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Component Database:
The benefits to manufacturers and other stakeholders

Richard Armstrong

NEC

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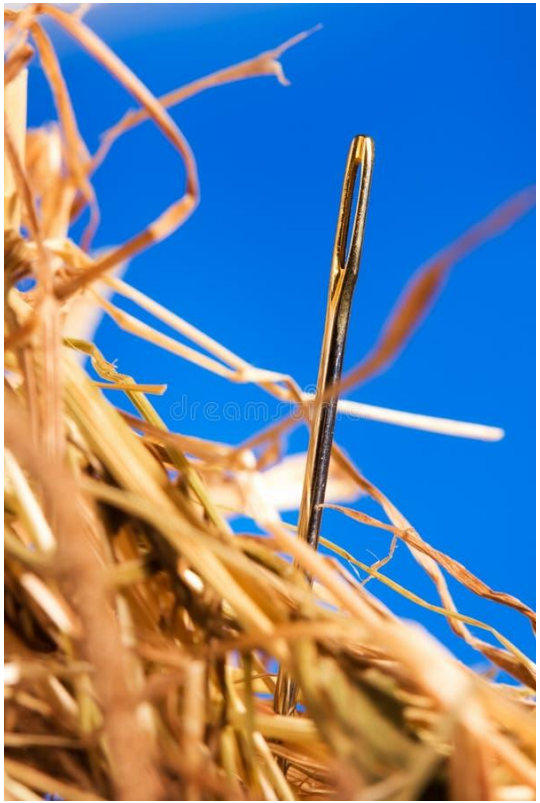
Why Classify Product Data?



High level of granularity describing device attributes supports:

- Patient safety through device surveillance by identifying attributes associated with increased risks of revision
- Group similar devices based on attributes or identify variants within brands for sub analysis (camouflage detection)
- Enable the registry to assess the relative benefits (or risks) of implant attributes by pooling data of all products with the classification of interest. Examples include:
  - Highly cross-linked poly
  - Large Head
  - Metal on Metal
  - Modular Nexk
- Data validation and combination safety checks (size compatibility)
- Enhance data quality through system business rules to determine complete constructs match patient procedures

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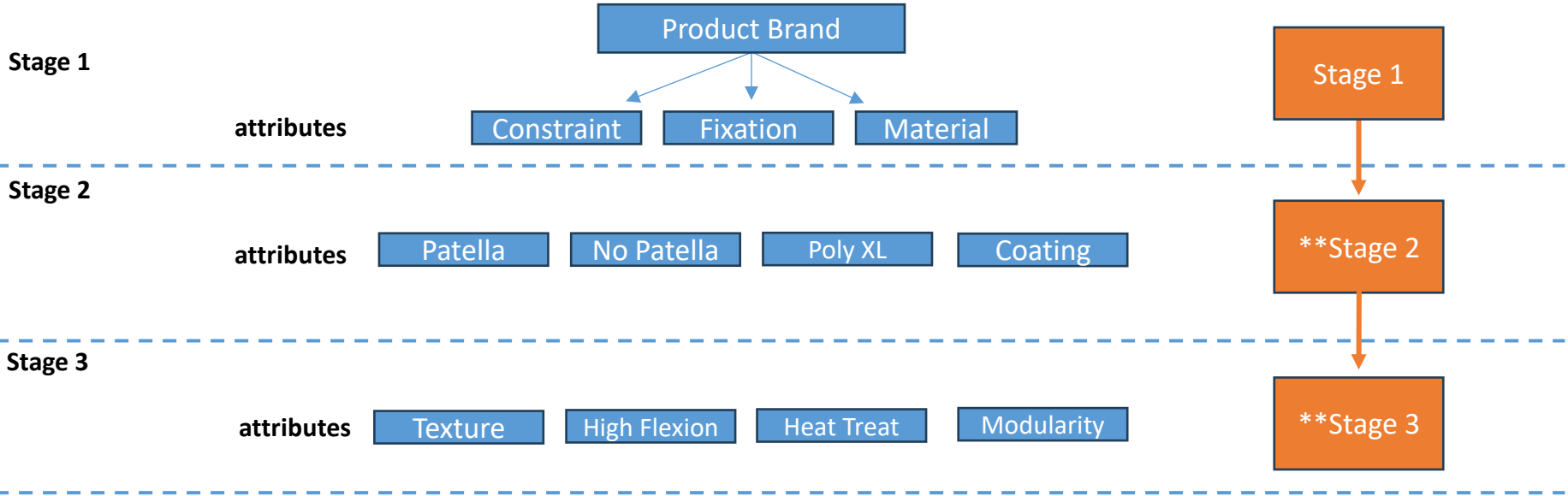
Identify product variants based on classification – TKR example (illustration only)

Brand level analysis may contain product variants. How can variants be identified with only product codes and brand names?



