

# IMPROVING THE SAFETY OF LEGACY AND NEW IMPLANTS IN TODAY'S EUROPE... THE ODEP AND BEYOND COMPLIANCE INITIATIVES

**Keith Tucker**  
Chair of ODEP and the  
Beyond Compliance advisory group

# **DECLARATION OF INTERESTS**

## **KEITH TUCKER**

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.

CORE MD JAN 2023

# ODEP FOR LEGACY PRODUCTS

ORTHOPAEDIC DATA EVALUATION PANEL

# ODEP 2002-23



- SET UP AFTER 3 M CAPITAL HIP BY NICE
- A “MINOR CHANGE”, A BIG EFFECT
- PRIOR TO 2002 THERE WAS NO OBLIGATION FOR MANUFACTURERS TO CHECK ON THE EFFECTIVENESS OF THEIR JOINT REPLACEMENTS

- TO WORK WITH MANUFACTURERS TO ASSESS THE PERFORMANCE OF THEIR PRODUCTS
- TO INFORM SURGEONS, PATENTS AND HOSPITALS ABOUT THE PERFORMANCE OF INDIVIDUAL IMPLANTS
- TO REDUCE THE NUMBER OF REVISIONS
- TO PROMOTE GOOD IMPLANTS
- TO ASSESS IMPLANTS AGAINST AGREED BENCHMARKS

## WHAT DO WE MEAN BY A BENCHMARK?

- AN AGREED STANDARD
- AGAINST WHICH ALL IMPLANTS OF THE SAME TYPE ARE JUDGED
- AT A CERTAIN TIME POINT
- THE BENCHMARK IS THE MINIMUM ACCEPTABLE STANDARD BASED ON THE “NON INFERIORITY” CONCEPT

# ODEP 2002-22



- TO OBTAIN AN ODEP BENCHMARK MANUFACTURERS HAVE TO LOOK AT THEIR DATA
- ODEP ENSURES THAT THEY LOOK!
- NOT ONLY THEIR REVISION RATE BUT ALSO WHY

# ODEP HISTORY



- 2003 HIPS
- 2014 KNEES
- 2015 NETHERLANDS JOINED
- 2017 SHOULDERS
- 2017 UNI-CONDYLAR KNEES
- 2021 ELBOWS
- 2022 SPINES.. CERVICAL DISCS
- 2023 WRISTS



## WHAT DO WE MEAN BY A BENCHMARK?

- ODEP IS NOT A COMPETITION
- IT IS VOLUNTARY ..... HOWEVER!
- SELLING IMPLANTS WITHOUT AN ODEP RATING IS VERY DIFFICULT IN THE UK, THE NETHERLANDS AND MANY PARTS OF THE WORLD

# Hits on ODEP website 2015-March 2022

111,441



1.	United Kingdom	<b>46,547</b> (40.80%)
2.	United States	<b>13,081</b> (11.47%)
3.	Netherlands	<b>5,532</b> (4.85%)
4.	Italy	<b>3,980</b> (3.49%)
5.	Germany	<b>3,546</b> (3.11%)
6.	India	<b>3,043</b> (2.67%)
7.	France	<b>2,806</b> (2.46%)
8.	Switzerland	<b>2,775</b> (2.43%)
9.	Japan	<b>2,479</b> (2.17%)
10.	Spain	<b>2,422</b> (2.12%)

# WHO ARE WE?

**(THERE ARE ABOUT 50 OF US )**

- MAINLY SENIOR EXPERIENCED ORTHOPAEDIC SURGEONS
- MANY OF US HAVE BEEN INVOLVED IN THE DESIGN OF JOINT REPLACEMENTS
- EXPERTS IN PROCUREMENT
- RETIRED EMPLOYEES OF IMPLANT MANUFACTURERS
- STATISTICIANS
- DATA TECHNOLOGISTS / ANALYSTS
- PEOPLE WHO GIVE THEIR TIME WITHOUT FINANCIAL REWARD

# FUNDING

- EXPENSES PAID BY SCCL (Essentially NHS)
- MASSIVELY SUPPORTED BY NEC
- OUR SERVICES ARE FREE TO MANUFACTURERS
- NO CONFLICTS

# SO HOW DOES ODEP WORK?

# THE STRATEGY

- MANUFACTURERS SUBMIT DATA TO SUPPORT THE CONTINUING USE OF THEIR PRODUCT ON THE BESPOKE SUBMISSION FORM.....  
**THEY COLLECT THE DATA**
- ODEP AWARDS “BENCHMARKS” ON THE BASIS OF MANUFACTURERS SUBMISSION
- THE NUMBER REPRESENTS THE YEARS OF USE AND THE LETTER THE STRENGTH OF THE EVIDENCE
- IMPLANTS HAVE TO PROGRESS THROUGH THE BENCHMARKS OTHERWISE THEY LOSE THEIR BENCHMARK

# 15 year Hip rating

Criteria - Total Hip Replacement						
Criteria - A* Ratings	3A*	5A*	7A*	10A*	13A*	15A*
Minimum number of centres outside development centre(s)	3	3	3	3	3	3
Minimum number of surgeons outside of development centre(s)	3	3	3	3	3	3
Minimum total cohort	150	250	350	500	500	500
Minimum at risk at benchmark time	150	225	300	400	400	400
Maximum revision rate ‡	3.0%	3.5%	4.0%	5.0%	6.5%	8.0%
Criteria - A Ratings	3A	5A	7A	10A	13A	15A
Minimum number of centres and surgeons	3	3	3	3	3	3
Minimum total cohort	150	250	350	500	500	500
Minimum at risk at benchmark time	72	66	60	51	42	40
Maximum revision rate ‡	5.0%	5.5%	6.0%	7.0%	8.5%	10.0%
‡ 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	15B
Minimum number of centres and surgeons	1	1	1	1	1	1
Minimum total cohort	100	100	100	100	100	100
Minimum at risk at benchmark time	40	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%	8.0%
Pre-Entry *	Pre-Entry					
Product launched under Beyond Compliance	Product details supplied to ODEP					

