Royal National Orthopaedic Hospital NHS
NHS Trust

Device Evaluation Centre

THE IMPACT OF THE PROPOSED CHANGES IN THE MEDICAL DEVICE DIRECTIVES ON INDUSTRY

ODEP
Orthopaedic Data Evaluation Panel

HOW THE ORTHOPAEDIC DEVICE EVALUATION PANEL (ODEP) HAS CHANGED THE WAY SURGEONS AND THE NHS USE HIP AND KNEE

Keith Tucker

Phil Lewis

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- HOW IT WORKS
- WHAT WE HOPE TO HAVE ACHIEVED
- WHERE WE GO NEXT

THE TEAMS

HIPS

- EVERT SMITH
- IAN STOCKLEY
- (PETER KAY)

- KEITH TUCKER
- MARTIN PICKFORD
- PHIL LEWIS
- ANDY SMALLWOOD
- OLGA TAYLOR

- A.N.OTHER WANTED!

KNEES

- TIM WILTON
- RICHARD PARKINSON
- COLIN ESLER

- KEITH TUCKER
- MARTIN PICKFORD
- PHIL LEWIS
- ANDY SMALLWOOD
- OLGA TAYLOR

- A.N.OTHER WANTED!

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NICE

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- WITH NJR, STARTED IN 2003 WITH HIPS FOLLOWING THE 3M CAPITAL HIP DISASTER
- REGULARLY REVIEWED AND UP GRADED
- BECOMING MORE SOPHISTICATED
- NOW ASSESSING KNEES
- SHOULDERS UNDER CONSIDERATION

USE OF ODEP BENCHMARKS (HIPS)

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THE STRATEGY

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- MANUFACTURERS TO SUBMIT DATA TO SUPPORT THE CONTINUING USE OF THEIR PRODUCT
- ODEP TO AWARD “BENCHMARKS” ON THE BASIS OF MANUFACTURERS SUBMISSION
- BENCHMARKS PRESENTLY AVAILABLE ARE AT 3,5,7 AND 10 YEARS
- THE NUMBER REPRESENTS THE YEARS OF USE AND THE LETTER THE STRENGTH OF THE EVIDENCE

THE STRATEGY

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- IMPLANTS HAVE TO PROGRESS FROM ONE BENCHMARK TO THE NEXT UNTIL THEY REACH 10A OR 10A*

- MANUFACTURERS ARE GIVEN ONE YEAR OF GRACE TO COLLECT DATA BEFORE THEY HAVE TO SUBMIT FOR THEIR NEXT BENCHMARK

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VERY IMPORTANT MESSAGE!

- ODEP DOES NOT TELL YOU WHETHER ONE IMPLANT IS BETTER THAN ANOTHER
- IT TELLS YOU SOMETHING ABOUT HOW LONG THE PRODUCT HAS BEEN IN USE (A NUMBER)
- IT TELLS YOU ABOUT THE STRENGTH OF EVIDENCE THAT IS AVAILABLE TO SUPPORT ITS USE (A LETTER)
- IT COULD BE THAT A 3A WILL TURN OUT TO BE BETTER THAN ANOTHER IMPLANT WITH 10A IN THE COURSE OF TIME

ODEP …….HIPS

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- SET UP BY NICE IN 2003 TO IMPLEMENT NICE GUIDANCE
- NOW HOSTED AND FACILITATED BY NHS SUPPLY CHAIN
- PROVIDES REVISION RATES FOR THR AT DEFINED PERIODS (BENCHMARKS)
- PROGRESS THROUGH BENCHMARKS ESSENTIAL TO MAINTAIN STATUS
- STEMS AND CUPS ASSESSED SEPARATELY

VERY IMPORTANT MESSAGE!

