Clinical Outcome Review Programme Policy
(Previously known Confidential Enquiries)

Incorporates:
National Confidential Enquiry into Patient Outcome and Death (NCEPOD)
Confidential Enquiry into Maternal deaths, stillbirths and perinatal deaths (MBRRACE, formerly CMACE)
National Confidential Inquiry into Suicide and Homicide (NISH)

This procedural document supersedes: CORP/COMM 20 v.2 – National Confidential Enquiry (NCE) Policy.

Did you print this document yourself?
The Trust discourages the retention of hard copies of policies and can only guarantee that the policy on the Trust website is the most up-to-date version. If, for exceptional reasons, you need to print a policy off, it is only valid for 24 hours.

| Name and title of author/reviewer: (this version) | Mandy Dalton, Head of Risk and Legal Services
Dr David Northwood, Consultant Anaesthetist and Local NCEPOD Reporter
Andrea Squires Patient Safety Midwife |
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<tr>
<td>Date written/revised:</td>
<td>July 2014</td>
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<tr>
<td>Approved by (Committee/Group):</td>
<td>Policy Approval and Compliance Group</td>
</tr>
<tr>
<td>Date of approval:</td>
<td>22 October 2014</td>
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<tr>
<td>Date issued:</td>
<td>25 November 2014</td>
</tr>
<tr>
<td>Next review date:</td>
<td>July 2017</td>
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<tr>
<td>Target audience:</td>
<td>Trust Wide clinical staff</td>
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**Amendment Form**

Please record brief details of the changes made alongside the next version number. If the procedural document has been reviewed *without change*, this information will still need to be recorded although the version number will remain the same.

<table>
<thead>
<tr>
<th>Version</th>
<th>Date Issued</th>
<th>Brief Summary of Changes</th>
<th>Author</th>
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| Version 2 | 25 November 2014 | • Policy now reflects the Clinical Outcome Review Programmes  
• Changes made to accommodate organisational changes to clinical management structure and reporting lines | Mandy Dalton/ David Northwood/ Andrea Squires |

| Version 1 | June 2012 | • This was originally part of CORP/COMM 10 v.2 - Policy for the receipt, distribution and review of national reports and guidance (incorporating NICE, NSF’s, National Confidential Enquiries and High Level Enquiries)  
Now a stand-alone document: please read in full | Mandy Dalton & David Northwood |

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1. INTRODUCTION

The Clinical Outcome Review Programmes (previously known as Confidential Enquiries), are designed to help assess the quality of healthcare, and stimulate improvement in safety and effectiveness by systematically enabling clinicians, managers and policy makers to learn from adverse events and other relevant data.

The programmes aims to complement and contribute to the work of other agencies such as NICE; CQC, the Royal Colleges and academic research studies with the aim of supporting changes that can help improve the quality and safety of healthcare delivery.

The Clinical Outcome Review Programmes are commissioned by HQIP on behalf of NHS England, DHSSPS Northern Ireland, the Health Department of the Scottish Government, the Welsh Government, the Channel Islands and the Isle of Man.

Current programmes and suppliers:

- **Medical and Surgical programme**: National Confidential Enquiry into Patient Outcome and Death (NCEPOD) >>

- **Mental Health programme**: National Confidential Inquiry into Suicide and Homicide for people with Mental Illness (NCISH - University of Manchester) >>

- **Child Health programme**: Currently undergoing procurement with contract award due Winter 2014

- **Maternal, Newborn and Infant programme**: MBRRACE-UK >>

- **National Review of Asthma Deaths**: Royal College of Physicians >>

- **Children’s Head Injury Project*: University of Cardiff >> *not included in 2012/13 Quality Accounts >>

This procedural document has been developed to ensure that the Trust has in place, a systematic approach for participation in all of these programmes. It will demonstrate:

- a system is in place to respond to requests for data and information

- a systematic approach to reviewing the findings and responding to the recommendations of the clinical outcome programmes

- a process to identify shortfalls and deficiencies within the Trust following review of the recommendations of the clinical outcome programmes

- how clearly defined action plans with agreed staff responsibilities will be formulated to deal with any identified shortfalls and deficiencies.
2. DUTIES

2.1 Board of Directors (“The Board”)

The Board of Directors receives details of all clinical outcome review programmes within the Trust via the Clinical Governance and Quality Committee.

In accordance with annual guidance from Monitor, a report on the Trust’s participation in Clinical Outcome reviews will be submitted as part of the Quality Accounts.

2.2 Medical Director

The Board delegates the responsibility of participation in all clinical outcome reviews to the Medical Director.