# 15 year TKR rating

Criteria - Total Knee Replacement						
Criteria - A* Ratings	3A*	5A*	7A*	10A*	13A*	15A*
Minimum number of centres outside development centre(s)	3	3	3	3	3	3
Minimum number of surgeons outside of the development centre	3	3	3	3	3	3
Minimum total cohort	150	250	350	500	500	500
Minimum at risk at benchmark time	150	225	300	400	400	400
Maximum revision rate ‡	3.5%	4.0%	4.5%	5.0%	6.0%	6.5%
Criteria - A Ratings	3A	5A	7A	10A	13A	15A
Minimum number of centres and surgeons	3	3	3	3	3	3
Minimum total cohort	150	250	350	500	500	500
Minimum at risk at benchmark time	66	60	55	51	45	42
Maximum revision rate ‡	5.5%	6.0%	6.5%	7.0%	8.0%	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	13B
Minimum number of centres and surgeons	1	1	1	1	1	1
Minimum total cohort	100	100	100	100	100	100
Minimum at risk at benchmark time	40	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%	6.5%
Pre-Entry A*	Pre-Entry					
Product launched under Beyond Compliance	Product details supplied to ODEP					



# SHOULDERS

Criteria - A* Ratings	3A*	5A*	7A*	10A*
Minimum number of centres outside development centre(s)	3	3	3	3
Minimum total cohort	100	150	200	250
Minimum at risk at benchmark time	100	125	150	175
Maximum revision rate ‡	5.0%	7.0%	9.0%	12.0%
Mandatory linked PROMS score (any validated score on at least 50 patients)				
‡ The upper 95% confidence interval for KM revision rate (1 - Survival) must be lower than the specified level				
Criteria - A Ratings	3A	5A	7A	10A
Minimum number of centres and surgeons	3	3	3	3
Minimum total cohort	100	150	200	250
Minimum at risk at benchmark time	40	40	40	40
Maximum revision rate ‡	5.0%	7.0%	9.0%	12.0%
Voluntary linked PROMS score (any validated score)				
‡ 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
Minimum number of centres and surgeons	1	1	1	1
Minimum total cohort	50	50	50	50
Minimum at risk at benchmark time	10	10	10	10
Maximum value of 95% lower confidence limit for revision rate	5.0%	7.0%	9.0%	12.0%
Pre-Entry A*	Pre-Entry			
Product launched under Beyond Compliance	Products details provided to ODEP			

# SPINE

Criteria - A* Ratings	3A*	5A*	7A*	10A*
Minimum number of centres outside development centre(s)	3	3	3	3
Minimum total cohort	100	150	200	250
Minimum at risk at benchmark time	100	125	150	175
Maximum revision rate (to include interbody fusions, removal and replacement, fusion with replacement left in situ)	3.0%	5.0%	7.0%	10.0%
Percentage of patients who have undergone adjacent segment surgery	3.0%	5.0%	7.0%	10.0%
Linked PROMS score (any validated score on at least 50 patients) available				
The upper 95% confidence interval for KM revision rate (1 - Survival) must be lower than the specified level				
Criteria - A Ratings	3A	5A	7A	10A
Minimum number of centres and surgeons	3	3	3	3
Minimum total cohort	100	150	200	250
Minimum at risk at benchmark time	40	40	40	40
Maximum revision rate (to include interbody fusions, removal and replacement, fusion with replacement left in situ)	3.0%	5.0%	7.0%	10.0%
Percentage of patients who have undergone adjacent segment surgery	3.0%	5.0%	7.0%	10.0%
Voluntary linked PROMS score (any validated score on at least 50 patients) not available				
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
Minimum number of centres and surgeons	1	1	1	1
Minimum total cohort	50	50	50	50
Minimum at risk at benchmark time	10	10	10	10
Maximum value of 95% lower confidence limit for revision rate. (Revisions to include Removal, replacement and fusion)	3.0%	5.0%	7.0%	10.0%
Percentage of patients who have undergone adjacent segment surgery	3.0%	5.0%	7.0%	10.0%
Voluntary linked PROMS score (any validated score on at least 50 patients) Available / Not available				
Pre-Entry A*	Pre-Entry			
Product launched under Beyond Compliance	Products details provided to ODEP			

## DATA SOURCES

- REGISTRY DATA
- RCTs
- PEER REVIEWED PUBLICATIONS
- PODIUM PRESENTATIONS
- IN HOUSE DATA COHORTS FROM VARIOUS SOURCES CAN BE SUMMATED
  
- ODEP BENCHMARKS IMPLANTS FROM ALL AROUND THE WORLD EVEN IF THEY ARE NOT USED IN THE UK
- SOME MANUFACTURERS DO NOT HAVE A “LOCAL” REGISTRY

## REGISTRIES WHICH MANUFACTURERS HAVE SUCCESSFULLY USED IN 2022



- NJR
  - RIPO (Italy)
  - AUSTRALIAN
  - NEW ZEALAND
  - LROI (Netherlands)
  - NORWEGIAN AND FINLAND
  - SHAR & SKAR (Sweden)
  - SIRIS (Switzerland)
  - EPRD (Germany)
  - SAR (Slovakia)
  - AJRR (USA)
- 
- ODEP CAN ASK THE REGISTRY TO CONFIRM THAT THE DATA THEY SUPPLIED MATCHES WHAT ODEP HAS RECEIVED

# HOW DID WE ARRIVE AT THE BENCHMARKS?

## ORIGINALLY

- PROSCRIBED BY NICE
- WHAT WAS AVAILABLE IN 2002
- THE GRANNY TEST!