**Cautionary approach with further staged stratification potentially due to low numbers

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Safety Checks Using Device Classification

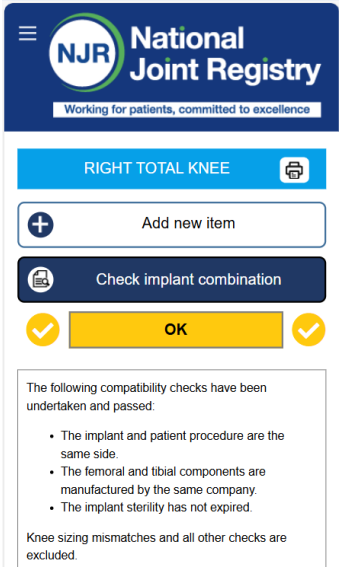
- NJR monitors and supports prevention of Never Events for hip, knee and shoulder replacements through a support tool
- Publicly available
- Utilises implant classification to undertake safety checks

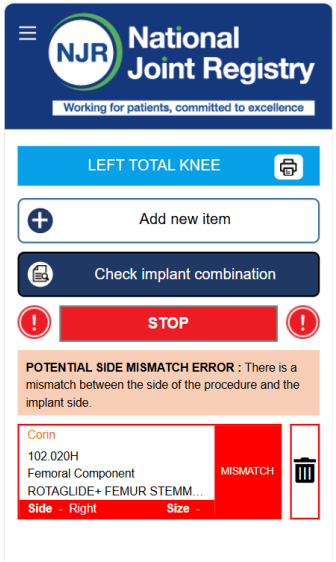
Support your local safety processes

Check in real time:

- THR/TKR mix and match
- THR size mismatch
- TKR side mismatch
- Sterility expiry date
- Hips-MoM

- Free of charge
- Developed jointly by the NJR and Scan4Safety
- 'Never Event' prevention
- Use in any device with a web browser
- Print or save the results to attach to patient's notes





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NJR Implant Summary Report
Report Demonstration – Knee Report

Implant Summary Report for: Example Subscriber

Sample TKR

Comprising PRIMARY knees implanted up to:	**08 September 2019**
NJR Database extract:	**07 November 2019**
Produced on:	**25 November 2019**
Licensed for use until:	**25 March 2020**

Contents

Recorded Usage in NJR	2
Patient and Procedure Details	3
Revision and Survivorship	4
Patient Reported Outcomes	11
APPENDICES – Component Lists	16

This report has been produced by the National Joint Registry of England, Wales and Northern Ireland (NJR). It summarises usage and outcomes associated with the Sample TKR up to the specified dates. This analysis is based on data collected by the NJR and PROMs data collected by NHS Digital for the components listed in the appendices.

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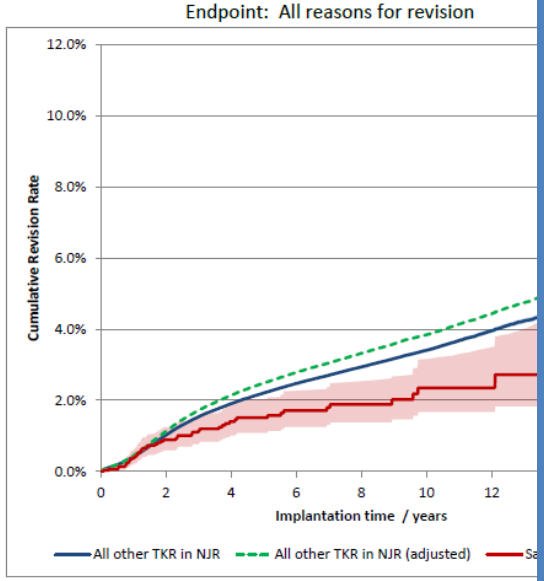
PMS Report for:

Revision and Surviv

Cumulative Revision Rate



Cox Proportional Hazards model for revision risk ratio of Sample TKR / All other TK
endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	*p*-value
Unadjusted.	0.71 (0.54 - 0.94)	0.017
Adjusted for age, gender, year cohort and indications.	0.63 (0.48 - 0.84)	0.001

PMS Report for: Sample TKR

Revision and Survivorship

Analysis by Implant Combination

Patella Resurfacing	Implanted	Endpoint: any revision PTIR	Group PTIR	p.PTIR	Revised	Expected Revisions	p Log-rank
Patella not Resurfaced	1868	0.31	0.39	0.229	36	49.4	0.054
Patella Resurfaced	1131	0.20		0.015	13	27.9	0.003

