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.
Registries only deliver an impact if they change healthcare practices

**Direct registry activities**
- Transparent data collection and analysis
- Identification and dissemination of quality indicators
- Changes in clinical practices

**Influence of registries on the health system**
- Improved outcomes; effectiveness; and appropriateness

**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 “feedback 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 mechanisms

1. **More effective**
   - Decreased mortality
   - Enhanced quality of life / decreased diminished quality of life

2. **More efficient**
   - Decreased avoidable costs (reduced infections, readmissions etc)
   - Opportunities for disinvestment (reducing the number of procedures for the same or better outcomes)

3. **More appropriate**
   - Compliance with guidelines and standards
   - Improved visibility of outlying performers

### Mechanism of action

- Well designed and run registries identify outcome indicators, like mortality, enable feedback loops to improve these outcomes.
- Variation in harder to track metrics, including quality of life, patient-reported outcome measures (PROMS), patterns of care (e.g., time to diagnosis and treatment), morbidity-related indicators are also measured and fed back.
- Where poor outcomes drive costs in the health system (e.g., a readmission), registries can reduce expenditure through feedback of information.
- By capturing patient profiles and co-morbidities as well as outcomes, registries can identify healthcare activity which is not improving patient outcomes, allowing disinvestment.
- Where best practices are set out through guidelines and agreed standards, registries enable benchmarking and tracking of compliance against these benchmarks.
- As a central repository, registries are able to identify and feedback to outlying performers, providing opportunities for actions to be taken to improve performance.

Source: Health Outcomes Australia analysis
## 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.  
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

**Perspectives on registry impact**

### 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

### 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.

### 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

<table>
<thead>
<tr>
<th>Identify indicators of changed practice</th>
<th>Infer change in outcome (if required)</th>
<th>Compare to control group</th>
<th>Assess economic value of change</th>
</tr>
</thead>
</table>
| **Find relevant indicators:**          | **Infer impact of improved process measures based on published evidence or observed outcomes**  
- Process measures  
  - Compliance with clinical guidelines  
  - Measures of clinical quality  
  - Length of stay  
- Patient outcomes  
  - Morbidity  
  - Mortality  
  - Long-term function | **Interview expert clinicians to understand**  
  - Impact and extent of use of registry  
  - Confounding changes over time period | **Improvements in life expectancy and quality of life**  
  - Based on value of a statistical life year and burden of disease |

**Control for confounding changes by comparing to a group with no/less feedback**  
- Later registry contributors  
- Groups not receiving or accessing feedback

**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

<table>
<thead>
<tr>
<th>Basis</th>
<th>Valuation method</th>
<th>Most appropriate for</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human capital/ cost of illness</td>
<td>Value of loss of work, medical expenses</td>
<td>Forecasting impact on economic output</td>
<td>Not valid for non-working individuals, no allowance for pain and suffering</td>
</tr>
<tr>
<td>Willingness to pay</td>
<td>Value that individuals place on avoiding risk of injury or death</td>
<td>Informing policy to value reductions in risk of physical harm through the value of a statistical life (VSL)</td>
<td>Individual willingness to pay may not reflect ability to pay</td>
</tr>
<tr>
<td></td>
<td>• Wage-risk – wage premium required to fill higher risk jobs</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Consumer behaviour – price premium e.g. for safer motor vehicles</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Stated preference - surveyed willingness to pay</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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)
Economic value of CQRs

Support slides – case studies
Economic Value of CQRs

Case Study 1 - Victorian Prostate Cancer Registry
Vic PCR founded in 2009 and has grown to 33 sites

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

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

2009
Registry inception
Collection of data and feedback through annual and biannual reports

2010-11
Gradual increase in enrolment of participating sites

2013
No new entrants post year end 2012

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

- 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).

![Negative and Positive Surgical Margins](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**

<table>
<thead>
<tr>
<th>Clinical tumour</th>
<th>T1 or T2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Gleason*</td>
<td>1-3</td>
</tr>
<tr>
<td>Secondary Gleason</td>
<td>1-3</td>
</tr>
<tr>
<td>Prostate specific antigen</td>
<td>10 ng/mL or Less</td>
</tr>
<tr>
<td>Number of cores positive</td>
<td>Less than 3</td>
</tr>
</tbody>
</table>

* (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.
# Overview of benefits from Vic PCR

<table>
<thead>
<tr>
<th>Indicator of changed clinical practice</th>
<th>Control(s)</th>
<th>Patient outcome</th>
<th>Conversion to economic value</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive surgical margin rates</td>
<td>Comparison of sites: Early contributors to the registry versus more recent</td>
<td>Mortality&lt;br&gt;Morbidity (PROMS)&lt;br&gt;Reduced need for secondary treatment</td>
<td>Mortality ($/life year)&lt;br&gt;Morbidity (weighted $/life year)&lt;br&gt;Avoided 2ndry treatment cost&lt;br&gt;$/change in quality of life</td>
<td></td>
</tr>
<tr>
<td>Rates of intervention when pt. PRIAS criteria</td>
<td>Compared to other states (South Australia/NSW)&lt;br&gt;Outliers within state (Gippsland project)</td>
<td>Avoided surgery and complications (incontinence, sexual dysfunction)</td>
<td>Avoided costs of procedures&lt;br&gt;$/change in quality of life</td>
<td></td>
</tr>
<tr>
<td>Earlier Treatment</td>
<td></td>
<td>Improved outcomes</td>
<td>Mortality ($/life year)&lt;br&gt;$/change in quality of life</td>
<td></td>
</tr>
<tr>
<td>Other changes in patterns of care</td>
<td></td>
<td>Patient reported outcomes (PROMS)</td>
<td>$/change in quality of life</td>
<td></td>
</tr>
</tbody>
</table>

**Indicators for evaluation**<br>Measured by the registry directly

**Data accessed and analysed**

**PROMS included in PRIAS evaluation**

Source: Health Outcomes Australia analysis
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

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.

