<table>
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<tr>
<th>Policy Title</th>
<th>National Office of Clinical Audit (NOCA) - Monitoring &amp; Escalation Policy</th>
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<tbody>
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<td>NOCA Audits Clinical Leads</td>
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<td>NOCA National Clinical Audit Governance Committee’s</td>
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<td>Health Service Executive (HSE) Acute Hospitals Division (AHD)</td>
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<td>HSE Quality Improvement Division</td>
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<td>HSE Quality Assurance &amp; Verification Division</td>
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<td></td>
<td>Hospital Group Chief Executive Officers</td>
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<td>National Clinical Effectiveness Committee (NCEC) Quality Assurance Review Teams</td>
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<td>Approved by</td>
<td>NOCA Governance Board</td>
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<td>1st January 2017</td>
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1.0 Policy Statement

That National Office of Clinical Audit (NOCA) produces annual national clinical audit reports across multiple areas of clinical care that aim to improve patient care and outcomes by systematic, structured review and evaluation of clinical care against explicit clinical standards conducted on a national basis.

2.0 Purpose

The purpose of the policy is to ensure that:

2.1 The NOCA Audit Coordinator and the NOCA Audit Clinical Lead continually monitor clinical audit data and informs a hospital of any data quality issues in a timely manner

2.2 The Hospital Audit Clinical Lead and the Hospital Data Coordinator/Nurse will investigate and resolve all data quality issues in a timely manner so as to ensure their data is complete and accurate for inclusion in the national clinical audit reports

2.3 The NOCA Audit Clinical Lead notifies a Hospital, Group and relevant National Director of a statistical outlier in a timely manner.

2.4 There is an identified Senior Accountable Person in each hospital who will ensure that all statistical outliers arising from national clinical audit are reviewed and any required actions taken within agreed timelines.

2.5 NOCA escalates to the appropriate accountable level in the HSE, as defined in the HSE Accountability Framework

2.6 NOCA will share key learnings and recommendations with the relevant HSE National Director and other key stakeholders

3.0 Scope of this Policy

This policy applies to all audits under the governance of NOCA regardless of policy date.
4.0 Glossary of Terms and Definitions

<table>
<thead>
<tr>
<th>Terms</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Quality Indicators</td>
<td>Also known as Key Performance Indicators (KPIs) - Quality Indicators are specific and measurable elements of practice that can be used to assess quality of care. Indicators are quantitative measures of structures, processes or outcomes that may be correlated with the quality of care delivered by the healthcare system (HSE, 2013).</td>
</tr>
<tr>
<td>Statistical outlier</td>
<td>Each Audit stream will have pre-determined quality indicators, which are primarily process and outcomes measures,</td>
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<tr>
<td></td>
<td>An outlier is a result that is statistically significantly further from the expected value of an agreed quality indicator than would occur by chance alone. The definition of an outlier therefore is based on setting an expected value for an indicator and defining what level of variation / acceptable limits from the expected value is acceptable, based on statistical probability and / or clinical judgement.</td>
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<td></td>
<td>The expected value may come from the data itself (such as the mean/ median value) or from external sources such as research evidence or national targets such as all patients with a traumatic hip fracture should have surgery within 48 hours. The expected value should be established by the Audit Governance Committee or Audit Provider. Acceptable limits for the observed outcomes are statistically calculated as follows:</td>
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<td>• a deviation more than 2 standard deviations from the (‘target’ / ‘expected’ is an ‘alert’;</td>
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<td></td>
<td>• more than 3 standard deviations is an ‘alarm’ (UK Department of Health, Healthcare Quality Improvement Partnership (HQIP), 2011).</td>
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<tr>
<td>Statistical outlier</td>
<td>Statistical outliers are defined as results that fall:</td>
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<td>• two standard deviations on or above the expected value across two consecutive reporting periods; or</td>
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<td>• three standard deviations on or above the expected comparator value in one or more reporting period (ICNARC, 2015).</td>
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<tr>
<td>Statistical outlier</td>
<td>A finding of a statistical outlier does not in the first instance indicate a problem with the quality of care, but rather a difference between the expected value and a result that is unlikely to have arisen from random variation. This should trigger further analysis and review in the hospital. It is in this context that statistical outliers will be identified by NOCA audit specific governance committees.</td>
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### Terms and Definitions

#### Data Quality

The quality of data can be determined through assessment against a number of dimensions which include accuracy, validity, reliability, timeliness, relevance, legibility and completeness (HIQA, 2013). When accessing statistical outliers, at a minimum the following criteria should be considered:

- **Case ascertainment** (also called coverage): the number of patients included compared to number eligible, derived from external data sources for example from HIPE. This can impact on the generalisability (representativeness) of the results.

- **Data completeness**: in particular performance indicator data and data on patient characteristics required for case-mix adjustment.

