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

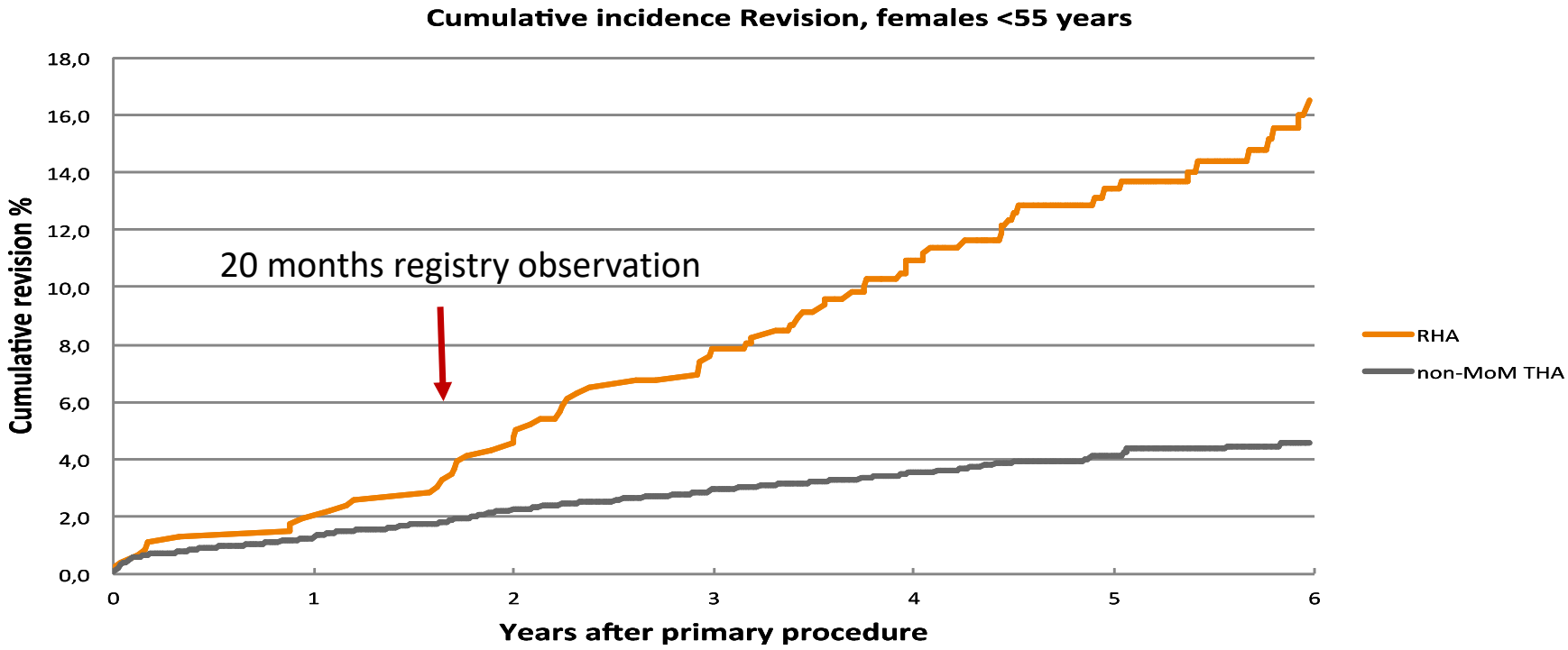
Working Breakfast
STOA – Panel for the future of science and technology

European Parlaiment, 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

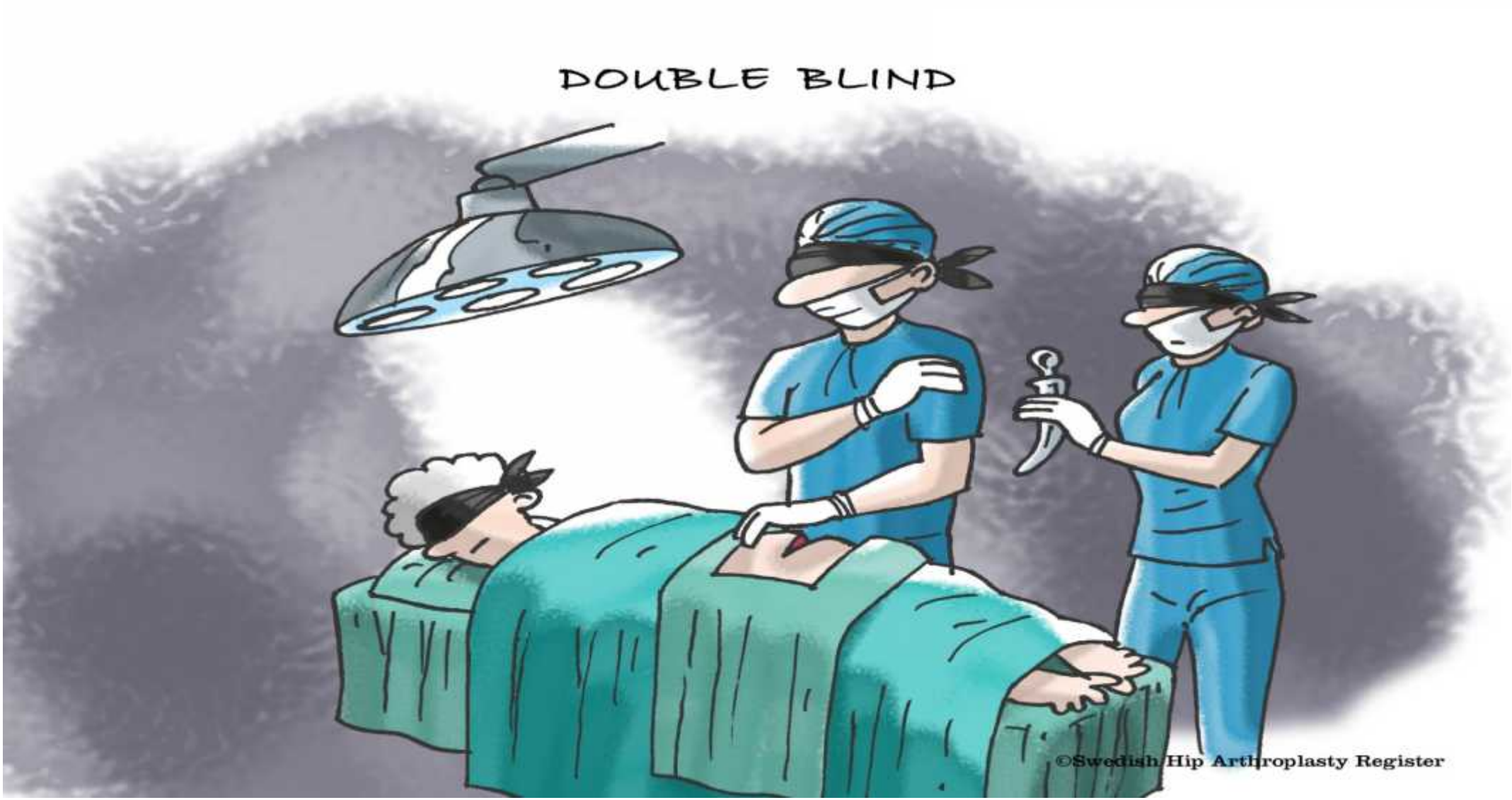
Metal-on-metal THA: Early registry observation

