Senate Community Affairs References Committee

ANSWERS TO QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Inquiry into the Regulatory Standards for the Approval of Medical Devices
27 September 2011

Question no: 1

Topic: The implementation of the December 2009 *Review of Health Technology Assessment in Australia* (HTA Review) recommendations 13, 14 and 15.

Hansard Page: 59

Senator Moore asked: …. "in terms of the report of the **Health Technology Assessment review, what is happening with the three recommendations, I think, that the government did not pick up on—recommendations 13, 14 and 15**?"

Answer:
In accepting the Report of the *Review of Health Technology Assessment in Australia* (HTA Review) on 27 February 2010, the Government asked the Department of Health and Ageing to:

1. immediately commence implementation of the 13 (of 16) recommendations that could be implemented within existing resources; and
2. provide further policy advice on recommendations 13, 14 and 15 which relate to post market surveillance, due to the financial costs associated with their implementation.

These three recommendations remain under consideration by Government, and no decision has been made regarding the manner or timing of their implementation.

Senate Community Affairs References Committee

ANSWERS TO QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Inquiry into the Regulatory Standards for the Approval of Medical Devices
27 September 2011

Question no: 2

Topic: First meeting of OEWG

Hansard Page: 47

Senator Xenophon asked:

When did the Orthopaedic Expert Working Group first meet?

Answer:

8 August 2007.

Senate Community Affairs References Committee

ANSWERS TO QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Inquiry into the Regulatory Standards for the Approval of Medical Devices
27 September 2011

Question no: 3

Topic: Information exchange with OEWG

Hansard Page: 49

Senator Xenophon asked:

Can TGA provide the exchange of information between the TGA and the Orthopaedic Expert Working Group (OEWG) relating to the ASR hip, where the OEWG said 'We don't need to do any more on this'?

Answer:

The minutes of OEWG meetings are provided in the response to a separate question. The relevant extract can be found at Item 5.4 of the OEWG meeting outcome record for the meeting of 21 May 2008, indicating OEWG was happy that no further action was required at that stage but that continued monitoring remains appropriate.

Senate Community Affairs References Committee

ANSWERS TO QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Inquiry into the Regulatory Standards for the Approval of Medical Devices
27 September 2011

Question no: 4

Topic: Minutes of OEWG meetings

Hansard Page: 50

Senator Xenophon asked:

Can TGA please provide the minutes of the Orthopaedic Expert Working Group in the period from when it was convened in 2007 to December 2009, when the ASR hip was removed from the Australian market.

Answer:

Attached are:

A. Minutes of 8 August 2007 meeting
B. Minutes of 21 February 2008 meeting
C. Minutes of 21 May 2008 meeting
D. Minutes of 18 June 2008 meeting
E. Minutes of 9 December 2009 meeting

ORTHOPAEDIC EXPERT WORKING GROUP (OEWG)
2007/1 MEETING
8 August 2007, 6.30PM

DRAFT MEETING RECORD & OUTCOMES

List of Participants:

Members:	Professor Guy Maddern (Chair) Mr Peter Devane Professor Stephen Graves Mr Bruce Love A/Professor David Morgan Dr Peter Myers
TGA advisers:	Dr Richard Pembrey, Chief Clinical Advisor, Office of Devices, Blood & Tissues Dr Larry Kelly, A/g Director, Office Devices Blood and Tissues Ms Shelley Tang, Head, Medical Devices Assessment Section Dr Jorge Garcia, Manager, Devices Program, TGA Laboratories Ms Linda Punyer, Head, Marketing Vigilance and Monitoring Unit
Secretariat:	Ms Suzanne Petrie Mr Shawn Hazel Ms Jennifer Terwiel
Apologies:	Dr David Hale (joined meeting late)

Item 1 Welcome

1.1 The Chair welcomed members.

Item 2 Disclosure of Interest

2.1 One member provided a conflict of interest disclosure.

Item 3 Terms of Reference for the Orthopaedic Expert Working Group

3.1 The committee found the terms of reference adequate and were accepted. The agreed terms of reference are as follows.

1. To review available clinical data and other relevant information provided by the manufacturer and advise on whether the early revision rate is acceptable for the prostheses of concern identified in the 2006 report of the NJRR. This includes –

- assessment of clinical data and other relevant information and advice on whether the early revision rates associated with the joint replacement are acceptable;

- consideration of whether the higher than average rates of early revision for the identified implants is related to implant design or manufacture;
- if there is a link between implant design or manufacture and the revision rates, advice on whether the benefit of joint replacement exceeds the higher risk of early revision, and consideration of features of the implant design and expected performance that compensate for the early revision rate associated with the joint replacement;
- advise on whether there is reason to be concerned about the identified prostheses and whether there is a need for regulatory action.

2. To advise on whether a higher level of TGA review of clinical evidence at the pre-market phase may have identified implants with the higher revision rates.
3. To advise whether the risk classification of orthopaedic implants needs to be upgraded from Class IIb to Class III, or whether other mechanisms for a greater level of pre-market assessment should be implemented.

The Expert Working Group is to report their findings to the MDEC and TGA.

Item 4 Report to the Orthopaedic Expert Working Group

4.1 A background report was given by a representative from the National Joint Replacement Registry (NJRR) outlining the role of the NJRR and the issues that have been identified through review of clinical data by the Registry. The 2007 Report identified a number of prosthesis with a high early revision rate of hips and unicompartment knees (knees are not included in this discussion). The outcomes from the Report by the Registry identified individual prostheses groups, regularly identifying an increased rate of revision of these prostheses at twice the anticipated rate compared to similar products. The standard used to identify higher than normal revision rates is 2x anticipated rate of revision compared against other prosthesis from the same prothesis group being cemented or non-cemented prosthesis.

4.2 For each of the hip prostheses identified in the 2006 NJRR report as having higher than normal revision rates, the TGA compiled the following information for the OEWG to consider in relation to Term of Reference 1:

a) A full report provided to the TGA from the NJRR database outlining the number implanted, the number revised, the component that was revised, the reasons for revision, and other implantation and revision information, including the number and spread of implanting and revising hospitals (but not their identity).

b) A full, unedited copy of the response from each prosthesis' sponsor in Australia to TGA's request for information dated 19 December 2006. The request for information asked for the manufacturer's own revision statistics. Importantly it also asked for a statement of benefits associated with their implant's design that may compensate for the perceived higher risk of revision associated with their implant.

c) A summary of the information provided in a) and b) above along with the TGA's initial assessment of the information provided.

In some cases, the OEWG also considered more up to date but as yet unpublished data from the NJRR.

The OEWG's deliberations in relation to each implant were as follows:

4.3 EPF PLUS CEMENTLESS ACETABULAR CUP
Sponsor/Manufacturer: Smith & Nephew.

4.3.1 Revision rates associated with dislocation due to head size (28) with a 50% revision rate. This decreased with the insertion of larger heads sizes 32-36.
Other reasons for early revision could be due to impingement or the use of poor instrumentation.

4.3.2 A question was raised: Why are there no revisions for infections included?

4.3.3 The reporting rate for many of the infections is low, at 0.3%.
Infection rates may also be underestimated, there are infections rates included in the loosening and pain groups. One of the assumptions is that if there is no problem with the packaging of the device, it is presumed there is no problem with infection across the board. Concerns were raised regarding whether the larger sized heads may cause edge wear.

4.3.4 Of the 400 prostheses implanted this year with larger head size, the revision rate is now running the same as other prostheses and is now considered acceptable by the NJRR.

4.3.5 A member requested the TGA to investigate further as many other implants use size 28 heads without any problems. The instrumentation appears to be problematic as it prevents the ability to optimise positioning of the device. If impingement is the cause, TGA needs to investigate now as high dislocation may be an early sign of impingement.

4.3.6 Recommendation: The OEWG advised that the TGA investigate the EPF Plus Cementless Acetabular Cup further.

4.4 INTER-OP CEMENTLESS ACETABULAR CUP
Sponsor / Manufacturer: Zimmer / Sulzer

4.4.1 This product was withdrawn from the market after a recall in 2000. Not in use in this country for at least 3 years. The lubrication oil used in the device was found to be endotoxic.

4.4.2 No further discussion on the Inter-op Cementless Acetabular Cup was conducted by the Working Group.

4.5 ARTEK CEMENTLESS ACETABULAR CUP
Sponsor/ Manufacturer: Centerpulse (Zimmer)/ Artek (Unsure of M/F)

4.5.1 This product was last used in 2002. Revision rate of prosthesis was 15% at 5 years. Integration with the back surface of the prosthesis was not successful and there was loosening in almost 60% of cases.

4.5.2 Recommendation: It is the OEWG's finding that the Artek Cementless Acetabular Cup revision rate is unacceptably high. The OEWG advised that there is a need for regulatory action and suggested that the prosthesis should not be made available on the Australian market and that it be withdrawn from the Register.

4.6 REVITAN CEMENTLESS FEMORAL STEM
Sponsor/Manufacturer: Centerpulse (Zimmer)/ Revitan (Unsure of M/F)

4.6.1 Revision rate of 7% at 3 years, company states discontinued supply of product in 2004. However, two prostheses were implanted in 2005 and one in 2006 raising the question as to whether some hospitals may still have stock of this device on consignment.

4.6.2 Committee agreed they do not support this product.

4.6.3 Recommendation: The OEWG advised that the TGA ask the sponsor to ensure that all Revitan Cementless Femoral Stems are removed from the market by contacting hospitals who may still have stock on shelves.

4.7 ALLOCLASSIC CEMENTLESS STEM/FITMORE ACETABULAR COMPONENT
Sponsor /Manufacturer: Zimmer

4.7.1 Two quite well established prostheses and have no issue with the revision rate. Professor Graves suggested the NJRR keep a watching brief and suggested it may be necessary later down the track to look for an explanation for the statistics for this combination as these two prostheses are amongst the better performing hips.

4.7.2 Recommendation: The OEWG advised that there was not a need for regulatory action at present in regard to the Alloclassic Cementless Stem/Fitmore Acetabular Component.

4.7.3 Action: TGA to keep a watching brief on the Alloclassic Cementless Stem/Fitmore Acetabular Component.

4.8 MARGRON DTC FEMORAL COMPONENT
Sponsor /Manufacturer: Portland Orthopaedics

4.8.1 Prosthesis is identified as having a higher than average revision rate which has been running at 10.6% at 4-5 years for a number of years. Prostheses performance in general is not very good. The OEWG noted the company's submission to the TGA, however considered the continued high revision rate to be unacceptable. Although the company claimed this device is used in revision surgery for very challenging cases and there are no other devise available to accommodate this specific need, the members did not agree with this argument noting these revisions are for primary surgery and there are prosthesis available for difficult revision surgery that perform very well. Members noted that approximately 650 implants were conducted on patients with normal OA.

4.8.2 Recommendation: It is the OEWG's finding that the revision rates for the Margron DTC Femoral Component is unacceptably high and that the implant has no redeeming design features that may compensate for the higher risk of revision associated with this implant. The OEWG advised the cancellation of the Margron DTC Femoral Component from the Register.

4.9 DELTA ACETABULAR COMPONENT
Sponsor/ Manufacturer: Orthotec Orthopaedic Group

4.9.1 Last year there were a small number of revisions- 235 procedures undertaken with 8 revisions in the first 12 months, two for infection, two for fracture, one for dislocation and three for loosening.

4.9.2 Revision rate is very high for this product mostly within the first 12 months relating to loosening after insertion. There have been no subsequent revisions, post initial revision.

4.9.3 Members acknowledged there is limited data and limited clinical evidence and suggested this prosthesis be targeted for a watching brief.

4.9.4 Recommendation: The OEWG advised that there was not a need for regulatory action at present in regard to the Delta Acetabular Component.

4.9.5 Action: TGA will keep a watching brief and undertake a review of the Delta Acetabular Component.

4.10 LIMA SHP BLIND ACETABULAR CUP
Sponsor/Manufacturer: Orthotec Orthopaedic Group / Lima

4.10.1 There have been 148 implanted with revision rate of 6.4% at 4 years and has increased over a number of years, but should be 3% at same stage with other cups. One of the problems identified is that it has been used with a number of other stems.

4.10.2 Reason for early revision for this cup is dislocation and loosening. Members noted that 120 have been used with the Margron hip and questions whether the problem is with the Lima acetabular cup or a mismatch with the Margron hip and requested further information.

4.10.3 Action: The NJRR to supply further information to the OEWG on the Lima SHP Blind Acetabular Cup.

4.11 ESOP CEMENTLESS FEMORAL STEM/ATLAS ACETABULAR COMPONENT
Sponsor/Manufacturer: Orthotec Orthopaedic Group

4.11.1 No further revisions, the rates have decreased with this combination, both the femoral and acetabular components are considered acceptable.

4.11.2 Recommendation: The OEWG advised that there was not a need for regulatory action at present in regard to the ESOP Cementless Femoral Stem/Atlas Acetabular Component.

4.11.3 Action: The NJRR to keep a watching brief on the ESOP Cementless Femoral Stem/Atlas Acetabular Component.

4.12 H MOOS CEMENTED FEMORAL STEM/MUELLER ACETABULAR COMPONENT.
Sponsor/Manufacturer: Orthotec Orthopaedic Group / Lima

4.12.1 Stem has had a high revision rate and has not been used in this country for many years. It is not known if this product has been officially withdrawn. The Mueller cup will be identified this year in the new Report as being a concern.

4.12.2 Recommendation: The OEWG found that the revision rate of the H Moos Cemented Femoral Stem/Mueller Acetabular Component is unacceptably high. The OEWG advised that the prosthesis should be cancelled from the Register.

4.13 CHARNLEY LPW ACETABULAR CUP/ELITE PLUS STEM
Sponsor/Manufacturer: Johnson & Johnson Medical

4.13.1 There is a growing concern within the orthopaedic community in regard to this combination. The revision rate is continuing to rise at a rate of 9.96% at 5 years even though the combination has not been used since 2003.

4.13.2 This combination is regularly used in New Zealand to treat fractured neck of femur and it was noted that the Elite Plus stem is dependant on the acetabular component used with it and does perform well with other acetabular cups.

4.13.3 Action: The OEWG will defer providing advice to the TGA regarding the Charnley LPW Acetabular Cup/Elite Plus Stem until more information is available from the NJRR.

4.14 ELITE PLUS FEMORAL STEM / APOLLO ACETABULAR CUP
Sponsor / Manufacturer: Johnson & Johnson (Depuy)

4.14.1 Only small numbers have been implanted and revision rates appear to be in decline.

4.14.2 Recommendation: The OEWG advised that there was not a need for regulatory action at present in regard to the Elite Plus Femoral Stem/Apollo Acetabular Cup.

4.14.3 Action: The NJRR to keep a watching brief on the Elite Plus Femoral Stem/Apollo Acetabular Cup.

4.15 PROFEMUR FEMORAL STEM
Sponsor/ Manufacturer: Advanced Surgical Technologies / Wright Medical Technologies

4.15.1 NJRR expressed disappointment to the company's response to the analysis report stating that the analysis could be for a number of products. What was reported last year related to one product, the Profemur Z. This year's report will identify the Profemur Z from all other models of the Profemur implants. Performance this year is indicating a revision rate of 8.4% after 2 years over 104 prostheses implanted.

4.15.2 Members were unanimously agreed there is a problem with this implant and suggested the company is aware of the issue. There has been no independent analysis of the company's response.

4.15.3 Recommendation: The OEWG advised that the TGA request that the sponsor show cause why the Profemur Femoral Stem should stay on the market.

4.15.4 Action: TGA to obtain further information and undertake a product review of the Profemur Femoral Stem.

4.16 LINEAGE ACETABULAR CUP SYSTEM
Sponsor / Manufacturer: Advanced Surgical Technologies / Wright Medical Technology

4.16.1 The Cup was considered by the members to be acceptable. The problem seems to be occurring when the Cup is used in a combination with certain stems such as the Profemur and the Margron. When used with other stems there has been only one revision.

4.16.2 Recommendation: The OEWG advised that there was not a need for regulatory action at present in regard to the Lineage Acetabular Cup System.

Item 5 Proposal for Reclassification of Joint Implants

5.1 There was a preliminary discussion on the proposal for the reclassification of Joint Implants from Class IIb to Class III.

5.2 It was noted that there appeared to be very little clinical data provided to the OEWG that could have flagged the issues relating to early revision rates before the products were approved for supply.

5.3 A comment was made that the amount of clinical evidence provided is minimal; therefore there may be a need to consider what type of data is required for the OEWG's consideration.

5.4 The TGA noted that there is a different level of scrutiny of the clinical evidence between class IIb and class III - a class IIb does not have the design examination which includes full review of clinical data. Example: Margron underwent a Conformity Assessment as a class IIb, which had an assessment to ensure that clinical evidence was present and complete and not a full review as with a design examination. The TGA will provide additional advice on its requirements and assessment processes for class IIB and III medical devices.

5.5 The TGA noted that the OEWG has the benefit of reviewing outcomes with five years of history. The TGA does not have this in a pre-market assessment. It is a choice between allowing access to devices or waiting for evidence to be generated.

5.7 It was noted that where clinical data is not strong, there should be limited release of the product.

5.10 A member noted that with well performing prostheses, if there is a change in the manufacturing process this can change the performance of the device.

5.11 A member raised concerns regarding the reclassification of the prostheses to class III, which will restrict products coming onto the market or limit access to new technologies.

5.12 The Chair noted that the EU has reclassified joint implants to class III. The issue of reclassification in Australia is to be addressed more fully at the next meeting.

Item 6 Next Meeting:

6.1 - Consider the issue of reclassification in depth;
- Review a number of identified prostheses after NJRR provides further data;
- Next meeting to be convened in 6 weeks – via teleconference.

6.2 The Chair will report on the Committee's progress at the next MDEC meeting (31 August 2007).

The Chair thanked members for participating. The meeting closed at 8.40pm.

Professor Guy Maddern
OEWG Chair
August 2007

ORTHOPAEDIC EXPERT WORKING GROUP (OEWG)
2008/1 MEETING
21 February 2008, 7.30PM EDST

RATIFIED MEETING RECORD & OUTCOMES

List of Participants:

Members: Professor Guy Maddern (Chair)
Mr Peter Devane
Professor Stephen Graves
Mr Bruce Love
Dr David Hale
Dr Peter Myers

TGA advisers: Rita Maclachlan, Director, Office of Devices, Blood & Tissues (ODBT)
Richard Pembrey, Chief Clinical Advisor, ODBT
Shelley Tang, Head, Medical Devices Assessment Section (ODBT)
Michael Flood, Head, Application Entry & Coordination Section (ODBT)
Jorge Garcia, Manager, Devices Program, TGA Laboratories
Secretariat: Jennifer Terwiel (ODBT)

Apologies: Professor David Morgan

Item 1 Welcome

1.1 The Chair welcomed members.

Item 2 Disclosure of Interest

2.1 One member disclosed a potential conflict of interest: he is in the process of developing sporting equipment with a company which manufactures joint replacements. This connection was not considered to be a conflict of interest for the purposes of the matters under discussion.

Item 3 Minutes of the Previous Meeting

3.1 The minutes of the 2007/1 OEWG meeting were accepted as a true and accurate record.

Item 4 Options for Assessment of Joint Implants

4.1 Members considered the paper prepared by the TGA on options for assessment of joint implants. The discussion related to the requirements for pre-market assessment, covering both the Essential Principles and Conformity Assessment procedures; whether

if an upgrade from Class IIb to Class III should be implemented as a mechanism for a higher level of TGA review of clinical evidence at the pre-market phase.

4.2 A member noted that his view of the issues in the paper for discussion is similar to those agreed by the Arthroplasty Society of Australia at its 2007 meeting. Other members concurred. The issue is not a matter of class, but the appropriate level of clinical evidence and how best to achieve this.

4.3 The alternatives to changing the classification of joint implants were discussed. These included looking at whether it would be more effective to establish guidelines to delay entry onto the Australian Register of Therapeutic Goods (ARTG) for new joint replacements until the device has been in the global market for two years to permit the device to be assessed for performance in a post-market framework. This would delay entry into the Australian market. A member noted that clinical demand for prostheses should be kept in mind. Concern was expressed in establishing a system which prevents new prostheses from entering the Australian market until two years of post-market data can be assessed if there is clinical demand from the orthopaedic community.

