National Neonatal Audit Programme (NNAP) Cause for Concern Policy

V1.0, February 2026

1. Policy statement

This policy outlines the procedures for identifying and managing a "Cause for Concern" within the National Neonatal Audit Programme (NNAP), ensuring patient safety and quality care.

2. Purpose

The policy aims to:

- Define the basis for the Cause for Concern process.
- Ensure responsible parties review and manage incidents appropriately.
- Notify relevant stakeholders of serious clinical practice issues or system failures.

Failure to follow up on identified concerns may impact patient safety. This policy mitigates risks through clear criteria and processes.

3. Scope

This policy applies to all qualitative data that is collected and processed by the NNNAP, including survey responses and staff-reported measures. A cause for concern relates to the circumstance(s) in which information submitted to the NNAP reasonably suggests the presence of very serious issues with clinical practice or system failure that presents a risk of harm to patients. This may include:

- Significant risk or harm from care delivered to an individual
- Dangerous or dysfunctional equipment
- Death attributable to abuse or neglect without cross-agency involvement
- Staff displaying abusive behaviour, serious misconduct, or dangerous lack of competency.

A cause for concern may be raised at any point during the audit, and by anyone involved in the audit (HQIP, Integrated Care Boards (ICBs), Local Health Boards (LHBs), individual neonatal services or units, clinicians, patients, and/or the NNAP itself). Where the cause for concern is already being responded to as part of the NNAP Outlier Identification and Management Policy, that policy takes precedent.

The following table describes three categories of concern which may be identified and describes some potential scenarios for each category.

The Royal College of Paediatrics and Child Health is a registered charity in England and Wales (105774) and in Scotland (SCO38299)

Table 1: Categories and example scenarios by which a Cause for Concern response may be triggered.

Category	Description	Examples

Category 1	Single case record level evidence	Evidence from the care delivered to a single individual (the source of which may be a case record / PREM / PROM / Carer questionnaire or other) reflects care which:
		• Has put the patient at significant risk of harm or has caused significant harm · Indicates a dysfunctional or dangerous department or organisation
		• Indicates a death of a child or adult attributable to abuse or neglect, but no indication of cross-agency involvement (i.e. no mention of safeguarding, social services, police or Local Safeguarding Children Board (LSCB))
		• Indicates a staff member displaying the following behaviours (and where it is unclear if the incident has been reported to senior staff):
		  ○ Abusive behaviour (including allegations of sexual assault)
		  ○ Serious professional misconduct
		  ○ Dangerous lack of competency

Category 2	Cluster of case note-level evidence	A cluster of discrete events for example: • More than one case record review from the same healthcare provider cohort indicates significant risk of harm or has caused significant harm • More than one source of evidence of dangerous or dysfunctional individual or team behaviours.
Category 3	Emerging aggregate data trends	Emerging data within year suggests a spike in mortality or morbidity at team or organisation level, which is significantly out of keeping with comparable healthcare providers.

4. Process for raising a Cause for Concern

If the NNAP project team identifies a cause for concern, the following process should be followed.

Due to the heterogenous nature of the information that could trigger a cause for concern, stage 1 below involves a discussion and agreement of the process for each case between the NNAP team

and HQIP, which in some circumstances will mean that the escalation stages and timelines are shortened or omitted. In other circumstances, both may agree that escalation is not warranted.

Table 2: Cause for concern escalation process.

Stage	Action	Responsible party	Working days
1	NNAP team to examine, with input from appropriate RCPCH support teams, information closely to determine its quality and completeness, the data handling and analyses performed to date, and the likely validity of the concern identified. 'No cause for concern' • Data and results revised in the NNAP records and details formally recorded • Details formally recorded *Process ends* 'Cause for concern' • NNAP contact HQIP to discuss the nature of the cause for concern and agree next steps. HQIP to be kept appraised of the subsequent escalation process. *Proceed to stage 2*	NNAP team	10
2	Inform the healthcare provider's lead clinician about the potential cause for concern and provide all relevant data and analyses. Request that the lead clinician identifies any data errors or justifiable explanation where possible. A copy will be sent to the organisation's CEO and medical director.	NNAP team	5
3	Lead clinician to provide a written response to the NNAP team.	Healthcare provider lead clinician	25
4	Review of the lead clinician's response to determine if the concern is valid. 'No case to answer' • It is confirmed that the data originally supplied contains inaccuracies and re-analyses of the accurate data no longer indicates cause for concern • Data is revised in NNAP records and details formally recorded • Lead clinician notified in writing, copying in organisation's CEO and Medical Director.	NNAP team	20

	Process ends 'Case to answer' • It is confirmed that the data originally supplied was accurate, thus confirming the initial designation of cause for concern; or • It is confirmed that, although the data originally supplied by the provider were inaccurate, analyses still indicate a significant cause for concern; or • No response from the lead clinician *Proceed to stage 5*		
5	Contact the healthcare provider's lead clinician to confirm the persistence of the cause for concern, requesting that a local review be undertaken, copying in the CEO and Medical Director. The requirement for the NNAP to inform authorities to be determined jointly by the HQIP Associate Director and NNAP Clinical Lead (Table 3).	NNAP team/HQIP	5
6	CEO and/or medical director acknowledges receipt of the notification and confirms that a local review will be undertaken.	Provider CEO and/or medical director	10
7	Send a reminder if no acknowledgment is received and notify relevant authorities* of non-compliance.	NNAP team	5

*The relevant authorities in each country are listed in table 3 below

Table 3: Relevant authorities in England, Wales and Scotland

Country	Authorities
England	Care Quality Commission, NHS Improvement, commissioners, and the relevant royal colleges.
Wales	Welsh Government (via wgclinicalaudit@gov.wales) and the relevant royal colleges.
Scotland	Scottish Government (via MaternalandInfantHealth@gov.scot) and the relevant royal colleges.

References

- HQIP Cause for Concern Guidance (February 2019)