

IMPLANTS BENCHMARKING ODEP & BEYOND COMPLIANCE

**KEITH
TUCKER**

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.

SIOT ROME 2019

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

- Una norma concordata
- A un certo punto nel tempo
- Contro cui tutti gli impianti sono giudicate
- Il benchmark è lo standard minimo accettabile sulla base di la non inferiorità concetto
- NB. Tutti devono essere giudicati esattamente
- NELLO STESSO MODO IN CUI NON SI TRATTI DI UN CONCORSO

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



ENSURES

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



ENSURES

THAT ALL NEW PRODUCTS ARE CAREFULLY MONITORED

THEIR ORIGINS

- BOTH ODEP AND BEYOND COMPLIANCE EVOLVED FROM DISASTERS

-  (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

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

Criteria - A* Ratings	3A*	5A*	7A*	10A*	13A*
Minimum number of centres outside development centre(s)	3	3	3	3	3
Minimum number of surgeons outside of development centre(s)	3	3	3	3	3
Minimum total cohort	150	250	350	500	500
Minimum at risk at benchmark time	150	225	300	400	400
Maximum revision rate ‡	3.0%	3.5%	4.0%	5.0%	6.5%

Criteria - A Ratings	3A	5A	7A	10A	13A
Minimum number of centres and surgeons	3	3	3	3	3
Minimum total cohort	150	250	350	500	500
Minimum at risk at benchmark time	72	66	60	51	42
Maximum revision rate ‡	5.0%	5.5%	6.0%	7.0%	8.5%
‡ The upper 95% confidence interval for KM revision rate (1 - Survival) must be lower than the specified level					

Criteria - B Ratings	3B	5B	7B	10B	13B
Minimum number of centres and surgeons	1	1	1	1	1
Minimum total cohort	100	100	100	100	100
Minimum at risk at benchmark time	40	40	40	40	40
Maximum value of 95% lower confidence limit for revision rate	3.0%	3.5%	4.0%	5.0%	6.5%

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

Criteria - A* Ratings	3A*	5A*	7A*	10A*	13A*
Minimum number of centres outside development centre(s)	3	3	3	3	3
Minimum number of surgeons outside of the development centre	3	3	3	3	3
Minimum total cohort	150	250	350	500	500
Minimum at risk at benchmark time	150	225	300	400	400
Maximum revision rate ‡	3.5%	4.0%	4.5%	5.0%	6.0%

Criteria - A Ratings	3A	5A	7A	10A	13A
Minimum number of centres and surgeons	3	3	3	3	3
Minimum total cohort	150	250	350	500	500
Minimum at risk at benchmark time	66	60	55	51	45
Maximum revision rate ‡	5.5%	6.0%	6.5%	7.0%	8.0%

‡ The upper 95% confidence interval for KM revision rate (1 - Survival) must be lower than the specified level

Criteria - B Ratings	3B	5B	7B	10B	13B
Minimum number of centres and surgeons	1	1	1	1	1
Minimum total cohort	100	100	100	100	100
Minimum at risk at benchmark time	40	40	40	40	40
Maximum value of 95% lower confidence limit for revision rate	3.5%	4.0%	4.5%	5.0%	6.0%

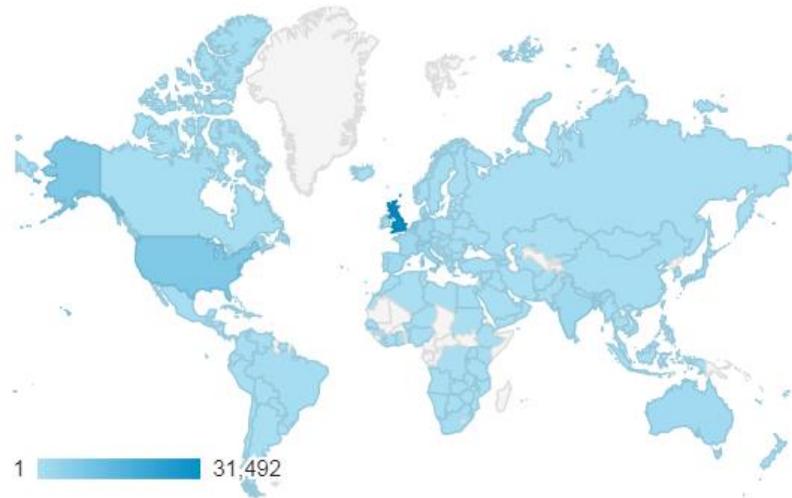
WHO USES US?