Patella Resurfacing	Implanted	Endpoint: Revision, excluding isolated patella exchange/resurfacing PTIR	Group PTIR	p PTIR	Revised	Expected Revisions	p Log-rank
Patella not Resurfaced	1868	0.27	0.32	0.365	31	41.4	0.119
Patella Resurfaced	1131	0.20		0.119	13	23.3	0.029

Fixation	Implanted	Endpoint: any revision PTIR	Group PTIR	p PTIR	Revised	Expected Revisions	p Log-rank
Cemented	2831	0.28	0.39	0.021	46	72.0	0.001
Cementless	142	0.20		0.602	2	4.4	0.342
Hybrid	14	0.94		0.338	1	0.5	0.373
Reverse Hybrid	4	0.00		1.000	0	0.2	1.000

Constraint	Implanted	Endpoint: any revision PTIR	Group PTIR	p PTIR	Revised	Expected Revisions	p Log-rank
Unconstrained Mobile	216	0.38	0.39	1.000	6	6.7	1.000
Posterior Stabilised Mobile	38	0.33		1.000	1	1.4	1.000
Unconstrained Fixed	2040	0.25		0.018	30	51.2	0.002
Posterior Stabilised Fixed	669	0.31		0.519	12	17.0	0.273
Constrained Fixed	27	0.00		1.000	0	0.7	1.000

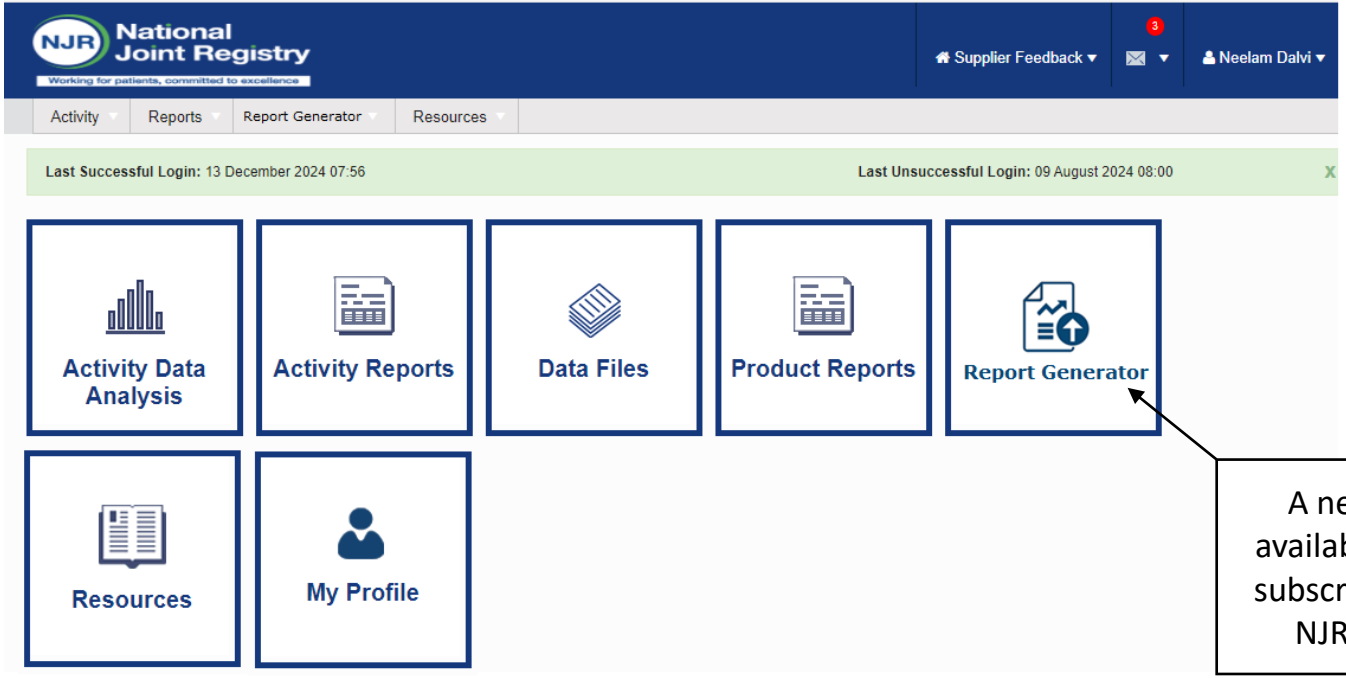
Tibial Construction	Implanted	Endpoint: any revision PTIR	Group PTIR	p.PTIR	Revised	Expected Revisions	p Log-rank
Modular Tibia	2706	0.29	0.39	0.046	45	68.0	0.004
Monoblock Tibia	285	0.19		0.214	4	9.0	0.096

Patient Time Incidence Rate (PTIR) is measure in revisions per 100 implant years

Expected revisions are based on All other TKR in NJR, and are adjusted for patient age, gender, year cohort, and indications. Significance is calculated from a stratified log-rank test.