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 across multiple sites. According to registry data, this amounts to circa 30% of clinicians. Benchmarking 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 across 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

<table>
<thead>
<tr>
<th>Improvement vs 2010</th>
<th>-</th>
<th>10.48%</th>
<th>12.29%</th>
<th>12.61%</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of radical prostatectomies prevented</td>
<td>-</td>
<td>70</td>
<td>81</td>
<td>68</td>
<td>219</td>
</tr>
<tr>
<td>Share of improvement attributed due to registry</td>
<td>15%</td>
<td>32%</td>
<td>35%</td>
<td></td>
<td>27%</td>
</tr>
<tr>
<td>Attributed reduction in radical prostatectomies</td>
<td>-</td>
<td>11</td>
<td>25</td>
<td>24</td>
<td>59</td>
</tr>
</tbody>
</table>

Source: Health Outcomes Australia analysis
### Evaluation of economic impact of avoidance of a single positive surgical margin

For an individual eligible patient

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Positive surgical margin</th>
<th>No positive margin</th>
<th>Difference</th>
<th>Unit used</th>
<th>Value of avoided positive surgical margin</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mortality</strong></td>
<td>Median age of death</td>
<td>69</td>
<td>74</td>
<td>5 (in 4.9%)</td>
<td>$182k/SLY</td>
</tr>
<tr>
<td><strong>Secondary treatment</strong></td>
<td>Salvage radiotherapy rate (%)</td>
<td>20%</td>
<td>4%</td>
<td>16%</td>
<td>$45k</td>
</tr>
<tr>
<td></td>
<td>ADT rate (%)</td>
<td>8%</td>
<td>1%</td>
<td>6%</td>
<td>$5k</td>
</tr>
<tr>
<td></td>
<td>Other (e.g. <em>combination therapy/chemotherapy</em>) (%)</td>
<td>4%</td>
<td>1%</td>
<td>3%</td>
<td>$50k</td>
</tr>
<tr>
<td><strong>Total value</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>$51,000</strong></td>
</tr>
</tbody>
</table>

Avoiding 20 PSMS...is predicted to avoid ~1 premature death, +5 years $860,000 + 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

<table>
<thead>
<tr>
<th>Year</th>
<th>Reduced positive surgical margins (patients)</th>
<th>Value per avoided positive surgical margin</th>
<th>Economic impact pre-discounting</th>
<th>Economic impact</th>
<th>Reduction in deaths</th>
<th>Avoided secondary treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td>11</td>
<td></td>
<td>$0.5m</td>
<td>$0.5M</td>
<td>0.5</td>
<td>3</td>
</tr>
<tr>
<td>2012</td>
<td>25</td>
<td>$51k</td>
<td>$1.3m</td>
<td>$1.2M</td>
<td>1.2</td>
<td>6</td>
</tr>
<tr>
<td>2013</td>
<td>24</td>
<td></td>
<td>$1.2m</td>
<td>$1.1M</td>
<td>1.2</td>
<td>6</td>
</tr>
<tr>
<td>Total (09-13)</td>
<td>59</td>
<td></td>
<td>$3.0m</td>
<td>$2.8M</td>
<td>3</td>
<td>15</td>
</tr>
</tbody>
</table>

| Basis for calculation | Registry data | Literature | Registry (inferred) |

Source: Health Outcomes Australia analysis. Discounted at 3% per annum.
Adherence to PRIAS protocol for low-risk patients

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

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)

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

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 comparison. In practice these 5 units started providing data to the registry demonstrably earlier than subsequent units.
Calculation of avoided active treatment attributed to registry

<table>
<thead>
<tr>
<th>Improvement vs 2010</th>
<th>-</th>
<th>4.83%</th>
<th>15.48%</th>
<th>21.06%</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of avoided treatments in PRIAS patients</td>
<td>-</td>
<td>17</td>
<td>41</td>
<td>33</td>
<td>91</td>
</tr>
<tr>
<td>Share of improvement attributed due to registry</td>
<td>-</td>
<td>136%</td>
<td>55%</td>
<td>62%</td>
<td></td>
</tr>
<tr>
<td>Attributed reduction in PRIAS treatments</td>
<td>-</td>
<td>23</td>
<td>23</td>
<td>20</td>
<td>66</td>
</tr>
</tbody>
</table>

Source: Health Outcomes Australia analysis
## 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

### Active treatment (12 month figures)

<table>
<thead>
<tr>
<th>Expected outcome</th>
<th>AA/WW</th>
<th>Radical Prostatectomy</th>
<th>Radiotherapy</th>
<th>Brachytherapy</th>
<th>Other</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost of treatment</td>
<td></td>
<td>72%</td>
<td>7%</td>
<td>15%</td>
<td>6%</td>
<td>$15,500</td>
</tr>
</tbody>
</table>

### Average incremental impact per case

<table>
<thead>
<tr>
<th>Cost of treatment</th>
<th>$1500*</th>
<th>$15,000</th>
<th>$45,000</th>
<th>$1,500</th>
<th>$49,000</th>
<th>$15,500</th>
</tr>
</thead>
</table>

### Conversion to economic value

<table>
<thead>
<tr>
<th>Conversion to economic value²</th>
<th>$14,000</th>
<th>N/A</th>
</tr>
</thead>
</table>

### Average value of one unit occurrence

<table>
<thead>
<tr>
<th>Average value of one unit occurrence</th>
<th>$14,000</th>
</tr>
</thead>
</table>

### Impact on Quality of Life³

<table>
<thead>
<tr>
<th>Impact on Quality of Life³</th>
<th>Urinary Bother</th>
<th>Bowel Bother</th>
<th>Sexual Bother</th>
<th>Conversion to economic value²</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urinary Bother</td>
<td>39.9%</td>
<td>50.4%</td>
<td>51.5%</td>
<td>11%</td>
<td>0.15 VSLY</td>
</tr>
<tr>
<td>Bowel Bother</td>
<td>19%</td>
<td>15.5%</td>
<td>38.3%</td>
<td>7%</td>
<td>0.15 VLSY</td>
</tr>
<tr>
<td>Sexual Bother</td>
<td>33.6%</td>
<td>76.4%</td>
<td>45.1%</td>
<td>19%</td>
<td>0.195 VSLY</td>
</tr>
</tbody>
</table>

### Total

<table>
<thead>
<tr>
<th>Total</th>
<th>$39,000</th>
</tr>
</thead>
</table>

Reducing 10 active treatments in PRIAS patients...prevents poorer quality of life in 6 patients and results in benefits of $155,000 in avoided treatment costs.

