

# **PICANet detecting and management of potential outliers**

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## Document History

Version	Author	Date	Comments
1.0	Hannah Buckley	03/05/2019	Based on an amalgamation of earlier (un-versioned) policies from 2005 and 2015 created by Gareth Parry and Roger Parslow, taking into account HQIP guidance

Next review date	Reviewed by	Date

## **1. Introduction**

PICANet is part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP) for England & Wales and was established to monitor and review outcomes of treatment episodes, amongst other objectives. As part of this monitoring and review process we identify healthcare providers whose performance falls outside defined limits. These are referred to as outliers and may reflect poorer or better performance. In this document, the term healthcare provider is used to refer to designated level 3 paediatric intensive care units (PICUs) and/or centralised transport services (CTS). This policy details the identification and management of potential outliers for healthcare providers who submit data to PICANet.

The first PICANet outlier policy was produced in 2005, with a minor revision in 2015. In 2011, the National Clinical Audit Advisory Group and the Healthcare Quality Improvement Partnership (HQIP) published outlier guidance, which was updated in 2017 [1]. As such, we are updating our policy in line with this updated guidance.

Outlier detection should be based on a valid performance indicator which has a clear relationship between the indicator and quality of care, and relates to events that occur frequently enough to give statistical power [1]. Choice of expected performance level (or target) needs careful consideration. Furthermore, it is possible to base targets on external sources such as Paediatric Intensive Care Society (PICS) standards [2], or to base them on internal data, such as average performance of all healthcare providers.

This document considers which performance indicators could be used to identify healthcare providers that are performing outside of an expected range and documents the process to be followed after a potential outlier has been identified.

## **2. Choice of performance indicator**

PICANet reports annually on the following key metrics in relation to healthcare provider performance:

- Critical care emergency transport mobilisation times
- Number of qualified nurses per funded level 3 bed
- Emergency readmission within 48 hours
- Risk-adjusted in-PICU mortality

Unplanned extubations is also an outcome of interest within the clinical community, in terms of quality of care, but is not included as one of the key metrics.

Case ascertainment is also estimated for the admissions data for the audit as a whole based on discrepancies identified during validation visits, between the number of admissions recorded locally at a PICU and the number reported to PICANet. Validation visits are conducted in each healthcare provider at least 2-yearly, such that case ascertainment estimates are based on a rolling sample of PICUs and admissions. This is a key metric, as it provides an indicator of the coverage of the audit. However, as it is an estimated value across the audit and as it is a measure of the audit process rather than performance, it is not suitable for outlier analysis.

Table 1 shows the PICANet team's current assessment of relative merits of detecting potential outliers based on each of the above outcomes, excluding case ascertainment. Whilst all the measures considered are useful in terms of the wider audit, on consideration of the information documented in Table 1, it is felt at present that risk-adjusted mortality is the only suitable performance indicator for outlier detection.

**Table 1:** Assessment of key metrics as performance indicators for outlier detection

Metric	Target (expected performance)	Benefits	Drawbacks	Conclusions
Critical care emergency transport mobilisation time	<p>Starting journey within 30 minutes of clinical decision that PIC transport is required*</p> <p>*Please note prior to April 2016 the target was 1 hour</p>	<ul style="list-style-type: none"> <li>Standard exists (within England): NHS England target for 95% of cases achieving the standard (PIC14) [3]</li> </ul>	<ul style="list-style-type: none"> <li>On occasion transport may be strategically delayed due to appropriate risk-based triaging which would mean the mobilisation target is missed but the team are providing good quality care</li> <li>Measure of system capacity more than quality of care</li> <li>Impact of timeliness of access to paediatric intensive care on clinical outcomes is not yet established (being assessed as part of the DEPICT study)</li> <li>Risk adjustment not accounted for in standards</li> <li>Starting the journey is only one part of timely access</li> </ul>	<p>Considered unsuitable for outlier analysis as does not meet the criteria in terms of clear relationship between indicator and quality of care. Additionally, whilst there is currently a standard available, it is recognised that this is aspirational at present [4]. To reassess suitability of this or a similar measure in future following results from the DEPICT study.</p>
Number of qualified nurses employed per	<p>UK = 7.01 WTE</p> <p>ROI = 5.6 WTE</p>	<ul style="list-style-type: none"> <li>Standard exists: PICS standard for UK is 7.01 WTE (L3-207) [2]</li> <li>Standard for ROI is 5.6 WTE [5, 6]</li> </ul>	<ul style="list-style-type: none"> <li>Process measure rather than outcome measure</li> <li>It is recognised that this is an aspirational target [4] which few providers currently meet</li> </ul>	<p>Considered unsuitable for outlier analysis as does not meet the criteria in terms of clear relationship between indicator and quality of care.</p>