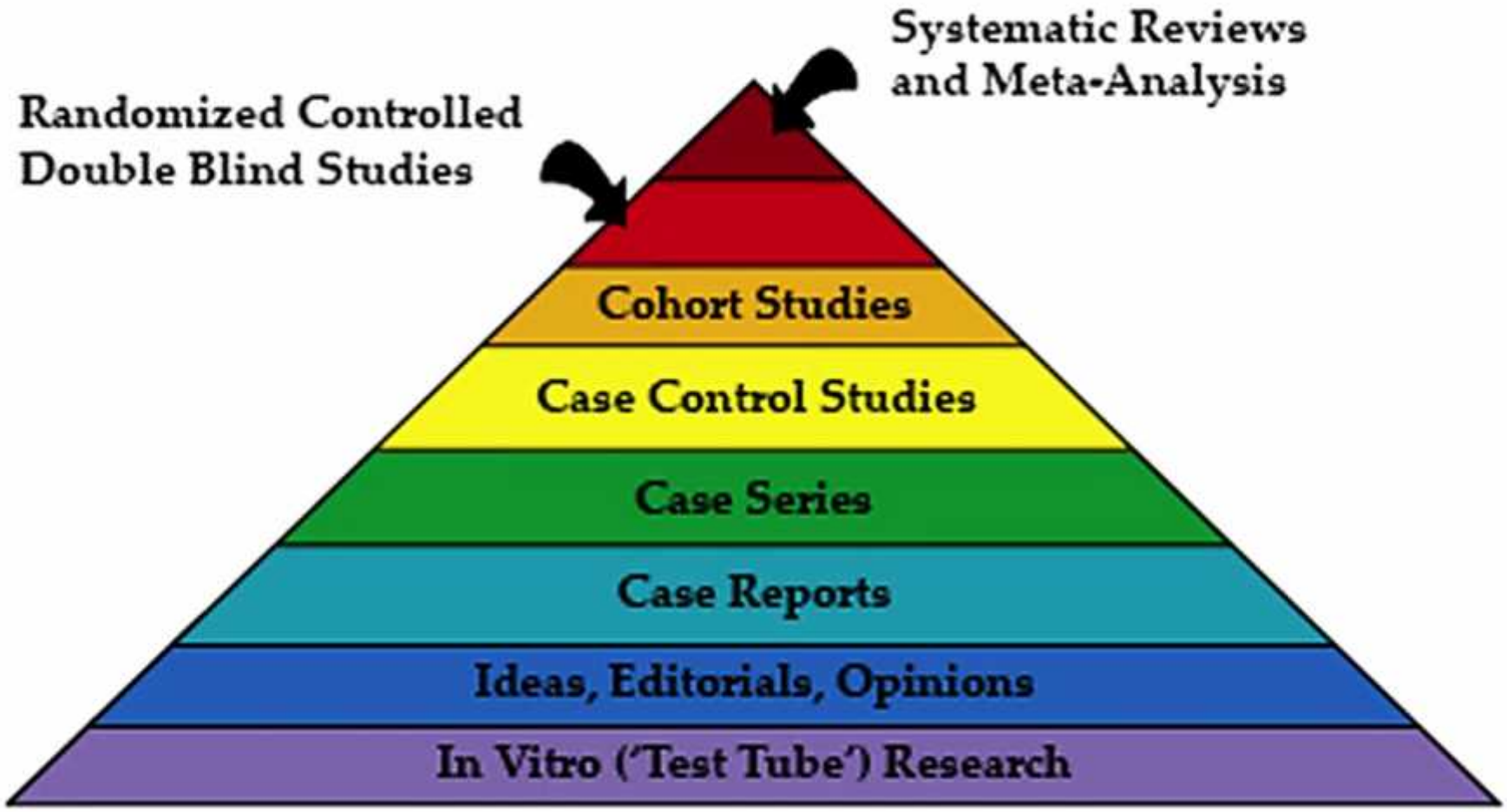


The metal-on-metal problems

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




Systematic Reviews
and Meta-Analysis
Randomized Controlled
Double Blind Studies
Cohort Studies
Case Control Studies
Case Series
Case Reports
Ideas, Editorials, Opinions
In Vitro ('Test Tube') Research


BIG
DATA
INFORMATION
STORAGE
LARGE
SETS
SOFTWARE
MANAGEMENT
ANALYSIS
RESEARCH
SEARCH
PETABYTES
TECHNOLOGIES
GOVERNMENT
VOLUME
PROCESS
DEVELOPMENT
TECHNOLOGY
MILLION
SCIENCE
NEW
BILLION
FUTURE
INTERNET
LEARNING
WORLD
BASED
DATABASES
PROCESSING
FRAMEWORK
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ANALYTICS
SIMULATIONS
EXABYTES
AMOUNT
APPLICATIONS
INFRASTRUCTURE
SAN
NAS
SOCIAL
NETWORKS
PARALLEL
INITIATIVE
ECONOMIC
TERABYTES
TIME

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

www.EFORT.org/NORE

EFORTnet

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- Mission and vision
- What we offer
- How we work
- Membership & Network
- History of EFORT
- Statutes
- EFORT Annual Reports
- Ethical Orthopaedics
- Network of Orthopaedic Registries of Europe (NORE)
  - Research & Publications
  - Meetings & Events
  - Projects & Activities

NORE Network of Orthopaedic Registries of Europe

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Largest registries - number THA + TKA

National Joint Registry
www.njrcentre.org.uk
Working for patients, driving forward quality

>1.2 million

AOA
AUSTRALIAN ORTHOPAEDIC ASSOCIATION

>700.000

Dutch Arthroplasty Register
LROI

>500.000

NARA
Nordic Arthroplasty Register Association

>700.000

DATA >3 million
THA & TKA procedures

Current orthopaedic registries mainly on:

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

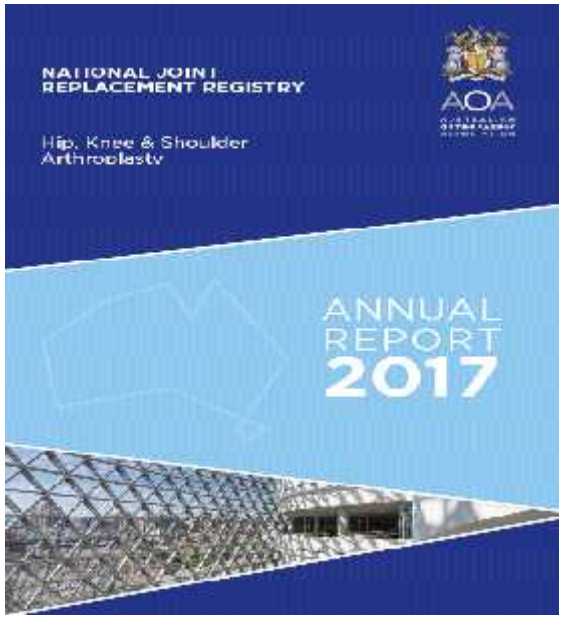
Annual orthopaedics implants used in patients in Europe:

- 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

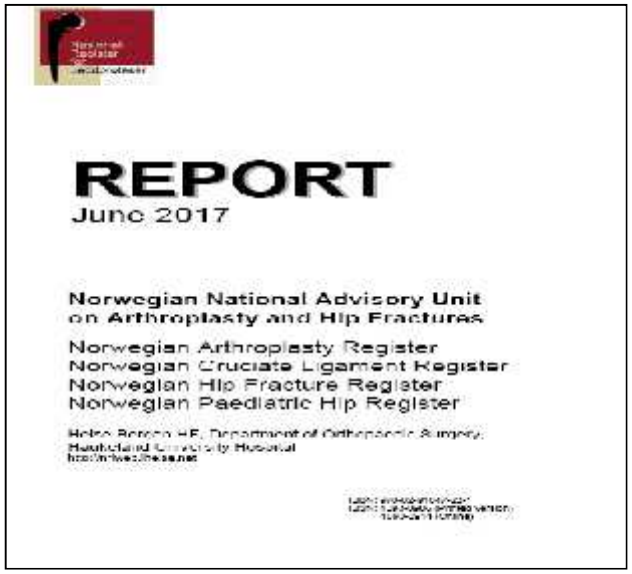
To improve the quality of treament and safety for our patients


NATIONAL JOINT REPLACEMENT REGISTRY
AOA
Hip, Knee & Shoulder Arthroplasty
ANNUAL REPORT 2017


Dansk Hoftealloplastik Register
Danish Hip Arthroplasty Register
National årsrapport 2017
www.dhr.dk


The Swedish Hip Arthroplasty Register
Annual Report 2016


Online LROI annual report 2017
10 years of registration, a wealth of information


REPORT
June 2017
Norwegian National Advisory Unit on Arthroplasty and Hip Fractures
Norwegian Arthroplasty Register
Norwegian Cruciate Ligament Register
Norwegian Hip Fracture Register
Norwegian Paediatric Hip Register


National Joint Registry
HIPS
KNEES
ANKLES
ELBOWS
SHOULDERS
PROMs
13th Annual Report
2016
National Joint Registry for England, Wales, Northern Ireland and the Isle of Man

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**

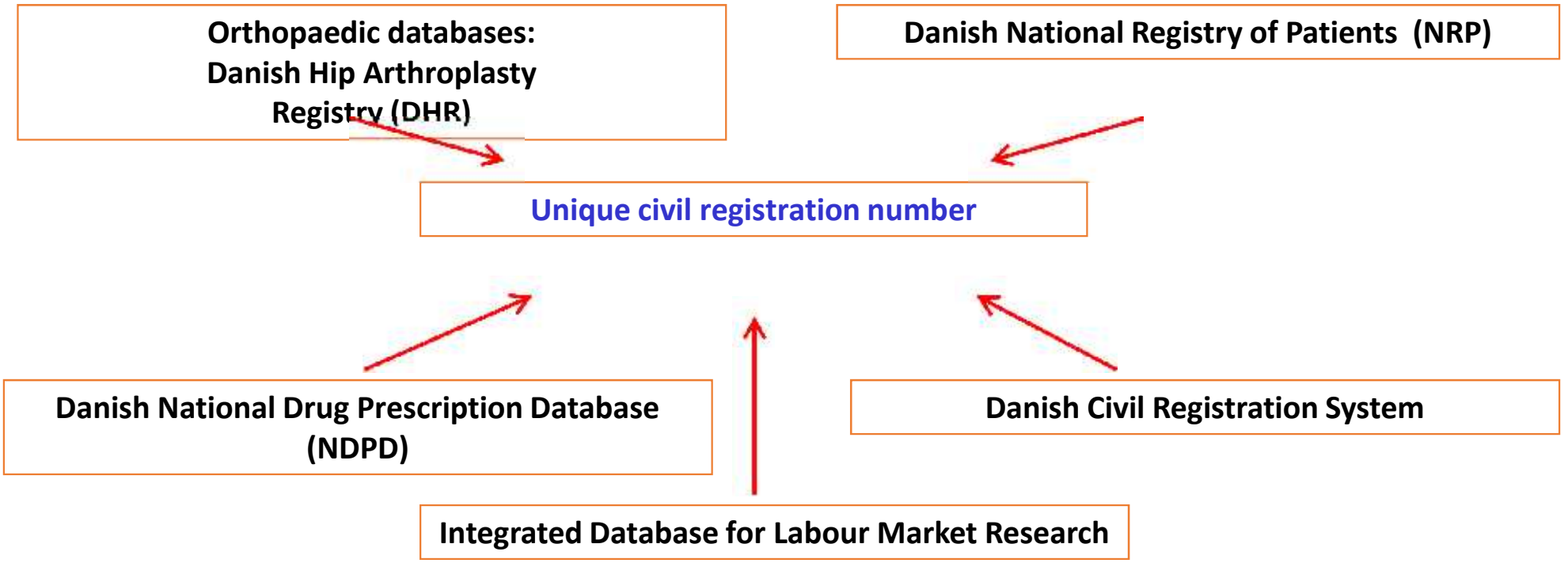
- **To link data from the registry to other national databases**

Registries to Improve healt 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



Mandatory for registers

- ***Coverage*: Goal is 100%**

$$\frac{\textbf{Number of units/departments reporting to DHR} \times 100\%}{\textbf{Number of units/departments reporting to the central registry in Denmark}}$$

Mandatory for registers

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

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

What is important about those not reported?

