



National Joint Registry

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National Joint Registry Accountability and Transparency Model:

Implant Mismatch Notification Process Standard Operating Procedure v1.0



National Joint Registry Accountability and Transparency Model

Implant Mismatch Notification Process Standard Operating Procedure

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SECTION A: STANDARD OPERATING PROCEDURE

1 List of diagrams and tables used

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Table 1	Implant Mismatch Notification process map descriptions	A brief description of the Implant Mismatch Notification process maps produced (detailed maps provided in Appendix 2)	9
Table 2	Organisational roles and responsibilities	Outlines the key roles and responsibilities of key stakeholders	10
Table 3	Forms, templates and MoUs/SLAs	Provides an overview of and links to key documentation relating to the Implant Mismatch Notification Process	12
Table 4	Key risks and issues	Provides the top risks/issues/dependencies that will need to be managed and monitored when implementing the Implant Mismatch Notification Process	13
Table 5	Key stakeholders engaged	Provides an overview of the key stakeholders engaged in developing the Standard Operating Procedure (SOP)	14

2 About the National Joint Registry

The NJR for England, Wales, Northern Ireland and the Isle of Man collects information on joint replacement surgery and monitors the performance of joint replacement implants. It was set up in 2002 by the Department of Health and Welsh Government, Northern Ireland joined in 2013 and the Isle of Man in July 2015.

NJR has following six goals:

1. Monitor in real time the outcomes achieved by brand of prosthesis, hospital and Surgeon, and highlight where these fall below an expected performance in order to allow prompt investigation and to support follow-up action
2. Inform patients, clinicians, providers and healthcare commissioners, regulators and implant suppliers of the outcomes achieved in joint replacement surgery
3. Evidence variations in outcome achieved across surgical practice in order to inform best practice
4. Enhance patient awareness of joint replacement outcomes to better inform patient choice and patients' quality of experience through engagement with patients and patient organisations
5. Support evidence-based purchasing of joint replacement implants for healthcare providers to support quality and cost effectiveness
6. Support suppliers in the routine post-market surveillance of implants and provide information to clinicians, patients, hospital management and the regulatory authorities

3 Background

The NJR and British Orthopaedic Association (BOA) met with NHS England's Medical Director (MD) on the 10th Jan 2017 to present an NJR proposal for the provision of a robust, safe and rigorous process that would enhance monitoring, management and communication of Surgeon and Unit performance using NJR data that would support patient safety.

The principles of the NJR "Accountability and Transparency Model" were accepted by the NHS MD and it was agreed that work would progress around articulating the seven processes that underpin and enable delivery of the model.

A meeting has been organised to present further detail to the NHS MD on the 26th September 2017.

The seven processes outlined were the:

1. Alert and Alarm Surgeon Process
2. Alert and Alarm Unit Process
3. Outlier Management System (OMS) Process
4. NJR Appraisal Enhancement Process

5. Annual Clinical Report (ACR) Process
6. Implant Mismatch Notification Process
7. Implant Outlier Process

4 Governance

4.1 NJR governance structure

The NJR is managed by the Healthcare Quality Improvement Partnership (HQIP) under a contract with NHS England (NHSE) as part of the delivery of the National Clinical Audit and Patient Outcomes Programme (NCAPOP).

The NJR Operational Management Team (NJR OMT) supports the work of the NJR Steering Committee and all its Sub-Committees.

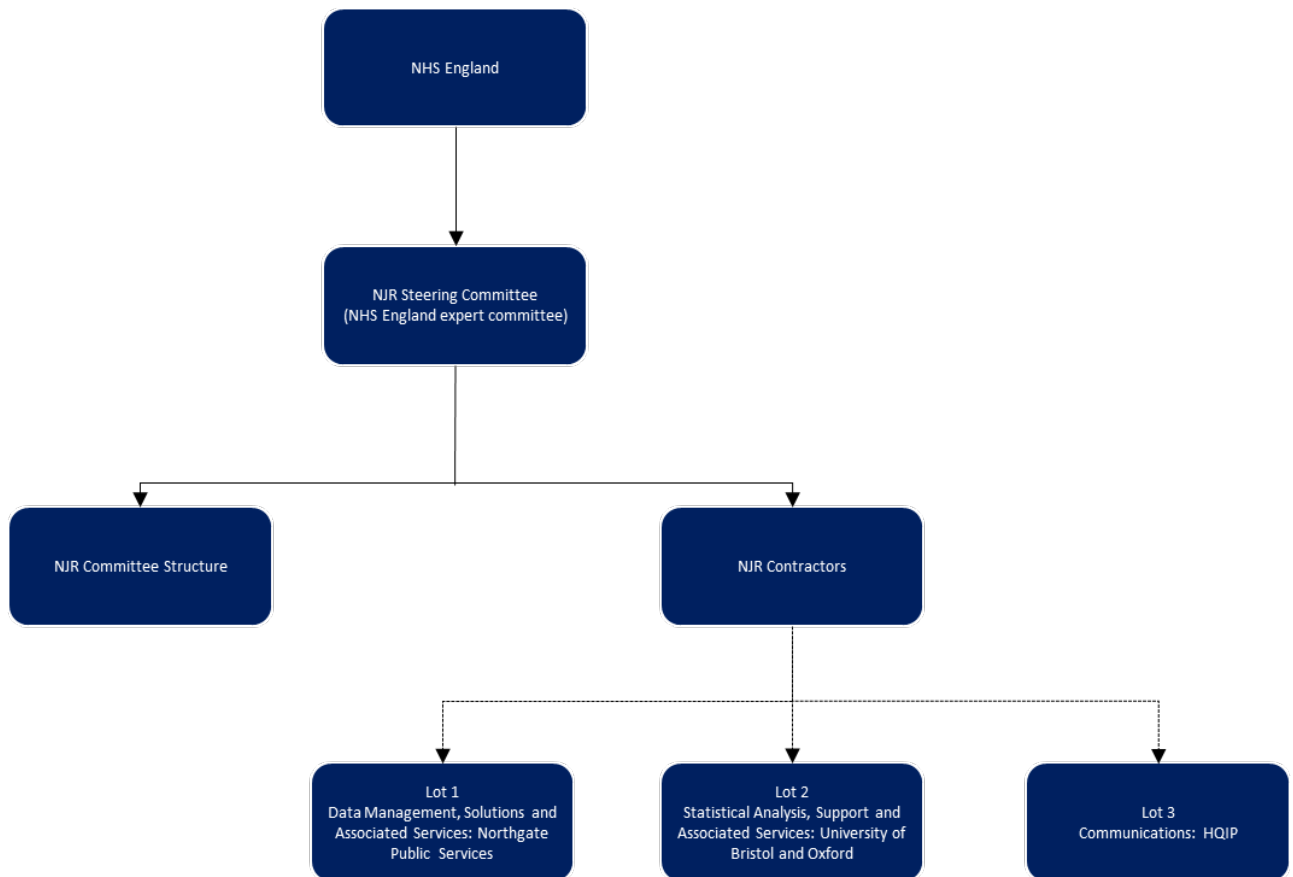


Diagram 1: NJR governance structure

4.2 NJR committee structure

The NJR Steering Committee is a NHS England Committee of experts and is responsible for the work and progress of the NJR.

