Technology and Innovation of Human Implants: The Importance of Joint Registries in observing implant performance

Working Breakfast
STOA – Panel for the future of science and technology
European Parliament, Brussels, Belgium
April 4, 2019

Per Kjaersgaard-Andersen, MD
Associate Professor
Section for Hip and Knee Replacement, Vejle Hospital, Denmark
&
President, EFORT
The metal-on-metal hip arthroplasty problem
Metal-on-metal THA: Early registry observation

Cumulative incidence Revision, females <55 years

20 months registry observation
The metal-on-metal problems

Data from Dutch, Danish and Australian registries per 1-1-2012 made these 3 countries to stop implanting metal-on-metal implants
I exaggerate to clarify the difficulty

DOUBLE BLIND
Advantages registry (Big Data) vs RCT:

- Large materials – “statistical power”
- Uncommon diagnoses, complications
- Uncommon techniques, devices
- Ability to avoid “performance bias”
- Follow-up length
- Costs
NORE Network of Orthopaedic Registries of Europe

NORE, the Network of Orthopaedic Registries of Europe, is an international registry network built up as a standing committee of EFORT and founded in 2015. The network is organised as an EFORT standing
Largest registries - number THA + TKA

- National Joint Registry (NJR)
  - >1.2 million

- Australian Orthopaedic Association (AOA)
  - >700,000

- Dutch Arthroplasty Register (LROI)
  - >500,000

- Nordic Arthroplasty Register Association (ONARA)
  - >700,000

DATA >3 million THA & TKA procedures
Current orthopaedic registries mainly on:

- Joint replacement implants
- Trauma (fractures)
- Pelvic osteotomies
- ACL reconstruction

Annual orthopaedics implants used in patients in Europe:

- App 2.2 mill
- Orthopaedics and cardiologists
  - app. 50% (Biomed Alliance)
Requirements to National Clinical Databases

The MAIN goal of a clinical database is always

To improve the quality of treatment and safety for our patients
The objective of the registry (THA)

- To facilitate continuous improvement of the outcome following primary and revision surgery both at a national and local level by evaluating:
  - Patient related risk factors
  - Surgical technique related risk factors
  - Prophylactic and operation theatre related factors
  - Implant related risk factors

- Early warning

- To examine the epidemiology of total THA, including both primary and revisions surgery

- To link data from the registry to other national databases
Registries to Improve health costs and service

- Health costs
  - Reduce costs
  - More / better treatment for same costs

- Orthopaedic services
  - Improve outcomes
    - Less revisions
    - Better PROMs
    - Safe implants

- Collect data – analyse – recommendations – record changes
- Remove / reduce outliers from the marked
- Focus on poor performing clinics / surgeons - feed-back
- Focus on patients characteristics and its impact on outcome
National databases: I.e. Denmark

Orthopaedic databases:
- Danish Hip Arthroplasty Registry (DHR)

Unique civil registration number

Danish National Drug Prescription Database (NDPD)

Danish National Registry of Patients (NRP)

Danish Civil Registration System

Integrated Database for Labour Market Research
Mandatory for registers

• **Coverage**: Goal is 100%

\[
\frac{\text{Number of units/departments reporting to DHR}}{\text{Number of units/departments reporting to the central registry in Denmark}} \times 100\%
\]
Mandatory for registers

- **Completeness**: Goal is > 90% (95%)

\[
\text{Number of THA in DHR } \times 100\% \\
\frac{\text{Number of THA in DHR and/or central register (CR)}}{}
\]

What is important about those not reported?

No bias in reporting: No systematic missing data
Mandatory for registers

• Valid data = data must be validated

Registry data and examples of major impact
Potentials by using National Databases

- Single implants – and compare to other similar implants
- Product line (i.e. cemented femoral stems)
- Institution / hospital
- Single surgeon
- National results – compared to other nations
- Patient characteristics
Fig. 4 Survivorship curves (with 95% confidence intervals) for total hip arthroplasty implants in the United States, Sweden, and Norway.

Surviving 1 billion SEK in 7 years compared to revision rate in USA

THA 1-year revision in a XX hospital

CUSUM of 1-yr revision rate THA 2011-2015 in a random hospital:

- Observed 1-yr revision rate higher than expected → not good
- WHY did this happen? → start using new/other prosthesis (learning curve)

Good:
- Observed - expected = 0
Manage outliers

• ‘Passive’ Approach
• (i.e. Reports National Registries)
All types cemented acetabular components: Revision within 1 yr
The Netherlands 2010-2013

Why Outlier?

mean number primary THA per type cemented acetabular component 2010-2013
Dutch Arthroplasty register: 79,689 TKA, 98 hospitals  
2010-2013: revision per 1 yr: 0.9%

Outliers in Revision?