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- ALL THE PRODUCTS WE REVIEW HAVE CE MARKS
- NOWADAYS HIPS AND KNEES ARE GRADED AS LEVEL 3 (USED TO BE LEVEL 2b)
- IT IS ILLEGAL TO STAND IN THE WAY OF A COMPANY WISHING TO MARKET A CE MARKED PRODUCT
- IT IS ILLEGAL FOR ANY GROUP TO INSIST THAT PURCHASERS ETC SHOULD NOT USE …….ETC

ODEP… THE PROCESS

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- MANUFACTURER SUBMITS DATA ON LINE
- PANEL MEETS TWICE A YEAR FOR EACH JOINT
- OUTPUT PRODUCED WITHIN 2 WEEKS OF MEETING
- APPEALS HEARD TWICE A YEAR
- COMPANIES INFORMED IF THEY ARE BEHIND WITH PROGRESS THROUGH BENCHMARKS

ODEP Rating guidance (HIPS and KNEES)

Pre-entry	3 years	5 years	7 years	10 years
Pre-entry A*	3A* rating	5A* rating	7A* rating	10A* rating
Product launched under Beyond Compliance	150 Joints (with data from beyond the developing centre submitted) with a minimum of three years follow up with actual revision rates of less than 3%. All deaths, loss to follow up, failures and indications for revisions recorded.	250 Joints (with data from beyond the developing centre submitted) with a minimum of five years follow up with actual revision rates of less than 5%. All deaths, loss to follow up, failures and indications for revisions recorded.	350 Joints (with data from beyond the developing centre submitted) with a minimum of seven years follow up with actual revision rates of less than 5%. All deaths, loss to follow up, failures and indications for revisions recorded.	500 Joints (including three centres in cohort & including data from beyond the developing centres) with a minimum of ten years follow up with a with actual revision rates of less than 5 % at 10 years i.e. demonstrating survivorship of better than 95%. All deaths, loss to follow up failures and indications for revision included in data
Pre-entry	3A rating	5A rating	7A rating	10A rating
Products registered with NJR. All primaries and revisions monitored via supplier feedback.	150 Joints (with data from beyond the developing centre submitted) with minimum three years follow up demonstrating less than 3% revision rates at three years, with Kaplan - Meier survivorship data showing confidence limits on the data.	250 Joints (with data from beyond the developing centre submitted) with minimum five years follow up demonstrating less than 5% revision rates at five years, with Kaplan - Meier survivorship data showing confidence limits on the data.	350 Joints (with data from beyond the developing centre submitted) with minimum seven years follow up demonstrating less than 7% revision rates at seven years, with Kaplan - Meier survivorship data showing confidence limits on the data.	500 Joints (with data from beyond the developing centre submitted) with minimum ten years follow up demonstrating less than 10% revision rates at ten years, with Kaplan - Meier survivorship data showing confidence limits on the data.
	3B rating	5B rating	7B rating	10B rating
	minmum 100	mimimum 100	minimum 100	minimum 100
	Data for a smaller cohort demonstrating less than 3% revision rates at three years, and PTIR or Kaplan-Meier survivorship data showing confidence limits on the data	Data for a smaller cohort demonstrating less than 5% revision rates at five years, and PTIR or Kaplan-Meier survivorship data showing confidence limits on the data	Data for a smaller cohort demonstrating 7% at seven years, and PTIR or Kaplan-Meier survivorship data showing confidence limits on the data	Data for a smaller cohort demonstrating 10% at ten years, and PTIR or Kaplan-Meier survivorship data showing confidence limits on the data

ODEP.. WHAT IS ON THE SUBMISSION FORM

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- DETAILS OF DEVICE…. HIP ACETABULUM OR STEM
- KNEE TYPE OF TKR
- CEMENTED / UNCEMENTED
- BENCHMARK APPLIED FOR

- IS THE CLINICAL DATA SUBMITTED REPRESENTATIVE OF ALL STUDIES CONDUCTED IN RELATION TO IT?
- REASONS FOR OMISSION OF ANY DATA

ODEP.. WHAT IS ON THE SUBMISSION FORM

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- CLINICAL STUDY DETAILS
- CLINICAL STUDY DESIGN
- PATIENTS AND CLINICAL RESULTS FULL COHORT
- REVISIONS FULL COHORT
- KM
- PTIR
- CLINICAL RESULTS OF FULL COHORT PAST THE BENCHMARK

HEIRARCHY OF DATA

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- REGISTRY DATA
- RCTS
- PEER REVIEWED PUBLICATIONS OR PRESENTATIONS
- VALIDATED IN HOUSE DATA

