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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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.

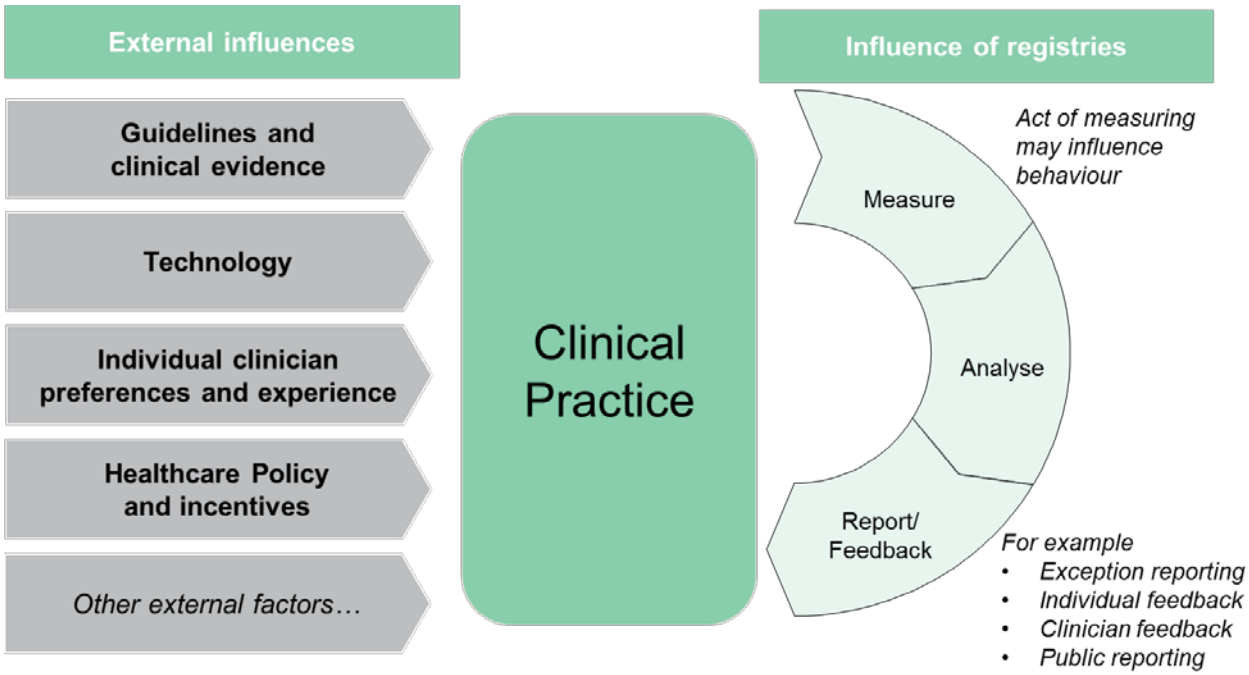
CQRs are defined by the Commission's Framework as "organisations that systematically monitor the quality (appropriateness and effectiveness) of health care, within specific clinical domains, by routinely collecting, analysing and reporting health-related information. The information is used to identify 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

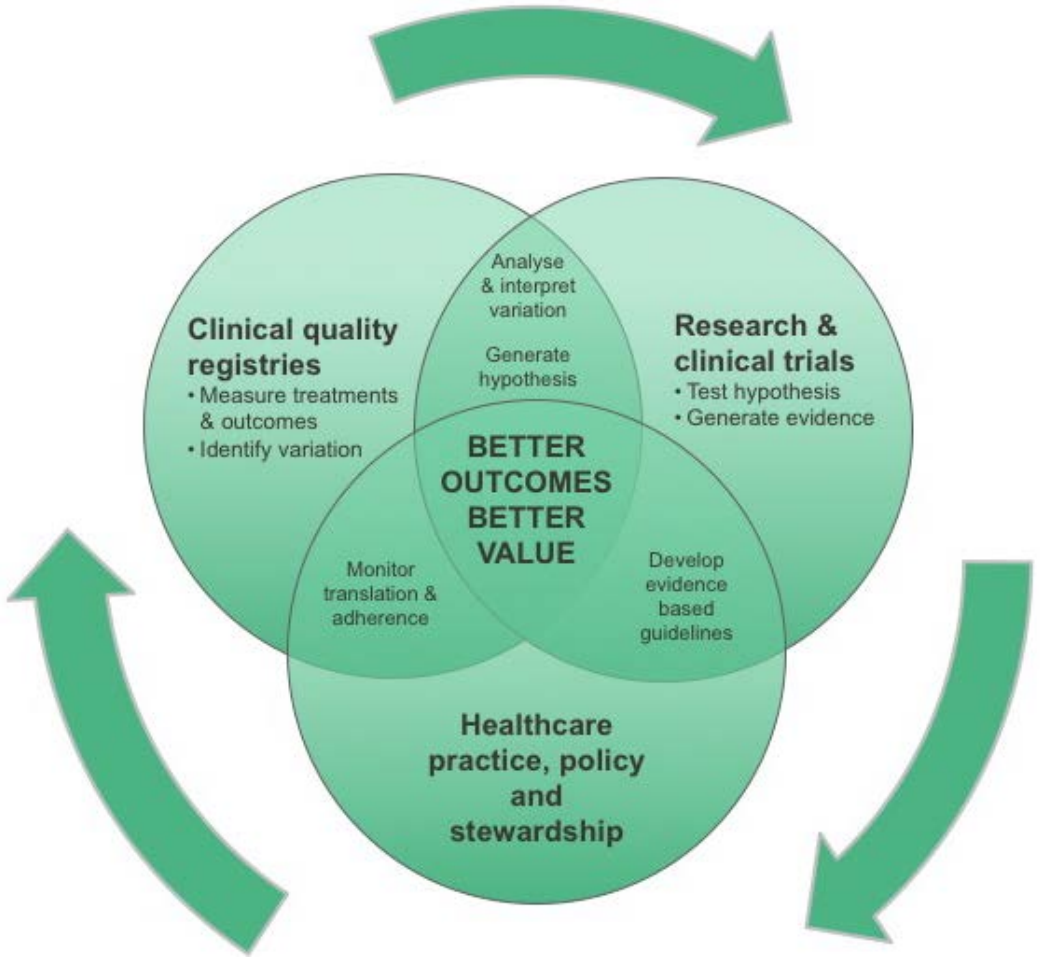
Figure 1: The position of registries within the broader clinical system



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

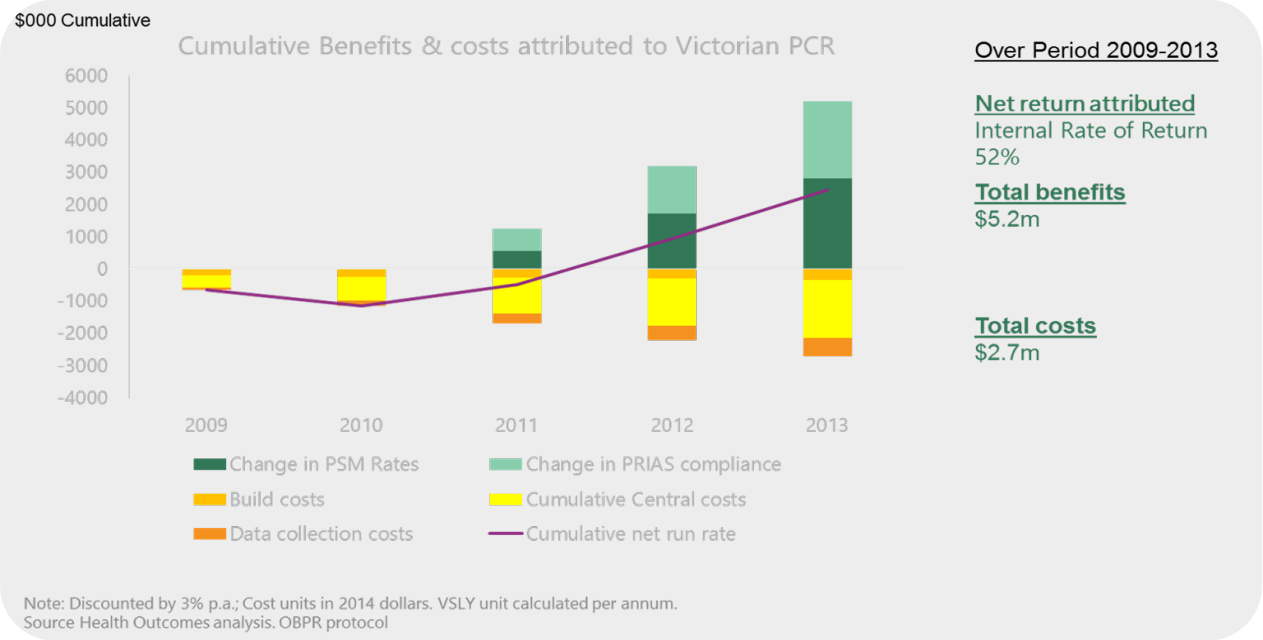
Period of analysis	Gross attributed benefit	Registry costs	Internal rate of return	Benefit to cost ratio
2009-2013	$5.2m	$2.7m	52%	2:1

[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

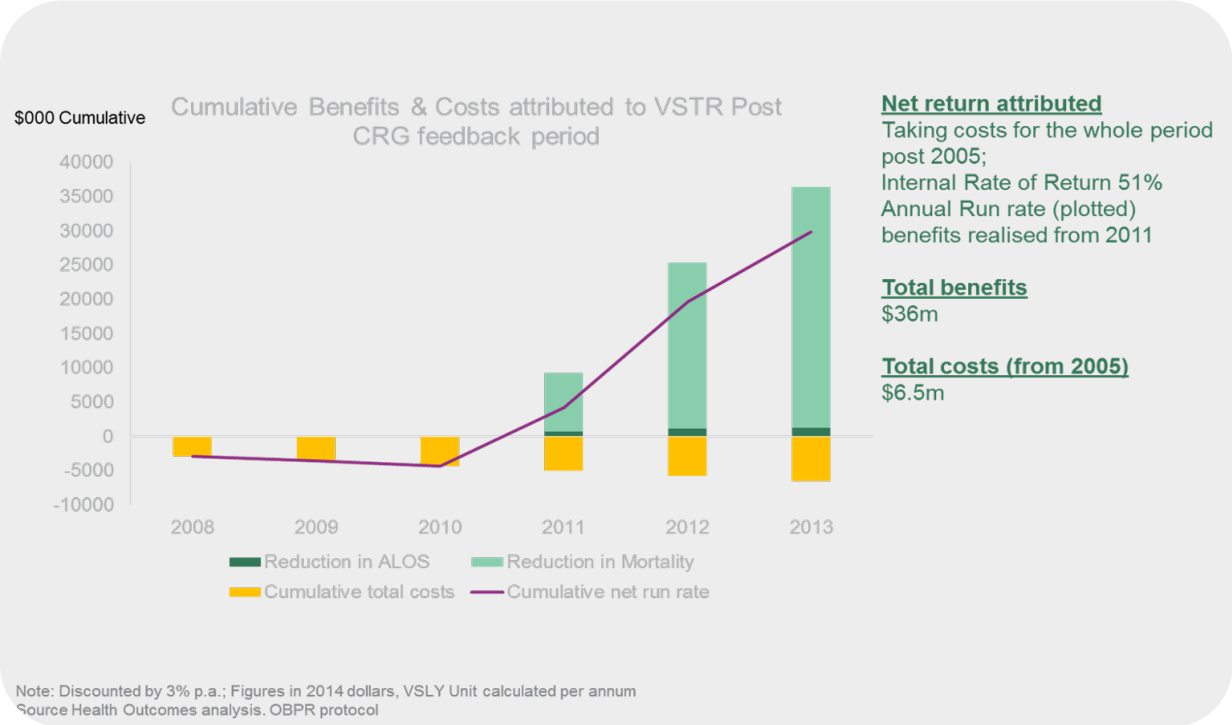
Period of analysis	Gross attributed benefit	Registry costs	Internal rate of return	Benefit to cost ratio
2005-2013	$36m	$6.5m	51%	6:1

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.

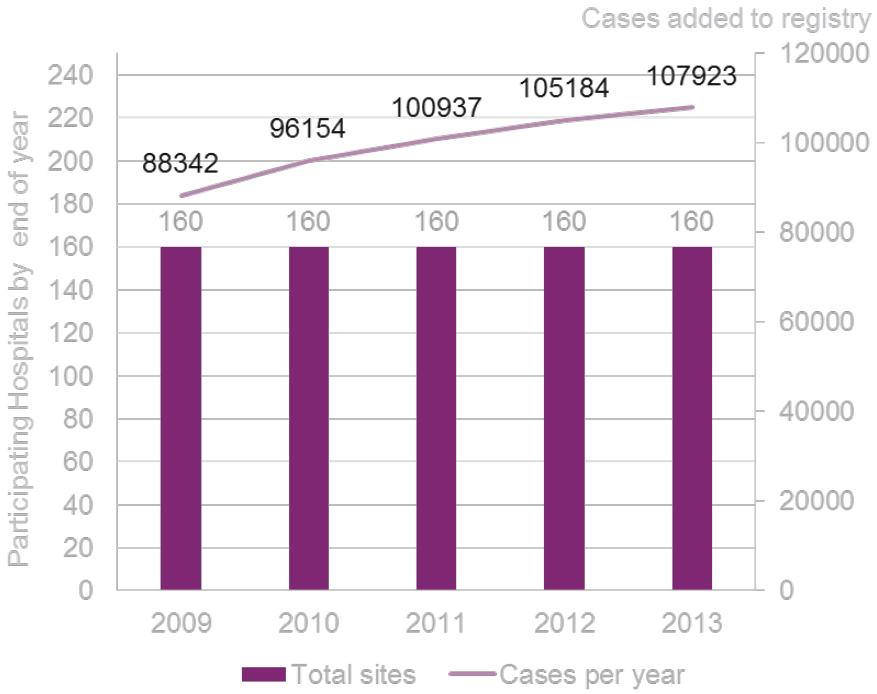
1. Adult Patient Database
2. ANZICS Paediatric Intensive Care
3. Critical Care Resources
4. Central Line Associated Bloodstream Infection

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.

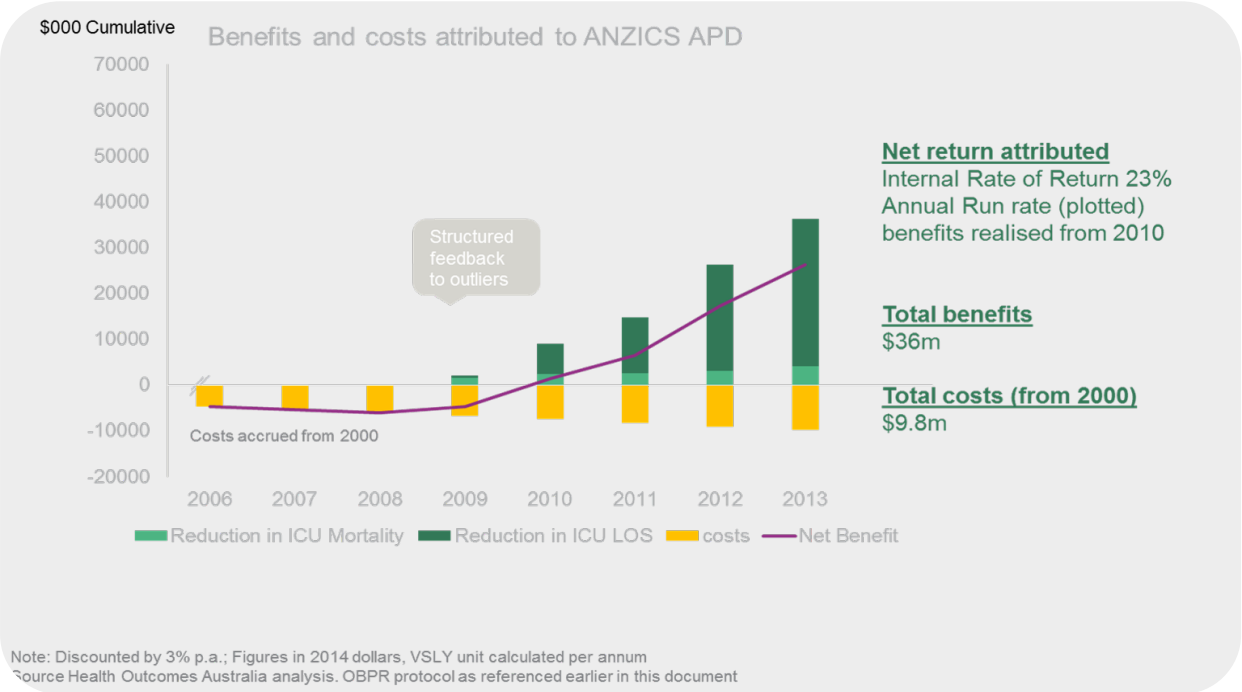
[69] There is a paucity of evidence around long-term survival of ICU patients. Research is underway using data from Tasmanian ICUs. Early analysis from this study suggests that survival is largely age dependent, with 3-year survival in the median age group at 50%. The Bohensky JCC 2012 study quoted 80%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

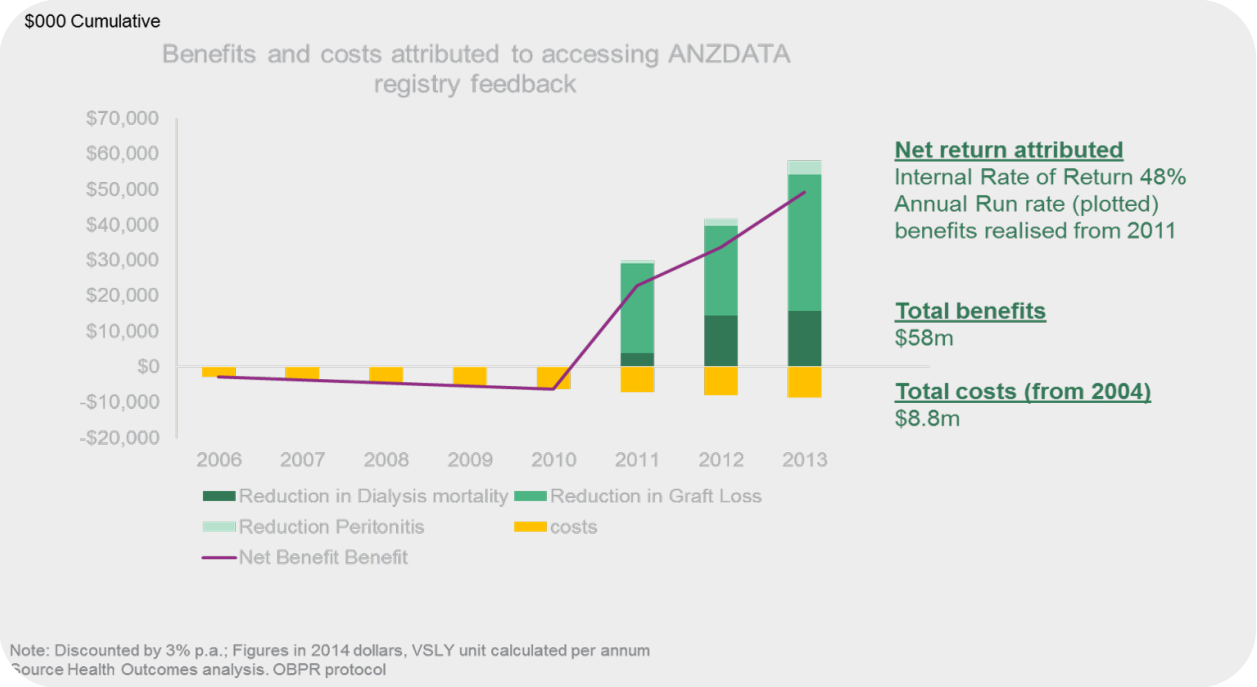
Appendix B, Table 11: Results of the ANZDATA registry case study

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

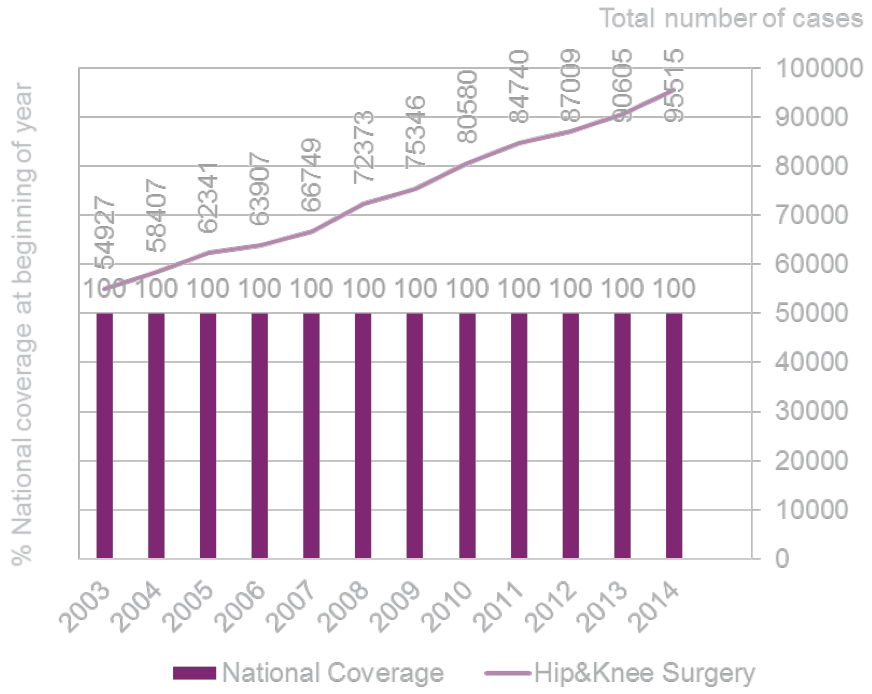
[85] For more details on the risk adjustments and variables of interest refer to the ANZDATA abridged Unit level reports for Transplant and Dialysis available through the registry website

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

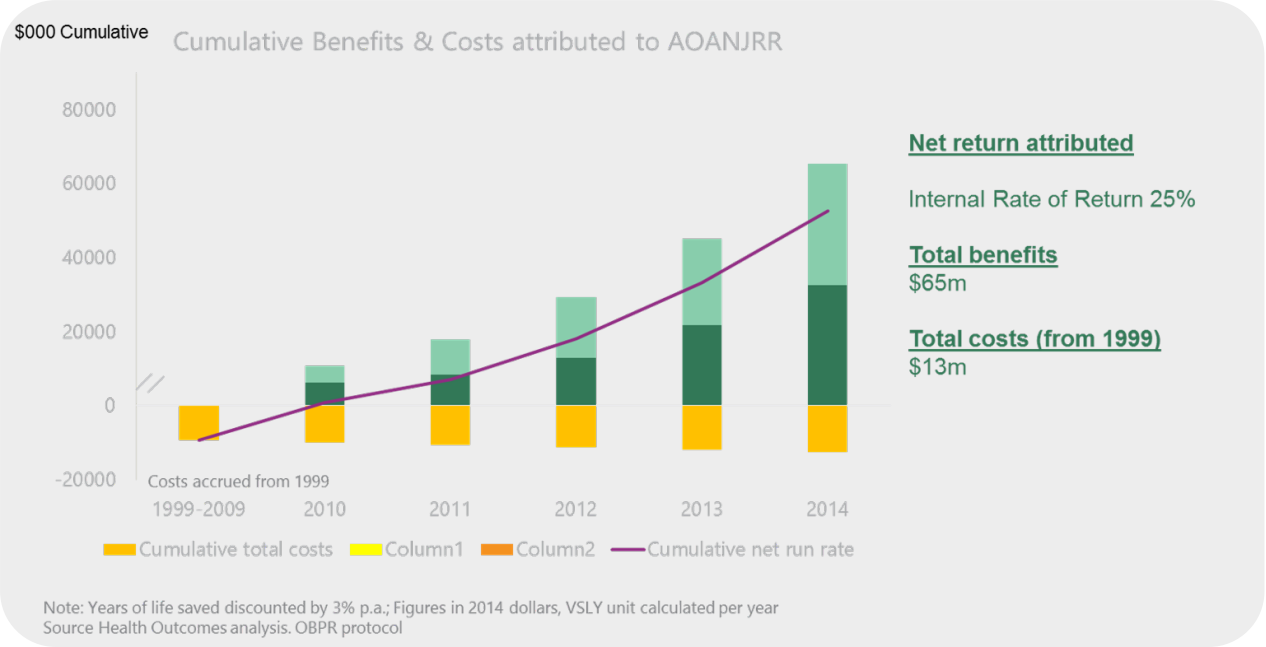
[100] Further information on TGA is available on support slide 102
[101] Interviews with registry stakeholders and subject experts.
[102] Support slides 103-104 revision rate changes over time in Australia, the United Kingdom and USA
[103] Support slides 110 and 114 present further information on the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

HEALTH OUTCOMES AUSTRALIA

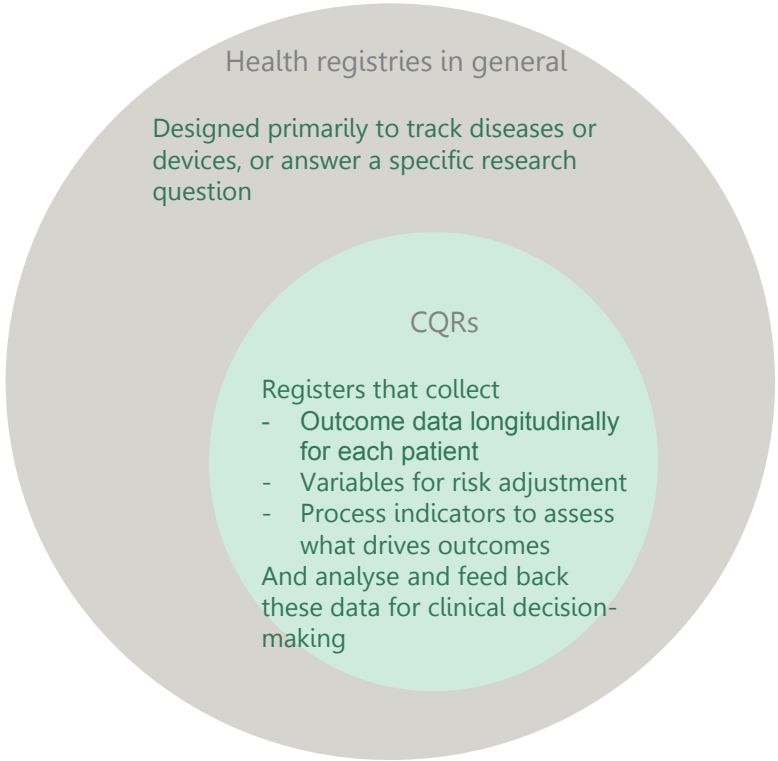
Economic Evaluation of Clinical Quality Registries (CQRs)

APPENDIX D - Support slides

The focus of the study is on a subset of clinical registries

Data collection and analysis occurs with differing intensity and purpose across a continuum of registry maturity in health care. CQRs are a particular subset of clinical registries at the end of this continuum. The Australian Commission on Safety and Quality (the Commission) Framework sets out the mechanism to meet the requirements of a CQR. A formal definition from this Framework is presented in the next slide.

The purpose of a clinical quality registry is to improve the safety or quality of health care provided to patients by collecting key clinical information from individual healthcare encounters which enable risk adjusted outcomes to be used to drive evidence based quality improvement.



Source: ACSQHC Operating Principles and Technical Standards for Australian Clinical Quality Registries. November 2008

CQRs as defined by the Commission's Framework

"CQRs are 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."

The aims of national CQRs are to:

1. Collect longitudinal health outcome data for the entire eligible population of the clinical domain.

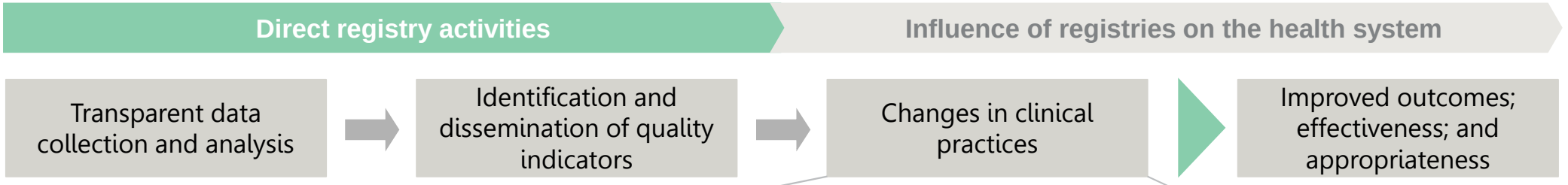
2. Generate risk-adjusted reports on the appropriateness and effectiveness of health care. Within the data governance framework, reports are provided to jurisdictions, healthcare providers, funders, clinical colleges and researchers, to identify significant variance and to benchmark nationally and internationally.

CQRs typically focus on conditions and procedures where:

a. there are serious consequences to the patient associated with poor quality of care;
b. unwanted variation in outcomes can be identified and addressed;
c. an evidence-based sequence of care improves patient care, (or there is a need to capture national data to develop an evidence base for care);
d. there is a significant cost burden associated with the condition / procedure / device (although low-volume registries also exist, for example, for cystic fibrosis);
e. the clinical condition/event is able to be systematically recognised; and
f. the information requirements for a successful CQR can be met.

Source: ACSQHC Operating Principles and Technical Standards for Australian Clinical Quality Registries. November 2008

Registries only deliver an impact if they change healthcare practices



Changing clinical practice does not happen automatically

In most cases, engaged clinicians will use the insights generated by high-quality registries to improve clinical practice

- In some cases, it may be appropriate for necessary changes to be made to system structures to facilitate changes in practice
- The "feed back loop" to service providers has been determined to be essential to creating changes in practice.

Value is delivered through improved outcomes, greater effectiveness and greater appropriateness of care

Source: Health Outcomes Australia analysis

Registries support more effective, efficient and appropriate care
Value can be delivered through a variety of mechanisms

Value mechanism	Example metrics	Mechanism of action
1 More effective	Decreased mortality	• Well designed and run registries identify outcome indicators, like mortality, enable feedback loops to improve these outcomes
	Enhanced quality of life/ decreased diminished quality of life	• Variation in harder to track metrics, including quality of life, patient reported outcome measures (PROMS), patterns of care (eg., time to diagnosis and treatment), morbidity related indicators are also measured and fed back.
2 More efficient	Decreased avoidable costs (reduced infections, readmissions etc)	• Where poor outcomes drive costs in the health system (eg., a readmission), registries can reduce expenditure through feedback of information
	Opportunities for disinvestment (reducing the number of procedures for the same or better outcomes)	• By capturing patient profiles and co-morbidities as well as outcomes, registries can identify healthcare activity which is not improving patient outcomes, allowing disinvestment
3 More appropriate	Compliance with guidelines and standards	• Where best practices are set out through guidelines and agreed standards, registries enable benchmarking and tracking of compliance against these benchmarks.
	Improved visibility of outlying performers	• As a central repository, registries are able to identify and feed back to outlying performers, providing opportunities for actions to be taken to improve performance.

Source: Health Outcomes Australia analysis

New York (NY) cardiac registry

International example of an established registry whose impact has been evaluated

Background and scope

Procedures covered: coronary artery bypass grafts, percutaneous coronary intervention and paediatric cardiac surgery
Geographic coverage: NY State
Managed by: NY State Department of Health Cardiac Services Program
Hosted by: University of Albany School of Public Health
Funding sources: NY State Department of Health and others
Principal Metrics: patient risk factors, in-hospital and 30-day mortality rates; procedure (e.g. coronary artery bypass graft, and valve with/without coronary artery bypass graft)
Analysis: quality control, data cleaning and auditing conducted by program staff, cross-checks against admin data. Risk-adjustments
Feedback processes: publically released annual reports by hospital, and for surgeons/cardiologists on rolling 3-year basis. Report cards include outlier status (higher, lower or not different to state average)

Evolution of registries

1986: Health Care Financing Administration (HCFA) commences annual studies into mortality, publishing grouped rates based on administrative data. Discontinued 1992 due to criticism of appropriateness of use of administrative data

1988: NY State Health Commissioner creates Cardiac Surgery Reporting System (CSRS) – a patient-level clinical database to assess outcomes for coronary artery bypass graft, concerned by 5-fold variation in in-hospital mortality rates

1989: Feeds back results to hospitals

1990: CSRS publishes site names and rates to NY Times

1992: CSRS publishes surgeon data, prompted by freedom of information request by *Newsday* Establishes Percutaneous Coronary Intervention Reporting System (PCIRS) to measure percutaneous coronary intervention outcomes

CSRS: Cardiac Surgery Reporting System; CABG: Coronary Artery Bypass Graft (surgery); PCI(RS): Percutaneous Coronary Intervention (Reporting System) Source: Hannan et al, J Am Coll Card, 2012

Impact of NY cardiac registry was described in 20-year review

Changed Outcomes

Improvement in cardiac outcomes:

- Absolute decrease in risk-adjusted mortality: from 4.17% (1989) to 2.45% (1992)
- NY's coronary artery bypass graft mortality improved faster than any other state with below average mortality
- Over 1994-99, risk-adjusted mortality 34% lower than other states

Changed Practice

Concentration of volumes by surgeon:

- Increased scrutiny of high-mortality, low-volume surgeons
- >20% of worst-quartile surgeons stopped performing coronary artery bypass graft within 2 years of publication (versus 5% in top 3 quartiles)

Reforms at some high-mortality sites

- Multidisciplinary reviews of emergency care (St Peter's)
- Quality assurance processes, staffing changes and dedicated nurses, assistants and anesthesia (Winthrop Hospital and Erie County Medical Centre)

Contribution to clinical research and evaluation

- Numerous studies informing policy, eg., comparing performance of different stents; percutaneous coronary intervention vs coronary artery bypass graft; volume-mortality relationship etc.

