RCPCH Detection and Management of Outlier Status for Clinical Indicators in National Clinical Audits

V2.0 Last updated: October 2018

Review Date: October 2019
Introduction

This document provides an overarching outlier policy statement for the national audit programmes managed and maintained by the Royal College of Paediatrics and Child Health (RCPCH). The outlier process is used to facilitate clinical improvement and reduce variation in practice by using audit data to identify areas where improvement is required and to encourage units to use quality improvement methodologies.

The policy sets out:

- the process by which data submitted by participating providers to the audits will be analysed to detect potential outlier status (data that falls outside a predefined range) defined by each individual audit
- the process by which the RCPCH audit team will engage with any data provider to the audit and relevant regulator, if data is identified as reaching outlier status.

The RCPCH has agreed analytical models for identifying outliers as part of the statistical and analytical plan for each audit, but as a general principle the College bases the actions regarding outliers upon the Healthcare Quality Improvement Partnership (HQIP) 2017 guidance for management of outliers, Detection and management of outliers for National Clinical Audits. (Welsh National Policy due in 2018).

RCPCH Managed Audits include:

- National Paediatric Diabetes Audit (NPDA)
- National Neonatal Audit Programme (NNAP)
- National Epilepsy and Seizures Audit (Epilepsy12)

1. Choice of performance indicators for outlier analysis

Performance indicators should be defined by the RCPCH Methodology and Dataset Groups and endorsed by the Project Board for each individual clinical audit. The performance indicators should:

- be valid and accepted measures of a provider's quality of care
- have clear relationships with quality of care
- occur frequently enough to provide sufficient statistical power for analysis to identify outlying performance.

The performance indicators should be based on professional standards, NICE guidelines, research evidence and audit board consensus.

Changes to evidence and guidelines are considered but dataset changes take some time to filter through to audit. Therefore, dataset changes and outlier performance indicators are
subject to continual review and implementation planning and may depend on participating provider data capture and clinical system updates.

The type and number of performance indicators set by each audit should not become a burden to the audit or the units. They should be limited to measures which can drive meaningful improvement and not those which may highlight country or system wide deficiencies, which could otherwise be highlighted within normal reporting methods.

The audit boards must be mindful of the burden on clinical staff and any consequent risk to patient care of highlighting an alarm level outlier status and ensure that there is sufficiently robust data collected to support selected measures.

2. **Choice of target (expected performance)**

The expected performance may be based either on external sources, (research evidence, clinical judgment, audit data from elsewhere), or on internal sources, (such as average performance of all data providers to the audit, though may exclude the provider in question or outliers). Generally, the target will reflect process, structure or outcome for a given participating provider and be agreed by the audit board.

3. **Data quality**

Three aspects of data quality are considered:

- Case ascertainment: number of patients included compared to number eligible, derived from external data sources. This affects how representative the results are.
- Data completeness: specifically minimising missing 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 data sources.

The systems used by RCPCH-managed audits to capture participating provider data vary, but all have built-in assessment of data completeness and data quality. This enables clinical leads of data providers to the audit, to assess and improve data completeness and data accuracy for any patient included the audit before the final data is submitted.

4. **Case-mix (risk) adjustment**

Comparison of providers takes account of differences in the case-mix of patients between participating data providers by adjusting for known, measurable patient factors that are associated with the performance indicator where appropriate.

For example, within the NPDA, HbA1c (a marker of diabetes control associated with long-term complication risk) is adjusted using a regression model. The model takes into account all statistically significant patient factors known to impact on this outcome that are deemed outside the participating data providers control. For pure process measures such as ‘the
percentage of patients receiving all key care processes within each unit’, no adjustment is required since these should be offered and received by all patients irrespective of their characteristics.

Where adjustment is deemed appropriate it is agreed and signed off by the methodology and dataset group for each audit.