1 QALY $182,000 + $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

<table>
<thead>
<tr>
<th>Year</th>
<th>Avoided treatment</th>
<th>Quality of life improvement*</th>
<th>Total economic impact pre-discounting</th>
<th>Total economic impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>Baseline</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td>23</td>
<td>$14,000</td>
<td>$0.7m</td>
<td>$0.7m</td>
</tr>
<tr>
<td>2012</td>
<td>23</td>
<td>$25,000</td>
<td>$0.9m</td>
<td>$0.8m</td>
</tr>
<tr>
<td>2013</td>
<td>20</td>
<td></td>
<td>$1m</td>
<td>$0.9m</td>
</tr>
<tr>
<td>Total</td>
<td>66</td>
<td></td>
<td>$2.6m</td>
<td>$2.4m</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Cost Heading</th>
<th>Responsible for cost</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>Total 09-13</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development and maintenance*</td>
<td></td>
<td>$200,000</td>
<td>$36,050</td>
<td>$36,050</td>
<td>$36,050</td>
<td>$36,050</td>
<td>$344,200</td>
</tr>
<tr>
<td>• Initial build costs</td>
<td>Monash</td>
<td>$200,000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$200,000</td>
</tr>
<tr>
<td>• Ongoing maintenance (IT &amp; infrastructure)</td>
<td>Monash</td>
<td>$36,050</td>
<td>$36,050</td>
<td>$36,050</td>
<td>$36,050</td>
<td>$36,050</td>
<td>$144,200</td>
</tr>
<tr>
<td>Central Costs</td>
<td></td>
<td>$383,254</td>
<td>$383,254</td>
<td>$383,254</td>
<td>$383,254</td>
<td>$383,254</td>
<td>$1,916,270</td>
</tr>
<tr>
<td>• Lead</td>
<td>Monash</td>
<td>$34,561</td>
<td>$34,561</td>
<td>$34,561</td>
<td>$34,561</td>
<td>$34,561</td>
<td>$172,805</td>
</tr>
<tr>
<td>• Biostatistics and analysis</td>
<td>Monash</td>
<td>$38,074</td>
<td>$38,074</td>
<td>$38,074</td>
<td>$38,074</td>
<td>$38,074</td>
<td>$190,370</td>
</tr>
<tr>
<td>• Research and administration</td>
<td>Monash</td>
<td>$129,364</td>
<td>$129,364</td>
<td>$129,364</td>
<td>$129,364</td>
<td>$129,364</td>
<td>$646,820</td>
</tr>
<tr>
<td>• Casual staff</td>
<td>Monash</td>
<td>$68,538</td>
<td>$68,538</td>
<td>$68,538</td>
<td>$68,538</td>
<td>$68,538</td>
<td>$342,690</td>
</tr>
<tr>
<td>• Overheads</td>
<td>Monash</td>
<td>$112,717</td>
<td>$112,717</td>
<td>$112,717</td>
<td>$112,717</td>
<td>$112,717</td>
<td>$563,585</td>
</tr>
<tr>
<td>Peripheral (data collection) costs1</td>
<td></td>
<td>$72,181</td>
<td>$82,021</td>
<td>$152,980</td>
<td>$155,181</td>
<td>$134,339</td>
<td>$596,702</td>
</tr>
<tr>
<td>• Data collection metro &amp; regional</td>
<td>Monash</td>
<td>$40,736</td>
<td>$46,289</td>
<td>$86,335</td>
<td>$87,577</td>
<td>$75,815</td>
<td>$336,752</td>
</tr>
<tr>
<td>• Data collection (outcomes)</td>
<td>Monash</td>
<td>$31,445</td>
<td>$35,732</td>
<td>$66,645</td>
<td>$67,603</td>
<td>$58,524</td>
<td>$259,949</td>
</tr>
<tr>
<td>Total cost per annum</td>
<td></td>
<td>$655,435</td>
<td>$501,325</td>
<td>$572,284</td>
<td>$574,484</td>
<td>$553,643</td>
<td>$2,857,000</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
<th>Source</th>
<th>2009-13 Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value of a life year</td>
<td>$50,000 to $182,000</td>
<td>OBPR(^1)</td>
<td>$0.7m to $2.5m</td>
</tr>
<tr>
<td>Years of life lost</td>
<td>5 to 8 years</td>
<td>Registry data</td>
<td>$2.5 to $3.9m</td>
</tr>
<tr>
<td>PSM baseline year (2010)</td>
<td>6% to 10% reduction to 2013</td>
<td>Registry data</td>
<td>$2.2m to $3.1m</td>
</tr>
<tr>
<td>PSM mortality rate incr.</td>
<td>4-18%</td>
<td>Papers(^2)</td>
<td>$2m to $9m</td>
</tr>
<tr>
<td>VSLY unit deflation to actual year</td>
<td>$156,000 to $182,000</td>
<td>OBPR</td>
<td>$2.4m to $2.5m</td>
</tr>
</tbody>
</table>

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).
Adherence to PRIAS protocol for low-risk patients

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

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
<th>Source</th>
<th>2009-13 Benefit ($k)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Range of unit</td>
<td>Base</td>
<td>Range of Impact</td>
</tr>
<tr>
<td>Value of a life year</td>
<td>$50,000-$182,000</td>
<td>$182,000</td>
<td>OBPR(^1)</td>
</tr>
<tr>
<td>Follow up surveillance costs</td>
<td>0-$50,000</td>
<td>$50,000</td>
<td>MBS PBS RACGP</td>
</tr>
<tr>
<td>Eventual active treatment in PRIAS**</td>
<td>0-30%</td>
<td>0%</td>
<td>Interview</td>
</tr>
<tr>
<td>PRIAS baseline year ('09 v 10)</td>
<td>11%-21% reduction to 2013</td>
<td>21% (2010)</td>
<td>Registry</td>
</tr>
</tbody>
</table>

*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.
Economic Value of CQRs

Case Study 2 – Victorian State Trauma Registry
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 VTSP 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 into 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 of 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

