# Cause for Concern Guidance

## Maternal Newborn and Infant Clinical Outcome Review Programme (MNI-CORP)

The purpose of this guidance is to support Clinical Outcome Review Programme service providers to identify and raise concerns that may arise from:

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| Part A | Case note review as part of a Clinical Outcome Review Programme. |
| Part B | Identifying units with 'perinatal mortality rates of concern' |
| Part C | Maternity Units with possible excess numbers of maternal deaths and/or a pattern of causes of deaths that gives rise to concern. |

### 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 | National Clinical Audits<br>and<br>Clinical Outcome Review Programmes (CORP)<br>(formerly known as Confidential Enquiries) |

### 2. Part A - Case note review as part of a Clinical Outcome Review Programme

Individuals taking part in case note review or reviewing questionnaire information containing individual patient level information as part of a Clinical Outcome Review Programme have a professional responsibility to alert a senior member of staff in the organisation for which they are undertaking the review, if they find an example of clinical practice or system failure that goes beyond the themes arising from the confidential enquiry (which will be publicly reported), and that presents a risk of harm to patients.

Case notes or questionnaires which are reviewed are historical, therefore incidents recorded may have taken place several months or years previously. Case notes will have been redacted and provide limited information. Therefore, the aim of cause for concern letters is to seek assurance from those responsible for services that incidents raising concern in case reviews have been, or will be, investigated and managed appropriately.

Examples of causes for concerns, for illustration only, could include:

- Death (child or adult) attributable to abuse or neglect, in any setting, but no indication of cross agency involvement (i.e. no mention of safeguarding, social services, police or LSCB
- Staff member displaying:
    - abusive behaviour (including allegations of sexual assault)
    - serious professional misconduct
    - dangerous lack of competency

  but not clear if incident has been reported to senior staff.
- Standards in care that indicate a dysfunctional or dangerous department or organisation, or grossly inadequate service provision.

Process

If a reviewer/review panel identify a case that prompts a cause of concern, MBRRACE-UK will contact the relevant HQIP Associate Director for discussion and agreement of the process for each case, 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. The supplier will then contact[*] the Trust/Health Board Medical Director (copying HQIP) seeking assurance that the incident has been appropriately reported and that they are aware of and are reviewing the incident.

If two weeks from initial notification no response has been received, a reminder letter to the Medical Director (copied to the hospital CEO and HQIP) will be sent. If no response is received within two weeks of sending the reminder letter, HQIP will be alerted. The matter will then be raised by HQIP with the relevant government lead and regulator.

## 3. Part B - Identifying units with 'perinatal mortality rates of concern'

Recent years have seen the emergence of Trusts/Health Boards with concerning reports of perinatal and maternal deaths and serious morbidity that have necessitated high profile external investigations. Several of these investigations have recommended the need to use all information available to identify those hospitals with concerning levels of clinical performance and outcomes at an early stage. This document outlines the approach MBRRACE-UK takes to use their data to support the identification of 'Units with perinatal mortality rates of concern'. The intention is that this process is 'indicative' and not confirmatory which is why we refer to it as 'Units with perinatal mortality rates of concern' and have specifically not used the term 'outliers'.

There is no single statistical metric suitable to use to identify concerningly high perinatal mortality rates in individual Trusts/Health Boards. Furthermore, basing any metric on single year mortality rates risks leading to spurious findings due to year on year variation which may occur on a random basis. Therefore, the approach uses the most recent three years of 'stabilised and adjusted' mortality rates.

[*] There may be a need to notify more than one agency if care was shared.