- ALL THE BIG 5 PLUS MOST OF THE WORLDS 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



British
Orthopaedic
Association

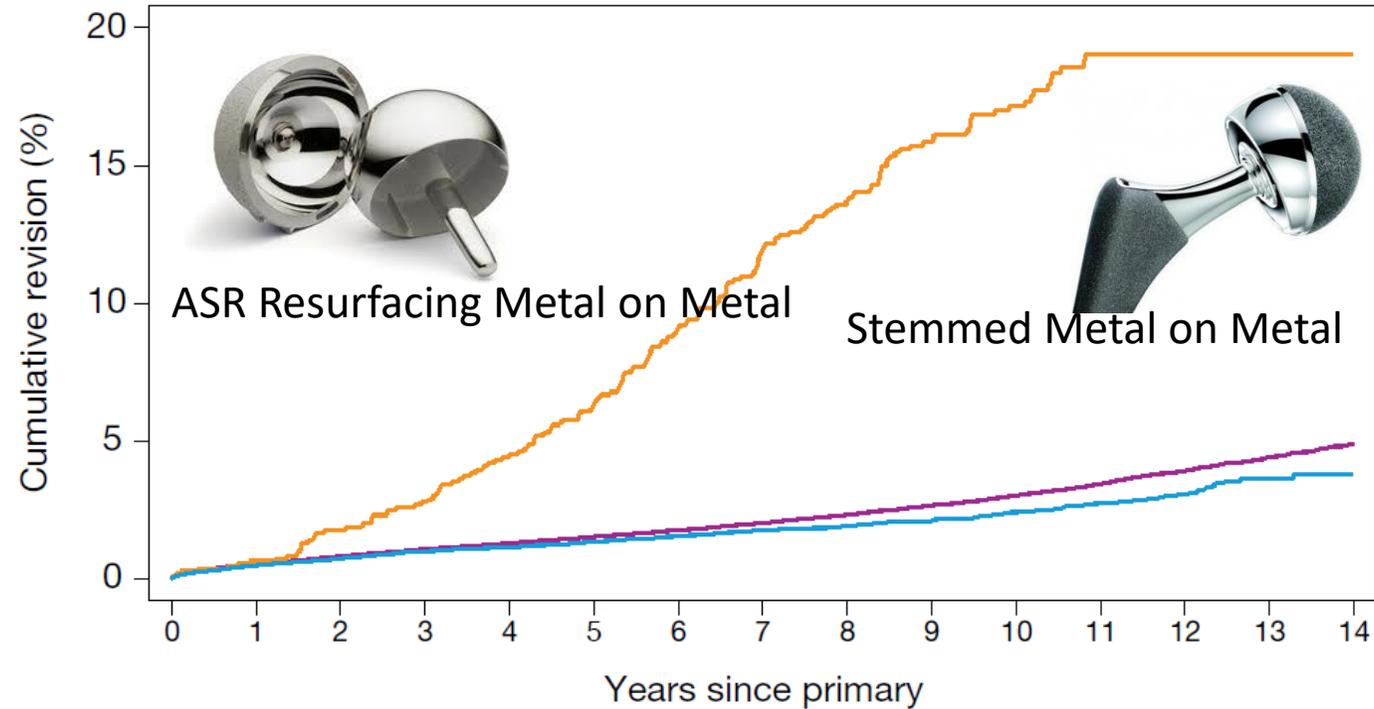


MONITORING
THE INTRODUCTION OF NEW DEVICES OR MODIFICATION OF
EXISTING ONES

“BEYOND COMPLIANCE”

