National Paediatric Diabetes Audit: Detection and management of outlier status for Paediatric Diabetes Units

Introduction

This document sets out the process for detection and management of outlier status in the National Paediatric Diabetes Audit (NPDA) for from 2018/19. It follows the process set out in the RCPCH outlier policy for national clinical audit, and outlines where the NPDA takes steps that diverge from those outlined in the RCPCH policy.

For the full RCPCH outlier policy for national clinical audit, please see here.

Choice of performance indicators for outlier analysis

The performance indicators subject to outlier analysis are selected by the NPDA Methodology and Dataset Group and endorsed by the NPDA Project Board.

Since the 2016/17 year, the NPDA has conducted outlier analysis on the following measures at unit level:

- **Overall health check completion rate for children and young people with Type 1 diabetes aged 12 and above.**

  The healthcare check completion rate is equal to the total number of key healthcare checks recorded for children and young people aged 12 and above completing a full year of care in [insert year] (n) divided by the maximum number of checks expected for this cohort (7n).

  Completion rate = sum of the number of healthcare checks recorded for n divided by 7n

  The seven key healthcare checks included in this analysis were HbA1c, BMI, foot examination and screening for retinopathy, albuminuria and thyroid disease.

- **Case mix adjusted mean HbA1c**

  A multiple linear regression model is constructed to estimate the predicted mean HbA1c of children and young people with Type 1 diabetes who had at least one valid HbA1c measurement within the
audit period after accounting for the following characteristics; age, sex, ethnicity, duration of diabetes, and level of deprivation.

The output of the regression was used to calculate the predicted median HbA1c for each individual child/young person. The predicted median HbA1c is the value we would expect to observe for a given set of characteristics. This was then used to calculate the individual level and unit level adjusted HbA1c.

Detection of a potential outlier

The NPDA identifies negative outliers between 2 and 3 standard deviations below expected performance (described as alert level) and at 3 or more standard deviations below expected performance (described as alarm level).

The NPDA also identifies positive outliers at 3 or more standards deviations above expected performance on the metrics used for negative outlier identification.

The expected target, or comparison standard for outlier analysis, is set at the national mean rate.

Management of a potential outlier

The NPDA follows the RCPCH process for outlier management:

<table>
<thead>
<tr>
<th>Stage</th>
<th>Working days</th>
<th>Description</th>
<th>Responsible person</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10</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>
</tr>
<tr>
<td>2</td>
<td>5</td>
<td>The clinical lead in the participating provider is informed, (Template letter 1 -Appendices A and B), 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 in stage 6 should there be a case to answer. All relevant data and analyses details can be made available to the clinical lead and queries will be prioritised and answered promptly.</td>
<td>RCPCH Audit team</td>
</tr>
<tr>
<td>3</td>
<td>25</td>
<td>Clinical lead in the participating provider to provide written response to the RCPCH audit team</td>
<td>Participating provider clinical lead</td>
</tr>
</tbody>
</table>
acknowledging the potential outlier status, and confirm that discussions with senior management will take place.

<table>
<thead>
<tr>
<th>Step</th>
<th>Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Review of response from the clinical lead in the participating provider to determine if there is:</td>
</tr>
<tr>
<td></td>
<td>‘No case to answer’</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 will always be made stating that an outlier status is unlikely.</td>
</tr>
<tr>
<td></td>
<td>- Data and results should be annotated within RCPCH audit records at this stage and within details of the provider’s response and the subsequent reports online and any CQC slides generated.</td>
</tr>
<tr>
<td></td>
<td>‘Case to answer’</td>
</tr>
<tr>
<td></td>
<td>- If it 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.</td>
</tr>
<tr>
<td></td>
<td>or</td>
</tr>
<tr>
<td></td>
<td>- It is confirmed that the originally supplied data were accurate, thus confirming the initial designation of outlier status.</td>
</tr>
<tr>
<td></td>
<td>They will proceed to Stage 5</td>
</tr>
<tr>
<td>5</td>
<td>Contact clinical lead of the participating provider, to confirm outlier status and advise of next steps. Clinical lead to be reminded to discuss their result with their Chief Executive and Medical Director.</td>
</tr>
<tr>
<td></td>
<td>The NPDA will notify the clinical lead managers of positive outliers. No further response will be required.</td>
</tr>
<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 (Appendix C).</td>
</tr>
<tr>
<td></td>
<td>All relevant data and statistical analyses, including previous response from the clinical lead of the participating provider, will be made available to the</td>
</tr>
</tbody>
</table>
Medical Director and CEO in writing, with copies going to the Clinical Lead and Regional Network Manager.