Mixed evidence of change

Shift in hospital market-shares

- Some evidence of concentration one month after first coronary artery bypass graft publication, but not sustained over longer-term. Evidence that quality impacted contracting negotiations

Case shifting to other states/sites

- Mixed evidence of shifting of difficult cases to other states
- Some high-risk patients may have been referred to other sites (which may have been in their interest)

Source: Hannan et al, J Am Coll Card, 2012; Chassin, Health Aff 2002

Lessons learned from NY cardiac registry's experience- how to maximise impact

Important to assure completeness and accuracy of data used

- Reports can impact quality of patient care
- Financial impact on providers and individuals

Acceptance and use of reports depends on manner of presentation to public and providers

- Approach was informed by early collection of mortality data, informed by administrative data
- Expert clinical committee helped to refined methodology and data collected
- Results were shared with providers before launching to the public
- Public interest was high – shared with, and demanded by the press

Being and outlier/fear of being an outlier is a powerful motivator

- Applies to individuals in their practices
- Also to providers – e.g. managing out worst performing, low-volume surgeons

Source: Hannan et al, J Am Coll Card, 2012

Methodology to evaluate benefits from registry

Evaluation of observed changes clinical practice, corrected for confounding factors

Identify indicators of changed practice	Infer change in outcome (if required)	Compare to control group	Assess economic value of change
Find relevant indicators: **Process measures** • Compliance with clinical guidelines • Measures of clinical quality • Length of stay **Patient outcomes** • Morbidity • Mortality • Long-term function	**Infer impact of improved process measures based on published evidence or observed outcomes** • e.g. decreased life expectancy following process safety management	**Interview expert clinicians to understand** • Impact and extent of use of registry • Confounding changes over time period **Control for confounding changes by comparing to a group with no/less feedback** e.g. • Later registry contributors • Groups not receiving or accessing feedback	**Improvements in life expectancy and quality of life** • Based on value of a statistical life year and burden of disease **Changes to cost of medical care** • Avoided/alternative cost of treatment
Evidence of changed clinical practice	**Quantification of impact**	**Impact attributed to registry**	**Value of benefits associated with registry**

Use of willingness to pay to evaluate economic impact on health

Basis	Valuation method	Most appropriate for	Limitations
Human capital/ cost of illness	Value of loss of work, medical expenses	Forecasting impact on economic output	Not valid for non-working individuals, no allowance for pain and suffering
Willingness to pay	Value that individuals place on avoiding risk of injury or death • Wage-risk – wage premium required to fill higher risk jobs • Consumer behaviour – price premium e.g. for safer motor vehicles • Stated preference - surveyed willingness to pay	Informing policy to value reductions in risk of physical harm through the value of a statistical life (VSL) • By convention "life" assumed to run for 40 more years • May be weighted by disease burden (quality of life) to reflect impairment	Individual willingness to pay may not reflect ability to pay

Australian Government Best Practice guidance sets the value of a statistical life year at $182,000 (2014)

Note: Private time preference discount rate of 3% preference applied; Source: Office of Best Practice Regulation (OBPR), Best Practice Regulation Guidance Note(December 2014); Abelson, Establishing a Monetary Value for Lives Saved: Issues and Controversies (2007)

HEALTH OUTCOMES AUSTRALIA

Economic value of CQRs

Support slides – case studies

HEALTH OUTCOMES AUSTRALIA

Economic Value of CQRs

Case Study 1 - Victorian Prostate Cancer Registry

Victorian Prostate Cancer Clinical Registry (Vic PCR) background

Vic PCR founded in 2009 and has grown to 33 sites

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

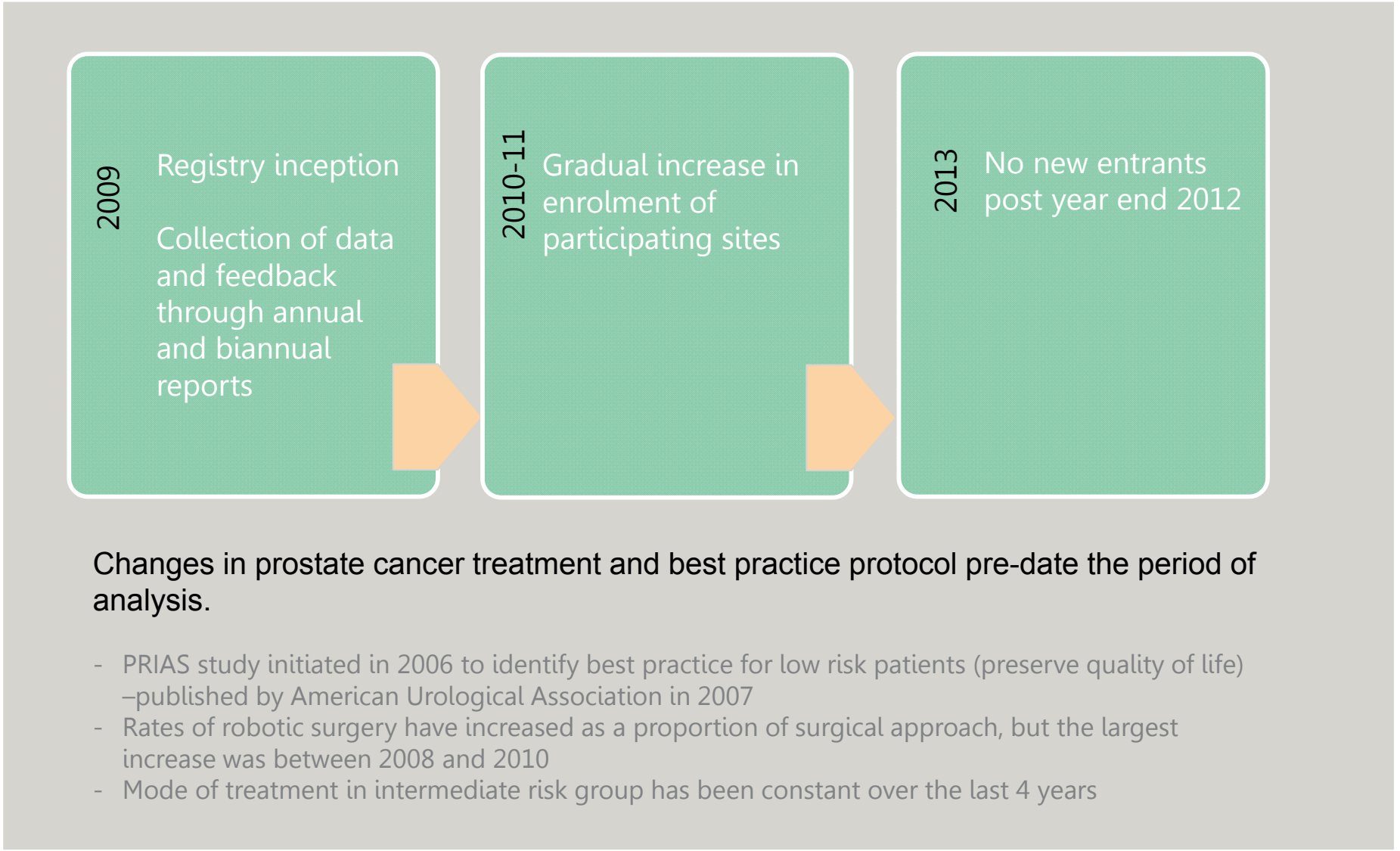
Has achieved coverage of 75% of Victorian incident cases

Patient coverage: prostate cancer, opt-out (<3% opt-out rate)
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

Background to the Vic PCR

- Australia's first prostate cancer clinical quality registry.
  - Increasing coverage since inception in 2009 with three metropolitan hospitals contributing data (Alfred, Austin, Cabrini).
- Now covers around 75% of incident cases (close to 10,000 over 5 years) through 33 hospitals.
- Collects data on mortality, morbidity, surgical outcomes, patterns in care (and variations thereof), PROMS related to quality of life and disease impact.
- 11 indicators are fed back to hospitals and urologists every 6 months through benchmarking reports to drive continuous improvement. Two examples where there is increasing evidence of impact on outcomes include;
  - Positive margin rates (where pathology reports show unequivocally that the tumour has extended resected tissue) have been independently associated with disease progression and mortality. The measure is used as a surrogate for disease prognosis. Surgical experience, technique, volume of surgery at centre, have been shown to impact on margin rates.
  - Prostate Cancer Research International Active Surveillance (PRIAS) protocol adherence: The PRIAS protocol has been designed to preserve quality of life in cases where invasive treatment (e.g. surgery, radiotherapy) is not indicated and active surveillance is more appropriate. The protocol seeks to avoid potential harm through unnecessary invasive procedures in cases were prostate cancer is unlikely to progress.

Timeline of significant events within the registry and broader prostate cancer care context



Changes in prostate cancer treatment and best practice protocol pre-date the period of analysis.

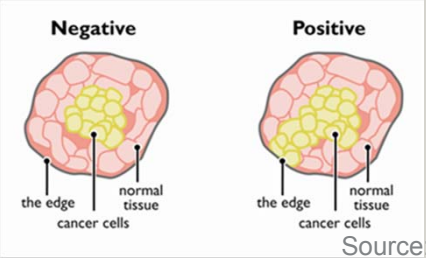
- PRIAS study initiated in 2006 to identify best practice for low risk patients (preserve quality of life) –published by American Urological Association in 2007
- Rates of robotic surgery have increased as a proportion of surgical approach, but the largest increase was between 2008 and 2010
- Mode of treatment in intermediate risk group has been constant over the last 4 years

Source: Health Outcomes Australia analysis, Qualitative Interviews. ACSQHC Australian Guidelines for the Prevention and Control of Infection in Healthcare

Positive surgical margins are a surrogate for likelihood of disease progression

Positive surgical margin rates

A measure of success of a radical prostatectomy is whether the cancer cells are contained within the resected prostate. If cancer cells are shown to have extended beyond the surgical margin, this is recorded as a positive surgical margin. Positive surgical margin rates are influenced by method of surgery (robotic versus open), site of surgery (>10 surgeries p.a. versus <10)



Source: orchid-cancer.org.uk

What does this mean for patients?

Studies have shown that patients with cancer at the resection margin are at increased risk of biochemical recurrence after Radical Prostatectomy.

Patients are therefore more likely to require secondary (additional) treatment after surgery. Research has also shown positive surgical margin to be an independent predictor of secondary treatment which usually takes the form below;

- Salvage radiotherapy 63%
- Other, typically androgen deprivation therapy (tablets depot injection or orchidectomy) 37%

What is the expected impact?

- **Lower positive surgical margin rate over time**

  Reduction in mortality associated with positive surgical margin (assumed to be 5% increase in time adjusted mortality in positive surgical margin versus non positive surgical margin)

  Reduction in costs and impact of secondary treatment
  - Salvage radiotherapy c$45,000 per patient per year
  - Other (mainly androgen deprivation therapy) c$5,000

  Reduction in positive surgical margin associated morbidity
  - As reported by patients at 12 and 24 months after intervention. Men with prostate cancer have a degree of urinary, bowel and sexual bother at baseline. The incremental change due to secondary intervention is included in this analysis.

Source: Health Outcomes Australia analysis

PRIAS protocol

PRIAS is a European study initiated in 2006 to preserve quality of life once cancer is diagnosed. Recommendations have been made on the role of active surveillance as management strategy for patients with localised cancer to avoid or delay potential harm through invasive treatment.

Criteria for low-risk patients

Clinical tumour	T1 or T2
Primary Gleason*	1-3
Secondary Gleason	1-3
Prostate specific antigen	10 ng/mL or Less
Number of cores positive	Less than 3

* (aggression/differentiation)

What does this mean for patients?

Patients who meet the PRIAS protocol are not likely to require invasive treatment and associated costs and side effects.

Surgery and other active treatment, such as radiotherapy, is associated with disease specific quality of life impacts. The main three categories of these, as set out below, have been recorded by the registry through self reported follow up at 12 and 24 months;

- Urinary bother
- Bowel bother
- Sexual bother

What is the expected impact?

Avoided procedures

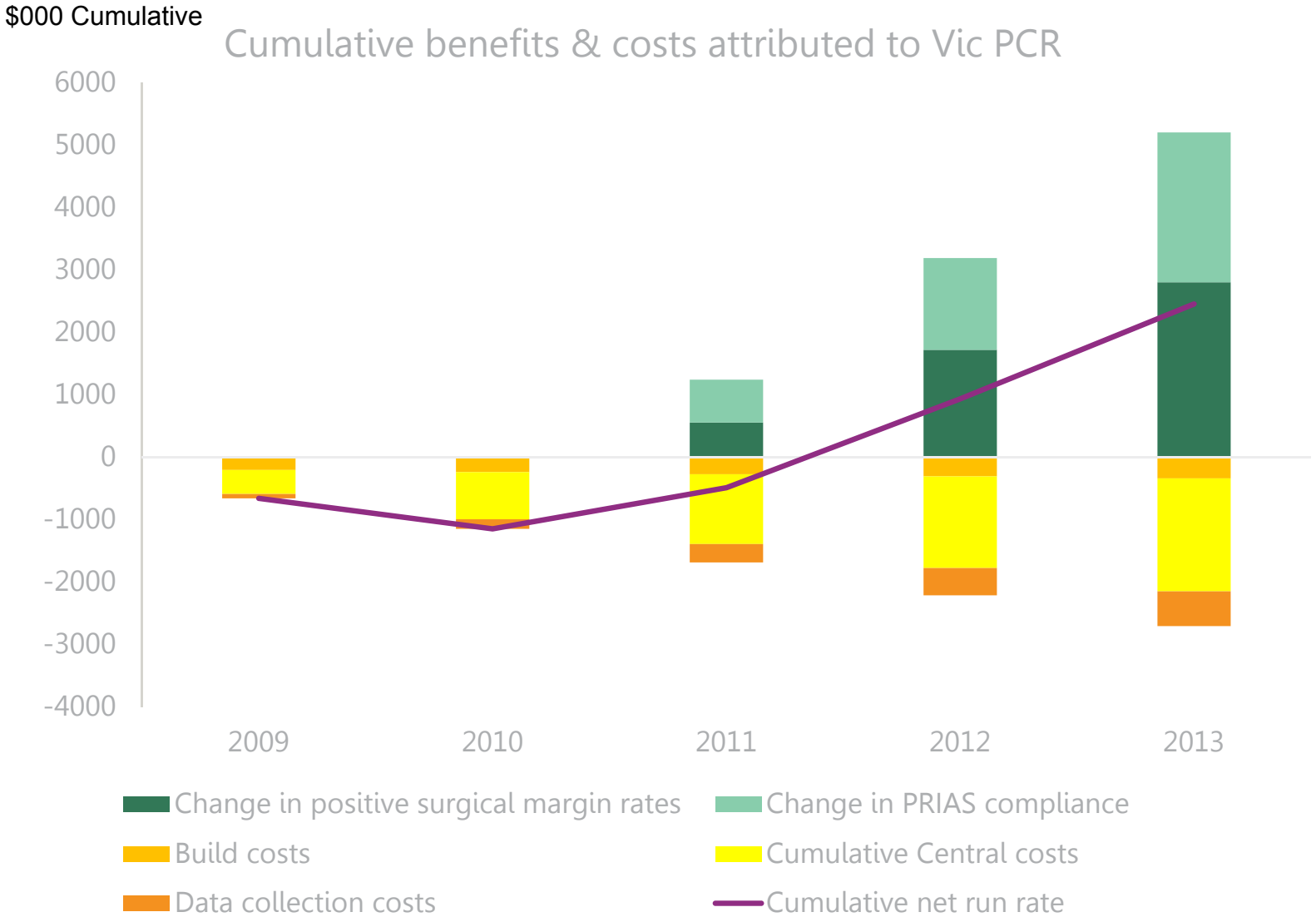
- Average cost of radical prostatectomy $15,000 (range of $13-18k)

Improved quality of life

- Disease-specific quality of life can be measured in weighted burden of disease on a statistical life year (or quality adjusted life years (QALY)). Disease weights have been taken from the WHO Burden of Disease Study, Australian Institute of Health and Welfare (AIHW) reports and disease specific publications. The unit value of a statistical life year is taken from the Office of Best Practice Regulation (OBPR) Value of a Statistical Life Year (VSLY).

Source: Health Outcomes Australia analysis

Vic PCR shows a net benefit of $2.4 million based on a comparison of early versus late registry adopters



Over period 2009-2013

Net return attributed
Internal rate of return 52%

Total benefits
$5.2m

Total costs
$2.7m

Year	Benefit to cost ratio
2009-2013	2:1

Note: discounted by 3% p.a.; cost units in 2014 dollars. VSLY unit calculated per annum. Values may not exactly sum due to rounding
Source Health Outcomes analysis. OBPR protocol

Overview of benefits from Vic PCR

	Indicator of changed clinical practice	Control(s)	Patient outcome	Conversion to economic value	Comment
1a	Positive surgical margin rates	Comparison of sites: Early contributors to the registry versus more recent	Mortality Morbidity (PROMS) Reduced need for secondary treatment	Mortality ($/life year) Morbidity (weighted $/life year) Avoided 2ndry treatment cost $/change in quality of life	Data accessed and analysed
1b	Rates of intervention when pt. PRIAS criteria		Avoided surgery and complications (incontinence, sexual dysfunction)	Avoided costs of procedures $/change in quality of life	
1c	Earlier Treatment	Compared to other states (South Australia/NSW) Outliers within state (Gippsland project)	Improved outcomes	Mortality ($/life year) $/change in quality of life	
1d	*Other changes in patterns of care*	Compared to other states Rate of improvement compared to registry adoption	Patient reported outcomes (PROMS)	$/change in quality of life	PROMS included in PRIAS evaluation

Indicators for evaluation

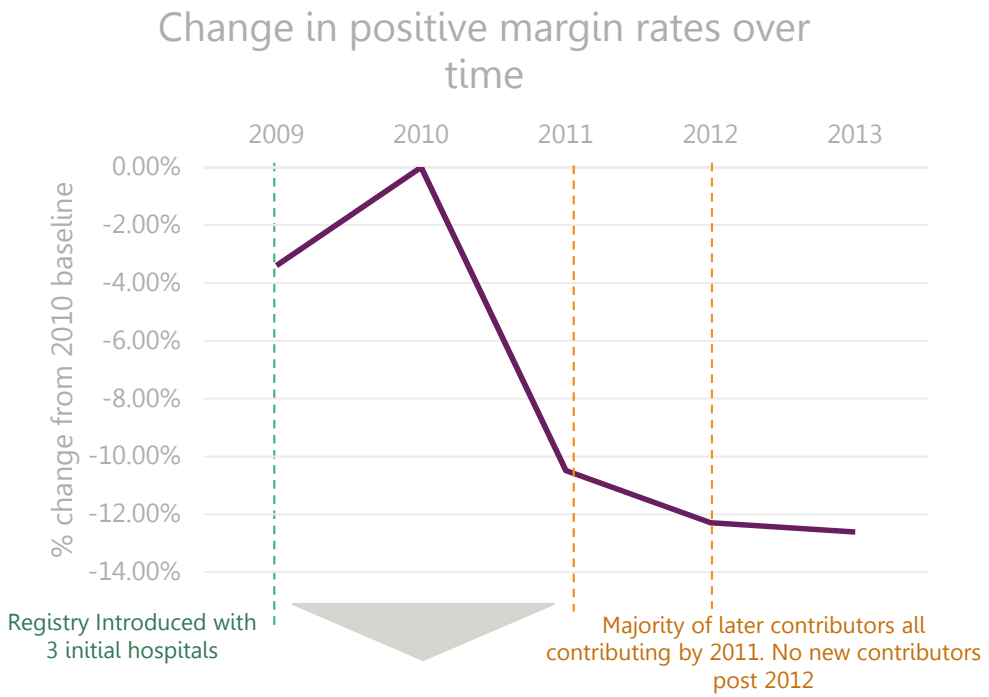
Measured by the registry directly

Source: Health Outcomes Australia analysis

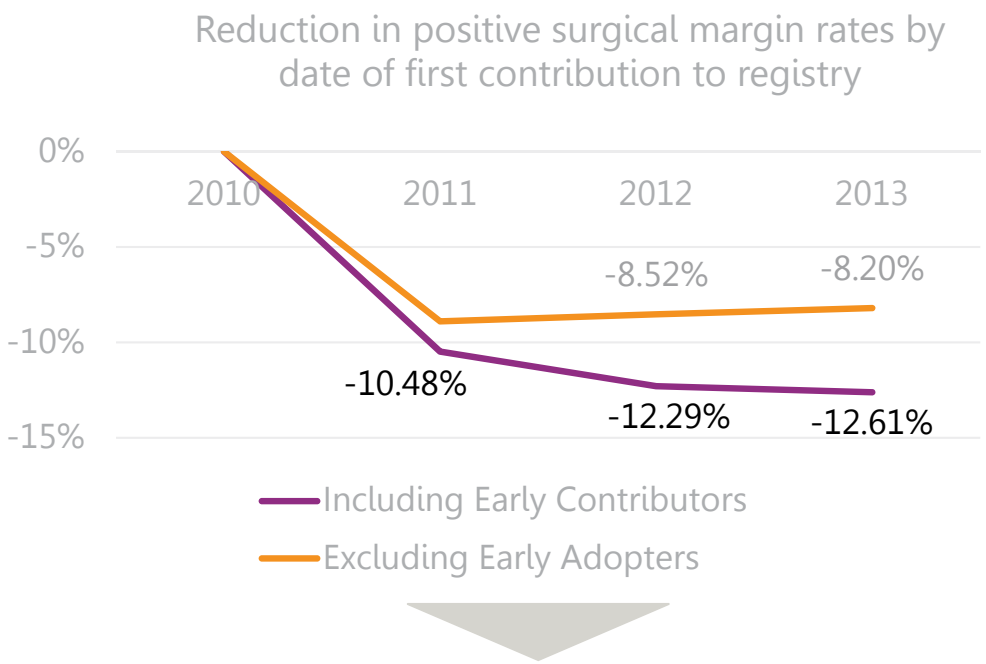
1a Reduction in positive surgical margins

VIC PCR shows evidence of change in positive surgical margin rates and associated impact on outcomes

12 percent point reduction in positive surgical margins (pT2 organ confined) since 2010



Demonstrable variation in rate of improvement between early versus late registry contributors



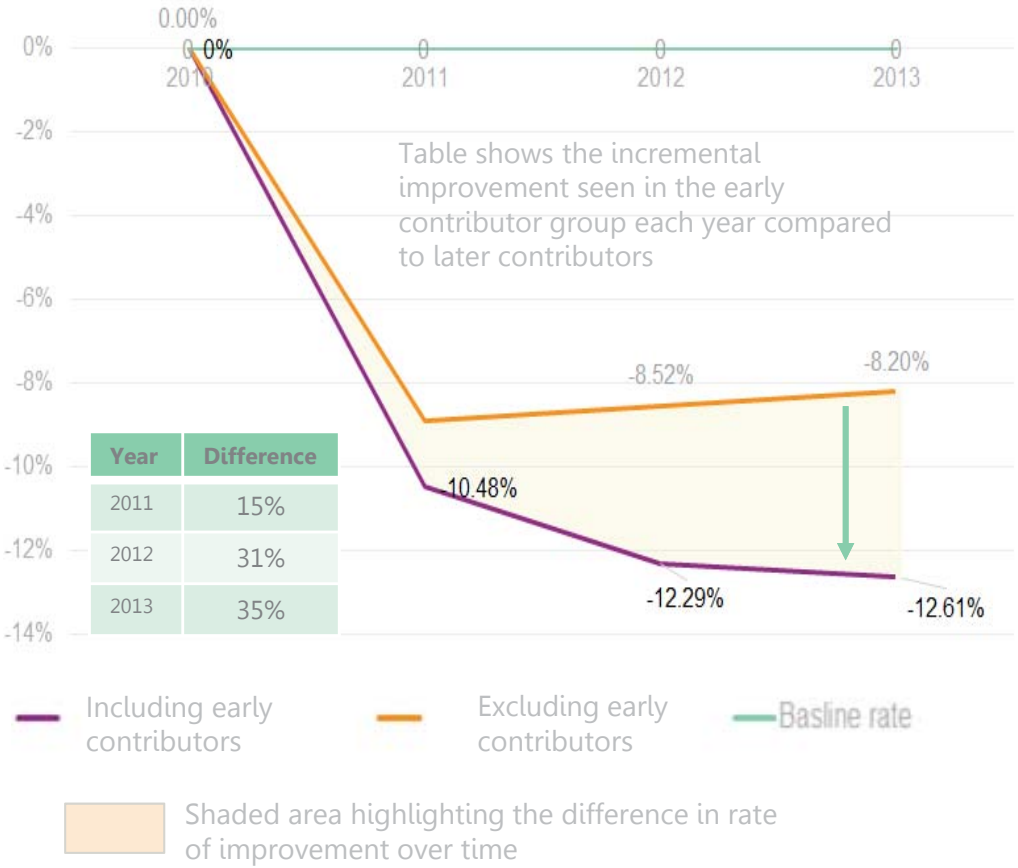
A 12 percentage point reduction in positive surgical margin rate since 2010 equates to 15 fewer life years lost and 15 fewer patients requiring secondary treatment over 5 years (attributed to the registry)

Rates of change in reduction in positive surgical margins, and (therefore improvements in practice/outcomes) are greater in hospitals that are early contributors to the registry compared to later contributors.

Source: Health Outcomes Australia analysis. Registry data. pT2 is equivalent to intermediate risk group of patients

Early registry contributors improved positive surgical margin rates more than later contributors of the registry

Rate of reduction in positive surgical margin rates greater in early contributors to the registry compared to later



Year	Difference
2011	15%
2012	31%
2013	35%

This corresponds to a mean attributable benefit of 27% from 2009-2013

The difference in the rate of improvement (green arrow) between the two groups can be attributed to the Vic PCR

- Early contributors joined in 2009
- Remaining hospitals contribute data from 2010
- A delay in effect of the registry is expected due to the time required to collect, analyse and feed back outcomes data to be subsequently acted upon.
- As early contributors receive feedback and show improved rates due to any impact of the registry, new late contributors are added up until the end of 2012. This slows the rate of improvement in this cohort and delays an expected eventual convergence in rate of improvement.
- The difference in rate of improvement between the two groups is attributed to the registry.

Changes outside the registry, such as those in guidelines and practices will likely effect hospitals uniformly, whether they are an early or late contributor.

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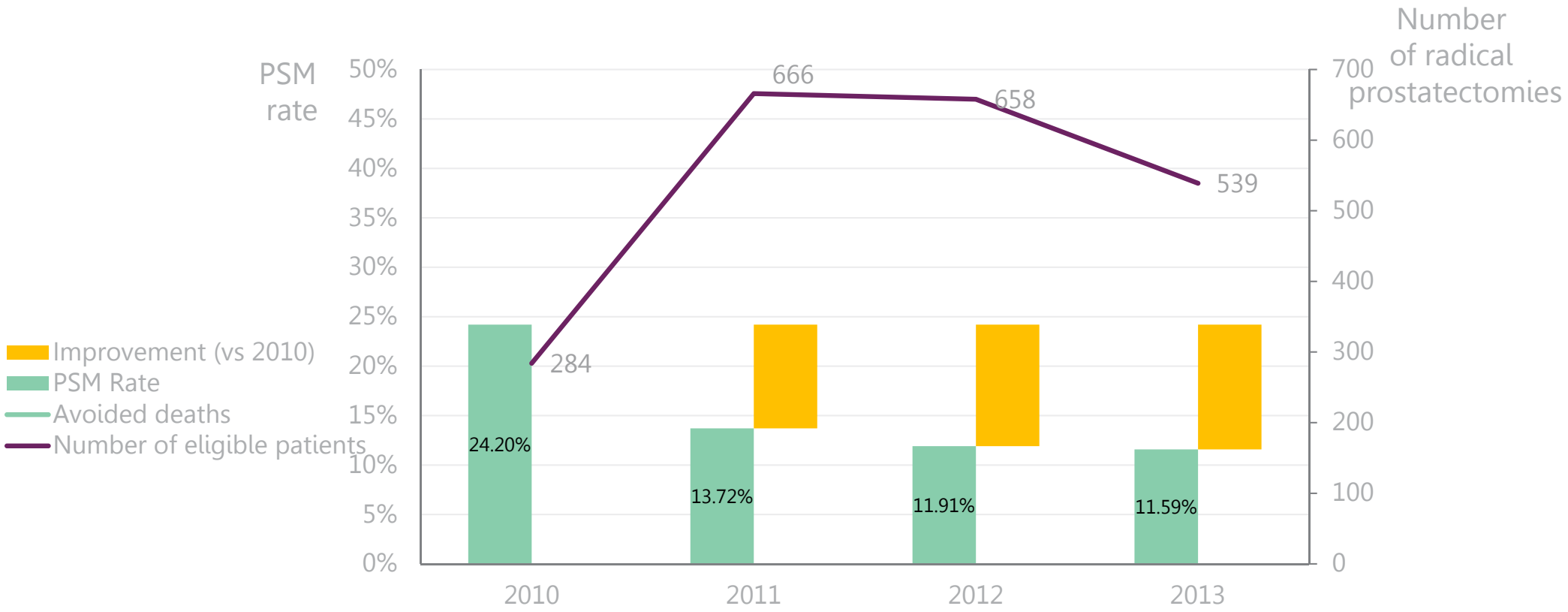
Source: Health Outcomes Australia Analysis. Sample size and hospital procedure frequency are controlled for in the attribution analysis (pT2 patient group analysed only). A potential remaining confounding factor is the possibility of clinicians working accross multiple sites. According to registry data, this amounts to circa 30% of clinicians. Benchamarking reports and feedback are centre specific and in practice usually delivered through MDT meetings (source Interviews Declan Murphy, Jeremy Millar). As a result the confounding impact of individual clinicians working accross sites is difficult to quantify. Anecdotal evidence suggests that the changes in overall practice caused by such site overlap would not be remarkable.

Calculation of avoided positive surgical margins attributed to registry



Improvement vs 2010	-	10.48%	12.29%	12.61%	Total
Number of radical prostatectomies prevented	-	70	81	68	219
Share of improvement attributed due to registry		15%	32%	35%	27%
Attributed reduction in radical prostatectomies	-	11	25	24	59

Source: Health Outcomes Australia analysis

1a Reduction in positive surgical margins

Evaluation of economic impact of avoidance of a single positive surgical margin

For an individual eligible patient

Outcome		Positive surgical margin	No positive margin	Difference	Unit used	Value of avoided positive surgical margin
Mortality	Median age of death	69	74	5 (in 4.9%)	$182k/ SLY	$42,000
Secondary treatment	Salvage radiotherapy rate (%)	20%	4%	16%	$45k	$7,300
	ADT rate (%)	8%	1%	6%	$5k	$310
	Other (e.g. *combination therapy/ chemotherapy)** (%)	4%	1%	3%	$50k	$1,500
Total value						**$51,000**

Avoiding 20 PSMs

…is predicted to avoid ~1 premature death,

+5 years

$860,000

and almost $200,000 in avoided secondary treatment costs

$182,000

***Columns may not sum exactly due to rounding**. Attribution step reduces number of PSMs avoided. Rate of PSM associated mortality and secondary treatments are sourced from a range of studies stating mortality rate in univariate analysis from 4-18% (e.g. Wright, J., Jurol 2010). Multivariate confounders identified in these papers, such as risk group, disease staging, are controlled for in this analysis through sampling pattern. Average life expectancies taken from registry. Secondary treatment rates source Evans. S, Millar, J, Frydenberg M Positive Surgical Margins: rate, contributing factors and impact on further treatment. Economic values source: AR-DRG IHPA, MBS, and PBS accessed online July 2015. Figures in 2014 dollars, including VSLY unit, and time preference rate discount of 3% p.a.

$2.8M benefit through reduction in positive surgical margin rate

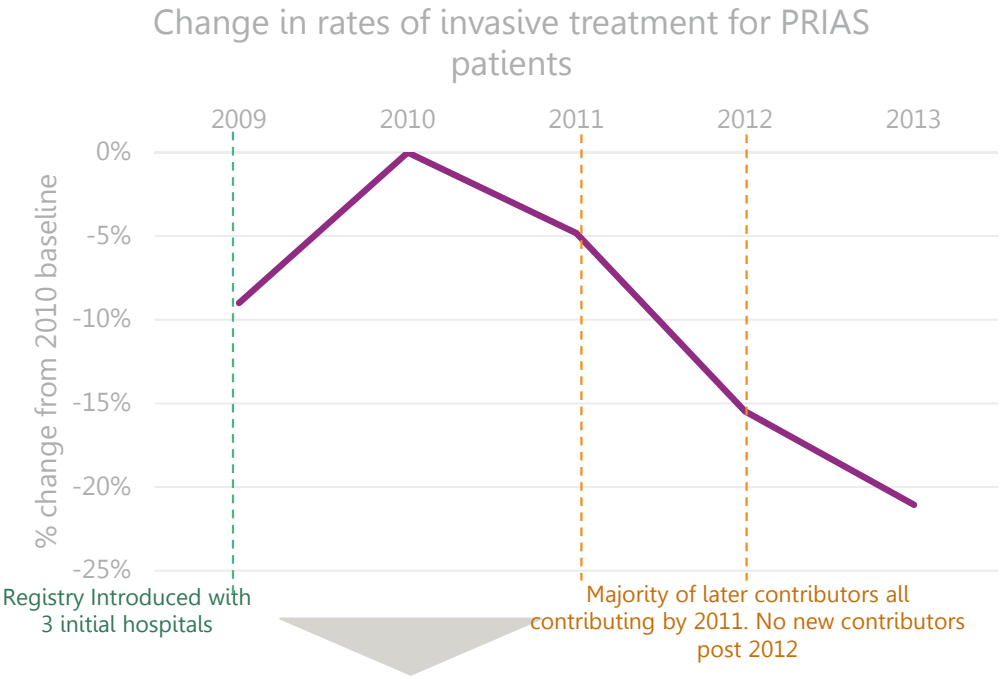
Based on reduction of positive surgical margin rate attributed to the registry

Year	Reduced positive surgical margins (patients)	Value per avoided positive surgical margin	Economic impact pre-discounting	Economic impact	Reduc-tion in deaths	Avoided secondary treatment
2010	Baseline					
2011	11	$51k	**$0.5m**	**$0.5M**	0.5	3
2012	25		**$1.3m**	**$1.2M**	1.2	6
2013	24		**$1.2m**	**$1.1M**	1.2	6
Total (09-13)	**59**		**$3.0m**	**$2.8M**	**3**	**15**
Basis for calculation	Registry data	Literature				Registry (inferred)

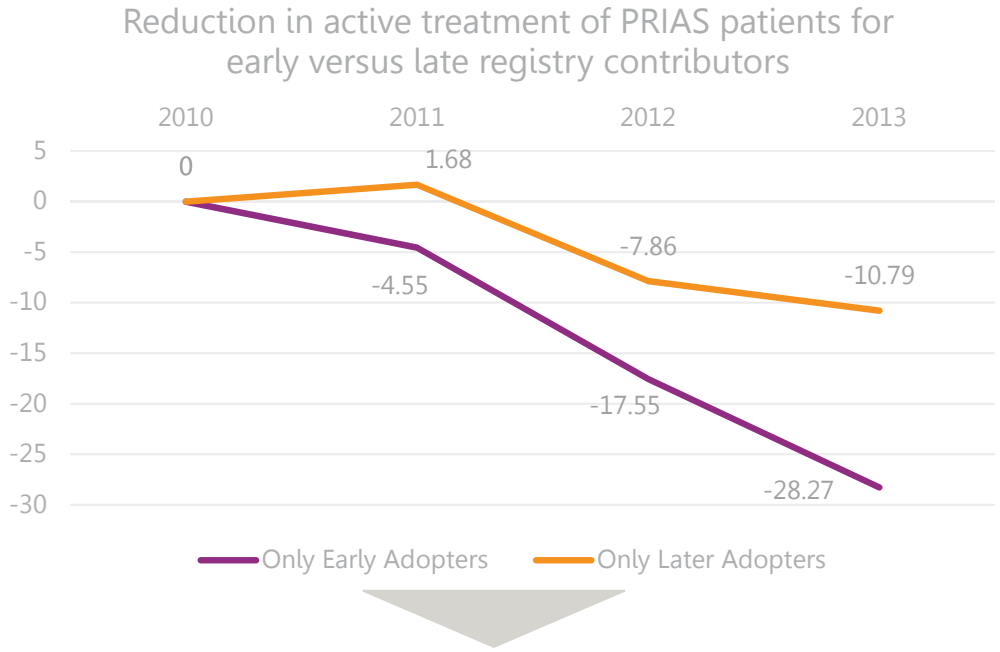
Source: Health Outcomes Australia analysis. Discounted at 3% per annum.

Vic PCR shows reduction in rate of PRIAS criteria patients undergoing active treatment

21 percent point reduction in rate of low-risk patients undergoing active treatment since 2010



Variation in rate of improvement between early registry contributors and later contributors

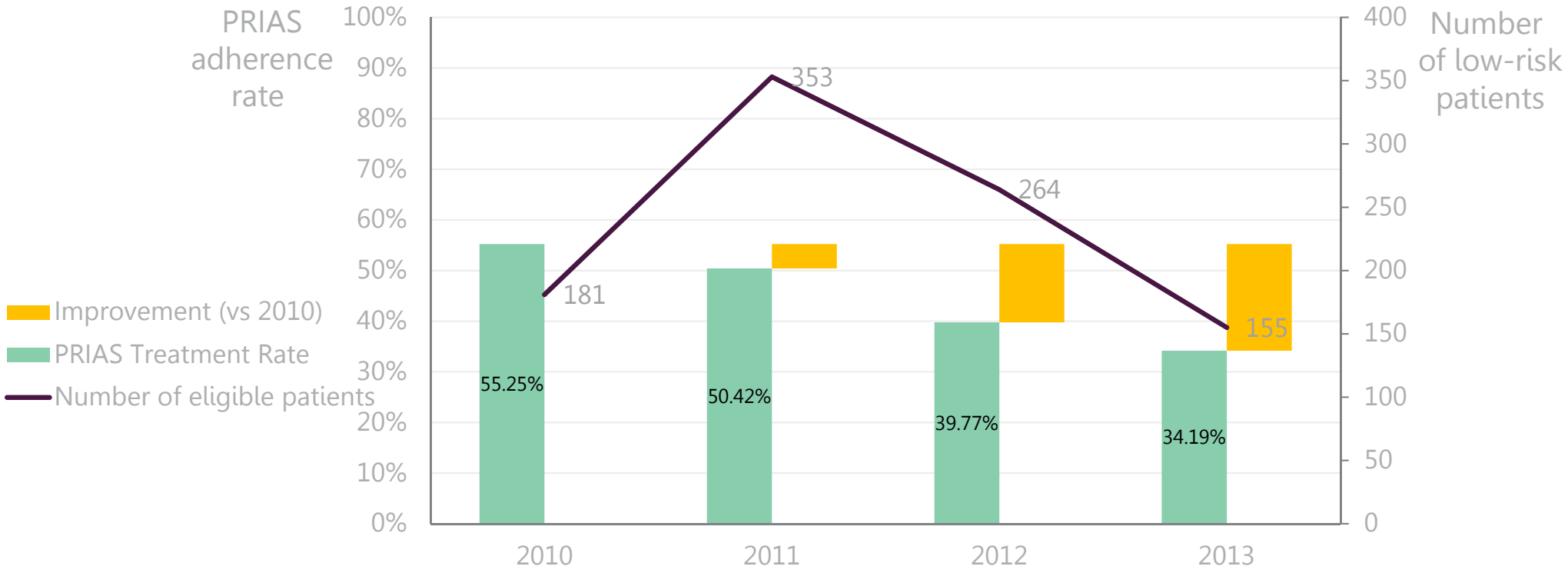


The overall reduction in rate over time equates to 66 avoided invasive/intensive therapies (when compared to 2010 rates) and 9.1 quality adjusted life years preserved (attributed to registry)

Rates of change in compliance with PRIAS guidelines are greater in hospitals that are early contributors to the registry compared to later contributors.