## MORE RECENTLY:

- REGISTRY DATA
- RACHETING UP
- OBSERVING THE REVISION RATES INCLUDED IN SUBMISSIONS TO ODEP

**ODEP KEEPS EVERYONE OF THEIR BENCHMARKS UNDER REVIEW**

# ODEP.. WHAT IS ON THE SUBMISSION FORM?

COPIES OF THE SUBMISSION FORMS WILL BE SENT TO YOU

<https://www.odep.org.uk/supporting-manufacturers/submit-a-product/>

ODEP IS UNIQUE.. IT IS A CLINICAL  
EVALUATION



BESIDES PATIENT DEMOGRAPHICS & DIAGNOSIS WE DEMAND  
REASONS FOR REVISION. **“WHY” IS IMPORTANT**

- INFECTION
- ASEPTIC LOSENING
- DISLOCATION
- IMPLANT FAILURE
- PERIPROSTHETIC #
- OTHER

# ODEP IS UNIQUE



- ODEP RATINGS ARE BASED ON BRANDS AND PRODUCT CODES
- MANUFACTURERS MUST DECLARE ALL PRODUCT CODES WITHIN A BRAND
- CAMOUFLAGE IS ALWAYS A WORRY



# CAMOUFLAGE, ALWAYS A WORRY



- BIG DATA CAN CAMOUFLAGE A VARIANT WHOSE PERFORMANCE DOES NOT MATCH THAT OF THE REST OF THE BRAND
- LIMITED DATA DOES NOT STAND UP TO STATISTICAL ANALYSIS
- BUNDLING CAN BE ACCEPTABLE

# CAMOUFLAGE.... EXAMPLES

- NEXGEN HIGH FLEX / GENDER SPECIFIC / OPTION TIBIA
  - STEMMED METAL ON METAL CAMOUFLAGED BY EXCELLENT BEARING COMBINATIONS
  - FEMALES DOING LESS WELL WITH SURFACE REPLACEMENT
  - NO PATELLA WITH JOURNEY 2 BCS OXINIUM TKRS
  - COBALT CHROME AND STAINLESS STEEL HIP STEMS AND PERI-PROSTHETIC #S
  - BASE PLATES IN TSR METAL v PEGGED
- 
- THERE ARE ALMOST CERTAINLY MANY MORE

ODEP IS UNIQUE.. IT IS A CLINICAL  
EVALUATION..... PROMS



- NOWADAYS MOST THRS AND TKRS ARE PERFORMING WELL
- WE WOULD LIKE TO CONFIRM THEY WERE ALL SATISFYING THE PATIENTS
- FAILURE OF SOME IMPLANTS DOES NOT LEAD TO REVISION BECAUSE REVISION WOULD NOT BENEFIT THE PATIENT.
- PROMS WILL HELP TO PICK THESE CASES OUT
- PROMS ARE REQUIRED IN THE MDR

# ODEP AND THE MDR



- ODEP SUBMISSIONS RELY ON CLINICAL DATA FOR THEIR COMPLETION
- THEREFORE THEY MUST SATISFY MOST OF THE REQUIREMENTS FOR THE CLINICAL INVESTIGATION FOR THE MDR FOR LEGACY DEVICES
- COPY AND PASTE IS THE GOAL

# ODEP HIP data... to date

- >1000 submissions
- 32 companies (WORLD WIDE)
- >400 devices

# ODEP 2003-22



- Removed from market – >100 products
- Unacceptable – >50 products
- **WE PROMOTE THE GOOD**

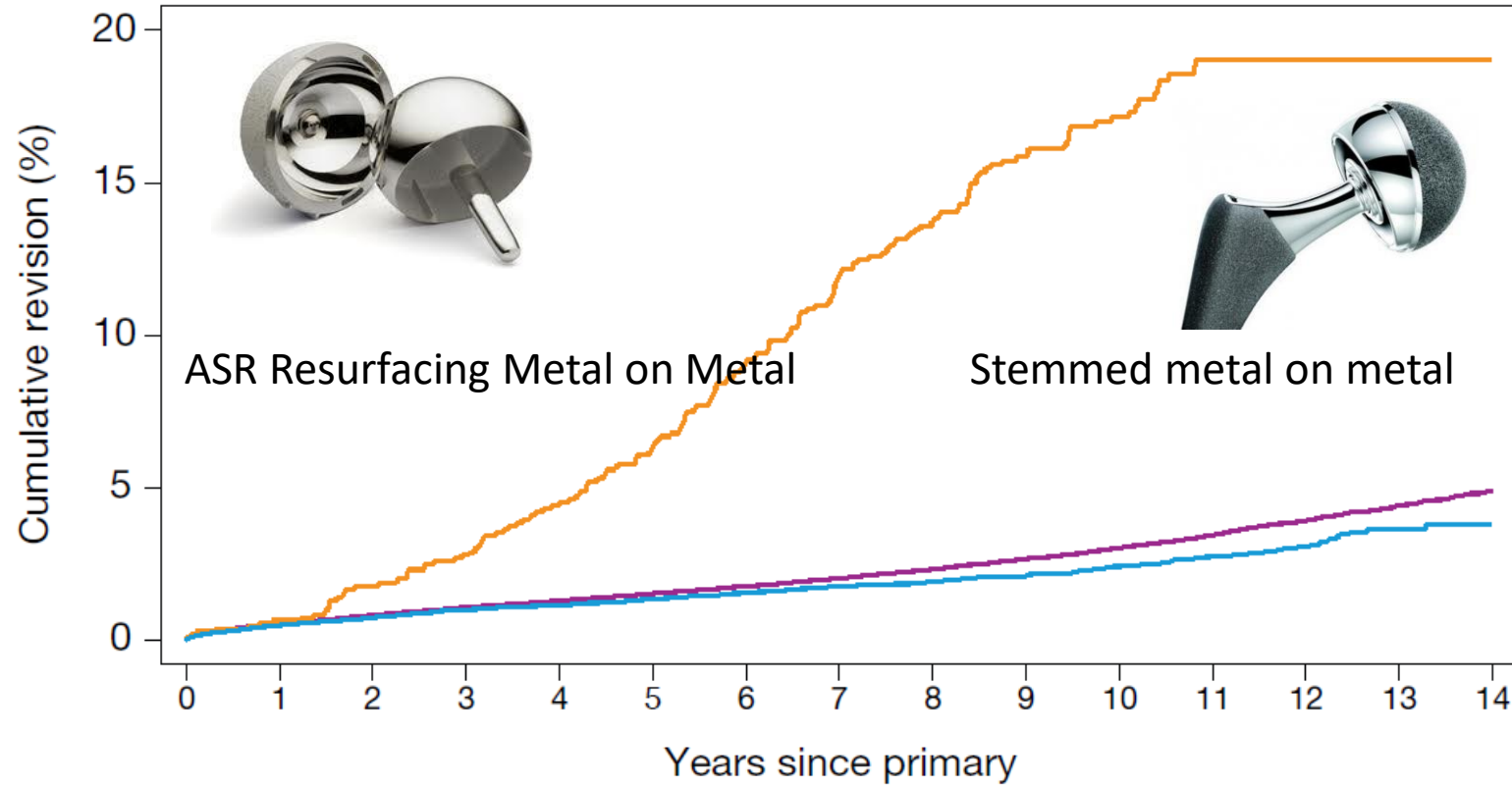
# FOR NEW PRODUCTS .....