Why Outliers?

mean number primary TKA per hospital 2010-2013
Data for 1st April 2003 to 31st July 2016

Surgeon risk adjusted 90-day mortality

In line with expected rate
Patient outcomes

Patient outcomes, featured in this second chart below, looks at mortality and revision. Please click on the ‘how to interpret this chart’ button for further information including additional notes on factors that may affect the results shown including whether the hospital is providing a full and accurate submission of first-time joint replacement and revision operation data to the NJR.

Data for 1 April 2003 - 31 July 2015

<table>
<thead>
<tr>
<th>Patient Outcomes Quality Measure</th>
<th>This Hospital</th>
<th>Patient Records Analysed</th>
<th>This Hospital Ratio</th>
<th>National Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>90 Day Mortality</td>
<td>OK</td>
<td>As Expected</td>
<td>2613</td>
<td>1.00</td>
</tr>
<tr>
<td>Revision Rate: Operations Apr03-Jul15</td>
<td>Better Than Expected</td>
<td>2763</td>
<td>0.49</td>
<td>1.00</td>
</tr>
<tr>
<td>Revision Rate: Operations Apr11-Jul15</td>
<td>OK</td>
<td>As Expected</td>
<td>1441</td>
<td>0.71</td>
</tr>
</tbody>
</table>

Click on the 🔄 to find out more about the quality measure and its source data.

How to Interpret This Chart

<table>
<thead>
<tr>
<th>Better than Expected</th>
<th>Expected Range</th>
<th>Worse than Expected</th>
</tr>
</thead>
<tbody>
<tr>
<td>NATIONAL AVERAGE</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Why Identify Outcome databasesOutlier?

- **Transparency:**
- Inform surgeons
- Re-assure patients
- Show Quality
Data from large databases the most valuable way to make sure we use safe and proven implants

ODEP
Orthopaedic Data Evaluation Panel

nore
Network of Orthopaedic Registries of Europe
Safe implants: Total hip arthroplasty and impact from European Registries

• Orthopaedic surgeons want to use safe implants, to improve the quality of life for many years for our patients.
• The quality of implants is already very good, why new implants should be investigated independently and compared with successful implants before they are introduced to the market.
• Registries on total hip and total knee replacements, which have been started in the early years by orthopaedic surgeons (initially in the Scandinavian Countries), have shown to detect early if an implant is inferior.
• Therefore, registries should be used as post-marketing tool of new implants, which in previous research seem to be promising.
• Registries may also be used to compare hospitals with each other to inspire and stimulate them to become better.
Main Theme: Registries & Impact on Practice

- Patient selection, Implant selection
- Implant survival, Prediction of outcome
- Value based healthcare, Revision rate
- Patient safety, Quality improvement
- Patient reported outcome
- Patient involvement
Thank you for your attention
Requirements Danish National Clinical Databases

Governmental decision

• Definition of 5-10 relevant indicators
  • Quality of the treatment
  • Prognosis of the treatment
  • Specific for each unit/department

Indicators have to be approved by the doctor/surgeons and health authorities
how do we get evidence in the field of TJR surgery?

- RCT – difficult or impossible
  - RSA-studies!
- prospective observational studies (Big Data, registry studies)
Who should “improve” Patient or

....... Surgeon
NORE Network of Orthopaedic Registries of Europe

NORE, the Network of Orthopaedic Registries of Europe, is an international registry network built up as a standing committee of EFORT and founded in 2015. The network is organised as an EFORT standing committee and reports to the EFORT Board.

NORE focuses on medical device surveillance and arthroplasty outcome in order to support improvements in patient care.

NORE provides advice and awareness to EFORT on international perspective, experiences and practices in medical device surveillance and outcome. This ranges from data capture (e.g. nomenclature on implant attributes) through data analysis and reporting techniques, to new methodology for evaluating performance of medical devices.
Indicators

1. Completeness
2. Blood transfusion within 7 days
3. Complications during surgery
4. Implant survival
5. Reoperation within 2 years
6. Readmittance within 3 months

- monitor treatment quality ?
- monitor prognosis of the treatment ?
- each specific unit/department ?
Survival TKA in the Netherlands
Major 1-yr revision per hospital

Major revision: revision of at least one of the fixed components (tibia or femur)
The metal on metal problems

The NOV released a moratorium per 1-1-2012 with the advice to stop inplanting metal on metal implants
Scotland: Outliers on Adverse Events

Adverse Events:

- Revision < 1 yr, 3 yr, 7 yr
- Hip dislocation < 1 yr
- DVT / Pulmonary emboli < 30 days
- Acute Myocardial infarction / CVA < 30 days
- Renal disease < 30 days
- Death