4.4 It was suggested the clinical assessment of the existing Prostheses Devices Committee (PDC) Clinical Advisory Groups (CAGs) which provide advice to the Minister for Health and Ageing on the prostheses and devices for private health insurance purposes could contribute to this process. TGA clarified that TGA has a different mandate to the CAGs. CAGs assessed among other matters, the cost effectiveness. The TGA does not consider cost effectiveness in assessing the safety, quality and performance of a device. A member noted that the CAGs are picking up a number of products where there is no evidence of performance. The need for feedback to the TGA was noted.

4.5 Members noted there can be no assurance that reclassifying joint replacement prostheses to Class III will mean that prostheses entering the Australian market will not require revision surgery earlier than expected.

4.6 Clarification was sought on the process for accessing clinical evidence when there is a modification to a device. TGA responded that for a Class III and depending on the type of new design, new clinical evidence may be provided by the sponsor. This may mean additional clinical studies. A member asked if an alternate manufacturer produces a version of product already available would this also require the manufacturer to provide additional clinical data. TGA responded that the manufacturer should do so, unless they can demonstrate clinical equivalence. A manufacturer may choose to, in part, demonstrate the performance of a device by demonstrating equivalence with a product already in the market.

4.7 The committee considered five options:

1. Maintain the classification as Class IIb using the same TGA processes for ARTG inclusion
2. Maintain Class IIb, but mandate an application audit for the prosthesis
3. Reclassify to Class III
4. Reclassify as Class III and mandate conformity assessment by the TGA
5. Reclassify as Class III, with TGA conformity assessment and require all new prostheses to be clinically superior to those already on the market

4.8 In considering the listed options all members concurred that Option 1 (maintain the classification as Class IIb without additional requirements) was not an option because of concerns expressed by a number of stakeholders that currently applications are made to CAGs where the clinical evidence is inadequate or lacking entirely.

4.9 Option 2 (maintain Class IIb, but mandate an application audit for the prosthesis) would allow TGA to request the manufacturer's clinical expert report. The TGA would assess the expert evaluation of the evidence. If the expert report does not satisfy the Essential Principles, TGA may reject the application for entry onto the ARTG. Option 2 could be introduced immediately through TGA's discretionary powers, and eventually could be mandated.

4.10 An application audit is not mandated by legislation for most Class IIb devices. A member asked whether a discretionary audit has been undertaken in the past for a prosthesis. TGA responded that such audits have been undertaken, but not for hip prostheses. A member asked whether the clinical evidence would be available for Class IIb devices where a discretionary application audit was undertaken. TGA responded that if the device has gone through the CE marking process, the evidence should be available.

4.11 One advantage in adopting Option 2, where joint replacement prostheses would remain as Class IIb with an application audit, is that it can be implemented immediately. Experience with this process may eventually lead to reclassification to Class III.

4.12 In considering Option 3 (reclassify to Class III), it was noted that Option 2 keeps TGA aligned with the Global Harmonization Task Force (GHTF) model. Option 3 would mandate an application audit, and with regard to assessing clinical evidence it would be the same as Option 2. It was noted that it would be possible to obtain evidence under Option 2, if this showed clinical evidence was not an appropriate level, then a case could be made to move to Class III with a full TGA clinical assessment.

4.13 Clarification was sought about interaction between TGA and GHTF. TGA explained that GHTF is a forum composed of the European Union, the United States, Japan, Australia and Canada. The GHTF aims to enhance convergence of medical device regulatory requirements to reduce duplication of assessments by regulation, reduce the burden on industry and provide an environment for enhancing patient safety.

4.14 Australia's regulation of medical devices is aligned closely with the GHTF framework. Changing the classification would be a significant step away from GHTF recommendations. However, the European Union has reclassified joint prostheses to Class III already. Option 2 would allow TGA to gather a body of evidence over approximately a twelve month period, and reconvene the OEWG for advice following implementation of the Option 2 proposal.

4.15 Option 4 (reclassify as Class III and mandate conformity assessment by the TGA). Members noted this option would mean that TGA would assess the clinical evidence in its entirety, including undertaking a literature review, assessing the manufacturing process, assessing the design of the prosthesis, and any clinical trial data. This is a lengthier, resource intense process. When asked if this would mean that manufacturers would be deterred from applying for their products to be placed on the ARTG, TGA noted that it would be a significantly more expensive process, but the patient safety is always the paramount consideration. It was noted that the level of information

available regarding models, brand names and other identifying information, on the ARTG for Class III products is significantly greater. This is an advantage in dealing with post-market incident report and recalls. TGA noted that the TGA does have flexibility within the regulations and if there are very clear public safety reasons, information could be recorded more fully on the ARTG.

4.16 Members came to the view that a more detailed listing on the ARTG to identify the individual devices would be of use, particularly if this could be mandated for Class IIb. It was noted this approach would require a change to the Therapeutic Goods (Medical Devices) Regulations 2002, but it can be done.

4.17 Option 5 (reclassify as Class III, with TGA conformity assessment and require all new prostheses to be clinically superior to those already on the market) was not supported. A number of difficulties were identified, including that the first device to market would be advantaged – this is anti-competitive in the context of the US Free Trade Agreement; possible delays in bringing state-of-the-art products to the Australian market, so that the timeliness of advances in treatment may be lost; and a number of practical difficulties such as the difficulty of defining "superiority", and a determination of whether the claimed superiority is clinically necessary.

4.18 The Working Group reached agreement on Option 2, which will allow TGA to gather data on whether companies do have clinical evidence, and if so if it is adequate, to review the situation after a twelve month period, to identify whether reclassification to Class III is warranted. It was noted that as part of the review process in twelve months, the OEWG could assist the TGA in identifying the crucial elements of the clinical evidence for joint replacement prostheses.

Recommendations:

The OEWG recommends that:

- **The class IIb classification should be maintained for orthopaedic implants, with the addition of a mandated application audit. This will enable the TGA to review:**
    - **a summary of the clinical evidence, including an expert report and evidence to support the expertise of its author**
    - **the risk analysis performed by the manufacturer**
    - **copies of representative information accompanying the device - labelling, instructions for use, and any advertising material**
    - **an essential principles checklist that summarises the conformity to each applicable essential principle**
    - **the design examination or type examination report**
    - **manufacturer's documentation supporting quality system audits**
- **Classification of orthopaedic implants as Class IIb should be reviewed after twelve months of implementation of the new requirement, to assess whether new applications are supported with appropriate clinical evidence.**

- **Identification of orthopaedic implants on the Australian Register of Therapeutic Goods should be improved, for example to include individual models and brand names where applicable, to assist in identification of these devices for post-market purposes.**
- **TGA undertake a retrospective review of clinical evidence for already approved orthopaedic implants.**

Item 5 Other business

5.1 A member asked when the follow up data from the National Joint Replacement Registry (NJRR) identified for discussion by the 2007/1 OEWG meeting would be available to the group, and when the 2007 NJRR report would be discussed. This data has been provided to the TGA by the NJRR.

Action item: Director ODBT to discuss this matter with the OEWG Chair.

Item 6 Next Meeting:

6.1 Members expressed a wish for a face to face meeting to aid in discussion of the information in the NJRR report.

Action item: TGA will endeavour to organise a face to face meeting for the OEWG.

6.2 The Chair will report on the Committee's progress at the next MDEC meeting (28 March 2008).

The Chair thanked members for participating. The meeting closed at 8.30pm.

Professor Guy Maddern
OEWG Chair
27 March 2008

ORTHOPAEDIC EXPERT WORKING GROUP (OEWG)
2008/2 MEETING
21 May 2008, 6.30PM EST

RATIFIED MEETING RECORD & OUTCOMES

List of Participants:

Members:	Professor Guy Maddern (Chair)
	Mr Peter Devane
	Professor Stephen Graves
	Mr Bruce Love
	Dr Peter Myers
TGA advisers:	Dr Larry Kelly, A/g Director, Office of Devices, Blood & Tissues
	Michael Flood, Office of Devices, Blood & Tissues
	Jorge Garcia, Manager, Devices Program, TGA Laboratories
Secretariat:	Jennifer Terwiel
	Shawn Hazel
	Fiona Mildner
Apologies:	Professor David Morgan
	Dr David Hale

Item 1 Welcome

1.1 The Chair welcomed members.

Item 2 Disclosure of Interest

2.1 One member disclosed a potential conflict of interest as he had a connection with two of the manufacturers whose products were reviewed. This connection was not considered to be a conflict of interest for the purposes of the matters under discussion.

Item 3 Minutes of the Previous Meeting and Action List

3.1 The minutes of the 2008/1 OEWG meeting were circulated out of session and accepted as a true and accurate record. Members reviewed the Action List.

Item 4 Review of prostheses identified at the 2007/1 OEWG meeting for further consideration

4.1 Delta Acetabular Component

4.1.1 The TGA observed that there was a low number of implants for this prosthesis, leading to wide confidence limits in the revision rate. Two of the eight revisions were due to infection, infection-related revisions do not generally indicate design-related

problems. Of the remaining revisions, the Delta acetabular component was removed on only two occasions. This observation was also made by the sponsor. TGA noted that the implant was used at a large number of hospitals across Australia, however the revisions were localised to four hospitals in Queensland.

4.1.2 Members considered that it would be advisable to observe the performance of the Delta Acetabular Component over a longer period of time.

Advice: The Working Group advised that the performance and revision rate of the Delta Acetabular Component should continue to be observed.

4.2 Charnley LPW Acetabular Cup/Elite Plus Femoral Stem

4.2.1 The TGA observed that the number of implants for this combination of prostheses is low, and the revision rate high. Of the nine revisions, four are due to infection. There do not appear to have been further implantations of this combination of components since the release of the 2006 NJRR report.

4.2.2 A member noted that this combination of prostheses may be used in different patient populations which may lead to different outcomes – for example this combination is sometimes used in the broken hip population which is prone to infection. Patient data is not available to the Working Group which makes it difficult to assess and compare some prostheses or combination of prostheses.

4.2.3 Members considered that it would be advisable to observe the performance of this combination over a longer period of time.

Advice: The Working Group advised that the performance and revision rate of the Charnley LPW Acetabular Cup/Elite Plus Femoral Stem combination should continue to be observed.

4.3 ESOP Cementless Femoral Stem/Atlas Acetabular Component

4.3.1 The TGA observed that the number of implants for this combination of prostheses is low, leading to a wide confidence limit on the revision rate. There have been four revisions by two surgeons, and no revisions in the 06/07 year. The revision rates have dropped dramatically, with the confidence limits overlapping that of the global average.

4.3.2 Members discussed the combination of prostheses, noting that the numbers are too low for a decision to be made regarding this implant. A member asked whether the combination was being implanted by a number of orthopaedic surgeons, or being implanted by one or two surgeons only. This data is not available through the NJRR, however the data indicates that the revision rate is a consequence of a learning curve.

4.3.3 Members considered that it would be advisable to observe the performance of this combination over a longer period of time.

Advice: The Working Group advised that the performance and revision rate of the ESOP Cementless Femoral Stem/Atlas Acetabular Component combination should continue to be observed.

4.4 Elite Plus Femoral Stem/Apollo Acetabular Cup

4.4.1 The TGA observed that since the release of the 2006 NJRR report there appears to have been no further implantations and two more revisions of this implant

combination. TGA noted that there are very low numbers for this implant combination (52 implanted and 7 revised), and that there may be an upward trend in revision. Both prostheses have the same manufacturer.

4.4.2 A member noted that the company has recommended that these joint replacement components should not be used together.

4.4.3 Members considered that it would be advisable to observe the performance of this combination over a longer period of time.

Advice: The Working Group advised that the performance and revision rate of the Elite Plus Femoral Stem/Apollo Acetabular Cup combination should continue to be observed.

4.5 Alloclassic Cementless Femoral stem/Fitmore Acetabular Component

4.5.1 The TGA observed that there have been a high number of implantations together with a high number of revisions for this combination. The number of implanting and revising hospitals is widespread. TGA noted that it is not clear that all the revisions recorded in the NJRR data are attributable to the Alloclassic Cementless Femoral Stem and the Fitmore Acetabular Component: Seven implants were revised for head only or cement spacer, these revisions may have been wrongly attributed to this combination of prostheses. TGA noted that in 2007 the manufacturer had stated that there were no reported incidents recorded.

4.5.2 A member noted that there is generally a significant difference between acetabular failure rates and femoral component failure. It is possible that a technical or design flaw may be showing up in the data for this combination. Surgeons generally can more reliably position a femoral component than an acetabular component.

4.5.3 Members discussed whether the acetabular cup could cause the femoral stem to fail, agreeing that the combination of particular cups with particular stems can be detrimental.

4.5.4 A member noted that the NJRR data is likely to lead surgeons to decide not to use this combination.

Advice: The Working Group advised that the performance and revision rate of the Alloclassic Cementless Femoral stem/Fitmore Acetabular Component combination should continue to be observed.

4.6 Lima SPH Blind Acetabular Component

4.6.1 The TGA observed that nine of the revisions were in conjunction with the Margron Stem and 30 with the F2L Multineck Stem which has itself experienced high revision rates with other acetabular components. The NJRR has identified that the SPH Blind Acetabular component has a significantly higher revision rate when it is used with cemented femoral components.

4.6.2 A member noted that the company may be in the process of withdrawing this prosthesis. Members requested that the TGA contact the company for further information on this. If company is withdrawing this prosthesis no further action is required.

Action item: The TGA will contact the sponsor of the Lima SPH Blind Acetabular component, seeking information from the company on the revision rate statistics identified by the NJRR.

Item 5 Products/Product combinations for consideration

5.1 F2L Multineck Femoral Stem/Delta Cementless Acetabular Component

5.1.1 The TGA observed that there are low numbers of this combination implanted, with a relatively high revision rate. The company is aware of the high revision rate for the F2L Multineck Femoral Component and has voluntarily withdrawn this prosthesis from the Australian market. The company keeps a small supply of implants for revision purposes in Australia. The company believes that the problematic element of this combination is the FL2 Multineck femoral component, not the Delta acetabular component, noting that of the six revisions in this combination only one was for the Delta acetabular component.

5.1.2 It was noted that the Company advised in their report they have voluntarily withdrawn this implant from the Australian market. Members concurred that the company had taken appropriate action in relation to this joint replacement combination, and that no further investigation by the TGA was required.

5.2 C-Stem (Cemented) Femoral Component/Pinnacle Cementless Acetabular Component

5.2.1 The TGA observed that the number of observed component years is relatively low, and that the low numbers may indicate a learning curve effect. The company submitted a response to the TGA's queries regarding this combination, indicating that the data supplied from the NJRR is insufficient as it lacks both surgeon-level and patient-level data.

5.2.2 The NJRR representative noted that the combination of the products is problematic, not the individual components which perform adequately in other combinations.

5.2.3 Members discussed possible design problems with the devices. A member noted that there are multiple bearing surfaces available with the Pinacle cup / C-stem combination. These bearings may have an effect on Revision rates over & above the effect of the stem or cup alone. It was noted that the combination of hard on hard metal in this situation may be problematic.

5.2.4 Members agreed that this implant combination should continue to be under observation and review.

Advice: The Working Group advised that the performance and revision rate of the C-Stem (Cemented) Femoral Component/Pinnacle Cementless Acetabular Component combination should continue to be observed.

5.3 MBA Acetabular Component

5.3.1 The TGA observed that there is a high revision rate for this component, but low overall number of implants. Only two of these involved the acetabular component. The manufacturer has reported that from 1998 to 2007 only three adverse events, all occurring in France, were received. Members noted the manufacturer's response, indicating that the disparity in reporting leads to a lack of confidence in the manufacturer's data.

5.3.2 Members queried whether the acetabular component has adversely affected the femoral component. A member noted that the revision rate appears to be statistically significant, and that whether the MBA acetabular component was used with cemented or cementless cups, the revision rate was high.

5.3.3 A member suggested that the low numbers may indicate that this is a problem at the surgical level. TGA noted that the revisions appear to occur in two hospitals only.

5.3.4 The NJRR representative advised members that the NJRR data indicates that this prosthesis should not be used in Australia. Members concurred.

Advice: The Working Group advised that the MBA Acetabular Component revision rate is unacceptably high. The Working Group suggested that the prosthesis should not be made available on the Australian market.

5.4 ASR resurfacing hip implant

5.4.1 The TGA noted that the manufacturer of the ASR resurfacing hip implant had approached the TGA recognising that the revision rate is unacceptable. The manufacturer advised that supply of the implant will no longer be possible unless the surgeon undergoes a training and mentoring program. It appears that many surgeons are reluctant to undertake this training, and the company reports that sales have decreased sharply since this measure began.

5.4.2 Members commented that the successful implantation of this device required a specific surgical technique.

5.4.3 A member noted that comparison of this relatively new implant with other resurfacing implants may need to take into account that revision data for the early years of some older resurfacing implants may not be available to the NJRR. The NJRR representative responded that there are a number of new resurfacing prostheses on the market that do not have the high revision rate of the ASR resurfacing hip implant.

5.4.4 The Working Group endorsed the actions of the company and will review the revision performance as reflected in the next NJRR report.

Advice: The Working Group endorsed the actions taken by the ASR resurfacing hip implant's sponsor towards requiring surgeons to undertake specific training for this implant as a condition of sale. The Working Group advised that the performance and revision rate of the ASR resurfacing hip implant should continue to be observed.

5.5 Durom resurfacing hip implant

5.5.1 The TGA observed that the reasons for revision for the Durom resurfacing hip implant appear to be consistent with other resurfacing implants, showing similar mechanisms leading to failure even for those implants which have better average revision rates. This indicates that the revision rate may be part of a learning curve.

5.5.2 Members discussed the reflection of a learning curve in the statistical data supplied for review. A member expressed misgivings with the company's estimate of 55 to 60 cases for most surgeons to place the femoral component where they had planned it to be. Data supplied from the company was from a prospective study on the BHR implant.

5.5.3 The Working Group noted that it may become clear within the next year or two whether the revision rate reflects a learning curve. Members suggested the TGA contact the company and seek information on what steps the company was taking to manage the learning curve.

Advice: The Working Group advised that the performance and revision rate of the Durom resurfacing hip implant should continue to be observed. The Working Group suggested that the TGA contact the sponsor and request information on what steps the company was taking to manage the learning curve for this implant.

5.6 Cormet 2000 (HAP) resurfacing femoral component/Cormet Acetabular Component

5.6.1 A member noted that this combination is no longer on the Australian market.

Advice: The Working Group endorsed the actions of the Cormet 2000 (HAP) resurfacing femoral component and Cormet acetabular component's sponsor to remove this joint replacement from the Australian market.

Item 6 Other business

6.6.1 A member sought information on the TGA's actions in regard to the Margron DTC Femoral Component. The TGA reported that when further information had been sought from the company regarding the NJRR's identification of a high revision rate, the company had voluntarily withdrawn this product from the Australian market.

Item 7 Next meeting

7.1 The next meeting will be on Wednesday 18 June at 6:30pm (EST), by teleconference.

The Chair thanked members for participating. The meeting closed at 8.00pm.

Professor Guy Maddern
OEWG Chair
June 2008

ORTHOPAEDIC EXPERT WORKING GROUP (OEWG)
2008/3 MEETING
18 June 2008, 6.30PM EST

MEETING RECORD & OUTCOMES

List of Participants:

Members: Professor Guy Maddern (Chair)
Mr Peter Devane
Professor Stephen Graves
Mr Bruce Love
Dr Peter Myers
Dr David Hale

TGA advisers: Dr Richard Pembrey, Office of Devices, Blood & Tissues
Michael Flood, Office of Devices, Blood & Tissues
Jorge Garcia, Manager, Devices Program, TGA Laboratories
Pam Carter Director, Market Vigilance and Monitoring Section ODBT
Secretariat: Shawn Hazel
Fiona Mildner

Apologies: Professor David Morgan

Item 1 Welcome

1.1 The Chair welcomed members.

Item 2 Disclosure of Interest

2.1 There were no disclosures of interest announced.

Item 3 Minutes of the Previous Meeting and Action List

3.1 The minutes of the 2008/2 OEWG meeting were circulated out of session and accepted as a true and accurate record. Members reviewed the Action List.

Item 4 TGA Comparison Data for Knee Prosthesis

Item 5 Products/Product combinations for consideration

5.1 Advance Uni-Compartmental Knee Prosthesis

5.1.1 The TGA observed that there were low numbers of this prosthesis implanted, but showed extremely high revision rate compared to other uni-compartmental products. It was noted by the NJRR that this prosthesis had not been used since 2006.

