

Component Database: The benefits to manufacturers and other stakeholders

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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



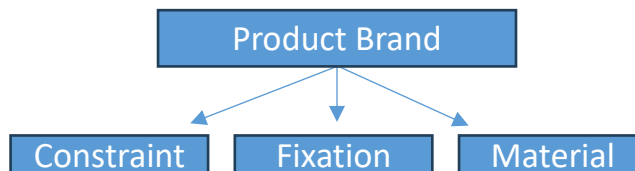
Identify product variants based on classification – TKR example (illustration only)

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

Stage 1

attributes



Stage 2

attributes



Stage 3

attributes



Stage 1

**Stage 2

**Stage 3

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

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

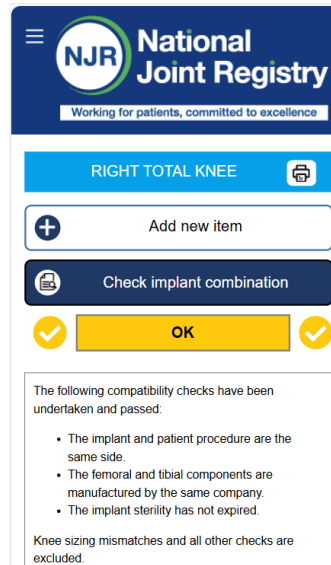
Support your local safety processes

 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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RIGHT TOTAL KNEE

+ Add new item

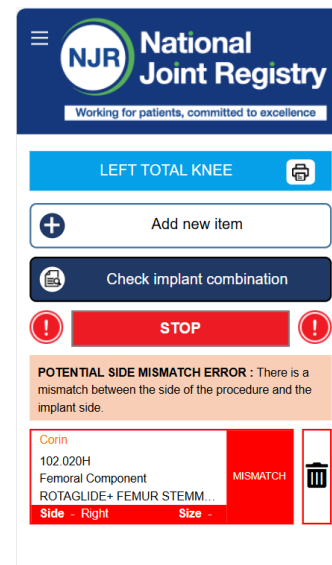
Check implant combination

OK

The following compatibility checks have been undertaken and passed:

- The implant and patient procedure are the same side.
- The femoral and tibial components are manufactured by the same company.
- The implant sterility has not expired.

Knee sizing mismatches and all other checks are excluded.



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LEFT TOTAL KNEE

+ Add new item

Check implant combination

STOP

POTENTIAL SIDE MISMATCH ERROR : There is a mismatch between the side of the procedure and the implant side.

| | | |
|------------------------|----------|---|
| Corin | MISMATCH |  |
| 102.020H | | |
| Femoral Component | | |
| ROTAGLIDE+ FEMUR STEMM | | |
| Side - Right | Size - | |

NJR Implant Summary Report

Report Demonstration – Knee Report

Implant Summary Report for:

Example Subscriber

Sample TKR

Comprising PRIMARY knees implanted up to:
NJR Database extract:

08 September 2019
07 November 2019

Produced on:
Licensed for use until:

25 November 2019
25 March 2020

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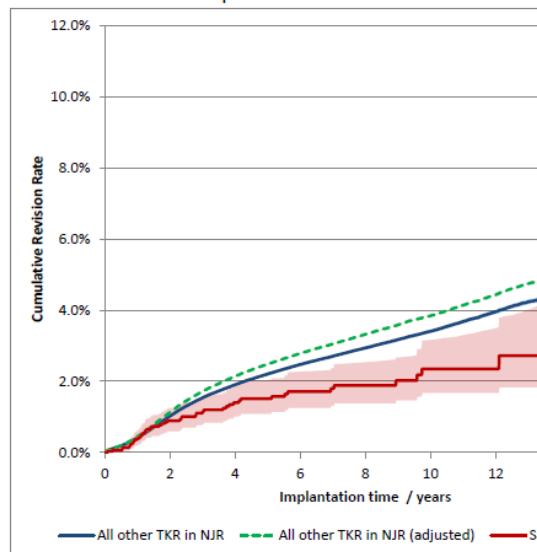
| | |
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This report has been produced by the National Joint Registry of England, Wales and Northern Ireland (NJR). It summarises usage and outcomes associated with the Sample TKR up to the specified dates. This analysis is based on data collected by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

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Cumulative Revision Rate

Endpoint: All reasons for revision



Cox Proportional Hazards model for revision risk ratio of Sample TKR / All other TKR 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 |

