National Maternity and Perinatal Audit (NMPA) Outlier Policy

Introduction

This document provides an overarching outlier policy statement for the National Maternity and Perinatal Audit (NMPA). The outlier process aims to facilitate clinical improvement and reduce variation in practice by using audit data to identify areas where improvement is required.

The policy sets out:

- How data submitted to the NMPA will be analysed to detect potential outliers (NHS maternity service providers that have a result for a specific performance indicator that falls outside a predefined range).
- How the NMPA team will engage with NHS maternity service providers that are identified as potential outliers.

Choice of performance indicators for outlier reporting

The NMPA performance indicators measure a range of processes and outcomes of maternity care. These indicators were selected on the basis of a number of criteria,[1] including that they need to:

- be valid and accepted measures of a provider's quality of care
- meet feasibility and data quality standards – that available information can correctly identify the required women and babies and their associated features and outcomes
- be fair – it should be possible to accurately adjust for the differing case mix of women and babies between participating data providers
- occur frequently enough to provide sufficient statistical power for analysis to identify outlying performance.

The performance indicators selected for outlier reporting were chosen because they represent adverse outcomes for women or babies with potential serious or long-term effects. The performance indicators included in the outlier reporting for the 2016/17 NMPA Clinical Report are:

- Proportion of women who sustained a 3rd or 4th degree perineal tear
- Proportion of women with an obstetric haemorrhage of 1500 ml or more
- Proportion of singleton, term, liveborn infants with a 5-minute Apgar score of less than 7

The level of reporting for the performance indicators is NHS Trust in England and Health Board in Scotland and in Wales.

The results for each of the performance indicators are adjusted for case-mix. For more detail about the data quality checks, the case-mix factors for these performance indicators, and how the performance indicators are defined and calculated, please see the NMPA Technical Specification.

[1] Geary RS, Knight HE, Carroll FE, Gurol-Urganci I, Morris E, Cromwell DA, van der Meulen JH. A step-wise approach to developing indicators to compare the performance of maternity units using hospital administrative data. BJOG. 2018 Jun;125(7):857-865.

Data sources

The analyses that the NMPA carries out are restricted to NHS maternity service providers that passed the NMPA Trust or Board level data quality checks. This means that there will be no results available for some Trusts and Health Boards. If that is the case, results for these Trusts or Health Boards will be listed as 'No data available/data unsuitable for analysis'.

Detection of a potential outlier

The target for the expected performance is based on the average performance of all maternity service providers. Statistically derived limits around this target are used to define whether a participating Trust or Health Board is a potential outlier.

A result for a performance indicator that is higher than the upper 99.8% control limit is considered to be an **'alarm'**. The Trust or Health Board is then deemed a potential outlier and will be required to follow all steps in the outlier management process shown below.

Results that fall in the range between the upper 95% and 99.8% control limits are considered to be **'alerts'**. A relatively large number of Trusts and Health Boards will have results for performance indicators within this range. These Trusts or Health Boards will be notified but they will not be required to follow the outlier management process.

Management of a potential outlier

The following table summarises the key steps that the NMPA will follow in managing potential outlier maternity service providers, including the action required, the people involved, and the maximum time scales.

Trusts and Health Boards need to invest the time and resources required to review the data when they are identified as a potential outlier. Trusts and Health Boards that are still considered to be potential outliers after completing all steps of the outlier management process will be reported to the CQC/NHS England and NHS Improvement (English Trusts), the Scottish Government (Scottish Health Boards) or the Welsh Government (Welsh Health Boards).

Outlier management process			
Stage	Action	Who?	Within how many working days?
1	If a Trust or Health Board is considered to be a potential outlier, the NMPA team will carry out a careful scrutiny of the data handling and analyses performed to determine whether there is: **'No case to answer'** • Potential outlier status not confirmed • Data and results revised in NMPA records • Details formally recorded **'Case to answer'** • Potential outlier status	NMPA team	10

2	The Clinical Director and Head of Midwifery in the identified Trust or Health Board will be informed about the potential outlier status and requested to identify any data errors or justifiable explanations if applicable. All relevant data and analyses will be made available to the Clinical Director. A copy of the request will be sent to the Medical Director and Chief Executive Officer of the involved Trust or Health Board.	NMPA team	5
3	The Clinical Director to provide a written response to the NMPA.	Clinical Director of Trust/Health Board	20 (NMPA to chase non-responders after 10 working days)
4	Review of the Clinical Director's response to determine whether there is: **'No case to answer'** • It is confirmed that the data contain inaccuracies. Re-analysis of accurate data no longer indicates outlier status or – in case re-analysis is not possible – further analysis demonstrates that the results are invalid.[2] • Invalid results will **not** be displayed in the published results. • The Clinical Director will be notified in writing with a copy sent to the Head of Midwifery, Medical Director and Chief Executive Officer. **'Case to answer'** Either: • It is confirmed that the NMPA data were accurate, thus confirming that the Trust or Health Board is still a potential outlier. Or: • It is confirmed that, although the data used for analyses were inaccurate, analysis indicates that the Trust or Health Board is still a potential outlier.	NMPA team	10

[2] Participating Trusts and Health Boards should be aware that while the NMPA has a duty to report on the data it holds, the NMPA is not responsible for the accuracy and completeness of the data it has received. This responsibility dually rests with the Trusts and Health Boards providing maternity services as well as with the providers of secondary datasets. Issues with audit data, whether case ascertainment, data completeness or data quality, must be addressed by the participating Trust or Health Board concerned. The NMPA will support the Trusts and Health Boards by identifying areas where data submission requires improvement, whilst providing consistent analysis and case mix adjustment of all data received from units, and in making the reports on structure, process and outcomes of care publicly available.