<table>
<thead>
<tr>
<th>Year</th>
<th>Benefit to cost ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005-2013</td>
<td>6:1</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Indicator of changed clinical practice</th>
<th>Control(s)</th>
<th>Patient outcome measure</th>
<th>Conversion to economic value</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduction in ALOS</td>
<td>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</td>
<td>Earlier discharge</td>
<td>Average cost of inpatient stay</td>
<td>Accessed and analysed 2005-2013</td>
</tr>
<tr>
<td>Compliance with transfer and triage guidelines</td>
<td>International</td>
<td>In hospital mortality</td>
<td>Mortality ($/life year)</td>
<td></td>
</tr>
<tr>
<td>Other changes in patterns of care</td>
<td>International</td>
<td>Morbidity</td>
<td>Morbidity (weighted $/life year)</td>
<td></td>
</tr>
<tr>
<td>Hospital system performance</td>
<td>International</td>
<td>Functional outcomes</td>
<td>$/change in quality of life</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Productivity – return to work</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Reduced episodes of care costs, reduced road trauma (paper)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>reduced loss to productivity, reduced disability payments etc.</td>
<td></td>
</tr>
</tbody>
</table>

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

2001 - Registry inception
Review of Trauma and Emergency Services report, integration of trauma care through VSTS and collection of outcomes

2005 - Complete coverage
Ethics procedures completed at all health services. Period of complete coverage is post-2005

2007 - Case review group established
CRG established for regional cases. Until 2011 issues identified were referred to Trauma Education Group and Coordination Group

2008 to 2010 - Adult Retrieval Victoria begins*
- CRG filters updated and expanded to Metro HS in 2009
- AIS updated to AIS2008 from AIS98 with previous cases mapped forwards

2011 - Case review group begins health service direct feedback
Case review group starts to feed back to individual health services based on a risk matrix of system and physiological factors

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
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

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

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

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**

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** – all remaining hospitals in the system when hospitals that received case review group feedback are removed from the data.

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

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

<table>
<thead>
<tr>
<th>Year</th>
<th>Attributed bed days saved at 2005 rate</th>
<th>Economic value¹</th>
<th>$ benefit before discounting</th>
<th>$ benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline (2005)</td>
<td></td>
<td>$3,236** per trauma bed day</td>
<td>$0.9m</td>
<td>$0.7m</td>
</tr>
<tr>
<td>2011</td>
<td>277</td>
<td></td>
<td>$0.9m</td>
<td>$0.7m</td>
</tr>
<tr>
<td>2012</td>
<td>127</td>
<td></td>
<td>$0.4m</td>
<td>$0.3m</td>
</tr>
<tr>
<td>2013</td>
<td>54</td>
<td></td>
<td>$0.2m</td>
<td>$0.2m</td>
</tr>
<tr>
<td>Total benefit</td>
<td>458</td>
<td></td>
<td>$1.5m</td>
<td>$1.2m</td>
</tr>
</tbody>
</table>

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.

Source: Health Outcomes Australia analysis. Registry data.

*1. Taken directly from the registry

*2. Inferred from the registry

*3. 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

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.

<table>
<thead>
<tr>
<th>Year</th>
<th>Total ISS&gt;12 patients</th>
<th>Avoided deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>2,136</td>
<td>0</td>
</tr>
<tr>
<td>2006</td>
<td>2,291</td>
<td>6</td>
</tr>
<tr>
<td>2007</td>
<td>2,231</td>
<td>-4</td>
</tr>
<tr>
<td>2008</td>
<td>2,526</td>
<td>70</td>
</tr>
<tr>
<td>2009</td>
<td>2,608</td>
<td>11</td>
</tr>
<tr>
<td>2010</td>
<td>2,706</td>
<td>76</td>
</tr>
<tr>
<td>2011</td>
<td>2,954</td>
<td>109</td>
</tr>
<tr>
<td>2012</td>
<td>2,968</td>
<td>97</td>
</tr>
<tr>
<td>2013</td>
<td>2,919</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>2,032</td>
<td>366</td>
</tr>
</tbody>
</table>

Source: Health Outcomes Australia analysis. VSTR data from VSTORM
Reduction in mortality is greatest in CRG-Hospitals from 2011 onwards

Change in Mortality Rate in CRG group versus non-CRG group over time

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

Source: Health Outcomes Australia analysis
The incremental avoided mortality is attributed to the feedback process of the registries case review group.

31 additional avoided deaths attributed to the presence of the registry and its additional structured feedback feedback 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
## 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

<table>
<thead>
<tr>
<th>Year</th>
<th>Relative Risk</th>
<th>Admissions*</th>
<th>Deaths</th>
<th>Attributed avoided deaths</th>
<th>Economic Value$ per avoided death</th>
<th>$ Rehab**</th>
<th>$ benefit pre-disc.</th>
<th>$ benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline (2005)</td>
<td>1</td>
<td>Baseline</td>
<td></td>
<td></td>
<td>$182,000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Discounted VSLY</td>
<td>Median age of cohort</td>
<td>Years Saved Per pt.</td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td>0.78</td>
<td>2954</td>
<td>346</td>
<td>7</td>
<td>$155k</td>
<td>79</td>
<td>9</td>
<td>$0.04m</td>
</tr>
<tr>
<td></td>
<td>2012</td>
<td>2968</td>
<td>321</td>
<td>14</td>
<td>$158k</td>
<td>80</td>
<td>9</td>
<td>$0.09m</td>
</tr>
<tr>
<td></td>
<td>2013</td>
<td>2919</td>
<td>324</td>
<td>10</td>
<td>$159k</td>
<td>80</td>
<td>9</td>
<td>$0.06m</td>
</tr>
<tr>
<td>Total benefit</td>
<td></td>
<td>8841</td>
<td>990</td>
<td>31</td>
<td>$1.4m</td>
<td></td>
<td></td>
<td>$0.2m</td>
</tr>
</tbody>
</table>

---

Columns may not sum due to rounding. 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)
Costs – VSTR totalled $6.5 million after discounting at 3% per annum

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

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 $7 million

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.
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

