IMPLANTS
BENCHMARKING
ODEP & BEYOND COMPLIANCE

KEITH TUCKER

SIOT ROME 2019
DECLARATION OF INTERESTS

Consultant Orthopaedic Surgeon.
President BHS 2007-8

Chair Beyond Compliance advisory group and ODEP

Past Member NJR Steering Committee.
Member NJR Implant performance committee,

In the past I received monies from J&J which were all paid into a research fund
I hold stock in Accentus Medical

I do not receive any financial reward for NJR, MHRA BEYOND COMPLIANCE or ODEP work. My travel expenses are reimbursed.
WHAT DO WE MEAN BY A BENCHMARK?
Cosa si intende per un benchmark?

• AN AGREED STANDARD
• AT A CERTAIN TIME POINT
• AGAINST WHICH ALL IMPLANTS ARE JUDGED
• THE BENCHMARK IS THE MINIMUM ACCEPTABLE STANDARD BASED ON THE NON INFERIORITY CONCEPT

• NB. THEY MUST ALL BE JUDGED IN EXACTLY THE SAME WAY
• IT IS NOT A COMPETITION
WHAT DO WE MEAN BY THE WORD BENCHMARK?
Che cosa si intende con la parola benchmark?

GUNS!

• The term benchmark, originates from the history of guns and ammunition, in regards to the same aim
• Il termine di benchmark, proviene dalla storia delle armi da fuoco e munizioni, in merito allo stesso scopo
IN A NUTSHELL

**ODEP**

ENSURES

THAT MANUFACTURERS HAVE TO PRODUCE DATA (AT THEIR EXPENSE) TO SUPPORT THE USE OF THEIR IMPLANT

**Beyond Compliance**

ENSURES

THAT ALL NEW PRODUCTS ARE CAREFULLY MONITORED
THEIR ORIGINS

• BOTH ODEP AND BEYOND COMPLIANCE EVOLVED FROM DISASTERS

• ODEP (AND NJR) FROM 3M CAPITAL HIP

• FROM METAL ON METAL DISASTERS
ODEP..... OUR AIMS

• TO INFORM SURGEONS ABOUT THR PERFORMANCE OF INDIVIDUAL IMPLANTS

• TO REDUCE THE NUMBER OF REVISIONS

• TO IMPROVE PATIENT SAFETY

• IT IS NOT ABOUT PROCUREMENT OR COST
THE STRATEGY.....BENCHMARKS

• MANUFACTURERS TO SUBMIT DATA TO SUPPORT THE CONTINUING USE OF THEIR PRODUCT

• ODEP ASSESS THE SUBMISSION AND AWARD “BENCHMARKS” ON THE BASIS OF MANUFACTURER’S DATA

• BENCHMARKS ARE AT 3,5,7,10 AND NOW 13 YEARS

• THE NUMBER REPRESENTS THE YEARS OF USE AND THE LETTER THE STRENGTH OF THE EVIDENCE

• THE IMPLANT HAS TO KEEP MOVING FROM ONE BENCHMARK TO THE NEXT

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DATA SOURCES

• REGISTRY DATA. MANUFACTURERS USE DATA FROM >12 WORLD WIDE REGISTRIES INCLUDING RIPO

• RCTS

• PEER REVIEWED PUBLICATIONS OR PRESENTATIONS (Our desire is to encourage local studies etc)

• VALIDATED IN HOUSE DATA
### Criteria - Total Hip Replacement

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Minimum number of centres outside development centre(s)</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Minimum number of surgeons outside of development centre(s)</td>
<td>3</td>
<td>3</td>
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<tr>
<td>Minimum total cohort</td>
<td>150</td>
<td>250</td>
<td>350</td>
<td>500</td>
<td>500</td>
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<tr>
<td>Minimum at risk at benchmark time</td>
<td>150</td>
<td>225</td>
<td>300</td>
<td>400</td>
<td>400</td>
</tr>
<tr>
<td>Maximum revision rate ‡</td>
<td>3.0%</td>
<td>3.5%</td>
<td>4.0%</td>
<td>5.0%</td>
<td>6.5%</td>
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</table>

<table>
<thead>
<tr>
<th>Criteria - A Ratings</th>
<th>3A</th>
<th>5A</th>
<th>7A</th>
<th>10A</th>
<th>13A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum number of centres and surgeons</td>
<td>3</td>
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<tr>
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<td>500</td>
<td>500</td>
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<tr>
<td>Minimum at risk at benchmark time</td>
<td>72</td>
<td>66</td>
<td>60</td>
<td>51</td>
<td>42</td>
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<td>Maximum revision rate ‡</td>
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<td>6.0%</td>
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‡ The upper 95% confidence interval for KM revision rate (1 - Survival) must be lower than the specified level.