Within this letter the CEO will also be informed of the publication schedule and that information of comparative performance that will identify their participating provider.

| 7 | 3 | RCPCH Audit teams will inform the CQC ([clinicalaudits@cqc.org.uk](mailto:clinicalaudits@cqc.org.uk)) of alarm level outliers in England and the participating provider CEO will be advised to inform commissioners and NHS Improvement ([nhsi.medicaldirectorate@nhs.net](mailto:nhsi.medicaldirectorate@nhs.net)) (Template Email 2 - Appendix A).

RCPCH audit teams will inform the Welsh Government ([wgclinicalaudit@gov.wales](mailto:wgclinicalaudit@gov.wales)) of alarm level outliers in Wales.

| 8 | 10 | Acknowledgement of receipt of the letter confirming that a local investigation will be undertaken with independent assurance, (identified at provider level).

- Providers in Wales are expected to copy in the Welsh Government ([wgclinicalaudit@gov.wales](mailto:wgclinicalaudit@gov.wales))
- 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](mailto:clinicalaudits@cqc.org.uk))

In England the CQC will assess this plan and ensure that outliers are pro-actively 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.*

| 9 | 5 | 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.

If an acknowledgement is not received within 5 working days, the relevant government agency will be notified of non-compliance; CQC and NHS Improvement in England, Scottish and Welsh Governments.

| 10 | 0 | Public disclosure of comparative information identifying providers through planned reporting and online reporting tools in line with the NHSE Standard Reporting Procedure. | RCPCH audit team |
If you have any questions about the NPDA outlier detection and management process, please contact the NPDA audit team via email: npda@rcpch.ac.uk or via telephone: 020 7092 6137.

Appendix A – Health check completion rate outlier notification

Sent via email to [insert name of clinical lead]

[date]

Dear Dr [insert],

Re: Outlier status for the [insert year] National Paediatric Diabetes Audit (NPDA)

As part of our contractual arrangement with our commissioners, the NPDA conducts outlier analysis to identify and highlight variation, enable local review of the causes of that variation and stimulate quality improvement. As part of this process, the NPDA are now writing to the clinical leads of paediatric diabetes units (PDU) who have been identified as potential outliers for the [insert] audit year.

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. Since outlier status is defined statistically, there will inevitably always be a small number of units identified as outliers on any specific metric. 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.

Metrics used for outlier analysis

Since the 2016/17 audit year, two metrics have been used to define outlier status:

1. Adjusted mean HbA1c
2. Healthcare check completion rate

Units with results falling outside of three standard deviations of the mean result for England and Wales on either of these measures are regarded as negative ‘Alarm’ level outliers.

After undertaking analysis of the [insert year] data, the healthcare check completion rate calculated for [name of] Hospital falls outside of three standard deviations of the overall rate, meaning that your unit is considered a negative ‘Alarm level’ outlier on this metric:

<table>
<thead>
<tr>
<th>Denominator</th>
<th>Completion rate (%)</th>
<th>Low 3SD limit (%)</th>
<th>High 3SD limit (%)</th>
</tr>
</thead>
</table>

[Table completed with values]
The healthcare check completion rate is equal to the total number of key healthcare checks recorded for children and young people aged 12 and above completing a full year of care in [insert year] \( n \) divided by the maximum number of checks expected for this cohort \( 7n \).

- Completion rate = sum of the number of healthcare checks recorded for \( n \) divided by \( 7n \)

The seven key healthcare checks included in this analysis were HbA1c, BMI, foot examination and screening for retinopathy, albuminuria and thyroid disease. The table below provides a summary of unit level performance for each healthcare check.

