

International Society of Arthroplasty Registries (ISAR) Annual Meeting

held in conjunction with the

American Academy of Orthopaedic Surgeons Annual Meeting

Las Vegas, USA

February 25 - 28 2009

Date of Meeting: Thursday, 26th February 2009
Time: Commencing at 5:00pm
Place: Venetian Hotel, Rooms 4601 – 4603

MINUTES

Attendees:

Chairperson	Professor Henrik Malchau (Sweden, USA)
Australia	Professor Stephen Graves, Dr Richard de Steiger, Ms Ann Tomkins
Austria/EFORT	Dr Gerold Labek
Canada	Dr Michael Dunbar, Dr Eric Bohm
Denmark (Knee)	Dr Claus Emmeluth, Dr Anders Odgaard
Israel	Dr Ari Kandel
Italy	Dr Luigi Bagra
New Zealand	Dr Peter Devane
Norway	Dr Ove Furnes, Professor Leif Havelin
Slovakia	Dr Libor Necas
South Africa	Professor Anton Schepers, Dr Dick van der Jagt
Sweden (Hip)	Professor Johan Karrholm, Ms Kajsa Erikson, Dr Göran Garellick, Dr Cecilia Rogmark, Dr Ola Rolfson, Professor Peter Herberts, Ms Karin Pettersson
Sweden (Knee)	Professor Otto Robertsson, Ms Annette W-Dahl
USA	Dr David Lewallen, Professor Richard Coutts, Dr Charles Bragdon (MGH/USA), Dr Michael Dohm (AJRR), Dr Bob Namba (Kaiser), Dr Liz Paxton (Kaiser), Dr Tad Funahashi (Kaiser), Dr Eric Yue (Kaiser), Dr Greg Maletis (Kaiser), Ms Maria Inacio (Kaiser), Dr Kevin Ong (Exponent), Dr Edmund Lau (Exponent), Ms Kim Williams (Regional Colorado), Mr Phil Noble

1. Welcome by Henrik Malchau

H Malchau opened the meeting and welcomed the attendees.

2. The Nordic Project – Nordic Arthroplasty Register Association (NARA) – Göran Garellick

Presentation available on website – www.isarhome.org.

This group consists of registries from Norway, Denmark and Sweden and started in 2007. Invitations have also been extended to Finland and Iceland.

The first paper produced by this group will be presented at the AAOS on 27th February and is entitled 'The first report of the Nordic Arthroplasty Register Association'.

There are currently over 300,000 primary hip procedures in the database dating from 1995 – 2007, with approximately 1,500 resurfacing procedures. The linkage of the knee database has been initiated.

Information about the association is available on the NARA website at www.nordicarthroplasty.org.

3. A National US Registry – Will it ever happen? – David Lewallen, Chair AJRR Oversight Committee

Presentation available on website – www.isarhome.org.

D Lewallen reported that development of the US registry is now moving forward as a result of the efforts of many people over a number of years.

The reasons for the recent progress include:

- Shifting US demographics
- Health economics
- Liability protection options
- Public concerns about failed implants and recalls
- Increased demand for safety, performance measures and quality metrics.
- Rising consensus on the value of a registry by a wide range of stakeholders.
- The 'threat' of registry related legislation.

He explained that US data collection is a large undertaking as there are over 5,000 hospitals. Medicare data is already being submitted by hospitals with the exception of side of procedure and procedure code. Therefore initially the objective will be to collect a minimum data set that will include side and procedure code.

The FDA is currently working on a Unique Device Identifier and it is anticipated this will be completed by January 2011. This should assist in prosthesis identification.

Once established the Registry will publish an annual report and will be used as an early warning system. The AJRR may also provide companies with information on their market share and revision data.

The objective is to have over 90% participation by US hospitals with a goal of 80% over the first five years. Incentives may be offered to hospitals to encourage participation.

To ensure success it is anticipated that the AJRR will provide:

- Incentives for hospital participation
- Protection of confidential data
- Data analysis and annual reporting
- Stable funding model, probably through an implant surcharge. Initial feedback from companies is positive
- Multi stakeholder governance structure

The AAOS has provided US\$ 300,000 in start up funds.

It is expected that governance of the AJRR will be through a board with representatives from key stakeholders and will include orthopaedic surgeons and representatives from industry, government agencies, hospitals and the public and private sector.

In summary, D Lewallen stated that there is now a unique opportunity to develop a successful US Registry that will be for the public good not profit with strong governance that will provide a tool for data driven improvement in joint replacement surgery.

Questions from the floor included:

Q: M Dunbar – How do you propose getting side and barcode information?

A: D Lewallen – There are several pathways; the most powerful is through the CMS and convincing them that it is in their best interest to incentivise data collection.

Q: P Noble – How will the information be protected in view of the US legal system processes?

A: D Lewallen commented that this will be covered by the Patient Safety Organisation legislation which was passed in 2005; the regulations however only became available in October 2008.

Q: S Graves – How will you handle patient confidentiality?

A: D Lewallen commented that there are stringent, robust patient protection laws in the US.

Q: S Graves – Would you be looking to use the 'opt off' approach to patient consent?

A: D Lewallen responded that there would be a standardised contract through agencies to get a blanket business agreement. It is not intended to go down the path of patient consent for Level 1 data; however this may be necessary for data collection of Level 2 data.

4. International Implant Database – Henrik Malchau

H Malchau believes it would be possible to create a single prostheses database using barcodes. The issue has been to convince industry leaders to provide the barcode details however there now appears to be growing support from industry. It will be necessary to foster communication with companies to inform us of changes to devices.

G Labek asked if there is a standardised format required for devices and suggested a workshop be held at the EFORT meeting in Vienna in June to demonstrate how implant details are being recorded in other registries.

S Graves commented that the AOANJRR prostheses database has been made available on the web via secure access to other registries on request.

5. Membership Fees – Henrik Malchau

H Malchau asked other countries to follow Australia's lead by contributing funds to run ISAR and suggested that a discussion be held to address issues related to the cost of running ISAR.

H Malchau has received a letter from Professor Bohler, Past President of EFORT with an offer to contribute funds.

6. ISAR Website – www.isarhome.org

H Malchau advised that information and presentations from previous meetings will be posted to the ISAR website together with the minutes and presentations from this meeting. The website can be accessed using the 'demo' 'demo' password at present but will be password protected in the future.

7. AAOS Symposium

H Malchau to organise a Registry Symposium for the next AAOS.

8. Clinical Orthopaedics and Related Research Issue focused on Registries

Dick Brand, Editor of CORR has expressed interest in a 'Registry' edition of CORR. There was general agreement that this would be worthwhile. H Malchau suggested that it could be done in a similar way to the publication of the Hip Society proceedings.

As it is intended that the Registries hold a symposium at the next AAOS meeting the proceedings of this could be published in CORR. In order to achieve this, papers would need to be submitted well ahead of time so that manuscripts could be reviewed before the meeting in readiness for printing at the end of 2010. S Graves will follow up.

9. Next Meeting

The next meeting will be held at the EFORT meeting in Vienna, 3 – 6 June 2009. G Labek to organise a meeting room for Friday 5th June, 4pm – 6pm.

10. New Business

Steering Committee Meeting

S Graves suggested that a Steering Committee meeting be scheduled in the near future. It was decided to hold a teleconference of the Steering Committee in April 2009. H Malchau will liaise with A Tomkins regarding the arrangements.

Meeting closed at 6.30pm

Minutes by: Ann Tomkins, Kajsa Erikson