# WHERE WE DID NOT DO WELL?

ORTHOPAEDIC DATA EVALUATION PANEL



# THE DISASTERS OF METAL ON METAL THRS



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

**WE WERE NOT PICKING UP NEW IMPLANTS  
THAT HAD A PROBLEM QUICKLY ENOUGH**

ORTHOPAEDIC DATA EVALUATION PANEL

# CE MARK is Compliance

A BADGE OF HOPEFUL EXPECTATION!

PROOF IS TIME DEPENDENT!

# THE CE MARK IS COMPLIANCE ?

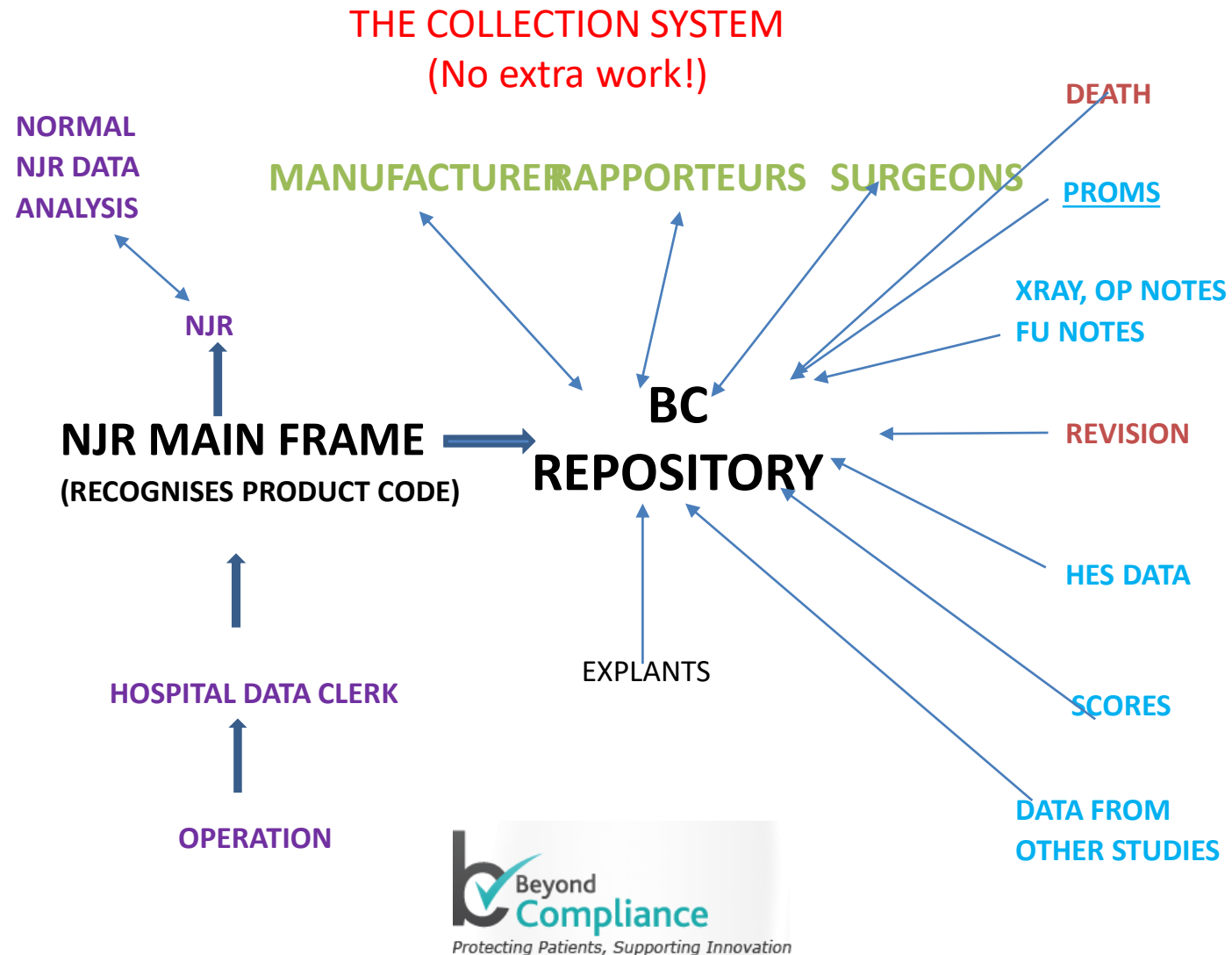


- SO, OUT OF FRUSTRATION, WE THOUGHT IT WAS ABOUT TIME WE WENT “BEYOND COMPLIANCE”
- IN VIGILANCE
- IN DILIGENCE
- IT IS VOLUNTARY BUT UPLOADING INTO NJR IS COMPULSORY
- IT IS INDEPENDENT
- THERE IS NO REASON WHY WE SHOULD NOT LINK WITH OTHER REGISTRIES

# BEYOND COMPLIANCE SERVICE EVALUATION

LINKED TO NJR AND ODEP





# HOW DOES BC WORK?



- RISK ASSESSMENT
  - DATA COLLECTION
  - REVIEWS
  - USER GROUP MEETINGS
- 
- WE ARE INDEPENDENT AND THE SURGEONS ARE UNPAID..... NO CONFLICTS

# REVIEWS

(ALL BC IMPLANTS ARE REVIEWED MONTHLY)



