National Paediatric Diabetes Audit: Policy on the
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) from the 2022/23 audit year onwards. It follows the process set out in the HQIP policy for the detection and management of outliers.

Choice of performance indicators for outlier analysis

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

The two metrics reported by the NPDA that are used for the identification of outliers are:

1. **Overall health check completion rate for children and young people with Type 1 diabetes (updated for 2022/23)**

   The healthcare check completion rate is equal to the total number of key healthcare checks recorded for children and young people completing a full year of care, divided by the maximum number of checks expected for this cohort based on their ages.

   The six key healthcare checks expected for children and young people with Type 1 diabetes aged 12 and above for this analysis are HbA1c, BMI, foot examination and screening for albuminuria and thyroid disease. The three expected for those age <12 years are HbA1c, BMI, and thyroid screen.

   \[
   \text{Total number of health checks received by children and young people of all ages} = \frac{\text{Number of children aged 11 and below} \times 3 + \text{Number of young people aged 12 and above}}{6}
   \]

2. **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 is 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 is used to calculate the individual level and unit level adjusted HbA1c.

**Non-participation in the NPDA**

From 2024 onwards, non-participation in the NPDA will confer negative outlier status, as will incomplete submission of data used to calculate performance against outlier metrics. Non-participating paediatric diabetes units (PDUs) will be treated as an alarm level outlier for all eligible metrics and followed up via standard processes with a note clarifying that status is due to non-participation.

**Detection of a potential outlier**

For the health check completion rate, the NPDA identifies alert level negative outliers as those in the bottom 5% of paediatric diabetes units (PDUs), and those in the bottom 3% as alarm level outliers.

For the case mix adjusted HbA1c metric, the NPDA identifies alert level negative outliers between 2 and 3 standard deviations below expected performance, and alarm level outliers at 3 or more standard deviations below expected (national mean) performance.

The NPDA also identifies positive outliers as those in the top 3% of PDUs on the health check completion rate metric, and 3 or more standard deviations above expected performance on the case mix adjusted HbA1c metric.

**Publication of outlier status within the NPDA**

Comparative data on performance against outlier metrics within the NPDA, including positive and negative outlier status, will be made available

- Within PDU level annual reports
- Within data files hosted on the NPDA website
- On the NPDA interactive reporting tool

Details of investigations resulting from notification of outlier status are not requested to be shared with the NPDA, and will not be reviewed or published by the NPDA should copies be shared with the NPDA team.
## Actions required for alarm level outliers

<table>
<thead>
<tr>
<th>Stage</th>
<th>Working days</th>
<th>Description</th>
<th>Responsible person</th>
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<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>The process underpinning the analysis of the outlier metric data of identifying the ‘alarm’ and ‘alert’ outliers will be validated by the senior analyst on the RCPCH audit team, at which point the audit will be satisfied that there is a ‘case to answer’ for those identified as such.</td>
<td>RCPCH Audit team</td>
</tr>
<tr>
<td>2</td>
<td>5</td>
<td>The clinical lead in the participating provider and their regional network manager are 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 will 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>14</td>
<td>Clinical lead in the participating provider to provide written response to the RCPCH audit team acknowledging the potential outlier status, and confirm that discussions with senior management will take place.</td>
<td>Participating provider clinical lead</td>
</tr>
<tr>
<td>4</td>
<td>10</td>
<td>Review of response from the clinical lead in the participating provider to determine if there is:</td>
<td>RCPCH Audit team</td>
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<tr>
<td></td>
<td></td>
<td>‘No case to answer’</td>
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<td></td>
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<td>If it is confirmed that the NPDA analysis was inaccurate, complete reanalysis of this metric will happen before audit results are published, and the outlier identification process will be reapplied.</td>
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<td>‘Case to answer’</td>
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<td>If is confirmed that, the data originally supplied by the participating provider were inaccurate. Where there has been errors in data entry by the clinical team, the outlier status is still confirmed. Issues with data quality must be addressed by the clinical team. Details of the provider’s</td>
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response and shared with the CQC/Welsh Government as well as Trust/Health Board management.