5	The NMPA team will contact the Clinical Director and Head of Midwifery in writing to confirm outlier status, prior to sending written confirmation to Medical Director and Chief Executive. All relevant data and statistical analyses, including previous responses from Clinical Director, will be made available to the Medical Director and the Chief Executive Officer.[3] The NMPA team will indicate that • Results for the Trust or Health Board will be published. • The CQC will be informed for Trusts in England, the Scottish Government for Health Boards in Scotland, and the Welsh Government for Health Boards in Wales. • The Trust or Health Board needs to inform commissioners, NHS England and NHS Improvement (England only), and relevant Royal Colleges.	NMPA team	5
6	Acknowledgement of receipt is required from the Trust or Health Board, confirming that a local investigation will be undertaken with independent assurance of the validity of this exercise, copying in the CQC at clinicalaudits@cqc.org.uk, the Scottish Government at nss.SNAP@nhs.net, or the Welsh Government at wgclinicalaudit@gov.wales as appropriate.	Clinical Director of Trust/Health Board	10 (NMPA to chase non-responders after 5 working days)
7	If an acknowledgement is not received within 10 working days, a reminder letter will be sent to the Trust or Health Board's Chief Executive Officer. The CQC/ NHS England and NHS Improvement, the Scottish Government or the Welsh Government (as appropriate) will be notified of non-compliance.	NMPA team	5
8	Public disclosure of comparative information identifying Trusts and Health Boards through planned reporting and online reporting tools.	NMPA team	On publication date

[3] Where a Trust or Health Board is identified as an outlier, the NMPA team will seek to support and provide additional help to trusts and boards wanting to review data entry and quality. Participating data providers or clinicians with concerns about data quality are urged to contact the NMPA at the earliest opportunity.

NMPA Cause for Concern Policy

Background

The National Maternity and Perinatal Audit (NMPA) is part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP). NCAPOP Suppliers that collect and analyse data on the quality of care at participating individual or unit level have a responsibility to alert the Medical Director (MD) and Chief Executive Officer (CEO) in healthcare provider units or organisations if the NCAPOP Provider find example(s) of clinical practice or system failure that presents a risk of harm to patients.

Purpose

The Cause for Concern Policy relates to the rare circumstance in which information submitted to the NMPA 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 the NMPA outlier process (available here), the outlier policy takes precedent.

Example of a Cause for Concern

The following table (also available via HQIP Cause for Concern Guidance) describes three categories of concern which may be identified and describes some potential scenarios for each category.

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):
		  ○ Abusive behaviour (including allegations of sexual assault)
		  ○ Serious professional misconduct
		  ○ 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.

Due to the design of the NMPA, it is unlikely that scenarios relating to Category 1 or 2 will be relevant. However, emerging aggregate data trends may lead to areas of concern being identified. For example a trust which has a high 'birth without intervention' rate and also has a high rate of admissions to NNU and high Apgar score rates below 7 could potentially be an area of concern.

Process

If the NMPA Project Team identifies a potential care incident that prompts a cause of concern, the team will:

• Notify the HQIP NCAPOP Associate Director

• Write to the Lead Clinician, copying in the Trust or Health Board Medical Director, Chief Executive Officer, Heads of Midwifery and HQIP.

The letter will include:

- An outline of the data submitted and from which the 'Cause for concern' has originated
- A request that the letter is formally acknowledged within twenty-five working days from receipt of the communication
- A request that details of any investigation and remedial action (which may involve resubmission and re-analysis of data if inaccurate data were originally submitted) that has been taken to address the possible underlying causes of the concern be summarised and communicated back to the NMPA Project Team raising the 'Cause for concern' as soon as possible
- A request to provide details of any submission of the incident(s) to the healthcare and/or professional regulator (if appropriate)
- Providing a link to the published project 'Cause for concern' policy

If a formal response has not been received within twenty-five working days of the initial letter raising the 'Cause for concern', a reminder letter will be sent to the Medical Director and Chief Executive Officer and HQIP notified. If no response is received within a further 10 working days, or the response is felt by the NMPA Project Team to be unsatisfactory, the issue will be discussed with HQIP. Agreement will then be reached on whether the healthcare and/or professional regulators should be notified.

The process is summarised with timeframes in the below tables for England and Wales respectively.

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:	NCAPOP Supplier	20

	'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*		
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[4] and for the Provider CEO to inform commissioners, NHS Improvement[5] and relevant royal colleges to be determined jointly by the HQIP Associate Director and the NCAPOP Supplier Clinical Lead.	NCAPOP Supplier lead	5

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

6	Acknowledgement of receipt of the letter confirming that a local review will be undertaken, copying in the CQC[6] 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[7] and NHS Improvement[8] notified of non-compliance.	NCAPOP Supplier	5

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	NCAPOP supplier lead	5

[6] Via clinicalaudits@cqc.org.uk
[7] Via clinicalaudits@cqc.org.uk
[8] Via nhsi.medicaldirectorate@nhs.net

	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)		
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.	NCAPOP Supplier lead	5

	The requirement for the NCAPOP supplier to inform Welsh Government[9] and relevant royal colleges to be determined jointly by the HQIP Associate Director and the NCAPOP Supplier Clinical Lead.		
6	Acknowledgement of receipt of the letter confirming that a local review will be undertaken, copying in the Welsh Government[10] 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

[9] Via wgclinicalaudit@gov.wales
[10] Via wgclinicalaudit@gov.wales