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
<th>Source</th>
<th>2011-13 benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range of unit</td>
<td>Base</td>
<td>Change impact</td>
<td>Base</td>
</tr>
<tr>
<td>Value of a life year</td>
<td>$50,000 to $182,000</td>
<td>$182,000 OBPR</td>
<td>$7.7m to $43m</td>
</tr>
<tr>
<td>Impairment to QALY* for deaths avoided</td>
<td>0-0.35 QALY*</td>
<td>0 AIHW Burden of Disease</td>
<td>$24m to $43m</td>
</tr>
</tbody>
</table>

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.
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

Cases added to registry

<table>
<thead>
<tr>
<th>Year</th>
<th>Total sites</th>
<th>Cases per year</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>160</td>
<td>88342</td>
</tr>
<tr>
<td>2010</td>
<td>160</td>
<td>96154</td>
</tr>
<tr>
<td>2011</td>
<td>160</td>
<td>100937</td>
</tr>
<tr>
<td>2012</td>
<td>160</td>
<td>105184</td>
</tr>
<tr>
<td>2013</td>
<td>160</td>
<td>107923</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>1a</th>
<th>Average length of ICU stay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long stays in ICUs are associated with high costs.</td>
<td></td>
</tr>
<tr>
<td>The average value of an ICU bed day is taken as $4,500 based on unpublished registry data and indexed data from NSW</td>
<td></td>
</tr>
<tr>
<td>Length of stay can be influenced by age, comorbidity, diagnosis amongst other factors. In this analysis these factors are standardised.</td>
<td></td>
</tr>
<tr>
<td><strong>Inclusion</strong></td>
<td></td>
</tr>
<tr>
<td>Age over 16</td>
<td></td>
</tr>
<tr>
<td>No readmissions in the same episode</td>
<td></td>
</tr>
<tr>
<td>ALOS expressed as median bed days</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1b</th>
<th>SMR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality rate in ICU is associated with case mix, age, patient numbers</td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td><strong>Inclusion</strong></td>
<td></td>
</tr>
<tr>
<td>Age over 16</td>
<td></td>
</tr>
<tr>
<td>No readmissions in the same episode</td>
<td></td>
</tr>
<tr>
<td>Mortality expressed as ratio of predicted to actual deaths (standardised mortality ratio, expressed over time SMR)</td>
<td></td>
</tr>
</tbody>
</table>

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

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

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

### 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

1992 to 2000
Registry inception
Collection of data and feedback through posted then emailed annual reports

2009
ANZICS CORE outlier management program with structured feedback to outlier units based on SMR

2013
Formation of the outlier working group to include increased regional clinician representation

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

The 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
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. Association in rate of reduction post outlier management program from 2009. Reduction in ALOS is equivalent to over 360,000 ICU bed days avoided over the 14 year period based on benchmark rate from 2000. Rate of reduction in ALOS is faster after the introduction of the outlier management program. Source: Health Outcomes Australia analysis.
$32 million benefit from reduction in average length of stay in late outliers (outlier management program feedback recipients) from 2009 to 2013

<table>
<thead>
<tr>
<th>Year</th>
<th>ALOS (Days) *</th>
<th>Admissions</th>
<th>Bed Days</th>
<th>Attributed bed days saved at 2000 rate</th>
<th>Economic value¹</th>
<th>$ benefit before discounting</th>
<th>$ benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline (2000)</td>
<td>4.7</td>
<td>Baseline</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2009</td>
<td>3.9</td>
<td>7644</td>
<td>29,546</td>
<td>171</td>
<td>$4,300 per ICU bed day</td>
<td>$0.7m</td>
<td>$0.6m</td>
</tr>
<tr>
<td>2010</td>
<td>3.7</td>
<td>8491</td>
<td>31,436</td>
<td>1875</td>
<td>$8m</td>
<td>$6m</td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td>3.6</td>
<td>8757</td>
<td>31,564</td>
<td>1842</td>
<td>$8m</td>
<td>$5.7m</td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>3.3</td>
<td>9344</td>
<td>31,033</td>
<td>3627</td>
<td>$16m</td>
<td>$11m</td>
<td></td>
</tr>
<tr>
<td>2013</td>
<td>3.3</td>
<td>11019</td>
<td>36,780</td>
<td>3051</td>
<td>$13m</td>
<td>$9m</td>
<td></td>
</tr>
<tr>
<td>Total benefit</td>
<td>45,255</td>
<td>160,359</td>
<td>10,566</td>
<td></td>
<td>$45m</td>
<td>$32m</td>
<td></td>
</tr>
</tbody>
</table>

*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

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)
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)

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

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.

Avoided Deaths in outlier management program (late) 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.
$4 million benefit from reduction in standardised mortality ratio in post-outlier management program outliers from 2009 to 2013

<table>
<thead>
<tr>
<th>Year</th>
<th>SMR*</th>
<th>Admissions</th>
<th>Deaths</th>
<th>Attributed deaths avoided at 2000 rate</th>
<th>Economic value(^1)</th>
<th>$ Benefit before discounting</th>
<th>$ Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline (2000)</td>
<td>0.94</td>
<td>Baseline</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2009</td>
<td>0.76</td>
<td>7479</td>
<td>630</td>
<td>11</td>
<td>$1.9m</td>
<td>$1.5m</td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td>0.82</td>
<td>8315</td>
<td>704</td>
<td>6</td>
<td>$1.2m</td>
<td>$0.9m</td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td>0.86</td>
<td>8589</td>
<td>754</td>
<td>1</td>
<td>$0.2m</td>
<td>$0.1m</td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>0.82</td>
<td>9013</td>
<td>683</td>
<td>4</td>
<td>$0.8m</td>
<td>$0.6m</td>
<td></td>
</tr>
<tr>
<td>2013</td>
<td>0.80</td>
<td>10868</td>
<td>804</td>
<td>8</td>
<td>$1.4m</td>
<td>$0.9m</td>
<td></td>
</tr>
<tr>
<td>Total benefit</td>
<td></td>
<td>44,264</td>
<td>3575</td>
<td>30</td>
<td>$5.5m</td>
<td>$4m</td>
<td></td>
</tr>
</tbody>
</table>

\(^1\) 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.