The committee's responsibilities include:

- Setting the NJR's work programme and monitoring its progress
- Providing advice to orthopaedic Units, hospitals and implant suppliers where the information shows concerns about the performance of certain prostheses
- Setting the cost of the levy, based on the contractual costs of running the registry and the work programme agreed
- Providing an annual report to Ministers on the performance of the NJR and, following agreement, to make publicly available
- Establishing and monitoring codes of conduct for the contractor dealing with orthopaedic Units within NHS Trusts and independent healthcare providers, as well as the orthopaedic implant industry
- Facilitating, where appropriate, the use of the NJR data for research purposes

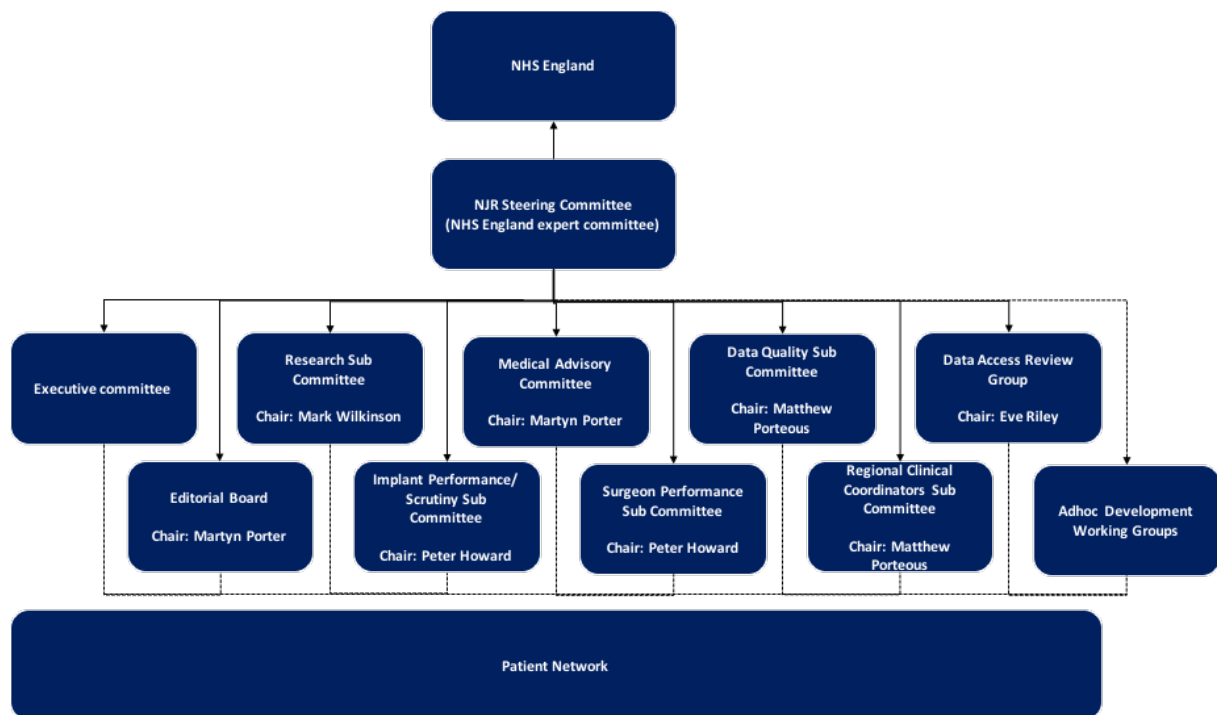


Diagram 2: NJR committee structure

4.3 Terms of Reference and membership

The NJR Steering Committee, the Executive Committee and each of the Sub-Committees have agreed Terms of Reference (ToR) which clearly detail:

- The scope of the Committee/Sub-Committee
- Agreed membership
- Meeting cycles

Appendix 1 provides all relevant ToR. Note these are currently under review and will be published in the 2017 ACR released in September 2017.

5 Purpose

The purpose of the NJR Implant Mismatch Notification Process SOP is to provide clarity and confirmation on the management and notification of potential implant mismatches, enabling Units to immediately recognise and correct data entry errors on the NJR system. It lists out what action should be taken, who should take it, and when, in order to ensure replication and quality control.

Whilst it is recognised that the majority of mismatches are data entry errors, having an early warning notification process in place to instantly identify potential implant mismatches at the point of data entry is vital. Where a genuine mismatch has occurred the notification process will assist early implant revision, if appropriate.

6 Scope

6.1 Scope of the Implant Mismatch Notification Process

The Implant Mismatch Notification Process applies to potential mismatches for primary hip and knee surgeries performed in England, Wales, Northern Ireland and the Isle of Man.

Trigger points for mismatch notification

The NJR records and reports on two potential mismatches of components:

- For hips – a mismatch in size, for example; between a hip cup or liner and head
- For knees – a mismatch in side, for example; a right-sided component recorded as being implanted for a left knee surgery

The notification process is triggered at the point of data entry if a user selects either different head and cup/liner sizes (for hips) or different procedure side and size of implants (for knees). This will activate a system generated automated pop-up, warning the data entry user that the selected choice represents a potential mismatch and that the component selection should be confirmed with the Surgeon.

The user will only be able to close the pop-up and continue entering data by selecting a button labelled 'I acknowledge'.

The data user at that point will follow one of three options

- a) Correct the data entry error
- b) Save the entry onto the Edit Stack
- c) Override and submit the entry

The Implant Mismatch Notification Process outlines the steps taken to deal with these options.

6.2 Frequency of mismatch notification

Outlier notifications are triggered every time the Hospital Data Manager (HDM) enters implant details into the NJR system. Details of outstanding mismatches will be reviewed regularly at the Surgical Performance Committee (SPC).

7 Process maps

The process maps in Table 1 have been developed. They outline the core activities relating to the Implant Mismatch Notification Process.

This process map should be used as a reference point and considered in relation to the purpose and scope outlined in this document.

Please refer to the Appendix number referenced in the table below to view the process map.

Reference	Name	Description	Appendix	Page
6.a)	Implant Mismatch Notification Process – Data Submitted	This process map sets out the steps by key stakeholder group for Implant Mismatch Notification in the case that mismatched data is submitted on the NJR system	2	16
6.b)	Implant Mismatch Notification Process – Data Saved	This process map sets out the steps by key stakeholder group for Implant Mismatch Notification in the case that mismatched data is saved onto the Edit Stack on the NJR system	2	17

Table 1: Implant Mismatch Notification Process map descriptions

8 Annual cycles

A notification cycle has been developed. This provides an overview of the key recurring activities that would take place each time a mismatch notification is triggered.

