The Role and Benefits of National Arthroplasty Registries.
Orthopaedic Surgeon Perspective

Presenter   SE Graves
Director AOANJRR
AOANJRR Background

- Fully owned by the Australian Orthopaedic Association
- Data collection commenced in 1999 with full national implementation in 2002
- Funded by the Federal Government (Federal legislation 2009 to ensure cost recovery process updated in 2015)
- Listed as a Federal Quality Assurance Activity
- Major impact on joint replacement surgery Nationally and Internationally
AOA Partners with

- South Australia Health and Medical Research Institute
- University of South Australia
AOANJRR Overview
(as of March 2016)

Participation Entirely Voluntary:

- Hospitals – 307 public & private (100%)
- Surgeons – 100% participation
- Patients – 34 ‘have opted off’
- Data on over 99% of procedures (Validated)
- Increasing at 5-7% per year (over 100,000 procedures p.a.)

Currently information on almost 1.2 million Procedures

- 502,397 hip procedures
- 597,435 knee procedures
- 33,288 shoulder procedures
- Almost 6 million individual prostheses components
Additional Devices

- Elbow
- Wrist
- Ankle
- Spinal Disc replacement
Purpose

Collect quality clinical evidence that can be used to identify and monitor the effect of factors impacting on the outcome of joint replacement surgery and provide that information to relevant stakeholders to enable action and continuous beneficial change.
Factors that Affect Outcomes

• Influenced by patient, surgeon, operative and prosthesis specific factors.
• The final result is a complex interaction between each of these.
• Registries are able to assess the relative importance of each of all relevant factors
• Almost all improvement in joint replacement in the last 10 years has been driven by registry data
Primary outcome measure

• Death
• Revision

• Reasons for revision
• Types of revision

• Patient, surgeon, hospital, and prosthesis factors that impact on revision
Additional Data Collection

- Comorbidity data (BMI ASA or more detailed)
- Adverse events other than revision
- PROM’s
- Radiological
- Prostheses Retrieval Data
- Data linkage (EHR, Administrative data sets, others)
Individual Devices
New prostheses 2003-2007

<table>
<thead>
<tr>
<th>Prostheses</th>
<th>Total</th>
<th>≥ 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hips</td>
<td>167</td>
<td>19.8%</td>
</tr>
<tr>
<td>Knees</td>
<td>99</td>
<td>28.3%</td>
</tr>
<tr>
<td>All</td>
<td>266</td>
<td>22.9%</td>
</tr>
</tbody>
</table>

New Prostheses introduced into Australia 2003-2007
## Outcomes

<table>
<thead>
<tr>
<th>Prosthesis</th>
<th>Total no. of components</th>
<th>Compared to the three best performing prostheses with CPR of 5 or more years</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>Better</td>
</tr>
<tr>
<td>Hip</td>
<td>33</td>
<td>0</td>
</tr>
<tr>
<td>Knee</td>
<td>28</td>
<td>0</td>
</tr>
<tr>
<td>All</td>
<td>61</td>
<td>0</td>
</tr>
</tbody>
</table>

Worse = p value < 0.05 on two tailed test
Prostheses 2008-2012

<table>
<thead>
<tr>
<th>Prostheses</th>
<th>Total</th>
<th>≥ 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hips</td>
<td>108</td>
<td>25.0%</td>
</tr>
<tr>
<td>Knees</td>
<td>63</td>
<td>31.7%</td>
</tr>
<tr>
<td>All</td>
<td>171</td>
<td>27.4%</td>
</tr>
</tbody>
</table>

New Prostheses introduced into Australia 2008-2012
### Outcomes

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<tr>
<td>Hip</td>
<td>27</td>
<td>0</td>
</tr>
<tr>
<td>Knee</td>
<td>20</td>
<td>0</td>
</tr>
<tr>
<td>All</td>
<td>47</td>
<td>0</td>
</tr>
</tbody>
</table>

Worse = p value < 0.05 on two tailed test
New prostheses 2003-2012

• Better outcome - 1 in 500
• Worse outcome - 30% not used in sufficient numbers to tell but of those where outcomes can be assessed then > 40% chance of worse outcome
AOANJRR Assessment of Devices

- Simultaneous comparison of all devices within the national setting
- There are differences in outcome individual devices, device specific features and whole classes of devices
- Patient and surgeon factors are always considered and they are important for some devices
- Statistically about 85% of devices perform the same as the best performing device in a particular class
- Of the remaining 15% some of those have a much higher rate of revision (outlier devices)
Australian Registry Approach to Identification of Prosthesis Outliers

- Multistage approach
  - Stage 1 (screening test 2x the risk of revision)
  - Stage 2 (review and further analysis examining impact of confounders)
  - Stage 3 Independent Panel Review
ASR XL Current Revision Rate