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).
Summary of benefits from reduced ALOS in ICU

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

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

**Variable** | **Value** | **Source** | **2009-13 benefit**
--- | --- | --- | ---
ICU bed day | Range of unit $4000 to $4300 | Base $4300 | Change impact $42m to $45m | Base $45m | %
Impact of readmission | 0-4% | 0 | Change impact $43.2m to $45m | Base $45m | 4

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.
Summary of benefits from decreased standardised mortality ratio

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

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
<th>Source</th>
<th>2009-13 benefit ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost of a life year</td>
<td>Range of unit: $50,000-$182,000</td>
<td>Base: $182,000</td>
<td>Range of Impact: $1.5m to $5.5m</td>
</tr>
<tr>
<td>Disability adjustment</td>
<td>0-0.373</td>
<td>0</td>
<td>Range of Impact: $3.45m to $5.5m</td>
</tr>
</tbody>
</table>

Avoided mortality

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)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ALL</td>
<td>Jurisdictional funding</td>
<td>$898,168</td>
<td>$932,758</td>
<td>$981,002</td>
<td>$941,311</td>
<td>$968,609</td>
<td>$4,721,848</td>
</tr>
<tr>
<td></td>
<td>Queensland private</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$16,909</td>
<td>$24,600</td>
<td>$41,509</td>
</tr>
<tr>
<td></td>
<td>Infrastructure funding</td>
<td>$0</td>
<td>$0</td>
<td>$141,145</td>
<td>$141,145</td>
<td>$141,145</td>
<td>$423,435</td>
</tr>
<tr>
<td>Total cost per annum</td>
<td></td>
<td>$898,168</td>
<td>$932,758</td>
<td>$1,122,147</td>
<td>$1,099,355</td>
<td>$1,134,534</td>
<td>$5,186,792</td>
</tr>
</tbody>
</table>

| Number of APD cases | 90110 | 97820 | 102419 | 106928 | 109625 |

- Cost data assimilated into 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.

Source: Health Outcomes Australia analysis, ANZICS CORE APD registry data
Economic Value of CQRs

Case Study 4 - Australia and New Zealand Dialysis and Transplant Registry
ANZDATA founded in late 1970s

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.

Source ANZDATA Annual report 2014
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 $58 million based on hospitals accessing registry analysis and feedback.

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

**1970s**
Registry inception
Collection of data and feedback through annual and biannual reports delivered through hard post and later by email

**2011**
KPI project
KPI reports recording and feeding back data quarterly on haemodialysis access and peritonitis rates

**2013**
Access to benchmarking reports made through a new system of self-directed log in to a secure online portal. The registry is able to track utilisation

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.

We have evaluated 3 indicators from the ANZDATA registry:

1. **Survival in renal replacement therapy**
   - **Control(s):** Comparison of sites who accessed registry feedback versus those that did not.
   - **Patient outcome:** Transplant mortality
   - **Conversion to economic value:** Mortality ($/life year), Morbidity (weighted $/life year), Avoided secondary treatment cost $/change in quality of life
   - **Comment:** Dialysis mortality only (this improved in the period)

2. **Transplant graft loss rate**
   - **Control(s):** Avoided alternative treatment
   - **Patient outcome:** Avoided secondary treatment cost, Morbidity (weighted $/life year)
   - **Conversion to economic value:** Avoided secondary treatment cost, Morbidity (weighted $/life year)

3. **Technique survival – peritonitis rates**
   - **Control(s):** Avoided treatment QALY benefit
   - **Patient outcome:** Decreased rates of cancer, better vascular access
   - **Conversion to economic value:** Morbidity (weighted $/life year)
   - **Comment:** Not in scope due to data access and timing

**Indicators for evaluation**
- Measured by the registry directly

**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).

**Attribution of benefit**

Incremental improvement in feedback access (case) group hospitals attributed to the registry.

*Volume of complete data sets and balance of units in each group defined the case/control log in count cut offs.*

Incremental improvement in outcomes from baseline

- Feedback access group
- Non-feedback access group

*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

<table>
<thead>
<tr>
<th>Dialysis mortality</th>
<th>Graft loss rate</th>
<th>Peritonitis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Log in group</strong></td>
<td><strong>Improvement</strong></td>
<td><strong>Proportion of cases</strong></td>
</tr>
<tr>
<td>2011</td>
<td>+35%</td>
<td>69%</td>
</tr>
<tr>
<td>2012</td>
<td>+73%</td>
<td>58%</td>
</tr>
<tr>
<td>2013</td>
<td>+19%</td>
<td>35%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Year</th>
<th>Total</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>-5%</td>
<td>-4%</td>
<td>0%</td>
<td>-3%</td>
<td>-1%</td>
<td>-13%</td>
<td>-11%</td>
<td>-18%</td>
<td>-15%</td>
<td>Total</td>
</tr>
<tr>
<td>Observed mortality</td>
<td>14150</td>
<td>1208</td>
<td>1202</td>
<td>1326</td>
<td>1459</td>
<td>1538</td>
<td>1414</td>
<td>1507</td>
<td>1485</td>
<td>1518</td>
<td></td>
</tr>
<tr>
<td>Avoided deaths</td>
<td></td>
<td>0</td>
<td>75</td>
<td>54</td>
<td>0</td>
<td>40</td>
<td>10</td>
<td>209</td>
<td>187</td>
<td>316</td>
<td>267</td>
</tr>
<tr>
<td>Avoided deaths attributed to registry</td>
<td></td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>45</td>
<td>133</td>
<td>18</td>
<td>196</td>
</tr>
</tbody>
</table>

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.
### Evaluation of economic impact of avoided dialysis mortality

For an individual patient

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Years saved</th>
<th>Value for a patient on dialysis</th>
<th>Value of avoided mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 avoided dialysis mortality</td>
<td>4.5</td>
<td>$104k</td>
<td>$469k</td>
</tr>
<tr>
<td>Mortality</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dialysis</td>
<td>-4.5</td>
<td>$80k</td>
<td>-$358k</td>
</tr>
<tr>
<td>Initial access</td>
<td>-4.5</td>
<td>$9000</td>
<td>-$9k</td>
</tr>
<tr>
<td><strong>Total value</strong></td>
<td></td>
<td></td>
<td><strong>$101k</strong></td>
</tr>
</tbody>
</table>

Avoiding 1 dialysis mortality is predicted save 4.5 years of life with additional ongoing dialysis costs. $469,000 + $-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,
Evaluation of economic impact of avoided dialysis mortality
Benefits attributed to the registry of $16m after discounting

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

Columns may not sum exactly due to rounding.