<table>
<thead>
<tr>
<th>HbA1c (%)</th>
<th>Thyroid (%)</th>
<th>BMI (%)</th>
<th>Blood Pressure (%)</th>
<th>Albuminuria (%)</th>
<th>Eye screen (%)</th>
<th>Foot exam (%)</th>
</tr>
</thead>
</table>

**Percentage of children and young people with Type 1 diabetes aged 12 and above who completed a full year of care receiving each of the individual key healthcare checks:**

**Process of outlier notification**

The NPDA process of outlier notification is based on the RCPCH policy on the Detection and Management of Outlier Status for clinical Indicators for Managed National Clinical Audits, which is in turn based on the policy of our commissioners. This letter represents Step 1 of the process, briefly summarised below. Please refer to the policy for full details and timings.

<table>
<thead>
<tr>
<th>Process for reporting outliers</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>The clinical lead of the service is informed of potential outlier status.</td>
</tr>
<tr>
<td>2.</td>
<td>The clinical lead is given the opportunity to query the data and/or provide justifiable explanation/s.</td>
</tr>
<tr>
<td>3.</td>
<td>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 Chief Executive Officer (CEO) and Medical Director to update them on the result.</td>
</tr>
<tr>
<td>4.</td>
<td>The audit team to review the response.</td>
</tr>
<tr>
<td></td>
<td>If the service is no longer identified as an outlier, the clinical lead will be notified in writing, copying in the CEO and Medical Director to explain the corrected status.</td>
</tr>
<tr>
<td>5.</td>
<td>If the service is confirmed as an outlier, the audit team will 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.</td>
</tr>
<tr>
<td>6.</td>
<td>Acknowledgement of receipt of the letter confirming actions to take place, copying in the CQC (England only) or Welsh Government (Wales only)</td>
</tr>
<tr>
<td>7.</td>
<td>If no response received by the NPDA, 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).</td>
</tr>
</tbody>
</table>
In line with the above, I would be grateful if you could reply to this letter and acknowledge this potential outlier status, notifying of any data errors or other explanations for the outlying result, and confirming that a discussion has or will take place with senior management by [insert date].

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

If you have any queries in relation to the information above, or the methodology used in the outlier process, do contact us at: npda@rcpch.ac.uk or on 020 7092 6167.

Yours sincerely

NPDA Manager
Royal College of Paediatrics and Child Health

Appendix B – Case-mix adjusted HbA1c outlier notification

Sent via email to [insert email of clinical lead]

Date

Dear Dr [insert],

Re: Outlier status for the [insert year] National Paediatric Diabetes Audit (NPDA)

As part of our contractual arrangement with our commissioners, the NPDA conducts outlier analysis to identify and highlight variation, enable local review of the causes of that variation and stimulate quality improvement. As part of this process, the NPDA are now writing to the clinical leads of paediatric diabetes units (PDU) who have been identified as potential outliers for the [insert] audit year.

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. Since outlier status is defined statistically, there will inevitably always be a small number of units identified as outliers on any specific metric. 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.

Metrics used for outlier definitions
Since the 2016/17 audit year, two metrics have been used to define outlier status:

8. Public disclosure of comparative information identifying providers through planned reporting and online reporting tools
3. Adjusted mean HbA1c
4. Healthcare check completion rate

Units with results falling outside of three standard deviations of the mean result for England and Wales on either of these measures are regarded as ‘Alarm’ level outliers.

After undertaking analysis of the [insert year] data, the adjusted mean HbA1c calculated for Morriston Hospital falls outside of three standard deviations of the national mean HbA1c and your unit is therefore considered to be a negative, alarm level outlier on this metric:

<table>
<thead>
<tr>
<th>Denominator</th>
<th>Mean HbA1c (mmol/mol)</th>
<th>Adjusted mean HbA1c (mmol/mol)</th>
<th>Low 3SD limit (mmol/mol)</th>
<th>High 3SD limit (mmol/mol)</th>
</tr>
</thead>
</table>

The case-mix adjusted mean HbA1c is calculated from the median HbA1c result recorded for each child and young person with Type 1 diabetes who had a recorded HbA1c at least 90 days following diagnosis and who had a valid data recorded for the patient characteristics used to calculate the case-mix adjustment. The case-mix adjustment is applied to each unit taking into account differences in patient characteristics between units which allows a fairer comparison across individual units. Details of the case-mix adjustment applied for [insert year] data are attached.