Source: Health Outcomes Australia Analysis. Registry data. For the purpose of the PRIAS analysis the first 5 contributing units were identified as early contributors to enable sufficient case volume for comparisson. In practice these 5 units started providing data to the registry demonstrably earlier than subsequent units

Calculation of avoided active treatment attributed to registry



Improvement vs 2010	-	4.83%	15.48%	21.06%	Total
Number of avoided treatments in PRIAS patients	-	17	41	33	91
Share of improvement attributed due to registry	-	136%	55%	62%	
Attributed reduction in PRIAS treatments	-	23	23	20	66

Source: Health Outcomes Australia analysis

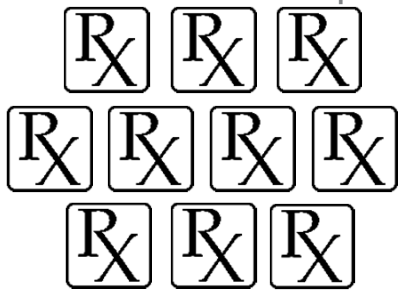
1b Adherence to PRIAS protocol for low-risk patients

$39,000 value per case from adherence to PRIAS guidelines

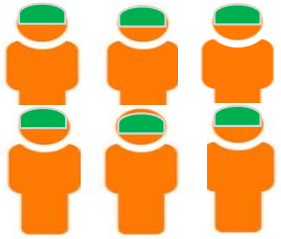
For an individual eligible low-risk patient

Expected outcome		AA/WW	Active treatment (12 month figures)					Average incremental impact per case		Conversion to economic value[2]		Average value of one unit occurrence
			Radical Prostat-ectomy	Radio-therapy	Brachy-therapy	Other	Average					
			72%	7%	15%	6%						
Cost of treatment		$1500*	$15,000	$45,000	$1,500	$49,000	**$15,500**	**$14,000**		**N/A**		**$14,000**
Impact on Quality of Life[3]								**12mnths**	**24mnths**			
	Urinary Bother	**39.9%**	50.4%	51.5%	51.5%	60.5%	**51.25%**	**11%**	**7%**	0.15 VSLY	$182,000/VLSY	**$25,000**
	Bowel Bother	**19%**	15.5%	38.3%	38.3%	45.9%	**22.34%**	**3.34%**	**2%**	0.15 VSLY		
	Sexual Bother	**33.6%**	76.4%	45.1%	45.1%	74%	**69.4%**	**35.8%**	**19%**	0.195 VSLY		
Total												**$39,000**

Reducing 10 active treatments in PRIAS patients



…prevents poorer quality of life in 6 patients



1 QALY

$182,000

and results in benefits of $155,000 in avoided treatment costs.

$155,000

* (not including $ benefits improved Quality of Life)

1. Active surveillance (AS)/watchful waiting (WW) 2. Using disease weights from AIHW 1999 Lower bound disease weights are used for conservative estimates 3. Quality of life values represent frequency of bother recorded within Vic PCR registry; we have estimated quality of life impairment for brachytherapy from those measured for radiotherapy. Active treatment "bother" ratings are sourced from the registry report. The table presents only the 12 month figures though 24 month bother was included in the analysis. *AS/WW cost for 1 patient for the evaluated period year period

$2.4m benefits from outcomes related to PRIAS treatment rate

Based on patient numbers attributed to the registry

Year	Avoided treatment		Quality of life improvement*	Total economic impact pre-discounting	Total economic impact
2010	Baseline				
2011	23	$14,000	$25,000	$0.7m	$0.7m
2012	23			$0.9m	$0.8m
2013	20			$1m	$0.9m
Total	66			$2.6m	$2.4m
Source	Registry data		Inferred from registry		Literature

***Rows may not sum exactly due to rounding and discounting**. *Using disease weights from AIHW 1999. Values used are 0.15 for urinary bother 0.195 for sexual bother, and estimated 0.15 for bowel bother. Disease weight for urinary could be 0.157 if "severe". Lower bound is used here. 2014 VSLY value used throughout $182,000. Discounted at 3% per annum

2 Victorian PCR costs amount to $2.7M from inception to 2013 after discounting (3% per annum)

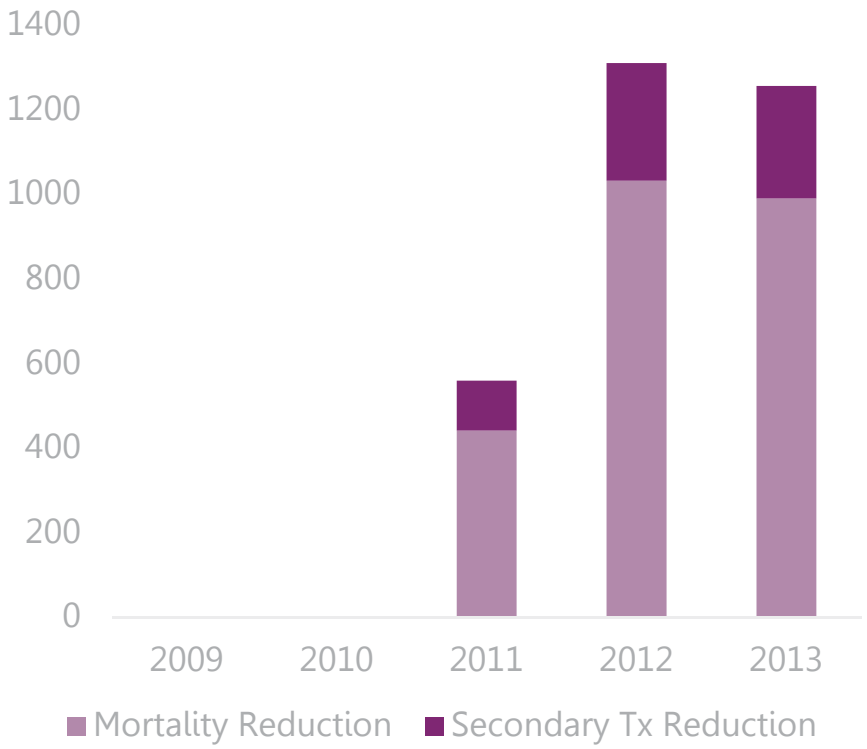
Cost Heading	Responsible for cost	2009	2010	2011	2012	2013	Total 09-13
Development and maintenance*		**$200,000**	**$36,050**	**$36,050**	**$36,050**	**$36,050**	**$344,200**
• Initial build costs	Monash	$200,000					**$200,000**
• Ongoing maintenance (IT & infrastructure)	Monash		$36,050	$36,050	$36,050	$36,050	**$144,200**
Central Costs		**$383,254**	**$383,254**	**$383,254**	**$383,254**	**$383,254**	**$1,916,270**
• Lead	Monash	$34,561	$34,561	$34,561	$34,561	$34,561	**$172,805**
• Biostatistics and analysis	Monash	$38,074	$38,074	$38,074	$38,074	$38,074	**$190,370**
• Research and administration	Monash	$129,364	$129,364	$129,364	$129,364	$129,364	**$646,820**
• Casual staff	Monash	$68,538	$68,538	$68,538	$68,538	$68,538	**$342,690**
• Overheads	Monash	$112,717	$112,717	$112,717	$112,717	$112,717	**$563,585**
Peripheral (data collection) costs[1]		**$72,181**	**$82,021**	**$152,980**	**$155,181**	**$134,339**	**$596,702**
• Data collection metro & regional	Monash	$40,736	$46,289	$86,335	$87,577	$75,815	**$336,752**
• Data collection (outcomes)	Monash	$31,445	$35,732	$66,645	$67,603	$58,524	**$259,949**
Total cost per annum		**$655,435**	**$501,325**	**$572,284**	**$574,484**	**$553,643**	**$2,857,000**
Number of cases in registry		1,181	1,342	2,503	2,539	2,198	9763

Annual running costs between $500k to 700k p.a., and scale with the amount of case load

1. Varies based on case load Source: Health Outcomes Australia Analysis. Registry data.

Summary of benefits from reduced positive surgical margins attributed to registry. Total attributed benefits of $3m before discounting from baseline to 2013

Total benefit of $3m since registry inception



Sensitivity analysis

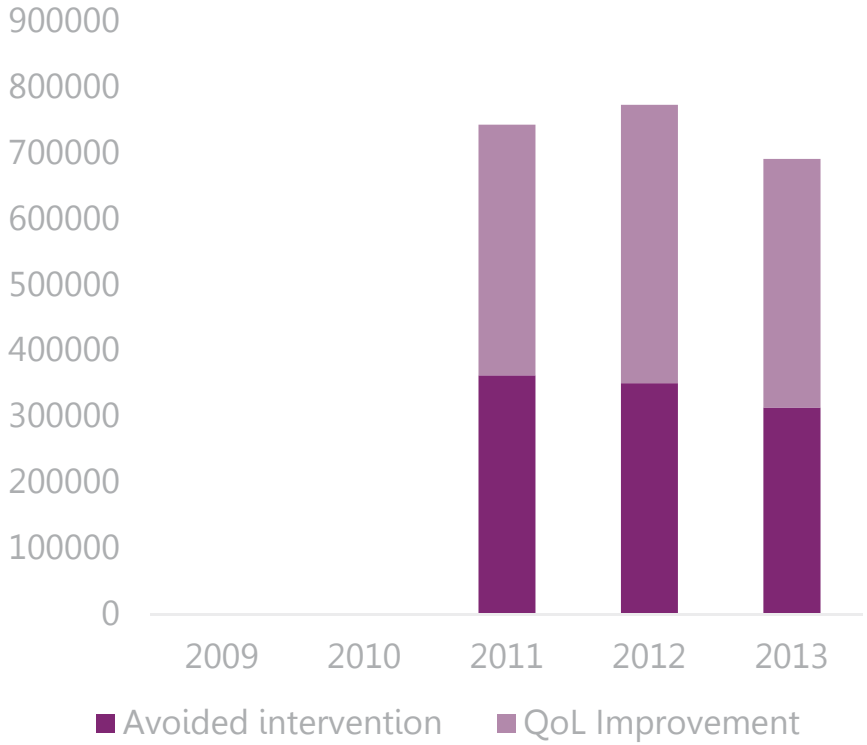
Variable	Value		Source	2009-13 Benefit		
	Range of unit	Base		Change impact	Base	%
Value of a life year	$50,000 to $182,000	$182,000	OBPR[1]	$0.7m to $2.5m	$2.5m	-72
Years of life lost	5 to 8 years	5	Registry data	$2.5 to $3.9m	$2.5m	-35
PSM baseline year (2010)	6% to 10% reduction to 2013	10%	Registry data	$2.2m to $3.1m	$3.1m	-29
PSM mortality rate incr.	4-18%	4.9%	Papers[2]	$2m to $9m	$2.5m	-72
VSLY unit deflation to actual year	$156,000 to $182,000	$182,000	OBPR	$2.4m to $2.5m	$2.5m	-4

Sensitivity range of reduced PSM related benefits of $1.8m to $9.5m from 2009 to 2013

Source: Health Outcomes Australia analysis. Registry data. 1. OBPR 2. Range of studies stating mortality rate in univariate analysis from 4-18% (e.g. Wright, J., Jurol 2010).

Summary of benefits from increased adherence to PRIAS due to registry: Total attributed benefits of $2.6m from baseline before discounting

Total benefit of $2.6m since registry inception



Sensitivity analysis

Variable	Value		Source	2009-13 Benefit ($k)		
	Range of unit	Base		Range of Impact	Base	%
Value of a life year	$50,000-$182,000	$182,000	OBPR[1]	$0.3m to $1.2m	$1.2m	-75
Follow up surveillance costs	0-$50,000	$50,000	MBS PBS RACGP	$0.95m to $1m	$0.95m	NA*
*Eventual active treatment in PRIAS***	*0-30%*	*0%*	*Interview*	*$1.54.m to $2.6m*	*$2.6m*	*-41*
PRIAS baseline year ('09 v 10)	*11%-21% reduction to 2013*	*21% (2010)*	*Registry*	*-$0.2m to $2.6m*	*$2.6m*	*-108*

*Follow up costs for 66 avoided active therapies reduces overall benefits negligibly ($8000 over the period due to PSA testing and periodic biopsy).

** No reliable data available from the registry. Rule of thumb from qualitative interviews suggests 30% will require eventual RP

Sensitivity range of reduced PRIAS indicator related benefits is $1.3m to $2.6m from 2009 to 2013***

Source: Health Outcomes Australia analysis. Registry data. 1. OBPR. Medicare Benefits Schedule, Pharmaceutical benefits scheme, Royal Australasian College of General Practitioners guidelines on active surveillance and watchful waiting in low risk prostate cancer. *** Not including eventual active treatment and 2009 baseline sensitivities due to lack of evidence and available data respectively.

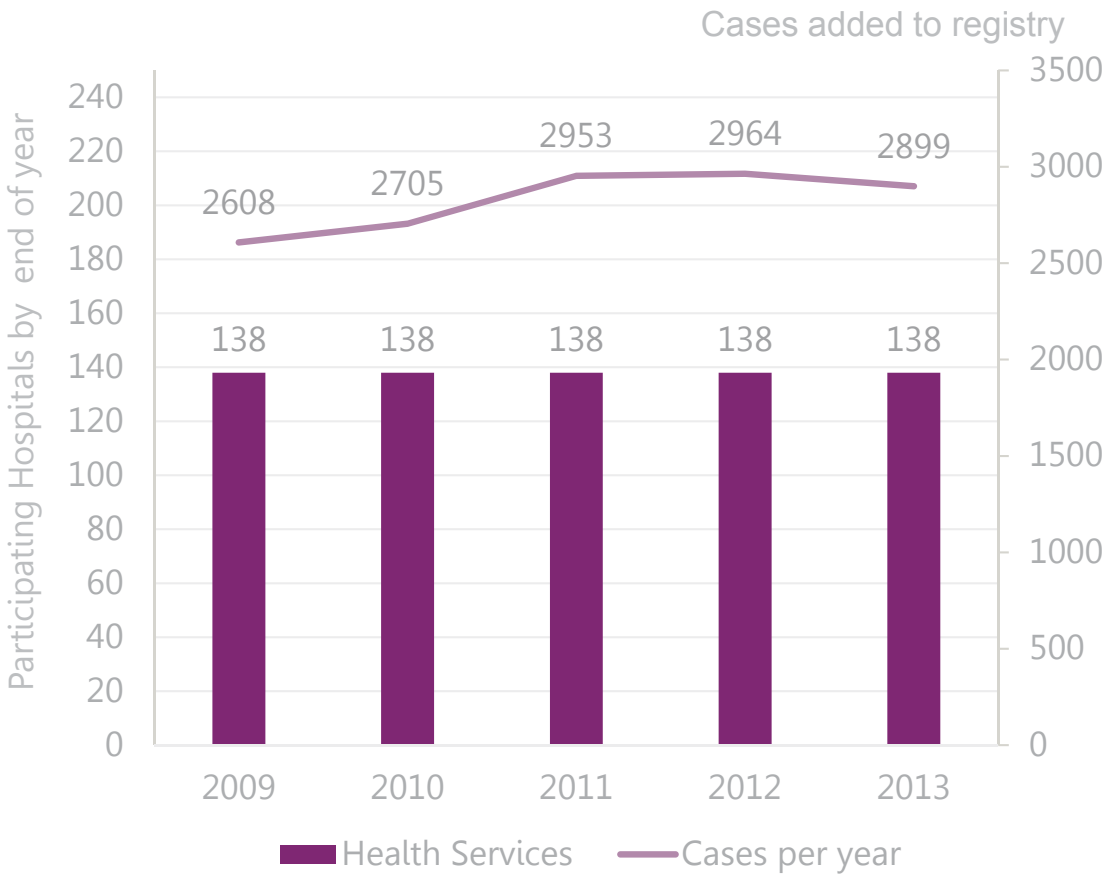
HEALTH OUTCOMES AUSTRALIA

Economic Value of CQRs

Case Study 2 – Victorian State Trauma Registry

Victorian State Trauma Registry (VSTR) background - summary

Established in 2001 following review of trauma and emergency services in Victoria



Full coverage achieved from 2005 and outlier feedback maturity from 2011

Patient coverage: State wide coverage of all major trauma patients in Victoria

Managed by: Victorian State Trauma Outcomes Registry Monitoring (VSTORM) Group 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 the Victorian state trauma system (VSTS). Identification and feed back to outlying units.

Feedback processes: Annual report, quarterly reports (to health services & DHHS) and structured feedback through a Case Review Group which meets 3 times a year.

Source Victorian State Trauma System and Registry 2014 Summary Report

Background to the VSTR

- The VTSR is the only state-wide, population based trauma registry in Australia. Funded by the Department of Health and Human Services and Transport Accident Commission.
- The VSTS came in to being as a result of a Ministerial Review of Trauma and Emergency Services (ROTES) report in 1999 which agreed the need for an integrated system of care for patients sustaining major trauma in Victoria.
- The VSTR was established in 2001 to monitor and evaluate the performance of the VSTS. **Without a system of collecting and feeding back outcomes, the broader system would not have functioned.**
- The VSTR captures data on all **major trauma cases in Victoria** across all phases of trauma care from 138 health services containing;
  - One paediatric and two adult major trauma services
  - Staged care through regional health services.
- There were around 3000 eligible patients in 2013-14, with the rate of new major trauma patients stable over the last 5 years.
- The registry collects data on patient and event demographics, clinical management, injuries, in hospital mortality, length of stay and long term functional outcomes at 6, 12, 24 months post injury.

Source VSTR Annual report 2013-2014/Ministerial Taskforce on Trauma and Emergency Services and the Department of Human Services Working Party on Emergency and Trauma Services 1999

Background to the VSTR

- Feedback occurs through an annual report, not specific to the individual unit (consolidated data). Quarterly reports are sent to the DHHS, CEOs and trauma directors at the health services. Feedback also occurs to the DHHS, to inform pre-hospital and health service compliance with **trauma triage guidelines**. **This has been a consistent process since registry inception.**
- Where cases are deemed to potentially be managed inappropriately, a separate process is initiated through the **Trauma Case Review Group,** a sub committee of the State Trauma committee. This process of structured feedback from this review group commenced in 2011.
- Comparison of registries between states is made difficult due to the absence of similarly integrated systems and the importance of geographic access and infrastructure considerations in determining trauma outcomes. International case studies are also thought to not be truly comparable. **In line with the remaining case studies, a conservative approach to benefits attribution is adopted, looking at just one key registry activity and its effect on two registry quality indicators.**

VSTR major trauma definition

All trauma patients with injury as their principal diagnosis who meet any the following criteria:

1. Death after injury
2. Injury severity score (ISS) more than 12
3. Admission to ICU for more than 24 hours, requiring mechanical ventilation
4. Urgent surgery for intracranial, intrathoracic intra-abdominal injury or fixation of pelvic or spinal fractures

Source Victorian State Trauma System and Registry 2014 Summary Report

VSTR covered approximately 3000 eligible patients in 2013-14

Inclusion Criteria: VSTR captures trauma patients whose principal diagnosis in injury, irrespective of age

- All deaths after injury
- All patients admitted to an ICU or high-dependency area for more than 24 hours and mechanically ventilated after admission
- Significant injury to two or more injury severity score body regions (an abbreviated injury scale of 2 or more in two or more body regions) or an injury severity score greater than 12
- Urgent surgery for intracranial, intrathoracic or intra-abdominal injury, or fixation of pelvic or spinal fractures
- Electrical injuries, drowning and asphyxia patients admitted to an ICU and having mechanical ventilation for longer than 24 hours or death after injury
- All patients with injury as their principal diagnosis whose length of stay is three days or more.
- All patients with injury as their principal diagnosis transferred to or received from another health service for further emergency care or admitted to a high dependency area.

First four inclusion criteria are based on the major trauma definition, with the remaining acting as screening filters to capture the wider group potential major trauma patients.

Source VSTR Annual report 2013-2014 –Excluded from eligibility: Isolated fractured neck of femur, isolated upper limb joint dislocation, girdle dislocation without vascular. compromise, toe/foot/knee dislocation. Isolated closed limb fracture (unless meets inclusion. criteria). Isolated injuries distal to the wrist and ankle (unless Inc. criteria), soft tissue injuries (unless meets inclusion criteria), burns to less than 10% of the body, isolated eyeball injury.

Trauma case review group

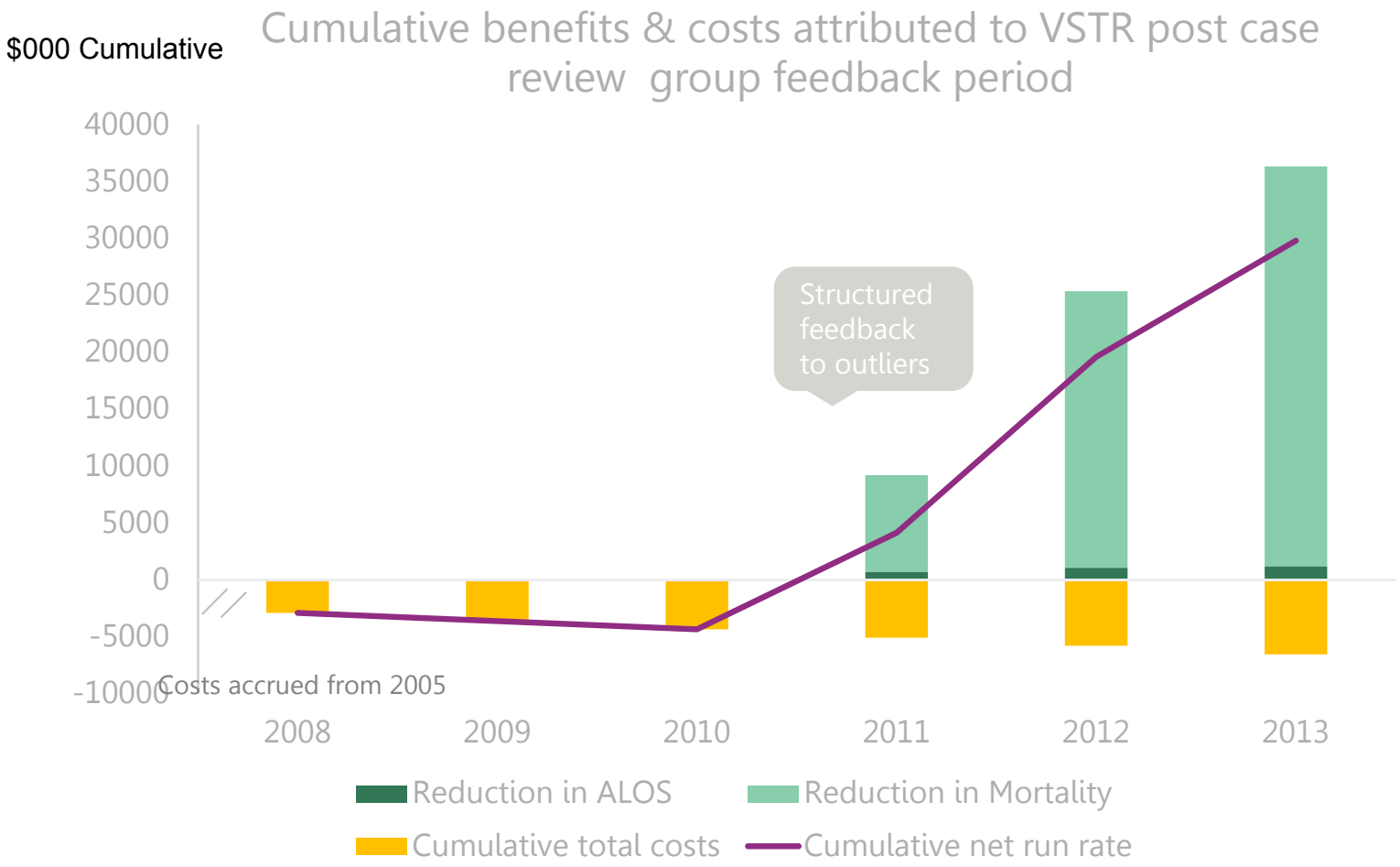
- Formed in 2007 to improve the safety and quality of all major trauma care by reviewing patient journey and management, the case review group reviews cases at metropolitan and regional services (not major trauma services) that may fall outside major trauma guidelines.
- Members are senior clinicians representing specialties including pre-hospital, retrieval, paediatrics, neurosurgery and emergency medicine. The group meets 3 times a year to review de-identified major trauma cases that meet certain outlier filters. Outlier filters broadly cover patient cases that meet one of 3 filters:

Were transferred to a non-major trauma service
Received definitive care at a non-major trauma service
Were a time-critical transfer that took more than 6 hours

- 2013 – 2014 case review group reviewed 173 major trauma cases. Many involved the second filter above, (where guidelines required that the patient be transferred to a major trauma service). Often these cases involve underestimation of the severity of injuries, poor care coordination/communication between services, and lack of contact with Adult Retrieval Victoria.
- Formal feedback commenced in 2011 from which point the case review group advises the State Trauma Committee of cases which require quality review and referral directly to the health service for possible sentinel/outlier event focus.
- Health services are informed when cases are identified as part of a whole of system quality analysis**.** As the trauma system is linked, (with inter-hospital transfers for definitive care) outcomes at major trauma services will be affected by the triage and transfer patterns of case review group impacted cases and vice-versa.
- In 2013 64 cases were referred back to 17 health services for the purpose of additional internal review.

Source Victorian State Trauma System and Registry 2014 Summary Report

VSTR shows a net overall benefit of almost $30 million based on targeted outlier feedback period



Net return attributed
Taking costs for the whole period post 2005;
Internal rate of return 51%
Annual run rate (plotted) benefits realised from 2011

Total benefits
$36m

Total costs (from 2005)
$6.5m

Year	Benefit to cost ratio
2005-2013	6:1

Note: Discounted by 3% p.a.; Figures in 2014 dollars, VSLY unit calculated per annum
Source Health Outcomes analysis. OBPR protocol

Overview of benefits from VSTR

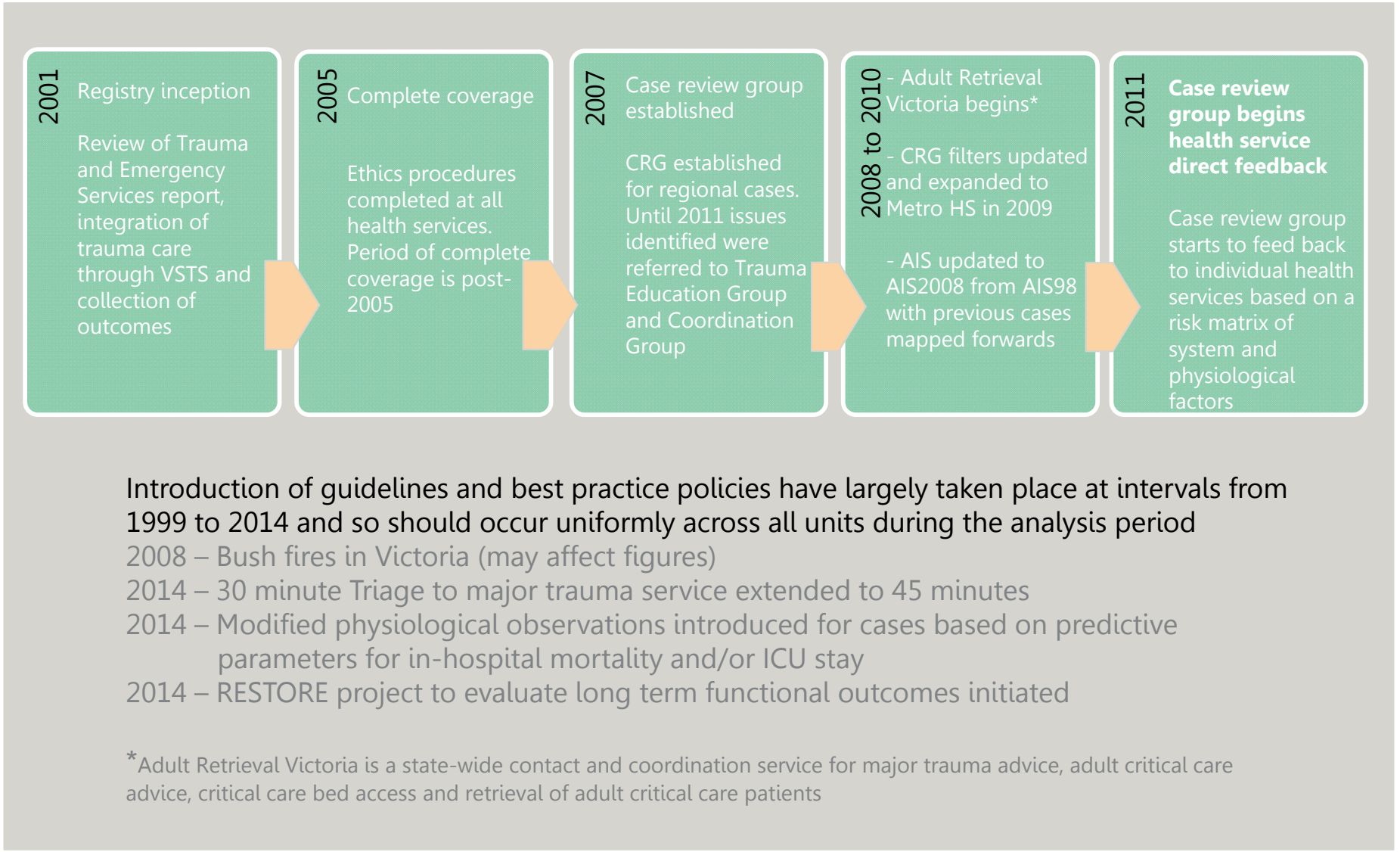
	Indicator of changed clinical practice	Control(s)	Patient outcome measure	Conversion to economic value	Comment
1a	Reduction in ALOS	Comparison within the registry itself. Pre and post case review group feedback commencement in 2011 and sites that have/have not received feedback under this system	Earlier discharge	Average cost of inpatient stay Average cost of follow up	Accessed and analysed 2005-2013
1b	Compliance with transfer and triage guidelines		**In hospital mortality** Morbidity	Mortality ($/life year) Morbidity (weighted $/life year)	
	Other changes in patterns of care		**Functional outcomes**	$/change in quality of life Productivity – return to work	Too early for data to be analysed. Long term outcomes project recently commenced.
	Hospital system performance	International	To be determined	Reduced episodes of care costs, reduced road trauma (paper) reduced loss to productivity, reduced disability payments etc.	Difficult to attribute to registry, not included

Indicators for evaluation

Measured by the registry directly

Source: Health Outcomes Australia analysis

Timeline of significant events within the registry and broader trauma care context



Introduction of guidelines and best practice policies have largely taken place at intervals from 1999 to 2014 and so should occur uniformly across all units during the analysis period

2008 – Bush fires in Victoria (may affect figures)

2014 – 30 minute Triage to major trauma service extended to 45 minutes

2014 – Modified physiological observations introduced for cases based on predictive parameters for in-hospital mortality and/or ICU stay

2014 – RESTORE project to evaluate long term functional outcomes initiated

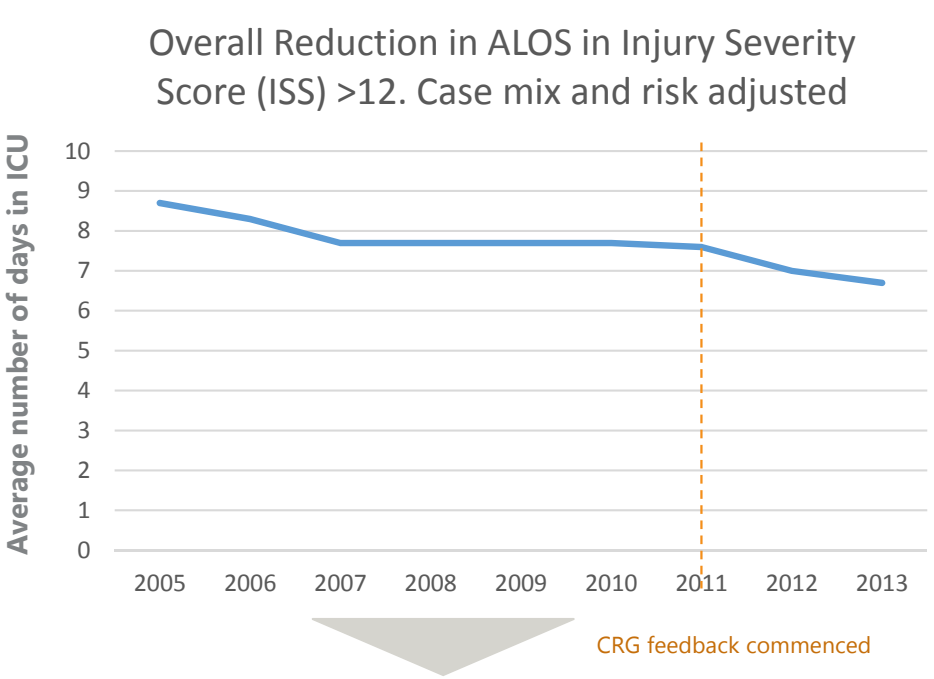
*Adult Retrieval Victoria is a state-wide contact and coordination service for major trauma advice, adult critical care advice, critical care bed access and retrieval of adult critical care patients

Source: Health Outcomes Australia analysis, qualitative interviews, registry annual report and grey literature

1a Reduction in average length of stay

VSTR shows a reduction in average length of trauma stay from 2005 to 2013/4

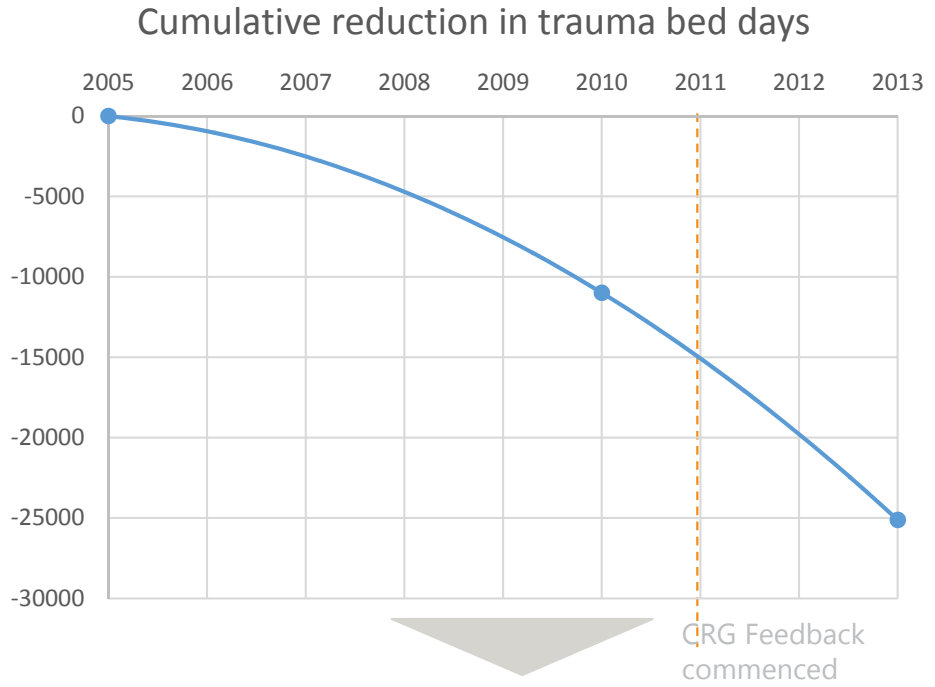
Overall reduction in ALOS for each major trauma patient from 8.7 to 6.7 days



Reduction in ALOS is equivalent to over 16,000 major trauma bed days avoided over the 9 year period based on benchmark rate from 2005

ALOS reduction rate is actually steady between 2006 and 2010 until the post-outlier feedback period when a sharp drop is seen that continues over subsequent years

Acceleration noted in rate of reduction post outlier management program from 2009



Based on actual patient prevalence (age, prevalence, case mix, head injury etc. standardised) the rate of reduction in bed days is over faster in the post case review group period compared to benchmarked control.

Source: Health Outcomes Australia analysis. VSTR data from Victorian State Trauma Outcomes Registry Monitoring Group (VSTORM)

Attribution of benefits to VSTR outlier feedback through the case review group

- In order to isolate benefits that can be clearly attributed to the presence of the registry, we have conducted an analysis of the reduction in ALOS as a trauma patient and risk adjusted mortality, before and after the introduction of the case review group structured feedback process to health services.
- This does not mean that benefits were not evident prior to the case review group feedback process as the registry has been central to the overall VSTS in measuring and reporting on major trauma outcomes to enable quality management, continuous improvement and provide evidence to inform guidelines. Indeed, ALOS and mortality have shown an overall decline over the period that data was available for analyses (2005-2013) not just in the post case review group period.
- The VSTR and VSTS are intrinsically linked. Due to the nature of staged patient care in trauma services, with inter-hospital transfer, dedicated centres for neurosurgery, spinal injury and microsurgery; it would not be legitimate to compare individual hospital units against each other or omit major trauma service outcomes from any analysis.
- For example, if a metropolitan hospital receives feedback from the case review group and improves its performance in transferring critically ill patients to major trauma service, there is a possibility that the resulting case mix change would mean there a greater proportion of frail/elderly patients with higher rates of mortality at the metropolitan hospital, whereas the major trauma service rates related to provision of definitive care may improve due to timely triage and transfer through the system.
- A system level approach to the control/attribution of benefits is taken in this analysis.