REGISTRY DATA

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- ONLY DATA FROM REGISTIES WHERE THERE IS A HIGH LEVEL OF COMPLIANCE ETC
- BEST DATA IS FROM REGISTRIES WITH COMPONENT DATA BASES
- NJR SUPPLIER FEEDBACK NOW BEING USED EXTENSIVELY IN ODEP SUBMISSIONS
- MORE REGISTRIES WITH SUPPLIER FEEDBACK WOULD BE GOOD

ODEP.. WHAT IS ON THE SUBMISSION FORM

PATIENTS AND CLINICAL RESULTS

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- NUMBER OF PATIENTS AT THE BEGINNING OF THE STUDY
- MALES / FEMALES
- MEAN AGE AND RANGE (COHORTS WITH MIN AGE > 80 QUESTIONABLE!)
- DIAGNOSIS (OA, RA, OTHER)
- NUMBER OF IMPLANTS AT START OF STUDY
- NUMBER OF PATIENTS WHO DIED (? MAX 25%)
- NUMBER OF PATIENTS LOST TO FOLLOW UP (MAX 25%)
- NUMBER OF IMPLANTS REVISED FOR ANY REASON (%)
- NUMBER OF IMPLANTS SRVIVING AT END OF THE STUDY (%)
- NUMBER OF PATIENTS EXAMINED IN PERSON
- NUMBER OF PATIENTS EXAMINED BY QUESTIONNAIRE / TELEPHONE
- MEAN FOLLOW UP AND RANGE (YEARS) OF IMPLANTS IN FULL COHORT

REVISIONS….. CAUSE

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- INFECTION
- DISLOCATION (HIPS)
- MALPOSITION, MALALIGNMENT
- ASEPTIC LOOSENING
- WEAR
- OTHER

Kaplan Meier survivorship (HIPS)

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- FOLLOW UP PERIOD (YEARS)

- NUMBER OF JOINTS AT FOLLOW UP PERIOD

- SURVIVAL RATE, ALL FAILURE MODES - STEM AND CUP %
- SURVIVAL RATE ALL FAILURE MODES - STEM %
- SURVIVAL RATE ALL FAILURE MODES – CUP %
- REVISION RAT FOR ASEPTIC LOOSENING – STEM %
- REVISION RATE FOR ASEPTIC LOOSENING – CUP %

CLINICAL RESULTS FOR COHORT PAST BENCHMARK FOR * RATING

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- MEAN FOLLOW AND RANGE (YEARS) OF IMPLANTS IN SELECTED COHORT
- MEAN AGE AND RANGE (YEARS)

- NUMBER OF IMPLANTS IN SELECTED COHORT
- NUMBER OF IMPLANTS LOST TO FOLLOW UP
- NUMBER IN COHORT REVISED FOR ANY REASON
- NUMBER OF IMPLANTS THAT HAVE SURVIVED BENCHMARK APPLIED FOR
- NUMBER OF DEATHS IN SELECTED COHORT
- (REASONS FOR REVISION)

HIPS
SUBMISSIONS TO DATE

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- >700 SUBMISSIONS (86 IN 2014)
- >28 COMPANIES
- >320 DEVICES
- >165CUPS
- >155STEMS

KNEES
SUBMISSIONS TO DATE

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- SUBMISSIONS 46
- COMPANIES 16
- DEVICES 46

KNEES

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- KNEES TO BE LOOKED AT AS ONE UNIT

- ATTRIBUTES PLACED IN ***BASK***ETS
- ODEP RATINGS WILL VARY WITHIN ONE *BASK*ET

- WILL BE MUCH EASIER FOR MANUFACTURERS WHEN THERE IS GREATER GRANULARITY IN COMPONENT DATABASES

KNEES

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- Made up of one choice of row associated with one choice in of each column
- Every column followed by a specific Range of implant codes applicable
- A unique set of attributes will apply to each ODEP application and those are the codes for which an ODEP rating is awarded

Basket Guidance

Pease provide a breakdown of the knee system being submitted for benchmark following the format below.