**“PROTECTING PATIENTS.....
SUPPORTING INNOVATION”**

THE DISASTERS OF METAL ON METAL



Number at risk

MoP	293,839	265,287	237,235	208,951	180,428	153,720	128,564	106,303	86,347	67,944	50,547	34,395	21,847	11,229	3,832
MoM	1,108	1,087	1,057	1,026	982	940	884	823	759	654	472	306	169	73	13
CoP	38,128	33,002	28,230	23,692	19,532	15,896	12,697	10,084	7,839	5,978	4,337	2,998	1,835	887	250

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

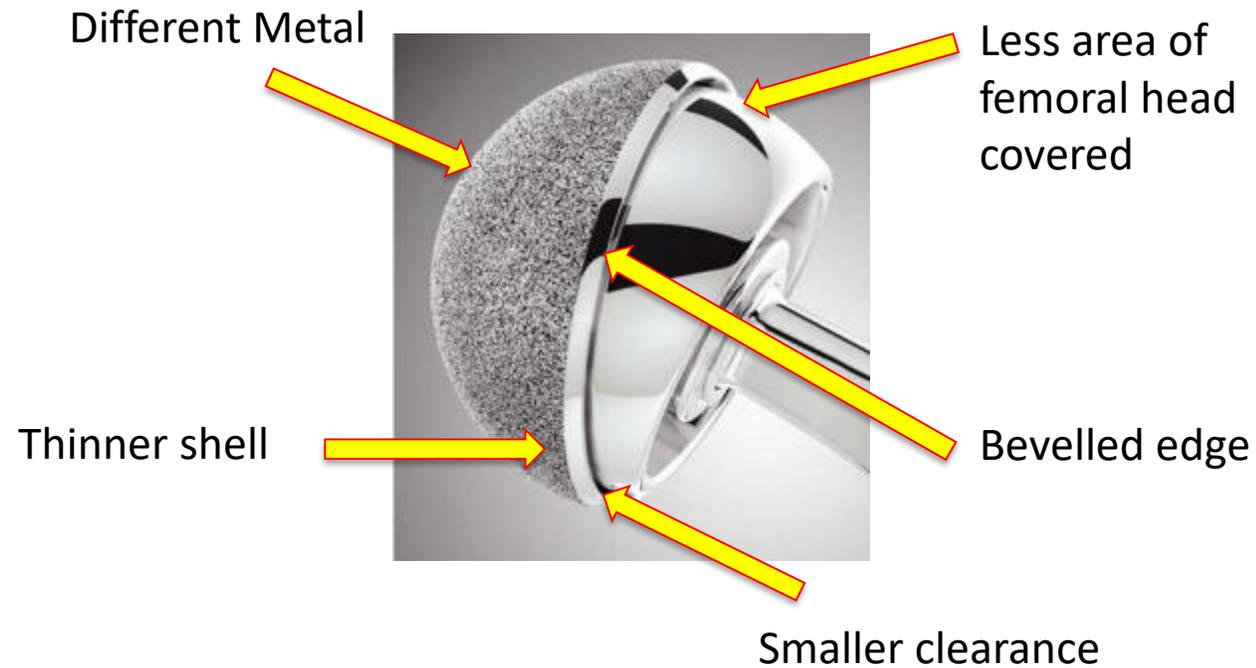
LEVEL 5 RISK

WHERE A SIMILAR PRODUCT HAS FAILED

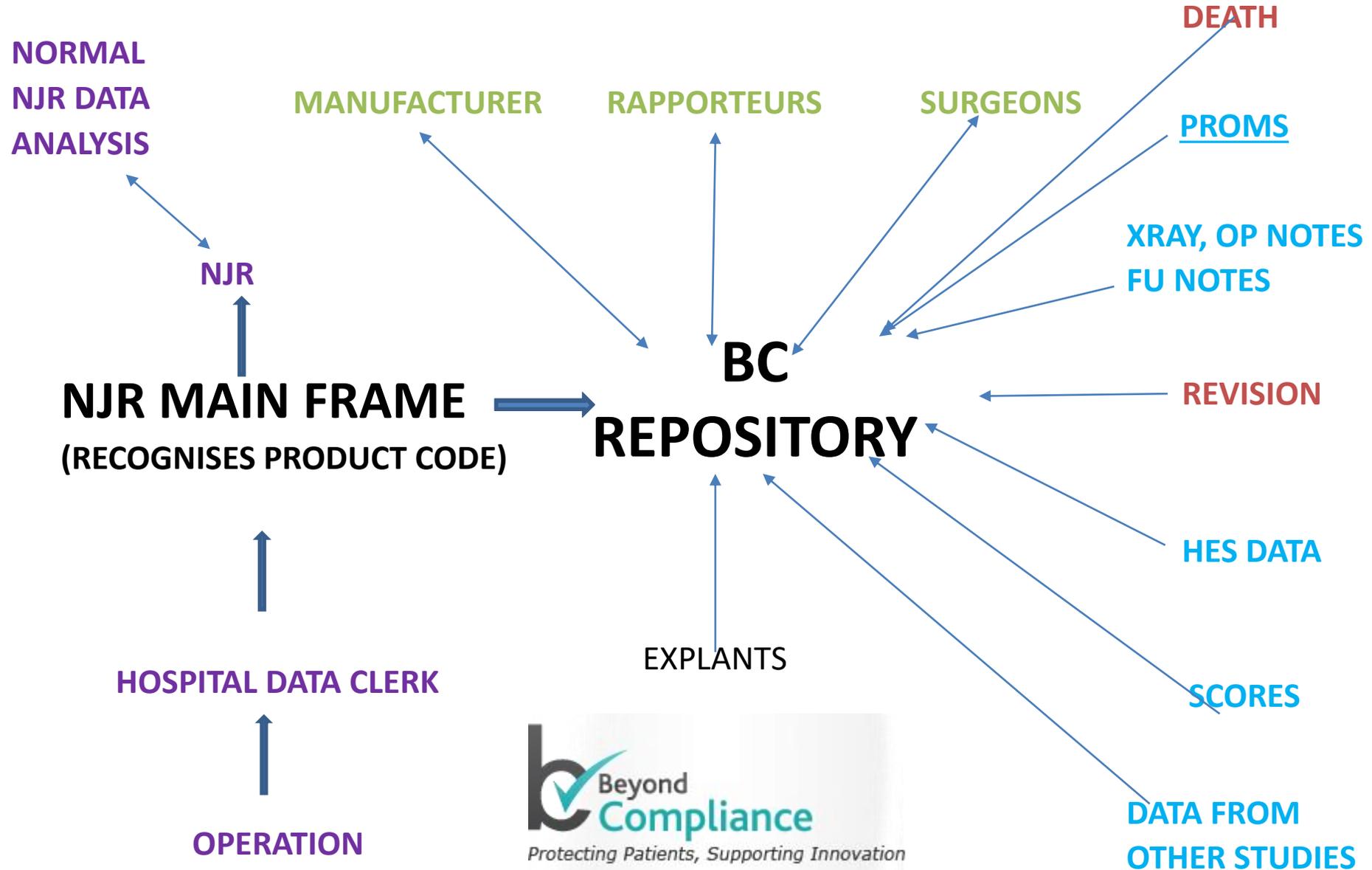
Rate of Introduction:- Limited

Monitoring:- Close monitoring

ASR 'design modifications' compared to BHR



THE COLLECTION SYSTEM



REVIEWS

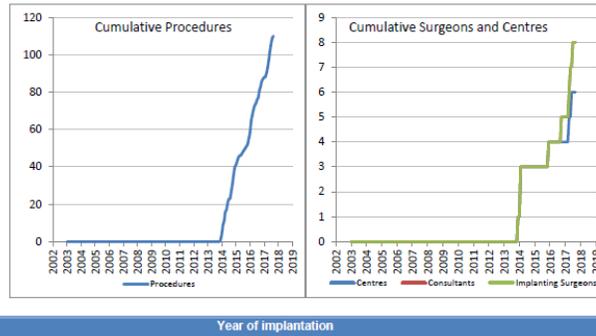
(USUALLY 8PM ON A MONDAY
EVENING)

CHAMPION SURGEON (S)
MANUFACTURER
NORTHGATE
BC RAPPORTEURS

A REPORT FOR A REVIEW (DUMMY)