## 6 MONTHLY REVIEWS

CHAMPION SURGEON  
MANUFACTURER  
NEC (CONTRACTOR)  
BC RAPPORTEURS

FURTHER USE OF IMPLANT  
DISCUSSED

## USER GROUP MEETINGS

- CHAMPION SURGEON (S)
- MANUFACTURER
- NEC
- BC RAPPORTEURS
- PLUS ALL THOSE SURGEONS WHO ARE USING THE IMPLANT

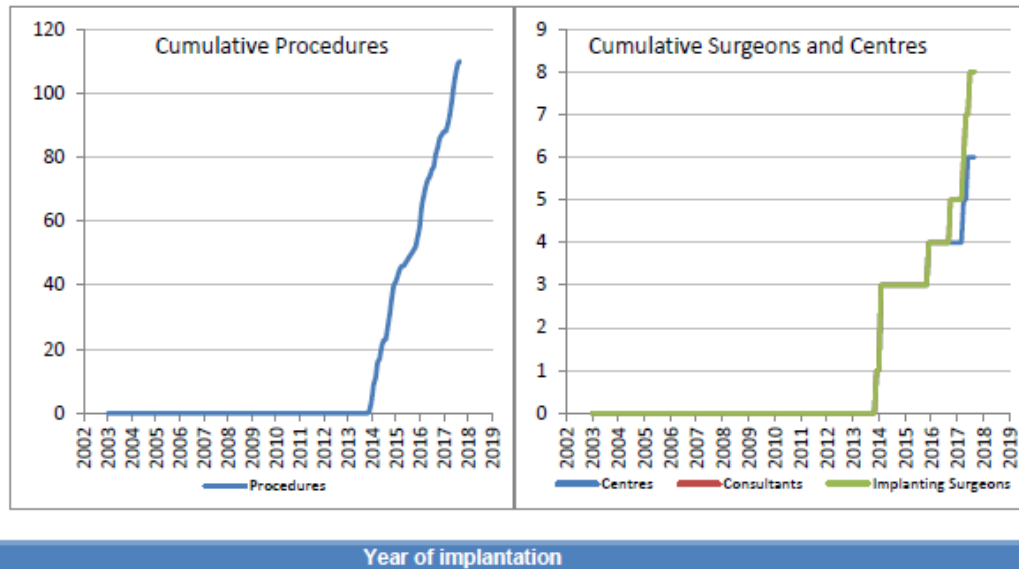
FULL DISCUSSION OF RESULTS,  
PROBLEMS ETC



# 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
<b>Demographics</b>		
Mean age	64.4	70.1
< 50	0.9%	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%
<b>ASA Grades</b>		
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%
<b>Indications</b>		
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)

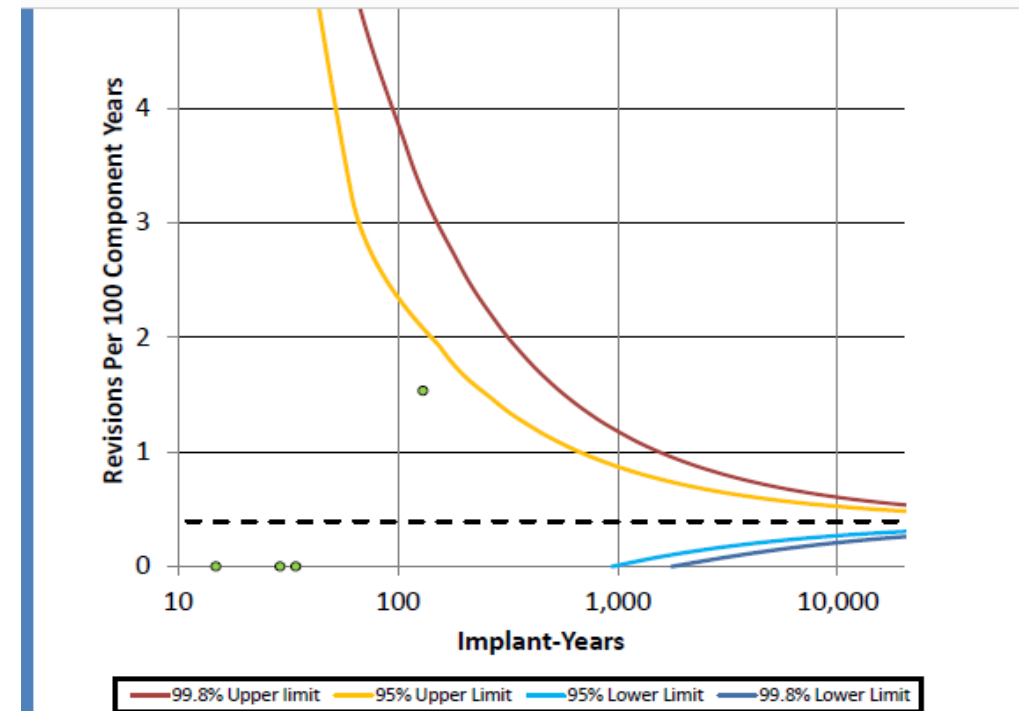
## REASONS FOR REVISION

Reason for Revision	Revised <sup>†</sup>	Expected Revisions <sup>*</sup>	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
<b>Total Revised</b>	<b>2</b>	<b>1.21</b>	<b>0.342</b>

<sup>†</sup> multiple reasons may be listed for one revision procedure

<sup>\*</sup> Adjusted for agegroup, gender and indications

## PERFORMANCE OF SURGEONS USING THE PROSTHESIS



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.