5.1.2 A Member voiced concerns pointing out that even though the prosthesis had not been implanted since 2006, who is to say that it will not be used in the future. The question

was raised should this product continue to remain on the Australian Register of Therapeutic Goods (ARTG)?

5.1.3 It was noted that the sponsor stated they had received only 2 reports of revisions and the high revision rate could be contributed to user technique, not design related.

5.1.4 It was discussed that if there are user related issues with the use of any prosthesis, there might be a need to get surgeon by surgeon level data if it is possible to get from the NJRR.

5.1.4 It was agreed that the NJRR would supply further data on surgeon by surgeon level before action is taken to industry.

Advice: The Working Group advised that the company should show cause why the Advance Uni-Compartmental Knee Prosthesis should continue to be supplied to the Australian market. The Working Group suggested that the product should not be made available on the Australian market.

5.2 AMC Uni-Glide Uni-Compartmental Knee Prosthesis

5.2.1 The TGA observed that there was a high revision rate with a large number of prosthesis implanted. The company had not submitted a response to the TGA. Most recent data indicates the revision rate continues to rise and is higher than two other implants of this type.

5.2.2 The NJRR representative noted that the revision rate of this prosthesis continues to rise. It was noted that the implant is used with reasonable frequency and that the revision rate was twice the average.

5.2.3 It was noted that the data supplied showed the revision rate was high in hospitals that used this prosthesis. The Group agreed that the learning curve excuse was not acceptable. A Member stated that Uni-compartmental prosthesis are not usually used in teaching hospitals.

Advice: The Working Group advised that the company should show cause as to why the AMC Uni-Glide Uni-Compartmental Knee Prosthesis should remain on the ARTG.

5.3 Preservation Mobile Uni-Compartmental Knee Prosthesis

5.3.1 The TGA observed that there is a high revision rate for this component, noting that in the company's response they indicate that the NJRR's statistics show that the revision rate appears to be decreasing.

5.3.2 The NJRR representative said they had provided the company with the information and the data supplied showed that the revision rate appears to worsen year by year.

5.3.3 Members noted that the company in their response stated that because the prosthesis was a new one the reason for the high revision rate was due to the "learning curve effect".

5.3.4 Members discussed this prosthesis, noting that if there is an increase in the revision rate of the prosthesis there is something wrong with the prosthesis. It was agreed that the company should show cause as to why this prosthesis should remain on the ARTG.

Advice: The Working Group advised that the company should show cause as to why the Preservation Mobile Uni-Compartmental Knee Prosthesis should remain on the ARTG.

5.4 Gemini MK II Knee Prosthesis

5.4.1 The TGA observed that the number of implants for this prosthesis was low but the revision rate was high. TGA noted there was no response from the company.

5.4.2 The NJRR representative stated that the NJRR registry showed that the prosthesis was no longer used, indicating that it may no longer be in the market.

5.4.3 Members agreed that if the prosthesis is no longer used, the company should show cause as to why this prosthesis should remain on the ARTG.

Advice: The Working Group advised that the company should show cause as to why the Gemini MK II Knee Prosthesis should remain on the ARTG.

5.5 Interax Knee Prosthesis

5.5.1 The TGA observed that the number of implants for this prosthesis is low but the revision rate was high. All revisions have occurred in a couple of hospitals in South Australia.

5.5.2 The NJRR representative stated that he thinks this prosthesis is no longer available.

5.5.3 Members agreed that if the prosthesis is no longer used, the company should show cause as to why this prosthesis should remain on the ARTG.

Advice: The Working Group advised that the company should show cause as to why the Interax Knee Prosthesis should remain on the ARTG.

5.6 Optetrak-PS Femoral Knee Prosthesis/Optetrak Tibial Component

5.6.1 The TGA observed that the revision rate of this prosthesis was twice the average of similar prosthesis of this type.

5.6.2 A member noted that the company has a large number of components that are used in combination. The data shows that specific combinations are not working well.

5.6.3 A member noted that of the thirty six revisions nine of them were for infection, this indicates a high rate of infection. The NJRR stated that they were aware of the issue with possible tampering of the packaging of the prosthesis, and wondered whether this could be the basis of the high rate of infection.

Advice: The Working Group advised that the Optetrak-PS Femoral Knee Prosthesis/Optetrak Tibial Component:

(1) That the OEWG continue to observe the rate of revision of this prosthesis,

(2) That TGA request from the NJRR information about the infections.

5.7 Profix Femoral Knee Prosthesis/Mobile Bearing Tibial Component

5.7.1 The TGA observed that the revision rate of this prosthesis is almost 3 times the average of all other similar implants. The TGA also noted that there was a recall on

the torque wrench that was supplied with the loan kits in 2006 due to the wrench loosening rather than tightening the rotation peg.

5.7.2 The members noted that there were two main components revised, they were the insert and the rotation peg. It was also noted that the rate of use of this prosthesis had decreased significantly possibly because of surgeons becoming increasingly aware of this issue.

5.7.3 Members agreed that if the use of this prosthesis has decreased the company should show cause as to why this prosthesis should remain on the ARTG.

Advice: The Working Group advised that the company should show cause as to why the Profix Femoral Knee Prosthesis/Mobile Bearing Tibial Component should remain on the ARTG.

5.8 Trac Knee Prosthesis

5.8.1 The TGA observed that the number of implants for this prosthesis is low but the revision rate was high. The revision rate compared to similar implants is increasing for the Trac system. The prosthesis appears to be a very poor performer.

5.8.2 Member noted that there is a large discrepancy on the number implanted provided by the company (600) and the number implanted provided by the NJRR (138). It was also noted that the prosthesis has not been used for 3 years.

5.8.3 Members agreed that if this prosthesis is no longer in use the company should show cause as to why this prosthesis should remain on the ARTG.

Advice: The TGA will contact the Sponsor of the Trac Knee Prosthesis, suggesting that the prosthesis be removed from the Australian Market as it has not been used for three years.

5.9 Cementlesss Profix Oxinium when used with Profix or Mobile Bearing Tibial Components

5.9.1 The TGA observed that the number of implants for this prosthesis is low but the revision rate is extremely high.

*[1]5.9.2 The NJRR Member advised that all Oxinium implants have been removed from the Australian Market.

Advice: The Working Group noted the advice that all Oxinium implants have been removed from the Australian Market.

5.10 Cementless Genesis II Oxinium, used with either Genesis II or Mobile Bearing Tibial Components

5.10.1 The TGA observed that the number of implants for this prosthesis is low but the revision rate is extremely high.

* Please note clarification regarding the Items 5.9.2 & 5.10.2. There were 2 versions of these implants cemented and uncemented. It has been identified that the uncemented version is the implant that has been withdrawn from the Australian Market and the cemented continues to be available.[1]

*5.10.2 The NJRR Member advised that all Oxinium implants have been removed from the Australian Market.

Advice: The Working Group noted the advice that all Oxinium implants have been removed from the Australian Market.

5.11 LCS Patella

5.11.1 The TGA observed that the revision rate of this prosthesis is almost two times the average of all other similar implants. During the early implantation period the LCS seemed to have comparable revision rates, but the cumulative revision rate is above the average for all other patellae at implantation periods above 3 years.

5.11.2 The NJRR Member to provide additional data to the TGA.

5.11.3 Members agreed that the company should show cause as to why this prosthesis should remain on the ARTG.

Advice: The Working Group advised that the company should show cause as to why the Interax Knee Prosthesis should remain on the ARTG.

Item 6 Other business

6.6.1 NJJR member informed the TGA that the FDA has requested to have a portal entry to the database for prosthesis. Therefore, the TGA was asked if they would like to have access to a portal to the prosthesis database. The AOA are the final decision makers to approve this request.

6.6.2 The NJRR Member asked the Group if they would be adverse to some of the NJRR data within Australia being released to New Zealand. The TGA voiced concerns about Company responses being made public. Members noted that the data is public and identified in reports. The TGA has agreed to the release of the NJRR data.

6.6.3 The TGA are to discuss the degree of extra data to be supplied by the NJRR and to contact the NJRR Member with details of what is required.

Item 7 Next meeting

7.1 The next meeting to be advised. It was agreed by the committee that all OEWG meetings continue to be held by teleconference.

The Chair thanked members for participating. The meeting closed at 7.45pm.

Professor Guy Maddern
OEWG Chair
August 2008

ORTHOPAEDIC EXPERT WORKING GROUP (OEWG)
2009/1 MEETING
09 December 2009, 6.30PM EST

DRAFT MEETING RECORD & OUTCOMES

List of Participants:

Members: Professor Guy Maddern (Chair)
Professor Stephen Graves
Associate Professor Bruce Love
Mr Peter Devane

TGA advisers: Michael Flood, Office of Devices, Blood & Tissues (ODBT)
Jorge Garcia, Director, Biomaterials and Engineering, Office of Laboratories and Scientific Services (OLSS)
Dr Jon Rankin, Clinical Advisor, ODBT
Pam Carter, Director, Market Vigilance and Monitoring Section, ODBT
Gary Burgess, A/g Director, Medical Devices Conformity Assessment Section, ODBT

Secretariat: Shawn Hazel
Zenobia Williams

Apologies: Dr David Hale

Item 1 Welcome

1.1 The Chair welcomed members.

Item 2 Conflicts of Interest

2.1 There were no conflicts of interest announced.

Item 3 Minutes of the Previous Meeting and Action List

3.1 The minutes of the 2008/3 OEWG meeting were circulated out of session and accepted as a true and accurate record.

3.2 The TGA reported on their follow-up with some recommendations made by the OEWG at its last meeting in June 2008, in relation to implants identified by the National Joint Replacement Registry's (NJRR) 2007 report.

3.3 The TGA stated that assessing the implants identified in 2009 as a member had recommended out-of-session had been impossible as many of the manufacturers for those implants had asked for extensions to submit a response.

3.4 The TGA reported that there have been approximately 30 implants identified in the 2008 and 2009 report that have a higher than average revision rate. Due to the slow response rate from the manufacturers, of the 30 implants, 10 will be discussed at this meeting and the remaining 20 will be discussed at subsequent meetings to be held early in 2010.

3.5 A member voiced their concerns on the slow action being taken on some of the recommendations made by the working group at previous meetings. There was robust discussion regarding timeframes and some of the prosthesis identified in previous meetings that were still on the ARTG.

3.6 The Chair expressed concern at the lack of meetings for the past 18 months of the working group and stated that this group will need to meet on a more regular basis to be of any benefit.

3.7 The TGA referred the OEWG to the Out of Session Item that was distributed prior to the meeting and included with the papers for consideration, highlighting the actions already taken by the TGA on previous OEWG recommendations. Some members felt that the actions had been too weak and too slow.

3.8 The TGA explained that there had been an internal review of the process for re-assessment of implants that had been identified as having higher than expected revision rates, and that the process had been halted during the review. But the process has now been cleared to continue. TGA expects to be able to process the implants that were identified in the 2008 and 2009 NJRR reports quite quickly, provided that the OEWG can meet a couple of times early in 2010.

Item 4 Products/Product combinations for consideration

4.1 UHR Partial Bipolar Femoral Head Prosthesis when used with the ABGII Femoral Prosthesis Component

4.1.1 The TGA observed that this implant was tracking well for the 0-3.5 year period but the revision rates rose markedly at 3.5 years due to fractures that were higher than the general implant group. The summary results provided by the manufacturer referenced clinical studies which indicated that the implant performed well but these did not relate to the UHR/ABGII combination.

4.1.2 There was discussion on the higher than average revision rates of this combination. It was noted by the Committee that the revision rates were not associated with the individual prosthesis, but with the combination of the two together.

4.1.3 A question was asked as to whether or not the surgeons are made aware of the revision rates and whether they could identify their revisions. The NJRR representative stated that orthopaedic surgeons now have access to the website where they are able to review revision rate reports.

4.1.4 The Committee agreed that surgeons should be made aware of the concerns with this combination.

Advice: The Working Group advised that the individual products should continue to be made available on the Australian market but should not be used in combination together.

4.2 UHR Partial Bipolar Femoral Head Prosthesis – when used with the Omnifit Femoral Prosthesis component

4.2.1 The TGA observed that the difference in revision rates between this implant combination and that of all others combined is not statistically significant but that the cementless Omnifit stem is not tracking as well. The company also noted the high revision rate for the cementless stem but did not offer any solutions, apart from surgeons using their clinical judgement.

4.2.2 The NJRR representative noted that the revision rate of this prosthesis continues to rise.

4.2.3 The Committee agreed that surgeons should be made aware of the concerns with the combination especially with the cementless stem.

Advice: The Working Group advised that the individual products should continue to be made available on the Australian market but should not be used in combination together

4.3 Bipolar Head Partial Bipolar Femoral Head Prosthesis

4.3.1 The TGA observed that this implant is used infrequently and there were 8 revisions which compares to 2.3 per 100. The data from the NJRR included a large number of fractures. Although the manufacturer's submission was brief it addressed all issues and attributes the large number of revisions to dislocation/disassociation to closed reduction or a dislocated joint which is consistent with NJRR figures.

4.3.2 The NJRR representative was surprised with the revision rate for this combination and felt there was plenty of choice of Bipolar products on the market that are performing well. Therefore the product should be cancelled from the ARTG.

4.3.3 There was debate about the approach taken on this implant and whether manufacturer's evidence was being ignored. The company has provided citations from clinical studies and in 2008 they made a design change which makes it easier to assemble the cases of mal-alignment.

4.3.4 TGA participants advised the Working Group that cancellation is a lengthy and sometimes difficult process. If the product was to be cancelled from the ARTG then the manufacturer's response had to be refuted, and the help of the Working Group will be needed to do that.

4.4.5 The Working Group suggested that appropriate wording may be "This implant has a high unacceptable rate of failure in the 1st year and therefore the product should be removed from the ARTG.

Advice: The Working Group advised that the product should be cancelled from the ARTG.

4.4 Adapter (cemented) Femoral Stem Prosthesis & Bionik Acetabular Cup

4.4.1 The TGA noted that there were a small number of implants and a high revision rate for this prosthesis. The manufacturer claimed that the revisions were for a single surgeon who is now retired. Revising surgeons cited poor cementing technique and poor positioning as causes for the problems with the implants.

4.4.2 The NJRR representative noted the trend of revisions and agreed with the manufacturer's comments.

Advice: The Working Group advised that the rate of revision for Adapter (cemented) Femoral Stem Prosthesis & Bionik Acetabular Cup combination should continue to be observed.

4.5 Anca Fit Femoral Stem Prosthesis

4.5.1 The TGA observed that although only a few of this prosthesis were implanted the revision rate was high for the 8 hospitals that used this implant. There were a total of 12 (6.5%) revisions in a series of 182 Anca Fit Stems.

4.5.2 Data provided by the manufacturer alleges that the Anca Fit stem design leads to a higher incidence of fractures and that extreme care needs to be used when fitting this prosthesis.

4.5.3 Members agreed that the company should show cause as to why this prosthesis should remain on the ARTG.

Advice: The Working Group advised that the Anca Fit Femoral Stem Prosthesis should be cancelled from the ARTG.

4.6 Hayes Consensus Femoral Stem Prosthesis

4.6.1 Between 1998 and 2001, a total of 125 Consensus Hip System (CHS) stems were supplied to Australia without matching femoral heads. The use of CHS stems with other equipment manufacturer heads is not recommended. Sales data from the new sponsor, Global Orthopaedics from 2002-2009 indicate that the femoral heads shipped to Australia were for those sold and used with the UniSyn system as recommended in the instructions for use. Consensus has been unable to reconcile records indicating how many of the "incorrectly placed" 125 CHS stems were included in the NJRR analysis. The TGA has since clarified that the data in the NJRR report relates ONLY to (correctly placed) UniSyn + CHS implants distributed since 2002. TGA has invited the sponsor to re-submit a response, but is still waiting for the follow up.

4.6.2 The NJRR representative reported that NJRR had consulted with the sponsor prior to reporting on this implant, and it was agreed that NJRR would report UniSyn cups plus Consensus Hip System (CHS) stems simply as "Consensus". The member observed that the revision rate for this prosthesis was high across the board.

4.6.3 Members agreed that due to the inconsistencies in the information provided by the manufacturer, there is no reason for this product to continue in the market, as there are other prosthesis that are available that do not have the same high revision rate.

Advice: The Working Group advised that the Hayes Consensus Femoral Stem Prosthesis should be cancelled from the ARTG.

4.7 Edinburgh Femoral Stem Prosthesis – when used with the Icon acetabular component

4.7.1 The TGA observed that only 3 hospitals have used this implant combination with one hospital only using one implant. The remaining 2 hospitals used the 45 implants but with a very high revision rate. The sponsor has "ceased recommending" the use of the two components together.

4.7.2 The NJRR representative stated that this combination has an extremely high revision rate and is not used anywhere else in the world and its use should be discouraged.

Advice: The Working Group advised that the company should <u>actively</u> discourage the use of the Edinburgh Femoral Stem Prosthesis in conjunction with the Icon acetabular cup, or remove either one or both from the market.

4.8 ASR Acetabular Cup

4.8.1 The TGA reported that the rate of revision for this device due to metal sensitivity is high. The Sponsor is taking steps to withdraw the product from the market but wishes to retain some components on the ARTG. Approximately 4000 devices were implanted and access to components will be beneficial when revision surgery is required.

4.8.2 There was discussion on the perceived benefit of certain components remaining on the Register for financial reasons or if the product should go onto the Special Access Scheme (SAS).

4.8.3 A member commented on ASR being problematic and the ongoing incidents reported to the Medical Devices Incident Reporting Scheme (MDIRC).

4.8.4 Members agreed that the ASR should no longer be available on the market, but that some components such as the femoral heads should be available for revision surgery. The TGA together with the company will make a decision as to what components will remain on the ARTG.

Advice: The TGA will contact the Sponsor of the ASR Acetabular Cup to determine what components of this device should remain on the ARTG

4.9 Recap Total Resurfacing Hip Replacement System

4.9.1 The TGA observed that of the 8 revisions for this device, 2 occurred within 3 months of implantation, 4 occurred within a year, and a further 2 within 2 years. The manufacturer's submission was brief but addressed many of the concerns and they also submitted clinical studies, two of which were from joint registries in counties (UK, Finland) where the use of Recap had been much greater than in Australia. One of the studies had a large revision rate but this included only 20 cases. This implant is performing about 'middle of the range" compared to other similar implants.

4.9.2 It was noted that even though the use of this product in Australia is limited the revision rate was 3 times higher than the average and that 5 out of the 8 revisions occurred at a single facility.

4.9.3 The NJRR representative commented that this was a new prosthesis on the market which the company failed to mention in its submission, and has tried to use the learning curve excuse as a reason for the high revision rate of this prosthesis. There are other implants that perform better than the Recap. Data from the UK Registry cannot be used to indicate performance of this prosthesis as patient consent is required to record any data, this in turn leads to high rates of under-subscription of patients. Ie the UK registry data is incomplete.

4.9.4 Members agreed that due to the higher than normal revision rate of this prosthesis, this prosthesis should no longer be available on the market.

Advice: The Working Group advised that the Recap Total Resurfacing Hip Replacement System be cancelled from the ARTG.

4.10 Eska RP Total Knee Prosthesis

4.10.1 The TGA observed that the low number of implants and the three hospitals where revisions occurred makes it difficult to establish any other trends other than the higher than expected revision rates.

4.10.2 The NJRR representative noted that the company's report was accurate in stating that it had not implanted any RP Knees since 2006 when they realised that the instrumentation was inadequate.

4.10.3 Members agreed that the product should be removed from the ARTG until the company resolves the issues relating to inadequate instrumentation.

Advice: The Working Group advised that all Eska RP Total Knee Prosthesis should be cancelled from the ARTG. The company will need to submit a new application once the instrumentation issue has been resolved.

Item 5 Other business

6.6.1 The TGA gave a summary on the responses received to the consultation papers on the re-classification of joint replacement implants from Class IIb to Class III. The responses were in favour of the reclassification as there it will involve a higher level of pre-market scrutiny.

6.6.2 TGA will soon have access to a portal to the NJRR's prosthesis database which will provide them with real time data and comprehensive information on usage, revision rates and detailed analysis.

Item 6 Next meeting

6.1 The papers for the next meeting will be ready by the middle of January 2010 and the next meeting of this group will be held by teleconference in the 2nd or 3rd week of February 2010.