- **Data accuracy**: tested using consistency and range checks, and if possible external sources.

National clinical audit governance committees should acknowledge that new audit sites will require consideration in terms of “bedding down” their data quality and this should always be the first point of analysis and review of a statistical outlier.

#### Patient Safety Incident

An event or circumstance which could have, or did lead to unintended and/or unnecessary harm. Incidents include adverse events which result in harm; near-misses which could have resulted in harm, but did not cause harm, either by chance or timely intervention; and staff or service user complaints which are associated with harm. Incidents can be clinical or non-clinical and include, but are not limited to, incidents associated with harm to:

- patients, service users, staff and visitors
- the attainment of national quality objectives
- Information and communications technology (ICT) systems
- data security e.g. data protection breaches
- the environment

(HSE, 2014).

**It is the responsibility of the service provider to log all patient safety incidents on the National Incident Management System (NIMS)**

### 5.0 About the National Office of Clinical Audit (NOCA)

NOCA was established in 2012 as a key enabler of clinical effectiveness which is a key component of patient safety and quality. The integration of best evidence in service provision, through clinical effectiveness processes, promotes healthcare that is up to date, effective and consistent. Clinical effectiveness processes include **guidelines, audit and practice guidance.**
6.0 Clinical Audit Definition

“Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and implementation of change. Aspects of the structure, process and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team or service level and further monitoring is used to confirm improvement in healthcare delivery.” (Principles of Best Practice in Clinical Audit endorsed by HQIP/National Institute for Health and Care Excellence (NICE) /Care Quality Commission (CQC) (UK).

National Clinical Audit is a cyclical process that aims to improve patient care and outcomes by systematic, structured review and evaluation of clinical care against explicit clinical standards conducted on a national basis. Clinical audit endorsed by the Minister will be titled ‘NCEC National Clinical Audit’. Endorsement will mandate that the appropriate services engage with the NCEC National Clinical Audit, thereby superceding all other national clinical audits on the topic. (NCEC Framework for Endorsement of National Clinical Audit October 2015)

7.0 Benefits of Clinical Audit - Improvement and Assurance

NOCA supports the view that Clinical Audit is fundamentally a quality improvement process, rather than data collection per se (although data analysis is an essential element of the clinical audit cycle). Clinical audit also plays an important role in providing assurances about the quality of services.

National clinical audit measures against national and international benchmarks, identifying areas of excellence and of concern. Recommendations for improvements are also provided. The benefits of national clinical audit include:

- Improved patient outcomes by identifying centres with good outcomes and implementing their good practices elsewhere
- Decreased poor outcomes by changes in practice in centres where suboptimal outcomes are identified
- Reduction in variation in practice and outcomes
- Enhanced culture of transparency, improvement and accountability - report openly on issues identified and measures taken locally and nationally to improve.
- Increased motivation of staff, as they can see improvements happening by documenting changes in quality measures
- Increased economic benefit e.g. reduced length of stay, rehabilitation care, state claims
- Reliable data for activity and performance reporting, research, case studies

However, NOCA is also clear that clinical audit is not an appropriate mechanism for investigating matters relating to the performance of individual healthcare professionals.
8.0 NOCA Monitoring & Escalation Process

**Statistical Outlier**

- NOCA identify potential data issue/statistical outlier & inform Hospital
- Hospital investigates & provides written response to NOCA
- NOCA notify Hospital CEO/Manager of statistical outlier & inform Group CEO, National Director, Hospital Audit Clinical Lead
- Hospital CEO/Manager appoints Senior Accountable Person to investigate
- Hospital CEO/Manager acknowledges notification and advises NOCA of:
  - Senior Accountable Person
  - Indicative timelines
- Senior Accountable Person reviews and completes report with required corrective actions
- Hospital CEO/Manager ensures corrective actions are added to Hospital QI Plan
- Hospital CEO/Manager sends report including corrective actions to Group CEO, National Director, NOCA
- Statistical outlier review update included in National Audit Report

**Data Quality Issue**

- NOCA identify potential data issue/statistical outlier & inform Hospital
- Hospital investigates & provides written response to NOCA
- Hospital corrects the data & notifies NOCA in writing

**Recommendations**

- NOCA Board publishes NOCA Annual Report with key learnings/recommendations
- NOCA submits Annual Report to relevant HSE National Director and DoH Patient Safety Office Director
- Recommendations reviewed & action plan put in place by HSE National Director
- Annual update provided by HSE National Director to NOCA
- Updates included in National Audit Report/NOCA Annual Report

All data queries/statistical outliers must be actioned within agreed timelines unless otherwise agreed with NOCA. NOCA will escalate in line with HSE Accountability Framework.