No bias in reporting: No systematic missing data

Mandatory for registers

- **Valid data = data must be validated**

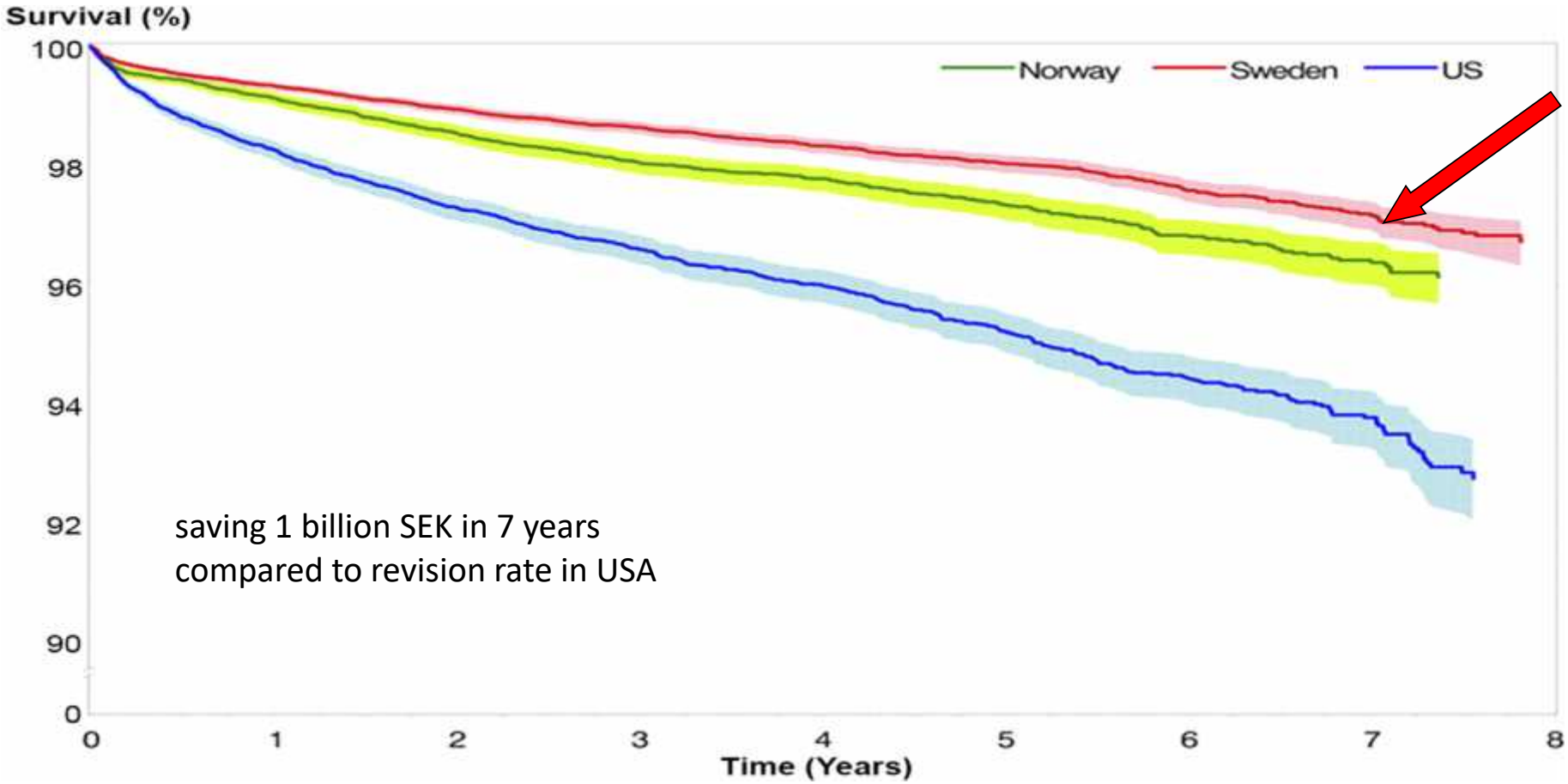
A. B. Pedersen, S. P. Johnsen, S. Overgaard, K. Søballe, H. T. Sørensen and U. Lucht. Registration in the Danish Hip Arthroplasty Registry. Completeness of total hip arthroplasties and positive predictive value of registered diagnoses and postoperative complications. Acta Orthop Scand 2005; 75 (4): 434-441.

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

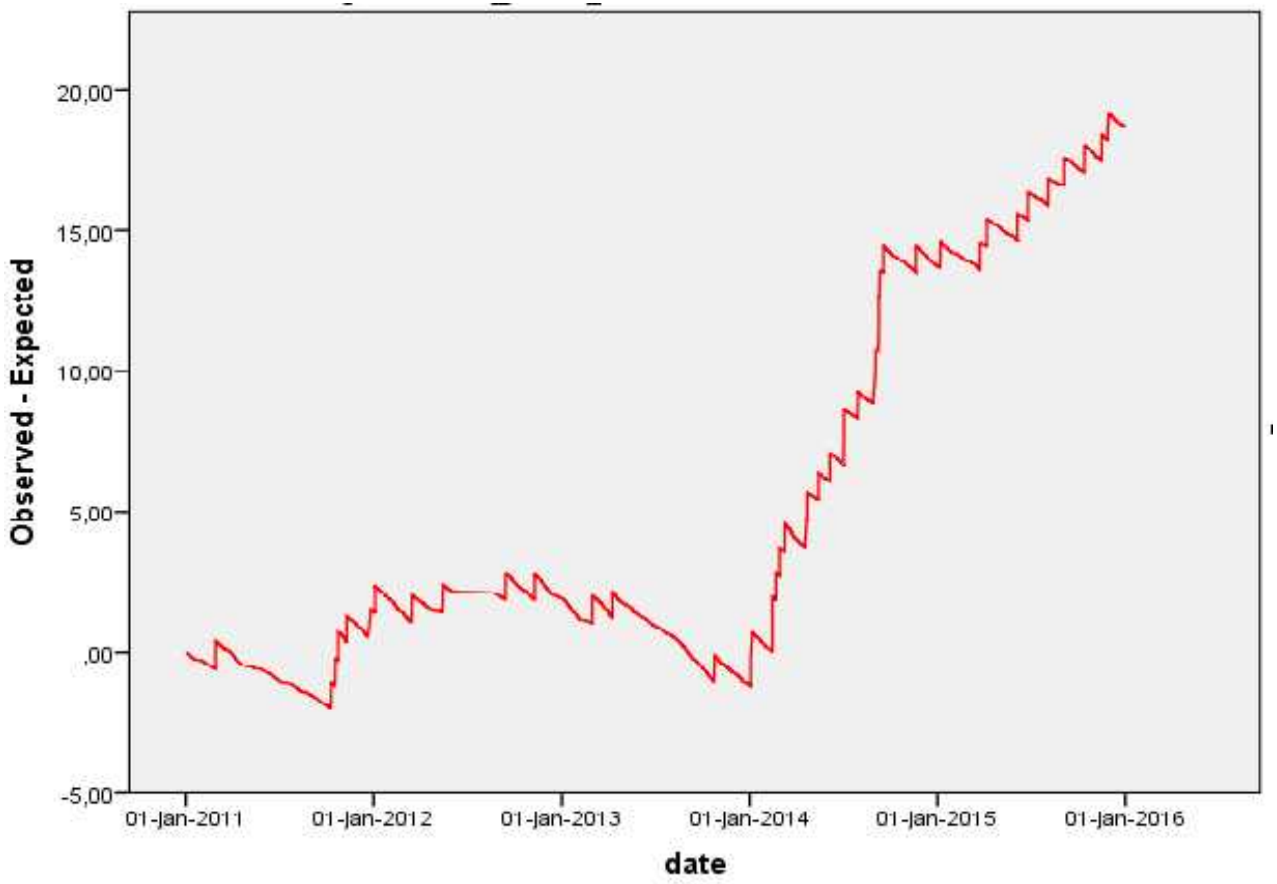
Fig. 4 Survivorship curves (with 95% confidence intervals) for total hip arthroplasty implants in the United States, Sweden, and Norway.