The notification cycle should be used as a reference point and considered in relation to the process map outlined in this document.

Please refer to Appendix 3 to view the notification cycle.

9 Organisational roles and responsibilities

The following table provides an overview of the main roles and responsibilities of key stakeholders in relation to the Implant Mismatch Notification Process.

The overview provided should be used as a reference point and considered in relation to the purpose, scope and process map outlined in this document.

Note: This table provides an overview only and does not replace a Responsible, Accountable, Consulted and Informed (RACI) matrix. See Appendix 4 for the RACI matrix which has been developed and agreed by all stakeholders.

Organisation/stakeholder group	Role/responsibilities	Key contacts
Northgate Public Services (Northgate), NJR Lot 1 Contractor	<ul style="list-style-type: none"> Mismatch notification System host and support Responsible for sending automated emails as required by the process Responsible and accountable for capturing all correspondence in the Master Mismatch Log 	Head of Health Solutions
NJR Regional Coordinator (RC)	<ul style="list-style-type: none"> Manages the end to end mismatch process and ensure accurate communications, follow up and escalation as required Responsible for confirming corrected data entries with the Unit Responsible for ensuring all correspondence is logged in the Master Mismatch Log Responsible for confirming potential mismatches with the HDM Responsible for informing the NJR OMT of any genuine mismatch events 	NJR RC

	<ul style="list-style-type: none"> Responsible for monitoring the final outcome of any genuine mismatch 	
Surgical Performance Committee (SPC) Surgeons	<ul style="list-style-type: none"> Responsible for calling the Unit to confirm genuine mismatch or data correction Responsible for formally writing to the Unit MD and Operating Surgeon in the case of a genuine mismatch 	SPC Chair
Hospital Data Manager (HDM)	<ul style="list-style-type: none"> Responsible for entering data into the NJR system Responsible for making data corrections Responsible for consulting with the Operating Surgeon to confirm genuine mismatches 	Individual HDMs in question
Operating Surgeons	<ul style="list-style-type: none"> Responsible for reviewing data and confirming corrections to the HDM when required Responsible for providing accurate data Responsible for initiating the patient safety process in the case of a genuine mismatch 	Individual Surgeon in question
Unit	<ul style="list-style-type: none"> Is advised in the case of genuine mismatch & ensures the Operating Surgeon takes appropriate action 	Unit MD
NJR Operational Management Team (NJR OMT)	<ul style="list-style-type: none"> Responsible for escalating potential & genuine mismatches to the NJR Surgeons for follow up Responsible for receiving the Master Mismatch Log from Northgate 	NJR Director of Operations

Table 2: Organisational roles and responsibilities

10 Forms, Templates and Memorandums of Understanding/Service Level Agreements

The following table provides an overview of key documentation relating to the Implant Mismatch Notification Process.

The documentation listed should be used as a reference point. Any letters sent should be amended as required based on relevant discussions.

Note, letter templates are to be uploaded onto the OMS and will be reviewed at regular intervals. Memorandum of Understanding (MoUs) will also need to be developed.

Template type	Template name	Description
Formal potential mismatch never event letter	6. Implant_Potential Never Event - Letter 1	SPC Surgeon letter to the Unit MD and Operating Surgeon formally informing them this is a potential mismatch never event
Formal potential mismatch never event follow up letter	6. Implant_Potential Never Event - Letter 2	Follow up letter from SPC Surgeon to Unit MD to ensure action is taken, in the case that no response was received from Letter 1
MoUs/ Service Level Agreements (SLAs)	To be developed	To be developed

Table 3: Forms, Templates and MoUs/SLAs

SECTION B: AREAS FOR CONSIDERATION

11 Risk/issues and dependencies

The following table provides the key risk/issues/dependencies that will need to be managed and monitored when implementing the Implant Mismatch Notification Process.

Key: **1-2 - low impact/probability**
 3-4 - medium impact/probability
 5 - high impact/probability

#	Risk/issue	Description	Impact	Impact (I) (1-5) <i>pre-mitigation</i>	Probability (P) (1-5) <i>pre-mitigation</i>	Overall likelihood (IxP)	Proposed mitigation
1	Risk	There is a risk that stakeholders are unclear on their roles and responsibilities	The processes developed and agreed are not implemented in line with timescales agreed	5	1	5	Dedicate time to developing and implementing, communication strategy and MoU where necessary to ensure agreement from all parties
2	Risk	There is a risk these changes will not be effectively communicated to all HDMs/ Surgeons/ Units	There will be low compliance and the correction of mismatch data will not be addressed early enough in the process	4	1	4	Dedicated time to develop and implement a communication strategy
3	Risk	There is a risk that NJR may be perceived as policing and regulating poor performance	Resistance by the orthopaedic community to data sharing	3	2	6	Ensure all escalation and subsequent action is carried out by other parties
4	Risk	There is a risk the HDM does not input data into the system until after the patient has been discharged	The potential mismatch will not be flagged soon enough to quickly undertake revision surgery and the patient will need to be re-admitted at a later date	5	3	15	Include in the process a time frame that all implant data should be input into the system by the HDM before the patient is discharged

Table 4: Key risks and issues

12 Other points to be aware of

This SOP is subject to change as the Implant Mismatch Notification Process is continuously refined.

Please contact the NJR lead noted in this document to ensure the latest version is referred to.

13 List of stakeholders engaged

The following key stakeholder groups have been involved in the development, review and sign off, of the Implant Mismatch Notification Process SOP.

Organisation/Stakeholder Group	Input
Northgate (NJR Lot 1 contractor)	Development
NJR Surgical Performance Committee (members of)	Development, review and sign off
NJR Operational Management Team (members of), including Members of the Model Development Working Group	Development, review and sign off
NJR Executive Committee (EC)	Development, review and sign off
NHSI	Review and sign off
CQC	Review and sign off
BOA	Review and sign off
MHRA	Review and sign off
HQIP	Review and sign off