funded level 3 bed			<ul style="list-style-type: none"> <li>• Data collected as a snapshot in November each year but not continuously.</li> <li>• The number of funded beds may be different to the number of open beds as demonstrated by the census data collected by PICANet</li> <li>• Bank and agency nurses may be used to ensure staffing is at a safe level for the number of beds open and the care needs of the relevant patients as demonstrated by the census data collected by PICANet.</li> </ul>	<p>Additionally, whilst there is currently a standard available, this is aspirational at present and data regarding the number of beds opened on a PICU at a particular time and the number of nurses on duty does not accurately match reported establishment figures.</p>
Emergency readmission within 48 hours (to same PICU)	None	<ul style="list-style-type: none"> <li>• Emergency readmissions are an established metric both for PICU and other specialities across the NHS</li> </ul>	<ul style="list-style-type: none"> <li>• Approximately 93% of patients discharged from PICU are discharged to another ward within the same hospital or to another hospital [7]. This means that the metric is highly dependent on the designation of the funded beds within the PICU (e.g. whether it has designated Level 2 beds) and its supporting local care facilities rather than necessarily being a reflection of the quality of care provided by a PICU.</li> </ul>	<p>Considered unsuitable for outlier analysis as does not meet the criteria in terms of clear relationship between indicator and quality of care.</p>

			<ul style="list-style-type: none"> <li>• There is no accepted target or standard (NHS England Quality Service Dashboard states that there is no target and that data is being collected to set a baseline % (PIC04) [3])</li> <li>• Likely to reflect the hospital and hospital policy rather than the PICU</li> <li>• Rare event (affects 1.6% of all admissions [8]) so may not occur frequently enough to give statistical power</li> <li>• Ongoing research work at Birmingham is investigating the impact of the various contributory factors on emergency readmissions</li> </ul>	
Unplanned extubations	None	<ul style="list-style-type: none"> <li>• Within unit measure which is not impacted by wider organisational influence</li> <li>• Interest within the clinical community as most commonly occurring adverse event</li> </ul>	<ul style="list-style-type: none"> <li>• No accepted target or standard</li> <li>• Relatively new data item and interpretation of the definition incorporates an element of subjectivity so data quality may not yet be to up to the required standards</li> <li>• Rare event (0.4 unplanned extubations per 100 intubated days</li> </ul>	Considered unsuitable for outlier analysis as data quality not yet sufficiently robust and is a rare event. PICANet to take steps to address clarity of definition and quality of reporting and reassess suitability in future updates of this policy.