5. Detection of a potential outlier

Statistically derived limits around the target (expected) performance should be used to define whether a participating data provider is a potential outlier. More than two standard deviations (SD) from the target is deemed an ‘alert’; more than three standard deviations is deemed an ‘alarm’. Although it is the ‘alarm level’ alerts which will trigger outlier status reportable to the Care Quality Commission (CQC) in England and the Welsh Government in Wales, the outlier metric data sent to the CQC or Welsh Government to populate their trust dashboards will highlight outliers at alert and alarm level.

The planned methodology for detection and final outlier selection may vary by audit but all selected measures will be limited to those of greatest effect and aimed at reducing variation, as agreed by the audit project board and governed by the Royal College of Paediatrics and Child Health Quality Improvement Committee (QIC).

6. Management of a potential outlier

The RCPCH hosted audit project board has a duty to identify outliers with respect to appropriate measures and to report these. Those identified at ‘alarm level’ (identified at 3 SD or more) will be reported to CQC or Welsh Government and as part of each participating data provider’s results within the audits online reporting system.

For alarm level outliers in England the CQC expect to see evidence of appropriate initial and substantive action plans. The CQC will consider the data as part of its monitoring process. The CQC will not usually take regulatory action if organisations are responding appropriately to each stage of the outlier management process at alert and alarm level.

Those identified at ‘alert level’ (normally identified at 2 SD) will not be subject to the outlier management process, but will be identified and reported as such. The audit annual report and online outputs show comparisons of performance indicators with other hospitals/units.

For health boards in Wales, the Welsh Government monitors the actions of organisations responding to outliers and takes further action as required. Health Inspectorate Wales (HIW) does not act as regulator and cannot take regulatory action in relation to NHS providers. However, HIW can request information on the actions undertaken by organisations to ensure safe services are being delivered. The Welsh Government can share information with HIW where appropriate and advise on the robustness of plans in place to improve audit results and outcomes.
All results are in the public domain once the main national annual report has been published.

Each audit project board will develop and agree a plan for each reporting period, to action outlier status notifications, in line with the table below.
<table>
<thead>
<tr>
<th>Stage</th>
<th>What Action?</th>
<th>Who</th>
<th>Working Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The process underpinning the analysis of the outlier metric data of identifying the ‘alarm’ and ‘alert’ outliers will be validated: At which point the audit will be satisfied that there is a ‘Case to answer’ for those identified.</td>
<td>RCPCH Audit Team</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>• A designation of potential outlier status will be annotated against identified units</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>The clinical lead in the identified participating provider is informed, <em>(Template letter 1 - Appendix A)</em>, about the potential outlier status at ‘Alarm Level’ and requested to identify any data errors associated with the data analysis. They are also asked to discuss the finding with senior management including the CEO in advance of communication from the audit team to the CEO later on should there be a case to answer.</td>
<td>RCPCH Audit Team</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>• All relevant data and analyses details can be made available to the clinical lead and queries <em>will</em> be prioritised and answered promptly.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Clinical lead in the participating provider to provide written response to the RCPCH audit team acknowledging the potential outlier status and confirming that discussion with senior management <em>will</em> take place.</td>
<td>Participating Provider Clinical Lead</td>
<td>10</td>
</tr>
<tr>
<td>4</td>
<td>Review of response from the clinical lead in the participating provider to determine if there is: ‘No case to answer’</td>
<td>RCPCH Audit Team</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>• If it is confirmed that there was data error within the data originally supplied which was outside the control of the submitting unit. Re-analysis of accurate data may be considered and published if possible depending upon timing and impact. But an indication <em>will</em> always be made stating that an outlier status is unlikely.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Data and results <em>will</em> be annotated within RCPCH audit records at this stage and within details of the provider’s</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
response and the subsequent reports online and any CQC slides generated.

‘Case to answer’

- If is confirmed that although the data originally supplied by the participating provider were inaccurate and analysis still indicates outlier status under exceptional circumstances mitigation messages can be annotated onto the online reporting; for example, equipment calibration failures or IT system errors.

or

- It is confirmed that the originally supplied data were accurate, thus confirming the initial designation of outlier status.