# A REPORT FOR A REVIEW (DUMMY)

## SURGERY

### Patient / Procedure Details

#### Intraoperative Adverse Events

Adverse Event	Number <sup>†</sup>	Event Rate *		p value
		Vanguard XP (Selected tibial trays only)	All other TKR in NJR	
None	110	100.00%	99.40%	1
Fracture	0	0.00%	0.16%	1
Patella Tendon Avulsion	0	0.00%	0.04%	1
Ligament Injury	0	0.00%	0.07%	1
Other	0	0.00%	0.34%	1

† multiple events may be listed for one procedure

\* As percentage of procedures for which adverse event data was recorded

	Significantly better, $p < 0.001$
	Significantly better, $p < 0.05$
	Significantly worse $p < 0.05$
	Significantly worse $p < 0.001$

## PROMS

### Patient Reported Outcomes

Comprising PROMs data up to and including: 30/12/2014

#### PROMs Analysis

Measure	Product Group	Pre-Op Records	Mean Pre-Op Score	6-month records	Mean 6 month Score	Health Gain	Improved	Unchanged / Worsened
Oxford Knee Score (0 - 48)	Vanguard XP (Selected tibial trays only)	29	22.5	25	37.5	15.0	84%	16%
	All TKR in NJR	228,547	18.4	189,026	34.7	16.3	93%	7%
EQ-5D Index (-0.59 - 1.00)	Vanguard XP (Selected tibial trays only)	24	0.49	25	0.81	0.32	85%	15%
	All TKR in NJR	217,346	0.39	182,024	0.72	0.33	80%	20%
EQ-VAS (0 - 100)	Vanguard XP (Selected tibial trays only)	24	72.7	25	78.9	6.2	75%	25%
	All TKR in NJR	206,115	67.1	181,789	72.9	5.8	54%	46%

PROMs scores are not case mix adjusted

## WHEN A PROBLEM IS DETECTED

- MANUFACTURERS WHO WANT TO BLAME THE SURGEONS
- STATISTICIANS WHO SAY THE NUMBERS ARE TOO SMALL
- IF THERE IS A SMELL... FOLLOW YOUR NOSE!

**CONTACT THE SURGEONS... FIND OUT WHAT IS HAPPENING  
BEFORE MORE PATIENTS ARE DAMAGED**

# OUR SUCCESSES AND FAILURES

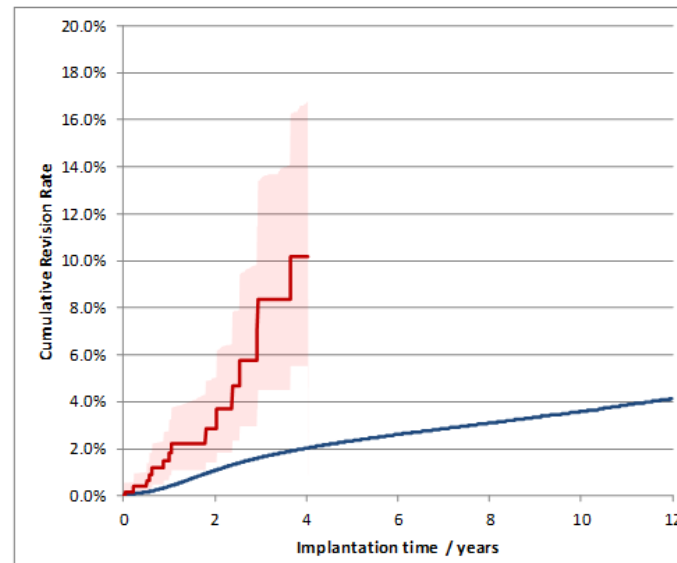
- IDENTIFYING ONE IMPLANT THAT HAD AN UN-ACCEPTABLE DESIGN
- IDENTIFYING AN OUTLIER HOSPITAL (INFECTION)
- IDENTIFYING A POTENTIAL PROBLEM WITH A TIBIAL BASEPLATE ( MANUFACTURER HAS SINCE REDESIGNED)
- IDENTIFYING A SURGEON WHO WAS CAUSING ONE IMPLANT TO APPARENTLY DOING BADLY
- IDENTIFYING A NEED FOR PATELLA RESURFACING

# RESURFACING THE PATELLA

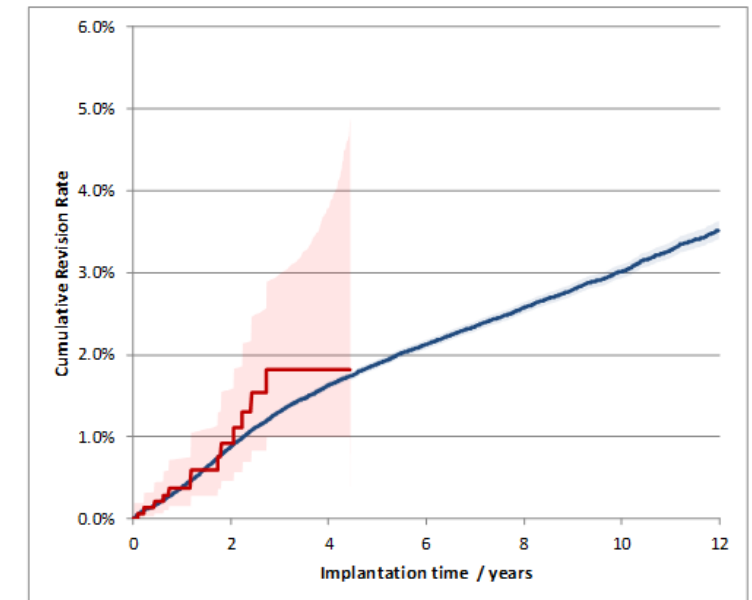
## NJR ANALYSIS

- NOT ALL PATELLAE NEED TO BE RESUFACED (NEXGEN)
- THE MAJORITY DO
- UK GUIDELINES ARE THAT THEY ALL SHOULD BE RESURFACED
- BASED ON REGISTRY DATA

Survivorship (Unresurfaced)



Survivorship (Resurfaced)



## NUMBER OF BC PRODUCTS TO DATE



- HIPS 44
- KNEES 35
- SHOULDERS 4
- TOTAL 81
- **22 MANUFACTURERS**

**ODEP**

Orthopaedic Data Evaluation Panel



British  
Orthopaedic  
Association



# THE NEW MDR



WHAT EFFECT WILL IT HAVE?  
WHERE DOES IT FIT WITH ODEP  
BEYOND COMPLIANCE  
AND THE MDR/UKCA?