Please highlight the description for each component of your knee variant in the table below

				Femoral Component			Tibial Component					Articular Insert			Patella (optional for TKR required for patello Femoral)							
Supplier	Brand Name - Overall Family	Brand Name - subset description	Group classification	Femoral component material	Fixation type femoral	Product Code Range	Tibial Implant type	Tibial component material	Tibial component surface finish	Fixation type tibial	Bearing mobility	Product code range	Articular insert material	Dishing variation	Product Code Range	Shape	Mobility	Pegs	Fixation	Material	Modularity	Thickness	Product code range
Lewis ortho	best knee	best knee gold	TKR CR	CoCr	Cemented - Non-porous	Fem1 to Fem 20	Metal backed	CoCr	Polished	Cemented - Non-porous	Fixed	TIB1 to TIB20	Poly - Highly-crosslinked	Standard	BEAR1 to BEAR100	Domed	fixed	single	cemented	cross linked	Monobloc	7mm	PAT1
			TKR Cruciate retaining	CoCr	Cemented - Non-porous		All Poly	Poly - Std	N/A	Cemented - Non-porous	Fixed		Poly - Std	Standard		Domed	Fixed	single	cemented	UHMWPE	Monobloc	<6mm	
			TKR Posterior stabilised	Oxidised zirconium (ceramicised metal)	Uncemented - Porous		Metal backed	Poly - Highly-crosslinked	Matt	Uncemented - Porous	Mobile		Poly - Highly-crosslinked	Dished / Conforming +		Saddle	Mobile	multiple	uncemented	moderatly cross linked	Modular	6mm	
			TKR Cruciate Sacrificing	Titanium-nitride surface coating	Uncemented - HA			CoCr	Polished	Uncemented - HA						anatomical				cross linked		7mm	
					Uncemented - HA + porous			Titanium		Uncemented - HA + porous										cross linked with antioxidant		8mm	
																				Ceramic		9mm	
			Unicondylar	CoCr	Cemented - Non-porous		All Poly	Poly - Std	N/A	Cemented - Non-porous	Fixed		Poly - Std	Std						metal backed		10mm	
				Oxidised zirconium (ceramicised metal)	Uncemented - Porous		Metal backed	Poly - Highly-crosslinked	Matt	Uncemented - Porous	Mobile		Poly - Highly-crosslinked							metal backed porous		>10mm	
				Titanium-nitride surface coating	Uncemented - HA			CoCr	Polished	Uncemented - HA													
					Uncemented - HA + porous			Titanium		Uncemented - HA + porous													
			Patello femoral	CoCr	Cemented - Non-porous		N/A	N/A		N/A	N/A		N/A	N/A									
				Oxidised zirconium (ceramicised metal)	Uncemented - Porous																		
				Titanium-nitride surface coating	Uncemented - HA																		
					Uncemented - HA + porous																		
			Bi-compartmental																				
			Other																				

This section starts from the left with other criteria being selected as appropriate

Area in yellow is an example

Basket 'spreadsheet'

Type	Bearing Mobility	code	Dishing Variant	Tibia Type	Tibia Material	code	Tibia surface finish	Tibia Fixation	Insert Material	code
TKR CR	Fixed or mobile		Standard dished	All Poly or MB	TiAlV or CoCr		Polished or matt	Cement porous plus HA	Poly or cross linked	
TKR PS	Fixed or mobile		Standard PS	All Poly or MB	TiAlV or CoCr		Polished or matt	Cement porous plus HA	Poly or cross linked	
UNI	Fixed or mobile		Standard	All Poly or MB	TiAlV or CoCr		Polished or matt	Cement porous plus HA	Poly or cross linked	
PFJ	Fixed or mobile		N/A	N/A	N/A		N/A	N/A	N/A	
Bi Condylar	fixed		standard	All Poly or MB	TiAlV or CoCr		Polished or matt	Cement porous plus HA	Poly or cross linked	

Basket Spreadsheet

Type	Femoral material	Femoral Fixation	Implant code	Patellar Material	Patellar Fixation	Implant Code	
TKR CR	CoCR Coating?	Cement Porous plus HA		Poly or MB	Cement porous plus HA		
TKR PS	CoCr Oxinium	Cement Porous plus HA		Poly or MB	Cement Porous plus HA		
UNI	CoCr Oxinium	Cement Porous lus HA		Poly or MB	Cement porous plus HA		
PFJ	CoCr Coating?	Cement Porous plus HA		Poly or MB	Cement porous plus HA		
Bi Condylar	CoCr Oxinium	Cement Porous plus HA		Poly or MB	Cement porous plus HA		

SHOULDERS

?2015

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SHOULDERS ARE DIFFERENT

- REVISION IS NOT OFTEN PERFORMED EVEN WHEN THE FUNCTION IS POOR
- PROMS IMORTANT TO MEASURE SUCCESS

- WE NEED SOME GOOD IDEAS!