Kurtz S. M. et.al. J Bone Joint Surg 2007:89:144-151

JBJS

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

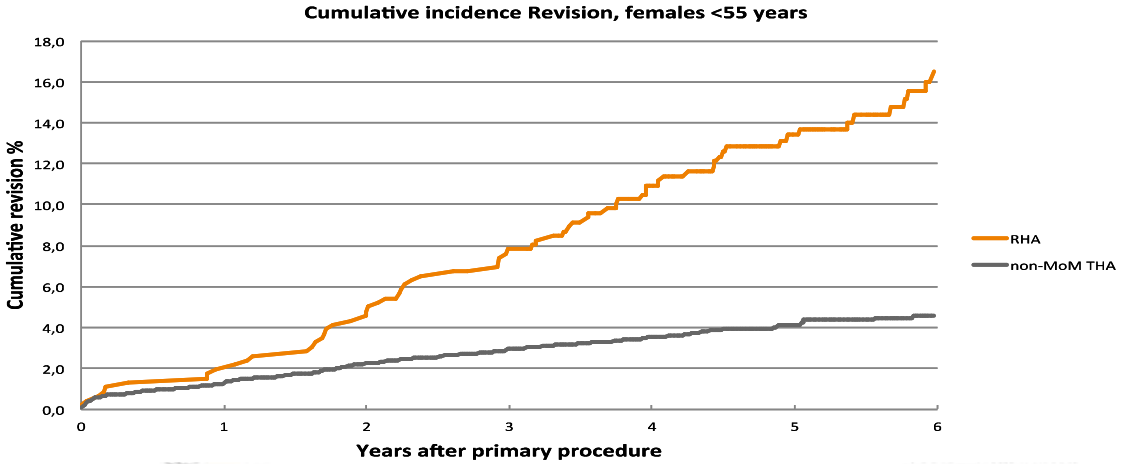
- ‘Passive’ Approach
- (i.e. Reports National Registries)

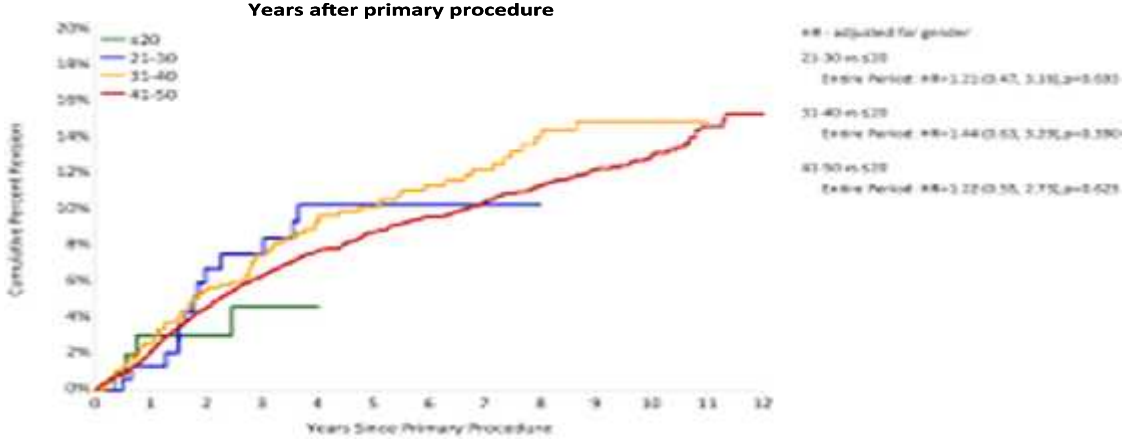
National Joint Registry
Working for patients, driving forward quality

AOA

Dutch Arthroplasty Register
LROI

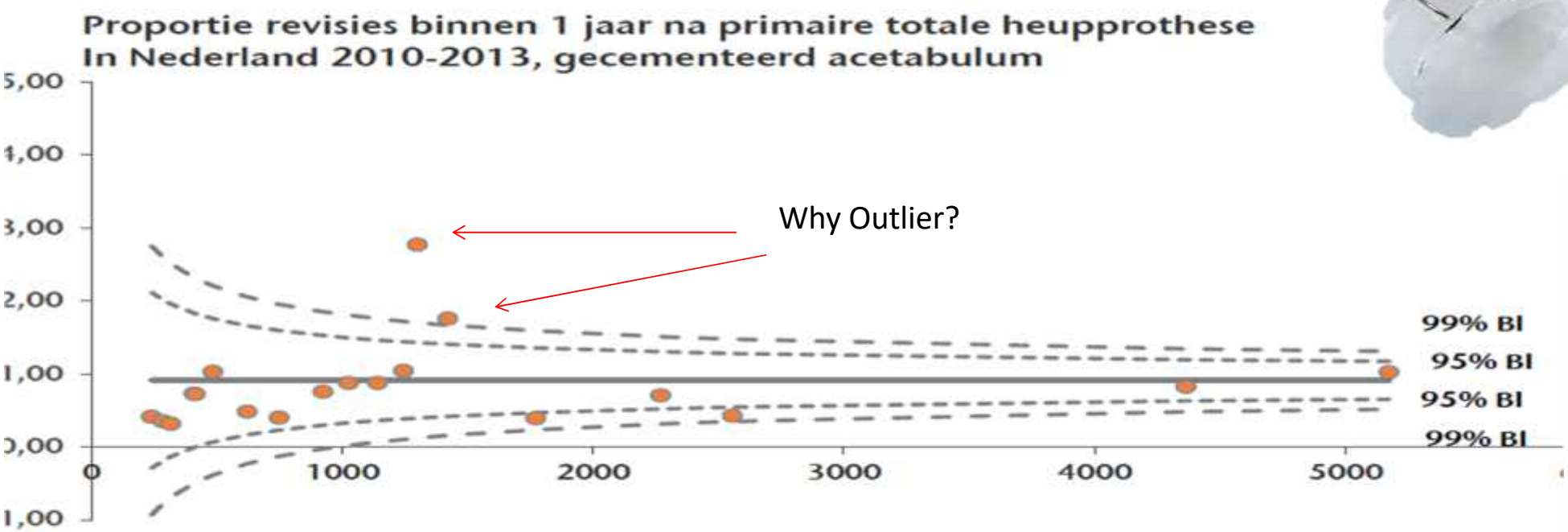
NARA





LROI
Dutch Arthroplasty Register

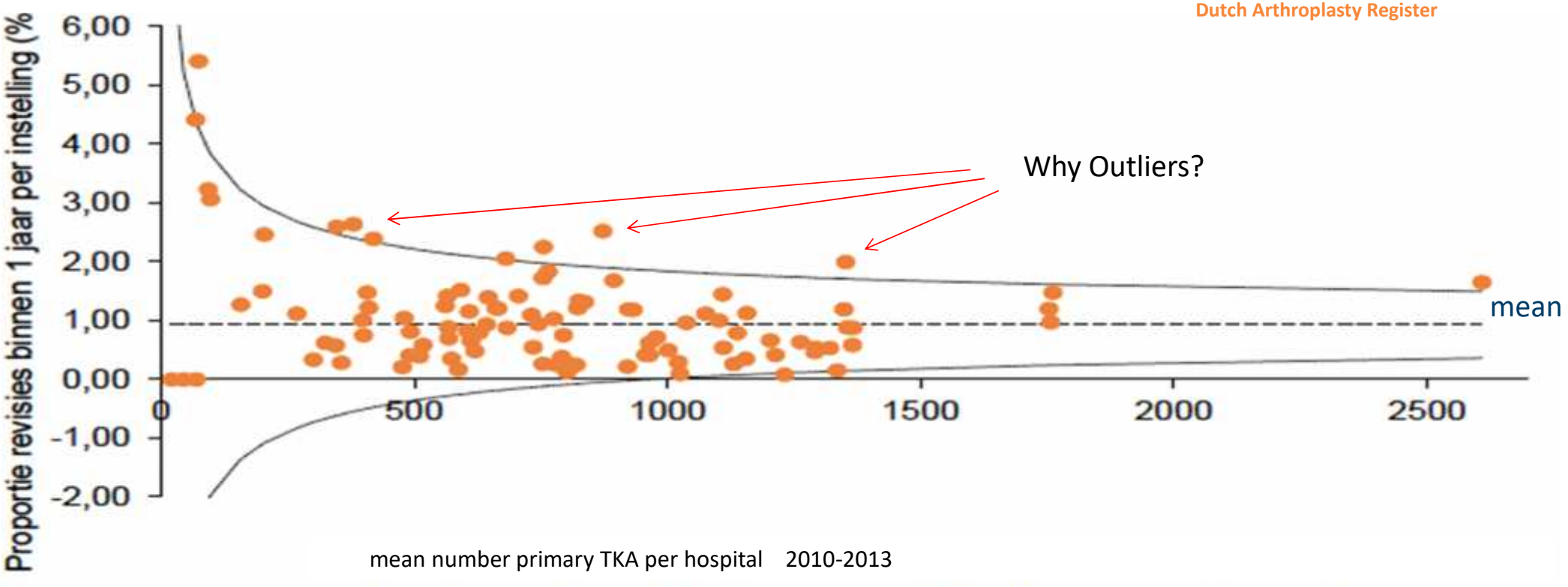
All types cemented acetabular components: Revision within 1 yr
The Netherlands 2010-2013



mean number primary THA per type cemented acetabular component 2010-2013

Outliers in Revision ?