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

Bespoke Report Generator Demo - Dashboard



A new “tile” is available to active subscribers within NJR Connect

Sample data

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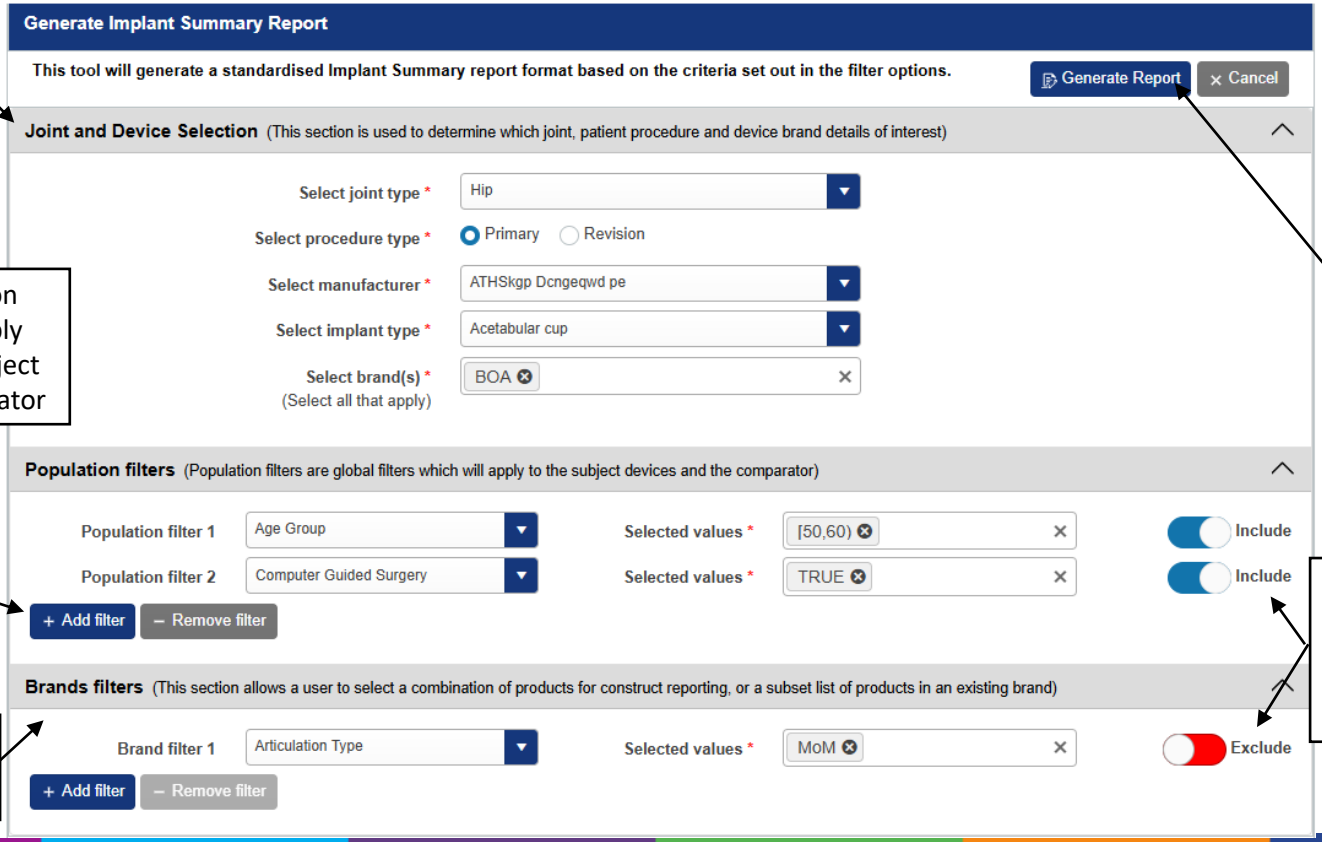
Bespoke Report Generator Demo – Form Selection

Select joint and device brand/s

Select "Population filters" which apply filtering to the subject device and comparator

Add / remove filters

Subset or construct reporting filters



Generate Report button, including case counts

Include or exclude records with applied filters

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Bespoke Report Generator Demo – Sample Report