<table>
<thead>
<tr>
<th>Criteria - B Ratings</th>
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<tbody>
<tr>
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<tr>
<td>Minimum total cohort</td>
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<tr>
<td>Minimum at risk at benchmark time</td>
<td>40</td>
<td>40</td>
<td>40</td>
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</tr>
<tr>
<td>Maximum value of 95% lower confidence limit for revision rate</td>
<td>3.0%</td>
<td>3.5%</td>
<td>4.0%</td>
<td>5.0%</td>
<td>6.5%</td>
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### Criteria - Pre-Entry A*

Product launched under Beyond Compliance

Pre-Entry

Products registered with NJR. All primaries and revisions monitored via supplier feedback.
## Criteria - Total Knee Replacement

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<td>45</td>
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</thead>
<tbody>
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<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Minimum total cohort</td>
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<td>6.0%</td>
</tr>
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</table>
WHO USES US?

• ALL THE BIG 5 PLUS MOST OF THE WORLD’S IMPLANT MANUFACTURERS

• LIMA, ADDLER, MEDACTA, CONFORMIS SYMBIOS, LINK ETC

• INDIAN AND CHINESE MANUFACTURERS

• THE IMPLANTS DO NOT HAVE TO BE SOLD IN THE UK MARKET TO BE BENCHMARKED BY ODEP
ODEP 2002-2019

- Approximately 50 submissions for each meeting
- 25% go to appeal
- ~10% fail
- WITHDRAWN FROM THE MARKET 120
Hits on ODEP website odep.org.uk from 2015 to 2019
73,637 users, 127,780 sessions

Users by location:
UK – 43%
Rest of the world – 57%

Top 10 countries
UK
USA
Netherlands
Italy
Germany
India
France
Switzerland
Spain
Japan
MONITORING
THE INTRODUCTION OF NEW DEVICES OR MODIFICATION OF
EXISTING ONES

“BEYOND COMPLIANCE”

“PROTECTING PATIENTS........
SUPPORTING INNOVATION”
THE DISASTERS OF METAL ON METAL

ASR Resurfacing Metal on Metal

Stemmed Metal on Metal

Cumulative revision (%)

Years since primary

Number at risk

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Number at risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>MoP</td>
<td>290,830</td>
</tr>
<tr>
<td>MoM</td>
<td>1,108</td>
</tr>
<tr>
<td>CoP</td>
<td>38,128</td>
</tr>
</tbody>
</table>

MoP: 266,267 267,255 267,257 269,951 180,428 153,720 126,584 106,033 86,347 67,944 50,547 34,597 21,847 17,122 11,136 3,832
MoM: 1,108 1,087 1,057 1,020 982 940 884 823 759 654 472 306 189 72 13
CoP: 38,128 33,002 28,230 23,692 19,532 15,896 12,697 10,084 7,839 5,978 4,317 2,998 1,885 887 250

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WHY
“BEYOND COMPLIANCE?"

• THE CE MARK IS COMPLIANCE

• ABOUT 7 YEARS AGO, OUT OF FRUSTRATION, WE THOUGHT IT WAS ABOUT TIME WE WENT “BEYOND COMPLIANCE”

• IN VIGILANCE
• IN DILIGENCE
• IT IS VOLUNTARY BUT UPLOADING INTO NJR IN THE UK IS COMPULSORY
• IT IS INDEPENDENT
HOW DOES BC WORK?

• RISK ASSESSMENT
• DATA COLLECTION
• REVIEWS
• USER GROUP MEETINGS

• WE ARE INDEPENDENT AND THE SURGEONS ARE UNPAID....... NO CONFLICTS
RISK ASSESSMENT

LEVEL 1 RISK
NO MAJOR CHANGE FROM BENCHMARK PREDICATE OR EQUIVALENT

LEVEL 2 RISK
ONE MAJOR CHANGE FROM BENCHMARK PREDICATE / EQUIVALENT

LEVEL 3 RISK
2 SIGNIFICANT CHANGES FROM BENCHMARK PREDICATE/EQUIVALENT
Rate of introduction:- Limited
Monitoring:- Full BC programme
RISK ASSESSMENT

LEVEL 4 RISK
PAUCITY OF BENCHMARK DATA, > 3 MAJOR CHANGES FROM THE PREDICATE / EQUIVALENT

Rate of Introduction:- Limited
Monitoring:- Close monitoring

LEVEL 5 RISK
WHERE A SIMILAR PRODUCT HAS FAILED

Rate of Introduction:- Limited
Monitoring:- Close monitoring
ASR ‘design modifications’ compared to BHR

- Different Metal
- Thinner shell
- Bevelled edge
- Less area of femoral head covered
- Smaller clearance
THE COLLECTION SYSTEM

NJR MAIN FRAME
(RECOGNISES PRODUCT CODE)

MANUFACTURER

RAPPORTEURS

SURGEONS

DEATH

PROMS

XRAY, OP NOTES

FU NOTES

REVISION

HES DATA

SCORES

DATA FROM OTHER STUDIES

EXPLANTS

HOSPITAL DATA CLERK

OPERATION

NORMAL NJR DATA ANALYSIS

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REVIEWS

(USUALLY 8PM ON A MONDAY EVENING)

CHAMPION SURGEON (S)
MANUFACTURER
NORHTGATE
BC RAPPORTEURS
A REPORT FOR A REVIEW (DUMMY)