Dutch Arthroplasty register: 79.689 TKA, 98 hospitals
2010-2013: revision per 1 yr: 0.9%



www.njrsurgeonhospitalprofile.org.uk/SurgeonProfile?gmccode=3172289

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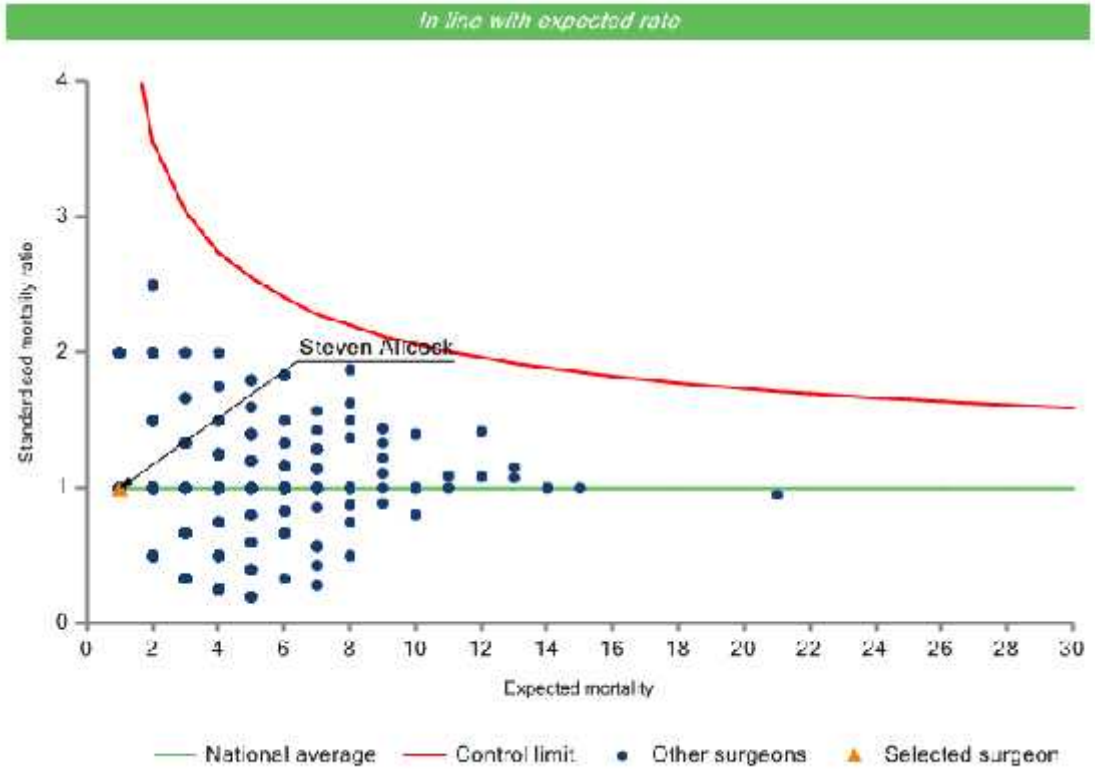
Data for 1st April 2003 to 31st July 2016

Surgeon risk adjusted 90-day mortality



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

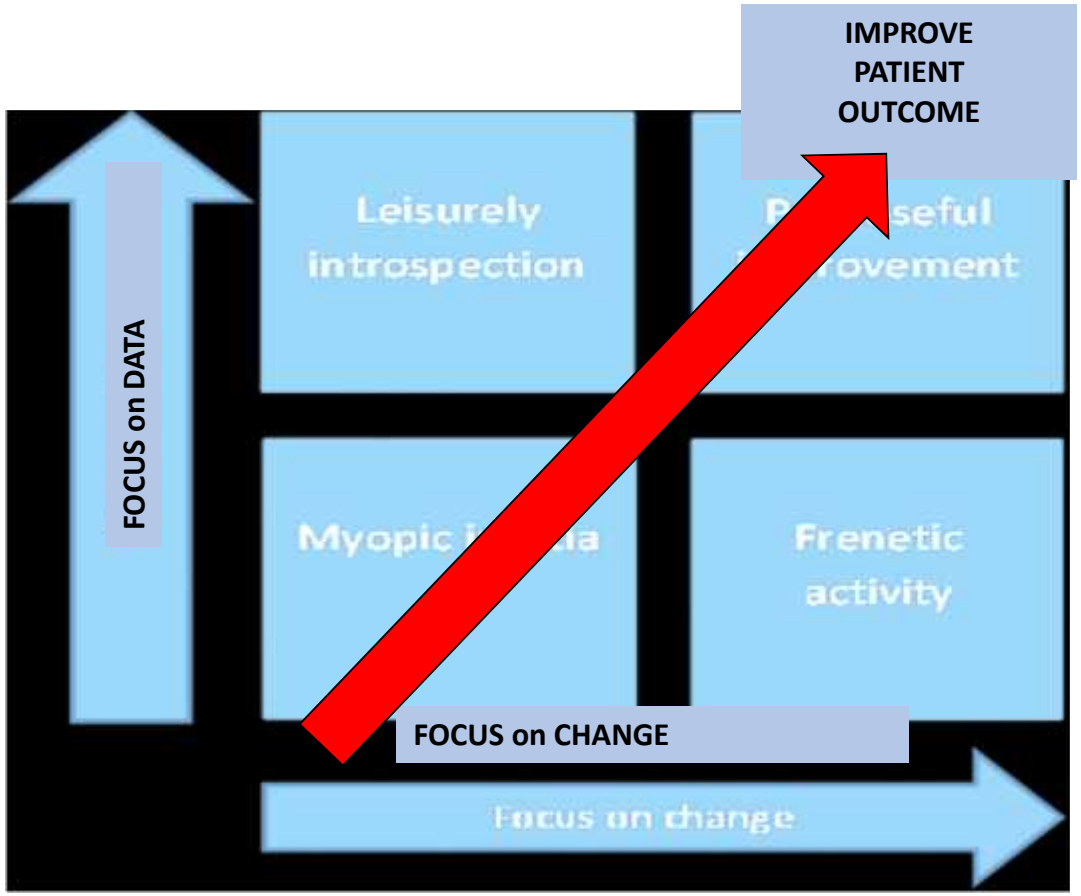
HOW TO INTERPRET THIS CHART

Patient Outcomes Quality Measure	This Hospital	Patient Records Analysed	This Hospital Ratio	National Ratio
90 Day Mortality	OK As Expected	2610	1.00	1.00
Revision Rate: Operations Apr03-Jul16	✓ Better Than Expected	2763	0.49	1.00
Revision Rate: Operations Apr11 Jul16	OK As Expected	1441	0.71	1.00

▶ ABOUT THE PATIENTS WHO WERE TREATED

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

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.

20th EFORT Annual Congress Lisbon ,June 5-7, 2019– Main **Theme**

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

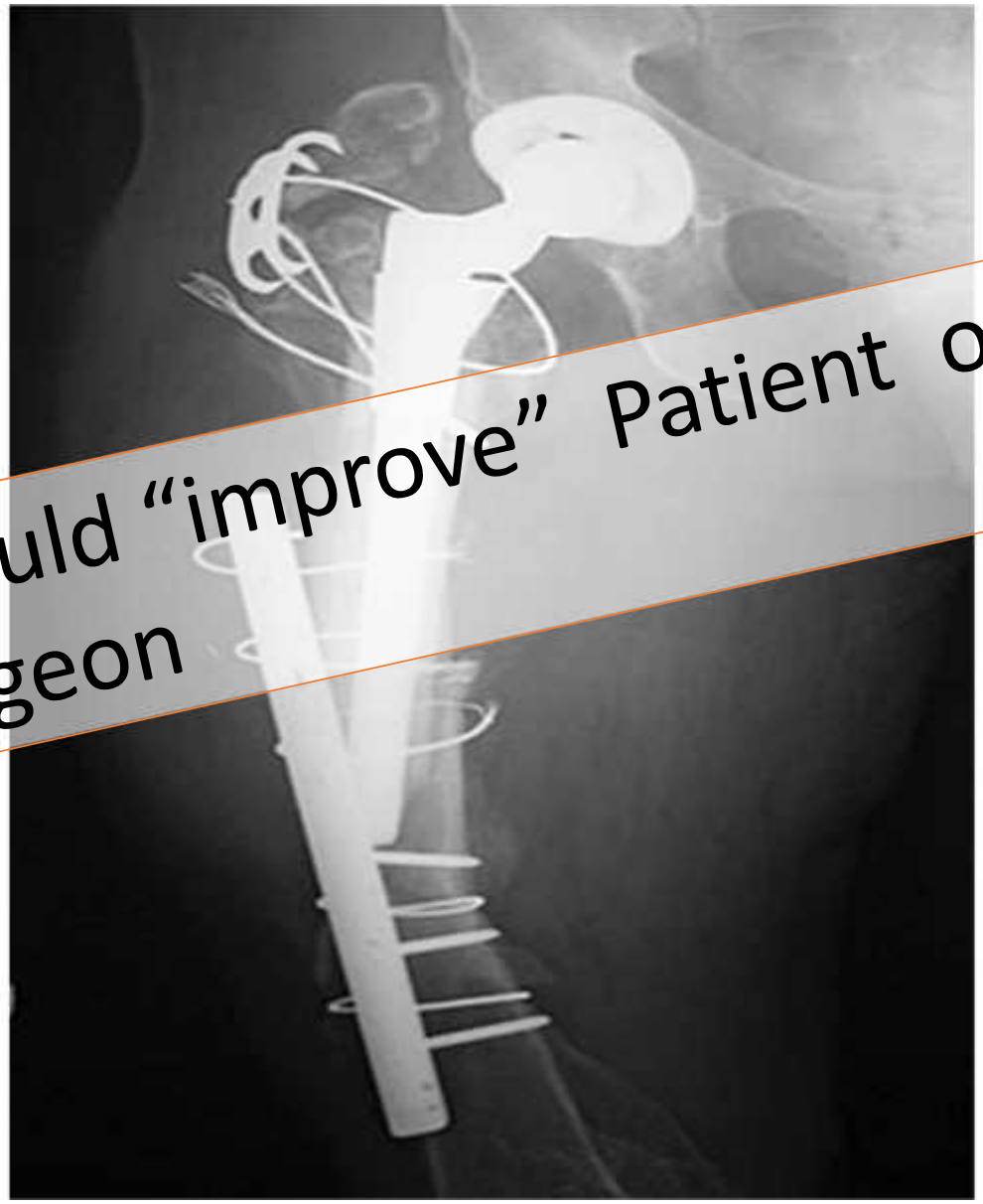
Govermental decision

- **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

- Mission, vision & activities
- The EFORT Constituency
- EFORT Board & Executive Committee
- Honorary Members
- The EFORT Committees
- Statutes
- What is EFORT?
- Ethical Orthopaedics
- Investor relations
- Network of Orthopaedic Registries of Europe (NORE)
  - Research & Publications
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NORE Network of Orthopaedic Registries of Europe