Revision and Survivorship

Analysis by Implant Combination

| | | Endpoint: any revision | | | | | |
|------------------------|-----------|------------------------|------------|--------|---------|--------------------|------------|
| Patella Resurfacing | Implanted | 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 |

| | | Endpoint: Revision, excluding isolated patella exchange/resurfacing | | | | | |
|------------------------|-----------|---|------------|--------|---------|--------------------|------------|
| Patella Resurfacing | Implanted | 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 |

| | | Endpoint: any revision | | | | | |
|----------------|-----------|------------------------|------------|--------|---------|--------------------|------------|
| Fixation | Implanted | 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 |

| | | Endpoint: any revision | | | | | |
|-----------------------------|-----------|------------------------|------------|--------|---------|--------------------|------------|
| Constraint | Implanted | 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 |

| | | Endpoint: any revision | | | | | |
|---------------------|-----------|------------------------|------------|--------|---------|--------------------|------------|
| Tibial Construction | Implanted | 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.

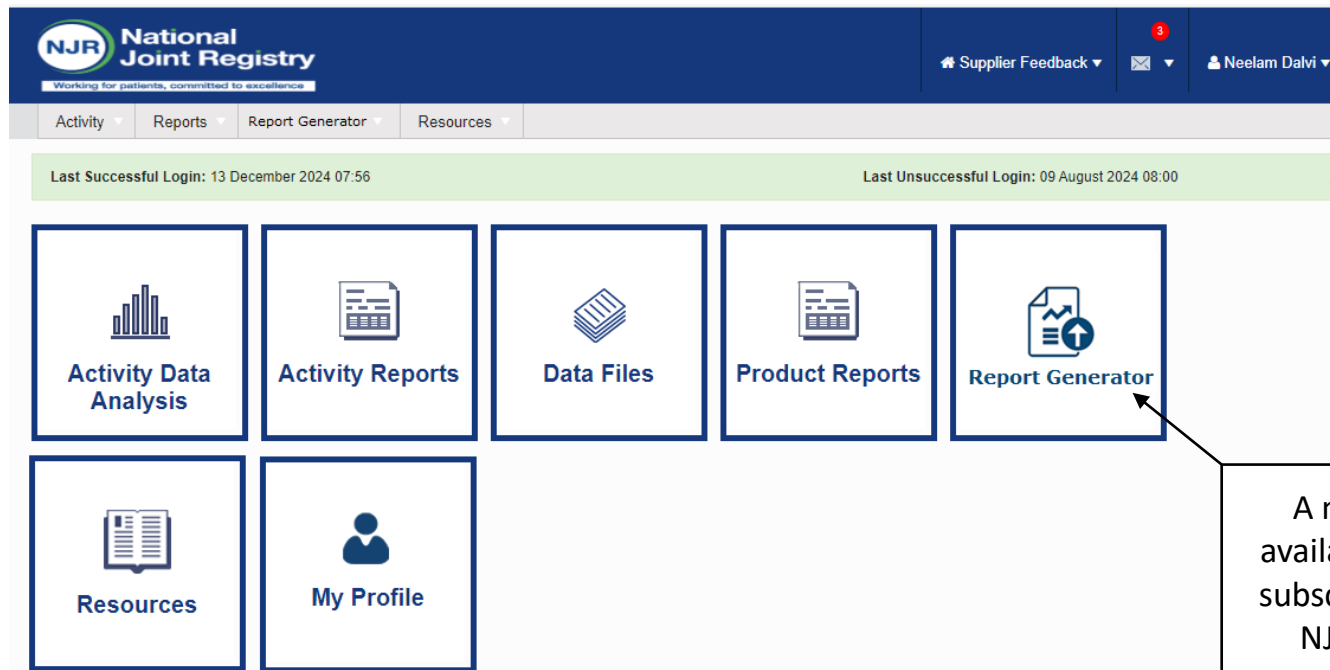
Significantly better, $p < 0.001$

Significantly better, $p < 0.05$

Significantly worse $p < 0.05$

Significantly worse $p < 0.001$

Bespoke Report Generator Demo - Dashboard



The dashboard features a dark blue header with the NJR logo and tagline. On the right, there are links for 'Supplier Feedback', an email icon with a red '3' badge, and a user profile for 'Neelam Dalvi'. Below the header is a navigation bar with tabs for 'Activity', 'Reports', 'Report Generator', and 'Resources'. A green status bar displays 'Last Successful Login: 13 December 2024 07:56' and 'Last Unsuccessful Login: 09 August 2024 08:00'. The main content area contains seven tiles: 'Activity Data Analysis' (bar chart icon), 'Activity Reports' (document icon), 'Data Files' (stack of papers icon), 'Product Reports' (document icon), 'Report Generator' (document with up arrow icon), 'Resources' (book icon), and 'My Profile' (person icon). An arrow points from a text box to the 'Report Generator' tile.