The Chair thanked members for participating. The meeting closed at 8.20 p.m.

Professor Guy Maddern
OEWG Chair
December 2009

Senate Community Affairs References Committee

ANSWERS TO QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Inquiry into the Regulatory Standards for the Approval of Medical Devices
27 September 2011

Question no: 5

Topic: Communication between TGA and NJRR

Hansard Page: 50

Senator Xenophon asked:

Can TGA please provide the communications between the National Joint Replacement Registry (NJRR) and the TGA on the ASR hip from the time the OEWG was convened in 2007, to December 2009, when the ASR hip was removed from the Australian market.

Answer:

In this time period, communication from the National Joint Replacement Registry (NJRR) was through the provision of its annual reports and detailed implant performance analyses for prostheses that were identified as having higher than anticipated rates of revision – including the ASR implants.

Every NJRR annual report since 2006 has made mention of the ASR Resurfacing implant and/or the ASR XL acetabular component. Copies of all of the NJRR annual reports are available at http://www.dmac.adelaide.edu.au/aoanjrr/publications.jsp?section=reports2011.

Copies of the 2007, 2008 and 2009 implant analyses reports for the ASR Resurfacing implants are at Attachments A and B and C respectively.

The TGA also received a detailed implant performance analysis for the ASR XL acetabular cup when it was identified as having higher rates of revision only when used in conjunction with the Corail femoral stem component in 2008. A copy of that implant analysis report is at Attachment D.

The TGA also received detailed implant performance analyses for the ASR XL acetabular cup when it was identified as having higher than anticipated revision rates in its own right - regardless of the femoral component used - in October 2009. A copy is at Attachment E.

Investigation

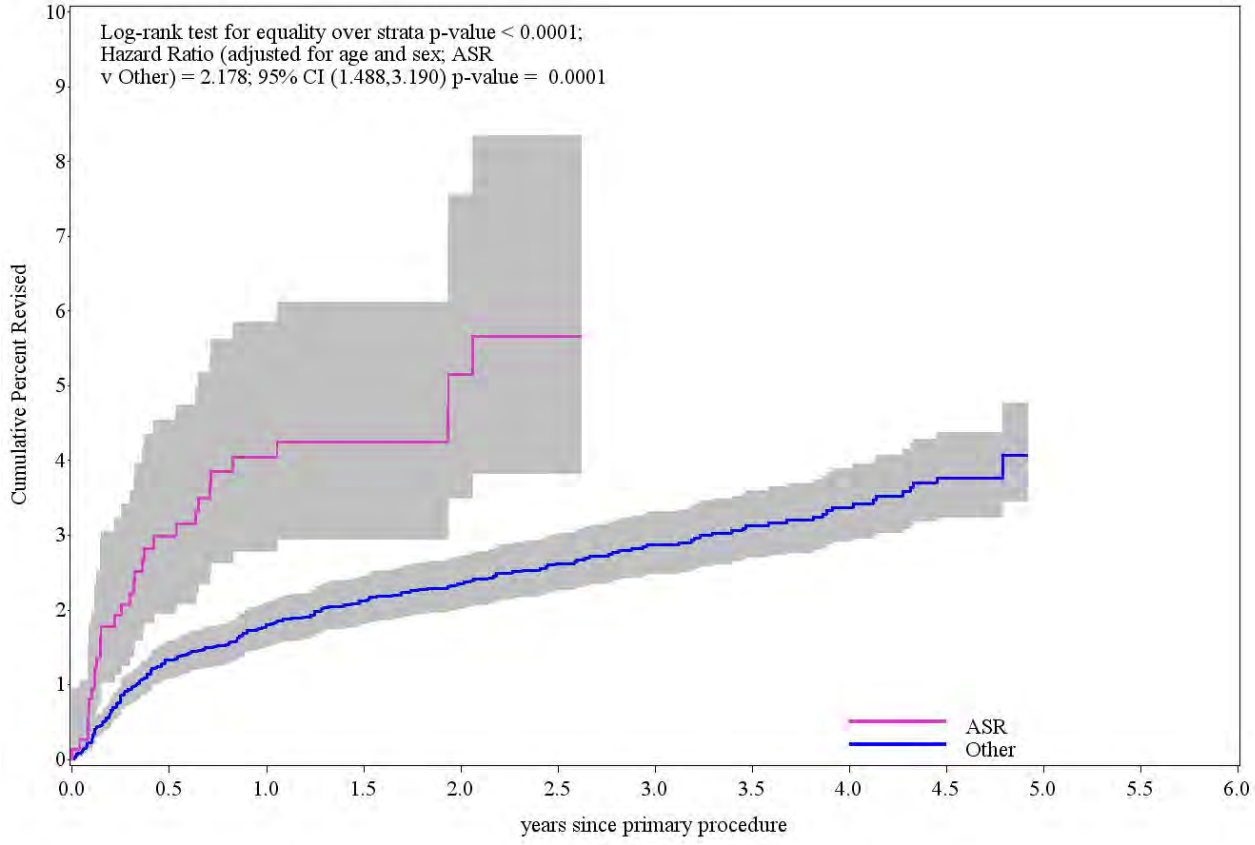
ASR – Resurfacing Hip Replacement

Revision rates

Component	Number revised	Total Number	% Revised	Observed 'component' years	Revisions per 100 observed 'component' years	Exact 95% CI
ASR	31	753	4.1	1042	3.0	(2.02, 4.22)
Other Resurfacing	218	8192	2.7	21922	1.0	(0.87, 1.14)
Total	249	8945	2.8	22964	1.1	(0.95, 1.23)

Revision rates

Number at risk at start of period	0	0.5	1	1.5	2	2.5	3.0	3.5	4.0	4.5	5.0	5.5	6.0
ASR	753	598	487	329	195	85	41	0	0	0	0	0	0
Other Resurfacing	8192	7340	6569	5790	5027	4281	3531	2816	2077	1356	730	318	91



Revision Rates at 1 to 6 years

label	1	2	3	4
Other Resurfacing	1.80 (1.52, 2.12)	2.35 (2.02, 2.73)	2.88 (2.49, 3.32)	3.37 (2.92, 3.89)
ASR	4.04 (2.78, 5.85)	5.16 (3.50, 7.56)	. (0.00, .)	. (0.00, .)

Type of Revision performed for Primary Failure

	Component				Total
	Other Resurfacing		ASR		
	N	%	N	%	N
Type of Revision					
Femoral Component Only	136	62.4	22	71.0	158
Femoral and Acetabular	48	22.0	5	16.1	53
Acetabular Component Only	28	12.8	3	9.7	31
Cement Spacer	4	1.8	.	.	4
Removal Prosthesis	2	0.9	.	.	2
Cable/Other Minor Components	.	.	1	3.2	1
Total	218	100.0	31	100.0	249

Revision diagnosis by days to revision for Other Resurfacing

	Days to revision																		Total		
	Same Day			<2 weeks			2-6 weeks			6 weeks - 6 months			6 months - 3 years			>=3 years					
	N	Col %	Row %	N	Col %	Row %	N	Col %	Row %	N	Col %	Row %	N	Col %	Row %	N	Col %	Row %	N	Col %	Row %
Revision Diagnosis																					
OTHER	.	.	.	.	.	.	1	5.0	4.3	4	5.0	17.4	13	13.5	56.5	5	19.2	21.7	23	10.0	100
DISLOCATION OF PROSTHESIS	.	.	.	.	.	.	1	5.0	12.5	.	.	.	6	6.3	75.0	1	3.8	12.5	8	3.5	100
FRACTURE	1	100	1.0	3	50.0	3.0	13	65.0	13.0	58	72.5	58.0	16	16.7	16.0	9	34.6	9.0	100	43.7	100
IMPLANT BREAKAGE STEM	.	.	.	.	.	.	1	5.0	50.0	1	1.3	50.0	.	.	.	.	.	.	2	0.9	100
INFECTION	.	.	.	.	.	.	2	10.0	10.0	1	1.3	5.0	14	14.6	70.0	3	11.5	15.0	20	8.7	100
LOOSENING	.	.	.	3	50.0	4.9	2	10.0	3.3	15	18.8	24.6	35	36.5	57.4	6	23.1	9.8	61	26.6	100
LYSIS	.	.	.	.	.	.	.	.	.	.	.	.	5	5.2	83.3	1	3.8	16.7	6	2.6	100
PAIN	.	.	.	.	.	.	.	.	.	1	1.3	11.1	7	7.3	77.8	1	3.8	11.1	9	3.9	100
Total	1	100	0.4	6	100	2.6	20	100	8.7	80	100	34.9	96	100	41.9	26	100	11.4	229	100	100

Revision diagnosis by days to revision for ASR

	Days to revision									Total		
	2-6 weeks			6 weeks - 6 months			6 months - 3 years					
	N	Col%	Row%	N	Col%	Row%	N	Col%	Row%	N	Col%	Row%
Revision Diagnosis												
OTHER	.	.	.	1	7.1	16.7	5	38.5	83.3	6	17.6	100
DISLOCATION OF PROSTHESIS	1	14.3	100	.	.	.	.	.	.	1	2.9	100
FRACTURE	5	71.4	23.8	12	85.7	57.1	4	30.8	19.0	21	61.8	100
INFECTION	.	.	.	.	.	.	1	7.7	100	1	2.9	100
LOOSENING	1	14.3	20.0	1	7.1	20.0	3	23.1	60.0	5	14.7	100
Total	7	100	20.6	14	100	41.2	13	100	38.2	34	100	100

Revision rates by Hospital

Component	Hospital	Number revised	Total Number	% Revised	Observed 'component' years	Revisions per 100 observed 'component' years	Exact 95% CI
ASR	Hospital 1	0	1	0.0	1	0.0	(0.00, 327.0)
ASR	Hospital 2	0	4	0.0	5	0.0	(0.00, 69.81)
ASR	Hospital 3	0	2	0.0	1	0.0	(0.00, 415.9)
ASR	Hospital 4	0	1	0.0	1	0.0	(0.00, 252.3)
ASR	Hospital 5	0	2	0.0	3	0.0	(0.00, 115.4)
ASR	Hospital 6	0	2	0.0	2	0.0	(0.00, 171.9)
ASR	Hospital 7	0	5	0.0	10	0.0	(0.00, 37.50)
ASR	Hospital 8	0	15	0.0	21	0.0	(0.00, 17.74)
ASR	Hospital 9	0	9	0.0	12	0.0	(0.00, 31.90)
ASR	Hospital 10	0	4	0.0	6	0.0	(0.00, 62.49)
ASR	Hospital 11	0	1	0.0	1	0.0	(0.00, 351.8)
ASR	Hospital 12	0	1	0.0	0	0.0	(0.00, 1248)
ASR	Hospital 13	1	2	50.0	2	59.5	(1.51, 331.4)
ASR	Hospital 14	0	1	0.0	2	0.0	(0.00, 233.9)
ASR	Hospital 15	1	9	11.1	5	21.0	(0.53, 117.2)
ASR	Hospital 16	0	2	0.0	1	0.0	(0.00, 618.1)
ASR	Hospital 17	0	1	0.0	2	0.0	(0.00, 206.0)
ASR	Hospital 18	0	2	0.0	1	0.0	(0.00, 660.5)
ASR	Hospital 19	0	16	0.0	19	0.0	(0.00, 19.67)
ASR	Hospital 20	0	3	0.0	4	0.0	(0.00, 92.79)
ASR	Hospital 21	2	4	50.0	3	64.7	(7.84, 233.7)
ASR	Hospital 22	0	1	0.0	1	0.0	(0.00, 379.5)
ASR	Hospital 23	3	21	14.3	24	12.7	(2.63, 37.24)
ASR	Hospital 24	0	2	0.0	1	0.0	(0.00, 418.4)
ASR	Hospital 25	0	1	0.0	2	0.0	(0.00, 199.0)
ASR	Hospital 26	1	3	33.3	4	25.5	(0.65, 142.2)
ASR	Hospital 27	0	2	0.0	3	0.0	(0.00, 140.1)
ASR	Hospital 28	0	6	0.0	8	0.0	(0.00, 44.10)
ASR	Hospital 29	0	1	0.0	1	0.0	(0.00, 353.6)
ASR	Hospital 30	0	3	0.0	5	0.0	(0.00, 68.71)
ASR	Hospital 31	0	1	0.0	2	0.0	(0.00, 211.8)
ASR	Hospital 32	6	289	2.1	470	1.3	(0.47, 2.78)
ASR	Hospital 33	2	18	11.1	14	13.9	(1.69, 50.28)
ASR	Hospital 34	0	1	0.0	3	0.0	(0.00, 142.0)
ASR	Hospital 35	1	2	50.0	5	21.9	(0.56, 122.2)

Component	Hospital	Number revised	Total Number	% Revised	Observed 'component' years	Revisions per 100 observed 'component' years	Exact 95% CI
ASR	Hospital 36	2	37	5.4	49	4.1	(0.49, 14.70)
ASR	Hospital 37	0	3	0.0	6	0.0	(0.00, 62.78)
ASR	Hospital 38	0	2	0.0	0	0.0	(0.00, 1005)
ASR	Hospital 39	4	116	3.4	134	3.0	(0.81, 7.62)
ASR	Hospital 40	0	7	0.0	9	0.0	(0.00, 41.27)
ASR	Hospital 41	1	12	8.3	18	5.7	(0.14, 31.72)
ASR	Hospital 42	7	111	6.3	155	4.5	(1.82, 9.31)
ASR	Hospital 43	0	3	0.0	2	0.0	(0.00, 208.6)
ASR	Hospital 44	0	1	0.0	1	0.0	(0.00, 260.6)
ASR	Hospital 45	0	6	0.0	11	0.0	(0.00, 33.93)
ASR	Hospital 46	0	1	0.0	1	0.0	(0.00, 302.1)
ASR	Hospital 47	0	1	0.0	2	0.0	(0.00, 187.9)
ASR	Hospital 48	0	3	0.0	4	0.0	(0.00, 101.7)
ASR	Hospital 49	0	2	0.0	2	0.0	(0.00, 158.1)
ASR	Hospital 50	0	10	0.0	5	0.0	(0.00, 71.97)
Other Resurfacing	Hospital 1	0	51	0.0	132	0.0	(0.00, 2.80)
Other Resurfacing	Hospital 2	1	43	2.3	129	0.8	(0.02, 4.33)
Other Resurfacing	Hospital 3	1	13	7.7	15	6.5	(0.16, 36.21)
Other Resurfacing	Hospital 4	1	109	0.9	181	0.6	(0.01, 3.08)
Other Resurfacing	Hospital 5	0	7	0.0	8	0.0	(0.00, 45.83)
Other Resurfacing	Hospital 6	0	13	0.0	16	0.0	(0.00, 23.29)
Other Resurfacing	Hospital 7	2	33	6.1	99	2.0	(0.25, 7.31)
Other Resurfacing	Hospital 8	0	5	0.0	15	0.0	(0.00, 25.23)
Other Resurfacing	Hospital 9	0	6	0.0	9	0.0	(0.00, 39.63)
Other Resurfacing	Hospital 10	2	173	1.2	477	0.4	(0.05, 1.52)
Other Resurfacing	Hospital 11	2	20	10.0	51	3.9	(0.47, 14.15)
Other Resurfacing	Hospital 12	1	77	1.3	195	0.5	(0.01, 2.86)
Other Resurfacing	Hospital 13	0	15	0.0	23	0.0	(0.00, 16.19)
Other Resurfacing	Hospital 14	0	10	0.0	16	0.0	(0.00, 23.62)
Other Resurfacing	Hospital 15	3	211	1.4	397	0.8	(0.16, 2.21)
Other Resurfacing	Hospital 16	3	40	7.5	94	3.2	(0.66, 9.31)
Other Resurfacing	Hospital 17	0	31	0.0	79	0.0	(0.00, 4.68)
Other Resurfacing	Hospital 18	0	22	0.0	54	0.0	(0.00, 6.80)
Other Resurfacing	Hospital 19	0	3	0.0	1	0.0	(0.00, 606.9)
Other Resurfacing	Hospital 20	1	8	12.5	26	3.8	(0.10, 21.07)
Other Resurfacing	Hospital 21	0	26	0.0	101	0.0	(0.00, 3.65)

Component	Hospital	Number revised	Total Number	% Revised	Observed 'component' years	Revisions per 100 observed 'component' years	Exact 95% CI
Other Resurfacing	Hospital 23	1	15	6.7	42	2.4	(0.06, 13.17)
Other Resurfacing	Hospital 24	0	3	0.0	4	0.0	(0.00, 94.95)
Other Resurfacing	Hospital 25	1	19	5.3	41	2.5	(0.06, 13.70)
Other Resurfacing	Hospital 26	0	3	0.0	5	0.0	(0.00, 78.75)
Other Resurfacing	Hospital 27	0	44	0.0	64	0.0	(0.00, 5.74)
Other Resurfacing	Hospital 28	0	4	0.0	6	0.0	(0.00, 63.05)
Other Resurfacing	Hospital 29	0	6	0.0	22	0.0	(0.00, 16.52)
Other Resurfacing	Hospital 30	0	3	0.0	12	0.0	(0.00, 30.51)
Other Resurfacing	Hospital 31	1	4	25.0	9	10.8	(0.27, 60.00)
Other Resurfacing	Hospital 32	11	411	2.7	1592	0.7	(0.35, 1.24)
Other Resurfacing	Hospital 33	5	77	6.5	192	2.6	(0.85, 6.09)
Other Resurfacing	Hospital 34	3	188	1.6	739	0.4	(0.08, 1.19)
Other Resurfacing	Hospital 35	1	25	4.0	105	1.0	(0.02, 5.31)
Other Resurfacing	Hospital 36	11	115	9.6	431	2.6	(1.27, 4.57)
Other Resurfacing	Hospital 37	0	10	0.0	27	0.0	(0.00, 13.85)
Other Resurfacing	Hospital 38	0	7	0.0	12	0.0	(0.00, 29.98)
Other Resurfacing	Hospital 39	37	2032	1.8	6431	0.6	(0.41, 0.79)
Other Resurfacing	Hospital 40	2	35	5.7	100	2.0	(0.24, 7.21)
Other Resurfacing	Hospital 41	5	71	7.0	209	2.4	(0.78, 5.58)
Other Resurfacing	Hospital 42	6	320	1.9	827	0.7	(0.27, 1.58)
Other Resurfacing	Hospital 43	0	29	0.0	63	0.0	(0.00, 5.84)
Other Resurfacing	Hospital 44	0	1	0.0	0	0.0	(0.00, 842.1)
Other Resurfacing	Hospital 45	2	66	3.0	232	0.9	(0.10, 3.12)
Other Resurfacing	Hospital 46	0	13	0.0	18	0.0	(0.00, 20.95)
Other Resurfacing	Hospital 47	0	11	0.0	21	0.0	(0.00, 17.80)
Other Resurfacing	Hospital 48	0	2	0.0	1	0.0	(0.00, 303.5)
Other Resurfacing	Hospital 49	2	19	10.5	54	3.7	(0.45, 13.31)

Revision rates by State

Component	State	Number revised	Total Number	% Revised	Observed 'component' years	Revisions per 100 observed 'component' years	Exact 95% CI
ASR	ACT/NT	1	9	11.1	5	21.0	(0.53, 117.2)
ASR	NEW SOUTH WALES	13	194	6.7	267	4.9	(2.60, 8.34)
ASR	QUEENSLAND	4	52	7.7	59	6.8	(1.84, 17.32)
ASR	SOUTH AUSTRALIA	6	290	2.1	471	1.3	(0.47, 2.77)
ASR	TASMANIA	0	2	0.0	1	0.0	(0.00, 418.4)
ASR	VICTORIA	6	203	3.0	232	2.6	(0.95, 5.63)

Component	State	Number revised	Total Number	% Revised	Observed 'component' years	Revisions per 100 observed 'component' years	Exact 95% CI
ASR	WESTERN AUSTRALIA	1	3	33.3	7	14.0	(0.35, 77.82)
Other Resurfacing	ACT/NT	4	327	1.2	598	0.7	(0.18, 1.71)
Other Resurfacing	NEW SOUTH WALES	86	2486	3.5	6021	1.4	(1.14, 1.76)
Other Resurfacing	QUEENSLAND	21	1308	1.6	2836	0.7	(0.46, 1.13)
Other Resurfacing	SOUTH AUSTRALIA	18	544	3.3	2010	0.9	(0.53, 1.42)
Other Resurfacing	TASMANIA	2	55	3.6	95	2.1	(0.25, 7.59)
Other Resurfacing	VICTORIA	80	3214	2.5	9407	0.9	(0.67, 1.06)
Other Resurfacing	WESTERN AUSTRALIA	7	258	2.7	954	0.7	(0.29, 1.51)
Total		249	8945	2.8	22964	1.1	(0.95, 1.23)