Table 5: Key stakeholders engaged

SECTION C: SUPPORTING INFORMATION

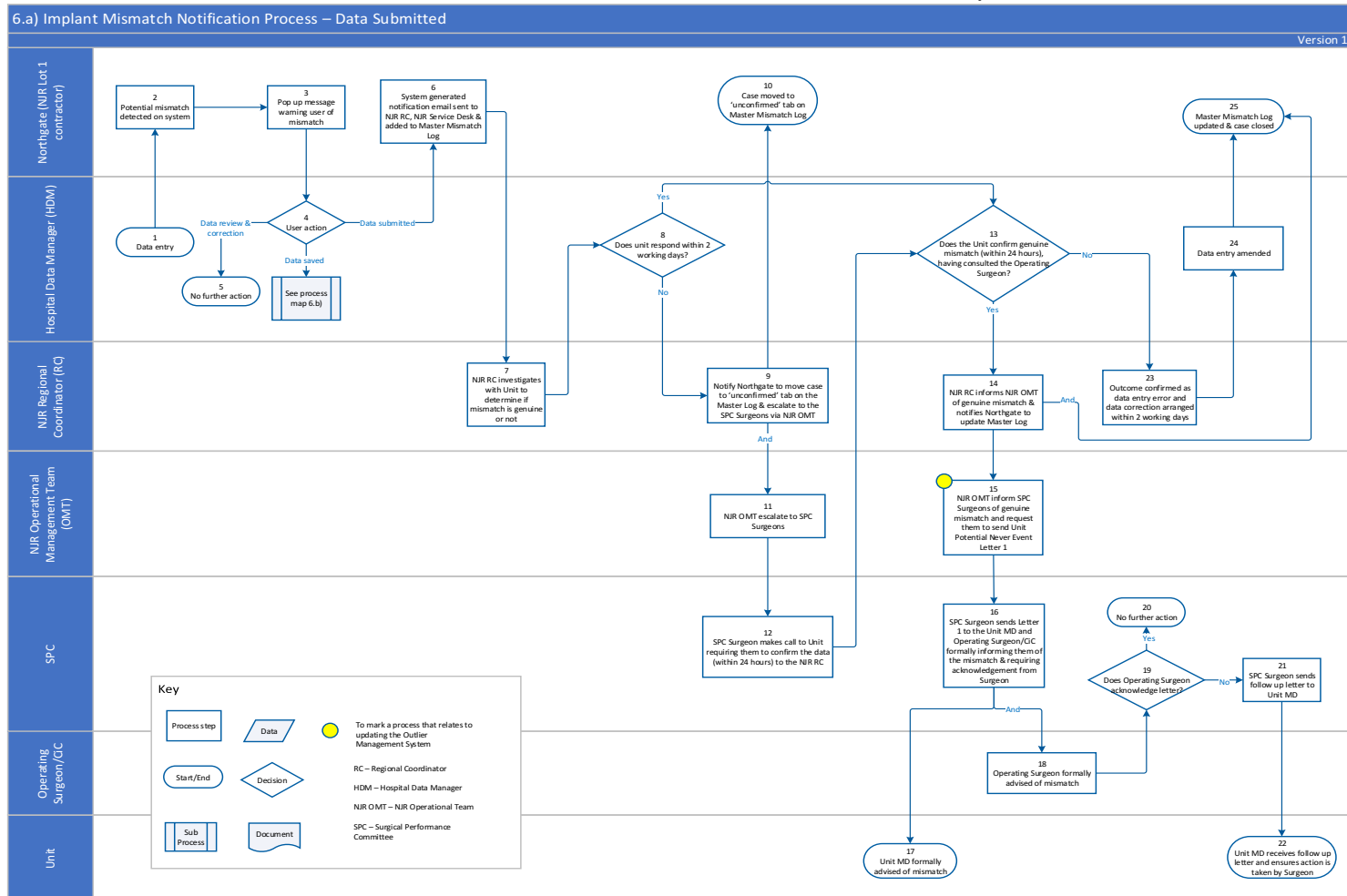
14 Appendix

14.1 Appendix 1: NJR Terms of Reference

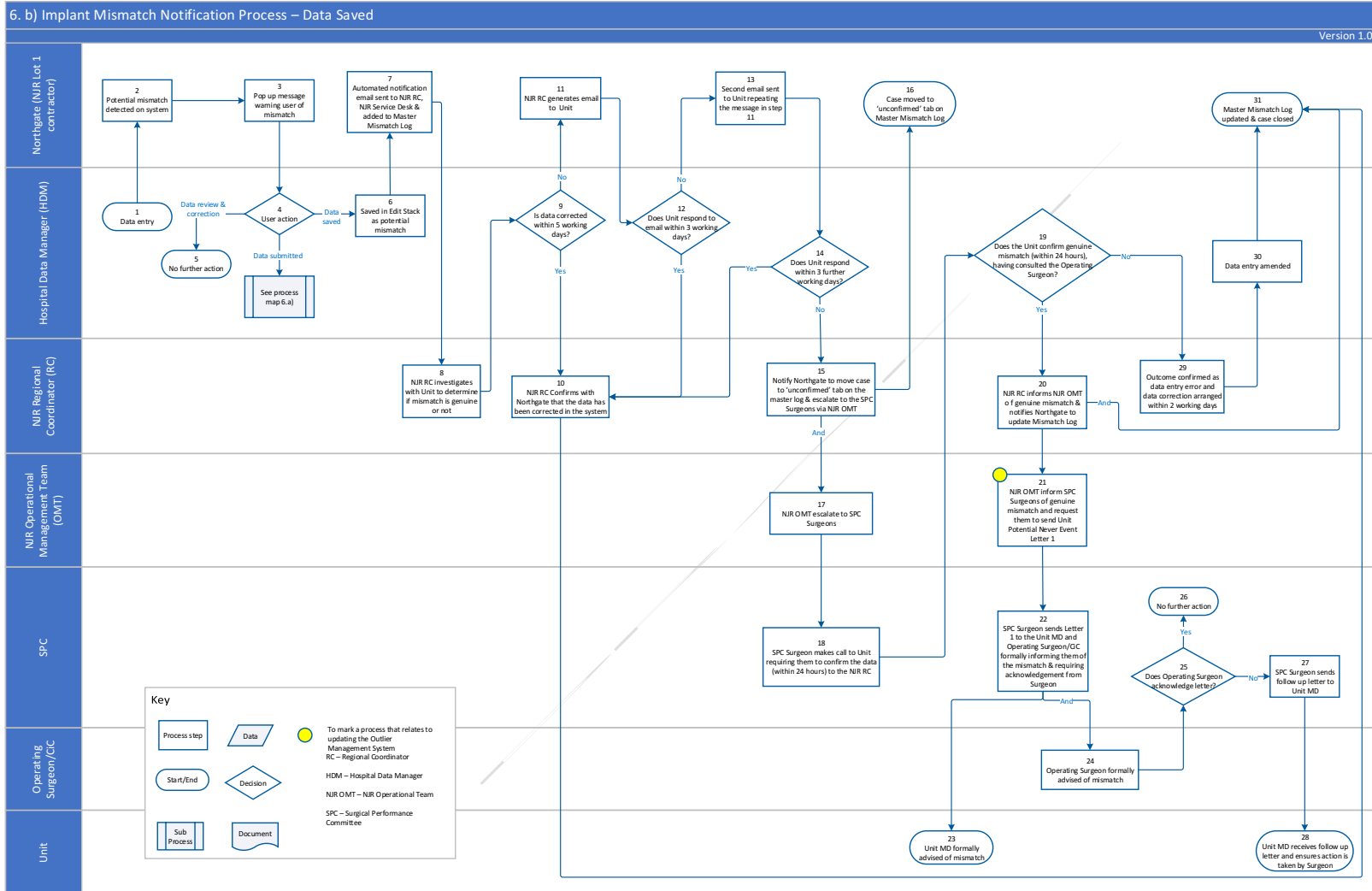
NJR Steering Committee and its Sub-Committees ToR can be found on <http://www.njrcentre.org.uk/njrcentre/AbouttheNJR/SteeringCommittee/tabid/80/Default.aspx>