National Joint Registry

Implant Summary Report for: Sample Manufacturer

Sample Stem

Comprising PRIMARY hips implanted up to: 01 October 2024
NJR Database extract: 31 October 2024

Produced on: 10 November 2024
Licensed for use until: 10 November 2025

Contents

Recorded Usage in NJR	2
Patient and Procedure Details	3
Revision and Survivorship	4
Patient Reported Outcome Measures	14
APPENDIX A – Component List	19

This report has been produced by the National Joint Registry (NJR). It summarises usage and outcomes associated with the Sample Stem up to the specified dates. Hemiarthroplasties and patients aged less than 18 have been excluded. This analysis is based on data collected by the NJR and PROMs data collected by NHS England for the following combinations of products:

Femoral components	Sample Stem
Acetabular Component	Any Acetabular Component from all manufacturers

Appendix A lists details of all Sample Stem components included in this report.

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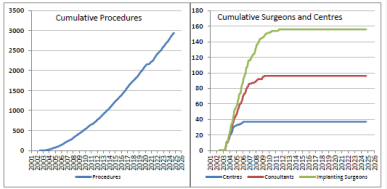
Summary Report for: Sample Stem

NJR Recorded Usage

Implant Usage

Date of first recorded usage in the NJR: **03 April 2003**
Date of last recorded usage in this dataset **28 September 2024**
Maximum implantation time: 21.5 years
Mean implantation time: 7.6 years

Totals Recorded in NJR	Cumulative Total
Procedures	2,949
Patients	2,946
Centres	37
Consultants	96
Implanting Surgeons	156



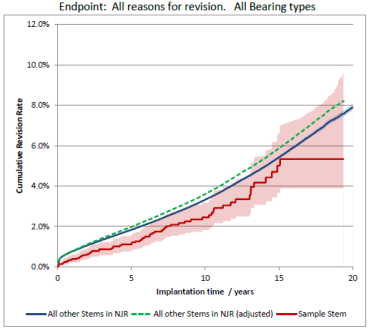
Current Outcome	Year of implantation: Pre-2013	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	Total	%
Death	335	41	33	26	23	19	17	9	5	7	2	2	0	519	17.6%
Revised	42	3	4	1	3	3	2	1	0	1	1	2	0	63	2.1%
Unrevised	530	103	134	125	175	149	149	190	101	189	176	187	159	2367	80.3%
Total	907	147	171	152	201	171	168	200	106	197	179	191	159	2949	100%

Summary Report for: Sample Stem

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All reasons for revision. All Bearing types



Cox Proportional Hazards model for revision risk ratio of Sample Stem / All other Stems in NJR, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
All bearings. Unadjusted.	0.75 (0.59 - 0.97)	0.025
All bearings. Adjusted for age, sex, ASA, BMI, Op.date and indications.	0.69 (0.53 - 0.88)	0.002

Summary Report for: Sample Stem

Patient Reported Outcomes

PROMs Analysis

Comprising PROMs data up to and including: 31/03/2022

Oxford Hip Score (0 - 48)	Sample Stem	All other Stems in NJR	All THR in NJR
Paired Records	634	360,055	367,478
PreOp score	18.1	17.9	17.9
6 month score	39.8	39.6	39.6
6 month score (adjusted)	39.6	39.6	39.6
Health gain	21.7	21.7	21.7
Health gain (adjusted)	21.7	21.7	21.7
p value (adjusted health gain)	0.95		
Score Improved	97.3%	97.3%	97.3%

EQ-5D Index (-0.59 - 1.00)	Sample Stem	All other Stems in NJR	All THR in NJR
Paired Records	585	332,259	338,955
PreOp score	0.354	0.351	0.352
6 month score	0.781	0.795	0.795
6 month score (adjusted)	0.780	0.795	0.795
Health gain	0.427	0.443	0.442
Health gain (adjusted)	0.428	0.442	0.442
p value (adjusted health gain)	0.4		
Score Improved	90.4%	89.7%	89.7%

EQ-VAS (0 - 100)	Sample Stem	All other Stems in NJR	All THR in NJR
Paired Records	565	319,362	325,896
PreOp score	62.8	64.6	64.6
6 month score	77.0	77.0	77.0
6 month score (adjusted)	76.9	77.0	77.0
Health gain	14.2	12.4	12.4
Health gain (adjusted)	12.3	12.4	12.4
p value (adjusted health gain)	0.97		
Score Improved	70.6%	66.7%	66.7%

Adjusted scores correspond to the NHS England version 3 casemix-adjustment model. This includes patient variables from PROMs, HES, and IMD data.
Figures in parentheses represent the 95% confidence interval for the mean

Sample data