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

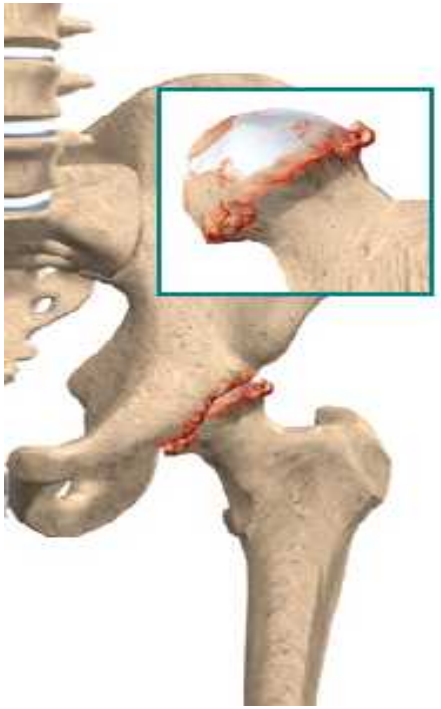
NORE Event on Medical Devices regulations
Engaging with the new EU regulatory landscape for medical devices – Challenges and Opportunities
NIMAC Symposium | Brussels, Belgium | 06 April 2018

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.

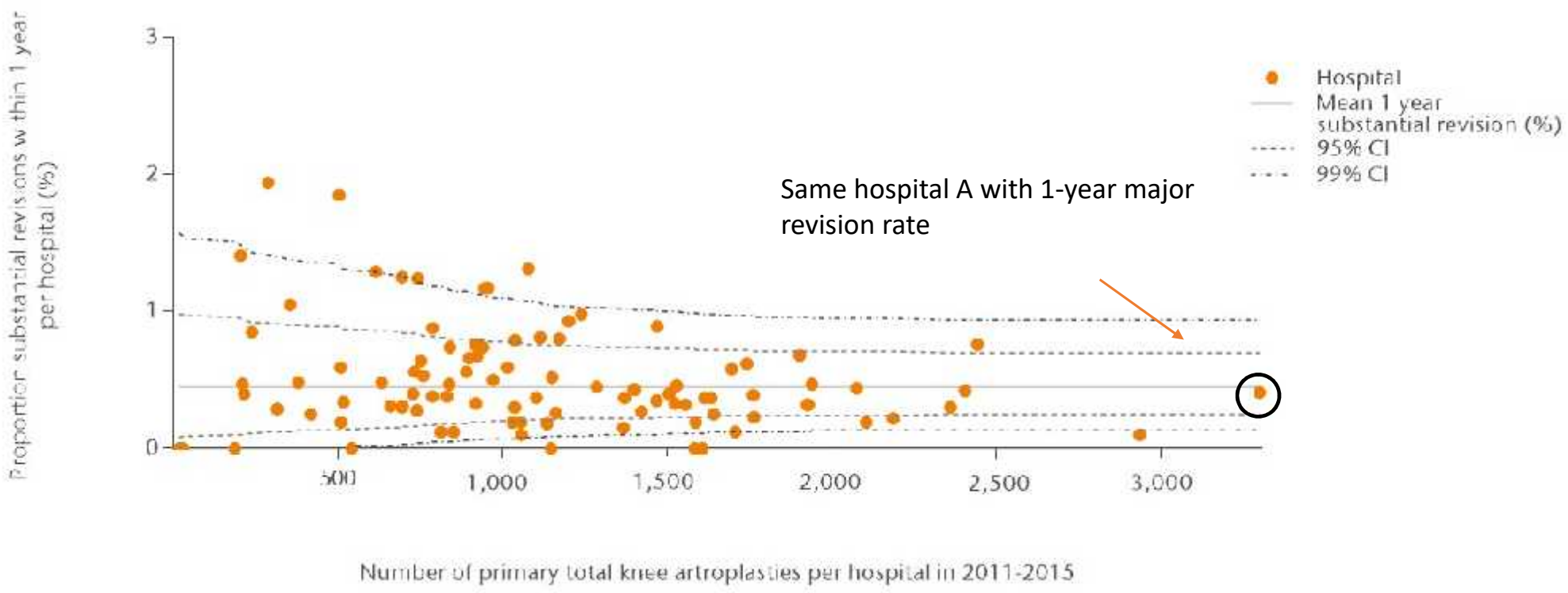
Indicators

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:

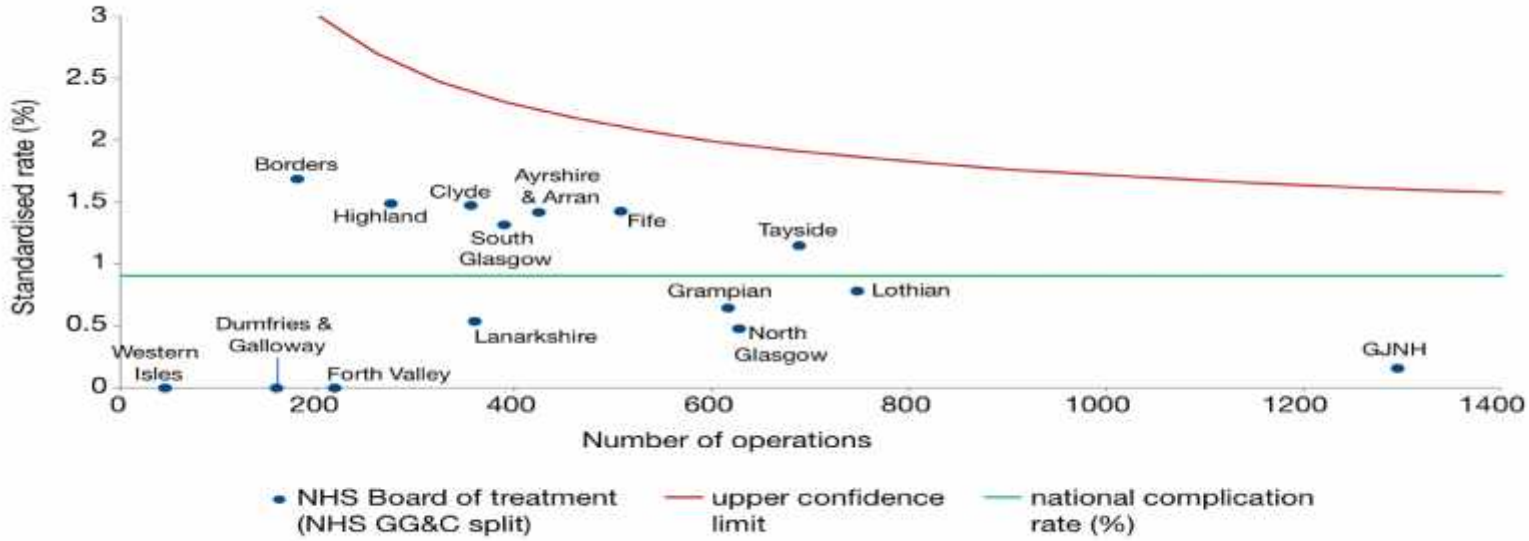
- Revision < 1 yr, 3 yr, 7 yr
- Hip dislocation < 1 yr
- DVT / Pulmonary emboli < 30 days
- Acute Myocardial infarction / CVA < 30 days
- Renal disease < 30 days
- Death