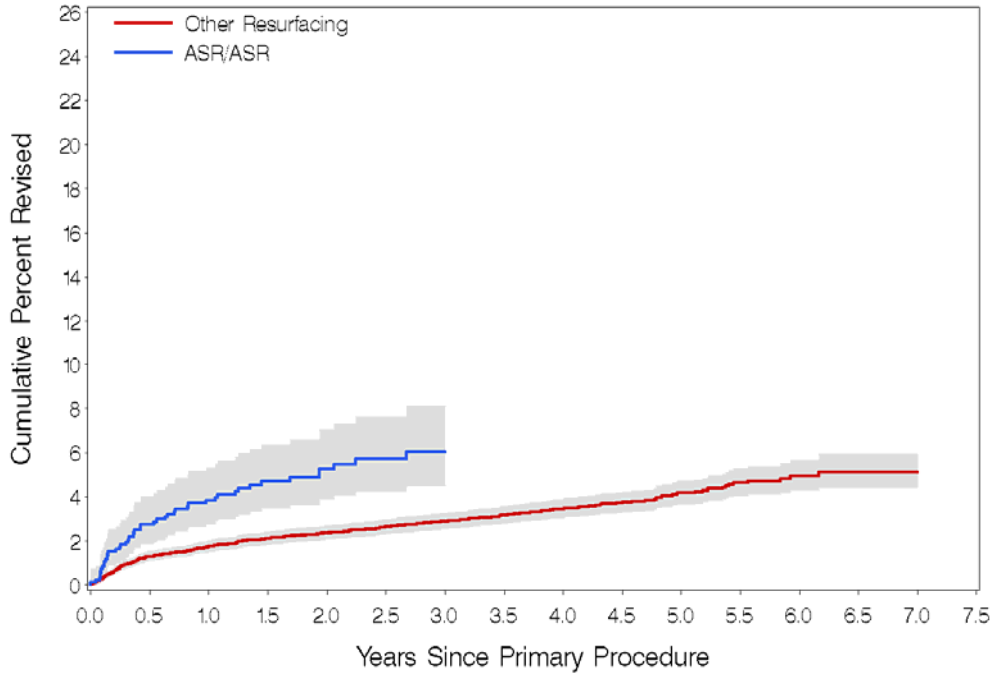
Revision rates by Year of Implant

		revision	Total	%
	Procedure Year			
ASR	2003	2	43	5.7
	2004	11	164	21.8
	2005	9	298	39.6
	2006	9	248	32.9
	Subtotal	31	753	100.0
Other Resurfacing	Procedure Year			
	2000	3	98	1.2
	2001	21	668	8.2
	2002	59	1406	17.2
	2003	52	1498	18.3
	2004	41	1516	18.5
	2005	28	1526	18.6
	2006	14	1480	18.1
	Subtotal	218	8192	100.0
Total		249	8945	100.0

ASR/ASR Total Resurfacing Hip Investigation

Revision rates

Component	Number Revised	Total Number	Observed 'Component' Years	Revisions per 100 Observed 'Component' Years	Exact 95% CI
Other Resurfacing	292	9678	30584	1.0	(0.85, 1.07)
ASR/ASR	48	945	1871	2.6	(1.89, 3.40)
Total	**340**	**10623**	**32455**	**1.0**	**(0.94, 1.17)**



Number at Risk	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs
Other Resurfacing	9678	8065	6530	5001	3506	2054	722	90
ASR/ASR	945	735	485	193	40	0	0	0

Cumulative Percent Revision

CPR	1 Yr	2 Yrs	3 Yrs	5 Yrs	7 Yrs
Other Resurfacing	1.8 (1.5, 2.0)	2.4 (2.1, 2.7)	2.9 (2.5, 3.3)	4.2 (3.7, 4.7)	5.1 (4.4, 5.9)
ASR/ASR	3.8 (2.7, 5.3)	5.3 (3.9, 7.1)	6.0 (4.5, 8.1)		

Hazard Ratio of ASR/ASR vs Other Resurfacing

Component	Total Number	Observed Component Years	Revisions per 100 Component Years	Hazard Ratio	P Value	HR 95% CI
ASR/ASR	945	1871	2.57	2.220	<.0001	(1.63, 3.03)

Primary Diagnosis for Revised Procedures

Primary Diagnosis	N	%
Avascular Necrosis	1	2.1
Developmental Dysplasia	2	4.2
Osteoarthritis	44	91.7
Rheumatoid Arthritis	1	2.1
Total	**48**	**100.0**

Revision Rates By Fixation for ASR/ASR

Fixation	Number Revised	Total Number	Observed 'Component' Years	Revisions per 100 Observed 'Component' Years	Exact 95% CI
Cemented	1	8	13	8.0	(0.20, 44.44)
Cementless	0	5	2	0.0	(0.00, 161.7)
Hybrid	47	932	1856	2.5	(1.86, 3.37)
Total	**48**	**945**	**1871**	**2.6**	**(1.89, 3.40)**

Type of Revision performed for Primary Failure

Type of Revision	Component				Total
	Other Resurfacing		ASR/ASR		
	N	%	N	%	N
Femoral Component Only	173	59.2	30	62.5	203
Femoral and Acetabular (THR)	80	27.4	13	27.1	93
Acetabular Component Only	29	9.9	4	8.3	33
Cement Spacer	7	2.4	.	.	7
Removal Prosthesis	3	1.0	.	.	3
Cable/Other Minor Components	.	.	1	2.1	1
Total	**292**	**100.0**	**48**	**100.0**	**340**

Revision diagnosis by days to revision for Other Resurfacing

Revision Diagnosis	1. <2wks			2. 2wks-3mths			3. 3mths-1yr			4. 1yr-3yrs			5. >=3yrs			Total		
	N	Col%	Row%	N	Col%	Row%	N	Col%	Row%	N	Col%	Row%	N	Col%	Row%	N	Col%	Row%
Other	1	11.1	2.4	5	6.9	12.2	6	6.9	14.6	15	18.8	36.6	14	21.9	34.1	41	13.1	100
Dislocation of Prosthesis	.	.	.	1	1.4	9.1	4	4.6	36.4	3	3.8	27.3	3	4.7	27.3	11	3.5	100
Fracture	5	55.6	4.1	53	73.6	43.1	41	47.1	33.3	10	12.5	8.1	14	21.9	11.4	123	39.4	100
Infection	.	.	.	4	5.6	14.3	7	8.0	25.0	13	16.3	46.4	4	6.3	14.3	28	9.0	100
Loosening	3	33.3	3.8	8	11.1	10.3	21	24.1	26.9	27	33.8	34.6	19	29.7	24.4	78	25.0	100
Lysis	.	.	.	.	.	.	4	4.6	33.3	4	5.0	33.3	4	6.3	33.3	12	3.8	100
Pain	.	.	.	1	1.4	5.3	4	4.6	21.1	8	10.0	42.1	6	9.4	31.6	19	6.1	100
Total	**9**	**100**	**2.9**	**72**	**100**	**23.1**	**87**	**100**	**27.9**	**80**	**100**	**25.6**	**64**	**100**	**20.5**	**312**	**100**	**100**

Revision diagnosis by days to revision for ASR/ASR

Revision Diagnosis	2. 2wks-3mths			3. 3mths-1yr			4. 1yr-3yrs			5. >=3yrs			Total		
	N	Col%	Row%	N	Col%	Row%	N	Col%	Row%	N	Col%	Row%	N	Col%	Row%
Other	1	6.3	12.5	3	15.0	37.5	3	20.0	37.5	1	50.0	12.5	8	15.1	100
Dislocation of Prosthesis	1	6.3	100	.	.	.	.	.	.	.	.	.	1	1.9	100
Fracture	13	81.3	48.1	12	60.0	44.4	2	13.3	7.4	.	.	.	27	50.9	100
Infection	.	.	.	1	5.0	33.3	1	6.7	33.3	1	50.0	33.3	3	5.7	100
Loosening	1	6.3	9.1	3	15.0	27.3	7	46.7	63.6	.	.	.	11	20.8	100
Lysis	.	.	.	.	.	.	2	13.3	100	.	.	.	2	3.8	100
Pain	.	.	.	1	5.0	100	.	.	.	.	.	.	1	1.9	100
Total	**16**	**100**	**30.2**	**20**	**100**	**37.7**	**15**	**100**	**28.3**	**2**	**100**	**3.8**	**53**	**100**	**100**

Revision Rates by Hospital for ASR/ASR

Hospital	Number Revised	Total Number	Observed 'Component' Years	Revisions per 100 Observed 'Component' Years	Exact 95% CI
Hospital 001	0	2	3	0.0	(0.00, 126.0)
Hospital 002	0	4	9	0.0	(0.00, 39.75)
Hospital 003	0	6	6	0.0	(0.00, 65.98)
Hospital 004	0	4	2	0.0	(0.00, 228.4)
Hospital 005	0	1	2	0.0	(0.00, 149.9)
Hospital 006	0	1	0	0.0	(0.00, 1036)
Hospital 007	0	2	5	0.0	(0.00, 70.99)
Hospital 008	0	2	1	0.0	(0.00, 443.2)
Hospital 009	0	2	4	0.0	(0.00, 88.99)
Hospital 010	0	5	15	0.0	(0.00, 24.87)
Hospital 011	0	1	0	0.0	(0.00, 2041)
Hospital 012	0	19	38	0.0	(0.00, 9.71)
Hospital 013	1	12	22	4.6	(0.12, 25.56)
Hospital 014	0	4	10	0.0	(0.00, 37.26)
Hospital 015	0	2	1	0.0	(0.00, 364.2)
Hospital 016	0	3	3	0.0	(0.00, 122.9)
Hospital 017	0	1	1	0.0	(0.00, 284.9)
Hospital 018	1	2	3	37.3	(0.94, 207.9)
Hospital 019	0	1	3	0.0	(0.00, 143.2)
Hospital 020	2	13	14	14.0	(1.69, 50.47)
Hospital 021	0	2	3	0.0	(0.00, 142.1)
Hospital 022	0	2	2	0.0	(0.00, 206.0)
Hospital 023	0	1	3	0.0	(0.00, 132.2)
Hospital 024	0	2	3	0.0	(0.00, 144.3)
Hospital 025	0	29	43	0.0	(0.00, 8.56)
Hospital 026	1	2	2	47.3	(1.20, 263.3)
Hospital 027	0	3	7	0.0	(0.00, 52.90)
Hospital 028	2	4	5	39.3	(4.76, 141.9)
Hospital 029	1	2	1	67.6	(1.71, 376.9)
Hospital 030	4	21	41	9.8	(2.66, 25.02)
Hospital 031	0	1	3	0.0	(0.00, 129.3)
Hospital 032	1	3	6	16.9	(0.43, 94.17)
Hospital 033	0	2	5	0.0	(0.00, 79.63)
Hospital 034	0	7	15	0.0	(0.00, 24.74)
Hospital 035	0	1	1	0.0	(0.00, 306.9)
Hospital 036	0	3	2	0.0	(0.00, 152.2)
Hospital 037	0	3	8	0.0	(0.00, 44.09)
Hospital 038	0	1	3	0.0	(0.00, 134.6)
Hospital 039	6	387	816	0.7	(0.27, 1.60)

Hospital	Number Revised	Total Number	Observed 'Component' Years	Revisions per 100 Observed 'Component' Years	Exact 95% CI
Hospital 040	3	20	30	10.0	(2.06, 29.15)
Hospital 041	0	1	4	0.0	(0.00, 102.5)
Hospital 042	1	2	6	18.0	(0.46, 100.2)
Hospital 043	3	49	91	3.3	(0.68, 9.58)
Hospital 044	0	3	9	0.0	(0.00, 41.57)
Hospital 045	0	2	2	0.0	(0.00, 155.9)
Hospital 046	11	130	252	4.4	(2.18, 7.82)
Hospital 047	0	1	1	0.0	(0.00, 452.1)
Hospital 048	0	8	16	0.0	(0.00, 22.92)
Hospital 049	1	16	30	3.3	(0.08, 18.66)
Hospital 050	10	119	261	3.8	(1.84, 7.05)
Hospital 051	0	4	5	0.0	(0.00, 69.63)
Hospital 052	0	1	2	0.0	(0.00, 152.8)
Hospital 053	0	6	17	0.0	(0.00, 21.87)
Hospital 054	0	1	2	0.0	(0.00, 166.1)
Hospital 055	0	1	3	0.0	(0.00, 124.5)
Hospital 056	0	5	9	0.0	(0.00, 43.32)
Hospital 057	0	2	4	0.0	(0.00, 85.17)
Hospital 058	0	11	16	0.0	(0.00, 23.25)
Total	**48**	**945**	**1871**	**2.6**	**(1.89, 3.40)**

Revision Rates by State

Component	State	Number Revised	Total Number	Observed 'Component' Years	Revisions per 100 Observed 'Component' Years	Exact 95% CI
Other Resurfacing	ACT/NT	6	402	957	0.6	(0.23, 1.36)
Other Resurfacing	NEW SOUTH WALES	111	2973	8669	1.3	(1.05, 1.54)
Other Resurfacing	QUEENSLAND	34	1632	4265	0.8	(0.55, 1.11)
Other Resurfacing	SOUTH AUSTRALIA	20	600	2558	0.8	(0.48, 1.21)
Other Resurfacing	TASMANIA	6	67	152	3.9	(1.45, 8.59)
Other Resurfacing	VICTORIA	106	3711	12758	0.8	(0.68, 1.00)
Other Resurfacing	WESTERN AUSTRALIA	9	293	1225	0.7	(0.34, 1.39)
ASR/ASR	ACT/NT	2	14	15	13.2	(1.60, 47.75)
ASR/ASR	NEW SOUTH WALES	17	224	460	3.7	(2.15, 5.91)
ASR/ASR	QUEENSLAND	5	70	118	4.2	(1.37, 9.88)
ASR/ASR	SOUTH AUSTRALIA	7	397	822	0.9	(0.34, 1.75)
ASR/ASR	TASMANIA	1	4	4	27.2	(0.69, 151.6)
ASR/ASR	VICTORIA	15	233	442	3.4	(1.90, 5.60)
ASR/ASR	WESTERN AUSTRALIA	1	3	9	10.9	(0.28, 60.84)
Total		**340**	**10623**	**32455**	**1.0**	**(0.94, 1.17)**

Revision Rates by Year of Implant

Component by Procedure Year		Revision	Total	%
Other Resurfacing	2000	3	98	1.0
	2001	26	668	6.9
	2002	71	1407	14.5
	2003	62	1502	15.5
	2004	51	1521	15.7
	2005	35	1530	15.8
	2006	32	1510	15.6
	2007	12	1442	14.9
	Subtotal	292	9678	100.0
ASR/ASR	2003	2	43	4.6
	2004	13	164	17.4
	2005	12	301	31.9
	2006	19	259	27.4
	2007	2	178	18.8
	Subtotal	48	945	100.0
Total		**340**	**10623**	**100.0**

Number of Procedures by Year of Implant

Year of Implant	2003	2004	2005	2006	2007
ASR/ASR	43	164	301	259	178

Attachment C

ASR-ASR Investigation
Primary Total Resurfacing Hip Replacement

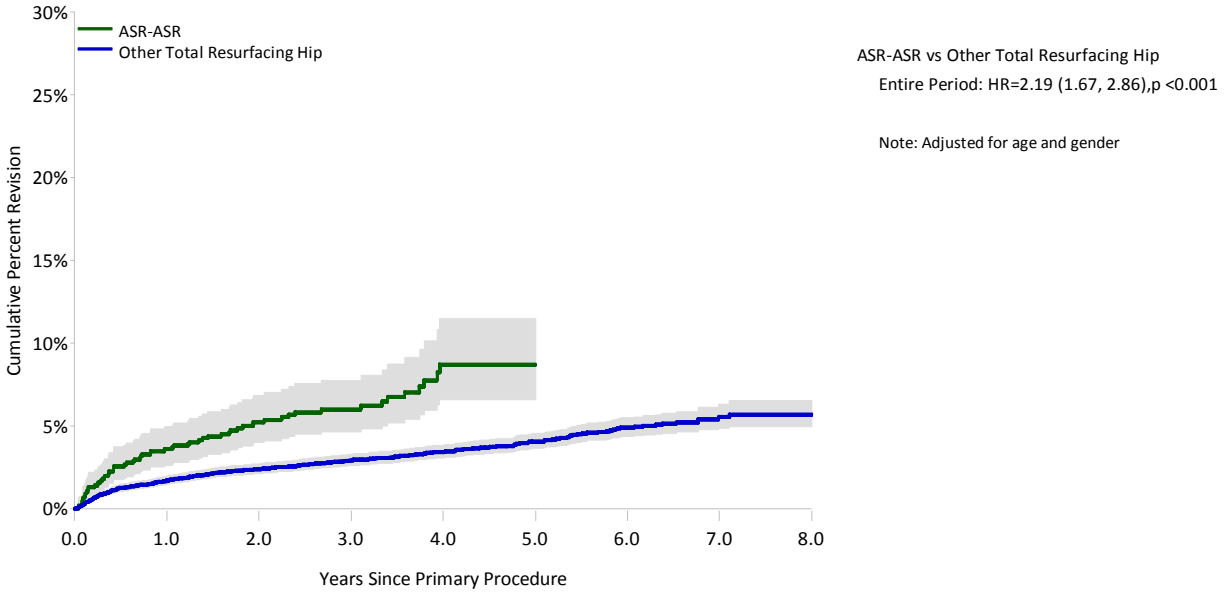
Table 1: Revision Rates of Primary Total Resurfacing Hip Replacement

Component	N Revised	N Total	Obs. Years	Revisions per 100 Obs. Yrs	Exact 95% CI
ASR-ASR	64	1073	2814	2.3	(1.75, 2.90)
Other Total Resurfacing Hip	373	11020	40533	0.9	(0.83, 1.02)
TOTAL	**437**	**12093**	**43347**	**1.0**	**(0.92, 1.11)**

Table 2: Yearly Cumulative Percent Revision of Primary Total Resurfacing Hip Replacement

CPR	1 Yr	3 Yrs	5 Yrs	7 Yrs	8 Yrs
ASR-ASR	3.6 (2.6, 4.9)	6.0 (4.6, 7.8)	8.7 (6.6, 11.5)		
Other Total Resurfacing Hip	1.7 (1.5, 2.0)	2.9 (2.6, 3.3)	4.1 (3.7, 4.6)	5.5 (4.9, 6.3)	5.7 (5.0, 6.5)

Figure 1: Cumulative Percent Revision of Primary Total Resurfacing Hip Replacement



Number at Risk	0 Yr	1 Yrs	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	8 Yrs
ASR-ASR	1073	905	717	479	185	41	0	0	0
Other Total Resurfacing Hip	11020	9510	7996	6483	4955	3468	2023	714	89

Table 3: Primary Diagnosis for Revised ASR-ASR Procedures

Primary Diagnosis	N	%
Avascular Necrosis	1	1.6%
Developmental Dysplasia	4	6.3%
Osteoarthritis	58	90.6%
Rheumatoid Arthritis	1	1.6%
TOTAL	**64**	**100.0%**

Table 4: Revision Rates of ASR-ASR Primary Total Resurfacing Hip Replacement by Fixation

Fixation	N Revised	N Total	Obs. Years	Revisions per 100 Obs. Yrs	Exact 95% CI
Cemented	1	8	20	5.1	(0.13, 28.50)
Hybrid	63	1065	2794	2.3	(1.73, 2.88)
TOTAL	**64**	**1073**	**2814**	**2.3**	**(1.75, 2.90)**

Table 5: Type of Revision Performed for Failure of Primary Total Resurfacing Hip Replacement