**Process of outlier notification**

The NPDA process of outlier notification is based on the RCPCH policy on the *Detection and Management of Outlier Status for clinical Indicators for Managed National Clinical Audits*, which is in turn based on the policy of our commissioners. This letter represents Step 1 of the process, briefly summarised below. Please refer to the policy for full details and timings.

<table>
<thead>
<tr>
<th>Process for reporting outliers</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The clinical lead of the service is informed of potential outlier status.</td>
</tr>
<tr>
<td>2. The clinical lead is given the opportunity to query the data or analysis and/or provide justifiable explanation/s.</td>
</tr>
<tr>
<td>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 Chief Executive Officer (CEO) and Medical Director to inform them of the result.</td>
</tr>
<tr>
<td>4. The audit team to review the response.</td>
</tr>
<tr>
<td>If the service is no longer identified as an outlier, the clinical lead will be notified in writing, copying in the CEO and Medical Director to explain the corrected status.</td>
</tr>
<tr>
<td>5. If the service is confirmed as an outlier, the audit team will 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.</td>
</tr>
</tbody>
</table>
In line with the above, I would be grateful if you could reply to this letter and acknowledge this potential outlier status, notifying of any data errors or other explanations for the outlying result, and confirming that a discussion has or will take place with senior management by [insert date].

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

If you have any queries in relation to the information above, or the methodology used in the outlier process, do contact us at: npda@rcpch.ac.uk or on 020 7092 6167.

Yours sincerely

NPDA Manager
Royal College of Paediatrics and Child Health

Appendix c- Letter to CEOs

[insert CEO name]

Chief Executive

[Insert Trust/LHB]

[Insert address]

[insert date]

Dear [Title surname],

Re: Confirmation of negative outlier status for NPDA [insert year] measure
As part of its annual reporting process, the NPDA conducts unit level outlier analysis on two key metrics. The purpose of the outlier process is to identify and highlight variation, enable local review of the causes of that variation and to stimulate quality improvement.

The NPDA 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 [name of clinic] is an outlier at alarm level (3 or more standards deviations below expected performance) for the [insert name of metric] metric. Please see the attached initial letter to the clinical lead informing of provisional outlier status for further detail.

Now that the analysis has been validated, we are writing to confirm the outlier status and to advise you of next steps.

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.

What do you need to do next?

The NPDA follows an outlier management process aligned with the RCPCH and the Healthcare Quality Improvement Partnership (HQIP) guidance on the Detection and management of outlier for National Clinical Audits. The RCPCH policy is available at www.rcpch.ac.uk/npda.

- As a next step, please acknowledge receipt of this letter by [insert date], by emailing [NPDA manager email address], copying in the Care Quality Commission (via clinicalaudits@cqc.org.uk)/Welsh Government (wgclinicalaudit@gov.wales)

Please note that the CQC/Welsh Government expect to see evidence of appropriate initial and substantive action plans, which should be sent directly to the them by [date]. The CQC/Welsh Government 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 nhsimедicaldirectorate@nhs.net).
The NPDA participates in the National Clinical Audit Benchmarking (NCAB) project, a collaboration between the Healthcare Quality Improvement Partnership (HQIP), the CQC, and the Clinical Outcomes Publication initiative. Outliers will be identifiable on NCAB slides and NPDA Results Online, which will be updated further to the launch of the national report (publication date TBC).

Yours Sincerely

National Paediatric Diabetes Audit (NPDA) Manager
Royal College of Paediatrics & Child Health
5-11 Theobalds Road
London WC1X 8SH

020 7092 6167

CCs:

Dr [insert name], Medical Director
Dr [insert name], Clinical Lead
[Insert name], regional network manager