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



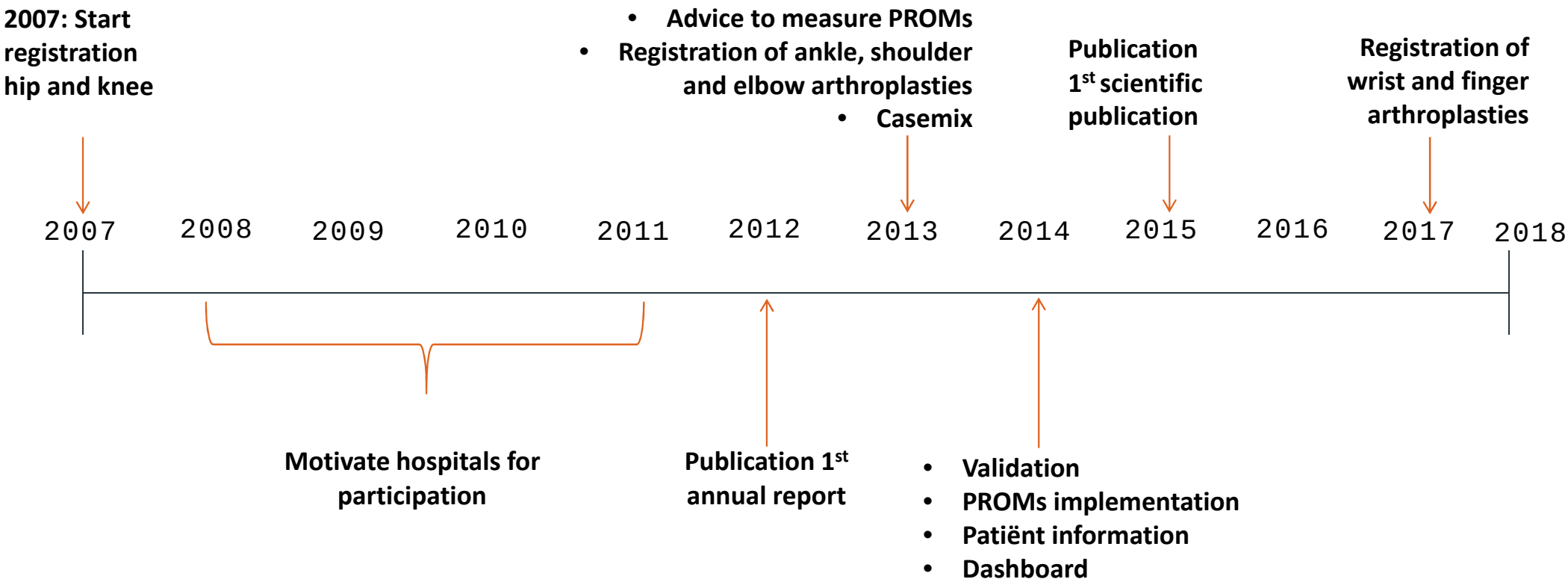
Scottish Rate averaged over 5 years 2010-2014.

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



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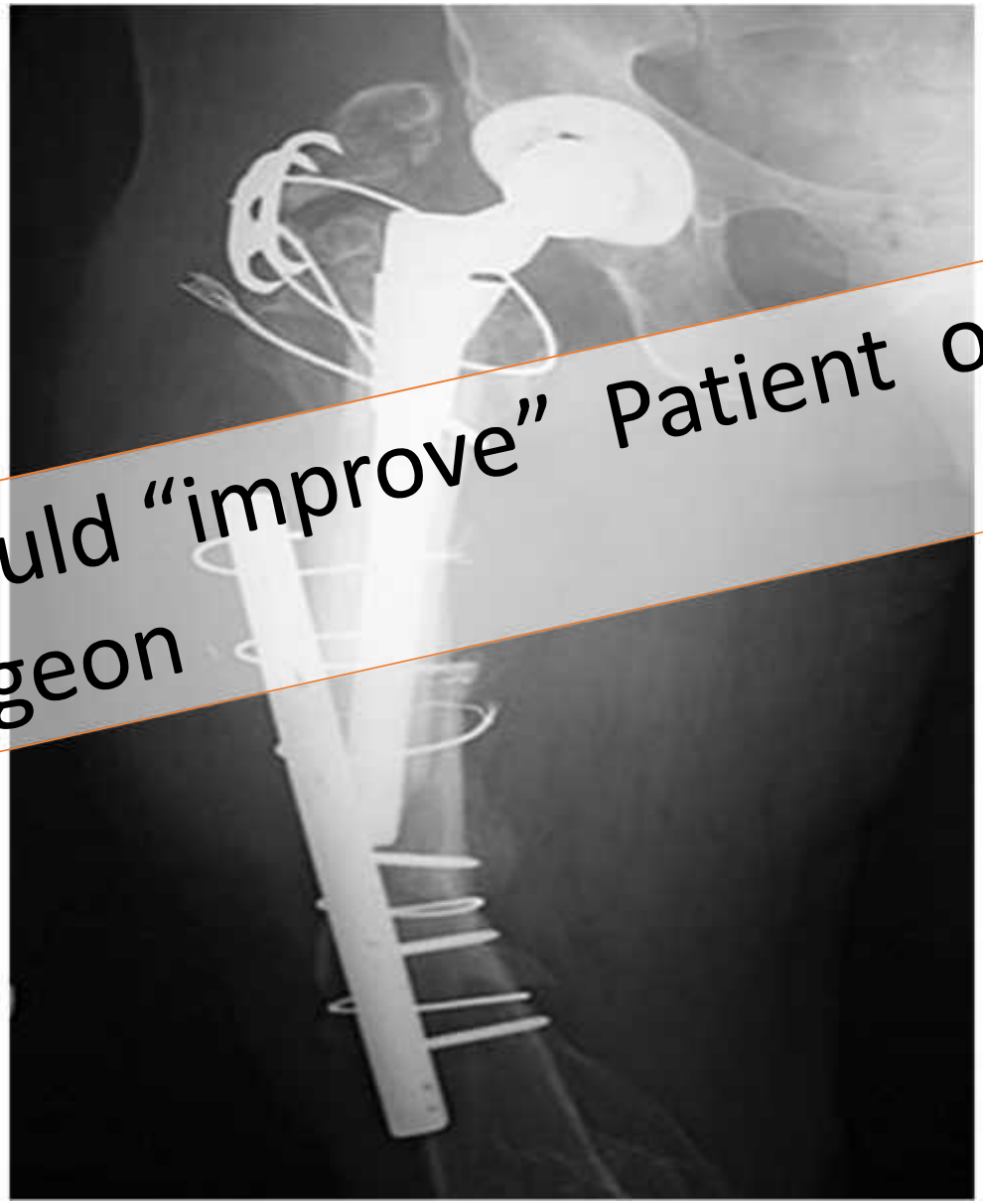
Network of Orthopaedic Registries of Europe



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www.njrcentre.org.uk
Working for patients, driving forward quality

NJR Surgeon and Hospital Profile

for hip, knee, ankle, elbow and shoulder joint replacement surgery

Glossary

Showing 1 to 10 of 133 entries

Show 10 entries Filter by letter : -

Term	Definition
ABHI	Association of British Healthcare Industries - the UK trade association of medical device suppliers.
Acetabular component	The portion of a total hip replacement prosthesis that is inserted into the acetabulum - the socket part of a ball and socket joint.

www.njrsurgeonhospitalprofile.org.uk/HospitalProfile?hospitalName=Alexandra%20Hospital

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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

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DATA >3 million
THA & TKA procedures

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

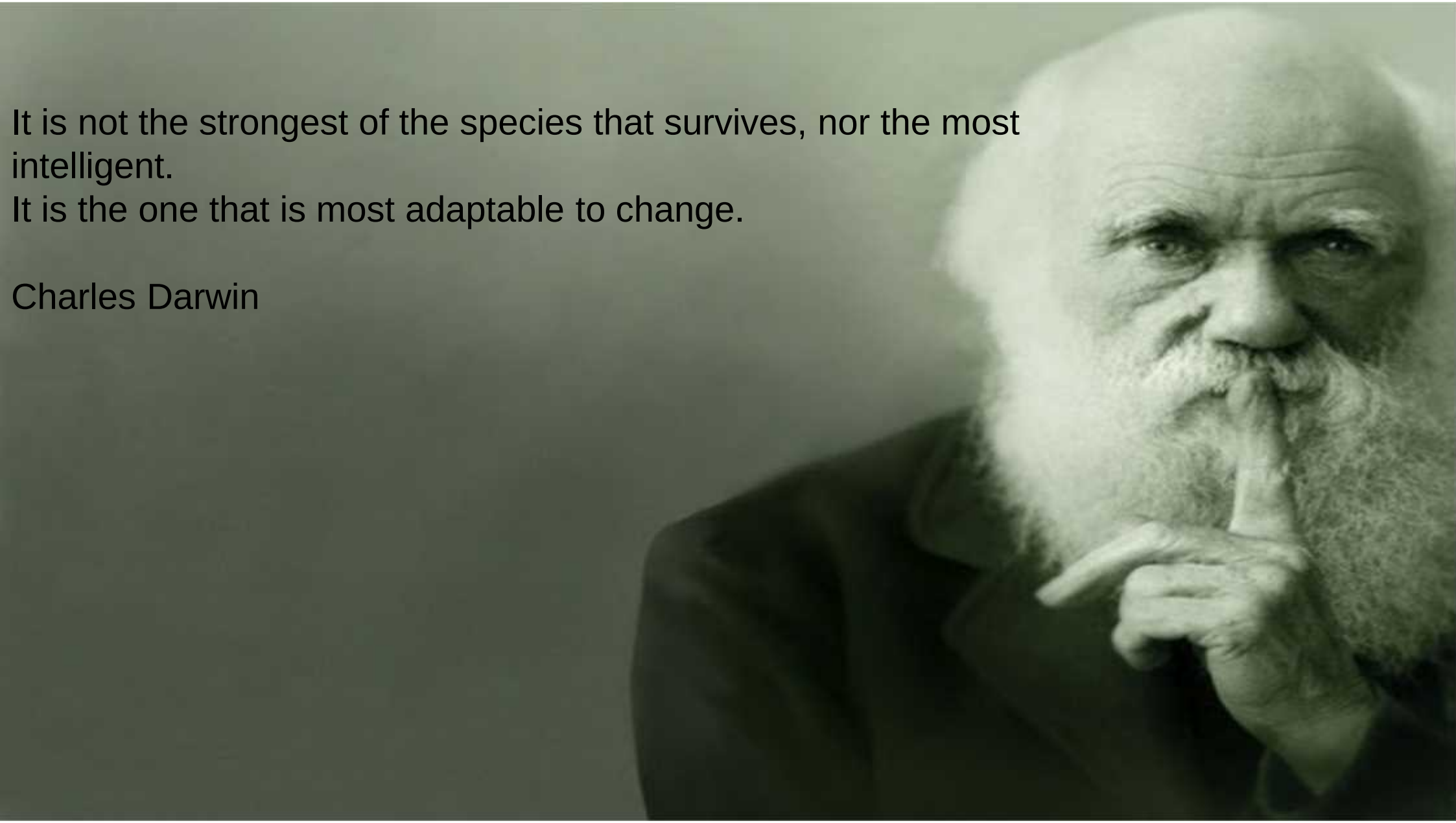
20th EFORT ANNUAL CONGRESS LISBON 2019 MAIN THEME: ***REGISTRIES & IMPACT ON PRACTICE***

Lisbon – Travel around the world without leaving Lisbon!