			<p>[8]) so may not occur frequently enough to give statistical power</p> <ul style="list-style-type: none"> <li>• May be linked to the sedation policy of the PICU.</li> </ul>	
Risk adjusted in PICU mortality	Observed mortality = expected mortality (i.e. SMR=1)	<ul style="list-style-type: none"> <li>• Risk adjustment model available (Paediatric Index of Mortality [9])</li> <li>• Unadjusted mortality is an objective, robust outcome measure which can be externally verified if required.</li> <li>• It is widely acknowledged that there is a clear relationship between mortality and quality of care once case-mix has been accounted for through appropriate risk adjustment</li> </ul>	<ul style="list-style-type: none"> <li>• There are limitations to the current risk adjustment model which may mean that case-mix is not fully adjusted for (e.g. PIM3 does not take into account certain life-limiting syndromes or co-morbidities which now form a significant proportion of PIC admissions).</li> <li>• Recalibration of the risk adjustment model to take into account changing patient case mix and improvements in survival can be sensitive to changes in the data</li> </ul>	<p>Despite the limitations in relation to current tools available for risk adjustment, this metric is considered suitable for outlier analysis as clear relationship between indicator and quality of care (although interpretation must be mindful of the limitations noted).</p>

### **3. Statistical methods for outlier detection**

#### **3.1. Data cleaning prior to outlier exploration**

PICANet undertake data cleaning prior to any analysis as detailed in the Statistical Analysis Plan. In brief, this includes examining relevant fields (such as PIM data and mortality information) for: completion rates; values being within range; and outstanding database validations. Where appropriate, queries are sent to the data provider to confirm or amend their data. For transparency, PICANet publish data completeness and case ascertainment in the Annual Report.

If a provider has more than 5% of its admission events (within a reporting period) with missing or unknown status at discharge (rather than alive or dead), then the relevant PICANet lead will be given written notification that their data completeness on this field requires improvement. The provider should review their data and correct any inaccuracies or provide further information where possible. If, following this, a provider continues to have missing or unknown status at discharge for more than 5% of its admission events, it will be considered for exclusion from the outlier analysis on the basis of poor data quality. Such status will be reported to the provider Clinical Lead and to the CQC as part of the National Clinical Audit Benchmarking Programme submission, and will be documented in the PICANet Annual Report and on My NHS.

#### **3.2. Calculating Standardised Mortality Ratios (SMRs)**

Risk-adjusted mortality will be used as the sole performance indicator to detect potential outliers. This will be presented using risk-adjusted standardised mortality ratios and funnel plots. Calculation of unadjusted and risk-adjusted SMRs are presented below.

##### **Unadjusted SMRs**

Unadjusted standardised mortality ratios (SMRs) are calculated by dividing the observed numbers of deaths in a specific PICU by the number of expected deaths in that PICU [10] and do not take into account case-mix.

First, the overall mortality rate in all PICANet PICUs in the reporting period is calculated as:

$$\text{Overall mortality rate} = \frac{\text{Total number of deaths observed in the reporting period}}{\text{Total number of admissions within the reporting period}}$$

This overall mortality rate is then used to calculate the unadjusted expected number of deaths for each PICU within the reported period:

*Expected deaths in a PICU*

*= Overall mortality rate*

*× number of admissions to PICU in reporting period.*

The unadjusted SMR for a PICU in the reporting period is then calculated as:

$$\text{Unadjusted SMR} = \frac{\text{Number of deaths observed in PICU in reporting period}}{\text{Number of deaths expected in PICU in the reporting period}}$$

An unadjusted SMR of 1 indicates that the number of observed deaths is equal to the number expected (the target); an SMR of greater than one indicates more observed deaths than expected and an SMR of less than one indicates fewer observed deaths than expected.

### **Risk-adjusted SMRs**

Risk-adjusted SMRs take into account case-mix and are calculated by dividing the observed number of deaths in each organisation by the expected number of deaths predicted using the current risk-adjustment model (this is currently done using Paediatric Indicator of Mortality 3 (PIM3) [9] which PICANet have been collecting since mid-2014 (prior to this adjustment was made using PIM2 [11] or PIM [12]). PIM scores are calculated for each individual admission, in cases of quick readmission PIM score associated with the initial admission will be used.

