National Joint Registry
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National Joint Registry Accountability and Transparency Model:

Implant Outlier Process
Standard Operating Procedure v2.0

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Implant Outlier Process Standard Operating Procedure

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National Joint Registry Surgical Performance Committee (SPC)	SPC Chair
Implant Scrutiny Committee (ISC)	ISC Chair
NJR Operational Management Team (NJR OMT)	NJR Director of Operations
MHRA	Data Integrity Team Manager Devices Information & Operations Group

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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.

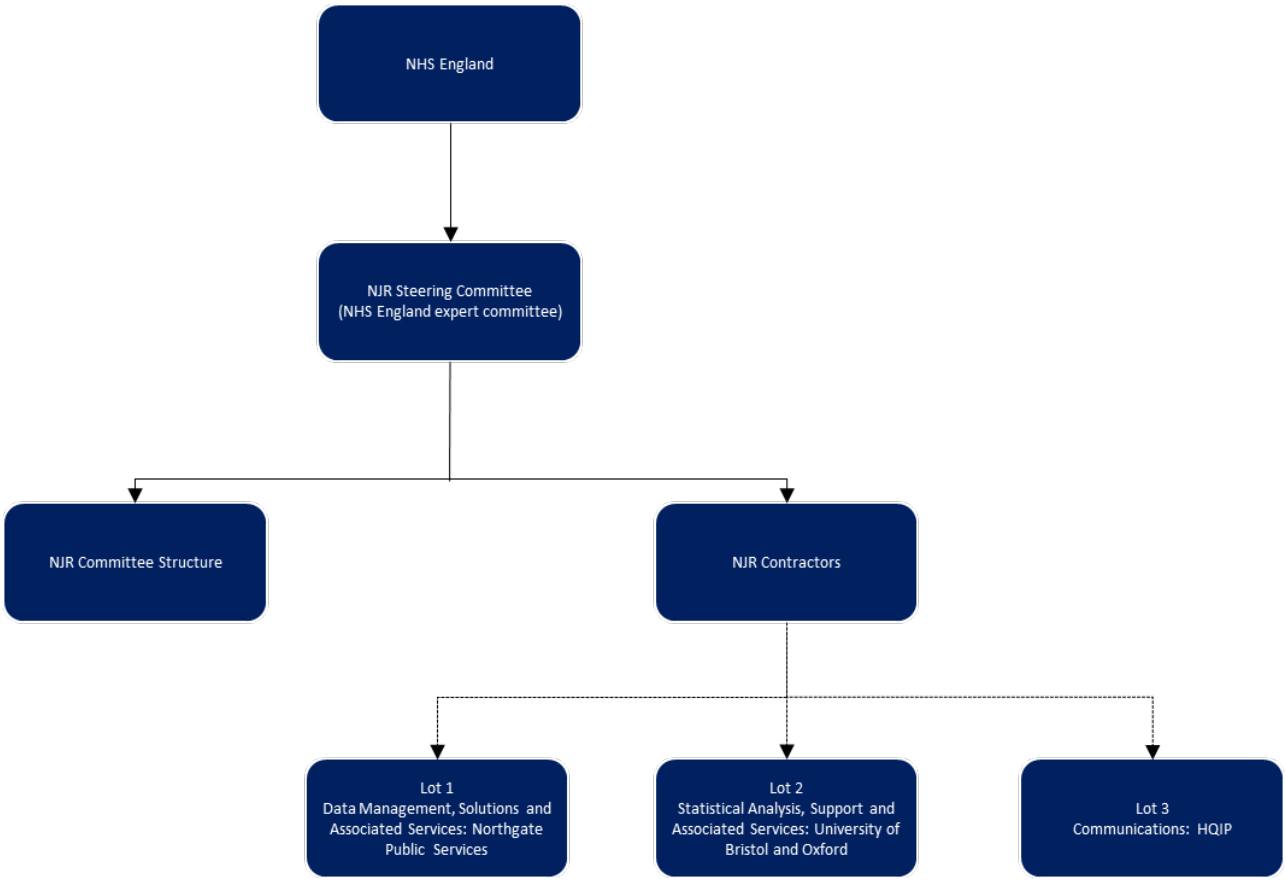


Diagram 1: NJR governance structure

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

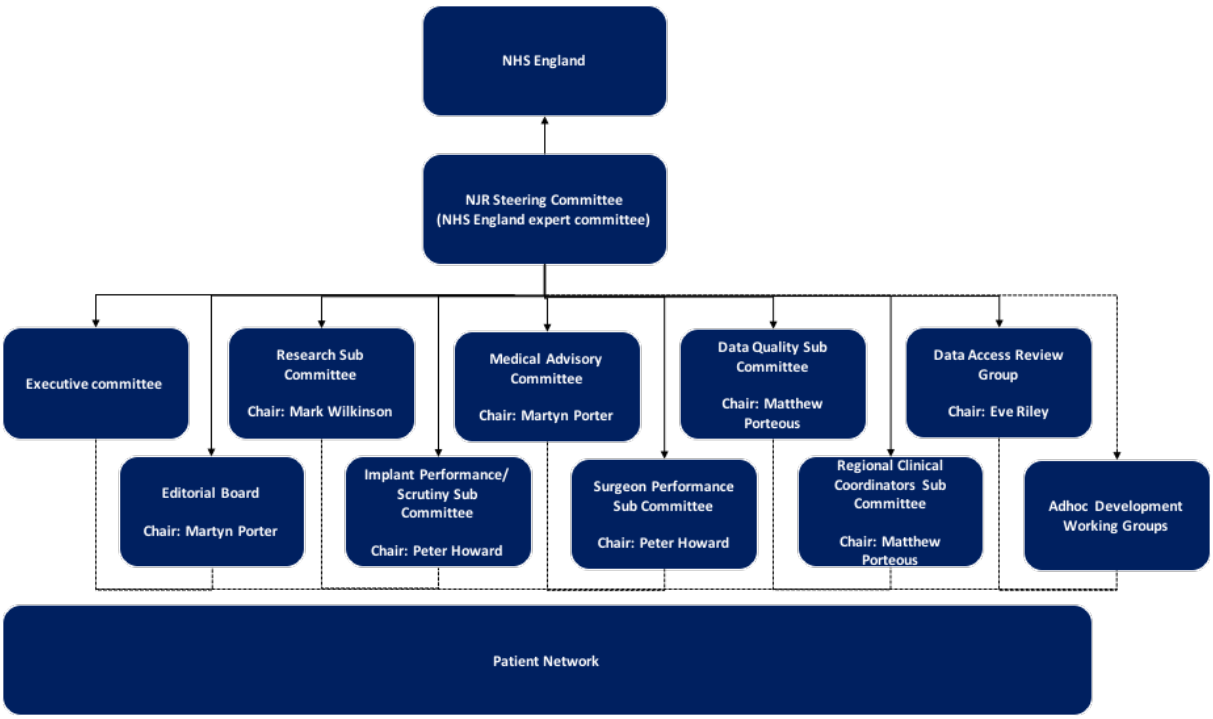


Diagram 2: NJR committee structure

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 Outlier Process SOP is to provide clarity and confirmation on the process steps for the identification and notification of implant outliers. It lists out what action should be taken, who should take it, and when, in order to ensure replication and quality control.

The NJR supports implant suppliers in the routine post-market surveillance of implants and provides information to clinicians, patients, hospital management and the regulatory authorities. Note that the Implant Outlier Process is not a substitute for pre-market properly designed and conducted randomised trials for new implant designs.

The NJR process identifies hip and knee implants which fall outside designated patient time incidence rate (PTIR) confidence intervals and is a defined mechanism for contacting the implant manufacturer and regulators in order to provide early warning of issues relating to patient safety, so appropriate action can be taken.

6 Scope

6.1 Scope of the Implant Outlier Process

The Implant Outlier Process applies to implant outlier reporting in England, Wales, Northern Ireland and the Isle of Man.

Trigger points for outlier notification

A **Level 1** implant outlier notification process is triggered when an implant has a patient time incidence rate (PTIR) of at least twice the overall PTIR, for implants that have been used in at least 100 primary operations in the NJR.

A **Level 2** implant outlier notification process is triggered when an implant has a PTIR of at least twice the overall PTIR, for implants that have been used in less than 100 primary

operations in the NJR. **Or** when an implant has a PTIR of at least one and a half times the overall PTIR, for implants that have been used in at least 100 primary operations in the NJR.

The definition and calculation of the PTIR can be found in *Section 15: Definitions* under the heading: *NJR Implant Performance Analysis Methodology*.