<table>
<thead>
<tr>
<th>5</th>
<th>Contact clinical lead of the participating provider, <em>(Template Email 1 – Appendix A)</em> to confirm outlier status, and advise of next steps. Clinical lead <em>will</em> be reminded to discuss their result with their Chief Executive and Medical Director.</th>
<th>RCPCH Audit Team</th>
<th>2</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>Written confirmation of alarm status to be sent to the CEO and copied to clinical lead, Medical Director, and regional network manager (where applicable). All relevant data and statistical analyses, including previous response from the clinical lead of the participating provider, <em>will</em> be made available to the Medical Director and CEO in writing, <em>(Template Letter 2 – Appendix A)</em>, with copies going to the Clinical Lead and Regional Network Manager. RCPCH Audit teams <em>will</em> inform the CQC <em>(<a href="mailto:clinicalaudits@cqc.org.uk">clinicalaudits@cqc.org.uk</a>)</em> of alarm level outliers in England and the participating provider CEO will be advised to inform commissioners and NHS Improvement <em>(<a href="mailto:nhsi.medicaldirectorate@nhs.net">nhsi.medicaldirectorate@nhs.net</a>)</em> <em>(Template Email 2 - Appendix A)</em></td>
<td>RCPCH Audit Team</td>
<td>3</td>
</tr>
</tbody>
</table>
|   | Acknowledgement of receipt of the letter confirming that a local investigation will be undertaken with independent assurance, (identified at provider level). Providers in England are expected to copy in the CQC and provide a realistic initial action plan by the planned date of report publication submitted directly to (clinicalaudits@cqc.org.uk).

CQC will assess this plan and ensure that outliers are proactively implementing strategies to move them away from outlier status in future audit rounds.

**Please note that the CQC expect to see evidence of appropriate initial and substantive action plans which they will assess. The plans can be developmental but need to be realistic. The CQC will not usually take regulatory action if organisations are responding appropriately to each stage of the outlier management process.**

Providers in Wales are expected to copy in the Welsh Government (wgclinicalaudit@gov.wales) of alarm level outliers in Wales.

Acknowledgement of receipt of the letter from health boards are required, confirming that a local investigation will be undertaken with independent assurance of the validity of this exercise for alarm level outliers, copying in the Welsh Government.

Policy officials within the Welsh Government will monitor and progress the action plans from health boards.

---

|   | If no acknowledgement received, a reminder letter will be sent to the clinical lead of the participating provider copying in the CEO and the CQC or Welsh Government as appropriate, *(Template Letter 3 – Appendix A).*

If an acknowledgement is not received within 5 working days, CQC and NHS Improvement will be notified of non-compliance, *(Template Email 3 – Appendix A).* For Wales, Welsh Government will be notified of non-compliance.

---

|   | Public disclosure of comparative information identifying providers through planned reporting and online reporting tools.

---

---

1 Via Wgclinicalaudit@gov.wales
7. Management of outlier status - alerts and alarms

Clinical teams and governance leads need to understand the meaning of these terms and the responses that they will require. Definitions of outlier, alert and alarm will be defined within each individual audit.

Participating data providers should be aware that while the RCPCH audit team has a duty to report on the data it holds, the RCPCH is not responsible for the accuracy and completeness of the data submitted. This responsibility rests with the clinical teams/hospitals/sites/NHS trust providing the service to patients. Issues with clinical audit data, whether; case ascertainment, data completeness or data quality must be addressed by the participating provider/trust concerned.

The audits will support the units 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.

8. The role of the RCPCH audit team

The primary role of the RCPCH audit team is to support clinical teams in providing high-quality, robust clinical audit data. It is anticipated that “outlier” status will be triggered rarely and that regular, transparent and accessible reporting will help to drive up clinical quality.