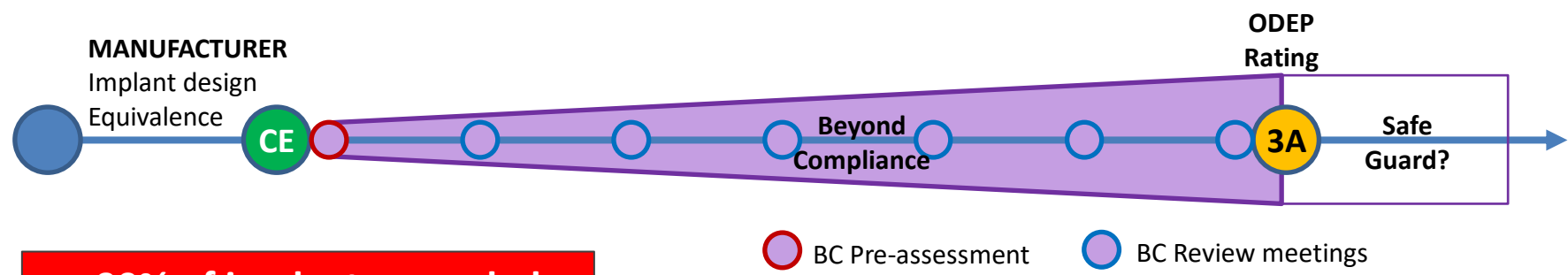
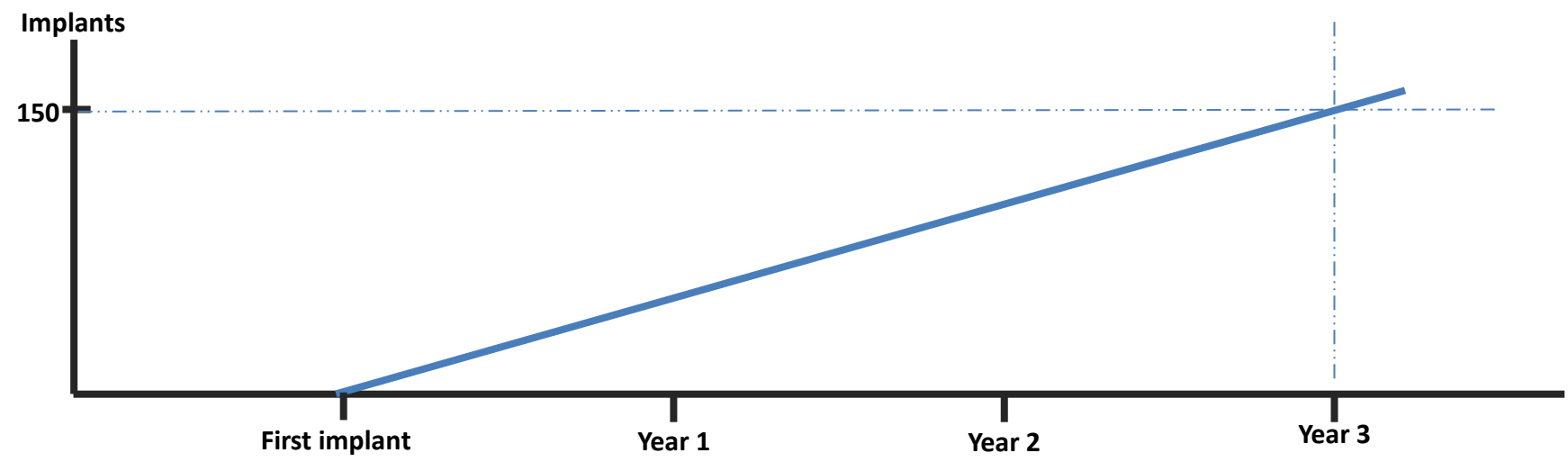