6.2 Frequency of mismatch notification

Outlier notifications are triggered every six months (March and August) after each data refresh. The timetable is set so data analysis can be fed into the NJR Annual Report, which are available to Units in October each year.

7 Process maps

The process map in Table 1 has been developed. It outlines the core activities relating to the Implant Outlier 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
7	Implant Outlier Process	This process map sets out the steps by key stakeholder group for implant outlier reporting	2	15

Table 1: Implant Mismatch Notification Process map descriptions

8 Annual cycles

An annual cycle has been developed. This provides an overview of the key recurring activities that would take place in each period for the Implant Outlier Process.

The annual 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 reporting 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 Outlier 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	• Responsible for producing data set at agreed time and providing it to the Lot 2 contractor • Outlier Management System (OMS) host and support	Head of Health Solutions
University of Bristol (UoB), NJR Lot 2 contractor	• Analyses and provides implant performance data in line with NJR requirements • Responsible for notifying the ISC of the outlier status of all implants under review	Contract Manager
Implant Scrutiny Committee (ISC)	• Responsible for oversight and sign off of the review and analysis of data provided by UoB. To ensure it is perceived as an accurate and fair representation • Responsible for all decision relating to implant performance • Responsible for informing the NJR OMT and MHRA of Level 1 implant outliers • Responsible for the management of ongoing monitoring of implant performance and manufacturer responses	ISC Chairman and Committee members
NJR Operational Management Team (NJR OMT)	• The NJR OMT are responsible and accountable for sharing Level 1 Implant details for the Annual Report	NJR Director of Operations
Implant Manufacturer	• Responsible for receiving (and internally managing) Level 1 status notifications • Responsible for responding to the ISC within 3 months with an action plan for Level 2 implant outliers	Manufacturing Company Representative

Medicines and Healthcare products Regulatory Agency (MHRA)	• Responsible for regulating implant performance • Responsible for undertaking investigations of Level 1 implants	MHRA President

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 Outlier 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
Level 1 implant outlier manufacturer notification	7. Implant_Level 1 Manufacturer_MHRA - Letter 3	ISC letter to the implant manufacturer(s) formally informing them of the Level 1 implant outlier
Level 2 implant outlier manufacturer notification	7. Implant_Level 2 Manufacturer - Letter 4	ISC letter to the implant manufacturer(s) formally informing them of the Level 2 implant outlier and request for response
Level 1 implant outlier MHRA notification	7. Implant_Level 1 Manufacturer_MHRA - Letter 3	ISC letter to the manufacturer is copied to the MHRA to formally inform them of the Level 1 implant outlier status
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 Outlier Process.

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

#	Risk/ issue	Description	Impact	Impact (I) (1-5) *pre-mitigation*	Probability (P) (1-5) *pre-mitigation*	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 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 regulators such as MHRA
4	Risk	There is a risk that time frames are not observed and underperforming implants remain on the market for too long	Patient welfare is at risk it they are receiving underperforming implants	5	2	10	Ensure any implant outliers are dealt with according to the process and all necessary implant outliers are escalated to MHRA as soon as possible

Table 4: Key risks and issues

12 Other points to be aware of

This SOP is subject to change as the Implant Outlier 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
University of Bristol (NJR Lot 2 contractor)	Development
NJR Implant Scrutiny 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

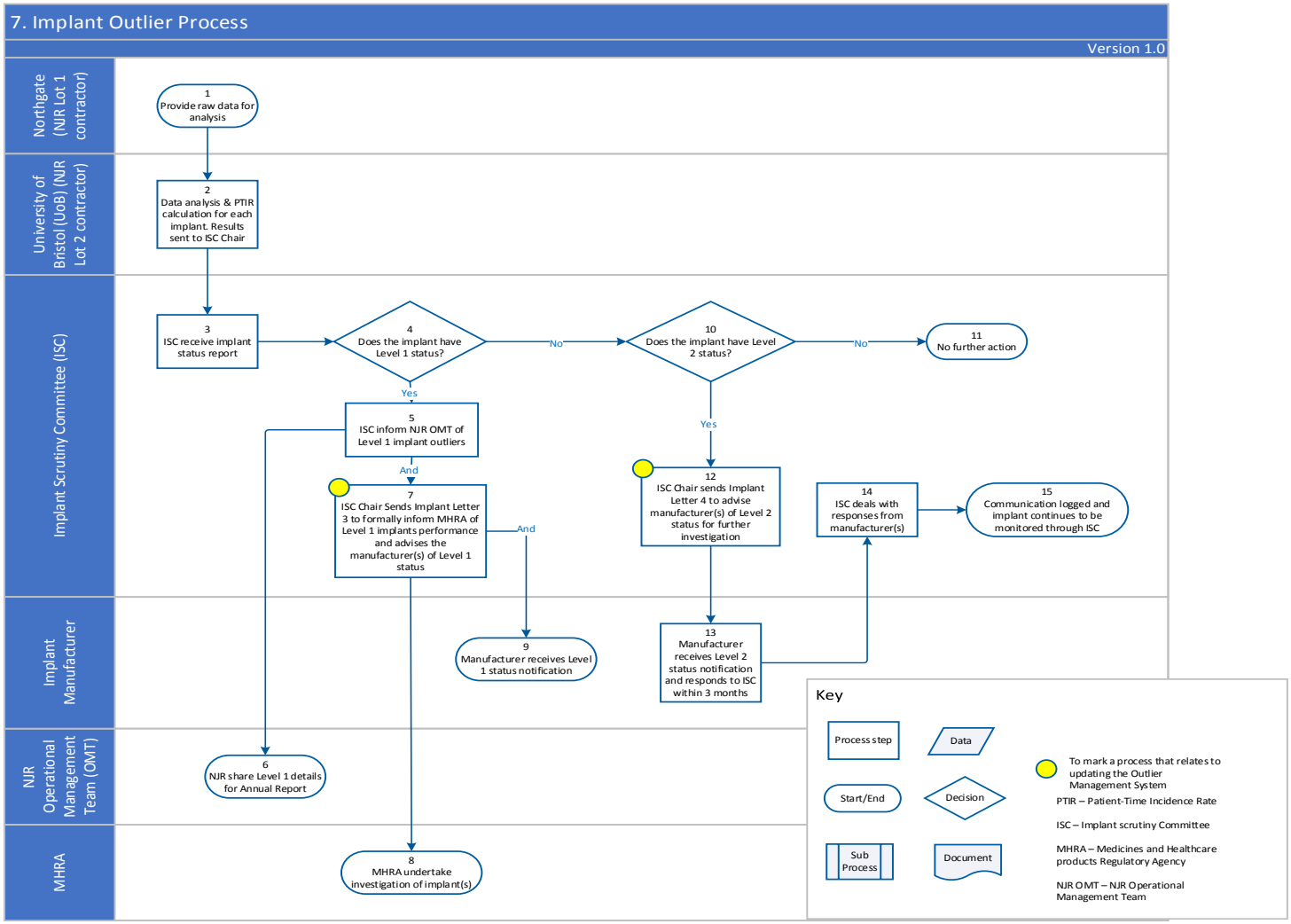
14 Appendix

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

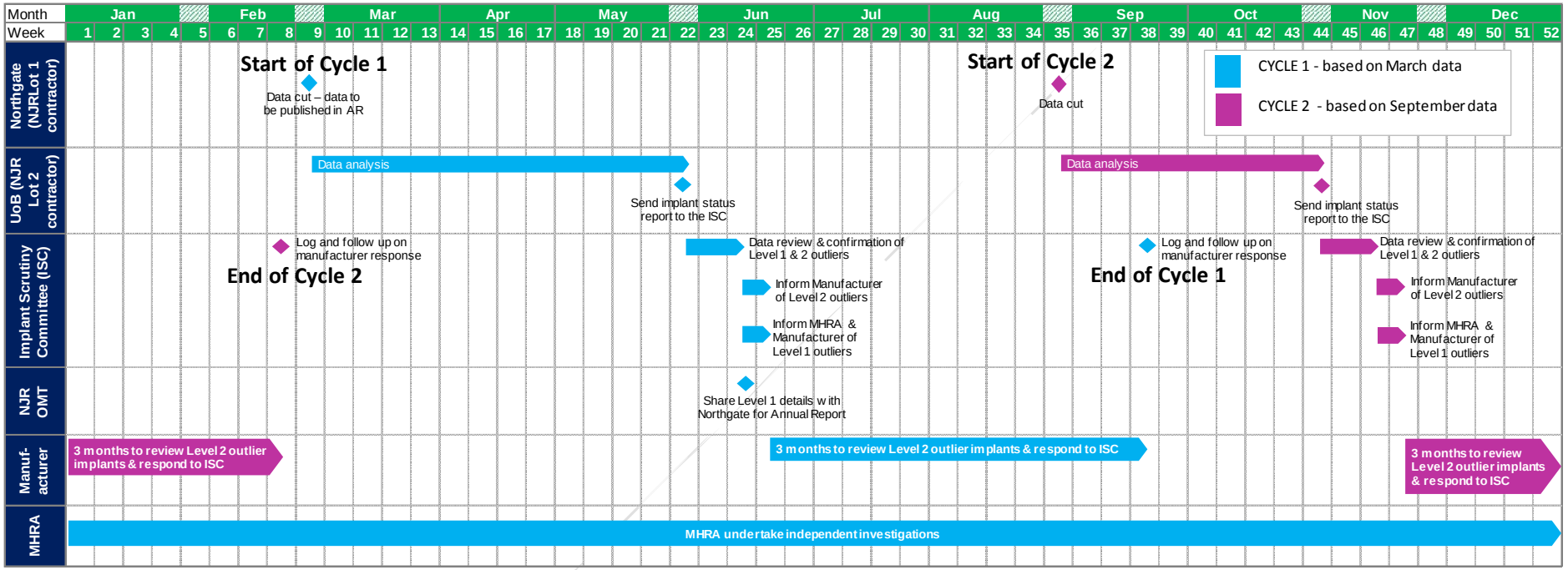
14.2 Appendix 2: Process maps

7. Implant Outlier Process. This process map sets out the steps by key stakeholder groups for the Implant Outlier Process



14.3 Appendix 3: Annual cycle

This notification cycle shows the scheduling of key activities to be undertaken throughout any given year by Northgate, UoB, NJR OMT, the ISC, MHRA and the implant manufacturer in question, in relation to the Implant Outlier Process



14.4 Appendix 4: RACI matrix

7. Implant Outlier Process. 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

				Data analytics	System host	NJR		Supplier	Regulators
Step	**Swim Lane**	**Step Detail**	**Activity Step/ Decision/ Data**	**UoB (NJR Lot 2 contractor)**	**Northgate (NJR Lot 1 Contractor)**	**NJR OMT**	**Implant Scrutiny Committee (ISC)**	**Implant Manufacturer**	**MHRA**
1	Northgate (Lot 1 contractor)	Provide raw data for analysis	Start	I	RA	I			
2	University of Bristol (UoB)	Data analysis & PTIR calculation for each implant. Results sent to ISC Chair	Activity Step	RA			I		
3	Implant Scrutiny Committee (ISC)	ISC receive implant status report	Activity Step				RA		
4	ISC	Does the implant have Level 1 status?	Decision				RA		
5	ISC	ISC inform NJR OMT of Level 1 implant outliers	Activity Step			I	RA		
6	NJR Operational Management Team (OMT)	NJR share Level 1 details for Annual Report	End		I	RA			
7	ISC	ISC Chair sends Implant Letter 3 to formally inform MHRA of Level 1 implants performance and advises the manufacturer(s) of Level 1 status	Activity Step				RA	I	I
8	MHRA	MHRA undertake investigation of implant(s)	End				C	R	RA
9	Implant Manufacturer	Manufacturer receives Level 1 status notification	Activity Step					RA	
10	ISC	Does the implant have Level 2 status?	Decision				RA		
11	ISC	No further action	End				RA		
12	ISC	ISC Chair sends Implant Letter 4 to advise manufacturer(s) of Level 2 status for further investigation	Activity Step				RA	I	
13	Implant Manufacturer	Manufacturer receives Level 2 status notification and responds to ISG within 3 months	Activity Step				I	RA	
14	ISC	ISC deals with responses from manufacturer(s)	Activity Step				RA		
15	ISC	Communication logged and implant continues to be monitored through ISC	End			I	RA		

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.

<u>Alert and Alarm Unit & Surgeon Process Data Analysis and Risk Adjustment:</u>

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

<u>NJR Implant Performance Data Analysis Methodology:</u>

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:

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

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.

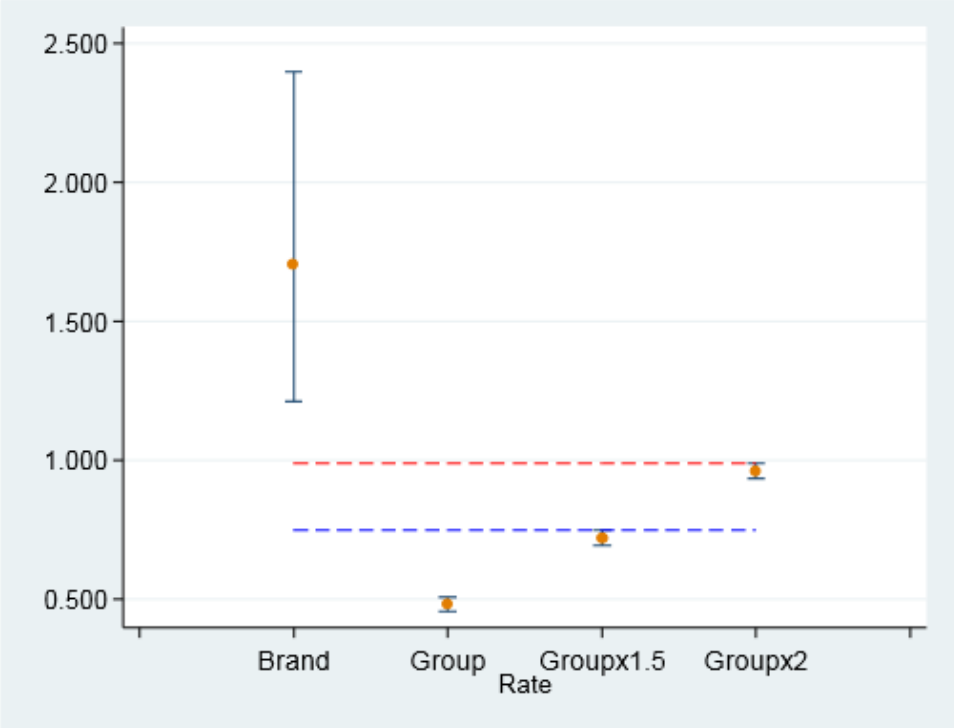


Figure 1: Illustration of level 1 outlier

• 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).

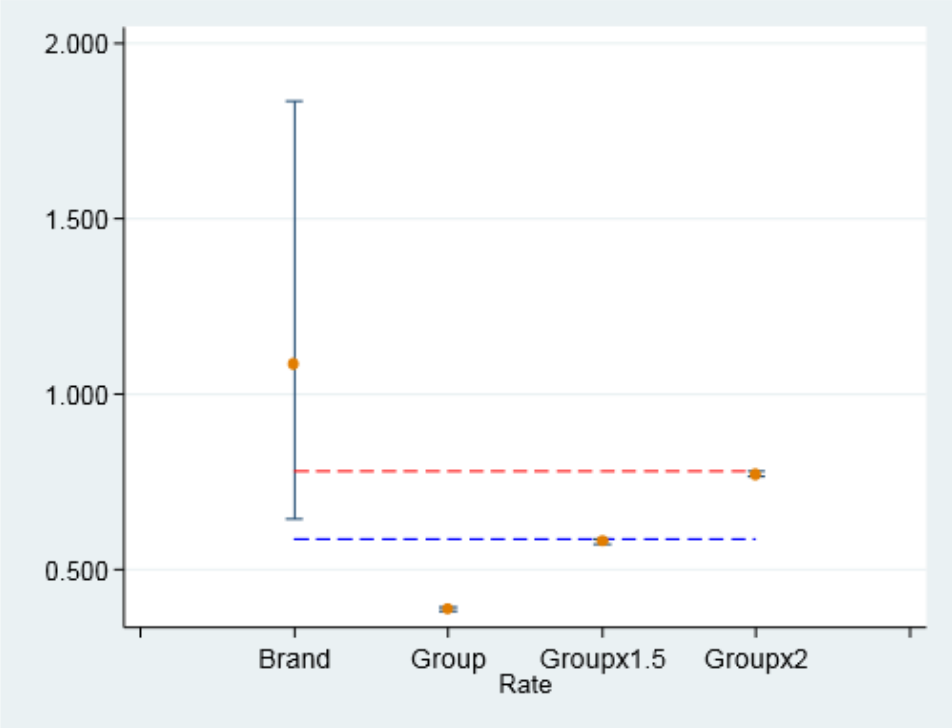


Figure 2: Illustration of level 2 outlier

• 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.