The PIM3 adjusted expected number of deaths for each PICU within the reported period is calculated as:

*Expected deaths in a PICU (risk adjusted)*

$$= \sum_i \text{PIM3 scores in the PICU in the reporting period.}$$

A risk-adjusted SMR for each PICU can then be calculated as:

*Risk adjusted SMR*

$$= \frac{\text{Number of deaths in PICU in reporting period}}{\text{Number of expected deaths (risk adjusted) in PICU in the reporting period}}$$

As with the unadjusted SMR, a risk-adjusted SMR of 1 indicates that the number of observed deaths is equal to the number expected (the target); an SMR of greater than one indicates more observed deaths than expected and an SMR of less than one indicates fewer observed deaths than expected.

## **Confidence intervals**

The unadjusted and adjusted SMRs follow a Poisson distribution [10] and confidence intervals can be calculated for both using standard formulae [13]. If a confidence interval around an SMR excludes unity (i.e.1) then there is a statistically significant difference between expected mortality and the mortality observed. In this scenario the PICU is deemed a potential outlier.

### **3.3. Detecting potential outliers**

Detection of potential outliers is undertaken for NHS PICUs in England, Wales, Scotland, Northern Ireland, plus PICUs in the Republic of Ireland and participating private PICUs and is based on risk-adjusted mortality. All patients admitted to participating PICUs within the three-year reporting period are included in analysis unless otherwise stated.

PICANet conduct outlier analysis based on funnel plots [14] and also provide continuous monitoring of mortality via risk-adjusted resetting probability ratio test (RSPRT) plots [15] and recommend internal review of mortality prior to the outlier analysis, if required.

In all outlier analysis, it should be noted that identification as a potential outlier is based on statistical significance and this does not necessarily mean that the potential outlier status is clinically significant.

## **Funnel plots**

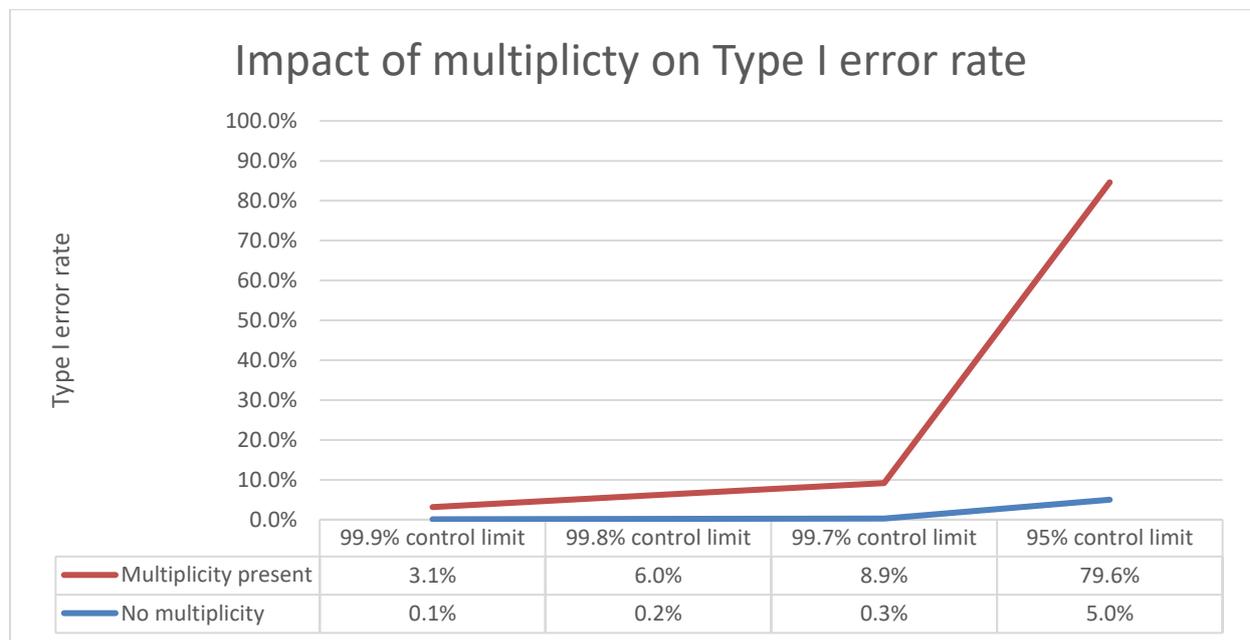
PIM3-adjusted SMRs are calculated for each PICU as detailed above. Funnel plots are used to represent the SMRs graphically and identify potential outliers [14]. The risk-adjusted SMRs are plotted on the y-axis against the number of admissions on the x-axis. Higher mortality rates are represented by points plotted above the line of unity, with those appearing outside the upper control limit indicating an unusual excess mortality (negative outlier). Lower mortality rates are represented by points plotted below the line of unity and those falling below the lower control limit indicate unusually low mortality (positive outlier).