	ASR-ASR		Other Total Resurfacing Hip		Total	
Type of Revision	N	%	N	%	N	%
Femoral Only	37	57.8%	214	57.4%	251	57.4%
THR (Femoral/Acetabular)	21	32.8%	114	30.6%	135	30.9%
Acetabular Only	4	6.3%	33	8.8%	37	8.6%
Cement Spacer	1	1.6%	8	2.1%	9	2.1%
Removal of Prostheses	.	.	4	1.1%	4	1.1%
Head Only	1	1.6%	.	.	1	1.6%
TOTAL	**64**	**100.0%**	**373**	**100.0%**	**437**	**100.0%**

Table 6: Revision Diagnosis by Days to Revision for ASR-ASR

	2wks-3mths			3mths-1yr			1yr-3yrs			≥3yrs			TOTAL		
Revision Diagnosis	N	Row%	Col%	N	Row%	Col%	N	Row%	Col%	N	Row%	Col%	N	Row%	Col%
Fracture	14	45.2	87.5	13	41.9	61.9	3	9.7	15.8	1	3.2	12.5	31	100.0	48.4
Loosening/Lysis	1	6.7	6.3	3	20.0	14.3	9	60.0	47.4	2	13.3	25.0	15	100.0	23.4
Infection	.	.	.	1	16.7	4.8	4	66.7	21.1	1	16.7	12.5	6	100.0	9.4
Metal Sensitivity	.	.	.	2	40.0	9.5	1	20.0	5.3	2	40.0	25.0	5	100.0	7.8
Avascular Necrosis	.	.	.	.	.	.	2	66.7	10.5	1	33.3	12.5	3	100.0	4.7
Malposition	.	.	.	.	.	.	.	.	.	1	100.0	12.5	1	100.0	1.6
Dislocation Of Prosthesis	1	100.0	6.3	.	.	.	.	.	.	.	.	.	1	100.0	1.6
Implant Breakage Head	.	.	.	1	100.0	4.8	.	.	.	.	.	.	1	100.0	1.6
Pain	.	.	.	1	100.0	4.8	.	.	.	.	.	.	1	100.0	1.6
TOTAL	**16**	**25.0**	**100.0**	**21**	**32.8**	**100.0**	**19**	**29.7**	**100.0**	**8**	**12.5**	**100.0**	**64**	**100.0**	**100.0**

Table 7: Revision Diagnosis by Days to Revision for Other Primary Total Resurfacing Hip Replacement

	<2wks			2wks-3mths			3mths-1yr			1yr-3yrs			≥3yrs			TOTAL		
Revision Diagnosis	**N**	**Row%**	**Col%**	**N**	**Row%**	**Col%**	**N**	**Row%**	**Col%**	**N**	**Row%**	**Col%**	**N**	**Row%**	**Col%**	**N**	**Row%**	**Col%**
Fracture	5	3.5	50.0	58	41.1	75.3	45	31.9	46.9	16	11.3	16.2	17	12.1	18.7	141	100.0	37.8
Loosening/Lysis	4	3.5	40.0	9	8.0	11.7	29	25.7	30.2	36	31.9	36.4	35	31.0	38.5	113	100.0	30.3
Infection	.	.	.	4	12.1	5.2	6	18.2	6.3	18	54.5	18.2	5	15.2	5.5	33	100.0	8.8
Metal Sensitivity	.	.	.	.	.	.	2	8.7	2.1	5	21.7	5.1	16	69.6	17.6	23	100.0	6.2
Pain	.	.	.	1	4.5	1.3	7	31.8	7.3	9	40.9	9.1	5	22.7	5.5	22	100.0	5.9
Dislocation Of Prosthesis	.	.	.	1	7.7	1.3	4	30.8	4.2	3	23.1	3.0	5	38.5	5.5	13	100.0	3.5
Avascular Necrosis	.	.	.	.	.	.	1	9.1	1.0	7	63.6	7.1	3	27.3	3.3	11	100.0	2.9
Malposition	1	14.3	10.0	2	28.6	2.6	1	14.3	1.0	3	42.9	3.0	.	.	.	7	100.0	1.9
Other	.	.	.	1	20.0	1.3	1	20.0	1.0	2	40.0	2.0	1	20.0	1.1	5	100.0	1.3
Progression Of Disease	.	.	.	.	.	.	.	.	.	.	.	.	1	100.0	1.1	1	100.0	0.3
Implant Breakage Acetabular	.	.	.	.	.	.	.	.	.	.	.	.	1	100.0	1.1	1	100.0	0.3
Synovitis	.	.	.	.	.	.	.	.	.	.	.	.	1	100.0	1.1	1	100.0	0.3
Implant Breakage Head	.	.	.	.	.	.	.	.	.	.	.	.	1	100.0	1.1	1	100.0	0.3
Leg Length Discrepancy	.	.	.	1	100.0	1.3	.	.	.	.	.	.	.	.	.	1	100.0	0.3
TOTAL	**10**	**2.7**	**100.0**	**77**	**20.6**	**100.0**	**96**	**25.7**	**100.0**	**99**	**26.5**	**100.0**	**91**	**24.4**	**100.0**	**373**	**100.0**	**100.0**

Table 8: Revision Rates of ASR-ASR Primary Total Resurfacing Hip Replacement by Hospital

Hospital Number	N Revised	N Total	Obs. Years	Revisions per 100 Obs. Yrs	Exact 95% CI
1	0	2	4	0.0	(0.00, 97.21)
2	0	4	6	0.0	(0.00, 65.60)
3	1	2	2	40.3	(1.02, 224.6)
4	10	470	1234	0.8	(0.39, 1.49)
5	1	2	7	15.2	(0.39, 84.90)
6	1	2	6	15.6	(0.40, 87.00)
7	1	2	4	27.2	(0.69, 151.3)
8	0	1	5	0.0	(0.00, 80.20)
9	1	6	11	9.2	(0.23, 51.25)
10	0	37	75	0.0	(0.00, 4.94)
11	0	7	22	0.0	(0.00, 16.83)
12	5	21	57	8.7	(2.83, 20.37)
13	0	1	4	0.0	(0.00, 98.56)
14	15	134	371	4.0	(2.26, 6.67)
15	0	2	2	0.0	(0.00, 209.9)
16	1	2	3	32.1	(0.81, 178.7)
17	0	2	5	0.0	(0.00, 80.87)
18	0	1	4	0.0	(0.00, 93.05)
19	0	5	14	0.0	(0.00, 27.27)
20	0	2	6	0.0	(0.00, 58.23)
21	0	2	5	0.0	(0.00, 74.81)
22	0	2	5	0.0	(0.00, 80.20)
23	0	9	25	0.0	(0.00, 14.75)
24	0	1	4	0.0	(0.00, 95.69)
25	0	4	13	0.0	(0.00, 27.76)
26	0	4	14	0.0	(0.00, 26.52)
27	1	12	33	3.0	(0.08, 16.98)
28	4	25	48	8.3	(2.26, 21.26)
29	0	4	7	0.0	(0.00, 56.73)
30	2	4	7	28.2	(3.41, 101.8)
31	0	2	7	0.0	(0.00, 51.23)
32	0	1	1	0.0	(0.00, 506.5)
33	0	6	23	0.0	(0.00, 16.12)
34	0	1	3	0.0	(0.00, 108.0)
35	0	1	2	0.0	(0.00, 202.9)
36	0	2	2	0.0	(0.00, 225.7)
37	0	1	3	0.0	(0.00, 106.5)
38	0	1	4	0.0	(0.00, 103.1)
39	1	17	45	2.2	(0.06, 12.27)
40	0	2	4	0.0	(0.00, 84.42)
41	2	16	27	7.3	(0.89, 26.47)
42	0	3	5	0.0	(0.00, 69.88)
43	1	4	9	11.3	(0.29, 63.04)
44	5	55	138	3.6	(1.17, 8.43)

Hospital Number	N Revised	N Total	Obs. Years	Revisions per 100 Obs. Yrs	Exact 95% CI
45	0	3	10	0.0	(0.00, 38.45)
46	0	1	2	0.0	(0.00, 160.6)
47	1	3	11	9.5	(0.24, 52.94)
48	11	132	374	2.9	(1.47, 5.26)
49	0	5	20	0.0	(0.00, 18.59)
50	0	2	3	0.0	(0.00, 122.3)
51	0	5	10	0.0	(0.00, 35.89)
52	0	2	6	0.0	(0.00, 59.99)
53	0	3	12	0.0	(0.00, 31.05)
54	0	11	27	0.0	(0.00, 13.72)
55	0	1	3	0.0	(0.00, 114.5)
56	0	1	1	0.0	(0.00, 490.0)
57	0	1	4	0.0	(0.00, 97.28)
58	0	19	57	0.0	(0.00, 6.47)
TOTAL	**64**	**1073**	**2814**	**2.3**	**(1.75, 2.90)**

Table 9: Revision Rates of Primary Total Resurfacing Hip Replacement by State

Component	State	N Revised	N Total	Obs. Years	Revisions per 100 Obs. Yrs	Exact 95% CI
ASR-ASR	NSW	21	249	676	3.1	(1.92, 4.75)
	VIC	20	244	663	3.0	(1.84, 4.66)
	QLD	8	78	184	4.3	(1.88, 8.56)
	WA	1	3	11	9.0	(0.23, 49.92)
	SA	11	478	1246	0.9	(0.44, 1.58)
	TAS	1	4	5	20.5	(0.52, 114.3)
	ACT/NT	2	17	29	6.9	(0.83, 24.82)
Other Total Resurfacing Hip	NSW	134	3404	11748	1.1	(0.96, 1.35)
	VIC	133	4162	16538	0.8	(0.67, 0.95)
	QLD	50	1915	5965	0.8	(0.62, 1.11)
	WA	11	325	1516	0.7	(0.36, 1.30)
	SA	28	661	3158	0.9	(0.59, 1.28)
	TAS	7	79	220	3.2	(1.28, 6.56)
	ACT/NT	10	474	1389	0.7	(0.35, 1.32)
TOTAL	**.**	**437**	**12093**	**43347**	**1.0**	**(0.92, 1.11)**

Table 10: Revision Rates of Primary Total Resurfacing Hip Replacement by Year of Implant

Component	Year of Implant	N Revised	N Total	Obs. Years	Revisions per 100 Obs. Yrs	Exact 95% CI
ASR-ASR	2003	2	43	216	0.9	(0.11, 3.35)
	2004	18	164	669	2.7	(1.59, 4.25)
	2005	14	301	1008	1.4	(0.76, 2.33)
	2006	26	258	591	4.4	(2.88, 6.45)
	2007	3	175	265	1.1	(0.23, 3.30)
	2008	1	132	65	1.5	(0.04, 8.61)
Other Total Resurfacing Hip	2000	3	98	764	0.4	(0.08, 1.15)
	2001	30	668	4788	0.6	(0.42, 0.89)
	2002	85	1409	8711	1.0	(0.78, 1.21)
	2003	74	1502	7948	0.9	(0.73, 1.17)
	2004	58	1524	6625	0.9	(0.66, 1.13)
	2005	41	1531	5213	0.8	(0.56, 1.07)
	2006	42	1510	3671	1.1	(0.82, 1.55)
	2007	33	1468	2161	1.5	(1.05, 2.14)
	2008	7	1310	653	1.1	(0.43, 2.21)
TOTAL	**.**	**437**	**12093**	**43347**	**1.0**	**(0.92, 1.11)**

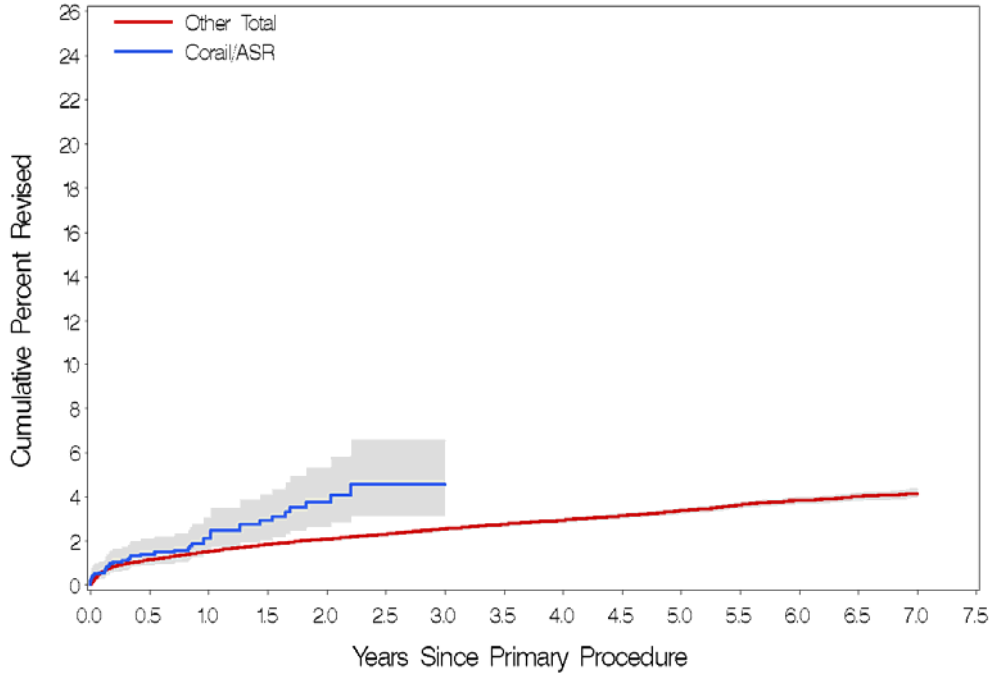
Table 11: Number of Procedures of ASR-ASR by Year of Implant

Year of Implant	N	Col%
2003	43	4.0%
2004	164	15.3%
2005	301	28.1%
2006	258	24.0%
2007	175	16.3%
2008	132	12.3%
TOTAL	**1073**	**100.0%**

Corail Femoral/ASR Acetabular Total Hip Investigation

Revision rates

Component	Number Revised	Total Number	Observed 'Component' Years	Revisions per 100 Observed 'Component' Years	Exact 95% CI
Other Total	3105	123355	386557	0.8	(0.78, 0.83)
Corail/ASR	40	1649	1904	2.1	(1.50, 2.86)
Total	**3145**	**125004**	**388461**	**0.8**	**(0.78, 0.84)**



Number at Risk	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs
Other Total	123355	100511	80054	60772	42910	26843	12658	3277
Corail/ASR	1649	847	302	23	0	0	0	0

Cumulative Percent Revision

CPR	1 Yr	2 Yrs	3 Yrs	5 Yrs	7 Yrs
Other Total	1.5 (1.4, 1.6)	2.1 (2.0, 2.2)	2.5 (2.4, 2.6)	3.4 (3.2, 3.5)	4.1 (3.9, 4.4)
Corail/ASR	2.1 (1.4, 3.1)	3.8 (2.6, 5.3)	4.5 (3.1, 6.6)		

Hazard Ratio of Corail/ASR vs Other Total

Component	Total Number	Observed Component Years	Revisions per 100 Component Years	Hazard Ratio	P Value	HR 95% CI
Corail/ASR	1649	1904	2.10	1.591	0.0036	(1.16, 2.18)

Primary Diagnosis for Revised Procedures

Primary Diagnosis	N	%
Avascular Necrosis	1	2.5
Developmental Dysplasia	1	2.5
Fractured Neck Of Femur	6	15.0
Osteoarthritis	32	80.0
Total	**40**	**100.0**

Revision Rates By Fixation for Corail/ASR

Fixation	Number Revised	Total Number	Observed 'Component' Years	Revisions per 100 Observed 'Component' Years	Exact 95% CI
Cementless	40	1648	1902	2.1	(1.50, 2.86)
Hybrid	0	1	2	0.0	(0.00, 179.9)
Total	**40**	**1649**	**1904**	**2.1**	**(1.50, 2.86)**

Type of Revision performed for Primary Failure

Type of Revision	Component				
	Other Total		Corail/ASR		Total
	N	%	N	%	N
Femoral Component Only	898	28.9	15	37.5	913
Acetabular Component Only	761	24.5	12	30.0	773
Head/Insert	617	19.9	.	.	617
Femoral and Acetabular (THR)	332	10.7	4	10.0	336
Head Only	207	6.7	.	.	207
Cement Spacer	129	4.2	1	2.5	130
Cable/Other Minor Components	57	1.8	8	20.0	65
Insert only	60	1.9	.	.	60
Removal Prosthesis	31	1.0	.	.	31
Reinsertion of Components	8	0.3	.	.	8
Cement Only	3	0.1	.	.	3
Bipolar head and Femoral Component	1	0.0	.	.	1
Cable and Cement	1	0.0	.	.	1
Total	**3105**	**100.0**	**40**	**100.0**	**3145**

Revision diagnosis by days to revision for Other Total

Revision Diagnosis	1. <2wks			2. 2wks-3mths			3. 3mths-1yr			4. 1yr-3yrs			5. >=3yrs			Total		
	N	Col%	Row%	N	Col%	Row%	N	Col%	Row%	N	Col%	Row%	N	Col%	Row%	N	Col%	Row%
Other	33	10.4	17.9	26	3.1	14.1	38	5.2	20.7	64	6.8	34.8	23	4.4	12.5	184	5.5	100
Dislocation of Prosthesis	130	41.1	12.2	364	43.1	34.2	218	30.1	20.5	244	25.8	22.9	109	20.7	10.2	1065	31.7	100
Fracture	94	29.7	18.5	168	19.9	33.1	99	13.7	19.5	82	8.7	16.1	65	12.3	12.8	508	15.1	100
Implant Breakage Acetabular	2	0.6	4.3	2	0.2	4.3	11	1.5	23.4	16	1.7	34.0	16	3.0	34.0	47	1.4	100
Implant Breakage Head	.	.	.	.	.	.	3	0.4	20.0	8	0.8	53.3	4	0.8	26.7	15	0.4	100
Implant Breakage Stem	.	.	.	2	0.2	11.8	2	0.3	11.8	4	0.4	23.5	9	1.7	52.9	17	0.5	100
Infection	4	1.3	0.8	155	18.4	31.2	115	15.9	23.1	165	17.5	33.2	58	11.0	11.7	497	14.8	100
Loosening	50	15.8	5.7	119	14.1	13.6	210	29.0	24.0	298	31.5	34.0	199	37.8	22.7	876	26.1	100
Lysis	.	.	.	4	0.5	7.0	7	1.0	12.3	17	1.8	29.8	29	5.5	50.9	57	1.7	100
Pain	3	0.9	4.1	3	0.4	4.1	16	2.2	21.9	40	4.2	54.8	11	2.1	15.1	73	2.2	100
Wear Acetabulum	.	.	.	1	0.1	5.9	5	0.7	29.4	7	0.7	41.2	4	0.8	23.5	17	0.5	100
Total	**316**	**100**	**9.4**	**844**	**100**	**25.1**	**724**	**100**	**21.6**	**945**	**100**	**28.2**	**527**	**100**	**15.7**	**3356**	**100**	**100**

Revision diagnosis by days to revision for Corail/ASR

Revision Diagnosis	1. <2wks			2. 2wks-3mths			3. 3mths-1yr			4. 1yr-3yrs			Total		
	N	Col%	Row%	N	Col%	Row%	N	Col%	Row%	N	Col%	Row%	N	Col%	Row%
Other	3	37.5	42.9	.	.	.	2	14.3	28.6	2	16.7	28.6	7	16.7	100
Dislocation of Prosthesis	1	12.5	16.7	3	37.5	50.0	2	14.3	33.3	.	.	.	6	14.3	100
Fracture	2	25.0	33.3	2	25.0	33.3	2	14.3	33.3	.	.	.	6	14.3	100
Infection	1	12.5	16.7	1	12.5	16.7	1	7.1	16.7	3	25.0	50.0	6	14.3	100
Loosening	1	12.5	5.9	2	25.0	11.8	7	50.0	41.2	7	58.3	41.2	17	40.5	100
Total	**8**	**100**	**19.0**	**8**	**100**	**19.0**	**14**	**100**	**33.3**	**12**	**100**	**28.6**	**42**	**100**	**100**

