specific group affected by this function. Two key prosthesis specific examples are additionally evaluated to quantify the potential additional benefit before the period of attribution analysis and to capture an indication of the residual registry benefit in the control group.[107]

A proportion of the gross observed benefit is attributable to the AOANJRR registry through its influence on selection of prostheses with better-reported outcomes. The residual improvement may be due to external changes in practice that occurred independent to the registry, such as changes in pre-, peri- and post-operative care (e.g. infection prophylaxis, technique/technology and rehabilitation respectively). Quantifying such external changes is beyond the scope of this evaluation.

In the AOANJRR case study the rates of improvement in burden of revision for hip and knee replacement surgery were compared between surgeons that logged in to the online portal to access individual surgeon level outcomes data (or who requested this information through personalised ad-hoc reports) and those that had not logged in to the online portal or requested ad-hoc reports.

Registry feedback takes the form of annual and supplementary reports with lay summaries. These consist of aggregated data with no association to individual clinicians or hospitals. From 2009, outcomes were linked to individual clinicians and fed back to them through an online portal. This data was accessible to surgeons who opted in to having their procedures linked to them through an anonymous code. From 2012, the IT system providing this system was updated and the frequency of log in for each anonymous code was possible to track for this evaluation.

From 2013, an opt-out system of linking outcomes to surgeons was adopted, leading to an increase in linkage from 86.3% to 93.3% in 2015. A separate online system is also available to medical device companies and government regulators to track outcomes data. Both systems provide real time results, with data entered on a daily basis, and are 90% complete within six weeks of the procedure date. This leads to a high level of engagement. Finally, ad-

[106] Further details are presented in support slides 110 and 114
[107] Further details are presented in support slides 115-119

hoc reports of detailed analyses are provided (245 in 2014) to the device industry, individual surgeons, hospitals, academic institutions, government and government agencies.

The overall approach for the attribution of benefits to this registry function are summarised in this section with further information available in the support slides.

Measure

In order to isolate benefits that can be clearly attributed to the presence of the registry, a differential application of the registry's feedback resources was identified and an analysis conducted of the rate of improvement in all cause hip and knee replacement revision rate, primary diagnosis osteoarthritis, adjusted for age and gender in the differentially affected groups.

Case and Control Group

In the period from 2010-2014, there is a distinction in frequency of access of registry feedback resources for each individual surgeon performing hip and knee replacement surgery.

To determine the proportion of the measured reduction in hip and knee replacement revision that can be attributed to the registry, rates of improvement for surgeons that accessed individual level outcomes feedback was compared to those that did not. Data on individual online feedback access was available from October 2012. The major assumption is that online access behaviour was consistent in the two years prior before a new IT system was introduced allowing access to be tracked. This is considered a fair assumption. Patient level variation was adjusted for through age and gender standardisation and primary procedure cause selection (osteoarthritis).

- Individual Outcomes Feedback Access Group: Surgeons who accessed the online portal one or more times or requested customised ad-hoc registry feedback.
- Individual Outcomes Feedback Non-Access Group: Surgeons who did not access the online portal or request customised ad-hoc registry feedback.[108]

A comparison of improvement in rate of hip and knee replacement revision was undertaken in both groups. As revision rate needed to be linked to individual surgeon in order to ensure there was no data overlap between the two groups, cumulative percent revision was used as the unit of comparison in the attribution analysis (as this is linked to the individual surgeon whereas burden of revision is not). The previously described issue of a short period of analysis compared to expected lifespan of prosthesis was not an issue in the case/control part of the analysis. This is because the focus of the attribution analysis is the difference in rate of improvement in the two groups over time. This time frame can be as short as required to determine a statistical difference (using hazard ratios).[109] In the absence of longitudinal data of greater duration, an assumption is made that this difference persists over time. As the CPR unit unfairly biases later years in an analysis (the longer prostheses survive, the more likely they are to require revision) two equal time blocks were compared between the case and control group. The improvement in revision rate in 2005-2009 compared to 2010-2014 for the group of surgeons that accessed individual outcomes feedback, was compared to those that did not.

[108] Both groups restricted to surgeons who had performed at least 10 hip or knee replacements since 2002.

[109] Hazard Ratios (HR) of survival to an event (revision) at a given time were compared between groups. For the analysis this point in time is as early as statistically significant in order to overcome the relatively short time frame of data compared to expected prosthesis survival. See Glossary for definition.