BASIC DATA

Totals Recorded in NJR	Cumulative Total
Procedures	110
Patients	106
Centres	6
Consultants	8
Implanting Surgeons	8



DEMOGRAPHICS

Total Procedures	110	931,111
Total Patients	106	765,348
Demographics		
Mean age	64.4	70.1
< 50	0.0%	1.8%
50 – 59	28.2%	11.2%
60 – 69	39.1%	32.5%
70 – 79	30.0%	38.5%
≥ 80	1.8%	16.1%
Median BMI	30	30
% BMI information available	94.5%	59.7%
Underweight (BMI < 18.5)	0.0%	0.3%
Normal (18.5 ≤ BMI < 25)	20.2%	10.1%
Overweight (25 ≤ BMI < 30)	26.0%	34.2%
Obese I (30 ≤ BMI < 35)	36.5%	32.3%
Obese II (35 ≤ BMI < 40)	11.5%	16.2%
Obese III (BMI ≥ 40)	5.8%	6.9%
% Male	42.7%	42.6%
ASA Grades		
P1 - Fit and healthy	34.5%	11.1%
P2 - Mild disease not incapacitating	59.1%	72.4%
P3 - Incapacitating systemic disease	6.4%	16.1%
P4 / P5	0.0%	0.4%
Indications		
Osteoarthritis	100.00%	97.30%
Rheumatoid Arthritis	0.00%	1.64%
Other Inflammatory Arthropathy	0.00%	0.65%
Previous Trauma	0.00%	0.55%
Avascular Necrosis	0.00%	0.33%
Other	0.00%	0.37%

A REPORT FOR A REVIEW (DUMMY)

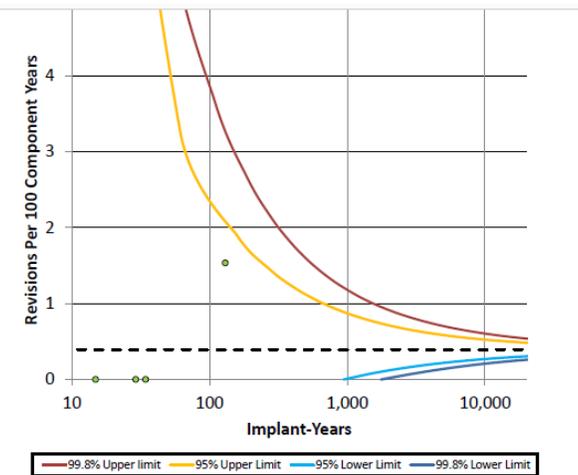
PERFORMANCE OF SURGEONS USING THE PROSTHESIS

REASONS FOR REVISION

Reason for Revision	Revised †	Expected Revisions ‡	p value
Infection	0	0.34	1
Progressive Arthritis Remaining	0	0.06	1
Aseptic Loosening Femur	0	0.07	1
Aseptic Loosening Tibia	0	0.17	1
Aseptic Loosening Patella	0	0.04	1
Pain	1	0.21	0.192
Stiffness	0	0.13	1
Malalignment	0	0.11	1
Instability	2	0.19	0.017
Dislocation / Subluxation	0	0.04	1
Periprosthetic Fracture	0	0.03	1
Wear of Polyethylene Component	0	0.02	1
Lysis - Tibia	0	0.04	1
Lysis - Femur	0	0.02	1
Component Dissociation	0	0.01	1
Implant Fracture	0	0.00	1
Other / Not recorded	0	0.09	1
Total Revised	2	1.21	0.342

† multiple reasons may be listed for one revision procedure

‡ Adjusted for agegroup, 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 ($p < 0.001$). Note that these rates have not been adjusted for case mix, or for variants of implant chosen.

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, EFORT BHS, BASK

Champion chirurgo(s)
Costruttore
NORTHGATE
BC relatori

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



THE NEW EUROPEAN MDR



WE ARE WORKING WITH BRUSSELS

NEW PRODUCTS =



LEGACY PRODUCTS =



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

ODEP & BEYOND COMPLIANCE FOR ITALY

ODEP & OLTRE LA CONFORMITÀ PER L'ITALIA

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