Revision Rates by Hospital for Corail/ASR

Hospital	Number Revised	Total Number	Observed 'Component' Years	Revisions per 100 Observed 'Component' Years	Exact 95% CI
Hospital 001	0	1	3	0.0	(0.00, 106.8)
Hospital 002	0	2	0	0.0	(0.00, 1433)
Hospital 003	0	4	2	0.0	(0.00, 172.7)
Hospital 004	1	9	9	10.9	(0.28, 60.71)
Hospital 005	0	10	6	0.0	(0.00, 59.43)
Hospital 006	0	5	4	0.0	(0.00, 85.33)
Hospital 007	1	56	83	1.2	(0.03, 6.71)
Hospital 008	0	2	2	0.0	(0.00, 179.4)
Hospital 009	0	6	7	0.0	(0.00, 54.31)
Hospital 010	0	8	6	0.0	(0.00, 58.53)
Hospital 011	0	5	4	0.0	(0.00, 102.9)
Hospital 012	0	6	8	0.0	(0.00, 45.72)
Hospital 013	1	122	155	0.6	(0.02, 3.59)
Hospital 014	0	8	18	0.0	(0.00, 20.57)
Hospital 015	0	45	42	0.0	(0.00, 8.75)
Hospital 016	0	10	21	0.0	(0.00, 17.18)
Hospital 017	0	1	2	0.0	(0.00, 189.5)
Hospital 018	0	2	4	0.0	(0.00, 92.92)
Hospital 019	0	2	3	0.0	(0.00, 112.8)
Hospital 020	0	8	13	0.0	(0.00, 28.53)
Hospital 021	0	11	22	0.0	(0.00, 17.13)
Hospital 022	0	18	13	0.0	(0.00, 28.78)
Hospital 023	0	1	1	0.0	(0.00, 698.1)
Hospital 024	0	2	6	0.0	(0.00, 60.88)
Hospital 025	0	4	5	0.0	(0.00, 68.22)
Hospital 026	0	30	35	0.0	(0.00, 10.47)
Hospital 027	0	2	5	0.0	(0.00, 71.14)
Hospital 028	0	6	3	0.0	(0.00, 108.4)
Hospital 029	0	10	10	0.0	(0.00, 35.81)
Hospital 030	2	108	108	1.9	(0.22, 6.70)
Hospital 031	1	18	31	3.3	(0.08, 18.23)
Hospital 032	1	20	18	5.7	(0.14, 31.67)
Hospital 033	0	10	27	0.0	(0.00, 13.81)
Hospital 034	0	2	1	0.0	(0.00, 294.2)
Hospital 035	0	12	7	0.0	(0.00, 53.15)
Hospital 036	0	2	0	0.0	(0.00, 1005)
Hospital 037	0	1	1	0.0	(0.00, 388.3)
Hospital 038	0	1	2	0.0	(0.00, 193.0)
Hospital 039	0	2	3	0.0	(0.00, 130.6)

Hospital	Number Revised	Total Number	Observed 'Component' Years	Revisions per 100 Observed 'Component' Years	Exact 95% CI
Hospital 040	0	7	9	0.0	(0.00, 42.12)
Hospital 041	0	2	1	0.0	(0.00, 280.1)
Hospital 042	1	10	13	7.7	(0.20, 43.10)
Hospital 043	0	32	33	0.0	(0.00, 11.10)
Hospital 044	0	10	8	0.0	(0.00, 47.95)
Hospital 045	0	2	1	0.0	(0.00, 274.4)
Hospital 046	1	26	19	5.3	(0.13, 29.57)
Hospital 047	0	17	18	0.0	(0.00, 20.27)
Hospital 048	0	5	4	0.0	(0.00, 89.64)
Hospital 049	0	2	2	0.0	(0.00, 169.7)
Hospital 050	0	1	1	0.0	(0.00, 670.3)
Hospital 051	0	9	5	0.0	(0.00, 79.30)
Hospital 052	1	15	12	8.5	(0.21, 47.12)
Hospital 053	0	10	13	0.0	(0.00, 27.46)
Hospital 054	0	2	3	0.0	(0.00, 109.4)
Hospital 055	0	3	2	0.0	(0.00, 234.7)
Hospital 056	0	4	5	0.0	(0.00, 69.63)
Hospital 057	1	1	0	3320.5	(84.07, 18500)
Hospital 058	2	5	2	89.9	(10.88, 324.6)
Hospital 059	0	2	2	0.0	(0.00, 221.6)
Hospital 060	0	18	21	0.0	(0.00, 17.49)
Hospital 061	0	4	7	0.0	(0.00, 55.42)
Hospital 062	0	1	3	0.0	(0.00, 138.5)
Hospital 063	0	61	88	0.0	(0.00, 4.19)
Hospital 064	0	26	24	0.0	(0.00, 15.59)
Hospital 065	0	1	0	0.0	(0.00, 969.3)
Hospital 066	3	52	79	3.8	(0.78, 11.06)
Hospital 067	0	7	11	0.0	(0.00, 34.73)
Hospital 068	1	19	14	7.1	(0.18, 39.57)
Hospital 069	2	49	60	3.3	(0.41, 12.09)
Hospital 070	3	48	31	9.8	(2.02, 28.66)
Hospital 071	0	1	3	0.0	(0.00, 122.0)
Hospital 072	0	16	5	0.0	(0.00, 73.59)
Hospital 073	10	172	123	8.1	(3.90, 14.95)
Hospital 074	2	53	130	1.5	(0.19, 5.54)
Hospital 075	0	1	1	0.0	(0.00, 405.8)
Hospital 076	0	5	10	0.0	(0.00, 35.70)
Hospital 077	0	1	1	0.0	(0.00, 246.8)
Hospital 078	0	4	6	0.0	(0.00, 64.25)
Hospital 079	0	1	1	0.0	(0.00, 667.0)

Hospital	Number Revised	Total Number	Observed 'Component' Years	Revisions per 100 Observed 'Component' Years	Exact 95% CI
Hospital 080	0	1	0	0.0	(0.00, 1308)
Hospital 081	1	31	15	6.8	(0.17, 37.71)
Hospital 082	3	103	196	1.5	(0.32, 4.47)
Hospital 083	0	13	6	0.0	(0.00, 57.09)
Hospital 084	1	91	59	1.7	(0.04, 9.43)
Hospital 085	1	6	4	23.6	(0.60, 131.6)
Hospital 086	0	11	9	0.0	(0.00, 42.64)
Hospital 087	0	1	2	0.0	(0.00, 235.1)
Hospital 088	0	1	2	0.0	(0.00, 154.7)
Hospital 089	0	1	2	0.0	(0.00, 175.0)
Hospital 090	0	1	1	0.0	(0.00, 265.2)
Hospital 091	0	3	3	0.0	(0.00, 146.0)
Hospital 092	0	2	3	0.0	(0.00, 128.8)
Hospital 093	0	2	1	0.0	(0.00, 381.7)
Hospital 094	0	74	109	0.0	(0.00, 3.38)
Hospital 095	0	1	1	0.0	(0.00, 526.3)
Hospital 096	0	1	2	0.0	(0.00, 229.1)
Hospital 097	0	29	27	0.0	(0.00, 13.76)
Total	**40**	**1649**	**1904**	**2.1**	**(1.50, 2.86)**

Revision Rates by State

Component	State	Number Revised	Total Number	Observed 'Component' Years	Revisions per 100 Observed 'Component' Years	Exact 95% CI
Other Total	ACT/NT	79	2789	8174	1.0	(0.77, 1.20)
Other Total	NEW SOUTH WALES	843	36056	102658	0.8	(0.77, 0.88)
Other Total	QUEENSLAND	525	19577	62568	0.8	(0.77, 0.91)
Other Total	SOUTH AUSTRALIA	282	13096	47517	0.6	(0.53, 0.67)
Other Total	TASMANIA	105	4386	14672	0.7	(0.59, 0.87)
Other Total	VICTORIA	853	33409	104650	0.8	(0.76, 0.87)
Other Total	WESTERN AUSTRALIA	418	14042	46317	0.9	(0.82, 0.99)
Corail/ASR	NEW SOUTH WALES	3	316	274	1.1	(0.23, 3.20)
Corail/ASR	QUEENSLAND	12	407	479	2.5	(1.29, 4.37)
Corail/ASR	SOUTH AUSTRALIA	4	187	249	1.6	(0.44, 4.11)
Corail/ASR	TASMANIA	2	201	274	0.7	(0.09, 2.64)
Corail/ASR	VICTORIA	9	337	493	1.8	(0.84, 3.47)
Corail/ASR	WESTERN AUSTRALIA	10	201	136	7.4	(3.53, 13.54)
Total		**3145**	**125004**	**388461**	**0.8**	**(0.78, 0.84)**

Revision Rates by Year of Implant

Component by Procedure	Year	Revision	Total	%
Other Total	1999	13	379	0.3
	2000	151	3699	3.0
	2001	421	11228	9.1
	2002	505	15827	12.8
	2003	570	17061	13.8
	2004	533	18108	14.7
	2005	400	18652	15.1
	2006	323	19029	15.4
	2007	189	19372	15.7
	Subtotal	3105	123355	100.0
Corail/ASR	2004	0	25	1.5
	2005	12	296	18.0
	2006	18	551	33.4
	2007	10	777	47.1
	Subtotal	40	1649	100.0
Total		**3145**	**125004**	**100.0**

Number of Procedures by Year of Implant

Year of Implant	2004	2005	2006	2007
Corail/ASR	25	296	551	777

Attachment E ASR XL update 2009

ASR Investigation
Primary Conventional Total Hip Replacement

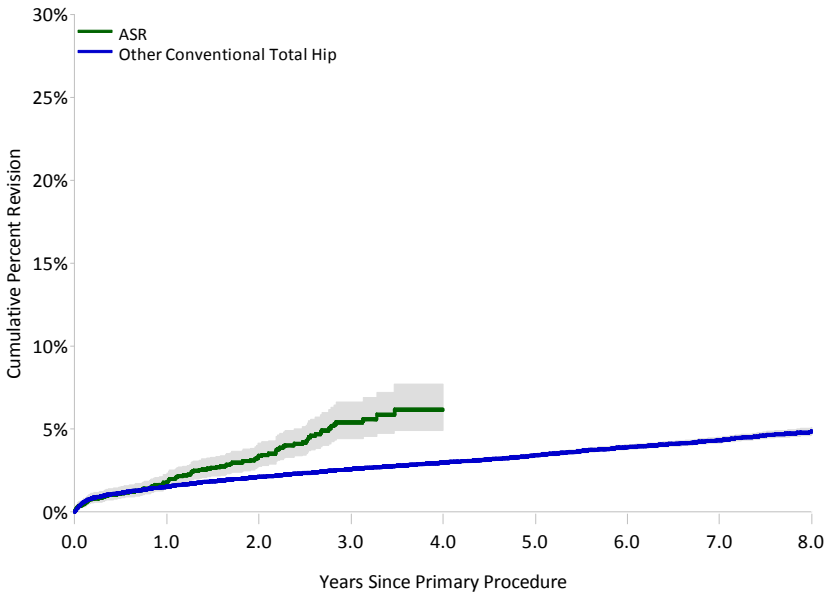
Table 1: Revision Rates of Primary Conventional Total Hip Replacement

Component	N Revised	N Total	Obs. Years	Revisions per 100 Obs. Yrs	Exact 95% CI
ASR	126	3971	6854	1.8	(1.53, 2.19)
Other Conventional Total Hip	3969	143451	504390	0.8	(0.76, 0.81)
TOTAL	**4095**	**147422**	**511244**	**0.8**	**(0.78, 0.83)**

Table 2: Yearly Cumulative Percent Revision of Primary Conventional Total Hip Replacement

CPR	1 Yr	3 Yrs	5 Yrs	7 Yrs	8 Yrs
ASR	1.8 (1.4, 2.3)	5.4 (4.4, 6.6)			
Other Conventional Total Hip	1.5 (1.5, 1.6)	2.6 (2.5, 2.7)	3.4 (3.3, 3.5)	4.3 (4.2, 4.5)	4.9 (4.6, 5.1)

Figure 1: Cumulative Percent Revision of Primary Conventional Total Hip Replacement



ASR vs Other Conventional Total Hip
0 - 2Wk: HR=1.35 (0.79, 2.30),p =0.270
2Wk - 1Mth: HR=0.33 (0.12, 0.87),p =0.025
1Mth - 2.5Yr: HR=1.81 (1.47, 2.24),p <0.001
2.5Yr - 3Yr: HR=5.41 (2.95, 9.91),p <0.001
3Yr+: HR=3.87 (1.60, 9.39),p =0.002

Note: Adjusted for age and gender

Number at Risk	0 Yr	1 Yrs	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	8 Yrs
ASR	3971	2733	1535	603	76	0	0	0	0
Other Conventional Total Hip	143451	118364	97308	77619	58949	41550	25873	12154	3114

Table 3: Primary Diagnosis for Revised ASR Procedures

Primary Diagnosis	N	%
Avascular Necrosis	6	4.8%
Developmental Dysplasia	5	4.0%
Fractured Neck Of Femur	7	5.6%
Osteoarthritis	107	84.9%
Other Inflammatory Arthritis	1	0.8%
TOTAL	**126**	**100.0%**

Table 4: Revision Rates of ASR Primary Conventional Total Hip Replacement by Fixation

Fixation	N Revised	N Total	Obs. Years	Revisions per 100 Obs. Yrs	Exact 95% CI
Cementless	124	3891	6731	1.8	(1.53, 2.20)
Hybrid	2	80	123	1.6	(0.20, 5.87)
TOTAL	**126**	**3971**	**6854**	**1.8**	**(1.53, 2.19)**

Table 5: Type of Revision Performed for Failure of Primary Conventional Total Hip Replacement

Type of Revision	ASR		Other Conventional Total Hip		Total	
	N	%	N	%	N	%
Femoral Only	30	23.8%	1172	29.5%	1202	29.4%
Acetabular Only	50	39.7%	957	24.1%	1007	24.9%
Head/Insert	.	.	751	18.9%	751	18.9%
THR (Femoral/Acetabular)	18	14.3%	468	11.8%	486	11.9%
Head Only	12	9.5%	262	6.6%	274	6.7%
Cement Spacer	11	8.7%	182	4.6%	193	4.8%
Minor Components	3	2.4%	67	1.7%	70	1.7%
Insert Only	.	.	66	1.7%	66	1.7%
Removal of Prostheses	2	1.6%	34	0.9%	36	0.9%
Reinsertion of Components	.	.	6	0.2%	6	0.2%
Neck Only	.	.	3	0.1%	3	0.1%
Bipolar Head and Femoral	.	.	1	0.0%	1	0.0%
TOTAL	**126**	**100.0%**	**3969**	**100.0%**	**4095**	**100.0%**

Table 6: Revision Diagnosis by Days to Revision for ASR

	<2wks			2wks-3mths			3mths-1yr			1yr-3yrs			≥3yrs			TOTAL		
Revision Diagnosis	**N**	**Row%**	**Col%**	**N**	**Row%**	**Col%**	**N**	**Row%**	**Col%**	**N**	**Row%**	**Col%**	**N**	**Row%**	**Col%**	**N**	**Row%**	**Col%**
Loosening/Lysis	4	7.8	28.6	6	11.8	31.6	13	25.5	43.3	24	47.1	41.4	4	7.8	80.0	51	100.0	40.5
Infection	1	3.4	7.1	5	17.2	26.3	6	20.7	20.0	17	58.6	29.3	.	.	.	29	100.0	23.0
Fracture	4	26.7	28.6	4	26.7	21.1	4	26.7	13.3	3	20.0	5.2	.	.	.	15	100.0	11.9
Metal Sensitivity	.	.	.	.	.	.	3	27.3	10.0	8	72.7	13.8	.	.	.	11	100.0	8.7
Dislocation Of Prosthesis	2	20.0	14.3	4	40.0	21.1	3	30.0	10.0	1	10.0	1.7	.	.	.	10	100.0	7.9
Other	.	.	.	.	.	.	.	.	.	3	100.0	5.2	.	.	.	3	100.0	2.4
Leg Length Discrepancy	2	66.7	14.3	.	.	.	1	33.3	3.3	.	.	.	.	.	.	3	100.0	2.4
Incorrect Sizing	1	50.0	7.1	.	.	.	.	.	.	1	50.0	1.7	.	.	.	2	100.0	1.6
Implant Breakage Stem	.	.	.	.	.	.	.	.	.	.	.	.	1	100.0	20.0	1	100.0	0.8
Pain	.	.	.	.	.	.	.	.	.	1	100.0	1.7	.	.	.	1	100.0	0.8
TOTAL	**14**	**11.1**	**100.0**	**19**	**15.1**	**100.0**	**30**	**23.8**	**100.0**	**58**	**46.0**	**100.0**	**5**	**4.0**	**100.0**	**126**	**100.0**	**100.0**

Table 7: Revision Diagnosis by Days to Revision for Other Primary Conventional Total Hip Replacement

	<2wks			2wks-3mths			3mths-1yr			1yr-3yrs			≥3yrs			TOTAL		
Revision Diagnosis	**N**	**Row%**	**Col%**	**N**	**Row%**	**Col%**	**N**	**Row%**	**Col%**	**N**	**Row%**	**Col%**	**N**	**Row%**	**Col%**	**N**	**Row%**	**Col%**
Dislocation Of Prosthesis	140	11.9	37.9	402	34.3	42.5	229	19.5	29.1	258	22.0	24.2	144	12.3	18.0	1173	100.0	29.6
Loosening/Lysis	61	5.4	16.5	141	12.4	14.9	232	20.4	29.5	359	31.5	33.6	346	30.4	43.3	1139	100.0	28.7
Infection	8	1.2	2.2	187	28.8	19.8	150	23.1	19.1	210	32.4	19.7	94	14.5	11.8	649	100.0	16.4
Fracture	109	18.8	29.5	180	31.0	19.0	98	16.9	12.5	89	15.3	8.3	104	17.9	13.0	580	100.0	14.6
Pain	2	2.5	0.5	2	2.5	0.2	15	19.0	1.9	39	49.4	3.7	21	26.6	2.6	79	100.0	2.0
Other	10	15.2	2.7	6	9.1	0.6	9	13.6	1.1	22	33.3	2.1	19	28.8	2.4	66	100.0	1.7
Leg Length Discrepancy	9	16.4	2.4	12	21.8	1.3	19	34.5	2.4	12	21.8	1.1	3	5.5	0.4	55	100.0	1.4
Implant Breakage Acetabular	3	5.6	0.8	4	7.4	0.4	8	14.8	1.0	18	33.3	1.7	21	38.9	2.6	54	100.0	1.4
Malposition	10	23.8	2.7	5	11.9	0.5	7	16.7	0.9	13	31.0	1.2	7	16.7	0.9	42	100.0	1.1
Implant Breakage Stem	.	.	.	2	7.7	0.2	3	11.5	0.4	6	23.1	0.6	15	57.7	1.9	26	100.0	0.7
Incorrect Sizing	11	45.8	3.0	3	12.5	0.3	4	16.7	0.5	6	25.0	0.6	.	.	.	24	100.0	0.6
Instability	3	13.0	0.8	.	.	.	3	13.0	0.4	10	43.5	0.9	7	30.4	0.9	23	100.0	0.6
Metal Sensitivity	1	4.8	0.3	.	.	.	2	9.5	0.3	10	47.6	0.9	8	38.1	1.0	21	100.0	0.5
Implant Breakage Head	1	5.6	0.3	.	.	.	3	16.7	0.4	8	44.4	0.7	6	33.3	0.8	18	100.0	0.5
Heterotropic Bone	.	.	.	.	.	.	1	12.5	0.1	5	62.5	0.5	2	25.0	0.3	8	100.0	0.2
Wear Acetabulum	1	14.3	0.3	1	14.3	0.1	2	28.6	0.3	1	14.3	0.1	2	28.6	0.3	7	100.0	0.2
Tumour	.	.	.	.	.	.	2	66.7	0.3	1	33.3	0.1	.	.	.	3	100.0	0.1
Synovitis	.	.	.	.	.	.	.	.	.	1	100.0	0.1	.	.	.	1	100.0	0.0
Progression Of Disease	.	.	.	.	.	.	.	.	.	.	.	.	1	100.0	0.1	1	100.0	0.0
TOTAL	**369**	**9.3**	**100.0**	**945**	**23.8**	**100.0**	**787**	**19.8**	**100.0**	**1068**	**26.9**	**100.0**	**800**	**20.2**	**100.0**	**3969**	**100.0**	**100.0**

Table 8: Revision Rates of ASR Primary Conventional Total Hip Replacement by Hospital