Observed improvement in graft loss rate is equivalent to 606 fewer grafts lost between 2004 and 2013.
# Evaluation of economic impact of avoided graft loss

For an individual eligible patient

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

Avoiding 1 graft loss is predicted save 2 QALYs

$425,000 + $358,000 = $783,000

...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.

Evaluation of economic impact of avoided graft loss

Benefits attributed to the registry of $39m after discounting

<table>
<thead>
<tr>
<th>Year</th>
<th>Number avoided (2004 rate)</th>
<th>Patients in Feedback Access Group</th>
<th>Attributed reduction in graft losses*</th>
<th>Unit $ Value</th>
<th>Economic benefit</th>
<th>Economic benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>%</td>
<td>Number</td>
<td>%</td>
<td>Number</td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td>99</td>
<td>52%</td>
<td>51</td>
<td>96%</td>
<td>49</td>
<td>$635k</td>
</tr>
<tr>
<td>2012**</td>
<td>84</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>$635k</td>
</tr>
<tr>
<td>2013</td>
<td>139</td>
<td>34%</td>
<td>48</td>
<td>57%</td>
<td>27</td>
<td>$635k</td>
</tr>
<tr>
<td>Total</td>
<td>322</td>
<td>99</td>
<td>76</td>
<td></td>
<td>$635k</td>
<td>$48m</td>
</tr>
</tbody>
</table>

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%
Observed improvement in peritonitis incidence rate is equivalent to 2573 fewer cases of peritonitis.
# Evaluation of economic impact of reduced peritonitis incidence

For an individual eligible patient

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

Avoiding 1 peritonitis hospital admission

...is predicted benefit QALYs

$\text{\$9,646}$

...and treatment costs

$\text{\$5,074}$

*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
### Evaluation of economic impact of reduced peritonitis incidence

Benefits attributed to the registry of $3.5m after discounting

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

*Columns may not sum exactly due to rounding.*

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

<table>
<thead>
<tr>
<th>Cost heading</th>
<th>Responsible for cost</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>Total 04-13</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development and maintenance</td>
<td>Not possible to break down</td>
<td>$1m</td>
<td>$1m</td>
<td>$1m</td>
<td>$1m</td>
<td>$1m</td>
<td>$10m</td>
</tr>
</tbody>
</table>

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.

Source: ANZDATA registry data – (interview)
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

Reduced dialysis mortality

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
<th>Source</th>
<th>2009-13 Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value of a life year</td>
<td>$50,000 to $182,000</td>
<td>OBPR</td>
<td>-$47m to $20m*</td>
</tr>
<tr>
<td></td>
<td>$182,000</td>
<td></td>
<td>$20m</td>
</tr>
</tbody>
</table>

Sensitivity analysis

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.
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

<table>
<thead>
<tr>
<th>Variable</th>
<th>Range of unit</th>
<th>Base</th>
<th>Source</th>
<th>Change impact</th>
<th>Base</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value of a life year QALY benefit</td>
<td>$50,000 to $182,000</td>
<td>$182,000</td>
<td>OBPR</td>
<td>$9m to $32m (minimum total benefit $25)</td>
<td>$32m</td>
<td>-72</td>
</tr>
<tr>
<td>Graft losses leading to re-graft</td>
<td>0-5.1%</td>
<td>0%</td>
<td>Registry data</td>
<td>$46m-$48m</td>
<td>$48m</td>
<td>-4</td>
</tr>
</tbody>
</table>

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 associated cost.
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

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
<th>Source</th>
<th>2009-13 Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Range of unit</td>
<td>Base</td>
<td>Change impact</td>
</tr>
<tr>
<td>Value of a life year QALY benefit</td>
<td>$50,000 to $182,000</td>
<td>$182,000</td>
<td>OBPR</td>
</tr>
</tbody>
</table>

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

Source: Health Outcomes Australia analysis; ANZDATA registry data. OBPR VSLY
Economic Value of CQRs

Case Study 5 – Australian Orthopaedic Association National Joint Replacement Registry
Established in 1999 with Australian Department of Health funding

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.

Source: Interview and AOANJRR 2015 Annual report
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

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**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.

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**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.*

<table>
<thead>
<tr>
<th>Loosening/lysis</th>
<th>Hip</th>
<th>Knee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection</td>
<td>47.8%</td>
<td>37.5%</td>
</tr>
<tr>
<td></td>
<td>14.1%</td>
<td>21%</td>
</tr>
</tbody>
</table>

---

**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

Cumulative benefits and costs attributed to AOANJRR

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

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

### 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

1999
Registry inception
- Funding from Department of Health
- Initially 9 South Australian Hospitals
- Declared a quality assurance activity*

2002
Complete coverage
- Staged national implementation. First full year of data presented in 2003 for hip and knee replacement

2007
Expansion to additional joints
- Shoulder, elbow, wrist ankle, spinal disc replacement covered with full national data reported from 2008

2008-9
Cost recovery
- Legislation passed in 2008 for Department of Health to cost recover from prosthetic device industry. Outcomes linked to individual surgeons through (opt-in) de-identified code

2012
Online system update
- Individual level outcomes provided through a new online environment that can be tracked in this analysis (Opt out from 2013 increased linkage from 86.3% to 93.3%).

Changes in guidelines and best practices should affect individual surgeons evenly. Where this isn’t true is in instances 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
The AOANJRR Identifies device outliers to inform licensing and selection through a three staged approach

<table>
<thead>
<tr>
<th>Stage 1 – Initial screening and identification of high revision rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automated analysis is performed within the registry to identify devices where the revision rate exceeds twice that of other similar devices in the same device category/class.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Stage 2 – Registry review and advanced analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registry staff (clinicians, statisticians, managers) review available information on all identified devices and examine the impact of known confounders (age, primary diagnosis, reason for revision etc.)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Stage 3 – Expert panel review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Senior clinicians from the Australian Orthopaedic Association review all analyses and meet with registry staff to critically evaluate the evidence and determine which devices should be reported as outliers.</td>
</tr>
</tbody>
</table>

**Identified devices are included in the Annual report** as 1) devices no longer used in Australia 2) devices identified as potential problems but still used 3) devices identified for the first time requiring further investigation.