Activity Data Analysis

Activity Reports

Data Files

Product Reports

Report Generator

Resources

My Profile

Last Successful Login: 13 December 2024 07:56

Last Unsuccessful Login: 09 August 2024 08:00

Supplier Feedback

Neelam Dalvi

3

Activity

Reports

Report Generator

Resources

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

Sample data

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 Implant Summary Report

This tool will generate a standardised Implant Summary report format based on the criteria set out in the filter options.

Generate Report
 ✕ Cancel

Joint and Device Selection (This section is used to determine which joint, patient procedure and device brand details of interest)

Select joint type *
Hip

Select procedure type *
☒ Primary
 ☐ Revision

Select manufacturer *
ATHSkqp Dcngeqwd pe

Select implant type *
Acetabular cup

Select brand(s) *
(Select all that apply)

BOA ✕

Population filters (Population filters are global filters which will apply to the subject devices and the comparator)

Population filter 1
Age Group

Selected values *
[50,60) ✕

☒ Include

Population filter 2
Computer Guided Surgery

Selected values *
TRUE ✕

☒ Include

+ Add filter

– Remove filter

Brands filters (This section allows a user to select a combination of products for construct reporting, or a subset list of products in an existing brand)

Brand filter 1
Articulation Type

Selected values *
MoM ✕

☐ Exclude

+ Add filter

– Remove filter

Generate Report button, including case counts

Include or exclude records with applied filters

Bespoke Report Generator Demo – Sample Report

Implant Summary Report for:



Sample Manufacturer

Comprising PRIMARY hips implanted up to:
NJR Database extract:

Sample Stem
01 October 2024
31 October 2024

Produced on:
Licensed for use until:

10 November 2024
10 November 2025

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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:

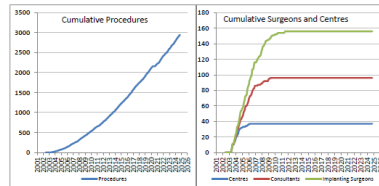
Sample Stem

NJR Recorded Usage

Implant Usage

Date of first recorded usage in the NJR: 03 April 2003
Date of last recorded usage in this dataset: 26 September 2024
Maximum implantation time: 21.5 years
Mean implantation time: 7.6 years

| Totals Recorded in NJR | Cumulative Total |
|------------------------|------------------|
| Procedures | 2,945 |
| Patients | 2,945 |
| Centres | 37 |
| Consultants | 96 |
| Implanting Surgeons | 156 |



| Current Outcome | Pre-2013 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 | 2024 | Total | % |
|-----------------|----------|------|------|------|------|------|------|------|------|------|------|------|------|-------|-------|
| Death | 355 | 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 | 153 | 134 | 125 | 175 | 149 | 149 | 190 | 101 | 189 | 176 | 187 | 159 | 2387 | 80.3% |
| Total | 867 | 147 | 171 | 152 | 201 | 171 | 168 | 200 | 106 | 197 | 179 | 191 | 159 | 2449 | 100% |



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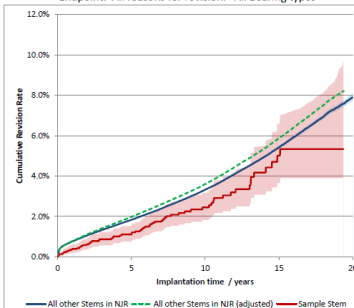
Summary Report for:

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 |



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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 | 360,255 | 367,478 |
| Pre-Op score | 18.1 | 17.6 | 17.6 |
| 6 month score | 39.8 | 39.6 | 39.6 |
| 6 month score (adjusted) | 39.8 | 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 (4.09 - 1.00) | Sample Stem | All other Stems in NJR | All THR in NJR |
|--------------------------------|-------------|------------------------|----------------|
| Paired Records | 668 | 332,259 | 338,858 |
| Pre-Op score | 0.354 | 0.351 | 0.352 |
| 6 month score | 0.781 | 0.795 | 0.795 |
| 6 month score (adjusted) | 0.760 | 0.795 | 0.795 |
| Health gain | 0.427 | 0.443 | 0.443 |
| Health gain (adjusted) | 0.428 | 0.442 | 0.442 |
| p value (adjusted health gain) | 0.4 | | |
| Score Improved | 60.4% | 69.7% | 69.7% |

| EQ-VAS (0 - 100) | Sample Stem | All other Stems in NJR | All THR in NJR |
|--------------------------------|-------------|------------------------|----------------|
| Paired Records | 666 | 319,382 | 326,896 |
| Pre-Op 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% | 69.7% | 69.7% |

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



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Sample data