20th EFORT Congress

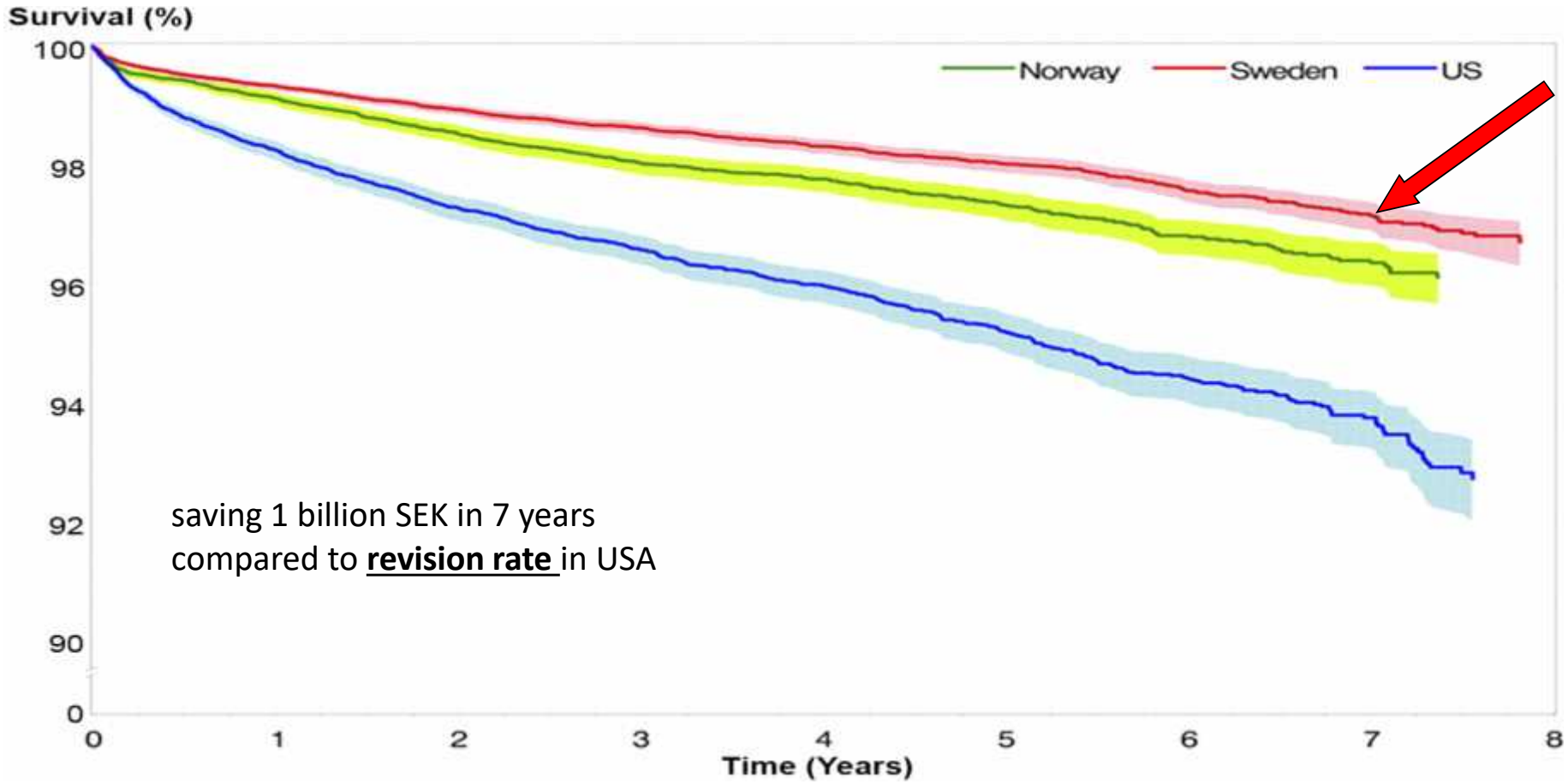
Come celebrate 20 years of progress

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.



Kurtz S. M. et.al. J Bone Joint Surg 2007:89:144-151

JBJS

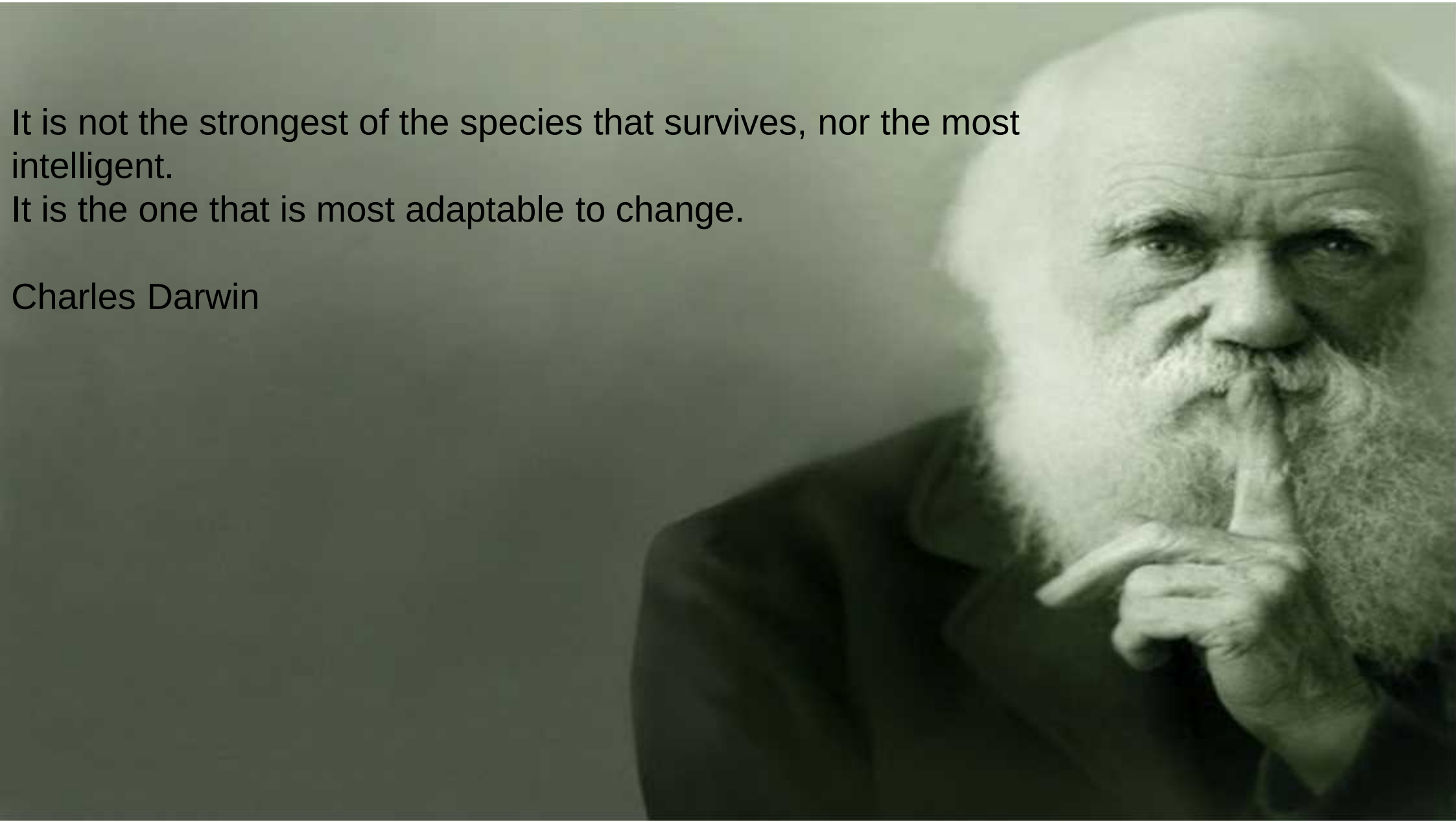
Key words in the talk: *"Safe implants: Total hip arthroplasty and impact from European Registries"*

- Safe implants; quality; registries; post-marketing investigated; total hip replacement

NARA

Nordic Arthroplasty Register Association

2006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