Hospital Number	N Revised	N Total	Obs. Years	Revisions per 100 Obs. Yrs	Exact 95% CI
1	0	9	24	0.0	(0.00, 15.41)
2	0	7	5	0.0	(0.00, 67.81)
3	4	243	475	0.8	(0.23, 2.16)
4	1	87	116	0.9	(0.02, 4.81)
5	0	3	5	0.0	(0.00, 69.74)
6	0	1	1	0.0	(0.00, 490.0)
7	0	1	0	0.0	(0.00, 922.9)
8	0	8	11	0.0	(0.00, 35.06)
9	0	1	1	0.0	(0.00, 383.9)
10	0	12	25	0.0	(0.00, 14.56)
11	1	7	11	8.9	(0.22, 49.43)
12	1	4	2	56.6	(1.43, 315.5)
13	9	264	516	1.7	(0.80, 3.31)
14	0	7	18	0.0	(0.00, 20.92)
15	0	1	4	0.0	(0.00, 105.3)
16	0	1	1	0.0	(0.00, 266.8)
17	0	17	23	0.0	(0.00, 16.29)
18	1	23	29	3.5	(0.09, 19.51)
19	0	6	6	0.0	(0.00, 63.52)
20	0	2	3	0.0	(0.00, 128.0)
21	2	10	13	15.0	(1.82, 54.15)
22	1	39	75	1.3	(0.03, 7.48)
23	0	11	21	0.0	(0.00, 17.73)
24	3	66	117	2.6	(0.53, 7.49)
25	1	11	15	6.5	(0.16, 36.22)
26	0	3	1	0.0	(0.00, 311.2)
27	0	1	0	0.0	(0.00, 2284)
28	1	39	54	1.8	(0.05, 10.25)
29	2	25	33	6.0	(0.73, 21.81)
30	0	9	5	0.0	(0.00, 71.40)
31	0	71	80	0.0	(0.00, 4.60)
32	1	1	0	3320.5	(84.07, 18500)
33	0	3	3	0.0	(0.00, 142.3)
34	21	332	380	5.5	(3.42, 8.44)
35	3	54	182	1.7	(0.34, 4.82)
36	0	6	11	0.0	(0.00, 34.31)
37	0	8	14	0.0	(0.00, 25.80)
38	0	1	3	0.0	(0.00, 118.6)
39	0	11	16	0.0	(0.00, 23.38)
40	1	4	14	7.2	(0.18, 40.04)
41	0	1	1	0.0	(0.00, 440.3)
42	0	1	2	0.0	(0.00, 241.0)
43	0	27	47	0.0	(0.00, 7.86)
44	0	5	10	0.0	(0.00, 36.94)

Attachment E ASR XL update 2009

Hospital Number	N Revised	N Total	Obs. Years	Revisions per 100 Obs. Yrs	Exact 95% CI
45	0	1	3	0.0	(0.00, 126.6)
46	0	10	18	0.0	(0.00, 21.04)
47	1	6	12	8.6	(0.22, 48.01)
48	0	1	1	0.0	(0.00, 466.2)
49	5	116	325	1.5	(0.50, 3.59)
50	0	1	3	0.0	(0.00, 110.7)
51	5	186	309	1.6	(0.53, 3.77)
52	1	74	155	0.6	(0.02, 3.60)
53	1	22	48	2.1	(0.05, 11.59)
54	0	10	34	0.0	(0.00, 10.72)
55	0	32	65	0.0	(0.00, 5.65)
56	0	12	13	0.0	(0.00, 27.53)
57	2	104	206	1.0	(0.12, 3.51)
58	0	3	1	0.0	(0.00, 287.3)
59	4	108	109	3.7	(1.00, 9.37)
60	0	1	0	0.0	(0.00, 2105)
61	0	2	6	0.0	(0.00, 62.81)
62	1	11	24	4.1	(0.10, 22.85)
63	0	6	11	0.0	(0.00, 33.54)
64	0	1	4	0.0	(0.00, 100.6)
65	0	6	5	0.0	(0.00, 67.77)
66	1	26	66	1.5	(0.04, 8.47)
67	0	4	5	0.0	(0.00, 70.36)
68	0	1	2	0.0	(0.00, 193.0)
69	0	4	3	0.0	(0.00, 120.2)
70	1	10	19	5.2	(0.13, 28.98)
71	0	13	31	0.0	(0.00, 11.99)
72	0	9	24	0.0	(0.00, 15.64)
73	0	2	7	0.0	(0.00, 51.31)
74	0	1	4	0.0	(0.00, 87.10)
75	0	1	3	0.0	(0.00, 108.9)
76	0	10	24	0.0	(0.00, 15.38)
77	1	6	8	12.1	(0.31, 67.61)
78	0	1	2	0.0	(0.00, 216.6)
79	0	3	1	0.0	(0.00, 484.7)
80	0	1	4	0.0	(0.00, 91.22)
81	2	56	109	1.8	(0.22, 6.63)
82	0	13	19	0.0	(0.00, 19.45)
83	0	40	50	0.0	(0.00, 7.37)
84	0	7	22	0.0	(0.00, 16.88)
85	0	22	30	0.0	(0.00, 12.19)
86	1	125	311	0.3	(0.01, 1.79)
87	1	6	12	8.3	(0.21, 46.42)
88	1	5	13	7.4	(0.19, 41.35)
89	0	3	6	0.0	(0.00, 66.67)
90	0	4	6	0.0	(0.00, 64.04)

Attachment E ASR XL update 2009

Hospital Number	N Revised	N Total	Obs. Years	Revisions per 100 Obs. Yrs	Exact 95% CI
91	0	2	5	0.0	(0.00, 74.40)
92	0	4	7	0.0	(0.00, 51.76)
93	0	1	1	0.0	(0.00, 391.7)
94	0	17	28	0.0	(0.00, 13.10)
95	0	6	14	0.0	(0.00, 26.20)
96	3	34	46	6.5	(1.34, 18.99)
97	0	1	2	0.0	(0.00, 205.7)
98	2	109	205	1.0	(0.12, 3.52)
99	1	17	36	2.8	(0.07, 15.44)
100	0	2	5	0.0	(0.00, 72.09)
101	5	113	197	2.5	(0.83, 5.93)
102	0	6	12	0.0	(0.00, 29.89)
103	11	216	372	3.0	(1.48, 5.29)
104	0	1	3	0.0	(0.00, 145.5)
105	1	8	11	9.1	(0.23, 50.76)
106	0	2	5	0.0	(0.00, 73.47)
107	0	1	1	0.0	(0.00, 504.6)
108	0	1	3	0.0	(0.00, 114.5)
109	0	1	1	0.0	(0.00, 554.5)
110	0	1	4	0.0	(0.00, 82.76)
111	1	1	2	45.8	(1.16, 255.0)
112	0	35	70	0.0	(0.00, 5.26)
113	0	2	7	0.0	(0.00, 50.92)
114	7	217	322	2.2	(0.87, 4.47)
115	2	13	26	7.6	(0.92, 27.42)
116	0	30	35	0.0	(0.00, 10.48)
117	0	21	35	0.0	(0.00, 10.53)
118	2	239	377	0.5	(0.06, 1.91)
119	0	9	16	0.0	(0.00, 22.47)
120	0	4	9	0.0	(0.00, 40.47)
121	0	2	1	0.0	(0.00, 283.7)
122	0	12	38	0.0	(0.00, 9.68)
123	0	4	2	0.0	(0.00, 186.4)
124	0	51	70	0.0	(0.00, 5.26)
125	3	25	30	10.2	(2.10, 29.70)
126	0	2	5	0.0	(0.00, 77.08)
127	0	45	69	0.0	(0.00, 5.32)
128	0	1	3	0.0	(0.00, 125.1)
129	0	1	4	0.0	(0.00, 85.55)
130	0	4	7	0.0	(0.00, 53.07)
131	0	6	9	0.0	(0.00, 43.28)
132	0	5	7	0.0	(0.00, 51.45)
133	0	1	1	0.0	(0.00, 333.5)
134	0	5	2	0.0	(0.00, 198.7)
135	7	157	234	3.0	(1.20, 6.17)
136	0	7	7	0.0	(0.00, 55.11)

Hospital Number	N Revised	N Total	Obs. Years	Revisions per 100 Obs. Yrs	Exact 95% CI
TOTAL	**126**	**3971**	**6854**	**1.8**	**(1.53, 2.19)**

Table 9: Revision Rates of Primary Conventional Total Hip Replacement by State

Component	State	N Revised	N Total	Obs. Years	Revisions per 100 Obs. Yrs	Exact 95% CI
ASR	NSW	38	1428	2449	1.6	(1.10, 2.13)
	VIC	17	566	1126	1.5	(0.88, 2.42)
	QLD	26	654	1105	2.4	(1.54, 3.45)
	WA	22	386	448	4.9	(3.08, 7.43)
	SA	16	654	1210	1.3	(0.76, 2.15)
	TAS	7	283	516	1.4	(0.55, 2.80)
Other Conventional Total Hip	NSW	1099	41917	136664	0.8	(0.76, 0.85)
	VIC	1096	39266	137096	0.8	(0.75, 0.85)
	QLD	682	22909	81660	0.8	(0.77, 0.90)
	WA	509	16186	59897	0.8	(0.78, 0.93)
	SA	350	14767	59241	0.6	(0.53, 0.66)
	TAS	131	5085	18876	0.7	(0.58, 0.82)
	ACT/NT	102	3321	10956	0.9	(0.76, 1.13)
TOTAL	**.**	**4095**	**147422**	**511244**	**0.8**	**(0.78, 0.83)**

Table 10: Revision Rates of Primary Conventional Total Hip Replacement by Year of Implant

Component	Year of Implant	N Revised	N Total	Obs. Years	Revisions per 100 Obs. Yrs	Exact 95% CI
ASR	2004	3	84	338	0.9	(0.18, 2.59)
	2005	31	582	1889	1.6	(1.12, 2.33)
	2006	44	957	2280	1.9	(1.40, 2.59)
	2007	31	1181	1711	1.8	(1.23, 2.57)
	2008	17	1167	636	2.7	(1.56, 4.28)
Other Conventional Total Hip	1999	14	379	2909	0.5	(0.26, 0.81)
	2000	167	3702	27235	0.6	(0.52, 0.71)
	2001	481	11227	74404	0.6	(0.59, 0.71)
	2002	580	15838	93628	0.6	(0.57, 0.67)
	2003	661	17071	86450	0.8	(0.71, 0.83)
	2004	599	18069	75870	0.8	(0.73, 0.86)
	2005	480	18387	61163	0.8	(0.72, 0.86)
	2006	436	18665	44667	1.0	(0.89, 1.07)
	2007	312	19171	27927	1.1	(1.00, 1.25)
	2008	239	20942	10137	2.4	(2.07, 2.68)
TOTAL	**.**	**4095**	**147422**	**511244**	**0.8**	**(0.78, 0.83)**

Table 11: Number of Procedures of ASR by Year of Implant

Year of Implant	N	Col%
2004	84	2.1%
2005	582	14.7%
2006	957	24.1%
2007	1181	29.7%
2008	1167	29.4%
TOTAL	**3971**	**100.0%**

Table 12: Revision Rates of Primary ASR Conventional Total Hip Replacement Combined with Stem Components

Acetabular Component	Stem Component	N Revised	N Total	Obs. Years	Revisions per 100 Obs. Yrs	Exact 95% CI
ASR	C-Stem	2	65	98	2.0	(0.25, 7.39)
ASR	Corail	85	2532	3939	2.2	(1.72, 2.67)
ASR	Corail RSA	0	4	11	0.0	(0.00, 33.07)
ASR	Echelon	0	1	0	0.0	(0.00, 929.2)
ASR	Fjord	0	2	7	0.0	(0.00, 55.27)
ASR	Proxima	1	6	10	9.7	(0.25, 53.95)
ASR	S-Rom	10	250	537	1.9	(0.89, 3.42)
ASR	Silent	0	19	39	0.0	(0.00, 9.43)
ASR	Solution	0	2	2	0.0	(0.00, 156.5)
ASR	Stability	0	1	0	0.0	(0.00, 2284)
ASR	Summit	28	1082	2203	1.3	(0.84, 1.84)
ASR	Taperloc	0	7	7	0.0	(0.00, 54.50)
TOTAL	**.**	**126**	**3971**	**6854**	**1.8**	**(1.53, 2.19)**

Senate Community Affairs References Committee

ANSWERS TO QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Inquiry into the Regulatory Standards for the Approval of Medical Devices
27 September 2011

Question no: 6

Topic: Information from the manufacturer

Hansard Page: 54

Senator Brown asked:

Can the TGA tell us exactly what information it received from the manufacturer on the issue of the ASR hip?

Answer:

The Therapeutic Goods Administration (TGA) met with the manufacturer, Johnson & Johnson Medical (J&J) in September 2007 to discuss high early revision rates for the ASR Surface Replacement device. J&J tabled a submission which proposed surgeons be required to undergo specific training on the ASR implant as a means of reducing the number of revisions. The documentation provided to TGA has not been attached to this response because it is claimed by J&J to be commercial in confidence. Following a recent Freedom of Information request, release of this information is currently the subject of a review by the Office of the Information Commissioner.

On 1 May 2008 the TGA received an update report from J&J on the actions undertaken in September 2007 in relation to the ASR Surface Replacement device (see preceding paragraph). This report is also claimed by J&J to be commercial in confidence and the matter has also been referred to the Office of the Information Commissioner.

The TGA received a letter from J&J, dated 8 December 2009, in relation to the discontinuation of the ASR system and resurfacing system. This information is also claimed by J&J to be commercial in confidence and, as with the cases above, is currently the subject of a review by the Office of the Information Commissioner.

Individual early revisions (revisions that take place <10 years after implantation) are considered to be reportable adverse events. To date the TGA has received 401 adverse event reports from J&J about ASR implants. Of these:

- 69 were received prior to December 2009 (the date of the withdrawal of the implant in Australia)
- 139 were received between January 2010 and December 2010

- 193 were received as a batch of summary reports covering the period January - March 2011

The TGA, while having no objection to the release to the Committee of the information claimed to be Commercial in Confidence, has not included this information in the response pending resolution of the matters before the Office of the Information Commissioner.

Senate Community Affairs References Committee

ANSWERS TO QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Inquiry into the Regulatory Standards for the Approval of Medical Devices
27 September 2011

Question no: 7

Topic: Timeline

Hansard Page: 54

Senator Moore asked:

Can TGA please provide a timeline outlining the sequence of events and interactions between the TGA, OEWG, NJRR and the manufacturer in relation to the ASR hip.

Answer:

The timeline is attached.

ASR timelines

Early 2004	TGA approves ASR Resurfacing
Early 2005	TGA approves ASR XL
Oct 2006	2006 National Joint Replacement Registry (NJRR) annual report released: Mentions ASR Resurfacing, but the difference in revision rates is noted in the report as not significant.
June 2007	Orthopaedic Expert Working Group (OEWG) established to review NJRR data
Aug 2007	OEWG meets for the first time – ASR NOT discussed because it had not been identified as an implant of concern at that stage.
Sept 2007	J&J discuss ASR Resurfacing revision rates with TGA. J&J Agreed to restrict supply to surgeons who undergo further training, and to issue a Safety Notice to all implanting surgeons advising them of the revision rates and J&J intention to supply only to specially trained surgeons.
Oct 2007	2007 NJRR annual report released Identifies ASR Resurfacing as an implant that is experiencing higher than expected revision rates.
Oct 2007	TGA notifies other regulatory agencies TGA notifies other regulatory agencies of J&J's intended actions regarding ASR Resurfacing in the Australian market through a process called National Competent Authority Reporting (NCAR).
May 2008	J&J provides status report J&J provides update on status of actions agreed in Sept 2007. Safety Notice sent – as a result of supply being conditional on re-training, 15 surgeons had abandoned the implant, another 16 said that they would continue to use it. Overall use dropped dramatically.
May 2008	TGA refers ASR Resurfacing issue to OEWG at its May meeting ASR Resurfacing, including J&J/TGA actions taken in Sept 2007 referred to OEWG for comment and/or endorsement. OEWG endorses actions taken and recommends that monitoring of the implant continue.
June 2008	OEWG meets once again No change to position regarding ASR Resurfacing
Sept 2008	Internal review of TGA process begins Following concerns over procedural fairness afforded by the TGA process being used to investigate implants identified as having higher than expected revision rates by the NJRR, TGA initiates an internal review of that process.
Oct 2008	2008 NJRR annual report released Re-identifies ASR Resurfacing as having high revision rates. Identifies that the ASR XL acetabular cup has higher than expected revision rates ONLY when used in conjunction with the Corail femoral stem component.
July 2009	Internal review of TGA process ends The review found that the process is fair and appropriate and was resumed – Implants that were identified for the first time in the 2008 NJRR annual report were processed in 2009.
Aug 2009	Out of Session Briefing provided to OEWG The briefing provided the OEWG a status on the process of consideration of implants identified as having high revision rates in the NJRR reports – with a view to restarting the process
Oct 2009	2009 NJRR annual report released

	Re-identifies ASR Resurfacing as having high revision rates. Identifies that the ASR XL acetabular has higher than expected revision regardless of which femoral stem component is used.
Oct 2009	TGA and J&J have further discussions about ASR TGA indicated that in light of the information in the 2009 NJRR report, J&J would be expected to justify on-going supply of the implant. J&J indicated that ASR sales had reduced dramatically, and that there was on-going concern about the implant. This was making the implant unviable – so J&J would be withdrawing the implant from the Australian Market – however requests that some components be allowed to remain for partial revision purposes
Dec 2009	OEWG meeting – includes discussion on ASR XL implant OEWG endorses the actions taken by J&J and the TGA – also endorses the request to allow some components to remain available.
Dec 2009	ASR Resurfacing and ASR XL removed from the market.
Feb 2010	6th Meeting of OEWG ASR issue had already been dealt with – no discussion on ASR
June 2010	7th Meeting of OEWG Discussion about Metal on Metal (MoM) hip implants like the ASR. OEWG advised that there should not be a blanket condemnation of MoM implants – also advised against routine analysis of blood samples for Cobalt and Chromium levels as an indicator of early implant failure.
Aug 2010	Worldwide recall of ASR implants
Oct 2010	2009 NJRR annual report released Re-identifies ASR Resurfacing and ASR XL as having high revision rates.
Nov 2010	8th Meeting of OEWG Action on ASR complete – the committee considered other implants
Mar 2011	9th Meeting of OEWG Action on ASR complete – the committee considered other implants
May 2011	10th Meeting of OEWG Further discussions on concerns regarding MoM implants. OEWG re-affirmed the recommendations provided at its 7th meeting in June 2010.
June 2011	11th Meeting of OEWG Action on ASR complete – the committee considered other implants

Senate Community Affairs References Committee

ANSWERS TO QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Inquiry into the Regulatory Standards for the Approval of Medical Devices
27 September 2011

Question no: 8

Topic: Toxicity

Hansard Page: 57

Senator Xenophon asked:

a) What research is the Department currently carrying out on cobalt and chromium levels in blood?

b) What are the symptoms of, and treatment for, cobalt and chromium toxicity?

c) What is the acceptable range in Australia and internationally for the presence of cobalt and chromium in blood? if this has been changed, when did this occur and why did it occur?

Answer:

a) The TGA has reviewed current scientific literature regarding blood levels of cobalt and chromium. The TGA is not a research body but will examine research results when they become available to determine any regulatory significance.

b) Heavy metals, such as cobalt and chromium, have been associated with hypothyroidism, cardiac toxicity and nerve damage. In general, where possible, treatment involves attempting to minimise exposure to the heavy metal and treating any associated organ damage.

c) There is no established reference (normal) range for serum cobalt and chromium. Serum cobalt and chromium level testing is performed only in a few Australian pathology laboratories and the quoted reference ranges vary. For instance, one large pathology company suggests a reference range for cobalt (0 - 20 nmol/L) and for chromium (10 - 100 nmol/L). In an article published in 2011 in the *Medical Journal of Australia*, the reference range for chromium was 0 - 100nmol/L {Mao et al MJA 2011;194(12):649 - 651}. The Sandwell and West Birmingham Hospitals, Birmingham UK, Trace Elements Laboratory quote reference ranges of <40 nmol/L for Chromium and <10 nmol/L for Cobalt in patients without hip replacements. There is acceptance that serum cobalt and chromium levels will be elevated in patients who have undergone well functioning metal on metal hip replacement relative to those without hip replacements. As well, the metal ion levels will vary over time even in patients who have well functioning implants and no symptoms suggesting any health problem.