WHAT EFFECT HAVE WE HAD?

2003-15

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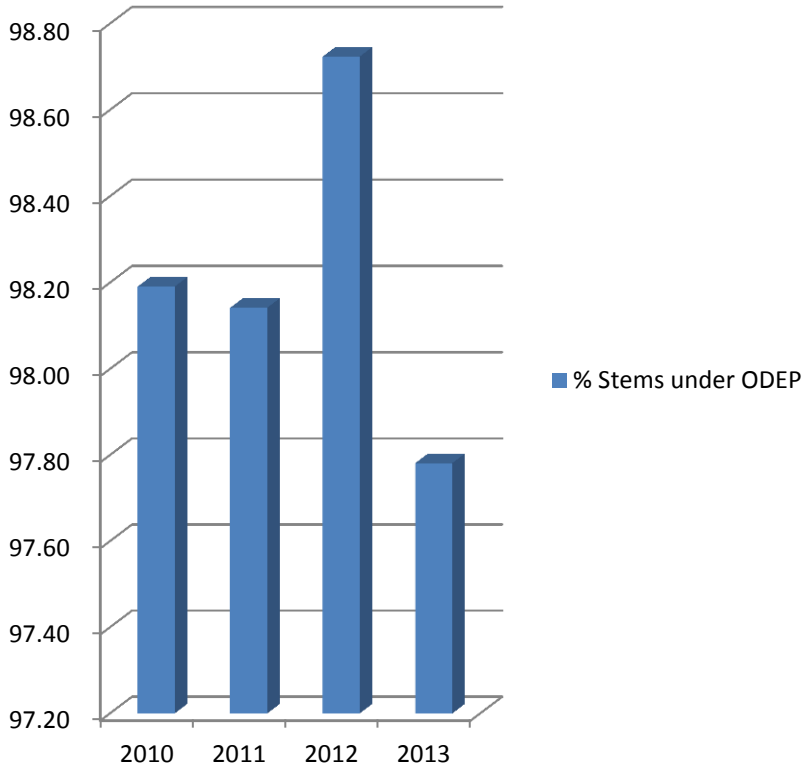
2006-14

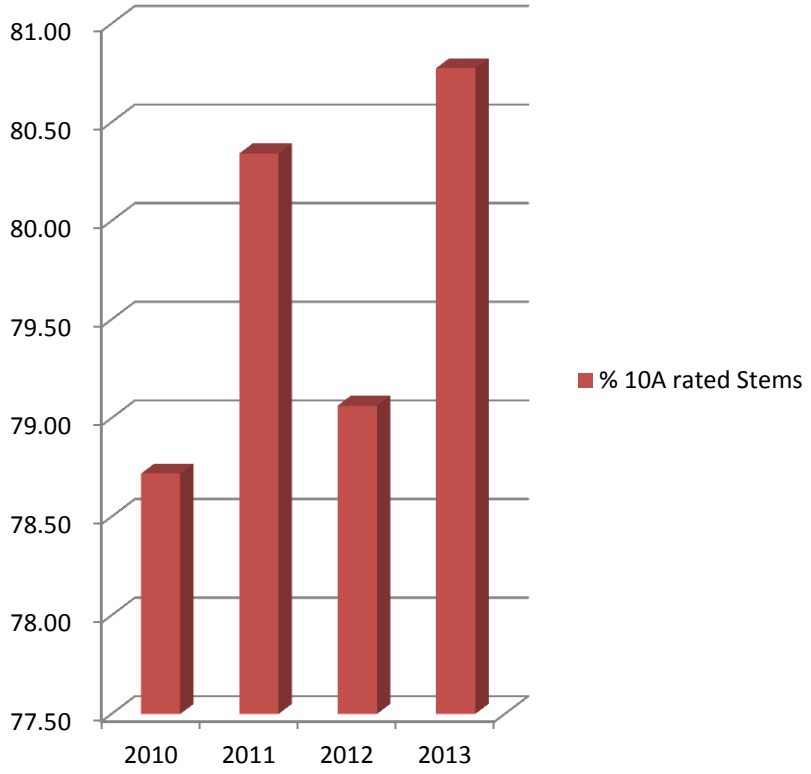
Summary of the ODEP evaluations as at December 2006	
Submissions received from 19 companies	
Total number of products submitted	172
Number of cups	80
Number of stems	92
Total number of products at 10 years	48
Number of products at 10A	24
Number of products at 10B	10
Number of products at 10C	14
Total number of products at 7 years	19
Number of products at 7A	8
Number of products at 7B	11
Total number of products at 5 years	23
Number of products at 5A	12
Number of products at 5B	11
Total number of products at 3 years	35
Number of products at 3A	30
Number of products at 3B	5
Total number of Pre-entry products	45
Total number of unacceptable products	2
Total number of separate datasets submitted	437