Cumulative Percent Revision

Years Since Primary Procedure

ASR vs Other Total Conventional Hip

0 - 1Mth: HR=0.69 (0.45, 1.08), p=0.102
1Mth - 9Mth: HR=1.11 (0.82, 1.50), p=0.506
9Mth - 1.5Yr: HR=3.47 (2.72, 4.42), p<0.001
1.5Yr - 2Yr: HR=5.95 (4.59, 7.72), p<0.001
2Yr - 3Yr: HR=12.66 (10.92, 14.68), p<0.001
3Yr - 5Yr: HR=23.08 (20.93, 25.44), p<0.001
5Yr - 5.5Yr: HR=27.39 (22.64, 33.13), p<0.001
5.5Yr - 6Yr: HR=22.71 (18.34, 28.13), p<0.001
6Yr - 8.5Yr: HR=16.82 (14.66, 19.31), p<0.001
8.5Yr+: HR=8.55 (5.57, 13.13), p<0.001

HR - adjusted for age and gender
Cementless Oxinium Genesis TKR

Cumulative Percent Revision

0%
10%
20%
30%
40%
50%
60%
70%
80%

Years Since Primary Procedure

Genesis II Oxinium Cless/MBK vs Other Total Knee

Entire Period: HR=17.28 (13.19, 22.63), p<0.001

HR - adjusted for age and gender
SMR Conventional Shoulder

Cumulative Percent Revision

Years Since Primary Procedure

SMR/SMR vs Other Total Conventional Shoulder

Entire Period: HR=3.36 (2.55, 4.41), p<0.001

HR - adjusted for age and gender
Individual Prostheses Identified

- Between 2004 and 2013 the Registry has identified 117 prostheses or combinations using this approach
  - 58 conventional hip
  - 6 resurfacing
  - 39 total knee
  - 9 Partial Knee
  - 5 conventional and/or reverse shoulder
# Best Prostheses

## 10 year Cumulative Percent Revision (OA, all Patients and all Reasons for Revision)

<table>
<thead>
<tr>
<th>Hips</th>
<th>Knees</th>
</tr>
</thead>
<tbody>
<tr>
<td>MS 30 Stem (n=2000)</td>
<td>Nexgen CR (n=10,500)</td>
</tr>
<tr>
<td>3 different acetabular components <strong>(2.4% - 3.5%)</strong></td>
<td><strong>(3.0%)</strong></td>
</tr>
<tr>
<td>Exeter V40 Stem (n=40,000)</td>
<td>Nexgen CR Flex (n=31,000)</td>
</tr>
<tr>
<td>6 different acetabular components <strong>(3.2% - 4.6%)</strong></td>
<td><strong>(2.9%)</strong></td>
</tr>
<tr>
<td>Secure Fit &amp; Secure fit Plus Stem (n=10,000)</td>
<td>PFC Sigma CR (n=21,500)</td>
</tr>
<tr>
<td>With Trident acetabular component <strong>(3.2% - 4.1%)</strong></td>
<td><strong>(3.7%)</strong></td>
</tr>
<tr>
<td>Summit Stem (n=3,500)</td>
<td>PFC Sigma PS (n=6,500)</td>
</tr>
<tr>
<td>Pinnacle acetabular component <strong>(2.9%)</strong></td>
<td><strong>(4.5%)</strong></td>
</tr>
</tbody>
</table>

50% of Hips have less than 5% revision at 10 years

25% of Knees have less than 5% revision at 10 years
Class of Device
Bearing Surfaces
Cumulative Percent Revision of Primary THR by Bearing Surface (OA)

MoM 15.5% at 12 years (Including large heads)
Cumulative Percent Revision of MoM Primary THR by Head Size (OA)

HR - adjusted for age and gender

Metal/Metal ≤28mm vs Metal/Metal ≤28mm
Entire Period: HR = 1.16 (0.90, 1.50), p = 0.240

Metal/Metal 36-40mm vs Metal/Metal ≤28mm
0 - 4.5Yr: HR = 1.87 (1.51, 2.32), p < 0.001
4.5Yr - 5Yr: HR = 3.53 (2.18, 5.74), p < 0.001
5Yr - 6.5Yr: HR = 2.16 (1.47, 3.17), p < 0.001
6.5Yr - 9Yr: HR = 3.36 (2.27, 4.98), p < 0.001
9Yr+: HR = 6.90 (3.75, 12.69), p < 0.001

Metal/Metal >40mm vs Metal/Metal ≤28mm
0 - 1Yr: HR = 1.28 (0.98, 1.67), p = 0.068
1Yr - 2Yr: HR = 2.37 (1.77, 3.17), p < 0.001
2Yr - 2.5Yr: HR = 4.24 (2.88, 6.23), p < 0.001
2.5Yr - 3Yr: HR = 4.24 (2.90, 6.18), p < 0.001
3Yr+: HR = 8.78 (7.17, 10.74), p < 0.001
# Cross-linked V’s Non Cross-linked Polyethylene in THR