The additional improvement in the group of surgeons that accessed their individual outcomes data through the feedback portal or ad-hoc reports (from the first full year of individual data), was attributed to the process of accessing and acting upon the registry's feedback of individual surgeon outcomes.

The additional impact (revisions not already attributed above) of reducing the utilisation of large head metal on metal implants in hip replacement procedures and uni-compartmental prostheses in knee replacement is estimated to have produced an additional benefit of around $78 million from 2003-2014.[110]

Opportunities to expand the analysis

Evaluation of reduced revision burden in additional joints covered by the registry was not feasible in this analysis due to the duration of longitudinal data available. This will be available in the future.

The economic impact of outpatient rehabilitation was beyond the scope of this analysis.

Quality of life impact was only applied over two years due to paucity of published evidence on longer-term complications and readmissions associated with joint replacement revision. Further evidence to this end would expand this analysis and likely increase the calculated benefit.

Economic impact of revision procedure complications and quality of life detriment is based on first total hip and first total knee replacement procedures due to paucity of published evidence across remaining types of hip and knee replacement and subsequent revisions.

Data on longer-term functional outcomes or patient reported outcomes was not available at the time of analysis. This could be made available through linked data collection for future evaluation.

The registry captures revision procedures where an exchange of prosthetic device occurs. There may be a small proportion of patients where outcomes of joint replacement are sub-optimal but that do not require a revision as defined currently by the registry. This could be addressed by the point above.

The incremental impact on risk of mortality associated with revision surgery was beyond the scope of this evaluation. This data could be accessed through existing linked data resources with a deeper analysis required that will need to take in to consideration any confounding factors that affect any increased risk.

The impact of selection of prostheses of different cost for use in different subgroups of patients, such as the use of Austin Moore type prosthesis in the over-85 age group with fractured neck of femur, was beyond the scope of the analysis. The relative effect on revision rate will be captured in the evaluation, but any additional impact on average prostheses cost for use in the market is not established.

Sensitivity analysis can be found on support slides 121-122.

[110] Further details on support slides 115-119

Appendix C: Glossary of main abbreviations

Term	Definition
AIHW	Australian Institute of Health and Welfare
AROC	Australian Rehabilitation Outcomes Centre
ARV	Adult Retrieval Victoria
BCR	benefits to cost ratio - ratio of the calculated attributed monetary benefits, relative to registry costs as reported by the registries themselves. Expressed in 2014-5 dollars
The Commission	Australian Commission for Safety and Quality in Healthcare
CPR	cumulative percent revision - the modelled probability of revision at a certain time.
CQR	clinical quality registry
GBD 2010	Global Burden of Disease Study 2010
HR	hazard ratio -A statistical expression of the chance of events occurring in one group versus another. They reflect time survived to an event (revision) and the rate at which this event occurs at a given time (i.e. probability of revision occurring in each group at a given point in time.) The earliest point in time that the HR could be compared is used in this analysis owing to the short timescale of available data.
IHPA	Independent Hospital Pricing Authority
IRR	internal rate of return - the rate of return, at which the net present value of all benefit (cash) flows from calculated registry benefits is equal to zero. Also defined as the discount rate at which an investment breaks even as the present value of all future benefit flows is equal to the initial investment.
NHMRC	National Health and Medical Research Council
MBS	Medicare Benefits Schedule
OBPR	Office of Best Practice Regulation
PBS	Pharmaceutical Benefits Scheme
PRIAS	Prostate Cancer Research International Active Surveillance
PROMS	patient reported outcomes measures

Term	Definition
PSM	positive surgical margin
QALY	quality adjusted life year – calculated using disease utility values and value of a statistical life year
ROI	return on investment
VSLY	value of statistical life year
WHO	World Health Organisation

Appendix D: Support slides

There are a set of presentation slides that provide further information on background, methodology and case study detail. Individual slides are referenced in this report.

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Australian Commission on Safety and Quality in Health Care

Level 5, 255 Elizabeth Street, Sydney NSW 2001
GPO Box 5480, Sydney NSW 2001

Phone: (02) 9126 3600
Fax: (02) 9126 3613

Email: mail@safetyandquality.gov.au
Website: www.safetyandquality.gov.au

AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE