British Spine Registry

Cause for Concern Policy

January 2026

Purpose

The British Spine Registry (BSR) exists to improve the quality of care for patients having spinal surgery, assessing complications, PROMs and PREMS.

The BSR also assesses implant related complications and revision surgery in conjunction with the Orthopaedic Device Evaluation Panel (ODEP) and Beyond Compliance (BC): https://www.odep.org.uk/

Scope

Data is submitted by the clinical team recording diagnosis, co-morbidities and details about surgical procedures. Patients complete PROMs and PREMs electronically.

Data submission is incentivised by a Best Practice Tariff (https://www.england.nhs.uk/long-read/25-26-nhsps-annex-c-guidance-on-best-practice-tariffs/). Whilst most hospitals contribute to the British Spine Registry, case compliance as too low to confidently identify outliers.

This Policy is developed from the HQIP: Identification and Management of Cause for Concern in National Clinical Audits and Clinical Outcome Review Programmes in England and Wales. It covers concern which may arise from:

- Case-level data
- Clusters of cases
- Aggregate trends
- PROMs and PREMs

Cause for Concern

Cause for Concern refers to information submitted to the BSR that could suggest a serious issue with clinical practice or system failure that presents a risk of harm to patients.

Category 1: Single case record level evidence:

This will not be identified from data collected in the BSR and serious untoward incidents should be managed through normal Trust processes.

Category 2: Cluster of case record-level evidence:

Case clusters will not be identified from data collected in the BSR and serious untoward incidents should be managed through normal Trust processes.

Category 3: Emerging Aggregate Data:

If BSR analysis suggests problems with an implant, such as failure of the implant or problems in surrounding tissues, a report will be produced for discussion with the ODEP spine members. If this is considered to be a genuine concern, MHRA will be informed.

Category 4: PROMs and PREMs:

With less than 100% compliance, it is not possible to define a level of at which PROMs or PREMs could be considered a cause for concern. This will be reviewed as more data is analysed.

The process for raising concerns will follow HQIP advice:

If an NCAPOP project team identifies a cause of concern, the following process should be followed. Note that Table 1. indicates the process for healthcare providers in England and Table 2 indicates the process for Wales:

This escalation process is based on the process included in HQIP's outlier guidance. Due to the more heterogeneous nature of the information that could trigger a cause for concern, stage 1 below includes a discussion and agreement of the process for each case between the NCAPOP supplier and the relevant HQIP Associate Director, which in some circumstances will mean that the escalation stages and / or timelines are shortened or omitted. In other circumstances both may agree that escalation is not warranted.

Table 1: Cause for Concern escalation process for healthcare providers in England

Stage	What action?	Who?	Within how many working days
1	• Information is examined closely to determine its quality and completeness, the data handling and analyses performed to date, and the likely validity of the concern identified : 'No case to answer' • data and results revised in NCAPOP records • details formally recorded 'Case to answer' • Contact the project's allocated Associate Director at HQIP to discuss the nature of the cause for concern and agree next steps. HQIP AD to be kept appraised of the progress of the subsequent escalation process. • *Proceed to stage 2*	NCAPOP supplier	10
2	The Lead Clinician in the provider organisation (or equivalent in community care, such as the Local Area Coordinators) informed about the potential cause for concern and requested to identify any data errors or justifiable explanation/s where possible. All relevant data and analyses should be made available to the Lead Clinician. • A copy of the request should be sent to the provider organisation CEO and Medical Director. (For social care providers this would be the CQC-Registered Manager)	NCAPOP supplier lead	5
3	Lead Clinician (or equivalent) to provide written response to NCAPOP supplier.	Healthcare Provider Lead Clinician (or equivalent)	25
4	Review of Lead Clinician's response to determine: 'No case to answer' • It is confirmed that the data originally supplied by the provider contained inaccuracies. Re-analysis of accurate data no longer indicates significant cause for concern. • Data and results should be revised in NCAPOP records. Details of the provider's response and the review result recorded. •Lead Clinician notified in writing copying in provider organisation CEO and Medical Director. *Process ends*	NCAPOP Supplier	20

	'Case to answer' • It is confirmed that although the data originally supplied by the provider were inaccurate, analysis still indicates a significant cause for concern; or • It is confirmed that the originally supplied data were accurate, thus confirming the initial designation of cause for concern; or • No response from the Lead Clinician is forthcoming. *proceed to stage 5*		
5	Contact Lead Clinician by telephone, prior to sending written confirmation of the persistence of the cause for concern to CEO copied to Lead Clinician and Medical Director. All relevant data and statistical analyses, including previous response from the Lead Clinician, made available to the Medical Director and CEO. The requirement for the NCAPOP supplier to inform CQC[1] and for the Provider CEO to inform commissioners, NHS Improvement[2] and relevant royal colleges to be determined jointly by the HQIP Associate Director and the NCAPOP Supplier Clinical Lead.	NCAPOP Supplier lead	5
6	Acknowledgement of receipt of the letter confirming that a local review will be undertaken, copying in the CQC[3] as required.	Provider CEO (healthcare) / CQC Registered Manager (social care)	10
7	If no acknowledgement received, a reminder letter should be sent to the CEO, copied to CQC. If not received within 5 working days, CQC[4] and NHS Improvement[5] notified of non-compliance.	NCAPOP Supplier	5

[1] Via clinicalaudits@cqc.org.uk
[2] Via nhsi.medicaldirectorate@nhs.net
[3] Via clinicalaudits@cqc.org.uk
[4] Via clinicalaudits@cqc.org.uk
[5] Via nhsi.medicaldirectorate@nhs.net

Table 2: Cause for Concern escalation process for healthcare providers in Wales

Stage	What action?	Who?	Within how many working days
1	• Information is examined closely to determine its quality and completeness, the data handling and analyses performed to date, and the likely validity of the concern identified : 'No case to answer' • data and results revised in NCAPOP records • details formally recorded 'Case to answer' • Contact the project's allocated Associate Director at HQIP to discuss the nature of the cause for concern and agree next steps. HQIP AD to be kept appraised of the progress of the subsequent escalation process. • *Proceed to stage 2*	NCAPOP supplier	10
2	The Lead Clinician in the provider organisation (or equivalent in community care, such as the Local Area Coordinators) informed about the potential cause for concern and requested to identify any data errors or justifiable explanation/s where possible. All relevant data and analyses should be made available to the Lead Clinician. A copy of the request should be sent to the provider organisation CEO and Medical Director. (For social care providers this would be the Director of social services)	NCAPOP supplier lead	5
3	Lead Clinician (or equivalent) to provide written response to NCAPOP supplier.	Healthcare Provider Lead Clinician (or equivalent)	25

4	Review of Lead Clinician's response to determine: 'No case to answer' • It is confirmed that the data originally supplied by the provider contained inaccuracies. Re-analysis of accurate data no longer indicates significant cause for concern. • Data and results should be revised in NCAPOP records. Details of the provider's response and the review result recorded. •Lead Clinician notified in writing copying in provider organisation CEO and Medical Director. *Process ends* 'Case to answer' • It is confirmed that although the data originally supplied by the provider were inaccurate, analysis still indicates a significant cause for concern; or • It is confirmed that the originally supplied data were accurate, thus confirming the initial designation of cause for concern; or • No response from the Lead Clinician is forthcoming. *proceed to stage 5*	NCAPOP Supplier	20
5	Contact Lead Clinician by telephone, prior to sending written confirmation of the persistence of the cause for concern to CEO copied to Lead Clinician and Medical Director. All relevant data and statistical analyses, including previous response from the Lead Clinician, made available to the Medical Director and CEO. The requirement for the NCAPOP supplier to inform Welsh Government[6] and relevant royal colleges to be determined jointly by the HQIP Associate Director and the NCAPOP Supplier Clinical Lead.	NCAPOP Supplier lead	5
6	Acknowledgement of receipt of the letter confirming that a local review will be undertaken, copying in the Welsh Government[7]as required.	Provider CEO	10
7	If no acknowledgement received, a reminder letter should be sent to the CEO, copied to Welsh Government. If not received within 5 working days, Welsh Government notified of non-compliance.	NCAPOP Supplier	5

[6] Via wgclinicalaudit@gov.wales
[7] Via wgclinicalaudit@gov.wales

Changes and Revisions

This SOP cannot be amended without document permission of the BSR sub-committee and BASS Executive. It should be evaluated for revision in February 2027.