14.2 Appendix 2: Process maps

6.a) Implant Mismatch Notification Process – Data Submitted. This process map sets out the steps by key stakeholder group for Implant Mismatch Notification in the case that mismatched data is submitted on the NJR system

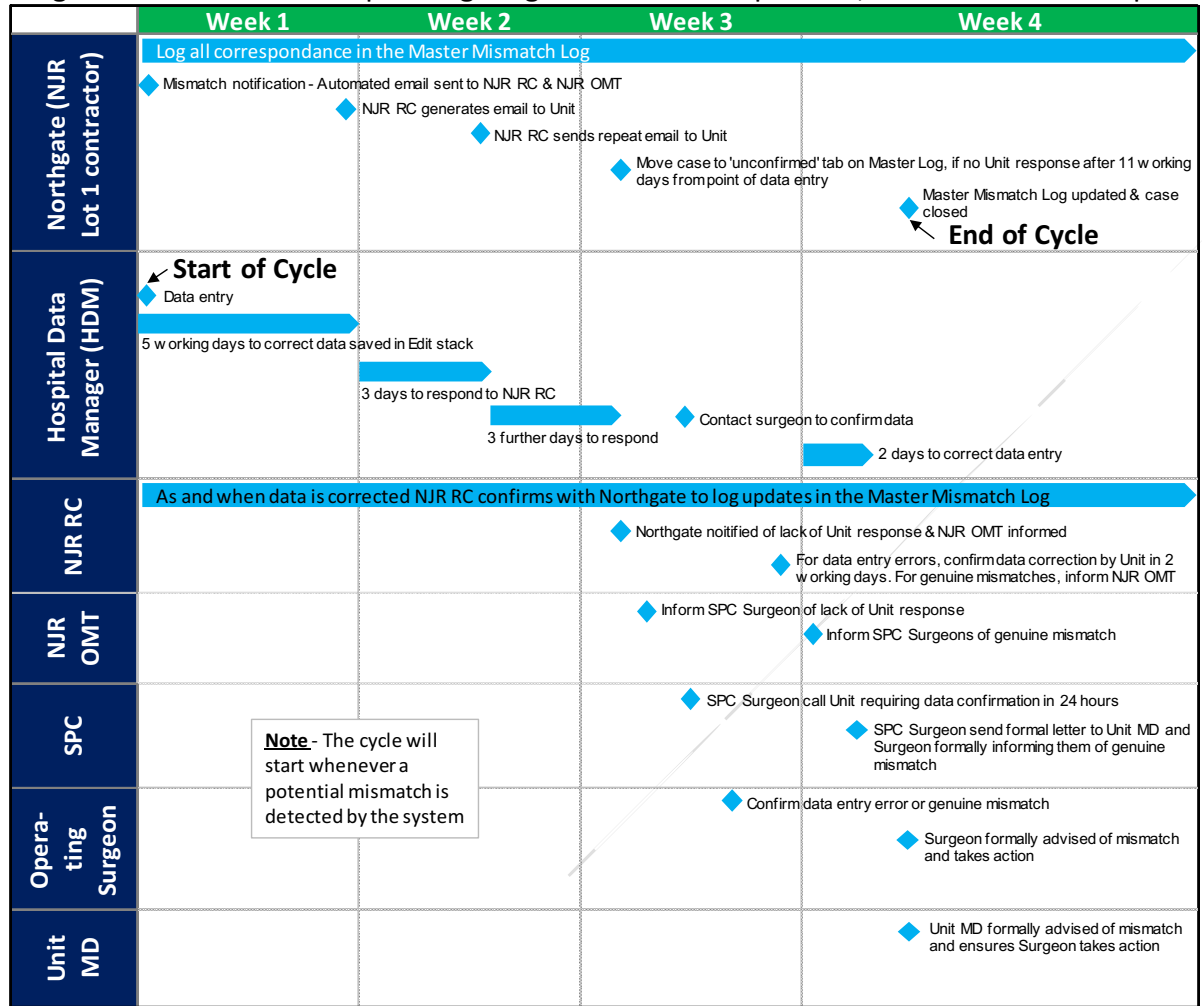


6.b) Implant Mismatch Notification Process – Data Saved. This process map sets out the steps by key stakeholder group for Implant Mismatch Notification in the case that mismatched data is saved onto the Edit Stack on the NJR system



14.3 Appendix 3: Notification cycle

This notification cycle shows the scheduling of key activities to be undertaken throughout any given year by Northgate, HDM, NJR RC, NJR Surgeons & OMT and the Operating Surgeons & Units in question, in relation to the Implant Mismatch Notification Process



14.4 Appendix 4: RACI matrix

6.a) Implant Mismatch Notification Process – Data Submitted. This RACI matrix has been developed and agreed by all stakeholders, showing who is Responsible, Accountable, Consulted and Informed at each step of the process