Summary of the ODEP evaluations as at December 2014	
Submissions received from 29 companies	
Total number of products submitted	287
Number of cups	132
Number of stems	155
Total number of products at 10 years	69
Number of products at 10A*	15
Number of products at 10A	42
Number of products at 10B	5
Number of products at 10C	7
Total number of products at 7 years	36
Number of products at 7A*	5
Number of products at 7A	25
Number of products at 7B	6
Total number of products at 5 years	31
Number of products at 5A*	3
Number of products at 5A	22
Number of products at 5B	6
Total number of products at 3 years	36
Number of products at 3A*	8
Number of products at 3A	27
Number of products at 3B	1
Total number of Pre-entry products	51
Pre-entry A*	3
Pre-entry	48
Total number of unacceptable products	22
Flagged as removed from market	40
Non-applicable products	2

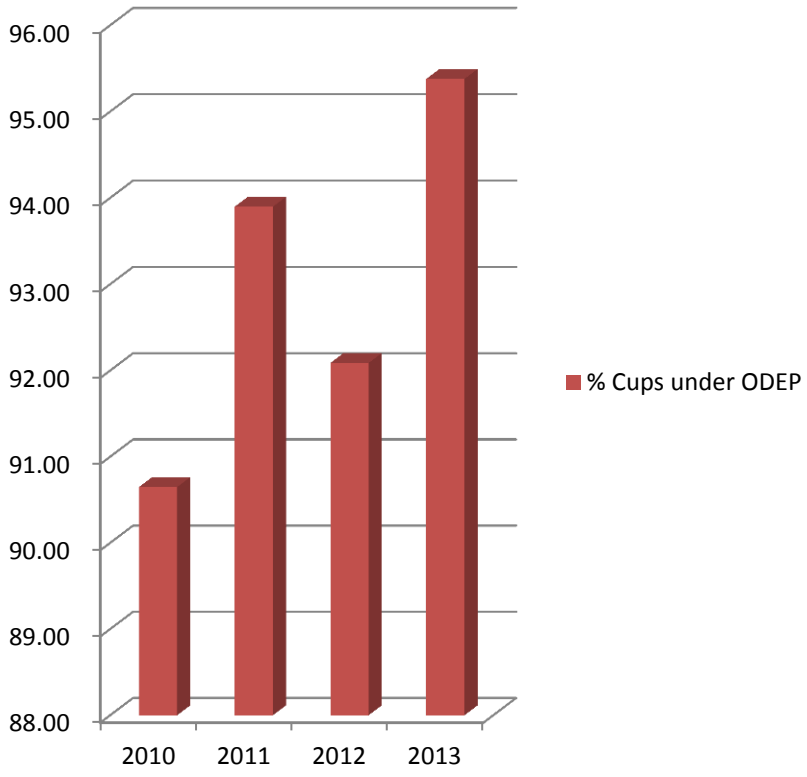
% Stems under ODEP



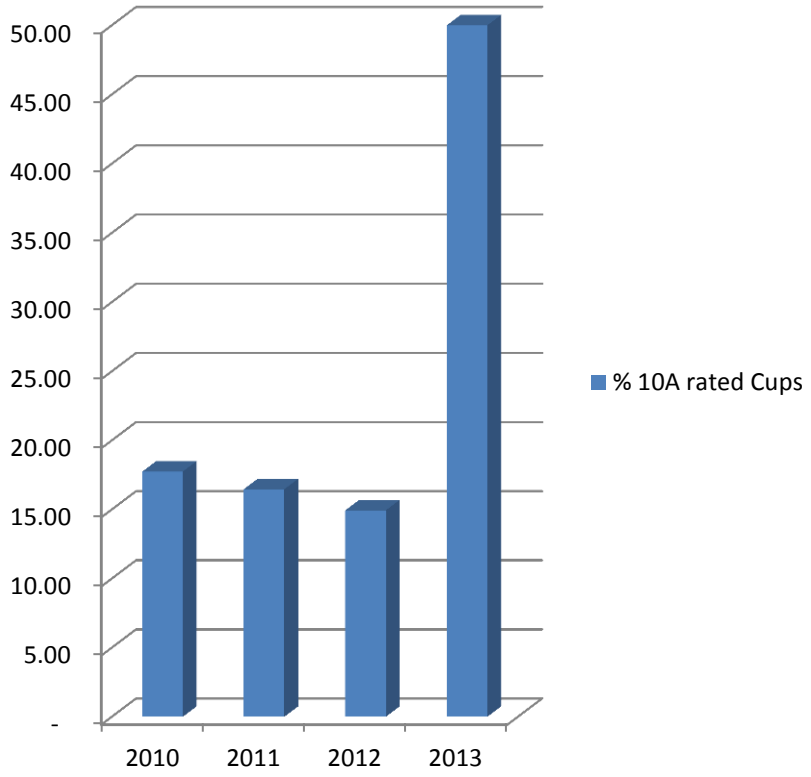
% 10A rated Stems



% Cups under ODEP



% 10A rated Cups



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How the Orthopaedic Device Evaluation Panel (ODEP) has changed the way surgeons and the NHS use hip and knee implants

Keith Tucker
Phil Lewis
ODEP

WHO USES ODEP

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- Manufacturers in their marketing strategy