99.9% control limits are set around the target performance (an SMR of 1) for each provider. Any provider which falls above the upper control limit would be considered a potential (negative) outlier and would trigger an 'alarm', requiring further investigation through our outlier management plan (see below).

Funnel plots for outlier identification are based on: (i) combined data from all three years of the reporting period, and (ii) data from the recent year alone. A provider is considered to be a potential outlier if they are a negative outlier on either of these funnel plots and will have an 'alarm' raised.

An important statistical consideration is the impact of multiplicity on the number of providers identified as potential outliers due to chance alone (false positives) [14]. Multiplicity (also called multiple testing or the multiple comparison problem) occurs when a number of statistical tests are performed simultaneously [16], as is the case when many providers are compared in our outlier analysis. The impact of multiplicity is an inflation of the Type I error rate (meaning our risk of falsely identifying a provider as a potential outlier is higher); specifically the larger the number of tests performed, the larger the Type I error [16]. This must be taken into account when setting control limits and considering the false positive rate (see Figure 1).

Figure 1: Graph showing impact of multiplicity on Type I error rate



Footnote: Calculated using  $\alpha_{FWER} = 1 - (1 - \alpha)^m$ , where  $\alpha_{FWER}$  is the family-wise error rate (or overall Type I error rate),  $\alpha$  is the Type I error rate for an individual provider and  $m$  is the number of providers examined (in this case 31).

For PICANet (with 31 providers), the Type I error rate associated with the plotted 99.9% control limits inflates from 0.1% to 3.1% (meaning our control limits are actually equivalent to 96.9% control limits). This is the lowest Type I error rate we can achieve with the current number of providers included in analysis. This rate means that there could be one provider per analysis which is falsely identified as a potential outlier and has ‘alarm’ status raised, consequently we may be over-identifying potential outliers. Additionally, when detecting potential outliers, we would rather make a false positive conclusion, identifying a provider as a potential outlier when it is not, than a false negative conclusion, missing identification of a true outlier, and so our approach is conservative.

Multiplicity is the reason that PICANet do not employ an 'alert' status. Were we to additionally plot 95% confidence limits, these would actually equate to 20.4% control limits and the associated Type I error rate would rise from 5% to 80.6% meaning that around 25 providers could have a false 'alert' per analysis. This is clearly impractical and uninformative. As such, we only have an 'alarm' status and use RSPRT plots to allow providers a mechanism of continuous monitoring of mortality rates; this also has other associated advantages (discussed below).

### **RSPRT plots**

In addition to the outlier analysis detailed above, providers are able to access PICU specific risk-adjusted mortality data in real time via risk-adjusted resetting probability ratio test (RSPRT) plots [15]. RSPRT plots present PIM3-adjusted mortality data on a cumulative basis and provide an indication that the provider may be heading towards becoming an outlier (positive or negative). These plots have the advantage of being in real time, allowing any potential issues to be identified and address quickly, allowing for quality improvement before potential identification as an outlier. PICANet will provide a prompt to providers on a quarterly basis for them to review their RSPRT plot.