Association of British Healthcare Industries



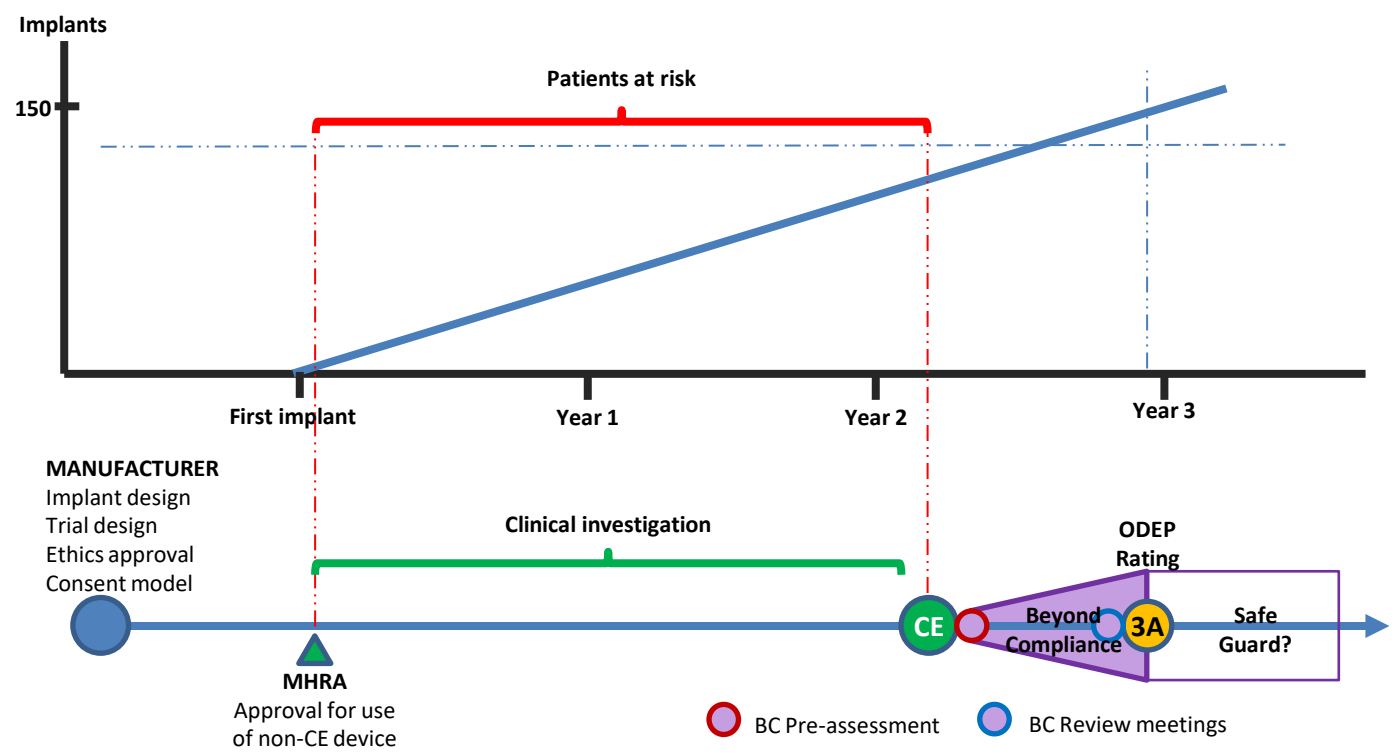


# Current BC Service

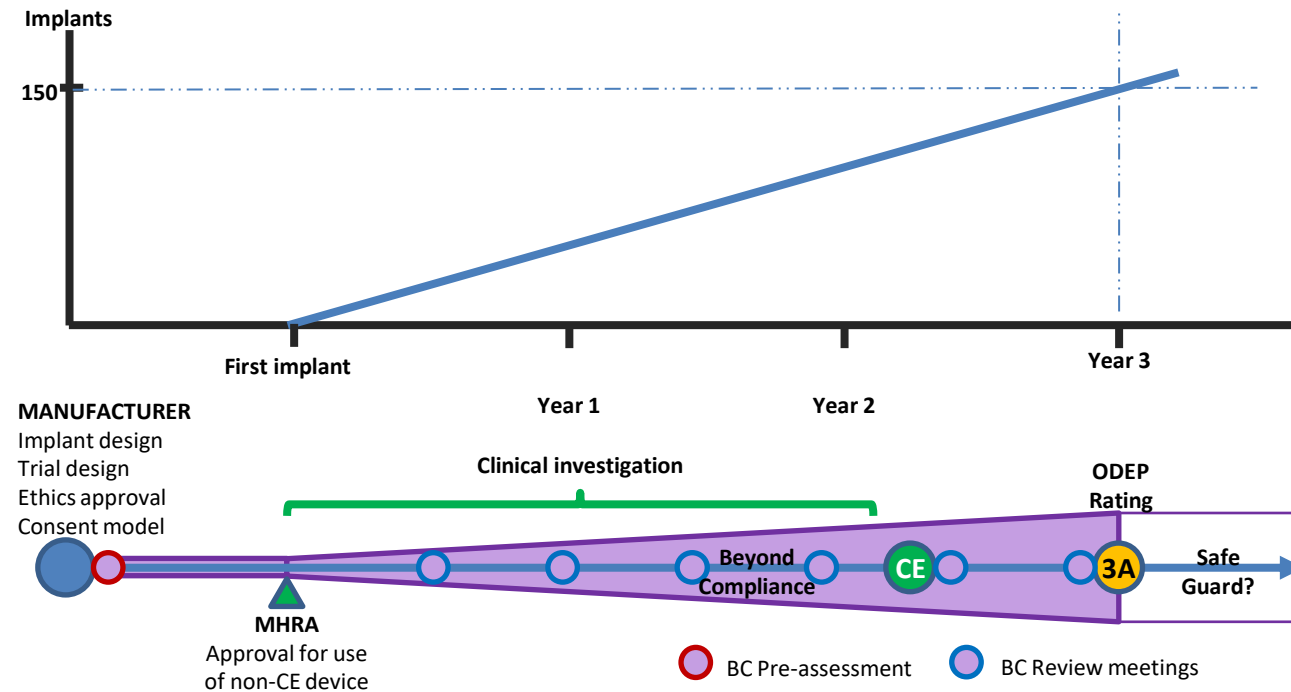


**+90% of implants awarded CE mark based on equivalence**

# Post-MDR Situation



# Proposed New Pre-CE BC Service, supported by MHRA, BSI and TUV



# MDR OUR AIMS

- WE WANT TO COLLECT ESSENTIALLY MUCH OF THE SAME DATA THAT MANUFACTURERS WILL BE COLLECTING FOR THE MDR BOTH FOR NEW AND LEGACY PRODUCTS
- MAYBE WE WILL WANT MORE DATA BUT WE EXPECT TO NEST THE MDR DATA REQUIREMENT IN ODEP AND BC
- OUR SLOGAN! .. “COPY AND PASTE”...FOR MANUFACTURERS WHENEVER POSSIBLE

# TAKE HOME MESSAGE

- ODEP HAS BEEN WORKING IN THIS FIELD FOR 21 YEARS
- BEYOND COMPLIANCE FOR 10 YEARS
- WE HAVE EVOLVED AND ARE ALWAYS LOOKING TO IMPROVE OUR SERVICE
- WE WORK WITH MANUFACTURERS AND THE REGULATORS
- WE WANT TO WORK CLOSELY WITH THE DEVELOPMENT OF THE MDR AND UKCA

## ADVERTISEMENT

# THE FIRST INTERNATIONAL MEETING OF SPINE REGISTRIES

- ROYAL NATIONAL ORTHOPAEDIC HOSPITAL STANMORE LONDON UK
- MARCH 23<sup>RD</sup> 2023
- FREE!
- SUPPORTED BY NEC
- ORGANISED BY ODEP
- ALL WELCOME

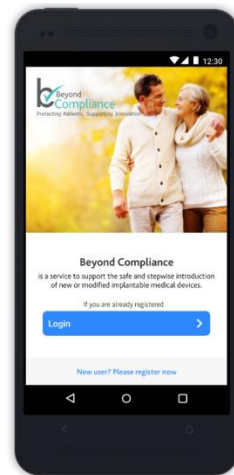
# THANK YOU FOR YOUR ATTENTION

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

[www.odep.org.uk](http://www.odep.org.uk)

# THE BC App

- Free
- Consent at the touch of a button
- Details of patient, operation and surgeon
- PROMS
- Available as and when



 Made in Intel