- Hospitals in their procurement process
- Surgeons defending the use of their favourite implant!

- In many different countries

- AN INTERNATIONALLY AGREED COMPONENT DATA BASE WOULD MAKE IT MUCH EASIER FOR EVERYONE!

EFFECTS

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- WE HAVE ENCOURAGED MANUFACTURERS TO LOOK AT THE PERFORMANCE OF THEIR IMPLANTS
- DISCOURAGED POORLY PERFORMING IMPLANTS TO STAY IN THE MARKET
- HELPED WITH THE INTRODUCTION OF “BEYOND COMPLIANCE”

Beyond Compliance
Protecting Patients, Supporting Innovation

BEYOND COMPLIANCE

“PROTECTING PATIENTS.....

SUPPORTING INNOVATION”

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WHY "BEYOND COMPLIANCE"?

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- THE CE MARK IS "COMPLIANCE"

- BOA, ABHI, MHRA HAVE ALL SUGGESTED IT IS SOMETIMES APPROPRIATE FOR MANUFACTURERS TO GO

"BEYOND COMPLIANCE"

(BY DEFINITION IT MUST BE VOLUNTARY)

- IT IS NOT A RE-RUN OF THE CE MARK ASSESSMENT

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WHY “BEYOND COMPLIANCE”?

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- WE HAD CE, NJR,ODEP BEFORE
- ASR ETC
- WE NEED A TOUGHER SYSTEM AT THE ENTRY END
- SO! ODEP SEEMS TO HAVE DONE FINE BUT….
- NOW IT LINKS WITH BEYOND COMPLIANCE IT SHOULD DO EVEN BETTER