The RSPRT plot is presented in two halves: the cumulative log-likelihood of the odds of mortality doubling is plotted on the top half of the graph (indicating that mortality rate is higher than expected) and the cumulative log-likelihood of the odds of mortality halving is plotted on the bottom half of the graph (indicating that mortality rate is lower than expected).

Two sets of control limits are plotted on the RSPRT plot, the less stringent (orange lines) are set such that  $\alpha=\beta=0.05$ , and the more stringent limits (red line) are set such that  $\alpha=\beta=0.01$ .

- In between the orange lines is the 'safe zone' representing the variability that you might normally expect over a twelve month period.
- The area between the upper orange and upper red line is defined as a 'warning zone', indicating mortality rates are temporarily higher than one would expect to see over a twelve month period.
- The top half of the graph resets if the upper red line is touched or crossed, indicating that mortality rates are significantly higher than one would expect to see over a twelve month period.
- The area between the lower orange and lower red line indicates mortality rates are temporarily lower than one would expect to see over a twelve month period.
- The bottom half of the graph resets if the lower red line is touched or crossed indicating that mortality rates are significantly lower than one would expect to see over a twelve month period.

A more complete and technical explanation of RSPRT plots is provided on the [PICANet website](#) [17].

If the upper half of the plot remains in the ‘warning zone’ for three or more consecutive months, PICANet will recommend that a healthcare provider closely monitors their performance on a monthly basis over the next few months.

If the plot resets due to crossing the upper red line, PICANet will urgently recommend that the PICU checks their data for completeness and cleanliness. If, following data checks, the revised RSPRT plot still shows cause for concern, then PICANet recommend an internal review of your mortality cases.

#### 4. Negative potential outlier management

If a provider is identified as a potential negative outlier in the outlier analysis (funnel plots) then the appropriate management is required. Table 2 shows actions, responsibilities and timelines upon detection of a potential outlier and adapted from HQIP guidance [1]. This process must be followed, and adhere to the timelines detailed if a PICU based in England is identified as a potential outlier. If a PICU based in Wales, Scotland, Northern Ireland or the Republic of Ireland is identified as a potential outlier, then it is strongly recommended that the same process is followed.

Further details of data and analytical checks to be performed in Stage 1 can be found in Table 3.

**Table 2:** Outlier management details

Stage	What action?	Who?	Timelines (working days)
1	<p>Providers with a performance indicator ‘alarm’ require careful scrutiny of the data handling and analyses performed (Table 3) to determine whether there is:</p> <p><u>‘No case to answer’</u> - potential outlier status is not confirmed, data and results are updated and details formally recorded.</p> <p><u>‘Case to answer’</u> - potential outlier status. Proceed to stage 2.</p>	PICANet	10

2	A letter is sent to the Lead Clinician in the provider organisation informing them about their potential outlier status and requesting that they identify any data errors or justifiable explanation(s). All relevant data and analyses should be made available to the Lead Clinician. A copy of the letter should be sent to the provider organisation CEO and Medical Director (after the Lead Clinician has been informed).	PICANet Co-PIs & Senior Statistician	5
3	Lead Clinician to provide written response to PICANet.	Provider Lead Clinician	25
4	Review of Lead Clinician's response to determine:  <u>'No case to answer'</u> - original data confirmed as containing inaccuracies and re-analysis no longer indicates outlier status. Data and results are updated and details formally recorded. Lead Clinician notified in writing copying in provider organisation CEO and Medical Director.  <u>'Case to answer'</u> - original data confirmed as containing inaccuracies but re-analysis still indicates outlier status OR original data confirmed as accurate confirming the initial designation of outlier status. Proceed to stage 5.	PICANet	20
5	Contact Lead Clinician by telephone, prior to sending written confirmation of 'alarm' status to CEO (copied to Lead Clinician and Medical Director).  All relevant data and statistical analyses, including previous response from the Lead Clinician, made available to the Medical Director and CEO.  PICANet to inform CQC <sup>‡</sup> and HQIP <sup>**</sup> (if provider located within England) and provider CEO advised to inform commissioners, NHS Improvement <sup>†</sup> (if provider located within England) and Royal College of Paediatrics and Child Health (if provider located within UK). CEO informed that PICANet will be	PICANet Co-PIs	5