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.

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

- 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*

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.

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Log in group</td>
<td>Improvement</td>
</tr>
<tr>
<td>Compared to non log-in</td>
<td>+25%</td>
</tr>
<tr>
<td>Proportion of cases</td>
<td>61%</td>
</tr>
</tbody>
</table>

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.
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%

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.

Equivalent to 6500 avoided revisions over the 12 year period

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.
Economic impact of reduced revision burden in hip replacement
For an individual eligible patient

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

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

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

<table>
<thead>
<tr>
<th>Year</th>
<th>Revisions avoided</th>
<th>Incremental improvement in case group</th>
<th>Proportion procedures in case group</th>
<th>Attributed revisions avoided*</th>
<th>Total benefit before discounting</th>
<th>Treatment costs avoided</th>
<th>Quality of life benefit</th>
<th>Total benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2003</td>
<td>70</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2004</td>
<td>229</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2005</td>
<td>305</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2006</td>
<td>411</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2007</td>
<td>538</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2008</td>
<td>564</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2009</td>
<td>686</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td>655</td>
<td>28%</td>
<td>61%</td>
<td></td>
<td>112</td>
<td>$7,890,492</td>
<td>$3,936,377</td>
<td>$2,292,449</td>
</tr>
<tr>
<td>2011</td>
<td>230</td>
<td>39%</td>
<td></td>
<td></td>
<td></td>
<td>$2,768,176</td>
<td>$1,340,754</td>
<td>$780,822</td>
</tr>
<tr>
<td>2012</td>
<td>501</td>
<td>86</td>
<td></td>
<td></td>
<td></td>
<td>$6,042,659</td>
<td>$2,841,490</td>
<td>$1,654,814</td>
</tr>
<tr>
<td>2013</td>
<td>1,033</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$12,455,184</td>
<td>$5,686,317</td>
<td>$3,311,571</td>
</tr>
<tr>
<td>2014</td>
<td>1,266</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$15,253,255</td>
<td>$6,760,927</td>
<td>$3,937,398</td>
</tr>
<tr>
<td>Total benefit</td>
<td>6486</td>
<td></td>
<td></td>
<td></td>
<td>629</td>
<td>$44,409,764</td>
<td>$20,565,867</td>
<td>$11,977,057</td>
</tr>
</tbody>
</table>

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
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

<table>
<thead>
<tr>
<th>vs &lt;=2002 baseline</th>
<th>-0.79</th>
<th>-0.15</th>
<th>-0.75</th>
<th>-0.66</th>
<th>-0.65</th>
<th>-0.72</th>
<th>-0.93</th>
<th>-0.64</th>
<th>-0.97</th>
<th>-0.91</th>
<th>-1.27</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avoided revision episodes</td>
<td>-</td>
<td>224</td>
<td>45</td>
<td>248</td>
<td>226</td>
<td>234</td>
<td>283</td>
<td>286</td>
<td>324</td>
<td>473</td>
<td>465</td>
<td>676</td>
</tr>
<tr>
<td>Attributed avoided revision episodes</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>69</td>
<td>78</td>
<td>113</td>
<td>112</td>
</tr>
</tbody>
</table>

Source: Registry data. Columns may not sum due to rounding.
Economic impact of reduced revision burden in knee replacement
For an individual eligible patient

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Change points</th>
<th>Unit used</th>
<th>Value of avoided knee revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 less revision procedure</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Treatment costs</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost of revision surgery</td>
<td>Major 66%</td>
<td>$46,317</td>
</tr>
<tr>
<td></td>
<td>Minor 34%</td>
<td>$23,473</td>
</tr>
<tr>
<td>Cost of complications</td>
<td>Readmission 3.9%</td>
<td>$5,007</td>
</tr>
<tr>
<td></td>
<td>Pulmonary embolism admission 0.16%</td>
<td>$6,573</td>
</tr>
<tr>
<td></td>
<td>Deep vein thrombosis 2.02%</td>
<td>$4,211</td>
</tr>
<tr>
<td></td>
<td>Pneumonia 0.8%</td>
<td>$2,374</td>
</tr>
</tbody>
</table>

| Quality of life adjustment       | Incremental QALY outcomes primary vs revision | 0.15 | 182,000 | $44,671 |

| Total value                      |                                           |       |         | $83,573 |

Avoiding 1 revision surgery $38,642 + $16,744 $55,386

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

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

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

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 attribution 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 prosthesis, 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 survivorship 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.

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 survival curve as described further in the annual report. *Based on qualitative 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

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

- 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 $1 million per annum over the total period of function**

Source: Health Outcomes Australia Analysis. AOANJRR data
Summary of benefits from reduction in hip replacement revision

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

Sensitivity analysis

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
<th>Source</th>
<th>2010-14 benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value of a life year QALY benefit</td>
<td>$50,000 to $182,000</td>
<td>OBPR</td>
<td>$4.5m to $16.3m</td>
</tr>
</tbody>
</table>

Source: Health Outcomes Australia analysis; AOANJRR registry data

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

<table>
<thead>
<tr>
<th>Year</th>
<th>Benefit ($k)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>5,600</td>
</tr>
<tr>
<td>2011</td>
<td>6,800</td>
</tr>
<tr>
<td>2012</td>
<td>8,000</td>
</tr>
<tr>
<td>2013</td>
<td>9,200</td>
</tr>
<tr>
<td>2014</td>
<td>10,400</td>
</tr>
</tbody>
</table>

Reduced revision burden

Sensitivity analysis

<table>
<thead>
<tr>
<th>Variable</th>
<th>Range of unit</th>
<th>Base</th>
<th>Change impact</th>
<th>Base</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value of a life year QALY benefit</td>
<td>$50,000 to $182,000</td>
<td>$182,000</td>
<td>OBPR</td>
<td>$6.5 to $23.8m</td>
<td>$6.5m</td>
</tr>
</tbody>
</table>

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

Source: Health Outcomes Australia analysis; AOANJRR registry data