Identification and Management of Cause for Concern in National Clinical Audits and Clinical Outcome Review Programmes in England and Wales

Guidance prepared by HQIP in consultation with National Clinical Audit and Patient Outcomes Programme Suppliers, CQC, and the Welsh Government , February 2019.

Title	Identification and Management of Cause for Concern in National Clinical Audits and Clinical Outcome Review Programmes in England and Wales
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Circulation List	Chief Executives, Medical Directors, Clinical Directors, Commissioners, Provider Organisations, Suppliers of National Clinical Audits, Specialist Societies, Regulatory Bodies.
Description	This guidance is designed to support NCAPOP suppliers in identifying the steps to be taken if information they acquire indicates a serious risk of harm to patients. The guidance primarily pertains to the National Clinical Audit and Patient Outcomes Programme (NCAPOP), but may also be useful to Non-NCAPOP projects.
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Cause for concern guidance - National Clinical Audit and Patient Outcomes Programme (NCAPOP)

1. Introduction

All projects in the NCAPOP are designed to systematically assess care quality and highlight, for a given cohort or sample of patients, the quality of care delivered, the outcomes of care, and where poor practice and opportunities for improvement can be identified.

Three pieces of NCAPOP guidance govern how instances of care quality which fall outside of the expected range should be managed. These guidance documents are listed in the table 1 below.

Table 1: NCAPOP guidance relating to the identification of care quality falling outside the expected range

Title	Applies to:
'*Detection and management of outliers for National Clinical Audit*'	National Clinical Audits
'Detection and management of outliers for national clinical audits: Implementation guide for NCAPOP providers'	
Cause for Concern Guidance (this document)	National Clinical Audits and Clinical Outcome Review Programmes (CORP) (formerly known as Confidential Enquiries)

Where the above guidance applies, and based on these documents, all NCAPOP suppliers should develop and publish topic-specific protocols for both outliers and cause for concern.

2. Purpose

The purpose of this guidance is to:

- Describe what the term 'Cause for Concern' means in the context of NCAPOP delivery.
- Support NCAPOP suppliers to:
    - Understand in relation to Cause for Concern:
        - Their own responsibilities,
        - What they should expect from healthcare providers and / or healthcare commissioners, and
        - How HQIP should be engaged in the process.
    - Develop their project-specific Cause for Concern policies

3. Cause for Concern as it relates to the NCAPOP

For national clinical audits, the systematic, statistics-based assessment of care quality delivered for a cohort of patients, and the process of identifying and managing outliers is covered by the outlier guidance referenced above.

- Cause for concern guidance applies to both national audits and clinical outcome review programmes.
- It relates to the rare circumstance in which information submitted to the NCAPOP supplier could reasonably suggest the presence of very serious issues with clinical practice or system failure that presents a risk of harm to patients.
- Where the information is already being responded to as part of an audit's normal outlier process, the outlier policy takes precedent.
- Raising a Cause for Concern does not commit the NCAPOP providers to any additional responsibilities under Duty of Candour beyond notifying the healthcare provider of the concern identified. This is because the Duty is a requirement placed on 'registered persons when they are carrying on a regulated activity'.

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

Table 2: Categories and example scenarios by which a Cause for Concern response may be triggered

Category no.	Category description	Example scenarios
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): o Abusive behaviour (including allegations of sexual assault) o Serious professional misconduct o Dangerous lack of competency

Category 2	**Cluster of case record-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 an NCAPOP project team identifies a cause of concern, the following process should be followed. Note that Table 3. indicates the process for healthcare providers in England and Table 4 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 3: 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' o 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* '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 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

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

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

Table 4: 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' o 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] Via clinicalaudits@cqc.org.uk
[4] Via clinicalaudits@cqc.org.uk
[5] Via nhsi.medicaldirectorate@nhs.net

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