

Measuring quality: ODEP and Beyond Compliance

Misurare la qualità: ODEP e Beyond Compliance



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.

WHAT SHOULD WE MEAN BY QUALITY OF AN IMPLANT?

- SAFE FOR PATIENTS
- LOW FAILURE RATE
- REPRODUCIBLE RESULTS IN A LARGE NUMBER OF PATIENTS
- EASE OF USE

WHO SHOULD BE RESPONSIBLE FOR THE QUALITY OF IMPLANTS?

- THE MANUFACTURER?
- THE NOTIFIED BODIES AND THE COMPETENT
AUTHORITIES (CE MARK) ?
- SURGEONS?
- MONITORING AGENCIES?
- WE ARE ALL RESPONSIBLE!

MONITORING WHAT DO WE HAVE IN THE UK TO HELP ENSURE QUALITY?

- NJR (National Joint Registry of England, Wales, Northern Ireland and the Channel Isles)
- ODEP (Orthopaedic Data Evaluation Panel)
- BEYOND COMPLIANCE

ODEP 2003-20

- SET UP AFTER 3 M CAPITAL HIP BY NICE
- A “MINOR CHANGE”, A BIG EFFECT
- THE NETHERLANDS JOINED WITH THE UK FOR ODEP 2015

- ODEP BENCHMARKS **IMPLANTS**, NOT OPERATIONS

ODEP HISTORY

2003 HIPS

- 2014 KNEES
- 2017 SHOULDERS
- 2017 UNI-CONDYLAR KNEES
- 2020 ELBOWS
- 2022 SPINES
- 2023 WRISTS (HANDS TO FOLLOW)

ODEP WILL CONTINUE TO EVOLVE

- 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

- IT IS NOT A COMPETITION
- IT IS VOLUNTARY

THE STRATEGY

- MANUFACTURERS TO SUBMIT DATA TO SUPPORT THE CONTINUING USE OF THEIR PRODUCT
- ODEP TO AWARD “BENCHMARKS” ON THE BASIS OF MANUFACTURERS SUBMISSION
- THE NUMBER REPRESENTS THE YEARS OF USE AND THE LETTER THE STRENGTH OF THE EVIDENCE
- THEY CANNOT STOP MOVING THROUGH THE EARLY BENCHMARKS

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					

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			

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/>

DATA SOURCES

- REGISTRY DATA
- RCTs
- PEER REVIEWED PUBLICATIONS
- PODIUM PRESENTATIONS
- IN HOUSE DATA COHORTS FROM VARIOUS SOURCES CAN BE SUMMATED

REGISTRIES WHICH MANUFACTURERS HAVE SUCCESSFULLY USED IN 2022



- NJR
- RIPO (Italy)
- AUSTRALIAN
- NEW ZEALAND
- LROI (Netherlands)
- NORWEGIAN AND FINILAND
- SHAR & SKAR (Sweden)
- SIRIS (Switzerland)
- EPRD (Germany)
- SAR (Slovakia)

- AJRR (USA)
- RIAP
- BSR AND EUROSPINE FOR SPINES

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

Hits on ODEP website 2015-March 2022

111,441



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

BEYOND COMPLIANCE SERVICE EVALUATION

LINKED TO NJR AND ODEP
Since 2012



HOW DOES BC WORK?

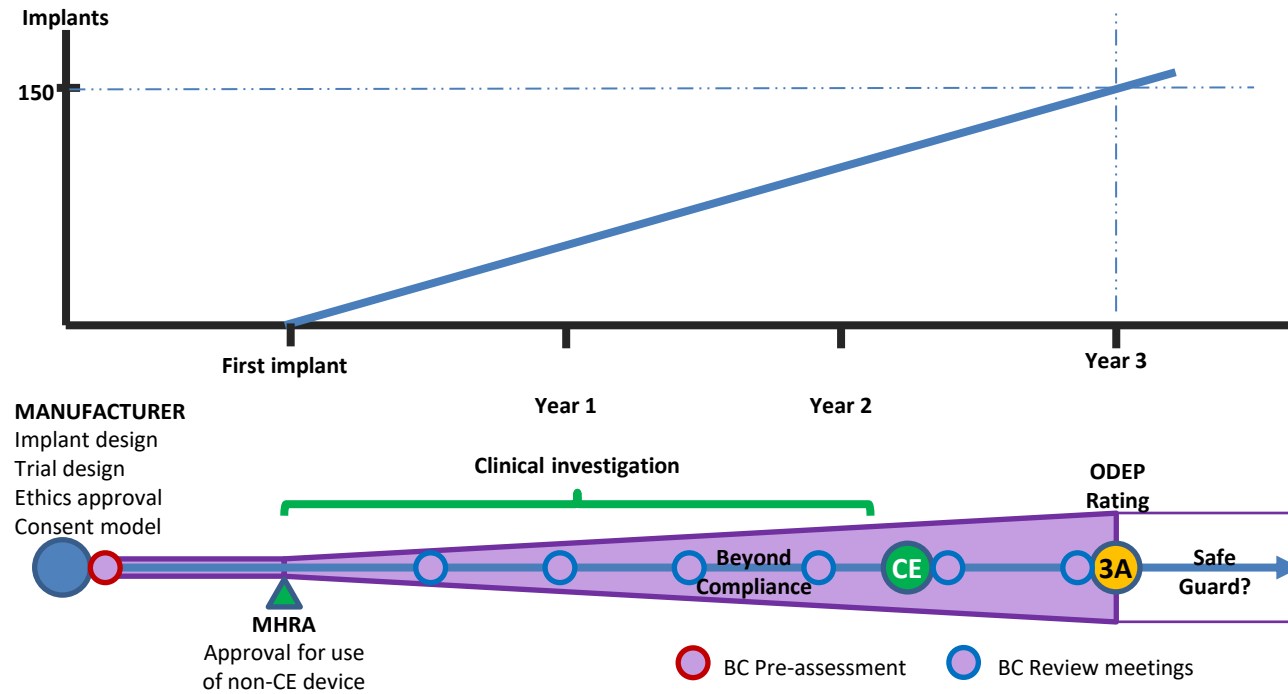


- RISK ASSESSMENT
 - DATA COLLECTION
 - REVIEWS
 - USER GROUP MEETINGS
-
- WE ARE INDEPENDENT AND THE SURGEONS ARE UNPAID..... NO CONFLICTS

NEW MDR

- MUCH LESS RELIANCE ON EQUIVALENTS
- PRE CE CLINICAL INVESTIGATION STUDIES FOR NOVEL DEVICES
- INTRODUCTION OF BRUSSELS PANEL
- MONITORING OF LEGACY DEVICES
- PROMS
- ODEP AND BC..... COPY AND PASTE!

Proposed New Pre-CE BC Service



DATE FOR YOUR DIARY

- ODEP SPINE AND NEC WILL BE HOSTING THE FIRST INTERNATIONAL MEETING OF SPINE REGISTRIES IN MARCH 2023
- YOU ARE ALL WELCOME
- DETAILS AVAILABLE SHORTLY

THANK YOU FOR YOUR ATTENTION

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

www.odep.org.uk

www.beyondcompliance.org.uk