Step	Swim Lane	Step Detail	Activity Step/ Decision/ Data	System host		NJR		Unit		
				Northgate (NJR Lot 1 contractor)	NJR RC	NJR OMT	SPC Surgeon	Hospital Data Manager	Surgeon	Unit MD
1	Hospital Data Manager (HDM)	Data entry	Start	I				R		A
2	Northgate (NJR Lot 1 contractor)	Potential mismatch detected on system	Activity Step	RA						
3	Northgate	Pop up message warning user of mismatch	Activity Step	RA				I		
4	HDM	User action	Decision					R		A
5	HDM	No further action	End					R		A
6	Northgate	System generated notification email sent to NJR RC, NJR Service Desk & added to Master Mismatch log	Activity Step	RA	I	I				
7	NJR RC	NJR RC investigates with Unit to determine if mismatch is genuine or not	Activity Step		RA			I		
8	HDM	Does unit respond within 2 working days?	Decision					R		A
9	NJR RC	Notify Northgate to move case to 'unconfirmed' tab on the Master Log & escalated to SPC Surgeons via NJR OMT	Activity Step	I	RA	I				
10	Northgate	Case moved to 'unconfirmed' tab on Master Mismatch Log	End	RA						
11	NJR Operational Management Team (OMT)	NJR OMT escalate to SPC Surgeons	Activity Step			RA	I			
12	SPC	SPC Surgeon makes call to Unit requiring them to confirm the data to the NJR RC	Activity Step	I	I	I	RA	I		
13	HDM	Does the Unit confirm genuine mismatch, having consulted the Operating Surgeon?	Decision		I			R	C	A
14	NJR RC	NJR RC informs NJR OMT of genuine mismatch & notifies Northgate to update the Master Log	Activity Step	I	RA	I				
15	NJR OMT	NJR OMT inform SPC Surgeons of genuine mismatch and request them to send Unit Potential Never Event Letter 1	Activity Step			RA	I			
16	SPC	SPC Surgeon sends Letter 1 to the Unit MD and Operating Surgeon/CiC formally informing them of the mismatch	Activity Step			R	A		I	I
17	Unit MD	Unit MD formally advised of mismatch	End							RA
18	Operating Surgeon/CiC	Operating Surgeon/CiC formally advised of mismatch	Activity Step						RA	
19	SPC	Does Operating Surgeon acknowledge letter?	Decision				I		RA	
20	SPC	No further action	End				RA			
21	SPC	SPC Surgeon sends follow up letter to Unit MD	Activity Step				RA			I
22	Unit MD	Unit MD receives follow up letter and ensures action is taken by Surgeon	End						I	RA
23	NJR RC	Outcome confirmed as data entry error and data correction arranged within 2 working days	Activity Step	I	RA	I	I			
24	HDM	Data entry amended	Activity Step	I				R		A
25	Northgate	Master Mismatch Log updated & case closed	End	RA		I				

6.b) Implant Mismatch Notification Process – Data Saved. This RACI matrix has been developed and agreed by all stakeholders showing who is Responsible, Accountable, Consulted and Informed at each step of the process

Step	Swim Lane	Step Detail	Activity Step/ Decision/ Data	System host				Unit		
				Northgate (NJR Lot 1 contractor)	NJR RC	NJR OMT	SPC Surgeon	Hospital Data Manager	Surgeon	Unit MD
1	Hospital Data Manager (HDM)	Data entry	Start	I				R		A
2	Northgate (NJR Lot 1 contractor)	Potential mismatch detected on system	Activity Step	RA						
3	Northgate	Pop up message warning user of mismatch	Activity Step	RA				I		
4	HDM	User action	Decision					R		A
5	HDM	No further action	End					R		A
6	HDM	Saved in Edit Stack as potential mismatch	Activity Step	I				R		A
7	Northgate	Automated notification email sent to NJR RC, NJR Service Desk & added to master log	Activity Step	RA	I	I				
8	NJR Regional Coordinator (RC)	NJR RC investigates with Unit to determine if mismatch is genuine or not	Activity Step		RA			I		
9	HDM	Is data corrected within 5 working days?	Decision		I			R		A
10	NJR RC	NJR RC Confirms with Northgate that the data has been corrected in the system	Activity Step	I	RA					
11	Northgate	NJR RC generates email to Unit	Activity Step	R	A			I		
12	HDM	Does Unit respond to email within 3 working days?	Decision	R	I			R		A
13	Northgate	Second email sent to Unit repeating the message in step 11	Activity Step	I	CI					
14	HDM	Does Unit respond within 3 further working days?	Decision		R	I				
15	NJR RC	Notify Northgate to move case to 'unconfirmed' tab on the Master Log & escalated to SPC Surgeons via NJR OMT	Activity Step	I	RA	I				
16	Northgate	Case moved to 'unconfirmed' tab on Master Mismatch Log	End	RA						
17	NJR Operational Management Team (OMT)	NJR OMT escalate to SPC Surgeons	Activity Step			RA	I			
18	SPC	SPC Surgeon makes call to Unit requiring them to confirm the data to the NJR RC	Activity Step	I	I	I	RA	I		
19	HDM	Does the Unit confirm genuine mismatch, having consulted the Operating Surgeon?	Decision		I			R	C	A
20	NJR RC	NJR RC informs NJR OMT of genuine mismatch & notifies Northgate to update Mismatch Log	Activity Step	I	RA	I				
21	NJR OMT	NJR OMT inform SPC Surgeons of genuine mismatch and request them to send Unit Potential Never Event Letter 1	Activity Step			RA	I			
22	SPC	SPC Surgeon sends Letter 1 to the Unit MD and Operating Surgeon/CIC formally informing them of the mismatch	Activity Step				RA		I	I
23	Unit MD	Unit MD formally advised of mismatch	End							RA
24	Operating Surgeon/CIC	Operating Surgeon/CIC formally advised of mismatch	Activity Step						RA	
25	SPC	Does Operating Surgeon acknowledge letter?	Decision				I		RA	
26	SPC	No further action	End				RA			
27	SPC	SPC Surgeon sends follow up letter to Unit MD	Activity Step				RA			I
28	Unit MD	Unit MD receives follow up letter and ensures action is taken by Surgeon	End						I	RA
29	NJR RC	Outcome confirmed as data entry error and data correction arranged within 2 working days	Activity Step	I	RA	I				
30	HDM	Data entry amended	Activity Step	I				R		A
31	Northgate	Master Mismatch Log updated & case closed	End	RA		I				

15 Glossary

A list of terms and abbreviations used:

ACR – Annual Clinical Report

BK – Bruce Keogh

BOA – British Orthopaedic Association

CEO – Chief Executive Officer

CLR – Consultant Level Report

CQC – Care Quality Commission

EC – Executive Committee

GMC – General Medical Council

HDM – Hospital Data Manager

HQIP – Healthcare Quality Improvement Partnership

ISC – Implant Scrutiny Committee

KPI – Key Performance Indicator

MAC – Medical Advisory Committee

MHRA – Medicines and Healthcare products Regulatory Agency

MoU – Memorandum of Understanding

NCAPOP – National Clinical Audit & Patient Outcomes Programme

NHSE – NHS England

NHSI – NHS Improvement

NJR – National Joint Registry

NJRSC – National Joint Registry Steering Committee

NJR OMT – NJR Operational Management Team

OMS – Outlier Management System

PPC – Professional Practice Committee

PTIR – Patient Time Incidence Rate

RACI – Responsible, Accountable, Consulted & Informed

RCS – Royal College of Surgeons

SLA – Service Level Agreement

SOP – Standard Operating Procedure

SPC – Surgical Performance Committee

SRR – Standardised Revision Ratio

ToR – Terms of Reference

UoB – University of Bristol

UAT – User Acceptance Testing

16 Definitions

OMS Process case status definitions:

Actively monitored - All previously opened cases are followed up for a minimum of five years for Alarm cases and three years for Alert cases. The transition from active monitoring to closed is formally approved and recorded by the SPC

Clear - A Surgeon or Unit that has never been through the Alert or Alarm Process (i.e. remained under the 95% line)

Closed case - Previously open case that has been actively monitored for a minimum of five years (Alarm) or three years (Alert) and whose recent performance is judged adequate by the SPC, or where the Surgeon has been confirmed as either dead or retired

New case - A case which changes status from Clear to Alert or Alarm

Open case - Investigation underway (Alarm cases under investigation and Alert cases until letter confirmation received)

A list of definitions of terms used:

Active Monitoring - Any Lead Surgeon or Unit that has triggered an Alert or Alarm Process. These will be reviewed at each SPC meeting to ensure there is an improvement in their performance trajectory for a minimum period of five years (for an Alarm) or three years (for an Alert).