*Required minimum. Others may be added on a case by case basis*
## 9.0 NOCA Monitoring & Escalation Process

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<thead>
<tr>
<th>Ref</th>
<th>Process Step</th>
<th>Details</th>
<th>Responsible Person</th>
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<tbody>
<tr>
<td>1.</td>
<td>NOCA identify data issue/ statistical outlier &amp; inform Hospital</td>
<td>The NOCA Audit Coordinator/NOCA Audit Clinical Lead email the Hospital Audit Clinical Lead and Audit Coordinator, regarding a data quality issue e.g. change in trend, statistical outlier indicator in quarterly reports, within <strong>15 working days</strong>. NOCA will add to their data quality action log and track for resolution within <strong>35 working days</strong>.</td>
<td>NOCA Audit Coordinator, NOCA Audit Clinical Lead</td>
</tr>
<tr>
<td>2.</td>
<td>Hospital investigates &amp; provides written response to NOCA</td>
<td>The Hospital Audit Clinical Lead and Hospital Data Coordinator investigate and inform the NOCA Audit Coordinator in writing of the outcome within <strong>20 working days</strong> unless otherwise agreed with NOCA.</td>
<td>Hospital Audit Clinical Lead and Data Coordinator</td>
</tr>
</tbody>
</table>
| 3.  | Data Quality Issue? | Decision  
Step 4  
**Yes** – Hospital corrects the data & notifies NOCA in writing.  
Step 5  
**No** – The NOCA Audit Clinical Lead will notify Hospital CEO/ Manager of statistical outlier & inform Group CEO, National Director, Hospital Audit Clinical Lead |
| 4.  | Hospital corrects the data & notifies NOCA in writing | The Hospital Audit Clinical Lead and Hospital Data Coordinator correct the data & notifies the NOCA Audit Coordinator in writing within **15 working days** unless otherwise agreed with NOCA.  
The NOCA Audit Coordinator may carry out additional statistical analysis to verify correction of the data quality issue. | Hospital Audit Clinical Lead and Data Coordinator |
| 5.  | NOCA notify Hospital CEO/ Manager of statistical outlier & inform Group CEO, National Director, Hospital Audit Clinical Lead * | The NOCA Audit Clinical Lead will write to Hospital CEO/ Manager notifying them of a statistical outlier. NOCA will also inform the:  
- Hospital Group CEO  
- National Director e.g. AHD  
- Hospital Audit Clinical Lead  
- Hospital Audit Data Coordinator  
The **NOCA notification letter** will outline the details of the statistical outlier and required next steps (See Appendix 1). | NOCA Audit Clinical Lead, NOCA National Clinical Audit Governance Committee |
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<tr>
<th>Ref</th>
<th>Process Step</th>
<th>Details</th>
<th>Responsible Person</th>
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|     |              | *Required minimum.* Others may be added on a case by case basis e.g. Professional Bodies, Clinical Programmes  

The NOCA Audit Coordinator will maintain a log of all statistical outliers and will also inform the relevant governance committee. |
| 6.  | Hospital CEO/Manager appoints Senior Accountable Person to review | The Hospital CEO/Manager will nominate a Senior Accountable Person to lead on the review and analysis of the statistical outlier. | Hospital CEO/Manager |
| 7.  | Hospital CEO/Manager acknowledges notification and advises NOCA of:  
- Senior Accountable Person  
- Indicative timelines | Within **15 working days** of receipt of the **NOCA notification letter**, the Hospital CEO/Manager will in writing acknowledge receipt of the NOCA notification letter and provide details of:  
1. Name and contact details of Senior Accountable Person.  
2. Indicative timelines for completion of review. | Hospital CEO/Manager |
| 8.  | Senior Accountable Person reviews and completes report with required corrective actions | Senior Accountable Person will complete a review and analysis of the statistical outlier and prepare a report outlining the key findings and required corrective actions. See **Appendix 2 – National Clinical Audit Outlier Report Guidance.** | Senior Accountable Person (Hospital) |
| 9.  | Hospital CEO/Manager ensures corrective actions are added to Hospital QI Plan | Hospital CEO/Manager is accountable for ensuring that the required corrective actions are added to the Hospital QI Plan and implemented within agreed timeframes. | Hospital CEO/Manager |
| 10. | Hospital CEO/Manager sends report including corrective actions to Group CEO, National Director, NOCA | Hospital CEO/Manager or a nominee sends the statistical outlier report with associated corrective actions to:  
- Hospital Group CEO  
- Relevant HSE National Director  
- Relevant NOCA National Clinical Audit Governance Committee via NOCA Audit Coordinator so as to include update in next national report. | Hospital CEO/Manager |
<table>
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<tr>
<th>Ref</th>
<th>Process Step</th>
<th>Details</th>
<th>Responsible Person</th>
</tr>
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</table>
| 11. | Statistical outlier review update included in National Audit Report | An update on the findings/ progress of the statistical outlier review carried out by the hospital in the relevant annual national clinical audit report. | NOCA Audit Coordinator  
NOCA Audit Clinical Lead |
| 12. | NOCA Board publishes NOCA Annual Report with key learnings/ recommendations | A summary of key learnings and recommendations arising from national clinical audits will be included in the NOCA Annual Report. | NOCA Executive Director |
| 13. | NOCA submits Annual Report to relevant HSE National Director and other Key Stakeholders | The NOCA Annual Report will be shared with the HSE National Directors and other key stakeholders as appropriate e.g. Department of Health (DoH), HIQA, Specialty Organisations and Academic Institutions. | NOCA Executive Director |
| 14. | Recommendations reviewed & action plan put in place by HSE National Director | The relevant HSE National Director will review the NOCA recommendations and determine a suitable action plan. This action plan will be monitored at National Directorate Level. | HSE National Director |
| 15. | Annual update provided by HSE National Director to NOCA | The relevant HSE National Directorates will provide an end of year status to the NOCA Board via NOCA Executive Director on the progress to date to implement recommendations put forward by NOCA. | HSE National Director |
| 16. | Updates included in National Audit Report/ NOCA Annual Report | NOCA will include the progress updates on recommendations provided to HSE / DoH in:  
  - Relevant National Clinical Audit Report  
  - NOCA Annual Report | NOCA Executive Director  
NOCA Audit Coordinator |
10.0 Escalation - HSE Accountability Framework