Where such triggers are activated, the RCPCH audit team will seek to support and provide additional help to providers wanting to review data entry and quality. Participating data providers or clinicians with concerns about data quality are urged to contact the RCPCH audit team at the RCPCH at the earliest opportunity to discuss them. It is not the role of the RCPCH audit team to performance manage units that are identified as having outlier status.
Appendix A – Template Communications

Template letter 1 (stage 2): Notification of provisional outlier status to provider clinical lead

Name
Address line 1
Address line 2
Address line 3
Postcode
Country

[Date]

Dear [clinical lead name],

Provisional notification of low outlier status for [Audit name] [audit year] measures

As part of its annual reporting process the [audit name] conducts unit level outlier analysis on [description of measures subject to outlier status]. The purpose of the outlier process is to identify and highlight variation, enable local review of the causes of that variation and stimulate quality improvement.

Since outlier status is defined statistically, there will inevitably always be a small number of units whose results show them as outliers for any specific measure. However, it is crucial that all stakeholders and organisations understand that while units could have outlying results, this does not automatically mean that there are performance issues. Furthermore, where verified results do show units to be outlying for specific processes, this should be viewed as the beginning, or continuance, of a quality improvement process.

[Paragraph describing data quality assurance process to date, i.e. for the NNAP, details of the quarterly reporting review period.]

The [audit name] defines outliers between 2 and 3 standard deviations below expected performance (National average result) as ‘alert’ level outliers and, and those outside of 3 or more standard deviations below expected performance as ‘alarm’ level outliers.

The [audit name] also identifies outliers between 2 and 3 standard deviations above expected performance (known as excellent) and at 3 or more standards deviations above expected performance (known as outstanding).

Analysis suggests that that [unit name] is an outlier at alarm level (3 or more standard deviations below expected performance) for the audit measure [measure name].

[results table]

The raw result of interest for this measure is XX%. A method was applied to the raw result, which improves the estimate by drawing on the information from the other units when the units have similar rates, this is known as a shrinkage estimate. The shrinkage estimate for this measure is XX%.

What do you need to do next?

The process for notifying and managing outliers follows a staged process:

<table>
<thead>
<tr>
<th>Process for notifying outliers</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The clinical lead of the service is informed of potential outlier status.</td>
</tr>
</tbody>
</table>

RCPCH October 2018 Outlier Management Policy V2.0 Final
2. The clinical lead is given the opportunity to query the data and/or provide justifiable explanation/s.

3. The clinical lead is to provide a written response to the audit team acknowledging the potential outlier status and confirming that a discussion will take place with senior management, including CEO and Medical Director.

4. The audit team to review the response.
   If the service is no longer identified as an outlier, the clinical lead will be notified in writing, copying in the chief executive officer (CEO) and Medical Director to explain the corrected status.

5. If the service is confirmed as an outlier, the audit team to contact the clinical lead to inform them that written confirmation of alarm status will be sent to the CEO and copied to the clinical lead, network manager and Medical Director.

6. Acknowledgement of receipt of the letter confirming that a local investigation will be undertaken with independent assurance, (identified at provider level), of the validity of this exercise for alarm level outliers, copying in the CQC (England only), or the Welsh Government (wgclinicalaudit@gov.wales) (Wales only).

7. If no response received by the audit team, one reminder letter will be sent to the clinical lead, copying in the CEO and the CQC (England only), or the Welsh Government (Wales only).

8. Public disclosure of comparative information identifying providers through planned reporting and online reporting tools.

For full details, (please see the enclosed RCPCH policy, Detection and Management of Outlier Status for Clinical Indicators in National Clinical Audits. (Welsh National Policy due in 2018).

As a next step, please write to us by 10 August 2018 to acknowledge the potential outlier status for [measure name], and confirm that you will discuss the status with senior management, including your trust chief executive, who will be notified of your unit’s outlier status in due course. If you feel that there could be an error with your identification as an outlier, please contact us as soon as possible before this deadline.

Please also supply the names of your Chief Executive and Medical Director, and their Trust addresses by return.

