National Paediatric Diabetes Audit (NPDA) Cause for Concern Policy

V1.0, February 2025

1. Policy Statement

This policy outlines the procedures for identifying and managing a "Cause for Concern" within the National Paediatric Diabetes Audit (NPDA), 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.

3. Scope

This policy applies to all qualitative data that is collected and processed by the NPDA, including patient survey responses and staff-reported measures. A cause for concern relates to the circumstance(s) in which information submitted to the NPDA 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 paediatric services or units, clinicians, patients, and/or the NPDA itself). Where the cause for concern is already being responded to as part of the NPDA Outlier Identification and Management Policy, that policy takes precedent.

Causes for concern may be raised or become apparent in any of the NPDA data streams, including the Parent and Patient Reported Experience Measures questionnaires, the core NPDA audit, or NPDA spotlight audits. The following table describes three categories of concern which may be identified and describes some potential scenarios for each category.

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	- Contact from an Integrated Care Board regarding quality issues at a participating paediatric service within a particular Trust/Health Board. - Information from within a particular department indicating a cause for concern within the Trust/Health Board.
Category 2	Cluster of case note-level evidence	- Multiple cases indicating significant risk or harm from the same provider. - Evidence of dangerous or dysfunctional behaviour by individuals or teams.
Category 3	Emerging aggregate data trends	- Data showing a significant spike in mortality or morbidity out of keeping with comparable providers.

4. Process for Raising a Cause for Concern

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 NPDA 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	NPDA 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 NPDA records and details formally recorded • Details formally recorded • ***Process Ends*** 'Cause for concern' • NPDA contact HQIP to discuss the nature of the cause for concern and agree next steps. • ***Proceed to stage 2***	NPDA Team/Clinical Leads	10
2	Inform the healthcare provider's Lead Clinician about the potential cause for concern and provide relevant data. 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.	NPDA Team/Clinical Leads	5
3	Lead Clinician to provide a written response to the NPDA 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	NPDA Team/Clinical Leads	20

	• Data is revised in NPDA records and details formally recorded • Lead clinician notified in writing, copying in organisation's CEO and Medical Director. • ***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 Discuss with HQIP about informing relevant authorities (table 3).	NPDA Team/Clinical Leads	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.	NPDA Team/Clinical Leads	5

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

Table 3: Relevant authorities in England, Wales, and Jersey

Country	Authorities
England	Care Quality Commission, NHS Improvement, commissioners, and the relevant royal colleges.
Wales	Welsh government and the relevant royal colleges.
Jersey	HSS Clinical Audit Department (HssClinicalAuditdepartment@health.gov.je)

5. Risks

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

6. Policy Compliance

Guidance for NPDA participants, with additional advice available from the NPDA Project Manager or HQIP Project Manager.

8. References

- HQIP Cause for Concern Guidance (February 2019)