or

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

They will proceed to Stage 5

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
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<tr>
<td>5</td>
<td>Contact healthcare provider prior to sending written notification of confirmed 'alarm' outliers and/or non-participation outliers to healthcare provider CEO and medical director.</td>
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</tbody>
</table>
| 6    | Outlier confirmation letter will be sent to confirmed 'alarm' 3SD outliers and/or non-participation outliers to healthcare provider CEO and copied to healthcare provider clinical lead, and medical director. All relevant data and statistical analyses, including previous response from healthcare provider lead clinician should be made available to the healthcare provider medical director and CEO, as well as the NPDA outlier policy. **Trusts in England** will be requested to acknowledge receipt of the letter, and engage with their CQC local team. The CQC advise that during their routine local engagement with the providers, their inspectors will:
  - Encourage Trusts to identify any learning from their performance and provide the CQC with assurance that the Trust has used the learning to drive quality improvement
  - Ask the Trust how they are monitoring or plan to monitor their performance
  - Monitor progress against any action plan if one is provided by the trust. The CQC are not prescriptive concerning any such investigations but there needs to be a degree of independence so that the validity of the findings is acceptable.

If an investigation has been conducted in the Trust into an alarm outlier status, it is required that the CQC would be provided with the outcome and actions proposed.

**Health Boards in Wales** will be requested to acknowledge receipt of the written notification confirming that a local investigation will be undertaken with independent assurance of the investigation’s validity, copying in the Welsh Government. | RCPCH Audit team |

| 5    | RCPCH Audit team |
The NPDA will notify the CQC (clinicalaudits@cqc.org.uk) using the outlier template, NHS England (NHSE, England.clinicalaudit@nhs.net), the Welsh Government (wgclinicalaudit@gov.wales), and HQIP associate director and project manager of confirmed ‘alarm’ status. **All three organisations should confirm receipt of the notification.**

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<tbody>
<tr>
<td>8</td>
<td>15</td>
<td>Healthcare providers in England and Wales should acknowledge the alarm level confirmation letter within 15 days of receipt. For Welsh providers, if no acknowledgement is received, a reminder letter will be sent by the NPDA team to the healthcare provider CEO, copied to Welsh Government and HQIP. If not received within 15 working days, the Welsh Government will be notified of non-compliance, copying in HQIP.</td>
</tr>
<tr>
<td>9</td>
<td>-</td>
<td>Public disclosure of comparative information identifying providers through planned reporting and online reporting tools in line with the NHSE Standard Reporting Procedure.</td>
</tr>
</tbody>
</table>

### Actions required for alert-level outliers in England

The CQC, NHSE, and HQIP do not mandate a formal notification and escalation process for alert level beyond notification of the relevant clinical team. In the NPDA, alert level notifications to clinical teams will be included in PDU-level reports. The expectation is that NHS Trusts and Health Boards should use ‘alert’ information as part of their internal quality monitoring process. They should review alerts in a proactive and timely manner, acting accordingly to mitigate the risk of care quality deteriorating to the point of becoming an alarm level outlier, and Trusts in England may be asked as part of their routine engagement with the CQC how they are monitoring or planning to monitor their performance.

### Roles of the Welsh Government and Healthcare Inspectorate Wales in outlier management

The Welsh Government monitors the actions of organisations responding to outliers and takes further action as and when required. The Healthcare 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

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 6167.

### Changes to the NPDA outlier policy from 2022/23

The key changes to the NPDA outlier management policy from 2022/23 are:

- Inclusion of those aged under 12 in the health check completion metric
• Determination of outlier status for the health check completion metric based on percentage cut-offs rather than standard deviations
• Inclusion of non-participation as a reason for conferring outlier status
• Removal of formal obligation for PDUs in England to confirm details of their action plans to the CQC
• NHSE and HQIP to be included alongside CQC in alert and alarm reporting

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
Two metrics are used to determine outlier status within the NPDA:

1. Adjusted mean HbA1c
2. Health check completion rate

After undertaking analysis of the [insert year] data, the health check completion rate calculated for [name of] Hospital falls within the lowest 3% of those calculated for PDUs in England and Wales, 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>
The health check completion rate is equal to the total number of key health checks recorded for children and young people completing a full year of care, divided by the maximum number of checks expected for this cohort based on their ages.