<table>
<thead>
<tr>
<th>Years Since Primary Procedure</th>
<th>Non Cross-Linked</th>
<th>Cross-Linked</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 3Mth</td>
<td>HR=0.84 (0.74, 0.95), p=0.004</td>
<td></td>
</tr>
<tr>
<td>3Mth - 6Mth</td>
<td>HR=1.04 (0.82, 1.31), p=0.749</td>
<td></td>
</tr>
<tr>
<td>6Mth - 1.5Yr</td>
<td>HR=1.49 (1.30, 1.71), p&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>1.5Yr - 2.5Yr</td>
<td>HR=1.25 (1.05, 1.49), p=0.011</td>
<td></td>
</tr>
<tr>
<td>2.5Yr - 5Yr</td>
<td>HR=1.61 (1.41, 1.83), p&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>5Yr - 6.5Yr</td>
<td>HR=1.92 (1.59, 2.31), p&lt;0.001</td>
<td></td>
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<tr>
<td>6.5Yr - 9Yr</td>
<td>HR=2.25 (1.90, 2.67), p&lt;0.001</td>
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<tr>
<td>9Yr+</td>
<td>HR=3.10 (2.48, 3.89), p&lt;0.001</td>
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HR - adjusted for age and gender

Non Cross-Linked vs Cross-Linked
Reasons for Revision
Cross-linked V’s Non Cross-linked

Non Cross-Linked

Cross-Linked

Cumulative Incidence

Years Since Primary Procedure

Loosening/Lysis
Prosthesis Dislocation
Infection
Fracture
Pain
Excellent Post market surveillance system in an environment of ineffective Global Regulation

Joint replacement is a quality procedure which is being harmed by the current global approach to the introduction of new technology.

Need to change current approach to premarket technology assessment
Approaches to Premarket Clinical Evidence

- Mostly none
- Company Sponsored
- Beyond Compliance
- Australian Prostheses List
- Harvard Global Program
- FDA US Registries Coordinated Program

- Registries are integral to all the developing programs
Impact of Patient Factors
Resurfacing (Head Size & Gender)

HR - adjusted for age

Male <50mm vs Male ≥50mm
Entire Period: HR=2.06 (1.74, 2.45), p<0.001

Male ≥50mm vs Female ≥50mm
0 - 1.5Yr: HR=1.44 (0.83, 2.50), p=0.197
1.5Yr - 3Yr: HR=0.83 (0.46, 1.50), p=0.532
3Yr - 5Yr: HR=0.67 (0.38, 1.19), p=0.171
5Yr+: HR=0.50 (0.32, 0.79), p=0.003

Male <50mm vs Female <50mm
Entire Period: HR=0.60 (0.50, 0.71), p<0.001

Female <50mm vs Female ≥50mm
0 - 5Yr: HR=3.08 (1.83, 5.18), p<0.001
5Yr+: HR=2.05 (1.31, 3.20), p=0.001
Resurfacing (Head Size & Gender)

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Surgeon and Hospital
Surgeon Performance

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**Graph:**
- **X-axis:** Total Number of Procedures
- **Y-axis:** Standardised Rate

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**Legend:**
- Blue dots
- Red line
Surgeon Performance

![Graph showing surgeon performance with a point marked for Surgeon 404.](image-url)
Reasons why a Surgeon is an outlier can be identified.
Enhancing Surgeon Performance

• Surgeons can review their own performance through secure confidential website access
• Privacy of Information protected by Government Legislation
• Many examples of assisting surgeons to improve outcomes
• Registry increasing the information provided
• AOA addressing the issue of surgeons who don’t review data
• CPD points for contributing, reviewing and consulting with trusted colleagues about own performance
Hospital performance varies

• Standardised reports to assess hospital performance
• Hospitals use this information to identify problems and areas for improvement
• Develop policies to enhance outcomes based on registry data
• Some hospitals are considering releasing data publically
What makes a quality registry

Optimised to bring about beneficial change

- Governance
- Ownership
- Data Quality
- Availability and delivery of information to all stakeholders
- Integration into the health care system
- International collaboration
What makes a quality registry

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- International collaboration
AOANJRR Provides Information to Multiple Stakeholders

- Surgeons
- Consumers
- Government Health Departments
- Government Regulators
- Hospitals and Health Care Systems
- Medical Device Companies
- Health Insurers

Nationally and Globally
AOANJRR Provides Information to Multiple Stakeholders

• Annual Report (15 separate reports)
• Secure stakeholder specific internet access (surgeons regulators and government and industry)
• Ad hoc reports (300 individual data requests each year) from government, industry, surgeons and research organisations
• Stakeholder specific websites
Global Map of Data Use

214 countries
Integration into Health Care Systems

- Detailed analyses of identified prostheses provided to Regulator on release of annual report
- This is independently reviewed by regulator nominated physicians that provides advice to regulator on required actions.
- Up classification of joint prostheses from Class IIB to Class III
- Department Health uses data used to determine if devices are reimbursed and the level of reimbursement.
International Collaboration

• With other individual registries
• ISAR
• ICOR
• Benchmarking
• Registry nested trials
Are Registries Effective?

• The revision burden is decreasing:
  - *Revision hip procedures* have decreased as a proportion of all hip procedures from *13.1%* in 2002 to *10.2%* in 2014
  - *Revision knee procedures* have decreased as a proportion of all knee procedures from *8.8%* in 2004 to *7.7%* in 2014

• Over $600 million in savings to the Australian Health Care system in the last ten years

• Flow-on savings internationally
Thank You