BASIC DATA

DEMOGRAPHICS

SIOT ROME 2019
# Performance of Surgeons Using the Prosthesis

## Reasons for Revision

<table>
<thead>
<tr>
<th>Reason for Revision</th>
<th>Revised</th>
<th>Expected Revisions</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection</td>
<td>0</td>
<td>0.34</td>
<td>1</td>
</tr>
<tr>
<td>Progressive Arthritis Remaining</td>
<td>0</td>
<td>0.06</td>
<td>1</td>
</tr>
<tr>
<td>Aseptic Loosening Femur</td>
<td>0</td>
<td>0.07</td>
<td>1</td>
</tr>
<tr>
<td>Aseptic Loosening Tibia</td>
<td>0</td>
<td>0.17</td>
<td>1</td>
</tr>
<tr>
<td>Aseptic Loosening Patella</td>
<td>0</td>
<td>0.04</td>
<td>1</td>
</tr>
<tr>
<td>Pain</td>
<td>1</td>
<td>0.31</td>
<td>0.192</td>
</tr>
<tr>
<td>Stiffness</td>
<td>0</td>
<td>0.13</td>
<td>1</td>
</tr>
<tr>
<td>Malalignment</td>
<td>0</td>
<td>0.11</td>
<td>1</td>
</tr>
<tr>
<td>Instability</td>
<td>0</td>
<td>0.19</td>
<td>0.017</td>
</tr>
<tr>
<td>Dislocation / Subluxation</td>
<td>0</td>
<td>0.04</td>
<td>1</td>
</tr>
<tr>
<td>Periprosthetic Fracture</td>
<td>0</td>
<td>0.03</td>
<td>1</td>
</tr>
<tr>
<td>Wear of Polyethylene Component</td>
<td>0</td>
<td>0.02</td>
<td>1</td>
</tr>
<tr>
<td>Cyst - Tibia</td>
<td>0</td>
<td>0.04</td>
<td>1</td>
</tr>
<tr>
<td>Poly - Femur</td>
<td>0</td>
<td>0.02</td>
<td>1</td>
</tr>
<tr>
<td>Component Dislocation</td>
<td>0</td>
<td>0.01</td>
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</tr>
<tr>
<td>Implant Fracture</td>
<td>0</td>
<td>0.00</td>
<td>1</td>
</tr>
<tr>
<td>Other - Not Recorded</td>
<td>0</td>
<td>0.09</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total Revised</strong></td>
<td><strong>2</strong></td>
<td><strong>1.21</strong></td>
<td><strong>0.342</strong></td>
</tr>
</tbody>
</table>

1 multiple reason may be listed for one revision procedure  
* Adjusted for age, group, gender and indications

Each circle represents one surgeon. Red circles represent surgeons with a higher than expected revision rate (p < 0.001), and blue circles represent surgeons with a lower than expected revision rate (p = 0.801). Note that these rates have not been adjusted for case mix or for variants of implant choice.
USER GROUP MEETINGS
Riunioni del gruppo di utilizzatori

AT BOA CONGRESS, EFFORT BHS, BASK

CHAMPION SURGEON(S)
MANUFACTURER
NORTHGATE
BC RAPPORTEURS

PLUS ALL THOSE SURGEONS WHO ARE USING OR WHO MIGHT USE THE IMPLANT

A BOA CONGRESS, EFFORT BHS, BASK

Champion chirurgo(s)
Costruttore
NORTHGATE
BC relatori

E tutti i chirurghi che stanno utilizzando o chi potrebbe utilizzare l'impianto

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THE NEW EUROPEAN MDR

WE ARE WORKING WITH BRUSSELS

NEW PRODUCTS =

LEGACY PRODUCTS =

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RIAP / NJR / EPRD

SHORTLY RIAP, NJR AND EPRD WILL BE SHARING THE SAME VERY COMPREHENSIVE DATABASE

YOUR REGISTRIES SHOULD SUPPLY YOUR MANUFACTURERS WITH YOUR DATA

FOR YOU TO ODEP BENCHMARK IN ITALY

TO INCREASE THE SAFETY OF YOUR PATIENTS

TO PROMOTE THEIR GOOD PRODUCTS

SIOT ROME 2019
YOU WILL NEED:

- SURGEON COMPLIANCE
- A GOOD REGISTRY
- COMPLETENESS OF REGISTRIES
- A COMMITTED TEAM
- YOU HAVE A TEAM
- WE CAN WORK WITH YOU

HAI BISOGNO

- Il chirurgo la conformità
- di un registro di buoni
- la completezza dei registri
- un team impegnato
- AVETE UN TEAM
- possiamo lavorare con voi
THANK YOU FOR YOUR ATTENTION

“PROTECTING PATIENTS........
SUPPORTING INNOVATION”
ACKNOWLEDGEMENTS

• ALL THE PATIENTS WHO ALLOW US TO USE THEIR DATA
• BC AND ODEP SURGEONS
• TIM WILTON AND THE NJR
• THE TEAM AT NORTHGATE INCLUDING EDD CATON, RICHARD ARMSTRONG, PATRICK PALMER AND OLGA TAYLOR