Please write to us at [contact details].

The [audit name] participates in the National Clinical Audit Benchmarking (NCAB) project, a collaboration between the Healthcare Quality Improvement Partnership (HQIP) and Care Quality Commission (CQC), and the Clinical Outcomes Publication initiative.

The planned publication date [report name] is [publication date]. Outliers will be identifiable on [NNAP Online/NPDA Results Online], which will be updated on launch of the report.

Yours sincerely,

[Clinical lead signature, name and position]

[Project manager signature, name and position]

Encl. RCPCH, Detection and Management of Outlier Status for Clinical Indicators in National Clinical Audits.
Template email 2 (stage 5): Acknowledgement to clinical lead ahead of confirmation of outlier status.

Dear [clinical lead name],

Thank you for responding to the letter notifying you of provisional outlier status for one or more outlier measures in the [audit name].

As a next step, we will write to the Chief Executive of your trust/health board to confirm outlier status, copying in the Medical Director, and your regional network manager. We will also notify the [Care Quality Commission/ Welsh Government] to confirm outlier status.

*Please note that the CQC expect to see evidence of appropriate initial and substantive action plans which they will assess. The plans can be developmental but need to be realistic and appropriate. The CQC will not usually take regulatory action if organisations are responding appropriately to each stage of the outlier management process.*

Yours sincerely,

[Project manager name]
Template letter 2: Confirmation of outlier status to provider chief executive

Name
Address line 1
Address line 2
Address line 3
Postcode
Country

[Date]

Dear [CEO name],

Confirmation of low outlier status for [audit name] [audit year] measures

We recently wrote to [clinical lead name], clinical lead for the [service name, unit name] to notify them of provisional low outlier status for one or more [audit name] measures.

We received acknowledgement from the clinical lead along with [other information provided, e.g. discussion with senior management, action plans]. We are now writing to confirm the outlier status and to advise you of next steps.

As part of its annual reporting process the [audit name] conducts unit level outlier analysis on [description of measures subject to outlier status]. The purpose of the outlier process is to identify and highlight variation, enable local review of the causes of that variation and stimulate quality improvement.

Since outlier status is defined statistically, there will inevitably always be a small number of units whose results show them as outliers for any specific measure. However, it is crucial that all stakeholders and organisations understand that while units could have outlying results, this does not automatically mean that there are performance issues. Furthermore, where verified results do show units to be outlying for specific processes, this should be viewed as the beginning, or continuance, of a quality improvement process.

[Paragraph describing data quality assurance process to date, i.e. for the NNAP, details of the quarterly reporting review period.]

The [audit name] defines outliers between 2 and 3 standard deviations below expected performance (National average result) as 'alert' level outliers and, and those outside of 3 or more standard deviations below expected performance as ‘alarm’ level outliers.

We can confirm that [unit name] is an outlier at alarm level (3 or more standards deviations below expected performance) for the audit measure [measure name].

[results table]

What do you need to do next?

The [audit name] follows an outlier management process aligned with the RCPCH and the Healthcare Quality Improvement Partnership (HQIP) guidance Detection and management of outlier for National Clinical Audits. The RCPCH policy is enclosed.

As a next step, please acknowledge receipt of this letter by [DATE], copying in the Care Quality Commission (via clinicalaudits@cqc.org.uk)/ Welsh Government (via wgclinicalaudit@gov.wales).
Please note that the CQC expect to see evidence of appropriate initial and substantive action plans. Please send a copy of your action plan directly to the CQC by [DATE]. The CQC will not usually take regulatory action if organisations are responding appropriately to each stage of the outlier management process.

We also advise you to inform commissioners and NHS Improvement (via the email address nhsi.medicaldirectorate@nhs.net).

Please write to us at [contact details].

The [audit name] participates in the National Clinical Audit Benchmarking (NCAB) project, a collaboration between the Healthcare Quality Improvement Partnership (HQIP) and Care Quality Commission (CQC), and the Clinical Outcomes Publication initiative. (where applicable)

The [report name] will be published on [publication date]. Outliers will be identifiable on [NNAP Online/NPDA Results Online], which will be updated on launch of the report.