Some of these responsibilities are mutually agreed and delegated to the Local NCEPOD Reporter (LR) and MBRRACE reporter.

2.3 NCEPOD Reporter will:

- Provide data returns as described in section 4
- Receive new NCEPOD reports and ensure the relevant Care Group Clinical Directors and Care Group Clinical Governance Leads are aware of these.
- Inform the Medical Director, Deputy Director of Quality & Governance and appropriate Care Group Clinical Governance Leads about planned NCEPOD studies.
- Receive and ensure completion of Organisational questionnaires as requested by NCEPOD.
- Ensure initial study data requested by NCEPOD is collated and dispatched according to designated deadline.
- Ensure individual clinicians receive questionnaires and act as a source of help and information for clinicians.
- Maintain an overview of individual clinician compliance with regard to data submission to NCEPOD.
- Supply information to the Clinical Audit Manager to enable completion of the annual Quality Accounts.
- Submit an annual report regarding NCEPOD activity to Clinical Governance and Quality Committee via the Patient Safety Review Group
- Inform the Medical Director, Deputy Director of Quality & Governance and appropriate Care Group Clinical Governance Leads about launch dates for NCEPOD reports.
• Ensure Care Group Clinical Governance Leads and Care Group Clinical Directors receive finalised NCEPOD reports/summaries relevant to that speciality to enable review of recommendations made.

2.4 MBRRACE Reporter will:

• Receive new MBRRACE reports and undertake a gap analysis. (Appendix 1)
• Report to the Clinical Director, Head of Midwifery and General Manager of the Children and Families Care, the findings of the gap analysis.
• Report the recommendations and any actions to be taken to the Maternity Services Clinical Governance Group.
• Submit an annual report regarding MBRRACE activity to Patient Safety Review Group
• Assist the Medical Director in co-ordinating Trust response to recommendations which cross speciality boundaries.

2.5 NCISH

All incidences of suicide and homicide that occur in the UK are examined by the Centre for Suicide Prevention to determine if mental health services have been involved. The Trust contributes in providing data to this survey via HM Coroner.

2.6 Clinical Audit Manager

The Clinical Audit Manager maintains a database of relevant clinical outcome review activity to inform preparation of the Annual Quality Accounts.

2.7 Care Group Clinical Director

The Care Group Clinical Director is ultimately responsible for ensuring actions are taken in response to any clinical outcome reviews relevant to their specialty. This includes timely submission of data by clinical staff, review of published reports, gap analysis of practices and processes against recommendations and actions to be taken to address identified deficiencies. This co-ordination will be delegated to the Care Group Clinical Governance Lead.

2.8 Clinical Governance and Quality Committee (CG&QC)

The Clinical Governance & Quality Committee receive gap analysis reports from SCGLs and monitor action plans indentified for progress and completion.

Received annual report from Local NCEPOD Reporter and Maternity Services Patient Safety Lead.
Ensures compliance with this policy throughout the Trust, and reports to the Trust Board issues of non-compliance and service deficiencies identified from the gap analyses.

Documents the reasons for considered rejection of any confidential enquiry recommendations.

2.9 Medical Staff

The General Medical Council consider it to be good practice for all doctors to contribute to National Enquires. *Good Medical Practice* (2006 - para 14) and *Confidentiality* (October 2009 - para 30).

Consultants, whose patients are included in an NCEPOD study, are responsible for submitting the relevant data with accuracy, completeness and within the specified deadline.

3. PARTICIPATION IN CLINICAL OUTCOME REVIEWS

3.1 MEDICAL AND SURGICAL PROGRAMME: The National Confidential Enquiries into Patient Outcome and Death (NCEPOD)

The National Confidential Enquiries into Patient Outcome and Death (NCEPOD) are conducted by an independent body which accepts suggestions from various stakeholders to investigate the standards of secondary care in England, Wales and Northern Ireland (including the Independent Sector).

Uniquely, the data collected by NCEPOD is submitted to peer review by practising healthcare personnel.

Quality of the process of delivering care is usually assessed using a 5 point scale:

1. Good practice
2. Room for improvement – clinical
3. Room for improvement – organisational
4. Room for improvement – clinical and organisational
5. Less than satisfactory.

These judgements are reviewed and each NCEPOD report will contain several recommendations based on the results which will improve the quality of patient care when implemented.

Participation will involve identifying and submitting data and patient details as requested by NCEPOD: the receipt, distribution and review of the subsequent reports; and the recognition of relevant recommendations and their implementation.
3.2 **MATERNAL, NEWBORN AND INFANT PROGRAMME: ‘MBRRACE-UK’**

Investigating Maternal Deaths, Stillbirths and Neonatal Deaths.