The benefits we attribute to post case review group feedback period are incremental to the overall impact the registry has had over time

Source: Health Outcomes Australia analysis

Attribution of benefits to VSTR outlier feedback through the case review group

- For the purpose of defining a clear comparison against a control group, against a defined benchmark, we are comparing system performance before and after the case review group health service feedback provision commenced and benchmarking this against the overall improvements within the same time-frame for the system by removing all units that received case review group feedback. We will thereby have a pre-post case review group feedback comparison, set against the benchmark of system performance in the total absence of case review group feedback.
- During the timeframe of 2005-2013, there is a clear delineation between the analyses and feedback provided to potential outlier metropolitan and regional centres before and after 2011 when the CRG commenced formal feedback. We will compare outcomes for;
  - CRG hospitals All hospitals within the VSTR, including those that have received feedback from the case review group over the period 2011-2013/4 including outcomes in this period from major trauma services. Findings will be scaled down to the proportion of patients that have been admitted to a unit that received case review group feedback only.
  - Non-CRG hospitals: All hospitals within the VSTR minus any unit that received additional case review group feedback.
- The difference in rate of improvement in the case review group units, pre and post the commencement of case review group feedback in 2011, will be attributed to the registry's feedback, set against the benchmark of any improvement seen in this same period in the non-case review group units

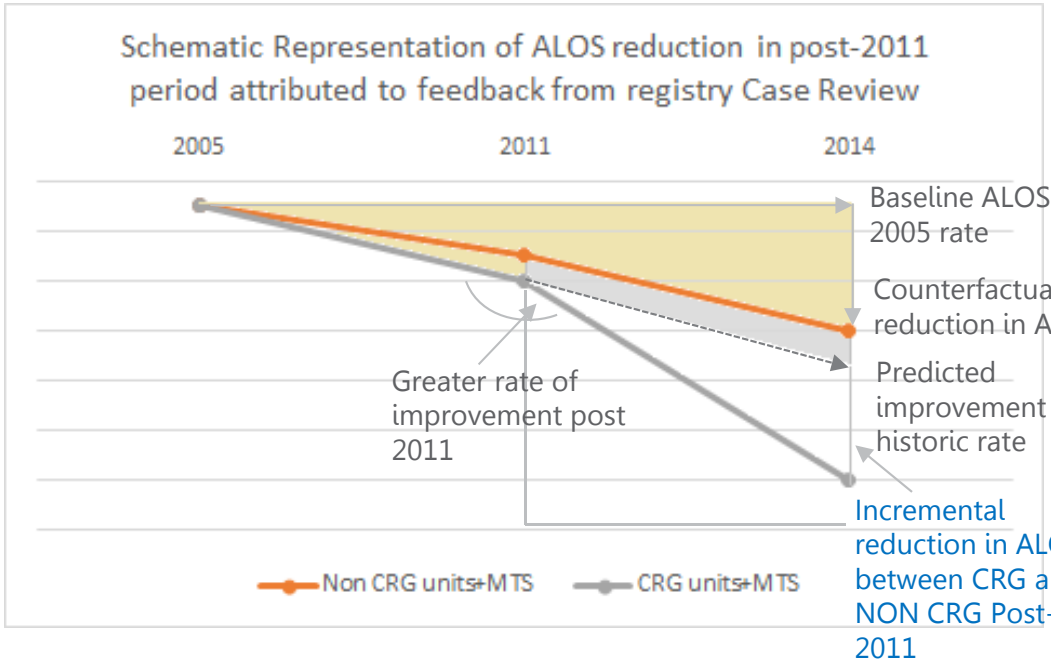
The following slide sets out how this approach was applied to the ALOS analysis.

ALOS – ISS>12, Mortality – All major trauma patients, risk adjusted for age, head injury, modality of injury, and prevalence are analysed in order to control for case mix changes over time and external events (bush fires etc.)

Source: Health Outcomes Australia analysis

The rate of reduction in ALOS was compared **PRE and POST** outlier feedback commenced through the case review group process from 2011

System level rate of improvement is greater post 2011 in hospitals that received CRG feedback



Shaded areas are deducted from the rate of improvement pre and post 2011 to leave the amount attributable to hospitals undergoing feedback through the registries CRG.

Rate of ALOS reduction in the case review group hospitals is faster than benchmarked control

The difference in rate of improvement post versus pre the case review group feedback process is attributed to the registry.

- **Case review group hospitals -** all hospitals within the system, including those that received outlier based feedback from the case review group are analysed for changes in ALOS before and after 2011.
- **Non case review group hospitals – a**ll remaining hospitals in the system when hospitals that received case review group feedback are removed from the data.
- Both groups contain system level data which includes the outcomes in the period from major trauma service hospitals.

Any incremental reduction in trauma bed days in the case review group hospital group due to faster rate post-2011 is scaled down according to the proportion of patients that were treated or admitted in each group. The same approach was employed for the attribution calculation for in-hospital mortality

Source: Health Outcomes Australia analysis

1a Reduction in average length of stay

$1.2 million attributed benefit from reduction in average length of stay in post-case review group period from 2011 to 2013

Year	Attributed bed days saved at 2005 rate	Economic value[1]	$ benefit before discounting	$ benefit
Baseline (2005)		$3,236** per trauma bed day		
2011	277		$0.9m	$0.7m
2012	127		$0.4m	$0.3m
2013	54		$0.2m	$0.2m
Total benefit	**458**		**$1.5m**	**$1.2m**

Taken directly from the registry

Inferred from the registry

Inferred from published sources

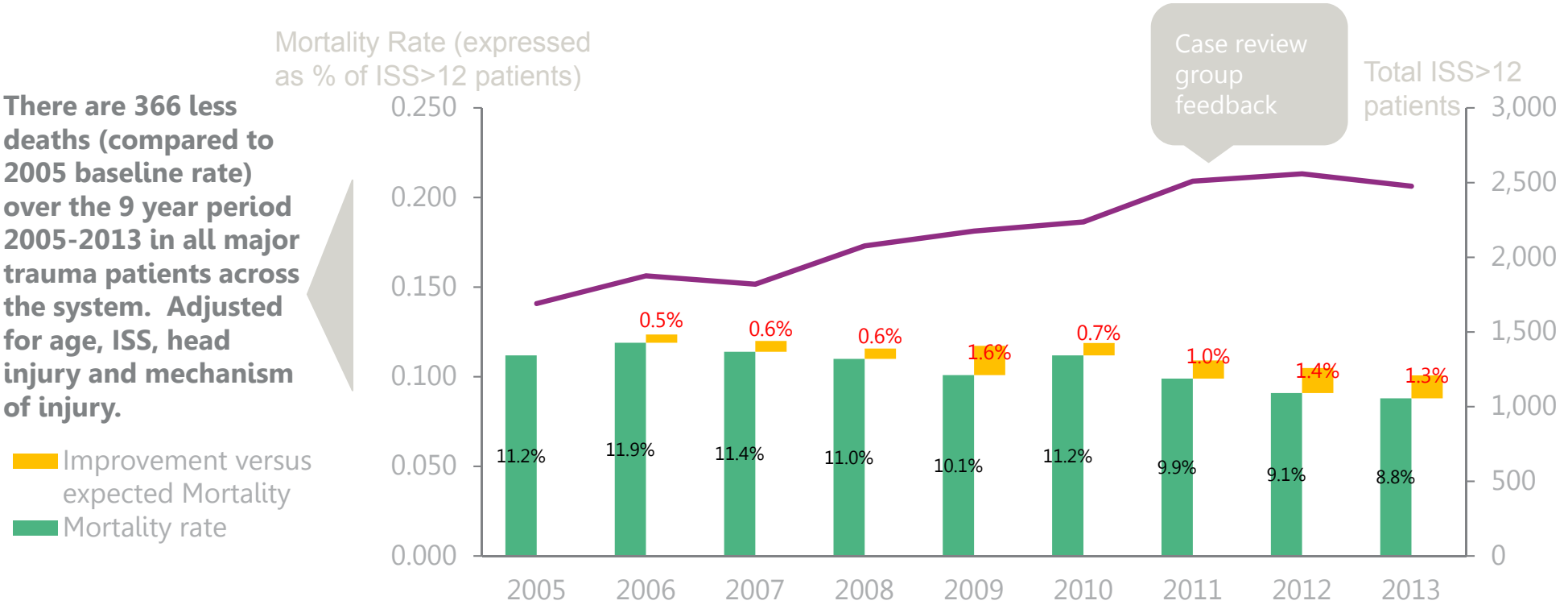
Source: Health Outcomes Australia analysis. Registry data. 1.Based on $3460 (2015 figure) indexed to each prior year. Calculated by funding analytics branch Emergency and Trauma Services, Department of Human Services Victoria. Discounted at 3% per annum

VSTR shows a reduction in risk adjusted hospital mortality from 2005 to 2013/4

Overall reduction in relative risk and crude mortality rate in all major trauma patients

Equivalent to a reduction of 366 deaths compared to 2005 rate

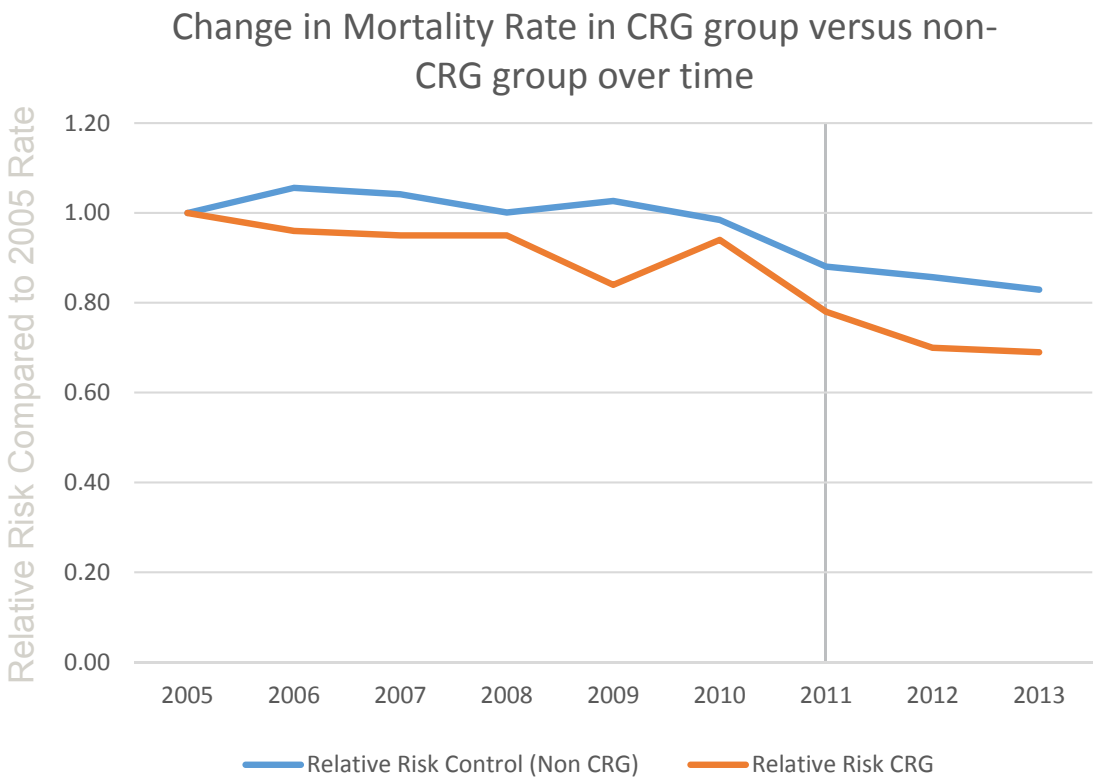
There are 366 less deaths (compared to 2005 baseline rate) over the 9 year period 2005-2013 in all major trauma patients across the system. Adjusted for age, ISS, head injury and mechanism of injury.



Total injury severity score eligible patients	2,136	2,291	2,231	2,526	2,608	2,706	2,954	2,968	2,919	Total
Avoided deaths		0	6	-4	70	11	76	109	97	366

Source: Health Outcomes Australia analysis. VSTR data from VSTORM

Reduction in mortality is greatest in CRG-Hospitals from 2011 onwards



	2011	2012	2013
Relative Risk Non CRG	0.88	0.86	0.83
Relative Risk CRG	0.78	0.66	0.7
Difference	0.1	0.2	0.13
Incremental Prevented deaths in CRG group	30	58	37
Patients in CRG Hospitals	38%	39%	43%
Scale reduction post versus pre 2011	62%	62%	62%
Attributed reduction in mortality	7	14	10

Source: Health Outcomes Australia analysis

The incremental avoided mortality is attributed to the feedback process of the registries case review group

31 of the reduced deaths can be attributed to the registry's feedback process through the CRG

31 additional avoided deaths attributed to the presence of the registry and its additional structured feedback feed back through the case review group.

This is based on deducting the impact seen in the case review group hospital cohort that is also being seen in the control group. The difference in rate of improvement is attributed to the registry and applied to the number of patients that the registry reports as having been admitted to a hospital in this cohort (around 40% of major trauma patients). The reduction in deaths that would be seen in the case review group hospitals if the rate of improvement continued at pre-2011 levels is also deducted from the attributed number.

Results in benefits of $35 million over the CRG feedback period.

Equivalent to $35m – based on

- Discounted VSLY (3%), $182,000
- Average life expectancy of median aged mortality in the selected years (from registry and ABS life tables)
- Circa 5 weeks follow up inpatient rehabilitation (broad estimates are applied for the scope of this analysis).*

Source: *Australian Rehabilitation Outcomes Centre and Faculty of Rehabilitation Medicine Annual report 2014. Discounted at 3% p.a

1b Reduction in hospital mortality

$36 million benefit from reduction in risk adjusted mortality ratio in eligible patient group of CRG feedback period 2011 to 2013

Year	Relative Risk	Admissions*	Deaths	Attributed avoided deaths	Economic Value[1] per avoided death			$ Rehab**	$ benefit pre-disc.	$ benefit
Baseline (2005)	1	Baseline			$182,000			-		
					Discounted VSLY	Median age of cohort	Years Saved Per pt.			
2011	0.78	2954	346	7	$155k	79	9	$0.04m	$11m	$9.2m
2012	0.66	2968	321	14	$158k	80	9	$0.09m	$20m	$16m
2013	0.7	2919	324	10	$159k	80	9	$0.06m	$14m	$11m
Total benefit		**8841**	**990**	**31**	**$1.4m**			**$0.2m**	**$45m**	**$36m**

Taken directly from the registry

Inferred from the registry

Inferred from published sources

Columns may not sum due to roungins. Source: Health Outcomes Australia Analysis. Registry data. *Adjusted for head injury, mode of injury, ISS, Age. **Conservative estimate of inpatient rehabilitation costs based on registry data on the proportion of patients discharged to in-patient rehabilitation. Further data on case mix and treatment duration not available at the time of analysis. 1.Based on OBPR VSLY in 2014, adjusted by 3% private time preference per year of survival. Discounted at 3% per annum. (Disc. – discounting)

2 Costs – VSTRtotalled $6.5 million after discounting at 3% per annum

Cost heading	Responsible for cost	2009	2010	2011	2012	2013	Total 2009-2013
Development and maintenance of database	**Monash**	**$52,424**	**$50,914**	**$61,249**	**$40,000**	**$40,000**	**$244,587**
• Information Technology (amortised)		$52,424	$50,914	$61,249	$40,000	$40,000	$244,587
Central costs		**$407,077**	**$431,786**	**$453,741**	**$462,371**	**$487,046**	**$2,242,021**
• Research and administrative staffing costs	**Monash**	$267,179	$287,596	$305,252	$315,637	$328,357	$1,504,021
• Overheads		$99,898	$104,190	$108,489	$106,734	$118,689	$538,000
• Data analysis / report writing		$40,000	$40,000	$40,000	$40,000	$40,000	$200,000
Peripheral (data collection) costs		**$349,383**	**$357,500**	**$356,580**	**$356,394**	**$438,943**	**$1,858,800**
• Health services' data collection patient outcomes' data collection	Regional health services' data collection costs taken over by Monash in 2013	$349,383	$357,500	$356,580	$356,394	$438,943*	$1,858,800
Total Cost per annum		**$808,884**	**$840,200**	**$871,570**	**$868,765**	**$964,989**	**$4,354,408**

2005 – 2008 expenditure matched reduced funding in this period of around $500,000 per annum. Total costs in the period of analysis (2005-2013) are estimated to amount to $7million

Annual costs around $800k before discounting

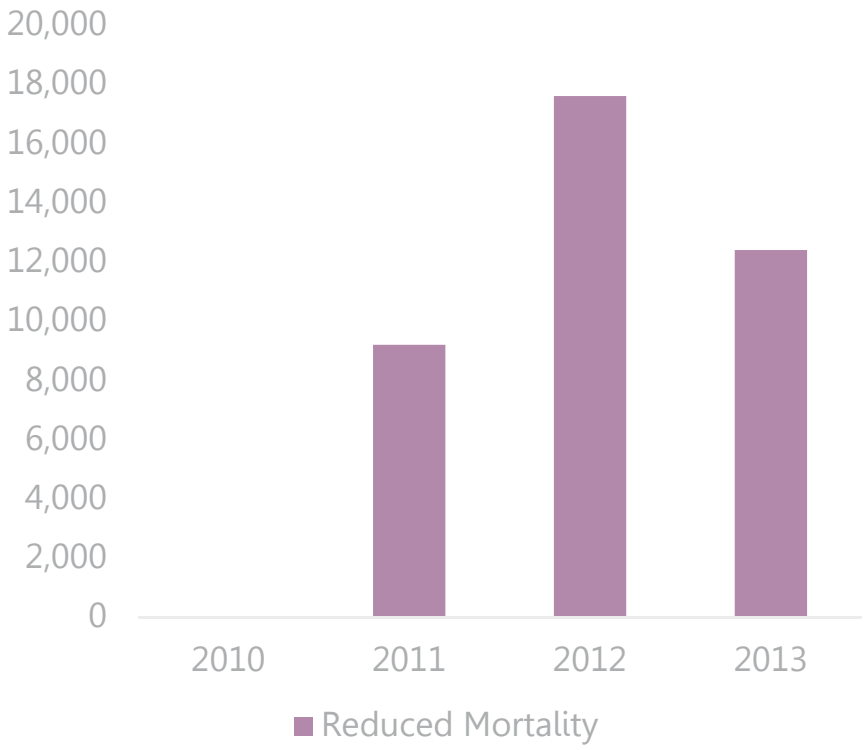
Source: Health Outcomes Australia analysis. VSTR data from Victorian State Trauma Outcomes Registry Monitoring Group (VSTORM). Discounted at 3% per annum.

Sensitivity analysis

Summary of benefits from reduced major trauma mortality rate

Total attributed benefits of $43m pre-discounting after case review group feedback started

Total benefit of $43m in the period 2011-13



Sensitivity analysis

Variable	Value		Source	2011-13 benefit		
	Range of unit	Base		Change impact	Base	%
Value of a life year	$50,000 to $182,000	$182,000	OBPR	$7.7m to $43m	$43m	-82
Impairment to QALY for deaths avoided	0-0.35 QALY*	0	AIHW Burden of Disease	$24m to $43m	$43m	-44

Sensitivity range of reduced major trauma mortality is between $7.7m and $43m

*Longer term impairment of major trauma patients is not known. As such the highest published impairment value for long term injury sequelae (0.35 – long term cranial injury WHO GBD 2010) is applied as a crude estimate of potential sensitivity for patients that survive their hospital stay but suffer ongoing impairment thereafter.

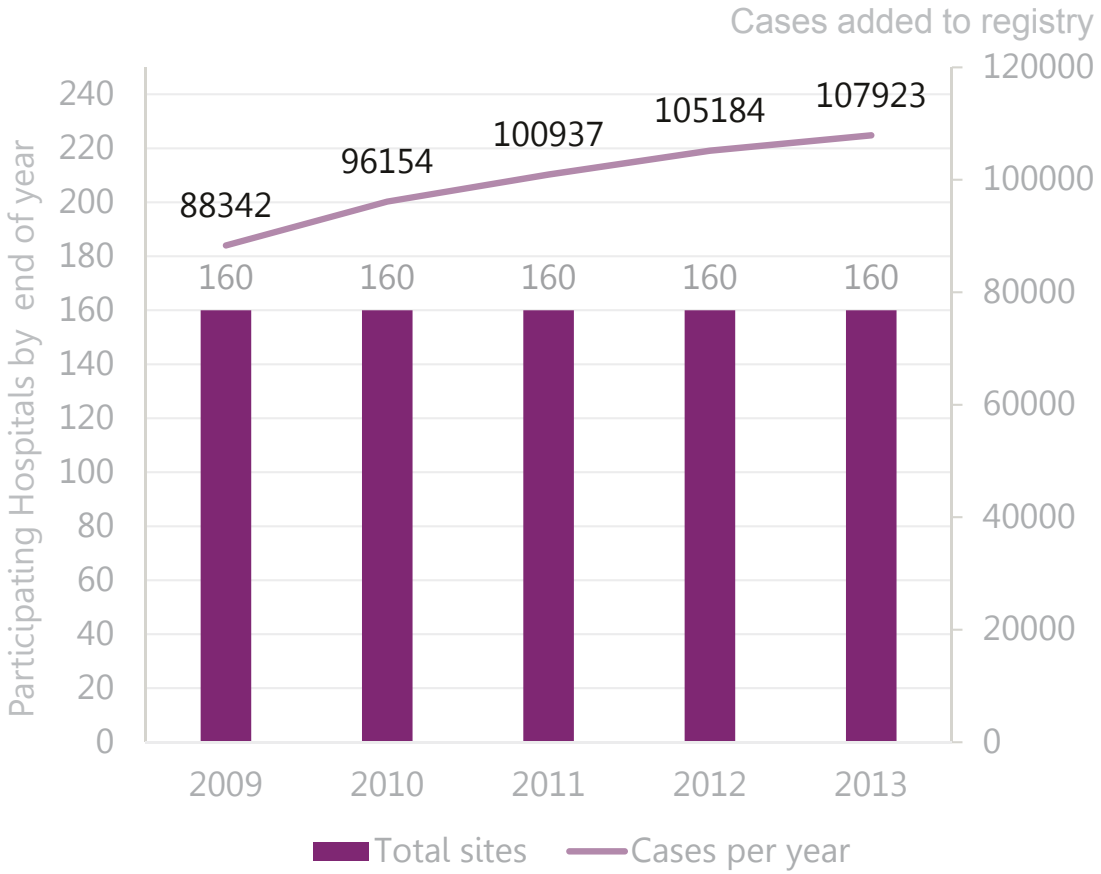
HEALTH OUTCOMES AUSTRALIA

Economic Value of CQRs

Case Study 3 – Australia and New Zealand Intensive Care Society Adult Patient Database

Australia and New Zealand Intensive Care Society (ANZICS) Adult Patient Database (APD)

In operation since 1992 now covering 160 Units



Bi-national registry forming part of a broader set of 4 linked clinical quality registries

Patient coverage: ICUs across Australia and New Zealand (c80% coverage)
Managed by: ANZICS Centre for Outcome and Resource Evaluation (CORE)
Funding sources: Federal government 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.

Source ANZICS Core website, stakeholder interview and grey literature

Background to the ANZICS ADP

- The ANZICS APD is a bi-national registry run by the CORE as part of a broader set of 4 linked, clinical quality registries that benchmark performance and analyse outcomes at ICUs across Australia and New Zealand.
    1. ANZICS ADP
    2. Australia and New Zealand Paediatric Intensive Care Registry (ANZPICR)
    3. Critical Care Resources (CCR) – staffing, resources, processes
    4. Central Line Associated Bloodstream Infection (CLABSI) (103 contributing ICU – less complete coverage)
- Audit and analysis of the performance of Australian and New Zealand intensive care since 1992
    - Currently around 160 contributing units across Australia and New Zealand. Circa 75% coverage in New Zealand and 85% in Australia. (Total 198 units in Australia and New Zealand).
    - Now covers over 100,000 admissions per annum in Australia alone. We will consider only Australian units in this analysis, public and private.
    - Participation recognised as a clinical performance indicator for hospitals by the Australian Council on Healthcare standards
- Collects data on standardised mortality, average length of stay, complications (sepsis, central line infections etc.)
- Feedback has occurred through quarterly and annual reports which enable units to analyse performance against benchmarked averages. Feedback is accessed through the online CORE portal Since 2008/9 individual outlier units have received additional template analysis through an outlier management program

ANZICS CORE – outlier management program

- Commenced in 2008 with data collection on unit level comparison on standardised mortality compared to risk adjusted mean. Feedback on outlier status direct to outlier units commenced in 2009. For this analysis "outlier" means those demonstrating poorer performance.
- A combination of routine monitoring, statistical analysis and contextual interpretation is used to identify outlier units by standardised mortality rate (SMR).
- Based on the premise that patient outcome after ICU admission is predominantly determined by initial severity of illness, and also affected by organisational factors and processes of care within each hospital.
- When an outlier is identified in the quarterly performance benchmarking as having an SMR above 99% confidence intervals off 12 month SMR, a structured program of notification and analysis is undertaken. If an outlier is determined to be a "true" outlier, that is to say that any poorer SMR rate cannot be explained by data quality issues, case mix adjustment, false SMR elevation due to risk modelling, a detailed review of processes of care is undertaken.
- The unit director, jurisdictional governance body/health department and clinician members of an outlier working group are notified prior to this occurring.

Figure 1 sets out the broad approach of the outlier management program

Source: Health Outcomes Australia analysis

Schematic of the ANZICS APD outlier management program

Stage 1: 12 Month funnel plots on SMR for each unit every quarter: identification of a unit above 99% confidence interval or ad hoc jurisdictional request. Unit and jurisdiction notified that outlier review process will commence within 7 days

Outlier analyses to be completed within 21 days

Stage 2	**Do data quality issues contribute to the high SMR?** (Exclusions, data completeness)
Stage 3	**Does case mix contribute to the high SMR?** Subgroups (e.g. ventilated, elective surgical, transfers, ICU/high dependency unit) APACHE III-J diagnoses (comorbidities)
Stage 4	**Are there processes & resources which differ at the unit?** After-hours admissions/discharge, delayed discharge, venous thromboembolism (VTE) prophylaxis Resources, beds, staffing, occupancy, refusals Process Issues; safety, quality, education, accreditation CLABSI rates

Outlier working group

CORE provide a report on the findings in stages 2, 3, 4

1. Review CORE report
2. Consider further analyses
3. Agree conclusions and finalise report
4. Notify jurisdiction and unit director on same day

Source: ANZICS Core Website and ANZICS CORE grey literature

Two key indicators show improved rates from 2000 to 2013

1a Average length of ICU stay

Long stays in ICUs are associated with high costs.

The average value of an ICU bed day is taken as $4,500 based on unpublished registry data and indexed data from NSW

Length of stay can be influenced by age, comorbidity, diagnosis amongst other factors. In this analysis these factors are standardised.

Inclusion

Age over 16
No readmissions in the same episode
ALOS expressed as median bed days

1b SMR

Mortality rate in ICU is associated with case mix, age, patient numbers

Predicted mortality is used to standardise the effect of case mix etc. The prediction is based on the Acute Physiology, age and Chronic Health Evaluation (APACHE) III-J mortality prediction model. The SMR is a ratio of the observed and predicted deaths.

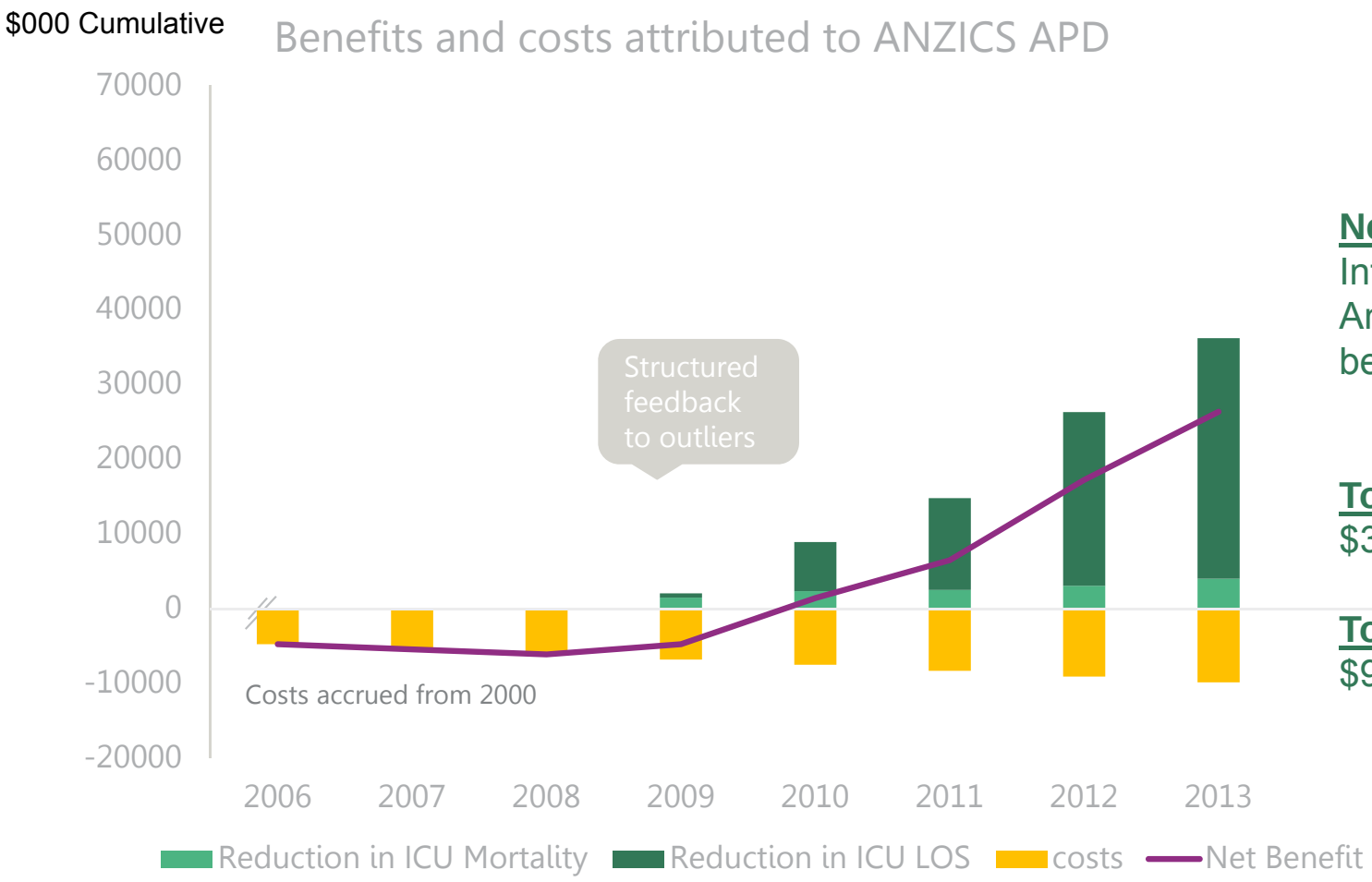
Inclusion

Age over 16
No readmissions in the same episode
Mortality expressed as ratio of predicted to actual deaths (standardised mortality ratio, expressed over time SMR)

The economic benefit in reduction in ALOS and SMR after the commencement of the outlier management plan will be measured (2009-13)

Source: 2004/05 NSW ICU cost data collection http://www0.health.nsw.gov.au/policies/gl/2011/pdf/gl2011_007.pdf

ANZICS APD outlier management program shows net attributed benefits of $26m in its 4 years of operation



Net return attributed
Internal Rate of Return 23%
Annual Run rate (plotted) benefits realised from 2010

Total benefits
$36m

Total costs (from 2000)
$9.8m

Year	Benefit to cost ratio (cumulative)
2000-2013	4:1

Note: Discounted by 3% p.a.; Figures in 2014 dollars, VSLY unit calculated per annum
Source Health Outcomes Australia analysis. OBPR protocol as referenced earlier in this document

Overview of benefits from ANZICS APD

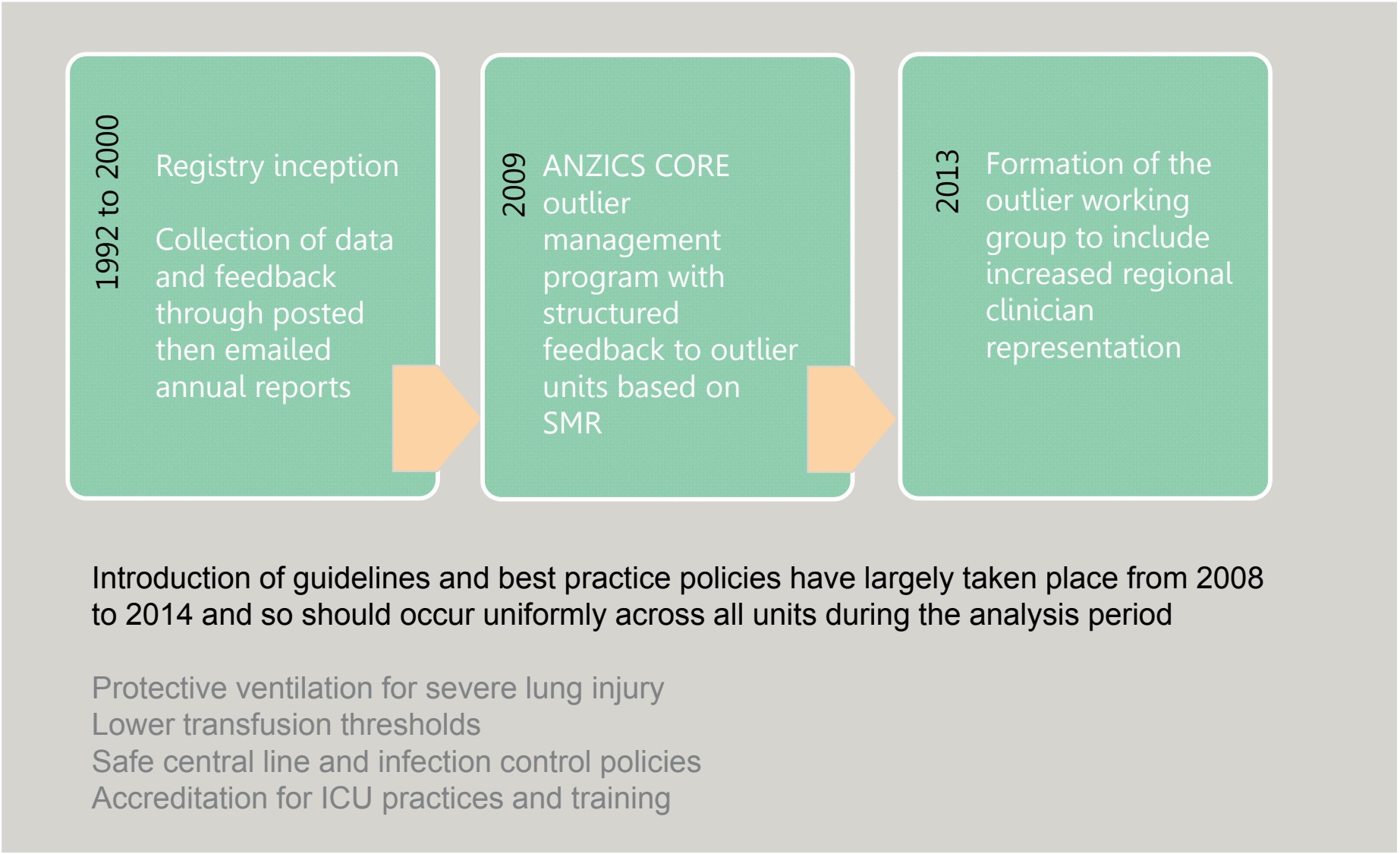
	Indicator of changed clinical practice	Control(s)	Patient outcome	Conversion to economic value	Comment
1a	Reduction in ALOS in ICU	Pre-post outlier management program which commenced in 2009 with targeted feedback to outlier units based on SMR	Reduced need for longer hospital stay	Avoided hospital bed day cost	Data accessed and analysed
1b	Reduced SMR		VSLY mortality adjustment	Mortality ($/life year)	
1c	Reduced rates of central line infection	Compared to non-registry contributing units Compared to international examples.	Improved QOL outcomes	$/change in quality of life $/change in quality of life	Decided not a priority compared to prior two indicators

Indicators for evaluation

Measured by the registry directly

Source: Health Outcomes Australia analysis

Timeline of significant events within the registry and broader intensive care context



Introduction of guidelines and best practice policies have largely taken place from 2008 to 2014 and so should occur uniformly across all units during the analysis period

Protective ventilation for severe lung injury
Lower transfusion thresholds
Safe central line and infection control policies
Accreditation for ICU practices and training

Source: Health Outcomes Australia analysis, qualitative interviews. ACSQHC Australian Guidelines for the Prevention and Control of Infection in Healthcare

Attribution of benefits to ANZICS APD core outlier management program

- In order to isolate benefits that can be clearly attributed to the presence of the registry, we have conducted an analysis of the reduction on ALOS and SMR before and after the introduction of the outlier management program
- This does not mean that benefits were not evident prior to the outlier management program's inception or that the registry has not been central to measuring and reporting on ICU outcomes to enable quality management and continuous improvement relating to these indicators. Indeed, ALOS and SMR have shown a steady decline over time over the period of data that was available for analyses (2000-2013).
- For the purpose of defining a clear comparison against a control group, against a defined external benchmark, we are comparing outlier performance before and after the outlier management program and benchmarking this against overall improvements within the same frame for units that have never been outliers.
- During the timeframe of 2009-2013, there is a clear delineation between the analyses and feedback provided to outlier ICUs before 2009 and post, when the outlier management program commenced.
    - Late outliers (post 2009) entered the outlier management program. Only "true" outliers are included here (data quality and case mix ruled out as a cause of outlier SMR status). "outlier management program outliers"
    - Early outliers (pre-2009) will not have received additional structured analysis and feedback, but will have had the ability to self-assess their performance using the generic annual benchmarking reports. "Pre-outlier management program outliers"
    - Inliers will have not received additional structured feedback at any point and are used as a benchmark
- The difference in rate of improvement between late and early outliers in the post-2009 period will be attributed to the registry's OMP, set against the benchmark of any improvement seen in this same period in the inlier group.