Data Cut - Refers to the reporting period the data relates to.

Escalation - An open case in which final correspondence or submission deadlines have been breached or action plans are in the view of the SPC are insufficiently robust to resolve the underlying issues, or an actively monitored case whose performance fails to improve after completion of an Alert process.

Historical Outlier - Any previously identified Alarm or Alert Lead Surgeon or Unit that is no longer deemed an Alarm or Alert after five years of active monitoring. (These cases will be passively monitored as part of the ongoing process).

Lead Surgeon - A Surgeon (usually a consultant) that is identified in an NJR submission as being the named Surgeon responsible for that joint replacement patient.

Model Development Working Group - The group of key individuals who supported the development of the NJR Accountability and Transparency Model, namely:

Elaine Young (NJR Director of Operations), Peter Howard (SPC Chairman), Martyn Porter (NJR Medical Director), Matthew Porteous (SPC Vice Chair), Carolina Arevalo (NJR Operations Manager).

Passive Monitoring - Continuous monitoring, on a six-monthly cycle, of any Lead Surgeon or Unit who has previously been through the Alert or Alarm Process.

Persistent Outlier - A previous Alarm case (unusually being actively monitored) whose performance fails to improve after completion of an Alert process.

Note - For the three reports published, the data cut periods vary depending on the report and section of report:

Annual Clinical Report (ACR)

For the ACR, volumetrics are calculated based on the latest three financial years. Funnel plots are produced for the SRR life of registry and the latest five years (SMR is currently the same as the life of the registry, due to it turning five years old later in 2017).

The data cut is on 1st March for the production of funnel plots and the data for volumetric calculations is cut at the point of report (September/October 2017)

Clinician Level Report (CLR)

For the CLR, volumetrics are calculated based on the latest twelve-month and thirty-six-month financial year period. The data cut is made end June/beginning of July. Funnel plots are produced for the life of registry as well as the latest five year SRR.

NJR Annual Report (AR)

For the AR, part one is based on the latest financial year, part two and four are based on the latest calendar year and part three is based on the life of registry.

The data for parts two, three and four is cut on 1st March, whilst the data for part one is cut on 1st April.

Alert and Alarm Unit & Surgeon Process Data Analysis and Risk Adjustment:

The following factors are used in calculating the rates of revision for both Units and Surgeons and for hip and knee:

Data is adjusted for age, gender and indication for original primary (Osteoarthritis versus other indications and specifically for hip trauma).

Repeat analyses are done for various subgroups that may change but currently include:

- a. Exclusion of withdrawn implants, three years after withdrawal
- b. Primaries within five years only (i.e. within five year interval prior to cut-point for data analysis)
- c. Subgroups of hips, namely cemented, uncemented and hybrid stemmed, non-metal on metal hips, all metal on metal hips and all resurfacings

- d. Subgroups of knees, namely cemented, uncemented/hybrid, unicondylar and patellofemoral

NJR Implant Performance Data Analysis Methodology:

Purpose: to use the data collected by the NJR about joint replacement surgery in order to provide an early warning of issues relating to patient safety. This includes issues around the comparative performance of implants and implant combinations.

Goals: to support suppliers in the routine post-market surveillance of implants and provide information to clinicians, patients, hospital management and the regulatory authorities. It is worthy of note that this process is not a substitute for pre-market properly designed and conducted randomised trials for new implant designs.

Implant performance analysis Aim: To detect primary implants with particularly high (or low) revision rates Indicator: Person time incidence rates with 95% confidence intervals (CIs)

Person time incidence rates (PTIR) Definition: the number of new cases (in this context revisions) per population at risk in a given time period. The NJR expresses the PTIR as the number of revisions per 100 patient years at risk.

Denominator: the sum of the person-time of the at risk population expressed as person years. For example, 100 person years could mean:

- 10 persons followed for 10 years
- 100 persons followed for 1 year
- 200 persons followed for 6 months

Comparator: the PTIR for a particular implant or brand are referenced against the group PTIR so in order to conduct that comparison, we need to know:

- Brand number of primaries
- Brand PTIR and corresponding upper and lower limits of 95% CIs
- 'Group' PTIR and corresponding upper and lower limits of 95% CIs
- Criteria for the thresholds of interest which are defined a priori

Group PTIR: An estimate of the PTIR that would be expected for the brand, based on the proportions of implants that are (i) cemented, uncemented, hybrid, reverse hybrid or resurfacing for hips and (ii) cemented, uncemented, hybrid, patellofemoral and unicondylar for knees; rates for these groups being derived from the whole hip or knee cohorts.

Calculation:

$$\text{Brand PTIR} = \frac{\text{Number of first revisions of brand over analysis period}}{\text{Total time all implants of this brand have been at risk of revision}}$$

As an example, the overall rates in 2016 were 0.53 (95%CI 0.53-0.54) per 100 patient-years in hips and 0.49 (95%CI 0.49-0.50) in knees.

Outlier status: in order to define whether an implant is an outlier, its PTIR and associated 95% confidence intervals are compared with the group PTIR and its 95% confidence intervals. Different thresholds are defined for different levels of outlier status (e.g. 2 times the group rate for Level 1 and 1.5 times the group rate for Level 2). In order to allow for any imprecision in the estimates around the calculation of the group rates and their multipliers, the upper 95% confidence interval is used as the threshold for comparison to the brand rate. The lower 95% confidence interval of the brand rate must therefore exceed the upper 95% confidence interval of threshold of interest. It is worth noting that the number of cases that contribute to the calculation of the group rates are now so large that the width of the 95% confidence interval is becoming negligible (typically in the order of PTIR 0.05).

Level 1 outlier status (figure 1): this is the highest level of outlier. To define whether an implant has a rate of revision that makes it a Level 1 outlier above the group revision rates:

- There must have been more than 100 primary procedures where the implant has been implanted (implants used in less than 100 cases are excluded from Level 1 outlier classification)
- The brand or implant PTIR must be at least two times higher than the group PTIR.

To do this the levels of uncertainty in the PTIR estimates (i.e. the 95% CIs) are taken into account, thus the lower limit of the brand or implant 95% CI must exceed the upper limit associated with a doubling of the group rate.