This enquiry covers both Maternal deaths and Perinatal and Infant deaths.

The following two processes apply:

**Maternal Deaths**

In line with the Guideline on Maternal Death (Maternity service guideline 121) the Supervisor of midwives attending the incident informs the Consultant on call, Executive on call, Head of Midwifery and General Manager, Local Supervising Authority (LSAs) and Coroner. One Clinician should co-ordinate the completion and submission to MBRRACE in liaison with a nominated Matron or Contact Supervisor. The Head of Midwifery (HOM) oversees the process.

**Perinatal & Infant Deaths**

Reporting of perinatal and infant deaths is made by a designated Neonatal Unit Sister – currently Regional Co-ordinator, direct to MBRRACE, following their death notification procedures.

4. **PROCESS FOR ENSURING THE TRUST RESPONDS TO REQUEST FOR DATA**

LR reviews the NCEPOD website at least monthly to identify new proposals for studies and their protocols.

NCEPOD send request to LR for initial data to identify patients to be entered into a new study and for submission of organisational data.

Appropriate staff identified and tasked by LR to obtain data and prepare this for submission to NCEPOD in required format. Copy of data stored by LR prior to submission to NCEPOD.

Requests for information from individual consultant staff is made via two possible routes:

1. NCEPOD sends request for information directly to individual concerned. LR informed by NCEPOD of consultants involved in the study and the deadlines for data submission.

   LR updated quarterly by NCEPOD about data returns received.

   LR encourages consultants to submit data, and reminds those who have not to do so.

2. NCEPOD send all requests for information to LR, who then distributes these to each consultant identified.
LR updated quarterly by NCEPOD about data returns received.

LR encourages consultants to submit data, and reminds those who have not to do so.

Compliance with data returns recorded by LR to form part of annual report to PSRG and submission to annual Quarterly Accounts.

Repeated non compliance by individuals reported to Medical Director.

The On call Supervisor of Midwives will ensure that any maternal death is reported to the local supervising authority.

5. PROCESS FOR IDENTIFYING RELEVANT DOCUMENTS

Relevant documents are identified as:

- Data collection questionnaires
- Guidelines concerning accurate completion of questionnaires
- NCEPOD reports and summary reports.
- Gap analysis forms.

All relevant documents can be found on the NCEPOD website at www.ncepod.org.uk

The LR identifies documents requires for each phase of each study and informs appropriate participants to obtain them from the website, or sends copies of the documents directly.

NCEPOD may send relevant documents directly to medical staff, LR or Medical Director.

6. IDENTIFICATION OF CLINICAL OUTCOME RECOMMENDATIONS RELEVANT TO THE SERVICE: PROCESS FOR CONDUCTING AN ORGANISATIONAL GAP ANALYSIS

Confidential enquiry reports are received by the NCEPOD reporter and the Maternity Services Patient Safety Lead. The NCISH report is received by the Medical Director. All of these enquiries will have a gap analysis undertaken. (See Appendix 1). The LR sends the NCEPOD report to Care Group Clinical Governance Leads and Care Group Clinical Directors of the relevant specialities with a request that a gap analysis is performed after review of the recommendations in the report.

LR suggests a deadline for completion of gap analysis (usually 3 months). Deputy Director, Quality & Governance is informed of gap analysis requested and deadline, to enable completed analysis to be placed on PSRG agenda.

NCEPOD “self assessment checklist for Trusts” sent with each NCEPOD report to facilitate completion and documentation of gap analysis.
Gap analysis conducted under auspices of relevant Care Group Clinical Governance Lead.

Should cross speciality gap analysis be required, the Deputy Director, Quality & Governance will be informed by LR who will form a cross speciality working group to complete the task.

7. PROCESS FOR ENSURING THAT RECOMMENDATIONS ARE ACTED UPON THROUGHOUT THE TRUST

Gap analysis will identify any actions required to meet the recommendations contained in the Confidential Enquiries. Action plans are then developed and presented to the PSRG within 4 months of confidential report publication.

Action Plans from cross speciality working groups are presented to PSRG by the Working Group Lead.

PSRG agree action plans and formulate schedule of monitoring their implementation including regular reporting back to PSRG

Status of confidential reports activity reported to Trust Board via minutes of PSRG

8. PROCESS FOR DOCUMENTING ANY DECISIONS NOT TO IMPLEMENT CLINICAL OUTCOME REVIEW RECOMMENDATIONS

Recommendations not considered relevant for implementation are recorded in PSRG and the appropriate Care Group Clinical Governance meeting minutes, having been identified during the gap analysis process.