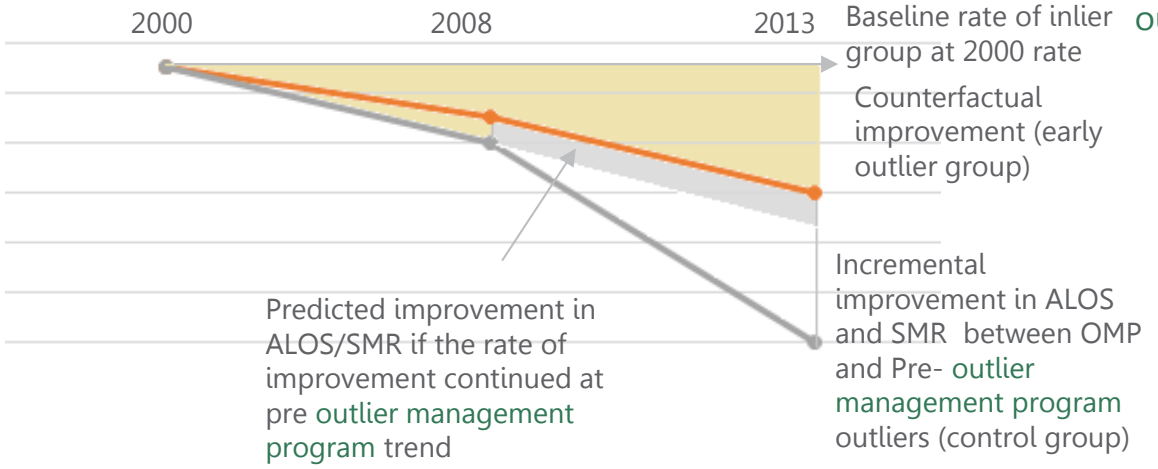
The following slide sets out how this approach was applied to the ALOS analysis.

Source: Health Outcomes Australia analysis

The rate of reduction (improvement) in ALOS and SMR was compared between outlier units that did/not undergo outlier management program analysis

Rate of improvement is greatest in the late outlier group after 2009

Schematic representation of attribution of ALOS reduction in post-2009 period to the outlier management program.



Shaded areas are **deducted** from the outlier management program outlier benefit to take in to account the improvements in the control group and baseline rate of reduction in counterfactual group. (Attributed amount is incremental improvement beyond this.)

Rate of improvement in this group is faster than benchmarked control (early outliers)

The difference in rate of improvement between outliers that did undergo analysis through the outlier management program, and those outliers that didn't (control) is attributed to feedback from the registry's outlier management program.

- Only outliers that were identified after 2009 received feedback from the outlier management program (late outliers)
- Control outliers appeared pre-2009 (early outliers) and still improved their ALOS/SMR, but to a lesser extent.
- Units that never appeared as an outlier (inliers) also improved ALOS/SMR over time, also to a lesser extent.
- Improvement in all groups is greater after 2009, corresponding to the date of inception of the outlier management program.
- The rate of improvement of inliers was used as the benchmark in order to control for general improvements in outcomes across all units over time, including outside of the outlier management program.

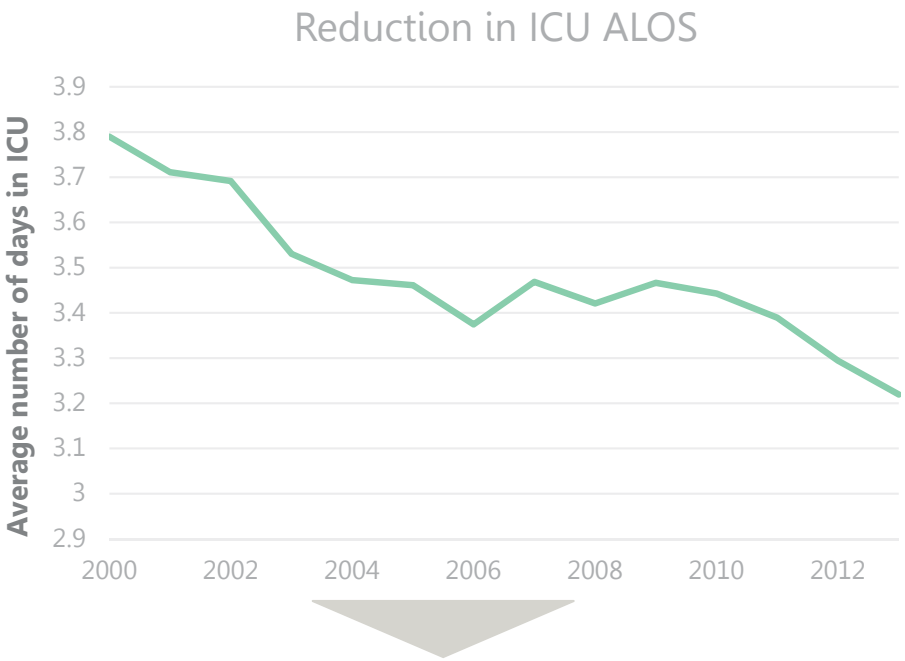
Only the incremental improvement in ALOS reduction rate for late outliers post 2009, (above that of early outliers) is attributed to the registry.

Source: Health Outcomes Australia analysis

1a Reduction in average length of ICU stay

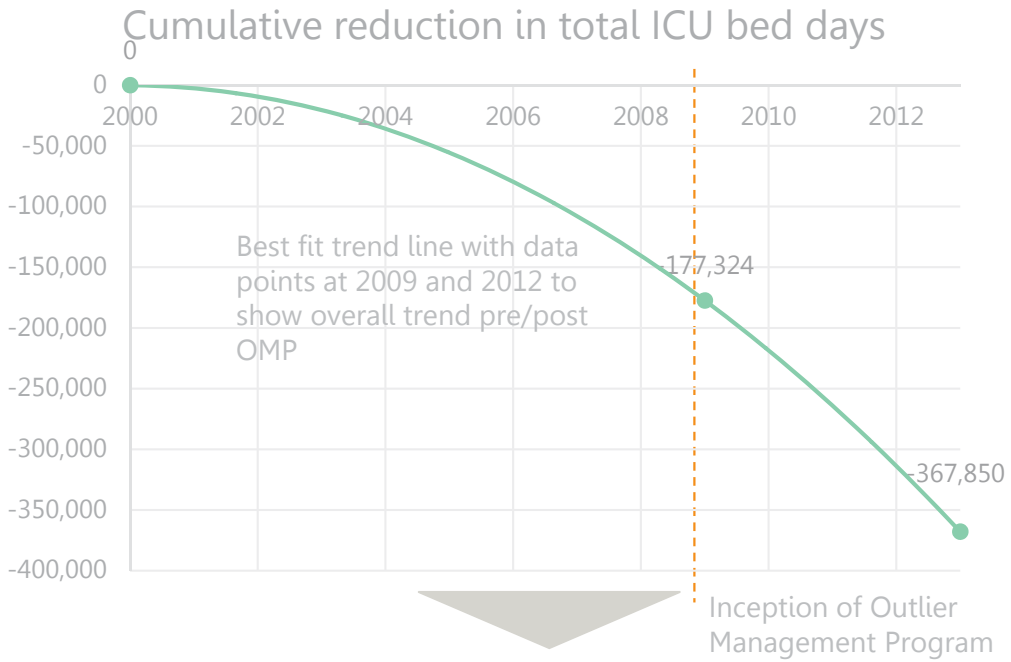
ANZICS APD shows a reduction in ALOS for each ICU patient from 2000 to 2013

Reduction in ALOS for each ICU patient from 3.8 to 3.2 days



Reduction in ALOS is equivalent to over 360,000 ICU bed days avoided over the 14 year period based on benchmark rate from 2000.

Acceleration in rate of reduction post outlier management program from 2009



Rate of reduction in ALOS is faster after the introduction of the outlier management program.

Source: Health Outcomes Australia analysis

1a Reduction in average length of ICU stay

$32 million benefit from reduction in average length of stay in late outliers (outlier management program feedback recipients) from 2009 to 2013

Year	ALOS (Days) *	Admissions	Bed Days	Attributed bed days saved at 2000 rate	Economic value[1]	$ benefit before discounting	$ benefit
Baseline (2000)	4.7	Baseline			$4,300 per ICU bed day		
2009	3.9	7644	29,546	171		$0.7m	$0.6m
2010	3.7	8491	31,436	1875		$8m	$6m
2011	3.6	8757	31,564	1842		$8m	$5.7m
2012	3.3	9344	31,033	3627		$16m	$11m
2013	3.3	11019	36,780	3051		$13m	$9m
Total benefit		**45,255**	**160,359**	**10,566**		**$45m**	**$32m**

Taken directly from the registry

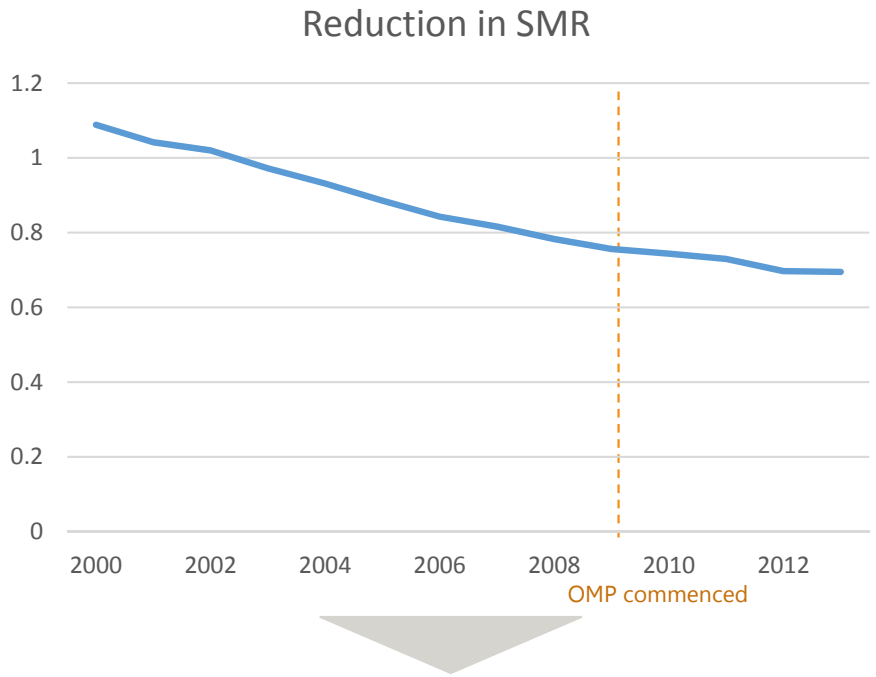
Inferred from the registry

Inferred from published sources

Source: Health Outcomes australia Analysis. Registry data. 1. Cost of Care Standards 2010 NSW Ministry of Health (3% pa inflation rate applied on 2009/10 figures) *ALOS within the late outlier group only. Only incremental improvements in this cohort are attributed to the OMP function in this analysis. Discounted at 3% per annum

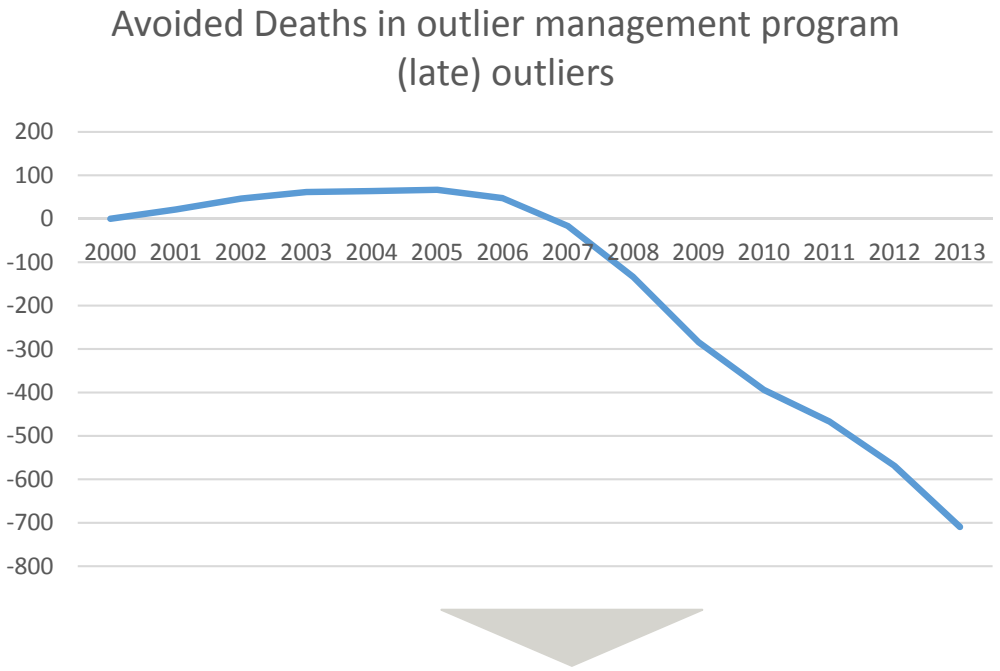
ANZICS APD shows a reduction in SMR from 2000 to 2013

Reduction in SMR from 1.09 to 0.69
(in adults, case mix standardised, APACHE 3 filtered)



The overall reduction in SMR over time equates to 36,000 fewer deaths in ICU when compared to 2000 baseline rate across all contributing units.

Rate of reduction in actual deaths is greater post 2009 in late outliers and when compared to early outliers



Reduction in SMR in late outliers (only) is equivalent to over 30 less deaths in ICU from 2009 to 2013 attributed to the registry's outlier management program

Source: Health Outcomes Australia Analysis. ANZICS Core APD registry data.

1b Reduction in mortality rate

$4 million benefit from reduction in standardised mortality ratio in post-outlier management program outliers from 2009 to 2013

Year	SMR*	Admissions	Deaths	Attributed deaths avoided at 2000 rate	Economic value[1]	$ Benefit before discounting	$ Benefit
Baseline (2000)	0.94	Baseline			$182,000 per year		
2009	0.76	7479	630	11		$1.9m	$1.5m
2010	0.82	8315	704	6		$1.2m	$0.9m
2011	0.86	8589	754	1		$0.2m	$0.1m
2012	0.82	9013	683	4		$0.8m	$0.6m
2013	0.80	10868	804	8		$1.4m	$0.9m
Total benefit		**44,264**	**3575**	**30**		**$5.5m**	**$4m**

Taken directly from the registry

Inferred from the registry

Inferred from published sources

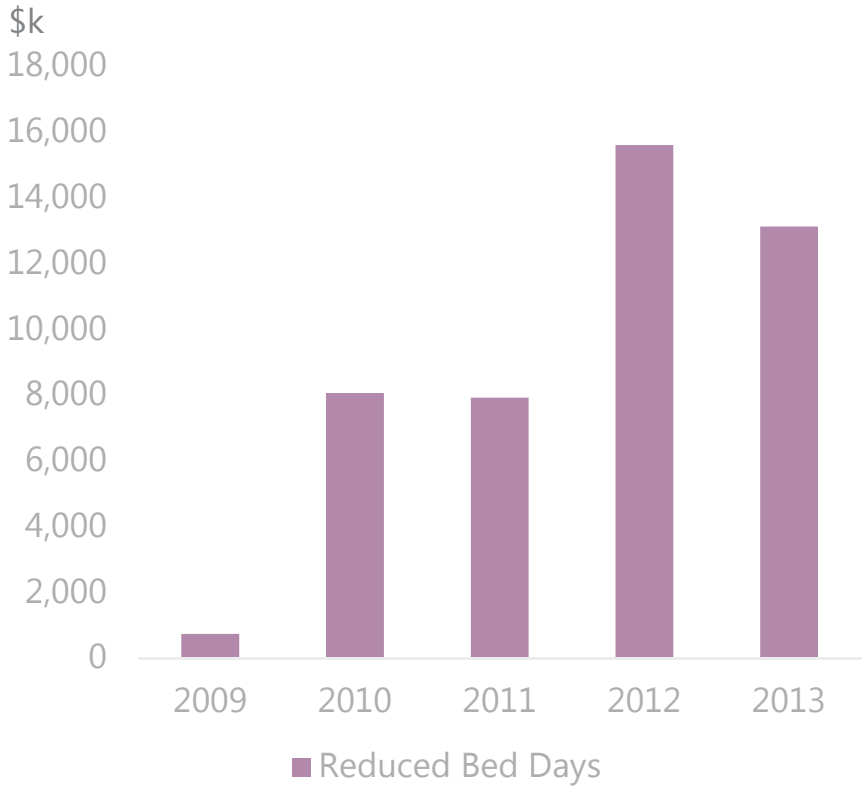
Source: Health Outcomes Australia Analysis. Registry data. 1. OBPR paper, based on conservative estimate of 1 year of life saved for each avoided mortality owing to paucity of evidence on long term outcomes on ICU patient survival. One Australian study quotes an 80% survival rate at 180 days post discharge (Bohensky JCC 2012).
* SMR within the late outlier group only. Only incremental improvements in this cohort are attributed to the OMP function in this analysis. Discounted at 3% per annum

1a

Summary of benefits from reduced ALOS in ICU

Total attributed benefits before discounting of $45m since outlier management program feedback started

Total benefit of $45m in the period 2009-13



Sensitivity analysis

Variable	Value		Source	2009-13 benefit		
	Range of unit	Base		Change impact	Base	%
ICU bed day	$4000 to $4300	$4300	Registry data versus NSW Govt paper[1]	$42m to $45mm	$45m	-7
Impact of readmission	0-4%	0	CCR activity report 2013/14	$43.2m to $45m	$45m	-4

Sensitivity range of reduced ICU ALOS is between $42m and $45m

Source: Health Outcomes Australia Analysis. Registry data. 1. Cost of Care Standards 2010 NSW Ministry of Health (3% pa inflation rate applied on 2009/10 figures)
In 2013/14 there were 148 sites that submitted readmission data to the CCR. Given that the impact on ALOS is not quantified in the scope of this analysis (the ALOS of readmitted patients is not known), readmission censored in the case study data. If each readmission reduced benefit commensurate to an admission, then a 4% sensitivity could be applied.

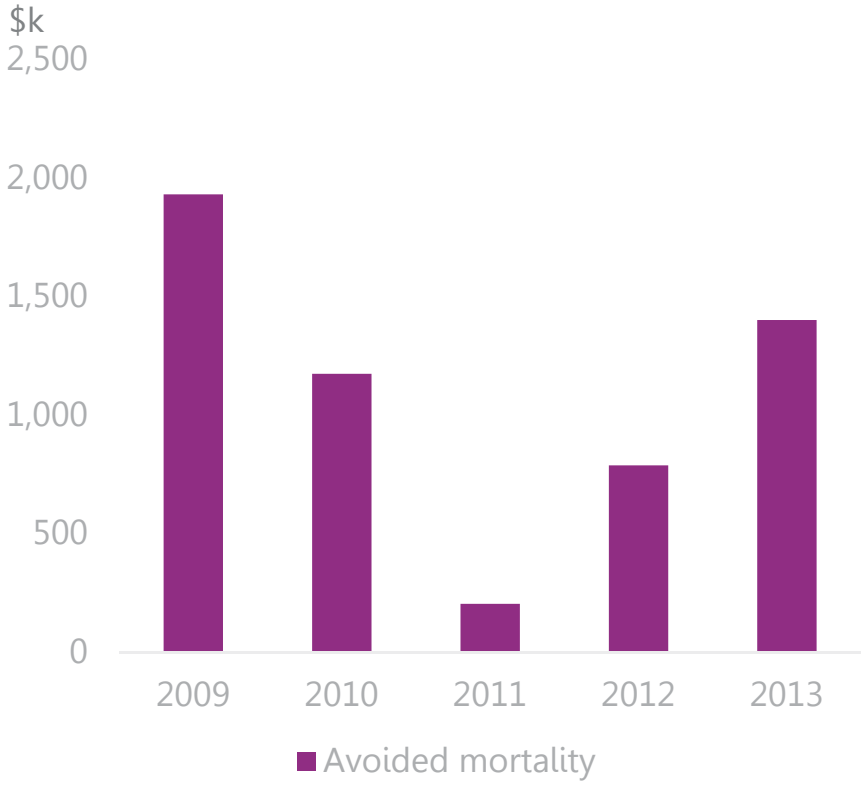
1b

Summary of benefits from decreased standardised mortality ratio

Reduction in mortality rate

Total attributed benefit of $5.5 million before discounting since outlier management program feedback

Total benefit of $5.5m since outlier management program inception in 2009 to 2013 in late outlier group



Sensitivity analysis

Variable	Value		Source	2009-13 benefit ($)		
	Range of unit	Base		Range of Impact	Base	%
Cost of a life year	$50,000-$182,000	$182,000	OBPR[1]	$1.5m to $5.5m	$13.8m	-72
Disability adjustment	0-0.373	0	AIHW[2]	$3.45m to $5.5m	$5.5m	-37

Sensitivity range of reduced ICU mortality is between $1.5m to $5.5m from 2009 to 2013

Source: Health Outcomes Australia Analysis. Registry data. 1. OBPR based on conservative estimate of 1 year of life saved for each avoided mortality owing to paucity of evidence on long term outcomes on ICU patient survival. One Australian study quotes an 80% survival rate at 180 days post discharge (Bohensky JCC 2012). 2. AIHW Burden of Disease Table B – since no data is available on longer term disability free survival, a conservative estimate of quality of life impairment is applied based on an acute episode of pneumonia.(AIHW)

ANZICS CORE registries costs estimated at a total of $9.8 million after discounting from 2000 to 2013 (based on 2009-2013 data)

Cost	Source of funding	2009	2010	2011	2012	2013	Total 2009-13
ALL	Jurisdictional funding	$898,168	$932,758	$981,002	$941,311	$968,609	$4,721,848
	Queensland private	$0	$0	$0	$16,909	$24,600	$41,509
	Infrastructure funding	$0	$0	$141,145	$141,145	$141,145	$423,435
Total cost per annum		**$$898,168**	**$932,758**	**$1,122.147**	**$1,099,355**	**$1,134,534**	**$5,186,792**
	Number of APD cases	90110	97820	102419	106928	109625	

- Cost data assimilated in to ANZICS financial budget. Difficult to segment by descriptor of central costs. Initial set up costs around 1992 not accessible.
- Peripheral data collection costs met by Units as a cost of normal business. Resource in kind is provided through access to software portal and reporting.
- Incremental cost for outlier management program is estimated to be $40,000 per annum. Routine reporting is automated and clinician in-kind support is provided for review of reports.
- 2009 cost has been de-inflated back annually to 2000 for the purpose of this evaluation. Total costs for the period 2000 to 2013 were measured against benefit. The premise is that the registry reaches a point of greater maturity of feedback through the outlier management program and the costs over time to reach this stage and continuously monitor and benchmark are included in the analysis.

Estimated annual costs before discounting of $900k

Source: Health Outcomes Australia analysis, ANZICS CORE APD registry data

HEALTH OUTCOMES AUSTRALIA

Economic Value of CQRs

Case Study 4 - Australia and New Zealand Dialysis and Transplant Registry

Australian and New Zealand Dialysis and Transplant Registry (ANZDATA) background – summary

ANZDATA founded in late 1970s

Source ANZDATA Annual report 2014

Coverage of all renal units in Australia and New Zealand

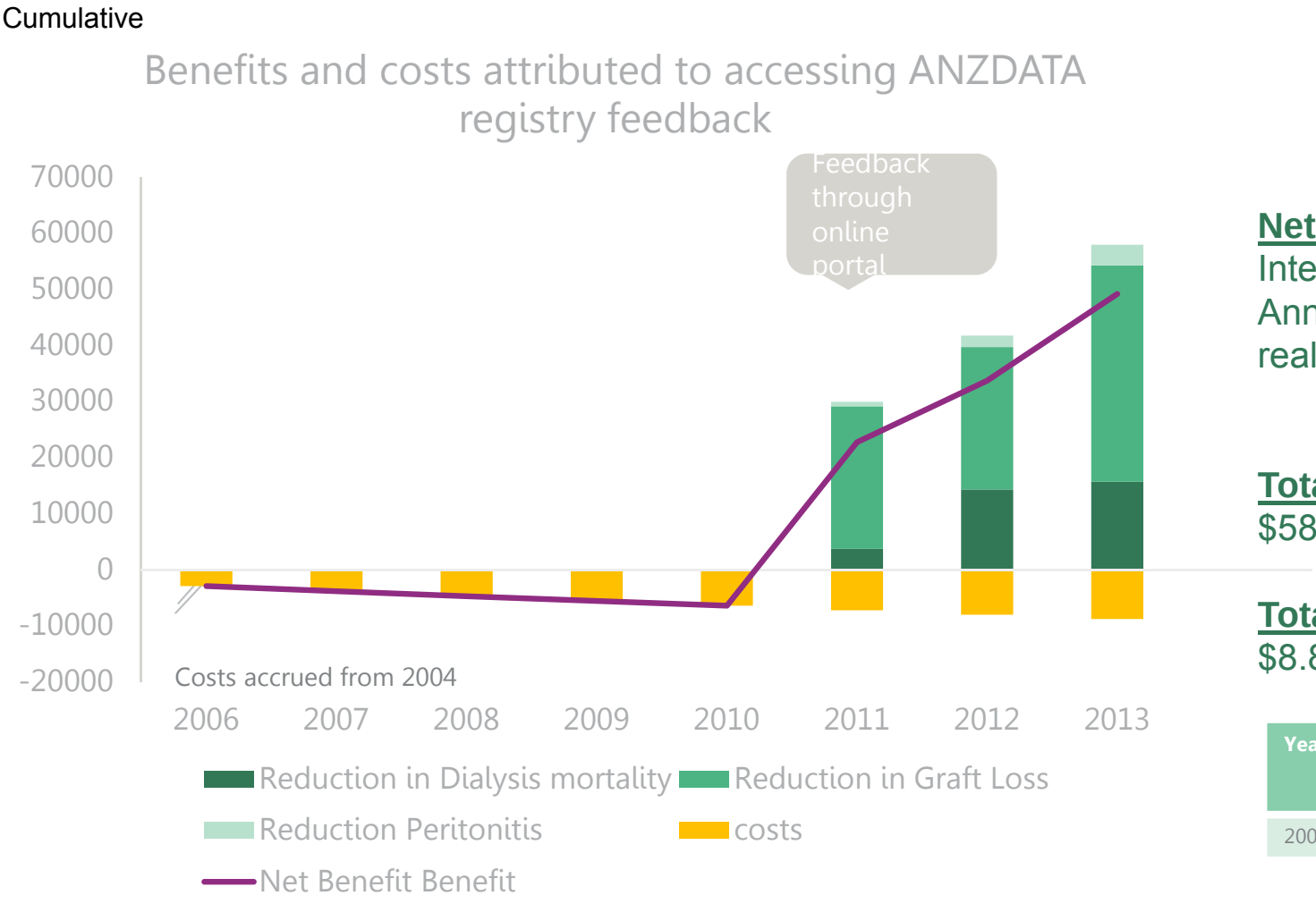
Patient coverage: All renal units providing details on renal replacement patients in Australia and New Zealand, including transplanting units, satellite hemodialysis units.
Managed by: ANZDATA – Royal Adelaide Hospital
Funding sources: Australian Organ and Tissue Authority, New Zealand Ministry of Health, Kidney Health Australia
Principal Metrics: renal replacement therapy (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 (KPIs) produced quarterly in addition regarding haemodialysis access and peritonitis. Access through online self log-in since 2011.

Background to the ANZDATA

- Bi-national renal registry that records the incidence, prevalence and outcome of dialysis and transplant for patients with end stage renal failure. Over 21,000 patients recorded in the registry as of the end of 2013.
- Covers all renal units in Australia and New Zealand and has been running for over 30 years.
- Main outcomes measures include mortality, (in transplant and dialysis), rates of transplanted graft loss/failure, rates of complications in dialysis. The most common manifestation of the latter is peritonitis, for which outcomes are collected within a dedicated sub-section of the registry (peritonitis registry).
- Indicators are fed back to individual hospital units through an annual report. Individual hospital level outcomes are also published for open comparison of hospital performance against benchmarked averages. Further feedback occurs through quarterly dialysis KPI reports. KPI reports commenced in 2011 to supplement the mortality outcome measure.
    - KPI project measures and reports on 2 markers, peritonitis and haemodialysis access at first treatment (based on real time ANZDATA data collection). Home dialysis access rates have been relatively constant over time. Peritonitis rates have improved.
    - Performance reports were originally emailed to units until 2011. Since 2011 units have had access to a secure input portal. After an initial overlap period, emailed reports were ceased in 2013 and it was up to units to log in to view their customised reports using a unique identifier. The same system is used for request and data management.

Source ANZDATA Annual report 2014

The ANZDATA registry shows a net overall benefit of $58million based on hospitals accessing registry analysis and feedback



Net return attributed
Internal rate of return 48%
Annual run rate (plotted) benefits realised from 2011

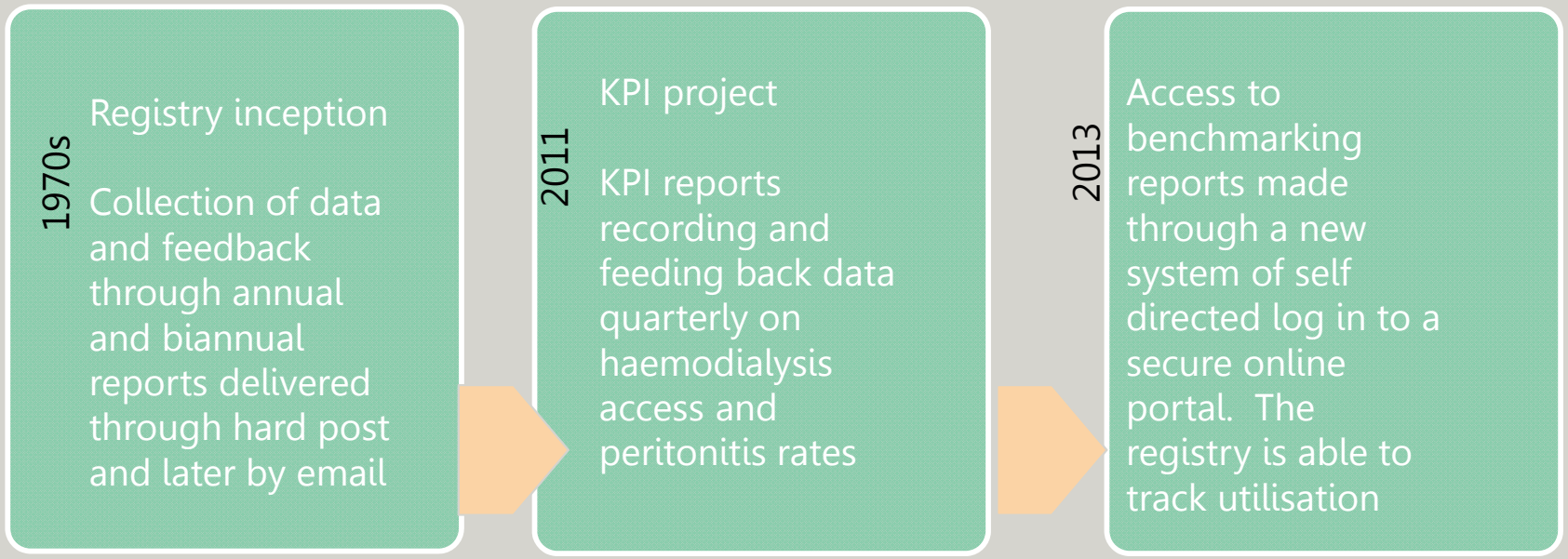
Total benefits
$58m

Total costs (from 2004)
$8.8m

Year	Benefit to cost ratio (cumulative)
2004-13	7:1

Note: Discounted by 3% p.a.; Figures in 2014 dollars, VSLY unit calculated per annum
Source Health Outcomes analysis. OBPR protocol

Timeline of significant events within the registry and broader RRT context



Changes have occurred in guidelines, profile of immunosuppressive medication and surgical equipment. General mix of treatment modality, comorbidity prevalence and demographics has been largely constant over recent years. Changes below should affect all units evenly.

- "call to action" on peritoneal dialysis and vascular access 2010 and current review*
- Immunosuppression: Sirolimus, everolimus, recent & IL-2 receptor antagonists at point of transplantation (2007)
- Caring for Australians with Renal Impairment (CARI) guidelines on peritonitis care (2014)

Source: Health Outcomes Analysis, Qualitative Interviews. ACSQHC Australian Guidelines for the Prevention and Control of Infection in Healthcare
*The International Society for Peritoneal Dialysis (ISPD) position statement on reducing the risk of peritoneal dialysis (PD) catheter-related infection

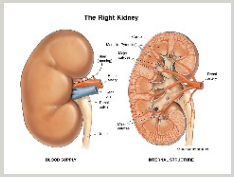
End stage kidney disease (ESKD) is equivalent to Stage 5 chronic kidney disease (CKD) (kidney failure)

Chronic Kidney Disease (CKD)

Chronic renal disease is the progressive loss of renal function over a period of months or years. As the disease increases in severity, renal function declines to a point where regular functions, such as the removal of waste products from the body, cannot be achieved effectively.

Guidelines classify the severity of CKD in five stages broadly based on an estimation of renal function through glomerular filtration rate (GFR).

1. Kidney Damage with normal GFR
2. Kidney Damage with decreased GFR
3. Moderate Decrease in GFR
4. Severe Reduction in GFR
5. Renal Failure



What does this mean for patients?

People with ESKD experience a range of symptoms and abnormalities in several organ systems due to severe loss of kidney function.

RRT in the form of dialysis or transplant is required for survival when renal function is no longer sufficient to sustain life. These can involve lifetime regular treatment sessions or long waiting times together with subsequent surgery and immunosuppressive medication respectively.

- Renal dialysis
  - Peritoneal dialysis 13%
  - Haemodialysis 74%
- Renal transplant 13%

What is the expected impact?

- **Incidence rates have been largely stable over almost 10 years. The number of prevalent dialysis patients has slowly decreased over this period with more people receiving transplants.**

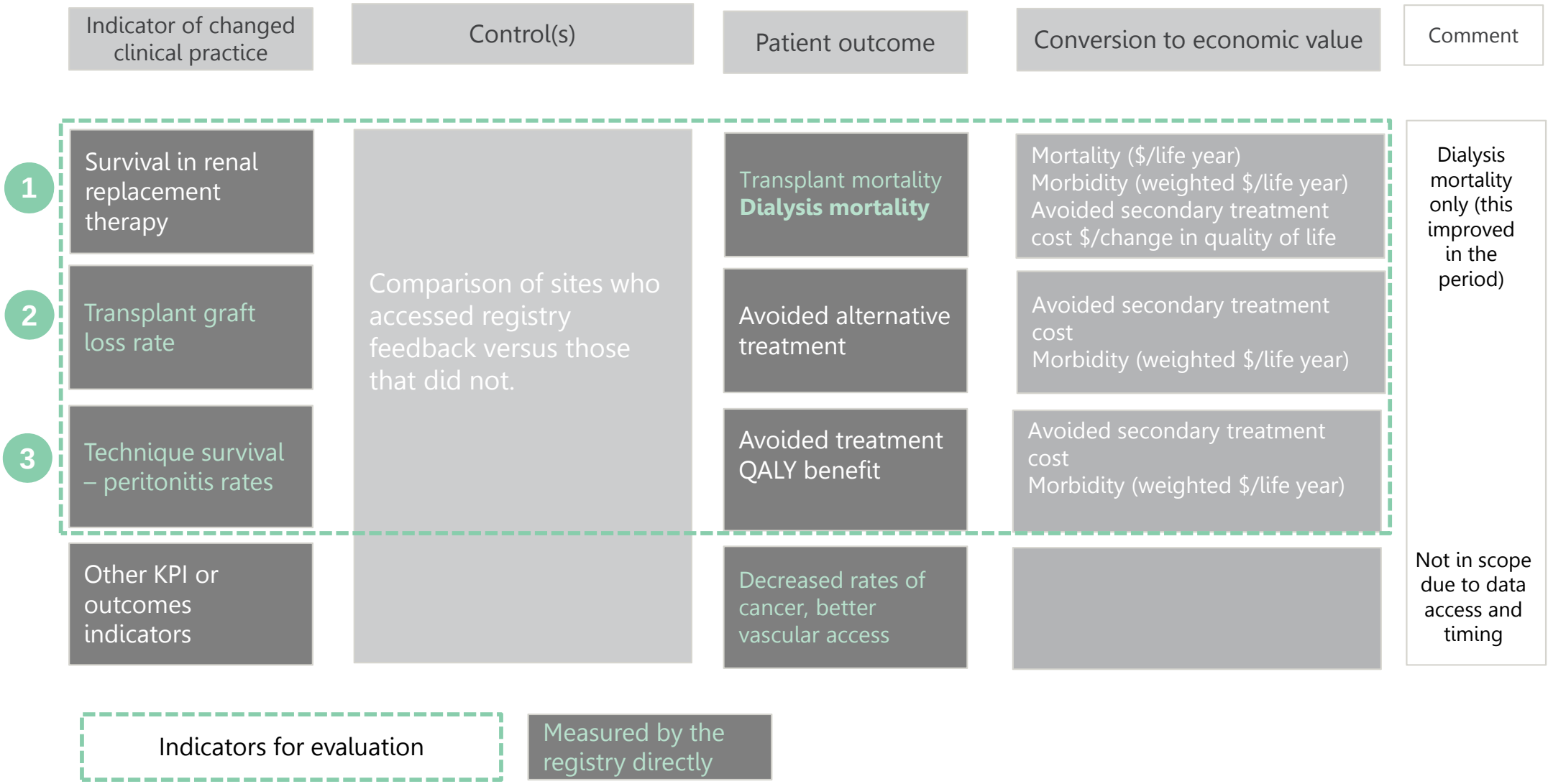
  Reduction in mortality associated with dialysis

  Reduction in complications associated with dialysis technique failure (mainly peritonitis rate)

  Reduction in rate of transplant graft loss and patients subsequently returning to dialysis.

Sources: Health Outcomes Australia analysis, ANZDATA Annual reports 2013 and 2014. Image http://www.arizonatransplantassociates.com/images/kidney_large_1.JPG

We have evaluated 3 indicators from the ANZDATA registry



Source: Health Outcomes Australia analysis

We attributed benefit to the registry by comparing outcomes at hospitals that do/do not access registry feedback resources

Registry feedback

Quarterly unit level benchmarking reports
- Dialysis report
- Transplant caring report
- Transplant performing report

Annual report
- Dialysis, transplant, mortality, complications, stock and flow etc.