Yours sincerely,

[Clinical lead signature, name and position]

[Project manager signature, name and position]

CC: [Clinical lead, Medical director, CQC/ Welsh Government, Regional network manager]

Encl.

- RCPCH, Detection and Management of Outlier Status for Clinical Indicators in National Clinical Audits.
- [Any relevant emails/documents previously provided by the clinical lead].
Template letter 3: Reminder letter to clinical lead following confirmation of outlier status to the chief executive

Name
Address line 1
Address line 2
Address line 3
Postcode
Country

[Date]

Dear [clinical lead name],

Reminder: Confirmation of low outlier status for [audit name] [audit year] measures

We recently wrote to the trust/health board Chief Executive to confirm the outlier status for one or more measures in the [audit name].

We asked the Chief Executive to acknowledge receipt of this letter by [DATE], copying in the Care Quality Commission (via clinicalaudits@cqc.org.uk)/ Welsh or Welsh Government (via wgclinicalaudit@gov.wales), and to then provide an action plan directly to the CQC / Welsh Government by [DATE].

We have not yet received a response. Please can you ensure that an acknowledgement is sent to us by [DATE]. If we don’t receive a response by this date, we will advise the [CQC/ Welsh Government] accordingly.

The [report name] will be published on [publication date]. Outliers will be identifiable on [NNAP Online/NPDA Results Online], which will be updated on launch of the report.

Yours sincerely,

[Clinical lead signature, name and position]

[Project manager signature, name and position]
Template email 2 (stage 5): Confirmation of alarm level outliers to the CQC/Welsh Government

To: clinicalaudits@cqc.org.uk / wgclinicalaudit@gov.wales

Subject: Notification of outlying providers at 3SD (alarm level) in the [audit name]

Dear colleague,

The [audit name] is currently undertaking its outlier management process for [year] data in line with the RCPCH policy for the Detection and Management of Outlier Status for Clinical Indicators in National Clinical Audits.

We are writing to confirm that the following providers have been identified as outliers for audit measures included in the [audit name]:

<table>
<thead>
<tr>
<th>Unit name</th>
<th>Trust/Health board</th>
<th>Audit measure</th>
</tr>
</thead>
</table>

Chief executives at the above provider organisations have been asked to acknowledge their outlier status, copying in the [CQC/Welsh Government] by [DATE], and to provide an action plan directly to you by [DATE].

Regards.

[Project manager]

Template email 3 (stage 7): Notification of non-responding outliers to the CQC/Welsh Government

To: clinicalaudits@cqc.org.uk / wgclinicalaudit@gov.wales

Subject: Notification of non-responding outlying providers in the [audit name]

Dear colleague,

Following on from our previous email notifying you of the providers who have been identified as outliers in the [audit name], we are writing to advise you that the chief executives of the following providers have not responded to acknowledge outlier status:

<table>
<thead>
<tr>
<th>Unit name</th>
<th>Trust/Health board</th>
<th>Audit measure</th>
</tr>
</thead>
</table>

The [audit name] has completed its outlier management process in line with the RCPCH policy for the Detection and Management of Outlier Status for Clinical Indicators in National Clinical Audits. We trust you will follow up directly with the provider. Regards.

[Project manager]
Appendix B – Audit Outlier Process Flow

START

Audit data submission, analysis, data completeness and outlier identification complete

Outlier data rechecked for accuracy

Analysis incorrect and updated

Analysis Correct

Clinical Lead supported with data and queries regarding status

Clinical Lead Challenge?

Yes

No Response

No

Clinical Lead Formally Notified of alarm level status

Trust CEO and Medical Director Contacted by Audit and Notice of Outlier sent to CQC or Welsh Government

Trust response

No

Yes

Follow up letter

No Further Action

Audit Publishes National Report