One surgeon all cases

MacPherson G et al JBJSAm 93A Supp3E 2011 81-88
Scotland: Ouliers on adverse events
Annual report

**Figure 9** – Percentage of 2014 hip arthroplasty patients with subsequent dislocation within one year

*Scottish Rate averaged over 5 years 2010-2014.*
Registries with maximum validity

- Unique civil registration number
- High coverage (100%)
- High completeness (> 95%)
- Data validated

- Confounders
- Different outcomes between registries
Development of the LROI

2007: Start registration hip and knee

2007

• Advice to measure PROMs
• Registration of ankle, shoulder and elbow arthroplasties
  • Casemix

2008

• Publication 1st annual report

2009

• Validation
• PROMs implementation
• Patient information
• Dashboard

2010

• Registration of wrist and finger arthroplasties

2011

2012

2013

2014

2015

2016

2017

2018
Who should “improve” Patient or ....... Surgeon
## Glossary

Showing 1 to 10 of 133 entries

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABHI</td>
<td>Association of British Healthcare Industries - the UK trade association of medical device suppliers.</td>
</tr>
<tr>
<td>Acetabular component</td>
<td>The portion of a total hip replacement prosthesis that is inserted into the acetabulum - the socket part of a ball and socket joint.</td>
</tr>
</tbody>
</table>
Hospital: Alexandra Hospital
Worcestershire Acute Hospitals NHS Trust

- SURGEONS WITH ACTIVITY RECORDED IN NJR
- 12-MONTH PRACTICE PROFILE (1 YEAR)
- 36 MONTH PRACTICE PROFILE (3 YEAR)

- HIPS

- PATIENT IMPROVEMENT AND OUTCOMES

This information display shows you how this hospital compares to the national rates for a range of patient improvement and outcomes measures used to demonstrate quality in joint replacement surgery. Against each measure, you will be able to see whether this hospital is
Patient outcomes

Patient outcomes, featured in this second chart below, looks at mortality and revision. Please click on the ‘how to interpret this chart’ button for further information including additional notes on factors that may affect the results shown including whether the hospital is providing a full and accurate submission of first-time joint replacement and revision operation data to the NJR.

Data for 1 April 2003 - 31 July 2015

Click on the i to find out more about the quality measure and its source data

<table>
<thead>
<tr>
<th>Patient Outcomes Quality Measure</th>
<th>This Hospital</th>
<th>Patient Records</th>
<th>This Hospital Ratio</th>
<th>National Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>90 Day Mortality</td>
<td>✔️ As Expected</td>
<td>2613</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Revision Rate: Operations Apr03-Jul15</td>
<td>✔️ Better Than Expected</td>
<td>2763</td>
<td>0.49</td>
<td>1.00</td>
</tr>
<tr>
<td>Revision Rate: Operations Apr11-Jul15</td>
<td>✔️ As Expected</td>
<td>1441</td>
<td>0.71</td>
<td>1.00</td>
</tr>
</tbody>
</table>

About the patients who were treated
Largest registries (consortium) number THA + TKA

DATA >3 million THA & TKA procedures

>1.2 million

>700,000

>700,000

>700,000

Dutch Arthroplasty Register
Prebenchmark
• 2 RSA
• 3

Benchmark
• 5
• 7
• 10

Datasources
• Registries:
  • >85% coverage
  • >85% completeness primary & revision
• Registered trials
• Lost FUP 10% prebenchmark; 20% Benchmark

Benchmark value
• A or star descriptor:
  • Non-inferiority (i.e. lower value 95% CI)
• B
  • Mean value
20th EFORT Annual Congress Lisbon 2019
05 - 07 June | Congress Center Lisbon CCL | Lisbon | Portugal

A few words on the Scientific Programme

20th EFORT ANNUAL CONGRESS LISBON 2019 MAIN THEME: REGISTRIES & IMPACT ON PRACTICE
Lisbon – Travel around the world without leaving Lisbon!

20th EFORT ANNUAL CONGRESS LISBON 2019 MAIN THEME: REGISTRIES & IMPACT ON PRACTICE
It is not the strongest of the species that survives, nor the most intelligent. It is the one that is most adaptable to change.

Charles Darwin
Thank you for your attention
Fig. 4 Survivorship curves (with 95% confidence intervals) for total hip arthroplasty implants in the United States, Sweden, and Norway.


saving 1 billion SEK in 7 years compared to revision rate in USA
Key words in the talk: “Safe implants: Total hip arthroplasty and impact from European Registries”

• Safe implants; quality; registries; post-marketing investigated; total hip replacement
It is not the strongest of the species that survives, nor the most intelligent. It is the one that is most adaptable to change.

Charles Darwin