KPI report
- Available since 2011
- Quarterly
- Hemodialysis Access and Peritonitis

ALL feedback provided by email and hard copy up until 2009. After an initial overlap period only method of report delivery from 2011 is the online portal (individual log-in access for each unit)

Case and control

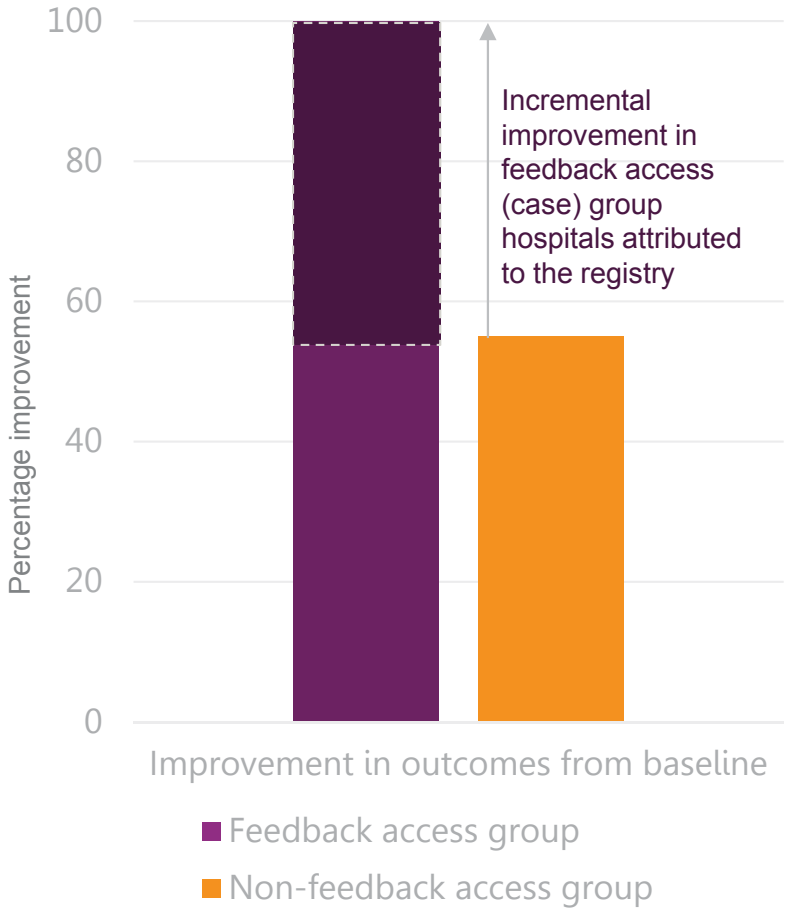
Hospitals' portal log-in (report access and download) behaviour is available for period 2014/15. Reports accessed in this period correspond to 2008-13 data.

Assume hospitals are not getting ANZDATA feedback through other sources (parallel reporting may occur e.g. Victorian KPI project).

Assume hospitals feedback access behaviour in 2014/15 is representative of analysis period 2011-13 (available outcomes data).

Case – Hospitals that access registry feedback
Control – Hospitals that do not
*Volume of complete data sets and balance of units in each group defined the case/control log in count cut offs.**

Attribution of benefit



*Dialysis analysis – removed equivalent of units with less than 10 dialysis patients, Control lower interval is < 2 log-ins for dialysis reports. Upper interval is equal number of units with >2 dialysis report log ins from upper bound. Graft Loss removed time equivalent of less than 10 transplants – Control group lower interval less than 4 log-ins for transplant reports, upper interval same number of units from upper bound >4. Peritonitis removed less than 10 episodes of peritoneal dialysis. Control group – lower interval less than 7 log-ins. Case group equivalent number of units in upper interval >7. Only incremental improvement in case group (scaled to proportion of patients in this group and improvement beyond control group hospitals in same period) is attributed to the registry. All data risk adjusted as consistently as feasible with ANZDATA annual report/unit level reports and denominators used for dialysis and transplant were on 100 patient/graft years respectively to account for duration of treatment of prevalence of disease.

Reduction in dialysis mortality, graft loss rate and peritonitis rate is greatest in hospitals that log in and access registry feedback

Dialysis mortality

Log in group	Improvement *	Proportion of cases
2011	+35%	69%
2012	+73%	58%
2013	+19%	35%

Graft loss rate

Log in group	Improvement	Proportion of cases
2011	+96%	52%
2012	+0%	-
2013	+57%	34.2%

Peritonitis

Log in group	Improvement	Proportion of cases
2011	+37%	49%
2012	+53%	47%
2013	+74%	49%

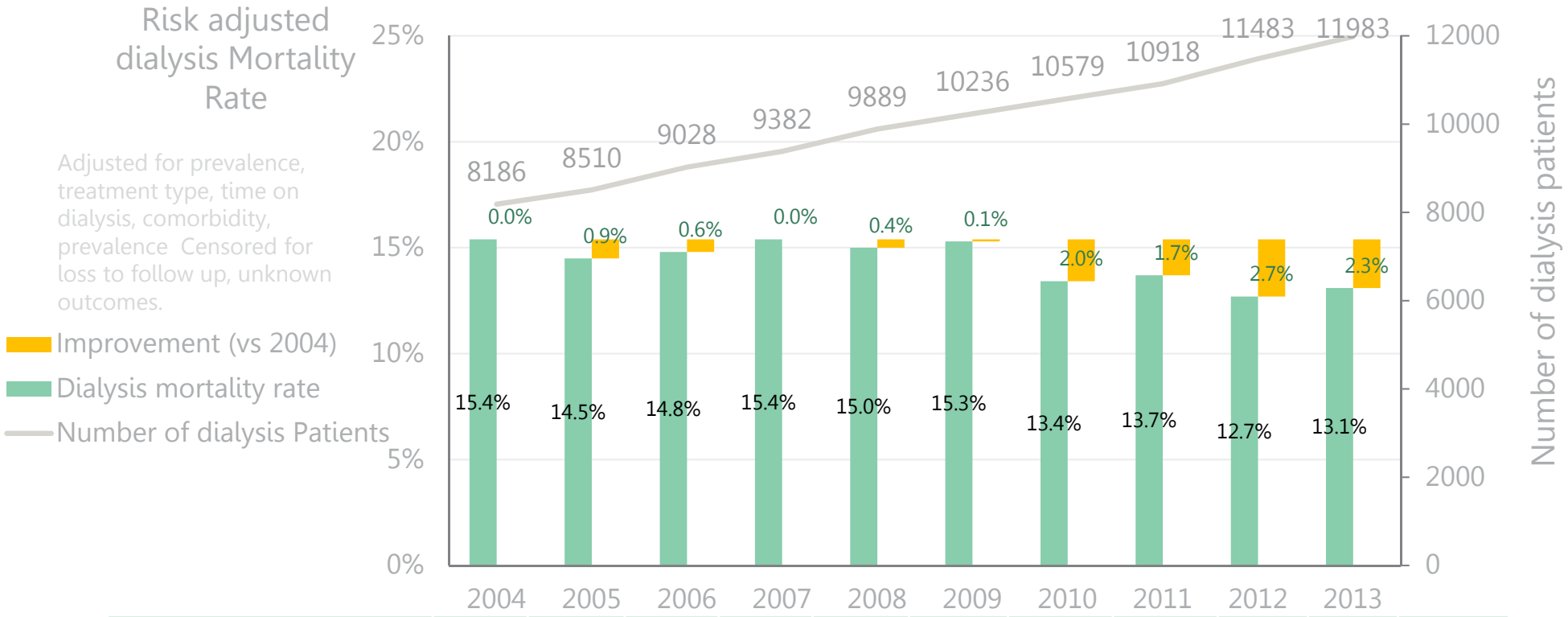
We compared rate of improvement over time for the three key clinical indicators in the period where feedback data and KPI reporting was available through the online portal from 2011-2013. Log in frequency was available for 2014 only and an assumption was made on the consistency of behaviour regarding access to feedback.

Log in group – hospitals who log in/log in frequently to access registry feedback

Non log group – hospitals that do not log in, or that log in infrequently compared to others

Source: Health Outcomes Australia Analysis. Registry analyses and data.

Observed reduction in dialysis mortality rate is equivalent to over 1100 avoided deaths from 2004 to 2013



Relative reduction in deaths vs 2004 baseline	-	-6%	-4%	0%	-3%	-1%	-13%	-11%	-18%	-15%	**Total**
Observed mortality	1208	1202	1326	1459	1493	1538	1414	1507	1485	1518	**14150**
Avoided deaths	0	75	54	0	40	10	209	187	316	267	**1156**
Avoided deaths attributed to registry	-	-	-	-	-	-	-	45	133	18	**196**

Source: Registry data. Columns may not sum due to rounding. Observed mortality may not match dialysis mortality rate from overall number of expressed dialysis patients due to correction for duration of treatment and removal of loss to follow up/overseas RRT. Data is presented as received from the database.

1 Evaluation of economic impact of avoided dialysis mortality

For an individual patient

Outcome 1 avoided dialysis mortality		Years saved	Value for a patient on dialysis	Value of avoided mortality
Mortality		4.5	$104k	$469k
Additional costs	Dialysis	-4.5	$80k	-$358k
	Initial access	-4.5	$9000	-$9k
Total value				**$101k**

Avoiding 1 dialysis mortality

…is predicted save 4.5 years of life

$469,000

With additional ongoing dialysis costs

$-367,000

Columns may not sum exactly due to rounding.

Source: Registry data. Howard, K., McDonald, S., et. al. University of Sydney: The cost effectiveness of increasing kidney transplantation and home-based dialysis – Journal Of Nephrology 2009,

1 Evaluation of economic impact of avoided dialysis mortality

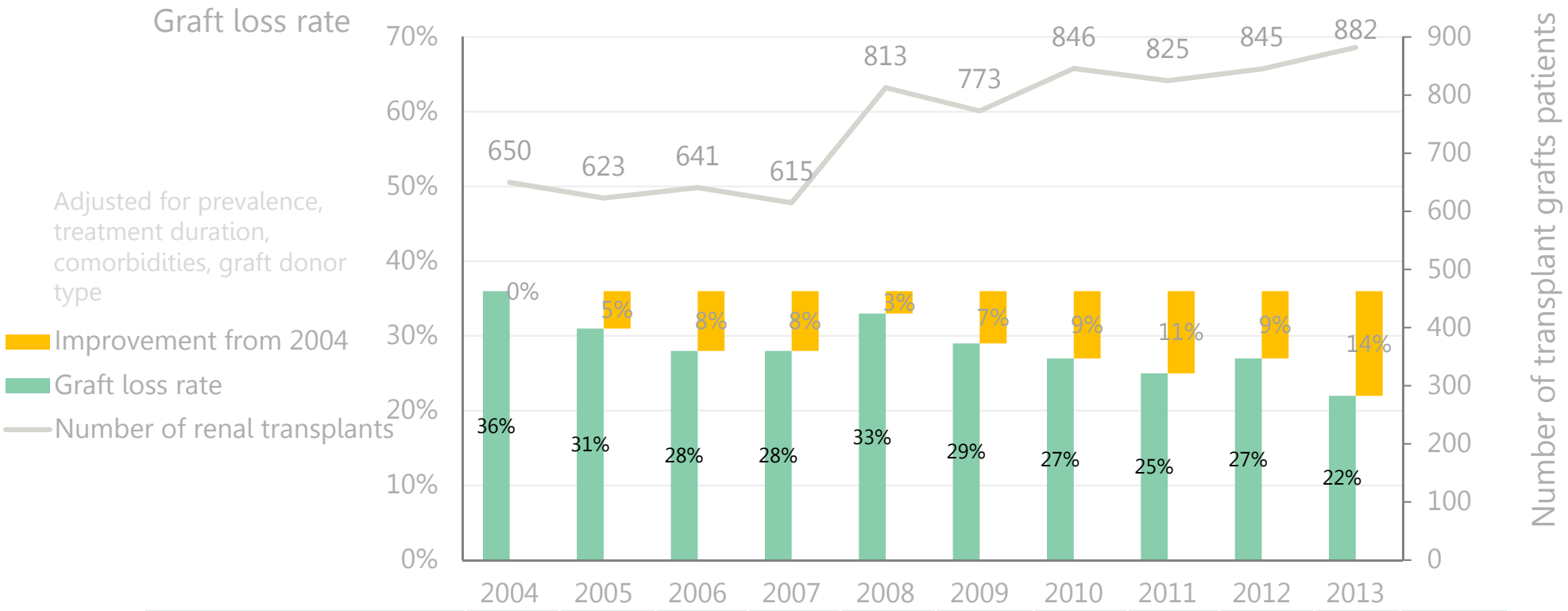
Benefits attributed to the registry of $16m after discounting

Year	Number avoided (2004 rate)	Patients in feedback access group		Attributed reduction in mortality*		Unit $ value	Economic benefit before discounting	Economic benefit
		%	Number	%	Number			
2011	187	69%	**129**	35%	**45**	$101k	**$4.6m**	**$3.7m**
2012	316	58%	**183**	73%	**133**	$101k	**$13.4m**	**$11m**
2013	267	35%	**93**	19%	**18**	$101k	**$1.8m**	**$1.3m**
Total	**770**	**405**		**196**		**$101k**	**$19.8m**	**$16m**

Columns may not sum exactly due to rounding.

Source: Registry data. Howard, K., McDonald, S., et. al. University of Sydney: The cost effectiveness of increasing kidney transplantation and home-based dialysis – Journal Of Nephrology 2009. *(incremental improvement in log in group) 2014 dollar values. Discounted by 3%

2 Observed improvement in graft loss rate is equivalent to 606 fewer grafts lost between 2004 and 2013



Relative improvement vs 2004 baseline		14%	22%	22%	8%	19%	25%	31%	25%	39%	**Total**
Expected losses at 2004 rate	212	221	231	247	257	288	280	322	336	358	212
Avoided graft losses		31	51	55	22	56	70	99	84	139	**606**
Attributed avoided losses	-	-	-	-	-	-	-	49	0	27	76

Source: Registry data. Columns may not sum due to rounding. Actual graft loss may not sum with loss rate and number of grafts due to adjustment for graft years, diagnosis year, loss year. Data is presented as received from the registry.

2

Evaluation of economic impact of avoided graft loss

For an individual eligible patient

Outcome 1 less transplant graft loss		Change points	Years saved	Unit used	Value of avoided graft loss
Graft loss	Graft losses leading to switch to dialysis		4.5	$80k/year	$358k
	Initial dialysis access		-	$9000	$9k
	Incremental improvement to Quality of Life	0.546	4.5	$182k*	$425k
Additional costs	Ongoing graft care	-	11	-$14,254**	-$157k
Total value					**$635k**

Avoiding 1 graft loss

…is predicted save 2 QALYs

$425,000

+

…and 4.5 years of dialysis

$358,000

-

With additional ongoing graft care costs

$-157,000

Columns may not sum exactly due to rounding and/or discounting.

Source: Registry data. Qualitative interviews and Howard, K., McDonald, S., et. al. University of Sydney: The cost effectiveness of increasing kidney transplantation and home-based dialysis – Journal Of Nephrology 2009.

2 Evaluation of economic impact of avoided graft loss

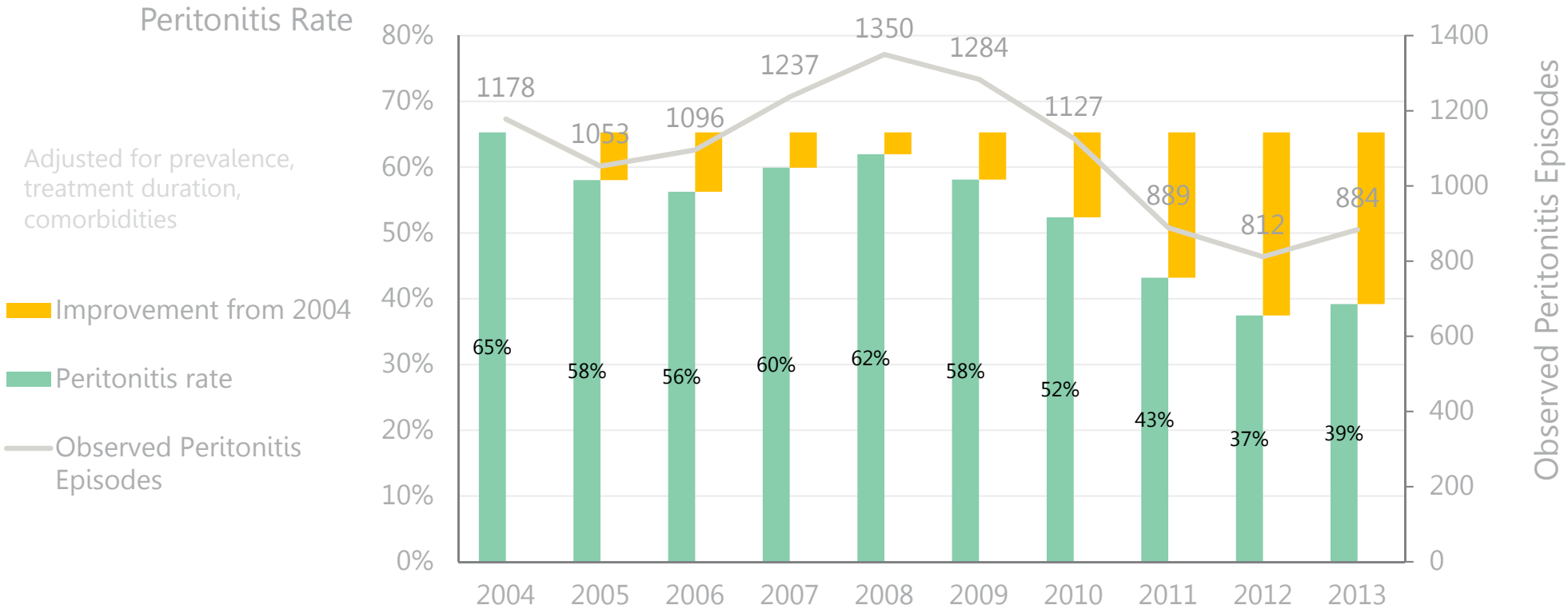
Benefits attributed to the registry of $39m after discounting

Year	Number avoided (2004 rate)	Patients in Feedback Access Group		Attributed reduction in graft losses*		Unit $ Value	Economic benefit	Economic benefit
		%	Number	%	Number			
2011	99	52%	**51**	96%	**49**	$635k	**$31m**	**$26m**
2012**	84	-	-	-	-	$635k	-	-
2013	139	34%	**48**	57%	**27**	$635k	**$17m**	**$13m**
Total	**322**	**99**		**76**		**$635k**	**$48m**	**$39m**

Columns may not sum exactly due to rounding.

Source: Registry data. Howard, K., McDonald, S., et. al. University of Sydney: The cost effectiveness of increasing kidney transplantation and home-based dialysis – Journal Of Nephrology 2009. *(incremental improvement in log in group). ** no difference noted between case and control group. Likely due to number of missing and incomplete data fields in this year observed during the analysis. 2014 dollar values used throughout. Discounted by 3%

3 Observed improvement in peritonitis incidence rate is equivalent to 2573 fewer cases of peritonitis



Relative improvement vs 2004 baseline		11%	14%	8%	5%	11%	20%	34%	43%	40%	**Total**
Expected losses at 2004 rate	1178	1185	1272	1348	1422	1443	1405	1344	1415	1472	13,483
Avoided peritonitis episodes	0	132	176	111	72	159	278	455	603	588	**2,573**
Attributed avoided admissions	-	-	-	-	-	-	-	56	103	148	307

Source: Registry data. Columns may not sum due to rounding. Actual graft loss may not sum with loss rate and number of grafts due to adjustment for graft years, diagnosis year, loss year. Data is presented as received from the registry.

3 Evaluation of economic impact of reduced peritonitis incidence

For an individual eligible patient

Outcome 1 less episode of peritonitis		Change points	Unit used	Value of Avoided Peritonitis Episode
In-patient admission	Proportion of incident cases	0.69		
	Incremental improvement to quality of life	0.053	$182,000	$9,646
Treatment costs	Average inpatient costs	-	$4,648*	$5,074
	Average follow up costs		$426	
Total value				**$14,720**

Avoiding 1 peritonitis hospital admission

…is predicted benefit QALYs

$9,646

…and treatment costs

$5,074

***Columns may not sum exactly due to rounding and/or discounting**.

Source: Registry data. Qualitative interviews and Howard, K., McDonald, S., et. al. University of Sydney: The cost effectiveness of increasing kidney transplantation and home-based dialysis – Journal Of Nephrology 2009. *Independent Hospital Pricing Authority Australian Refined Diagnosis Related Group (AR-DRG) T61B Acute infection

3 Evaluation of economic impact of reduced peritonitis incidence

Benefits attributed to the registry of $3.5m after discounting

Year	Number avoided (2004 rate)		Patients in feedback access group		Attributed reduction in peritonitis*		Unit $ Value	Economic benefit before discounting	Economic benefit
	Total	In-patient	%	Number	%	Number			
2011	455	314	49%	**152**	37%	**56**	$14,720	**$0.8m**	**$0.6m**
2012	603	416	47%	**197**	53%	**103**	$14,720	**$1.5m**	**$1.2m**
2013	588	406	49%	**200**	74%%	**148**	$14,720	**$2m**	**$1.7m**
Total	**1646**	**1136**		**549**		**307**	**$14,720**	**$4.5m**	**$3.5m**

Columns may not sum exactly due to rounding.

Source: Registry data. Howard, K., McDonald, S., et. al. University of Sydney: The cost effectiveness of increasing kidney transplantation and home-based dialysis – Journal Of Nephrology 2009. *(incremental improvement in log in group). 2014 dollar values used throughout. Discounted by 3% per annum

Costs – Total costs from 2004 to 2013 totalled $8.8m after discounting at 3% per annum

Cost heading	Responsible for cost	2009	2010	2011	2012	2013	Total 04-13
Development and maintenance	**Not possible to break down**						
		$1m	$1m	$1m	$1m	$1m	**$10m**

Costs – Taken as an average of $1 million per annum before discounting

- Central infrastructure costs (IT, data entry, management and analysis) support not just the ANZDATA registry, but also the organ donor registry and living kidney donor registry. The costs of the central infrastructure are largely met by the Australian organ and tissue donation and transplantation authority, with contributions from the New Zealand Ministry of Health and Kidney Health Australia and the Australia New Zealand Society of Nephrology. There are also important. “in kind" contribution from South Australia Department of Health (who provide the office facilities, and some staff time for medical support.)

- Peripheral data collection is performed by the individual renal units. Key events (e.g. dialysis start, transplants, death) are notified during the year when they occur. The costs for this are born by the individual renal units.

Control & attribution of benefits to the presence of the registry

- **By comparing units that access registry feedback resources with those that do not.**

Estimated annual costs before discounting of $1 million

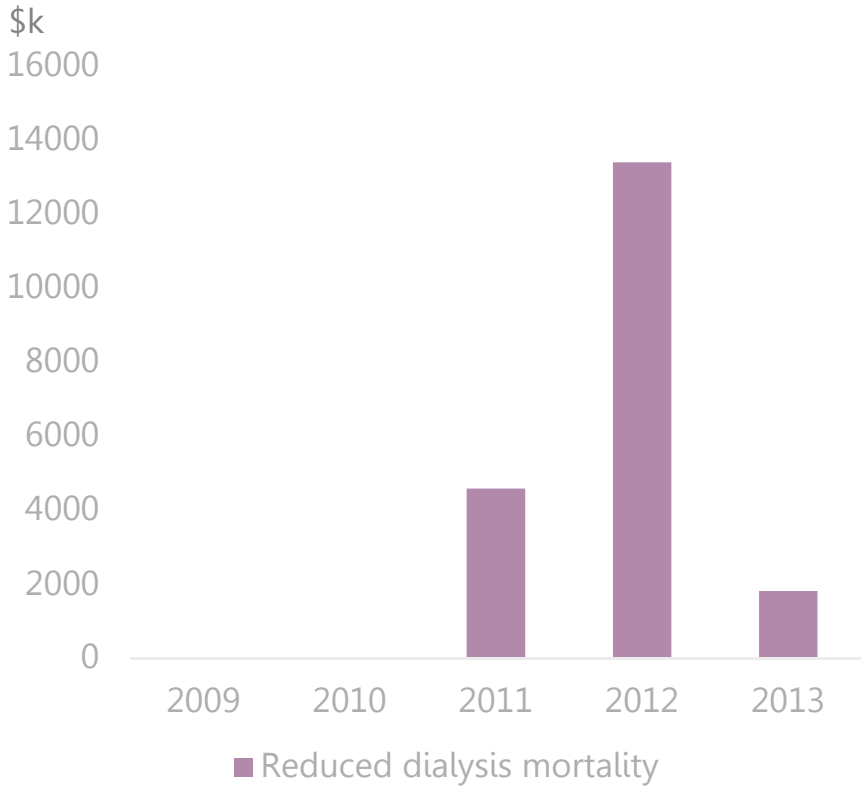
Source: ANZDATA registry data – (interview)

1a

Summary of benefits from reduction in dialysis mortality

Attributed benefits before discounting of $20m to hospitals accessing feedback

Total benefit of $20m in the period 2009-13



Sensitivity analysis

Variable	Value		Source	2009-13 Benefit		
	Range of unit	Base		Change impact	Base	%
Value of a life year	$50,000 to $182,000	$182,000	OBPR	-$47m to $20m*	$20m	-

Reducing the unit used for a life year is not applicable in the ANZDATA analysis due to high economic cost of dialysis

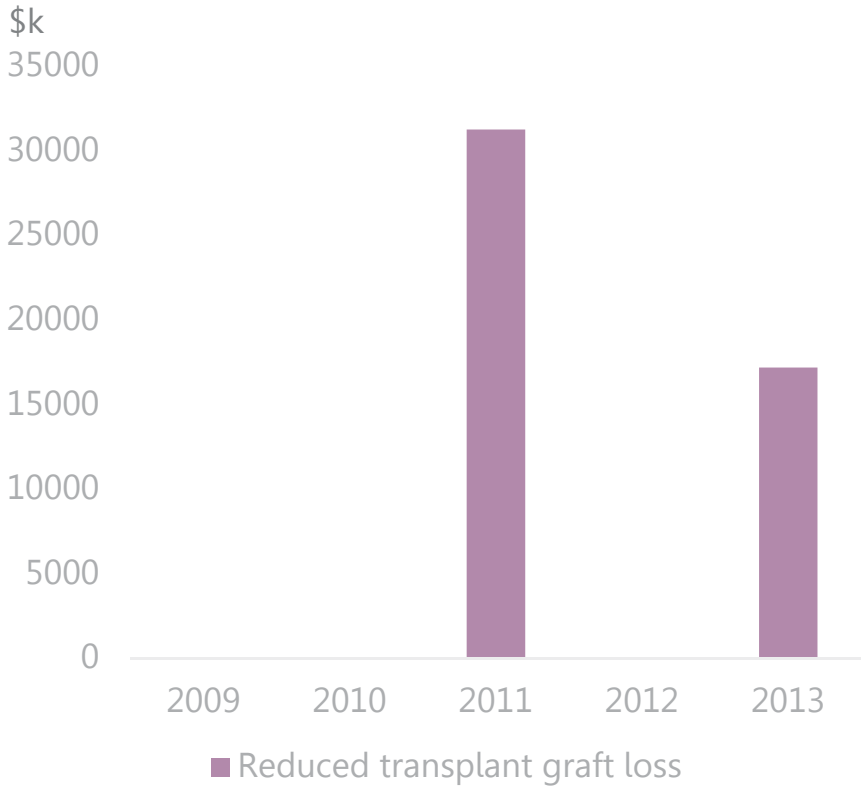
Source: Health Outcomes Australia Analysis; * Reducing the value of a quality adjusted lifeyear to a lower unit value undermines the analysis due to the high economic costs associated with renal dialysis. Preservation of life is deemed to be ultimately more valuable to the healthcare system and broader society. Accordingly the VSLY value is retained with the lower confidence interval utilised from the disease weight impairment.

2

Summary of benefits from reduction in transplant graft losses

Attributed benefits before discounting of $48m to hospitals accessing feedback

Total benefit of $48m in the period 2009-13



Sensitivity analysis

Variable	Value		Source	2009-13 Benefit		
	Range of unit	Base		Change impact	Base	%
Value of a life year QALY benefit	$50,000 to $182,000	$182,000	OBPR	$9m to $32m (minimum total benefit $25)	$32m	-72
Graft losses leading to re-graft	0-5.1%	0%	Registry data	$46m-$48m	$48m	-4

Sensitivity range of reduced transplant graft loss is between $25m and $48m

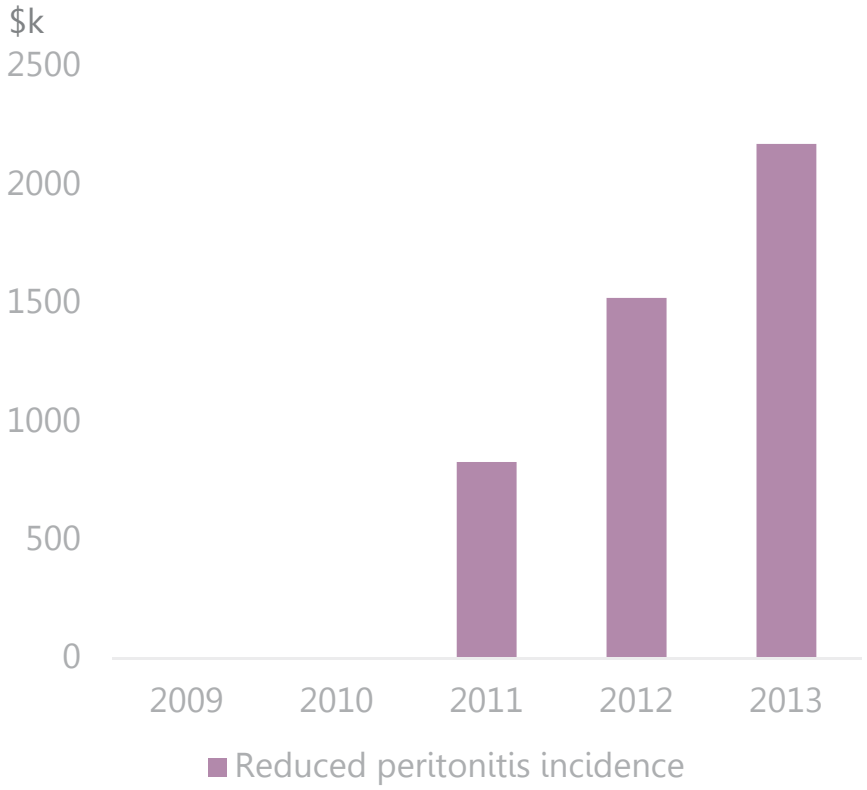
Source: Health Outcomes Australia analysis; ANZDATA registry data: The percentage of graft losses that lead to re-graft is 5.1% according to registry data analysis in the period 2004-2013 (Australia only). For the purpose of the sensitivity analysis, we assume the maximum (conservative) reduction to economic benefit that re-grafting could have. That is to say, we assume that a re-graft occurs immediately after initial graft loss, and therefore that the patient does not require interim dialysis and its assosicated cost.

3

Summary of benefits from reduction in peritonitis incidence

Attributed benefits before discounting of $4.5m to hospitals accessing feedback

Total benefit of $4.5m in the period 2009-13



Sensitivity analysis

Variable	Value		Source	2009-13 Benefit		
	Range of unit	Base		Change impact	Base	%
Value of a life year QALY benefit	$50,000 to $182,000	$182,000	OBPR	$0.8m to $3m (total benefit $2.4)	$32m	-72

Sensitivity range of reduced transplant graft loss is between $2.4m and $4.5m

Source: Health Outcomes Australia analysis; ANZDATA registry data. OBPR VSLY

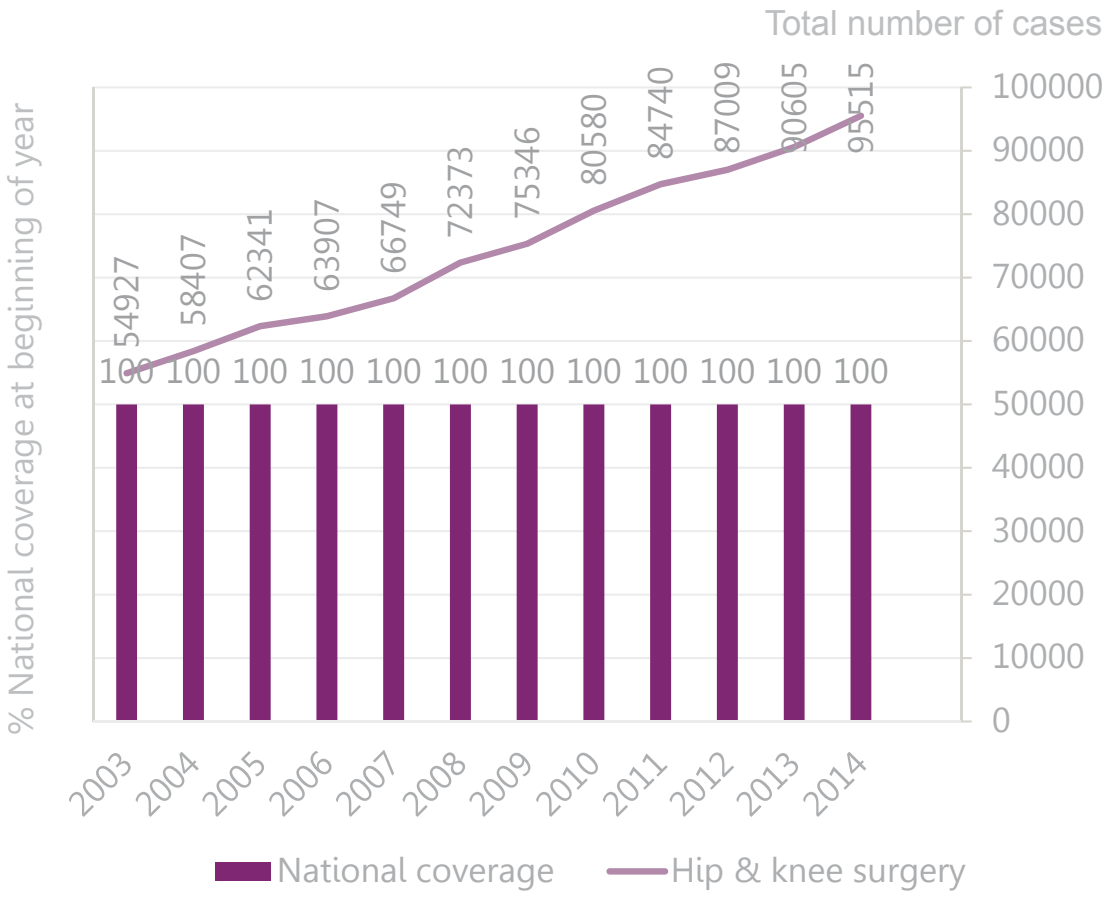
HEALTH OUTCOMES AUSTRALIA

Economic Value of CQRs

Case Study 5 – Australian Orthopaedic Association National Joint Replacement Registry

Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) Background – Summary

Established in 1999 with Australian Department of Health funding



Source Interview and AOANJRR 2015 Annual report

Full coverage achieved from 2002 following staged implementation across Australia

Patient coverage: Nationwide collection of all hip and knee replacement data from 2002 (full annual national data set thus from 2003)
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.

Background to the AOANJRR

The registry was established in 1999, to **define, improve and maintain the quality of care of individuals receiving joint replacement surgery.** It achieves this by collecting a defined minimum data set that enables outcomes to be determined on the basis of patient characteristics, prosthesis type and features, method of prosthesis fixation and surgical technique used.

- The registry was funded by the Australian Department of Health. Legislation was passed in 2009 enables the Department of Health to recover costs from the surgical prosthesis device industry to support financial sustainability.

- The AOANJRR came in to being as a result of the Australian Orthopaedic Association recognising in the early 1990s, the need for data collection on joint replacement and outcomes, (demographics of patients receiving joint replacement, surgical techniques used and types of prosthesis, survival of replacement) in a similar manner to what was already taking place in Sweden.

- Hip and knee replacement data collection started with 9 hospitals in South Australia, with staged implementation across states and territories occurring up to 2002. The first year of fully national data for hip and knee replacement is 2003. From November 2007 the registry also expanded to collection and analyses of full national data on shoulder, elbow, wrist, ankle and spinal disc replacement.

- The AOANJRR focusses on one key indicator **joint replacements that lead to a revision (including subsequent re-revisions).** This information is then used to inform surgeons, other health care professionals, governments, orthopaedic companies and the community. Associated data on outlying prostheses (particular prostheses that are associated with a disproportionately high rate of revision) and on patient mortality are also collected.

- There are around 300 hospitals providing data for 8000 joint replacement procedures per month. Currently more than 90,000 hip and knee replacements are undertaken each year in Australia. Osteoarthritis is the overwhelming primary cause in both.

Source AOANJRR Annual reports 2014 and 2015, Interview with registry stakeholders

Background to the AOANJRR

- Feedback occurs through publicly available annual and supplementary reports, journal publications. Individual surgeon data is also provided through an online facility for secure access. An additional resource is the provision of ad hoc reports (245 in 2014). Ad hoc reports are specific (usually detailed) analyses 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.**

- There are currently no comparable sources of information on outcomes of Australian procedures. Changes in outcomes are linked essentially to changes in practice relating to selection of prostheses. This is driven by individual surgeons, clinical units and hospitals. Data collection is voluntary, but there is a 100% eligible hospital compliance and a 98% capture rate.

