Postmarket surveillance & (Quality) Registries

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Professor & Chairman Orthopaedics, Leiden University Medical Center
Chairman NORE, a standing committee of EFORT
Dilemma: RCT patients ⇔ Your Practice

REAL World Data  =  Registry data
Largest registries (consortium) number TH + TK

> 95% completeness

DATA about 4 million TH TK procedures

> 1.5 million

> 720,000

> 630,000

> 730,000

Dutch Arthroplasty Register
### Aantal registraties op dit moment

<table>
<thead>
<tr>
<th>Body Part</th>
<th>Registrations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Totaal</td>
<td>600,305</td>
</tr>
<tr>
<td>Heup</td>
<td>332,394</td>
</tr>
<tr>
<td>Knie</td>
<td>256,488</td>
</tr>
<tr>
<td>Enkel</td>
<td>495</td>
</tr>
<tr>
<td>Schouder</td>
<td>10,131</td>
</tr>
<tr>
<td>Elleboog</td>
<td>636</td>
</tr>
<tr>
<td>Pols</td>
<td>50</td>
</tr>
<tr>
<td>Vinger/duim</td>
<td>111</td>
</tr>
</tbody>
</table>

**Deadline indienen abstracts**

**ISAR congres (IJssel)**
TKA n = 249,567  PS + CR

Revision TKA PS + CR

men

females

11.6% (95%-CI: 10.2-13.3)
6.6% (95%-CI: 5.7-7.6)
More than 95% completeness of reported procedures in the population-based Dutch Arthroplasty Register

External validation of 311,890 procedures

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Which Implant?
Implant register + Quality register

Real-time Patient specific Reflection
Benchmarking Own Practice vs Netherlands
NOV 1 A
• > 90% survival @ 10 yrs in at least 500 cases

NOV 1 B
• > 95% survival @ 5 yrs in at least 500 cases

NOV 2
• no data available: informed consent + prospective study

NOV classes based on data validated Registries (> 90% completeness)
### NOV 1A classification:

<table>
<thead>
<tr>
<th>Gecementeerde knieprothesen – Posterier Stabilized</th>
<th>Gecementeerde knieprothesen – Cruciate Retaining</th>
</tr>
</thead>
<tbody>
<tr>
<td>Merk</td>
<td>Aar</td>
</tr>
<tr>
<td>Smith &amp; Nephew</td>
<td>Genesis II CoCr</td>
</tr>
<tr>
<td>Zimmer Biomet</td>
<td>AGC V2</td>
</tr>
<tr>
<td>Zimmer Biomet</td>
<td>Nexgen</td>
</tr>
<tr>
<td>Smith &amp; Nephew</td>
<td>Genesis II CoCr</td>
</tr>
<tr>
<td>Smith &amp; Nephew</td>
<td>Genesis II Osseal</td>
</tr>
<tr>
<td>Zimmer Biomet</td>
<td>Vanguard Complete Knee</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gecementeerde knieprothesen – Cruciate sacrificing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Merk</td>
</tr>
<tr>
<td>MetOrtho</td>
</tr>
</tbody>
</table>

### NOV 1A 10 jaar resultaat

<table>
<thead>
<tr>
<th>Gecementeerde knieprothesen</th>
<th>Ungecementeerde knieprothesen – Cruciate Retaining</th>
</tr>
</thead>
<tbody>
<tr>
<td>Merk</td>
<td>Aar</td>
</tr>
<tr>
<td>DePuy</td>
<td>LCS complete (phacoat)</td>
</tr>
<tr>
<td>Zimmer Biomet</td>
<td>ROCO</td>
</tr>
<tr>
<td>Smith &amp; Nephew</td>
<td>Reflexion</td>
</tr>
<tr>
<td>Smith &amp; Nephew</td>
<td>ABG II</td>
</tr>
<tr>
<td>Smith &amp; Nephew</td>
<td>Stryker</td>
</tr>
<tr>
<td>Zimmer Biomet</td>
<td>CSF Allodoc</td>
</tr>
<tr>
<td>Zimmer Biomet</td>
<td>CLS Spotorno</td>
</tr>
<tr>
<td>Zimmer Biomet</td>
<td>Fitting</td>
</tr>
</tbody>
</table>
Effect publication on use 1A/1B Implants

Quality Acetabular component
1A: 90% survival at 10yr; 1B 95% survival at 5yrs; 2: no data

Quality Femoral component
1A: 90% survival at 10yr; 1B 95% survival at 5yrs; 2: no data

Denissen, Nelissen 2016
How to manage Outliers: the Dutch Approach

stepwise escalation: “Healthy Confidence, but Accountable”

Phase I: Detection Outliers
Phase II.1 Implants: Analysis + Actionplan

Phase I: Outlier detection

Anomisation disclosed of type of Implant by LROI + analysis International Registries

Industry feedback on Findings + Request why Implant is outlier and Why Safe to use

Scientific Commitee LROI recommends escalation Phase III based on
• Evidence Outlier
• Report Industry

Phase III Ouliers
Phase II.2 Surgeon Group: Analysis Outliers + Actionplan

Phase I: Outlier detection

(anomised) Outliers discussed by Quality commitee NOV

Anominisation disclosed by Quality subcommitee NOV

Quality subcommitee reports to Surgeon’s Group and Requests:
- reasons Outliers
- which actions

If
- Surgeon Group is Outlier 2nd time and
- Outlier cannot be explained and
- Outlier = high clinical impact

=> Phase III

“Healthy Confidence, but Accountable”
orthopaedic surgeons

Industry

Regulators
validated (= complete) Registries (> 95% completeness)
Feedback into Classification

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

AOA
Australian Orthopaedic Association

LROI
Dutch Arthroplasty Register

ONARA
Nordic Arthroplasty Register Association
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