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PLANNED DATA FLOW

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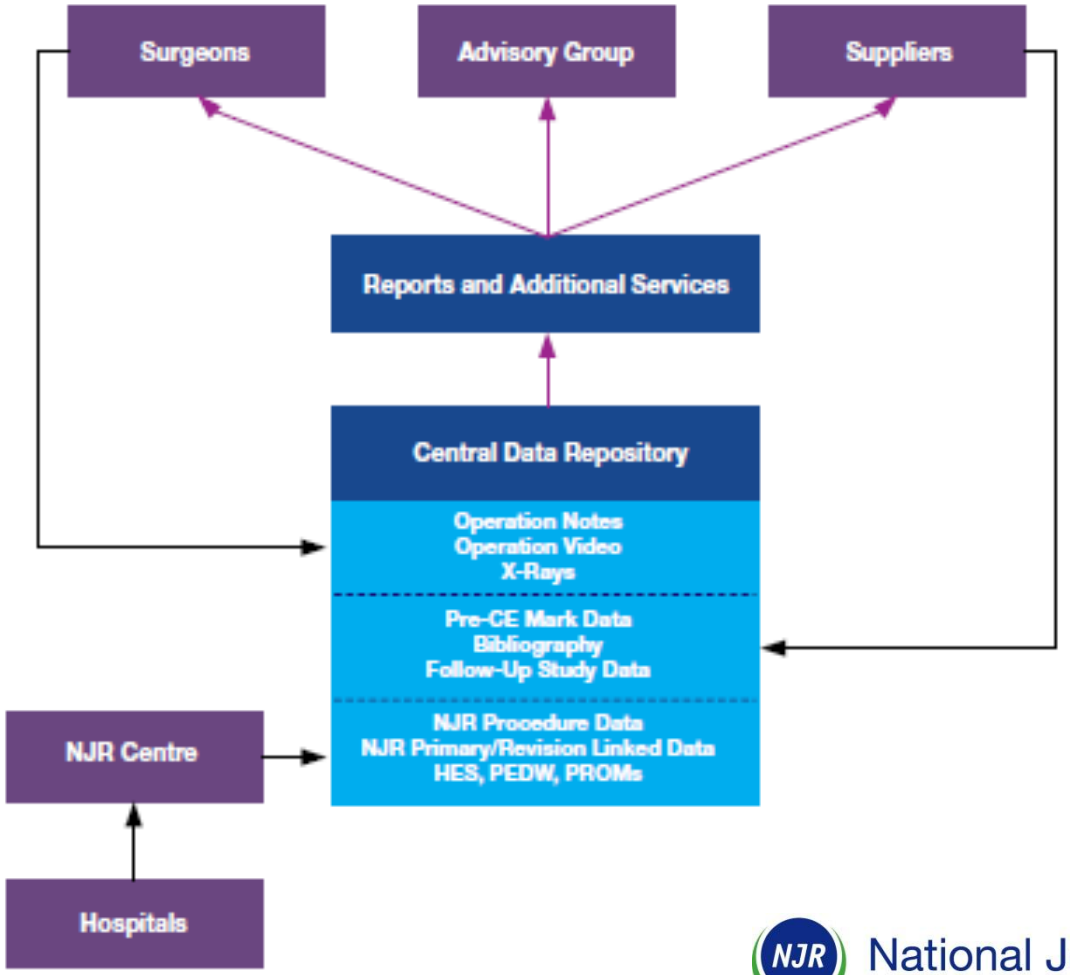
Protecting Patients, Supporting Innovation



NJR National Joint Registry
www.njrcentre.org.uk

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

SUMMARY OF FUNCTIONS OF THE ADVISORY GROUP

- ASSESS AND STRATIFY RISK, SUGGEST RATE OF INTRODUCTION TO MARKET
- SUPERVISE DATA COLLECTION
- DATA ANALYSIS AND REPORT

Beyond Compliance
Protecting Patients, Supporting Innovation

ODEP TODAY (POST NICE)

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- NOT ASKED TO ASSIST WITH DEVELOPMENT OF UPDATED GUIDANCE (2014)
- ASKED TO IMPLEMENT NEW GUIDANCE
- DELIGHTED TO HELP!
- (WE ARE NO LONGER PARENTED BY NICE)

NICE AND ODEP

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NICE 2014	ODEP'S VIEW
HIPS TO BE ASSESSED AS ONE	CUPS AND STEMS TO BE ASSESSED SEPARTELY
ONLY PROSTHESES WITH 5% FAILURE TO BE ACCEPTABLE	OLD RATINGS ALSO TO BE USED. 10A* TO BE AVAILABLE
LINEAR FAILURE RATE FROM 3 YEARS	NOT WORKABLE
PROGRESSION THROUGH BENCHMARKS OBLIGATORY	AGREED!
A PHYSICIAN AS CHAIRMAN	AN ORTHOPAEDIC SURGEON

National Joint Registry
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LOOKING FURTHER ON

- 15 YEAR BENCHMARK FOR HIPS
- 15 YEAR BENCHMARK FOR KNEES
- SHOULDERS (At an early stage)

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

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- MICK BORROFF

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THANK YOU

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