Non-implementation of recommendations due to circumstances outside the control or influence of the Trust will be entered onto the corporate risk register after review by the CG&QC

9. MONITORING OF COMPLIANCE WITH POLICY

LR to monitor compliance with initial data capture and dispatch to NCEPOD, and individual Consultant reporting

LR gives annual update to PSRG and Clinical Audit Manager for inclusion into annual Quality Accounts.

Standing item on PSRG agenda to receive progress reports from Care Group Clinical Governance Leads regarding gap analyses and action plans relevant to NCEPOD recommendations.

Trust Board receive Annual report via minutes of the Clinical Governance and Quality Committee (CG&QC ).
10. EQUALITY IMPACT ASSESSMENT

The Equality Impact Assessment which is required to consider the needs and assess the impact of this document in accordance with the Organisation-wide Document for the Development and Management of Procedural Documents will be undertaken by the author (Appendix 2).

11. ABBREVIATIONS USED IN THIS POLICY DOCUMENT

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>CEMACH</td>
<td>Confidential Enquiry into maternal and child health</td>
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<td>CG&amp;QC</td>
<td>Clinical Governance &amp; Quality Committee</td>
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<td>NCISH</td>
<td>National Confidential Inquiry into Suicide and Homicide</td>
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<td>LR</td>
<td>Local NCEPOD Reporter</td>
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<td>LSA</td>
<td>Local Supervising Authority</td>
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<tr>
<td>MBRRACE</td>
<td>Mothers and babies: reducing risk through audits and confidential enquiries. New body to continue the work of CMACE, investigating maternal deaths stillbirths and neonatal deaths</td>
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<tr>
<td>NCEPOD</td>
<td>National Confidential Enquiry into Patient Outcome and Death</td>
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<td>Health Quality Improvement Partnership</td>
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<td>PSRG</td>
<td>Patient Safety Review Group</td>
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12. REFERENCES

1. Reports from the National Confidential Enquiry into patient Outcome and Death (NCEPOD) are available at: www.ncepod.org.uk.

2. Reports from Maternal, Infant and Perinatal Programme (formerly Maternal and newborn programme, led by the centre for maternal and child enquiries (CMACE) are available at : www.hqip.org.uk.

3. Reports from the National Confidential Inquiry into Suicide and Homicide by People with Mental Illness (NCI/NCISH).
## APPENDIX 1 – GAP ANALYSIS

### TITLE OF REPORT:

Gap Analysis – DATE

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### Gap Analysis

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<th>No.</th>
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**NCEPOD REPORTER/MBRRACE REPORTER/ MEDICAL DIRECTOR Authorisation.**

Name: ................................................................. Signature: .................................................................

Please return your complete form to Clinical Audit Manager

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1 Compliance should be rated as full, partial or non-compliance
### APPENDIX 2 - EQUALITY IMPACT ASSESSMENT PART 1 INITIAL SCREENING

<table>
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<tr>
<th>Service/Function/Policy/ Project/Strategy</th>
<th>CSU/Executive Directorate and Department</th>
<th>Assessor (s)</th>
<th>New or Existing Service or Policy?</th>
<th>Date of Assessment</th>
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<td>POLICY – CORP/COMM 20 v.2</td>
<td>MEDICAL DIRECTOR</td>
<td>Mandy Dalton</td>
<td>Existing policy</td>
<td>29 August 2014</td>
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1) Who is responsible for this policy? Corporate Medical Directorate

2) Describe the purpose of the policy: To ensure compliance with National Confidential Enquiries

3) Are there any associated objectives? No

4) What factors contribute or detract from achieving intended outcomes? – None

5) Does the policy have an impact in terms of age, race, disability, gender, gender reassignment, sexual orientation, marriage/civil partnership, maternity/pregnancy and religion/belief? NO

• If yes, please describe current or planned activities to address the impact [e.g. Monitoring, consultation] – N/A

6) Is there any scope for new measures which would promote equality? [any actions to be taken] No

7) Are any of the following groups adversely affected by the policy? No

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<th>Affected?</th>
<th>Impact</th>
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<td>g) Race</td>
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<tr>
<td>i) Sexual Orientation</td>
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8) Provide the Equality Rating of the service / function /policy / project / strategy – tick outcome box

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<th>Outcome 3</th>
<th>Outcome 4</th>
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*If you have rated the policy as having an outcome of 2, 3 or 4, it is necessary to carry out a detailed assessment and complete a Detailed Equality Analysis form in Appendix 4*

Date for next review: July 2017

Checked by: Mandy Dalton

Date: 29 August 2014