Revision rate as the key indicator

The registry in practice focusses on one key indicator: rate of surgical revision. This is considered to be an unambiguous representation of the need for further intervention.

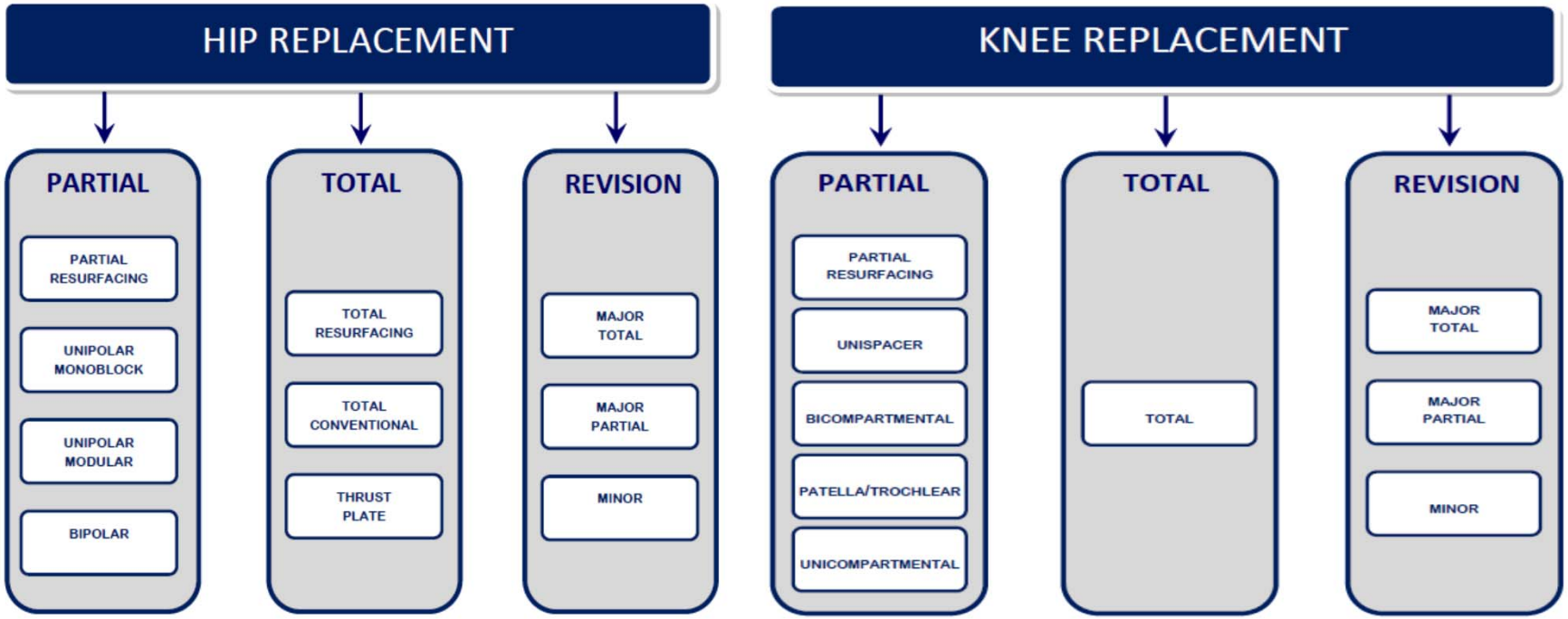
1. It is a key determinant of success of primary surgery, regardless of primary diagnosis, patient characteristics, method of fixation and surgical technique.
2. It is a key driver of additional costs and burden on patient quality of life
3. Provides a definitive, accurate, verifiable, comparable and accessible indicator metric that clinicians value
4. There is little discretion available for surgeons to "decide" whether a revision takes place. Typically this occurs only in 5% of cases where there is an absence of likely catastrophic consequences of conservative management.
5. However does not directly measure impact on PROMS, quality of life or revisions where an exchange is not required.

Source AOANJRR Annual report 2015 and interviews.

We focus on replacement of hip and knee joints due to the availability of a sufficiently longitudinal data set

Hip & knee replacement outcomes reporting commenced in 1999. Both can be partial, total or revision procedures

- There are over 100 different prostheses used for hip replacement and more than 50 different knee-replacement prostheses in Australia. There are also numerous combinations of prosthesis components used in joint replacement.
- Long-term survival rates for the vast majority of prostheses remain unknown. 10 year outcomes for hip and knee replacement procedures is reported through the registry.
- The registry reports on the performance of prostheses using cumulative percent revision tables. These effectively enable surgeons to determine when (how much time passes) before different prostheses types typically require revision, and how frequently this occurs. Rates of revision for specific prostheses are benchmarked against each other.



Source AOANJRR Annual report and AOANJRR Graves, S. Davidson D., MJA 2004; 180: S31–S34

Reduction in surgical revision burden is used as a measure of improvement in outcomes over time

Revision burden percentage

The registry defines revision of a joint replacement as any subsequent procedure that involves the insertion, removal and/or replacement of a prosthesis or implant. It can be major (total or partial) or minor.

The revision burden is the proportion of procedures undertaken each year that are revision operations.

What does this mean for patients?

Studies have shown that the outcomes of revision surgery are less favourable compared to successful primary joint replacement.

Patients require longer rehabilitation, are at higher risk of readmission and complication and experience impairment to quality of life in the period between primary and subsequent procedures. The most common underlying cause for revision is aseptic loosening.*

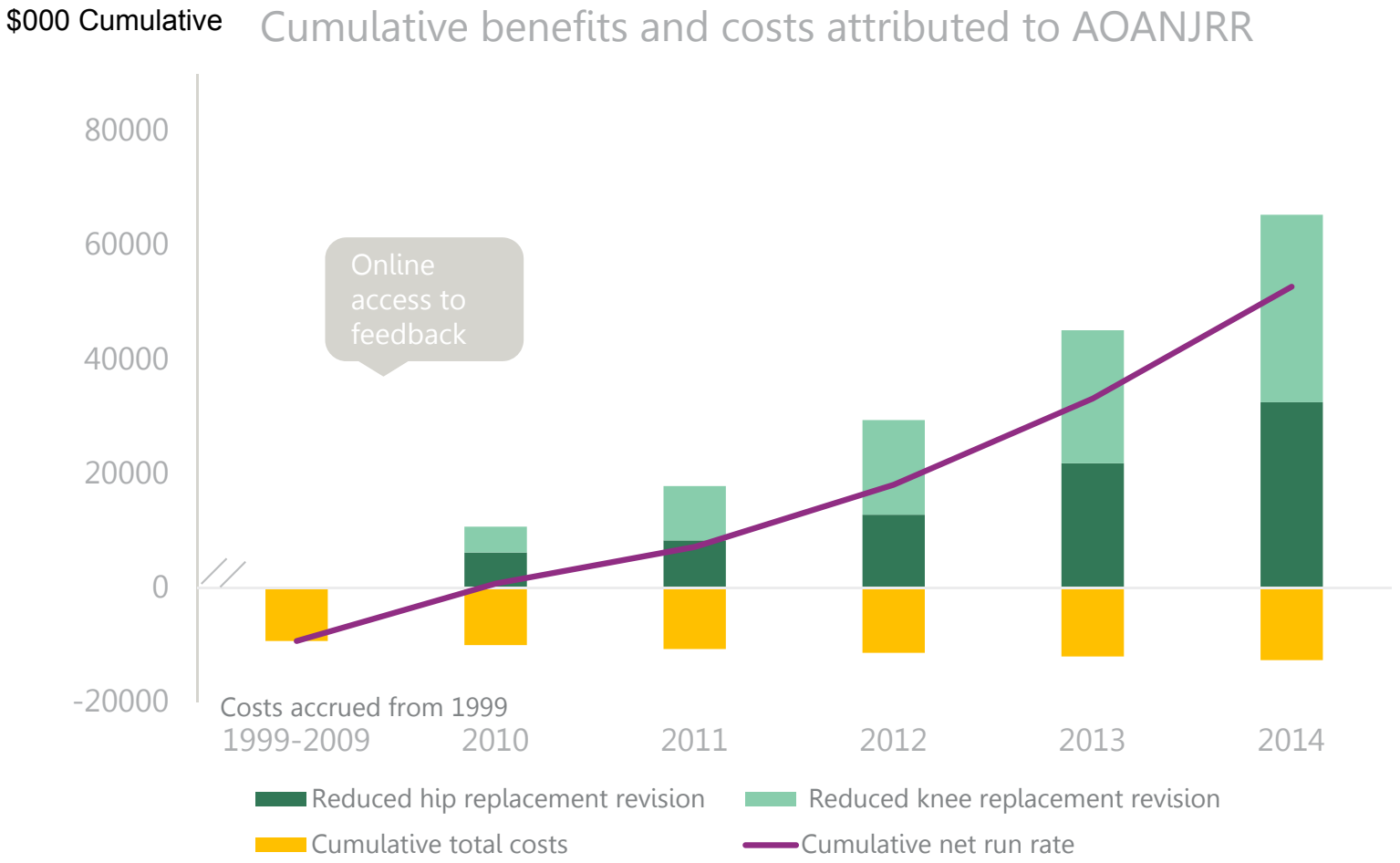
	Hip	Knee
Loosening/lysis	47.8%	37.5%
Infection	14.1%	21%

What is the expected impact?

- **Lower revision burden over time through improved prosthesis selection and identification of prosthesis with higher than expected revision rate.**
  - Reduction in treatment costs of secondary/subsequent treatment **($44,000/$39,000**) in AR-DRG costs for revision hip and knee respectively
  - Reduction of impact of secondary/subsequent treatment (Incremental QALYs)
    (Readmissions 5.4%)
    (Complications e.g. dislocation, wound infection 5.3%)
  - Incremental reduction of impact of requirement of secondary/subsequent treatment

Source: Health Outcomes Australia analysis, S Graves. ***Aseptic loosening occurs as a result of a localised inflammatory reaction induced by the production of wear particles**. The inflammation results in peri-prosthetic bone loss, with consequent component loosening and pain. The extent of inflammation depends on the number and nature of the particles produced, which is related to the type of prosthesis and its positioning, as well as extent of use and time since implantation. The occurrence of other reasons for revision, including recurrent dislocation, fracture, infection, ongoing pain of uncertain aetiology and component breakage, are also known to vary with the type of prosthesis.

AOANJRR shows a net overall benefit of almost $53 million based on access to feedback of individual surgeon level outcomes data



Net return attributed

Internal rate of return 25%

Total benefits
$65m

Total costs (from 1999)
$13m

Year	Benefit to cost ratio
1999-2014	5:1

Note: Discounted by 3% p.a.; Figures in 2014 dollars, VSLY unit calculated per year
Source Health Outcomes analysis. OBPR protocol

Overview of benefits from AOANJRR

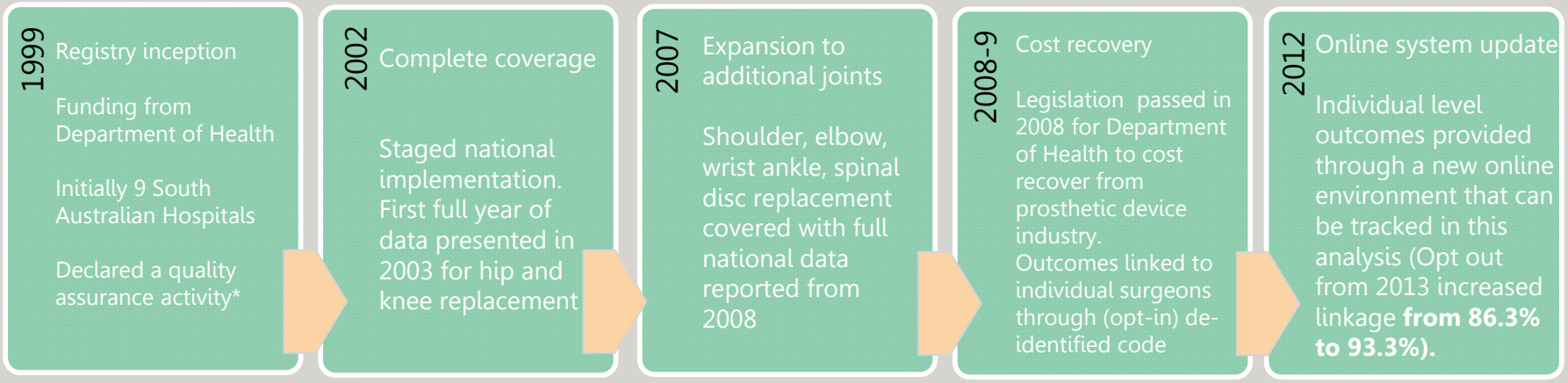
	Indicator of changed clinical practice	Control(s)	Patient outcome measure	Conversion to economic value
1a	Identification and reduction in use of prosthesis with poor performance*	Comparison within the registry itself. Surgeons that have logged in to view their individual feedback/surgical outcomes compared to those that have not.	**Reduction in revision rate**	Average cost of revision Incremental difference in QALY
1b	Reduction in revision rate		Quality of life, avoided secondary surgery	Average cost of revision Incremental difference in QALY
	Reduction in mortality (through linked data)		Years of life preserved	QALYs preserved

Indicators for evaluation

Measured by the registry directly

*The registry lists individual prostheses that have been identified as having two or more times the rate of revision when compared to all other prostheses that are similar in design. This difference also has to be significant (likely to be true). These are reported as "Prostheses with a higher than anticipated rate of revision".

Timeline of significant events within the AOANJRR and broader joint replacement context



Changes in guidelines and best practices should affect individual surgeons evenly. Where this isn't true is in instanced where hospitals have changed policy and have mandated specific prostheses for selection or non-selection. This is as a result of registry feedback and is thus captured in the broader analysis.

2003 – The registry identifies higher failure rates in unicompartmental knee arthroplasty procedures
2005 – The registry identifies that hip resurfacing arthroplasty has a high rate of revision in females
2007/8 – Peak utilisation of metal on metal type prosthesis.
2010 – Large head metal on metal type prosthesis recalled from the market

Source: Health Outcomes Analysis, Qualitative Interviews. Registry Annual report and interviews *The AOANJRR was initially declared a Federal Quality Assurance Activity in March 1999 (part of the Health Insurance act 1973). This was renewed in 2011, 2006 and for a further five years in August 2011. This declaration ensures freedom from subpoena and absolute confidentiality of information held by the Registry. Declaration under this legislation prohibits the disclosure of information which identifies individual patients or health care providers. The protection assures surgeons, hospitals and government that information supplied to the Registry remains confidential and secure and protects those engaging in good faith from civil liability in respect of those activities.

Registry feedback and reporting has changed clinical practice

Interviews identified some of the levers used by to improve practices following registry feedback

Changes in outcomes occur through changes implemented at 3 levels; the individual clinician, the hospital, and jurisdiction (national/international).

Individual clinician level

- Changes implemented at the individual clinician level are around 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. Two examples, of many mentioned, specific prostheses selection decisions informed by registry feedback are presented in the next slide.

Hospital level

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

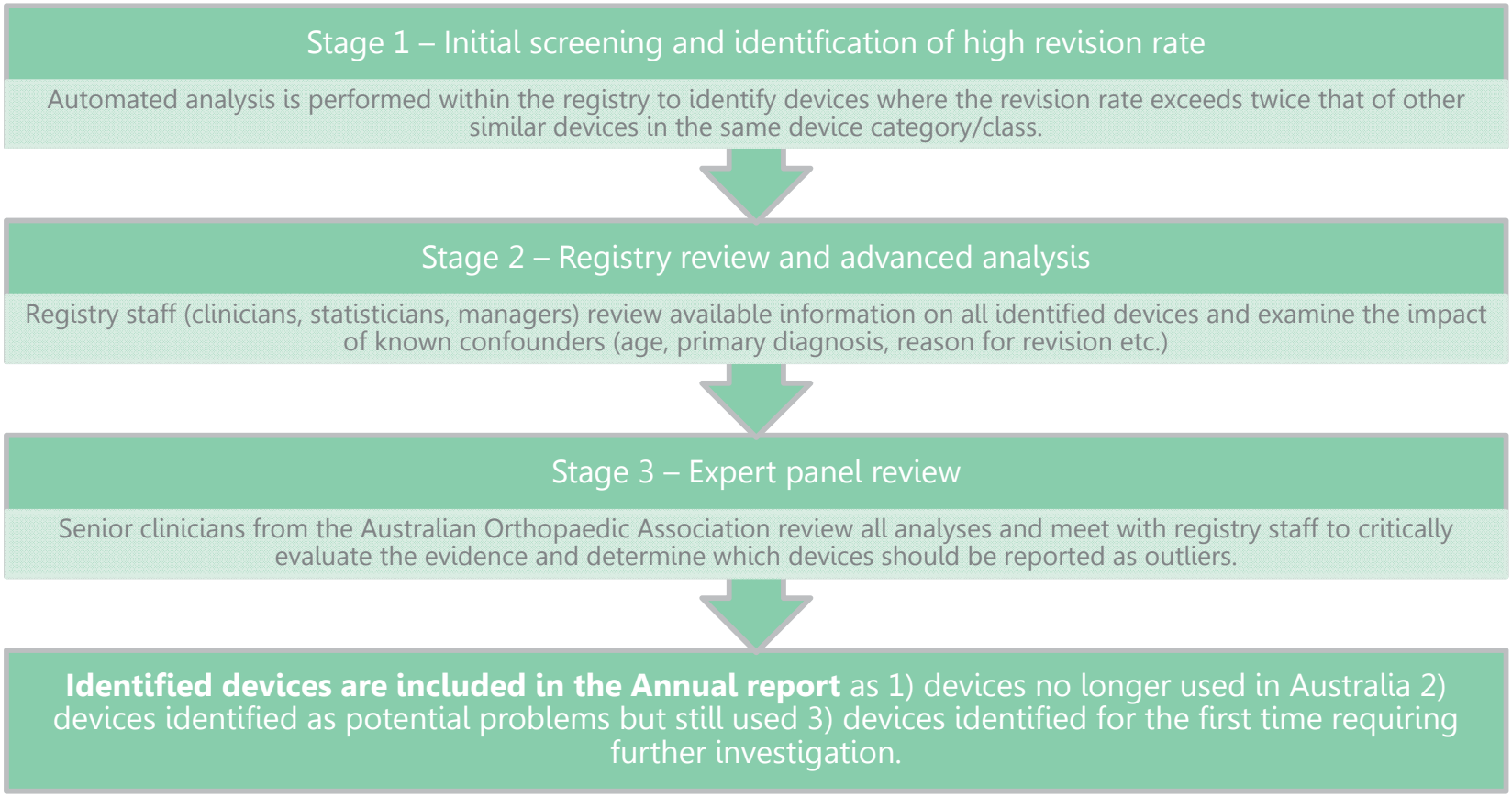
National level

- Identification (early) 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.
- Prostheses that are demonstrated to evidence "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 registry is considered to be high; participation is a quality activity, familiarisation and usage is integrated in to surgical training and continuous professional development. 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 individual surgeon performing primary procedure as of 2015 due to a low opt-out rate. Changes have recently been recommended to preclude the provision of continuing professional development recognition to surgeons who do not participate with the registry (log in and discuss outcomes with 2 colleagues).

Source Health Outcomes Australia Analysis, qualitative Interview

1a The AOANJRR Identifies device outliers to inform licensing and selection through a three staged approach



Between 2004-2011 the AOANJRR identified 78 prostheses of prosthesis combinations using this three staged approach. These included 42 conventional and 6 resurfacing hip prostheses and also 5 unicompartmental and 25 total knee prostheses

Once a prosthesis or prosthesis combination has been identified as an outlier, it generally continues to be identified in subsequent years.

All identified devices are investigated by the Therapeutic Goods Administration (TGA)

Source: Health Outcomes Analysis, qualitative interviews, AOANJRR report by Academy Health, de Steiger, R (2013). Joint registry approach for identification of outlier prostheses ACTA Orthopaedica 84 (4) 348-352

Device performance is reported to the TGA to inform policy, regulate the prosthesis device market and ensure public safety

The TGA is part of the Australian Department of Health and is responsible for regulating therapeutic goods including prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products.

- Medical devices are classified by the TGA according to the degree of risk involved in their use.
- In support of the TGA's post-market monitoring activities, the manufacturer of a medical device has ongoing responsibilities to report individual adverse incidents but individual clinicians/patients are not under the same obligation.
- AOANJRR coordinates with the TGA to evaluate the effectiveness of those procedures including the post-market performance of the associated devices, and to ensure that the health outcomes of all patients in receipt of these devices can be clinically assessed. The registry contributes information that might lead to a decision to recall a device.
- Following a TGA risk assessment and further investigation if required, subsequent action may include product recovery (recalls); issuing of hazard and safety alerts; product modification/ improvement by a manufacturer; and/or surveillance audits of manufacturing sites.
- The TGA can take regulatory action to suspend or cancel a device from the Australian Register of Therapeutic Goods where the safety or performance of the device is "unacceptable". The majority of recalls are undertaken voluntary by manufacturers, in cooperation with the TGA for practical and legal reasons.
- In voluntary recalls, the TGA expects that manufacturers will act in accordance with the Uniform Recall Procedure for Therapeutic Goods (URPTG). In mandatory recalls (that is, where the powers under the *Therapeutic Goods Act 1989* are used), the TGA will usually require sponsors to comply with particular parts of the URPTG.

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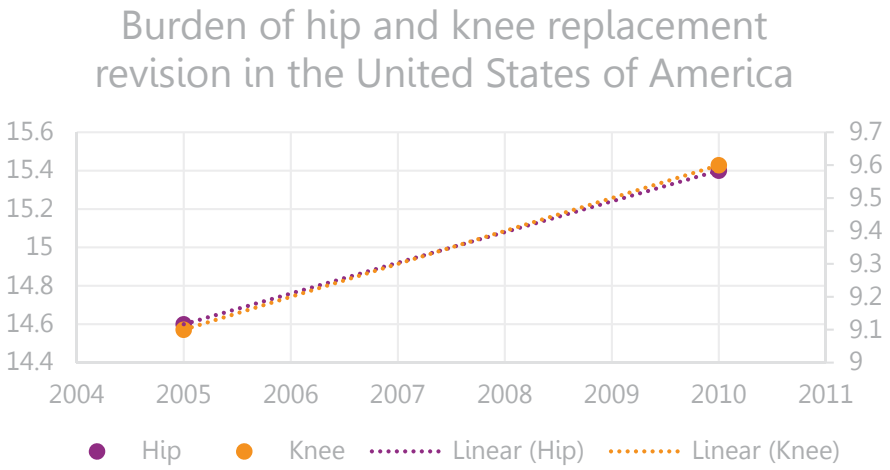
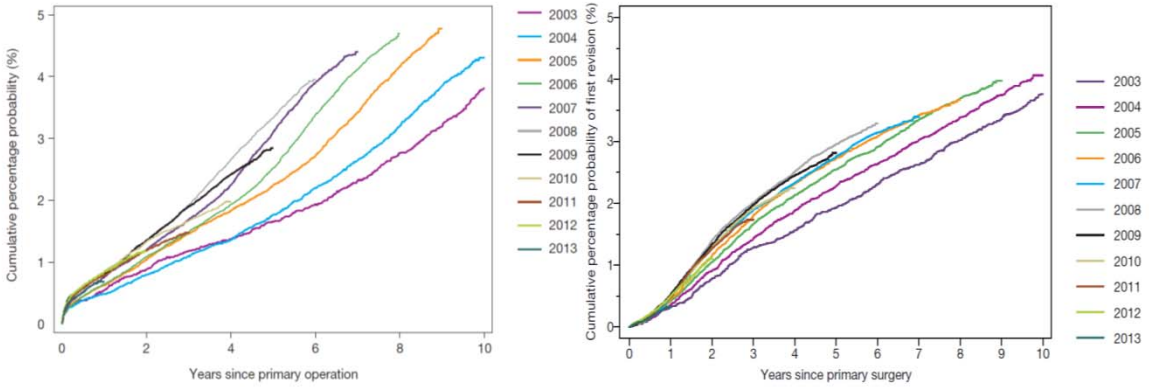
Source: Health Outcomes Australia Analysis, Qualitative Interviews with registry stakeholders and Australian Government Department of Health and Ageing Regulation Impact Statement: Clinical Registers for high risk implantable medical devices.25.09.2012 Further information available on URPTG: http://www.tga.gov.au/industry/recalls-urptg.htm.

Risk of revision in hip and knee arthroplasty has increased in the USA and UK

USA and UK revision rates for hip and knee arthroplasty have increased from 2003 to 2014





UK: Temporal changes in revision rates after primary hip replacement

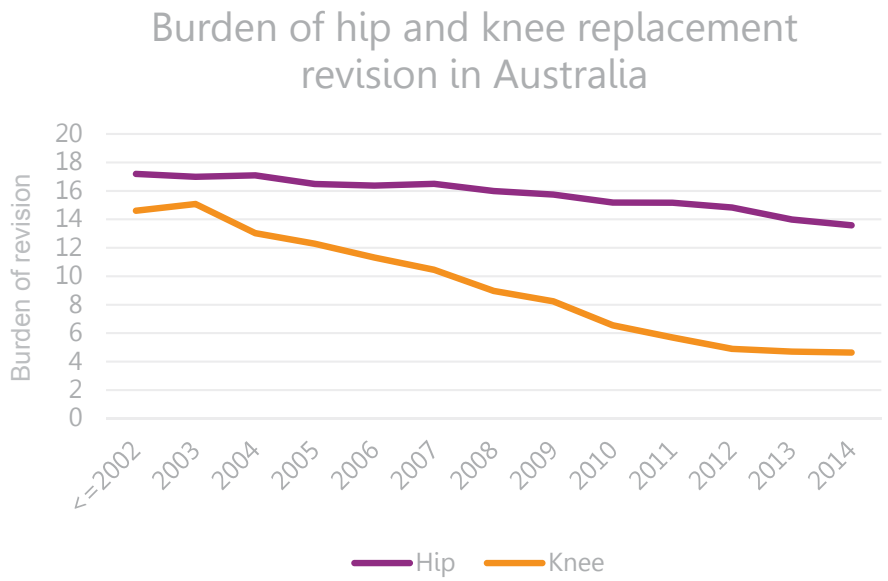
UK: Temporal changes in revision rates after primary knee replacement

- 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 (UK), cumulative percent revision for hip arthroplasty has increased each year from 2003 to 2009 in the first four years after primary joint replacement. Data 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.

Source: Bozic K. J., (2015) and NJR for England, Wales, Northern Ireland, and Isle of Man 2015. UK rates are cumulative percent probability of revision for each year

In the same period the revision rate has decreased in Australia

The overall reduction in revisions of hip and knee arthroplasties is equivalent to a benefit of **$618 million** from 2003 to 2014



If the full reduction in revision burden between 2002 to 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.**

Source: Registry data and Health Outcomes Australia analysis

Benefits are attributed by comparing surgeons that log in to view their individual outcomes feedback compared to those that do not

Registry feedback

Annual published report
- Hip and Knee and lay summary
- Supplementary reports
- Revision report and outlier prostheses reporting

Real time online reporting
- Individual surgeon outcomes
- Individual prostheses outcomes (Revision rates and demographics)

Ad hoc analyses and presentations
- Available since 1999
- In depth analyses
- Upon request by surgeons, hospitals, jurisdiction, regulator, researchers etc.

Feedback provided through the online system from 2009. Opt out linkage from 2009. IT system updated in 2012, and log ins from this period can be tracked in anonymous form.

Case and control

Surgeons that have logged in to view registry feedback (individual surgeon data) from **2010-2014.** This is the first full year from when surgeons were provided with an online password, until most recent available outcomes data.

Assume comparable information is not available through alternative sources.

Assume log in access consistent in the years where frequency of access cannot be verified due to usage of a legacy system (2010-11)

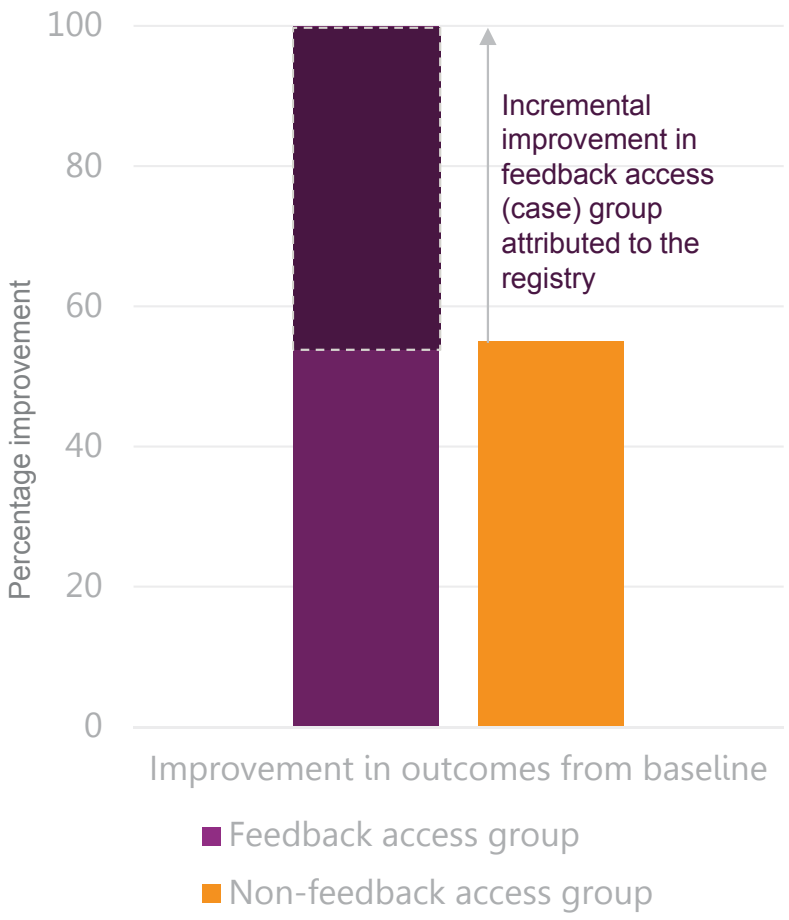
Assume hazard ratios (HR) are same for subsequent revisions as first revisions

Case – surgeons that access their individual outcomes

Control – Surgeons that do not

Only the additional improvement in outcomes relating to the proportion of cases associated with the surgeons in the case group will be attributed

Attribution of benefit



Source: Health Outcomes Australia Analysis. HR of survival to an event (revision) at a given time were compared between groups. For our analysis this point in time is as early as statistically significant in hip replacement revision to overcome the short time frame of data compared to expected prosthesis survival. Time to first revision is the outcome for comparison due to the short time period in the two time comparison groups (4 years). This is required by virtue of cumulative percent revision being the statistic of choice as this measure attributes revisions to the surgeon undertaking the first joint replacement. In this way we do not get an overlap of procedures in the two groups but have to overcome the right bias the cumulative percent revision measure produces due to longer expected prostheses overall (through better selection) and greater individual prosthesis revision probability over time.

Reduction in burden of revision in hip and knee arthroplasty is greatest in surgeons who access their individual outcomes data

HIP replacement: HR revisions 2005-2009 compared to 2010-2014

Log in group	Improvement
Compared to non log-in	+25%
Proportion of cases	61%

Knee replacement: HR revisions 2005-2009 compared to 2010-2014

Log in group	Improvement
Compared to non log-in	+48%
Proportion of cases	60%

We compared risk of revision in two time periods, 2005-2009 (before individual feedback) compared to 2010-2014 (after individual feedback become available). The improvement in outcomes between the two period was compared between the surgeons who logged in to view their individual feedback versus those who did not.

Log in group – surgeons who log in to view their individual outcomes data or request this through ad-hoc reports

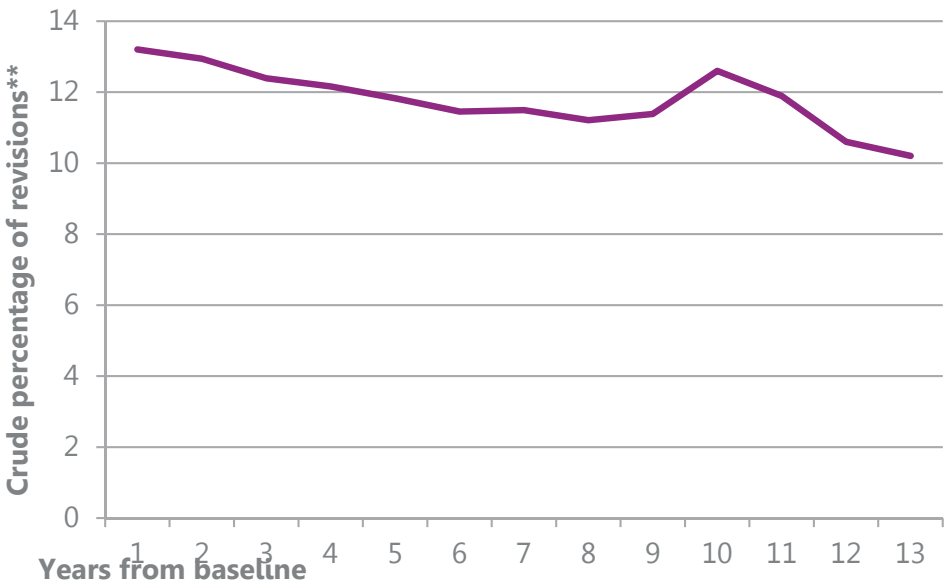
Non log group – surgeons who have never logged in to view their individual outcomes data or request this through ad-hoc reports

Source: Health Outcomes Australia Analysis. Registry analyses and data. For hip replacement revisions the HR at 1-3months is compared between surgeon groups. For knee replacement the HR at 1.5years is used as a relatively conservative estimate of difference between the two groups.

1b Reduction in revision rate

AOANJRR shows a 23% reduction in burden of revision in hip replacement from baseline* to most recent data (2014)

Overall reduction for hip replacement revision burden from 13.2% to 10.2%



Equivalent to 6500 avoided revisions over the 12 year period

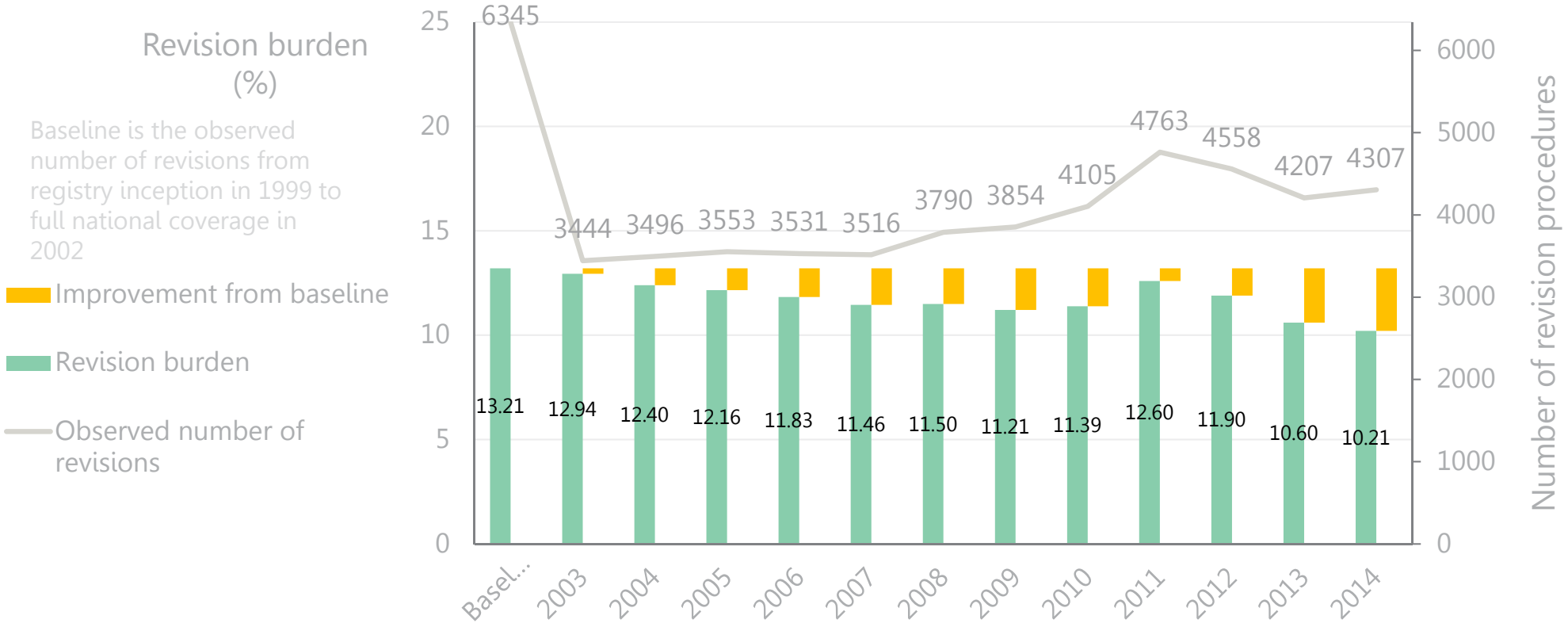
Through reduction in percentage of hip replacements that were revision procedures

Notes:

- Revisions for Osteoarthritis as primary diagnosis (88.9%)
- Includes all causes of revision
- Not adjusted for patient level factors which are thought not to have changed demonstrably over time. Any changes are partly attributed to registry data (i.e. selection of prosthesis based on age and gender).
- Includes re-revisions
- Revisions are attributed to the surgeon code that carried out the original surgery. This corrects for any revisions that are carried out by a different surgeon for the purpose of the case/control attribution analysis.