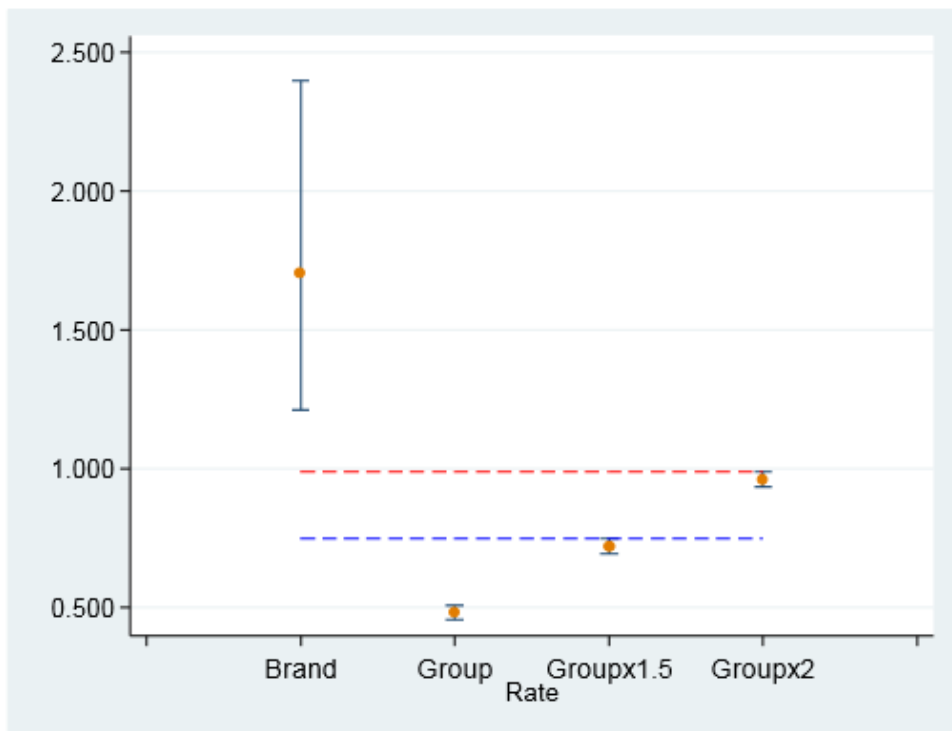


Figure 1: Illustration of level 1 outlier

- Figure 1 demonstrates a theoretical knee prosthesis with more than 100 implantations and a brand rate PTIR of 1.70 (95% CI: 1.21,2.40). In order to determine the group rate, the proportion of the implanted brand that were cemented, uncemented, hybrid, patellofemoral and unicondylar replacements is calculated. The group rate is then calculated according to the same proportion across the whole knee cohort, in this case the group rate PTIR is 0.48 (95% CI: 0.45,0.51). The blue dashed line indicates the upper 95% confidence interval of the 1.5 times the group rate estimate and the red dashed line, the upper 95% confidence interval for 2 times the group rate estimate. It can be seen that the lower 95% confidence interval of the brand PTIR exceeds both of these and therefore the implant is a Level 1 outlier.

Level 2 outlier status: this is the second level of outlier status and can apply to implants with either less than 100 implantations or those with more than 100 implantations. Level 2 outlier status with more than 100 primary implantations (figure 2):

- The brand or implant PTIR must be at least 1.5 times greater than the group PTIR and the lower limit of the brand or implant 95% confidence interval must exceed the upper limit associated with a 50% increase in the group rate (but not a doubling, which otherwise would define Level 1).

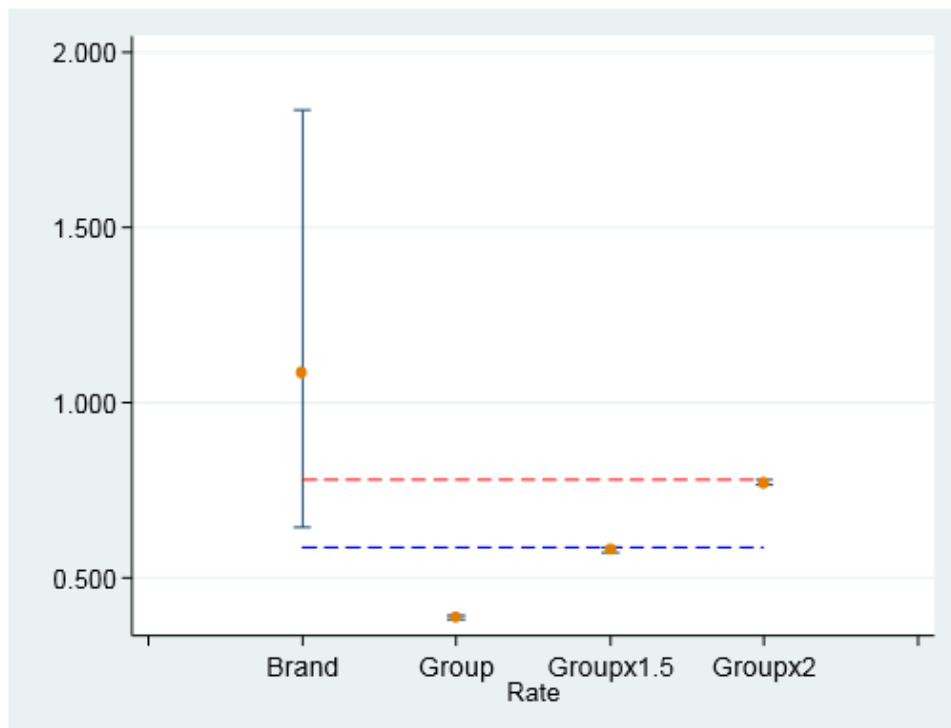


Figure 2: Illustration of level 2 outlier

- Figure 2 demonstrates a theoretical knee prosthesis with more than 100 implantations and a brand rate PTIR of 1.09 (95% CI: 0.64,1.83). In order to determine the group rate, the proportion of the implanted brand that were cemented, uncemented, hybrid, patellofemoral and unicondylar replacements is calculated. The group rate is then calculated according to the same proportion across the whole knee cohort, in this case the group rate PTIR is 0.39 (95% CI: 0.38,0.39). The blue dashed line indicates the upper 95% confidence interval of the 1.5 times the group rate estimate and the red dashed line, the upper 95% confidence interval for 2 times the group rate estimate. Even though the brand PTIR is more than double the group PTIR, it can be seen that the lower 95% confidence interval of the brand PTIR exceeds only the upper 95% confidence interval for 1.5 times the group rate and therefore this implant is a Level 2 outlier.

Level 2 outlier status with fewer than 100 primary implantations:

- The brand or implant PTIR must be at least two times greater than the group PTIR with consideration of the levels of uncertainty, as for Level 1.

Limitations

PTIR: Assumes the hazard rate (the risk of revision at any point in time given the implant has not been revised up to that point in time) is constant across the whole time implants are at risk of revision.

Registry data: Can demonstrate association but when considered in isolation, not causation.