The six key healthcare checks expected for children and young people with Type 1 diabetes aged 12 and above for this analysis are HbA1c, BMI, foot examination and screening for albuminuria and thyroid disease. The three expected for those age <12 years are HbA1c, BMI, and thyroid screen.

Percentages 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 health checks included in the metric:

<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>

Percentages of children and young people with Type 1 diabetes aged <12 who completed a full year of care receiving each of the individual key health checks included in the metric:

<table>
<thead>
<tr>
<th>HbA1c (%)</th>
<th>Thyroid (%)</th>
<th>BMI (%)</th>
</tr>
</thead>
</table>

**Process of outlier notification**

The NPDA process of outlier notification is based on the guidance published by the Healthcare Quality Improvement Partnership (HQIP), who are the commissioners of the NPDA. This letter represents Step 1 of the process, briefly summarised below. Please refer to the policy for full details and timings.

**Process for reporting outliers**

1. The clinical lead of the service is informed of potential outlier status.
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 Chief Executive Officer (CEO) and Medical Director to update them on the result.
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.
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.

6. Acknowledgement of receipt of the letter by the CEO copying in the Welsh Government (Wales only).

7. If no response received by the NPDA, one reminder letter will be sent to the CEO copying in the Welsh Government (Wales only).

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

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@rcpoch.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:

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 the adjusted HbA1c metric are considered ‘Alarm level’ outliers on this metric.

After undertaking analysis of the [insert year] data, the adjusted mean HbA1c calculated for [name of PDU] 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 take into account differences in patient characteristics between PDUs which allows a fairer comparison of performance. 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 [guidance published by the Healthcare Quality Improvement Partnership (HQIP)](https://www.hqip.org.uk), who are the commissioners of the NPDA. This letter represents Step 1 of the process, briefly summarised below. 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>
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<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>
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<td>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.</td>
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</table>
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.

6. Acknowledgement of receipt of the letter by the CEO copying in the Welsh Government (Wales only).

7. If no response received by the NPDA, one reminder letter will be sent to the CEO copying in the Welsh Government (Wales only).

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

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 possible 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 email 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

Sent via email to [insert email of CEO]

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 ‘Alarm level’ outliers as paediatric diabetes units with results falling outside of the expected range of results on one of two key metrics within the audit. We can confirm that [name of clinic] is an outlier at alarm level (3 or more standards deviations below expected performance/within the bottom 3% of results) 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 Healthcare Quality Improvement Partnership (HQIP) guidance on the detection and management of outliers for National Clinical Audits. The full NPDA policy is available at [www.rcpch.ac.uk/npda](http://www.rcpch.ac.uk/npda).

- As a next step, please acknowledge receipt of this letter by [insert date], by emailing npda@rcpch.ac.uk, copying in the Welsh Government (wgclinicalaudit@gov.wales) WALES ONLY

**CEOs of Trusts in England** are requested to acknowledge receipt of this letter, and engage with their CQC local team. The CQC advise that during their routine local engagement with the providers, their inspectors will:

- Encourage Trusts to identify any learning from their performance and provide the CQC with assurance that the Trust has used the learning to drive quality improvement
- Ask the Trust how they are monitoring or plan to monitor their performance
- Monitor progress against any action plan if one is provided by the trust. The CQC are not prescriptive concerning any such investigations but there needs to be a degree of independence so that the validity of the findings is acceptable.

If an investigation has been conducted in the Trust into an alarm outlier status, it is required that the CQC would be provided with the outcome and actions proposed.

**CEOs of Health Boards in Wales** will be requested to acknowledge receipt of the written notification confirming that a local investigation will be undertaken with independent assurance of the investigation’s validity, copying in the Welsh Government.

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 within PDU-level NPDA reporting, which will be published alongside the NPDA national report on the (publication date TBC).

Yours Sincerely

National Paediatric Diabetes Audit (NPDA) Manager

CCs:

Dr [insert name], Medical Director

Dr [insert name], Clinical Lead

[Insert name], regional network manager