NOCA will utilise the existing levels within the HSE Accountability Framework if the following arise:

- A data issue is not resolved within **30 working days** unless otherwise agreed with NOCA
- A statistical outlier is not actioned by the hospital within agreed timelines unless otherwise agreed with NOCA

The levels identified in the HSE Accountability Framework (2016) are as per the Table below:

<table>
<thead>
<tr>
<th>Level</th>
<th>Escalate to</th>
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<tr>
<td>Level 1</td>
<td>Minister for Health</td>
</tr>
<tr>
<td>Level 2</td>
<td>Director General</td>
</tr>
<tr>
<td>Level 3</td>
<td>National Director</td>
</tr>
<tr>
<td>Level 4</td>
<td>Hospital Group CEO/ CHO Chief Officer</td>
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<tr>
<td>Level 5</td>
<td>Hospital CEO/ Manager/ CHO Chief Officer</td>
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11.0 Medical Devices Escalation of Statistical Outliers

The Irish National Orthopaedic Register (INOR) has a separate process for the management of statistical outliers relating to Medical Devices and the subsequent reporting to the Health Products Regulatory Authority (HPRA) using the Medical Device Incident Report Form or alternative as determined but HPRA.

12.0 Applicable Standards

HIQA Standards Safer Better Healthcare. Available at
https://www.hiqa.ie/standards/health/safer-better-healthcare

13.0 Policy Revision and Audit

A planned review of this policy will take place in 1 year from date of approval.
14.0 References


NOCA Audit
Hospital Group
Hospital

To: Hospital CEO/ Manager

Date

Dear Hospital CEO,

Please be advised that the following statistical outlier has been identified for your hospital.

<table>
<thead>
<tr>
<th>Details of Audit findings outside the norm (Personal Data is not used in these reports.)</th>
</tr>
</thead>
</table>

Your hospital is now required to review this statistical outlier and complete a written report to include key findings and required action plan. Please refer to attached “National Clinical Audit Outlier Report Guidance” (Appendix 1).

This report should be sent to NOCA, your Group CEO and the relevant National Director.

Can you please provide us with the following information in writing by DD/MM/YYYY:

1. Name of Senior Accountable Person who will lead on the review of this statistical outlier
2. Indicative date for completion of report

Should you require further information on this, please contact your NOCA National Audit Coordinator [name, email, and phone]

Kindest regards,

NOCA Audit Clinical Lead
XXX Audit

- Hospital Group CEO
- National Director e.g. AHD
- Hospital Audit Clinical Lead
- Hospital Audit Data Coordinator
- Others can be included on a case by case basis eg Professional Bodies, Clinical Programmes
16.0 Appendix 2 – National Clinical Audit Statistical Outlier Report Guidance

The Senior Accountable Person is responsible for preparing a report outlining the review approach, key findings and required corrective actions.

Personal Data should not be used in this report.

The report should include the following sections

- NOCA Audit Title
- Hospital
- Report prepared by
- Date Issued
- Review Team
- Background - A brief summary of the statistical outlier
- Approach taken to review statistical outlier
- Time to complete the review
- Key findings
- Summary of any required hospital escalations arising from the review. This might include but not be limited to...
  - Patient Safety Incident – Raised on NIMS
  - Poor practice reported to relevant regulator
- Action Plan (included in Hospital QI Plan)
  - Summary of actions
  - Responsible Person
  - Responsible Manager
  - Timelines
  - Mechanism to be put in place to monitor implementation