	publishing. Information of comparative performance that will identify providers.		
6	Acknowledgement of receipt of the letter confirming that a local investigation will be undertaken with independent assurance of the validity of this exercise for 'alarm' level potential outliers (copying in the CQC if provider located within England) <sup>‡</sup> . Any investigation needs to be independent of the provider and undertaken by an expert panel of clinicians (it is strongly recommended that this will include representatives from the PICANet CAG). It is the responsibility of the organisation involved to obtain and fund this independent review. This review should be shared with Commissioners and, if the provider is located within England, CQC <sup>‡</sup> .	provider CEO*	10
7	If no acknowledgement received, a reminder letter should be sent to the CEO, (copied to CQC if provider located within England). If not received within 5 working days and provider located within England, CQC <sup>‡</sup> and NHS Improvement <sup>†</sup> notified of non-compliance.	PICANet	5
8	Public disclosure of comparative information that identifies providers (e.g. PICANet annual report, data publication online).	PICANet	N/A

<sup>‡</sup> CQC contacted via [clinicalaudits@cqc.org.uk](mailto:clinicalaudits@cqc.org.uk) (email address should be checked before use);

<sup>†</sup>NHS Improvement contacted via [nhsi.medicaldirector@nhs.net](mailto:nhsi.medicaldirector@nhs.net) (email address should be checked before use); \* It is accepted that acknowledgement of receipt of letter may come from an appropriate representative of the CEO such as clinical governance lead or another nominee. \*\* Inform HQIP via NCAPOP Project Manager via email prior to, or at the same time as, notifying CQC. Project Manager contact details can be found on the HQIP website: <http://www.hqip.org.uk/about-us/our-team/>.

**Table 3:** Outlier management - PICANet Stage 1 checks

<b>Data handling and analyses performed will be scrutinised by PICANet as follows:</b>
i) Re-validation of statistical programme to check for bugs and programming errors
ii) Review the data quality and completeness for the PICU on relevant fields. Any issues identified will be reported to the PICU should the process progress to Stage 2 (see Table 2 above).
iii) Review the data to see if there are any data driven reasons for the potential outlier status (such as an error in expected mortality or a surge in high risk patients that is not fully accounted for in the modelling. Checks include, but are not limited to:
a. Review the data to investigate whether there are data driven reasons for a PICU lying outside of the control limits (e.g. is the risk-adjustment adequate)
b. Plot the data quality indicators over time to identify whether the anomaly can be traced to a certain data collection period.
c. Plot the mortality ratio over time to identify whether the anomaly can be traced to a certain data collection period.
d. Plot the observed mortality over time to identify whether the anomaly can be traced to a certain data collection period.
e. Plot the expected mortality over time to identify whether the anomaly can be traced to a certain data collection period.
f. Investigate the primary reason for admission to the PICU. If the PICU has a markedly high proportion of a primary reason of admission to the PICU compared with other PICUs this may suggest further refinements to the risk-adjustment method are required.

## **5. Positive potential outlier management**

It is important to identify positive potential outliers in order to celebrate excellent performance and CQC can use these examples in discussions of good practice and to inform inspections. As such, PICANet will consider:

- inclusion in publication key messages;

- liaison with HQIP for inclusion in newsletters and bulletins;
- capturing impact on the quarterly contract review meeting Impact Forms.

## 6. Publication of outlier analysis results

Results from outlier analysis are published each year in the PICANet Annual Report which is freely available online. Data relating to key metrics and outlier status (where relevant) for English NHS PICUs and transport teams are also published on [MyNHS](#) [18] as part of NHS England's Clinical Outcomes Publication (COP) programme and on the [HQIP website](#) [19] as part of the National Clinical Audit Benchmarking (NCAB) programme.

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