For each Trust and Health Board, MBRRACE-UK prepares a specific report containing rates of stillbirth, neonatal death and extended perinatal death, including and excluding deaths due to congenital anomalies. For each rate MBRRACE-UK also includes a short sentence explaining the position of the rate in relation to the average for their comparator group. Rates are highlighted where they meet at least one of the criteria below. This information is contained within in the Trust/Health Board specific report each receives one week ahead of the publication of the rates via the MBRRACE-UK data viewer, which represents the standard notification process. The follow set descriptors are used:

Condition A - Red in latest year. No additional text.
Condition B - Consistent decline in RAG category over 3 years. Explanatory text: "Your stabilised & adjusted [type] rate has consistently worsened when compared to similar Trusts and Health Boards over the last three years."
Condition C - Red in latest year AND red in BOTH two preceding years. Explanatory text: "Your stabilised & adjusted [type] rate has been more than 5% higher than the average for similar Trusts and Health Boards for each of the last three years."
Condition D – Decline by at least 2 RAG categories in latest year. Explanatory text: "Your stabilised & adjusted [type] rate has worsened by [two or three] RAG categories since the previous MBRRACE-UK report."

Where a rate has been highlighted this is also included as part of the standard recommended actions:

"As the [type] rate(s) have been highlighted above, it is important to: a) review the data that was entered locally about your [Trust or Health Board] to ensure it is accurate and complete; and b) ensure that a review using the Perinatal Mortality Review Tool (PMRT) has been carried out for all the deaths in this report to assess care, identify and implement service improvements to prevent future similar deaths."

Where a rate meets Conditions B or C, this is also highlighted with a simple red dot 🔴 at the start of the recommended actions.

Trusts and Health Boards are informed of the availability of their specific report via an email to the lead MBRRACE-UK reporters at each organisation. The email also highlights any new data in the report and signposts the reader to the relevant pages.

A list of Trusts and Health Boards meeting these 'perinatal mortality rates of concern' criteria will also be sent to funders one week before the Trust/Health Board-specific reports are available. MBRRACE-UK will also provide supporting information to give the funders additional context.

No formal response is required from Trusts and Health Boards.

## 3.1 Modified procedure for Northern Ireland

Deaths in Northern Ireland are not reported directly to MBRRACE-UK by Health Boards. Deaths are first reported by the Health Board to Northern Ireland Maternal and Child Health (NIMACH), who then notify the death to MBRRACE-UK via the same system as other UK Trusts and Health Boards. As a consequence, MBRRACE-UK does not have direct contact with Northern Ireland Health Boards.

Registered reporters at the NIMACH office have direct access to the Health Board-specific reports for each Northern Ireland Health Board, and therefore are informed of any rates of concern via those reports. NIMACH

is not informed of any rates of concern separately, or provided with any additional supporting information as this relates to aspects of the reporting process which do not apply in Northern Ireland.

## 4. Part C - Maternity Units with possible excess numbers of maternal deaths and/or a pattern of causes of deaths that gives rise to concern.

This guidance outlines the process by which the Maternal, Newborn and Infant CORP will identify Maternity Units with possible excess numbers of maternal deaths and/or a pattern of causes of deaths that gives rise to concern.

- As maternal deaths are notified to the Maternal, Newborn and Infant CORP supplier office, the cases which occur in individual Units are monitored. At this stage the cause of death is only probable and as notified by the Unit where the death occurred.
- Alongside the estimated number of maternities in each Unit, Units with a possible excess number of maternal deaths and/or concerning pattern of causes of deaths are identified.
- Due to the small number of cases and thus limited power of statistical analyses, unit-specific rates are of no value to identify units of concern.
- A Cause for Concern letter is issued based on a pattern of deaths which indicates an unexpected excess due to a particular cause or group of causes e.g. direct causes, or if the confidential enquiry has identified concerning aspects of care of individual women which have not been identified in the local review processes.

<u>Process</u>

If a cause for concern is identified, MBRRACE-UK will contact the relevant HQIP Associate Director for discussion and agreement of the process for each case, 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. The supplier will then contact[†] the Trust or Health Board Medical Director (copying HQIP) requesting assurance that they are reviewing the incident.

If, two weeks from initial notification no response has been received, a reminder letter to the Medical Director (copied to the hospital CEO and HQIP) will be sent by MBRRACE-UK. If no response is received within two weeks of sending the reminder letter, HQIP will be alerted. The matter will then be raised by HQIP with the relevant government lead and regulator.

[†] There may be a need to notify more than one agency if care was shared.