Source: Health Outcomes Australia Analysis. Registry analyses and data. * Baseline is the percentage of joint replacements that are revision procedures from registry inception in 1999 to full national coverage in 2003. The rationale for including this period is that state level data on prosthesis performance influenced national decisions on prosthesis selection. **Proportion of joint replacement surgeries that are a revision. Revisions are attributed to the surgeon (de-identified code) that performed the original replacement.

Observed improvement in revision burden in hip replacement is equivalent to almost 6500 fewer revision procedures in 12 years



vs <=2002 baseline		-0.26	-0.81	-1.04	-1.38	-1.75	-1.71	-1.99	-1.82	-0.61	-1.31	-2.60	-3.00	**Total**
Avoided revision episodes	-	70	229	305	411	538	564	686	655	230	501	1033	1266	**6486**
Attributed avoided revision episodes	-	-	-	-	-	-	-	-	112	39	86	177	216	**629**

Source: Registry data. Columns may not sum due to rounding.

Economic impact of reduced revision burden in hip replacement

For an individual eligible patient

Outcome 1 less revision procedure			Change points		Unit used	Value of avoided hip revision
Treatment costs	Cost of revision surgery (and in hospital rehabilitation)		Major	84%	$46,875	$43,687
			Minor	16%	$26,946	
	Cost of complications	Readmission	10%		$5,007	$906
		Dislocation	8.4%		$8,276	
		Pulmonary embolism/deep vein thrombosis admission	0.8%		$6,573	
Quality of life adjustment	Incremental quality of life outcomes revision surgery		0.12		182,000	$25,969
Total value						**$70,562**

Avoiding 1 revision surgery …..avoided treatment costs …and predicted benefit to QALYs

+ $44,396 +

$25,969

***Columns may not sum exactly due to rounding and/or VSLY discounting**.

Source: Registry data. Phillips C. B.,Rates and Outcomes of Primary and Revision Total Hip Replacement in the United States Medicare Population, *J Bone Joint Surg Am*, 2003 Jan; 85 (1): 27 -32 . http://dx.doi.org/, AR-DRG values used for costs of revision surgery. Readmission based on 1 National Efficient Price (NEP) National Weighted Activity Unit (NWAU) 2015, complications data sourced from Mahomed, N. (2003), Rates and outcomes of primary and revision total hip replacement in the united states medicare population, JBJS. Surgery image sourced from http://ww1.prweb.com/prfiles/2010/06/23/457774/UHCsymbol8.jpg. Disease utility value from Bozic et. al. 2011 referenced in main report document.

$33 million benefit from reduction in revision burden in hip revision procedures attributed to log in group from 2010 to 2014

Year	Revisions avoided	Incremental improvement in case group	Proportion procedures in case group	Attributed revisions avoided*	Total benefit before discounting	Treatment costs avoided	Quality of life benefit	Total benefit
Baseline	0					Discounted at 3% p.a.	Discounted at 3% p.a.	Discounted at 3% p.a.
2003	70							
2004	229							
2005	305							
2006	411							
2007	538							
2008	564							
2009	686							
2010	655	28%	61%	112	$7,890,492	$3,936,377	$2,292,449	$6,228,826
2011	230			39	$2,768,176	$1,340,754	$780,822	$2,121,576
2012	501			86	$6,042,659	$2,841,490	$1,654,814	$4,496,305
2013	1,033			177	$12,455,184	$5,686,317	$3,311,571	$8,997,889
2014	1,266			216	$15,253,255	$6,760,927	$3,937,398	$10,698,326
Total benefit	6486			629	$44,409,764	$20,565,867	$11,977,057	$32,542,924

Taken directly from the registry

Inferred from the registry

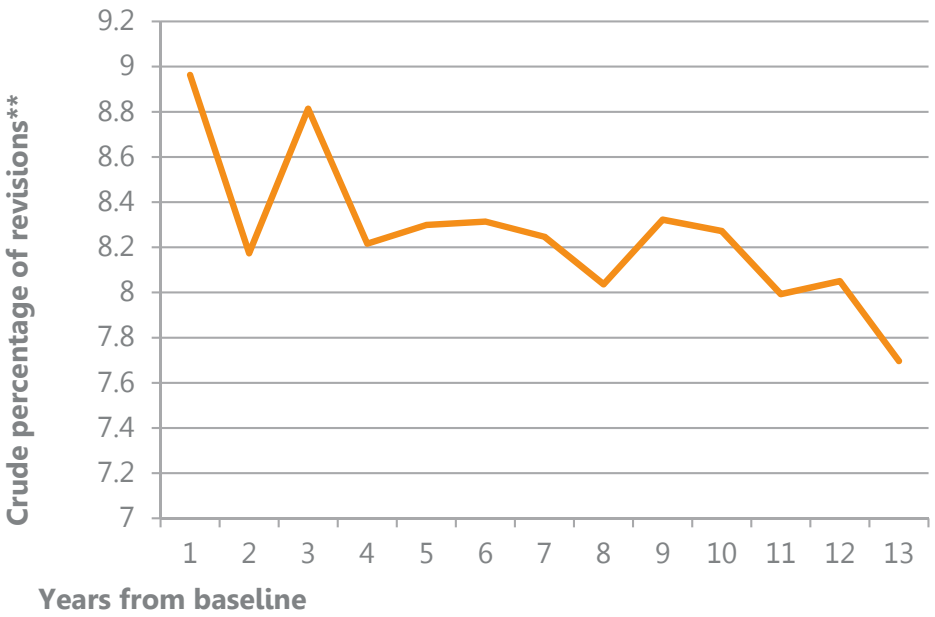
Inferred from published sources

Source: Health Outcomes Australia Analysis. Registry data. *attributed to surgeons who logged in to view their individual outcomes feedback. Discounted by 3% per annum. grp. – group. disc. - discounting

1b Reduction in revision rate

AOANJRR shows a 14% reduction in burden of revision in knee replacement from baseline* to most recent data (2014)

Overall reduction for knee replacement revision burden from 9% to 7.7%



Equivalent to 3900 avoided revisions over the 12 year period

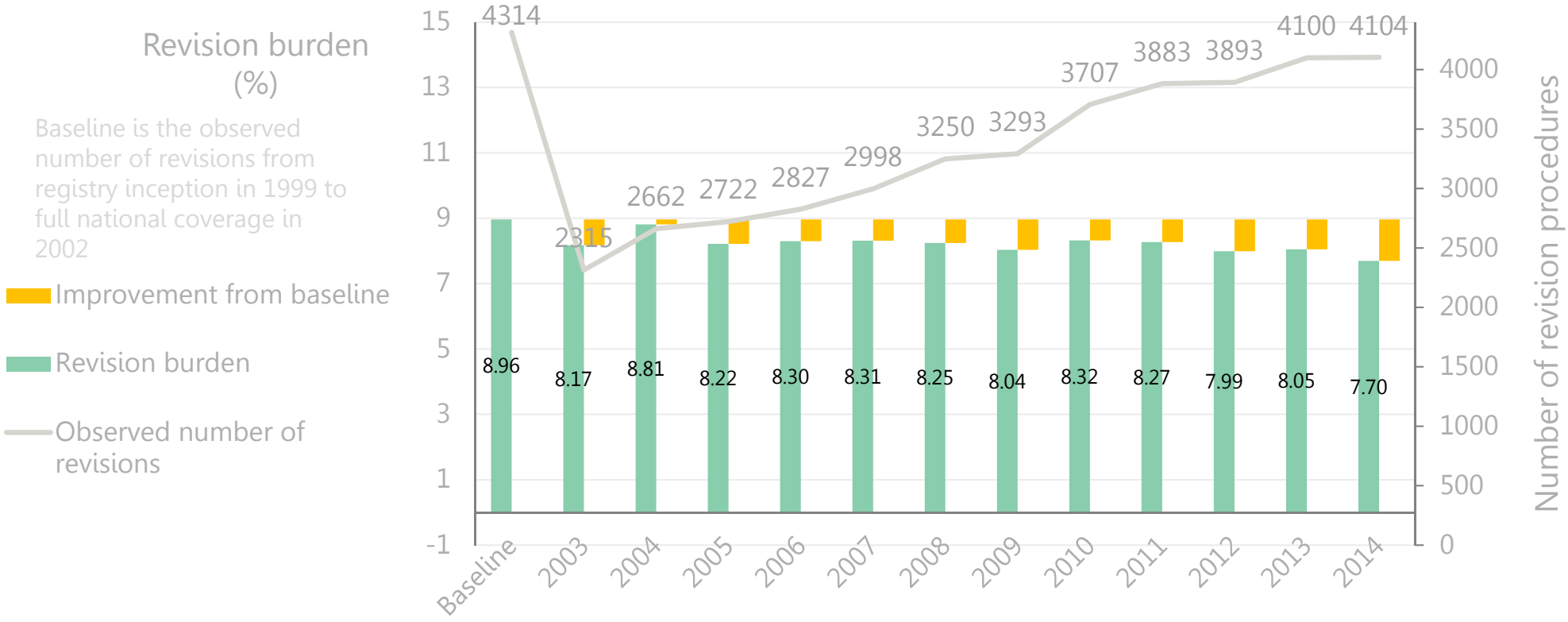
Through reduction in percentage of knee replacements that were revision procedures

Notes:

- Revisions for osteoarthritis as primary diagnosis (c98%)
- Includes all causes of revision
- Not adjusted for patient level factors, which are thought not to have changed over time.
- Includes re-revisions
- Revisions are attributed to the surgeon code that carried out the original surgery. This corrects for any revisions that are carried out by a different surgeon for the purpose of the case/control attribution analysis.

Source: Health Outcomes Australia Analysis. Registry analyses and data. * Baseline is the percentage of joint replacements that are revision procedures from registry inception in 1999 to full national coverage in 2003. The rationale for including this period is that state level data on prosthesis performance influenced national decisions on prosthesis selection. **Proportion of joint replacement surgeries that are a revision. Revisions are attributed to the surgeon (de-identified code) that performed the original replacement.

Observed improvement in revision burden in knee replacement is equivalent to almost 3900 fewer revision procedures in 12 years



vs <=2002 baseline		-0.79	-0.15	-0.75	-0.66	-0.65	-0.72	-0.93	-0.64	-0.69	-0.97	-0.91	-1.27	**Total**
Avoided revision episodes	-	224	45	248	226	234	283	380	286	324	473	465	676	**3863**
Attributed avoided revision episodes	-	-	-	-	-	-	-	-	69	78	113	112	162	**534**

Source: Registry data. Columns may not sum due to rounding.

Economic impact of reduced revision burden in knee replacement

For an individual eligible patient

Outcome 1 less revision procedure			Change points		Unit used	Value of avoided knee revision
Treatment costs	Cost of revision surgery		Major	66%	$46,317	$38,641
			Minor	34%	$23,473	
	Cost of complications	Readmission	3.9%		$5,007	$260
		Pulmonary embolism admission	0.16%		$6,573	
		Deep vein thrombosis	2.02%		$4,211	
		Pneumonia	0.8%		$2,374	
Quality of life adjustment	Incremental QALY outcomes primary vs revision		0.15		182,000	$44,671
Total value						**$83,573**

Avoiding 1 revision surgery

…..avoided treatment costs

$38,642

…and predicted benefit to QALYs

$16,744

***Columns may not sum exactly due to rounding and/or VSLY discounting**.

Source: Registry data. Rates and Outcomes of Primary and Revision Total Hip Replacement in the United States Medicare Population, *J Bone Joint Surg Am*, 2003 Jan; 85 (1): 27 - 32 . http://dx.doi.org/, AR-DRG values used for costs of revision surgery. Readmission based on 1 NEP Unit 2014 NWAU complications data 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. image sourced from http://ww1.prweb.com/prfiles/2010/06/23/457774/UHCsymbol8.jpg. Treatment costs from AR-DRG Independent Hospital Pricing Authority Appendix C accessed online November 2015. Disease utility value calculated from 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.

$33 million benefit from reduction in revision burden in knee revision procedures attributed to log in group from 2010 to 2014

Year	Revisions avoided	Incremental improvement in case group	Proportion procedures in case group	Attributed revisions avoided*	Total benefit before discounting	Treatment costs avoided	Quality of life benefit	Total benefit
Baseline	0	40%	60%			Discounted at 3% p.a.	Discounted at 3% p.a.	Discounted at 3% p.a.
2003	224							
2004	45							
2005	248							
2006	226							
2007	234							
2008	283							
2009	380							
2010	286			69	$5,729,208	$2,105,143	$2,417,546	$4,522,689
2011	324			78	$6,506,858	$2,321,246	$2,665,718	$4,986,964
2012	473			113	$9,477,702	$3,282,583	$3,769,717	$7,052,300
2013	465			112	$9,326,156	$3,136,015	$3,601,398	$6,737,413
2014	676			162	$13,551,787	$4,424,200	$5,080,749	$9,504,950
Total benefit	**3,863**			**534**	$44,591,712	**$15,269,190**	**$17,535,130**	**$32,804,320**

Taken directly from the registry

Inferred from the registry

Inferred from published sources

Source: Health Outcomes Australia Analysis. Registry data. *attributed to surgeons who logged in to view their individual outcomes feedback. Discounted by 3% oer annum.

Attributed benefits are likely to be extremely conservative due to the impact of the registry in determining prostheses availability

The attributed benefit to the registry is calculated by comparing differential application of registry feedback. It tells us the incremental ("extra") benefit of surgeons logging in to view their individual outcomes data. It does not include the broader effects of the registry on licensing and remuneration of prostheses or impact before individual outcomes data was made available, which is likely to be substantial.

In addition much of the improvement in the control group; (surgeons that did not access their individual feedback through the online portal or request ad-hoc reports), may be attributable to the registry due to its impact on determining which prostheses were available in the market for selection.

- Through the analysis of log in to view individual outcomes data, only the incremental improvement observed in the sub-set of surgeons that log in to view their individual data or request this through ad-hoc reports is included. This amounts to 42% of surgeons and roughly 60% of procedures.

- Only the improvement observed in the log in period (2010-2014) is attributed to the registry. From the first full year of data after individual outcomes were made available through the registry portal, to the most recent full year of outcomes data.

- In this period **3685** and **2223** hip and knee revisions were avoided respectively out of a total **6486** an **3863**. (Around 43% of avoided revision procedures are measured outside of the period of surgeon log-in analysis).

It is likely that a significant proportion of the 6486 and 3863 avoided hip and knee replacement revision procedures were due to feedback from the registry in the period prior to the attribution analysis. We know for example that the registry directly influenced changes in selection of devices such as the reduction in use of large head metal on metal hip replacement prostheses and unicompartmental knee replacement.

Evaluating the economic benefit of the reduction in use of large head metal on metal devices and unicompartmental knee replacement suggests an additional $78 million benefit. Attribution is through qualitative interview of registry impact and comparison to international practice.

More details on the potential additional benefit is provided in the next slides

Source: Health Outcomes Australia Analysis. Registry data and analysis based on peak utilisation rates of large head metal/metal in 2008 to 2010 when the attributon analysis will include the effect of withdrawing these prostheses from the market.

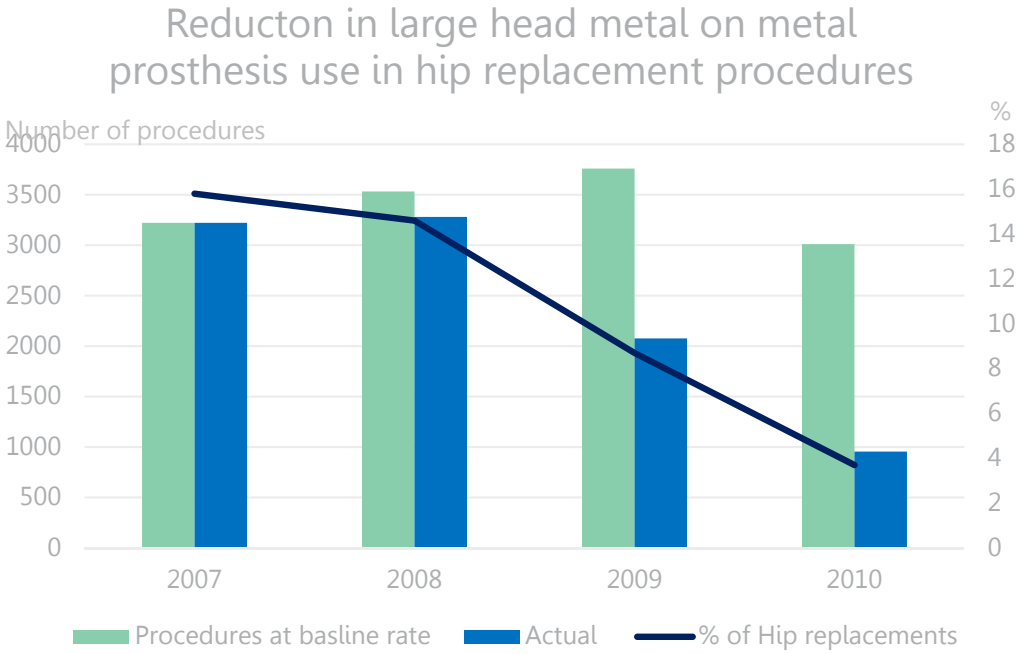
An additional $16 million of gross benefit is considered to be due to registry's effect on reducing use of large head m/m implants*

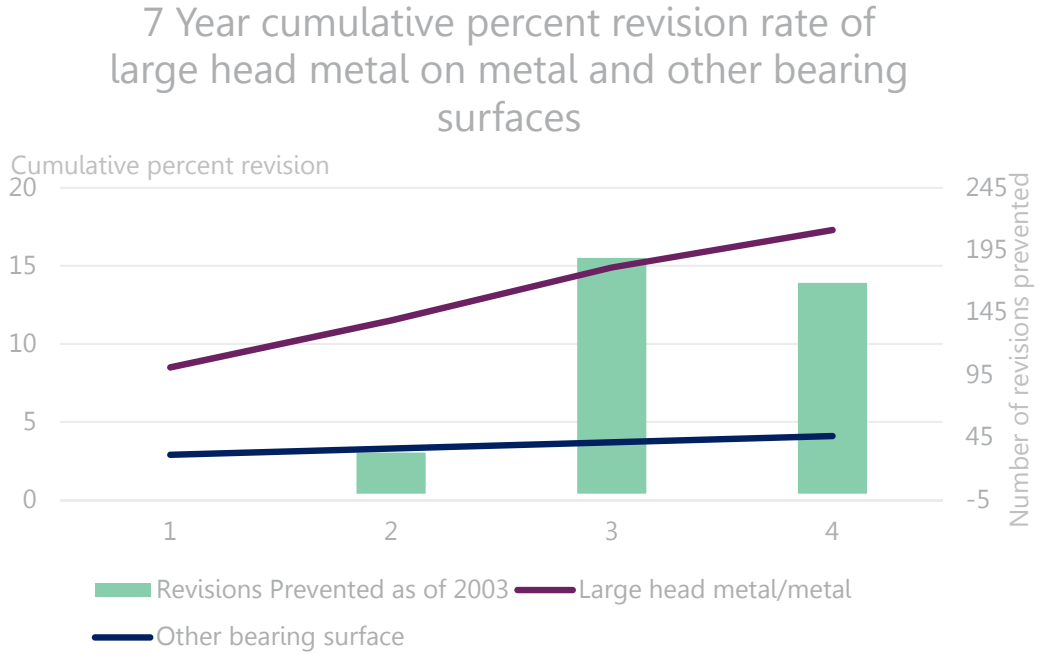
- The AOANJRR first published concerns regarding a specific type of hip replacement prostheses, the large head (greater than 32 mm) metal on metal prosthesis (large head m/m) in 2006/7.
- Patients that received this implant reported pain and disability and the revision rate was more than twice that of other resurfacing prostheses in its class.
- In the 2007 annual report this type of prosthesis was identified and published as an outlier following the three staged outlier identification process described. 7.8 percent of total hip replacements and 10.9 percent of resurfacing replacements using these prostheses needed to have revision surgery five years after initial replacement.
- Peak utilisation of this prosthesis type was in 2007-2008 when almost 16% of resurfacing hip replacements utilised large head metal on metal prostheses.
- Following identification, **year on year utilisation of this prosthesis type declined. One particular version, the Articular Surface Replacement (ASR) marketed by DePuy Orthopaedics was voluntarily withdrawn from the market in late 2010** following coordination between the manufacturer, the registry and the TGA.
- The AOANJRR was the first registry to identify, publish and report on outcomes relating to these prostheses. As a direct result of these reports, the UK National Joint Registry examined its data and corroborated findings leading to the voluntary global withdrawal of the ASR prosthesis in August 2010. In this way the Australian Registry has influenced global outcomes in relation to joint replacement surgery.
- If overall m/m utilisation had remained at peak utilisation rate at 2007, until the global market withdrawal following the UK NJR corroborating the Australian data, an additional 391 hip replacement revisions are predicted to have occurred. Some of these are accounted for in the attribution analysis through individual feedback access. For the remaining 279, based on the avoided treatment, rehabilitation, complications and quality of life impact described, this is equivalent to an **additional benefit of $16 million**. Ongoing economic impact of the market withdrawal after 2010 is captured in the attribution analysis.

Source: Health Outcomes Australia Analysis. Registry data and analysis. * Metal on Metal Implants. Avoided revisions between 2008 and 2010 calculated based on peak utilisation rate in 2008 (c16%) as percentage of observed total procedures each year. This leads to 33, 189, 169 avoided revision procedures each year from 2008. The number of additional avoided procedures in 2010(effectively the revisions avoided in the control group of non-log-in surgeons in this year) is reduced based on a very conservative assumption that all of the 112 attributed avoided revision procedures were for large head metal/metal prostheses to avoid any double counting in this year.

Additional benefit of $16 million measured following identification and reduction in use of large head m/m hip prostheses

Following identification by the registry, selection declined until its eventual withdrawal of a particularly prominent (in terms of use and revision rate) from the Australian market. The global market withdrawal following the UK registry corroboration of Australian findings is used as a control date. **The resulting decline in usage of this prosthesis relative to others in hip replacement procedures is equivalent to 279 additional avoided hip replacement revision procedures in 2008 to 2010**

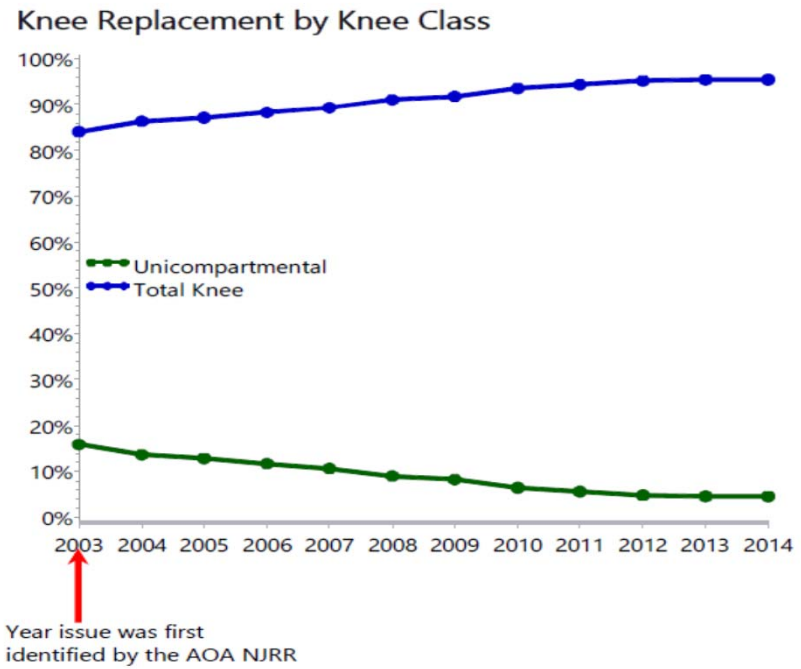




A reduction in the proportion of hip arthroplasties that use large head metal on metal prostheses is equivalent to almost 4000 less procedures of this type from 2008-2010. This is predicted to have avoided 391 revisions over this period, calculated using the difference in revision probability (through cumulative percent revision rate) between large head m/m replacements and other bearing surfaces in this period. **Subtracting the revisions that are already accounted for in the attribution analysis leaves 279 additional avoided hip replacement revision procedures and an associated benefit of $16 million.**

Source: Health Outcomes Australia Analysis. Registry data and analysis based on proportion of knee replacements that were unicompartmental procedures in 1999-2002. Cumulative percent revision rate is the probability of revision at a specific point in time. It is calculated using a kaplan-meier survivership curve as described further in the annual report. 2010 is selected as the end year for the analysis due to the global withdrawal late in this year. 5,6 and 7 year cumulative percent revision is used as these are the time scales that correspond to the calendar years being evaluated (2010 is 5 years from 2015, 2009 is 6 years from 2015 and 2008 is 7 years from 2015) Discounted at 3% per annum

The registry's broader influence is further demonstrated through the reduction in use of unicompartmental knee replacements



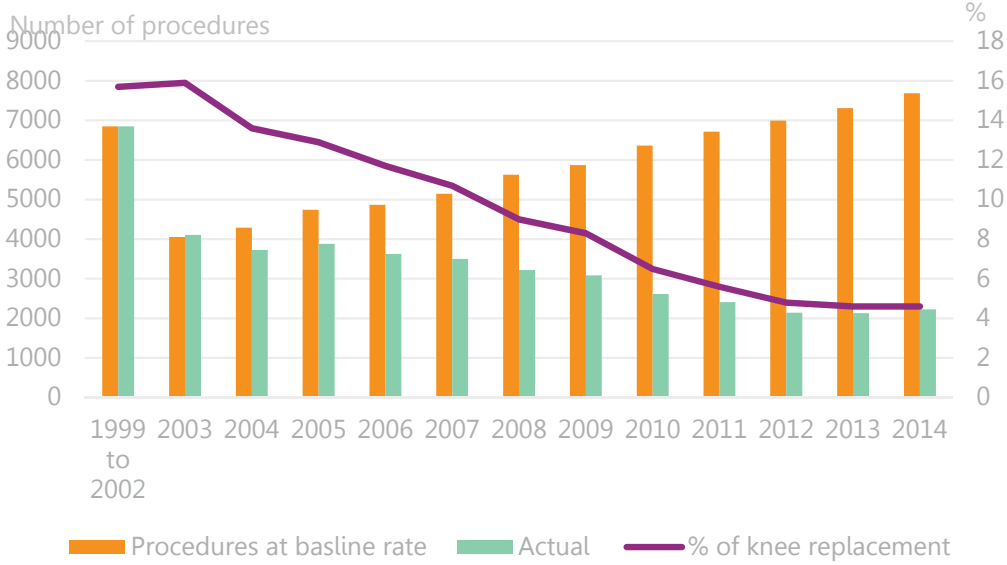
- The registry identified in 2003 that the unicompartmental arthroplasty procedure has a higher failure rate than total knee arthroplasty.
- Unicompartmental arthroplasty procedures have since become less common in Australia. This is depicted in the graph to the right
- Unicompartmental replacements at one point represented almost 16% of knee replacement procedures and have close to double the rate of revision compared to total knee replacement.
- This type of procedure now accounts for around 5% of knee replacements in Australia, whereas its use has remained constant in other countries such as the United Kingdom.*

Source Health Outcomes Australia Analysis, qualitative interview with registry stakeholders and clinicians. Registry data and analysis *rate of unicompartmental procedures has remained high in other countries including the UK as reported in the NJR Annual report 2015

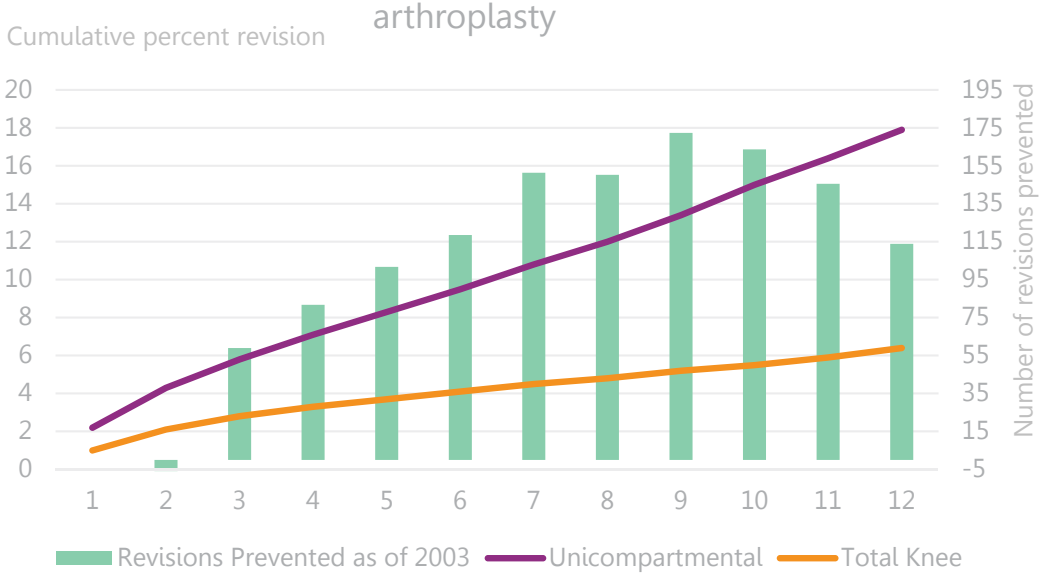
Additional benefit of **$62** million is measured following identification and reduction of unicompartmental knee arthroplasties

Following identification by the registry, this procedure has become less common in Australia in favour of total knee replacement. The procedure is still used internationally.* The resulting decline in this form of procedure in Australia relative to total knee replacement is equivalent to 881 additional avoided knee replacement revision procedures from 2003 to 2014.

Reduction in unicompartmental arthroplasty following registry identification of high revision rate



12 year cumulative percent revision rate of unicompartmental and total knee replacement arthroplasty



A reduction in the proportion of knee arthroplasties that are unicompartmental procedures is equivalent to almost 30,000 less procedures of this type from 2003-2014. This is predicted to have avoided 1318 revisions over this period, calculated using the difference in revision probability (through cumulative percent revision rate) between unicompartmental and total knee replacements in this period. **Subtracting the revisions that are already accounted for in the attribution analysis leaves 881 additional avoided knee replacement revision procedures and an associated benefit of $62 million.**

Source: Health Outcomes Australia Analysis. Registry data and analysis based on proportion of knee replacements that were unicompartmental procedures in 1999-2002 Cumulative percent revision rate is the probability of revision at a specific point in time. It is calculated using a kaplan-meier survivership curve as described further in the annual report. *Based on qualitiative interviews with registry stakeholders – percentage of unicompartmental arthroplasty has remained consistent in the UK. Discounted by 3% per annum

AOANJRR costs totalled $13 million after discounting at 3% per annum from inception in 1999 to 2014

Cost heading	Responsible for cost	1999-2015
Development and maintenance of database	**AOANJRR**	**$10,131,660**
Central costs		
Peripheral costs		
• Data collection	Each hospital nominates a hospital coordinator (usually theatre staff)	*Unknown*
• Data analysis, entry, reporting	AOANJRR	$5,219,340
Total cost		**$15,351,000**
Discounted total cost (3% per annum)		**$13 m**

- Data collection is performed by nominated coordinator at each hospital. This is normally a theatre nurse who liaises with the registry through a paper based record system.
- Data is validated through a multi level matching process against health department and unit record data. The validation process identifies procedures through records held by state/territory health departments.
- There is a 98% capture rate after validation.
- Main variable cost element is case volume and ad hoc report requests (200-300 per year) (Full time equivalent 7 data entry staff, 3 statisticians)
- Costs have risen year on year with current year funding (2015) estimated to be in the region of $2.2million. For this analysis the total costs from 1999-2014 are used.
- As a designated FQAA the Australian government introduced legislation in 2009 to provide sustained funding for NJRR maintenance and development. This is achieved through a levy paid by the device manufacturers whose devices are on the approved list for cost recovery. In 2013-14 the total levy was $2.162m.

Estimated registry costs are circa $1million per annum over the total period of function

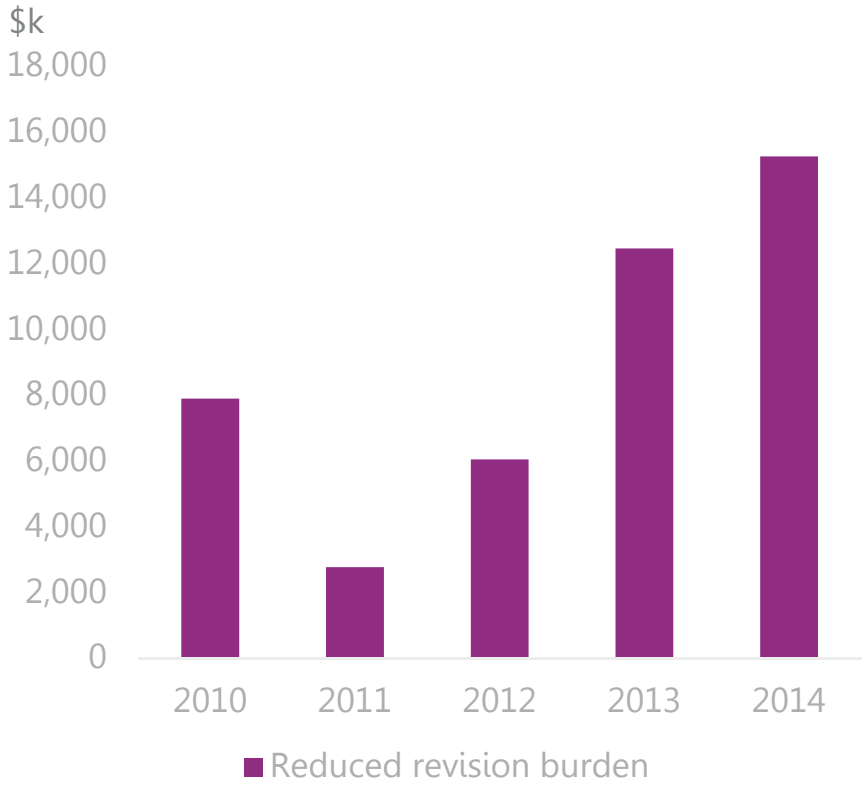
Source: Health Outcomes Australia Analysis. AOANJRR data

1b

Summary of benefits from reduction in hip replacement revision

Total attributed benefits before discounting of $44m: individual feedback group

Total benefit of $44m in the period 2010-14



Sensitivity analysis

Variable	Value		Source	2010-14 benefit		
	Range of unit	Base		Change impact	Base	%
Value of a life year QALY benefit	$50,000 to $182,000	$182,000	OBPR	$4.5m to $16.3m	$4.5m	-72

Sensitivity range of reduced hip replacement revision burden of $33m to $44m

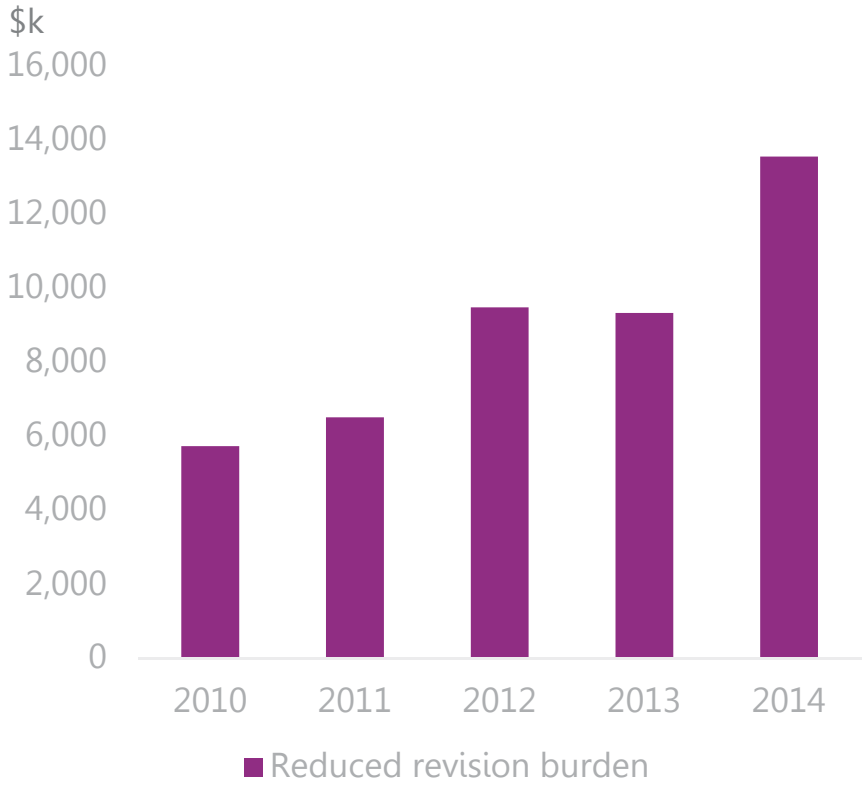
Source: Health Outcomes Australia analysis; AOANJRR registry data

1b

Summary of benefits from reduction in knee replacement revision

Total attributed benefits before discounting of $45m: individual feedback group

Total benefit of $45m in the period 2010-14



Sensitivity analysis

Variable	Value		Source	2010-14 benefit		
	Range of unit	Base		Change impact	Base	%
Value of a life year QALY benefit	$50,000 to $182,000	$182,000	OBPR	$6.5 to $23.8m	$6.5m	-72

Sensitivity range of reduced hip replacement revision burden of $27m to $45m

Source: Health Outcomes Australia analysis; AOANJRR registry data