PICANet detection and management of potential Level 3 outliers

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This policy is reviewed and updated annually, prior to the analysis for the PICANet State of the Nation Report.

This version of the policy is applicable from the **2023 State of the Nation Report** until further notice. Document history and review sign-off can be found in Appendix E. Any substantial changes made to this document have been presented to the PICANet Clinical Advisory Group for discussion prior to publication.

1 Introduction

PICANet is part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP), for England, 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, referred to as outliers, which may reflect poorer or better performance. PICANet also collects data from Wales, Scotland, Northern Ireland and the Republic of Ireland; this policy details the identification and management of potential outliers for healthcare providers providing Level 3 care (i.e. paediatric intensive care units) who submit data to PICANet.

In this document, the term healthcare provider is used to refer to designated level 3 paediatric intensive care units (PICUs), or, where the metric relates to transport, centralised transport services (CTS) / Specialist Paediatric Transport Services (SPTS).

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 the Paediatric Critical Care Society (PCCS) Standards[1] (2) or the NHS England Specialised Services PICU Quality Dashboard[2] (3), 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.

[1] The Paediatric Critical Care Society (PCCS) use to be called Paediatric Intensive Care Society (PICS).

[2] The published version of the Specialised Services PICU Quality Dashboard 2022/23 at the time of writing does not include targets therefore targets referenced in this document are based on the 2021/22 Dashboard. Correspondence with NHS England identified that revisions to information presented on the NHS England Website are expected and future versions of this document will use more concurrent references.

2 Choice of performance indicator

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

- Case ascertainment and timeliness of data completeness
- Specialist paediatric transport services (SPTS) emergency retrieval mobilisation times
- Unplanned extubations in PICU
- Emergency readmission within 48 hours
- Risk-adjusted in-PICU mortality

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

3 Statistical methods for outlier detection

3.1 Data cleaning prior to outlier exploration

PICANet undertake detailed data cleaning prior to any analysis. Additionally regular validation emails are circulated to PICUs which include identification of data quality issues on a more real time basis. 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 State of the Nation 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 for the provider 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 Care Quality Commission (CQC) as part of the National Clinical Audit Benchmarking (NCAB) Programme submission (4), and will be publically available through documentation in the annual PICANet State of the Nation Report.

3.2 Methods for monitoring mortality

PICANet uses two main methods for monitoring mortality:

1) Risk-adjusted resetting probability ratio test (RSPRT) plots providing monitoring on a 'real-time' basis;
2) Risk-adjusted standardised mortality ratios (SMRs) calculated annually.

3.2.1 RSPRT plots and interpretation

In addition providers are able to access PICU specific risk-adjusted mortality data in real time via risk-adjusted resetting probability ratio test (RSPRT) plots (5). RSPRT plots present PIM3-adjusted mortality data on a cumulative basis allowing trends in mortality to be seen. Unlike SMRs which provide a comparison between observed and expected mortality, RSPRT plots are based on the cumulative log-odds of mortality; summation of the log-odds begins in 2016 (when PIM3 was routinely collected in all participating units) and continues until the plot resets, at which point the cumulative log-odds are reset to zero and summation restarts.

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 odds of mortality in a given unit are 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 odds of mortality are lower than expected). Two sets of control limits are used, indicated by two pairs of lines with less stringent threshold limits displayed as a yellow/orange line and more stringent limits as red lines. If either half of the graph crosses a red threshold line then further investigation is required; if the plot stays between the orange and red for three consecutive months then close monitoring is required. Providers are prompted to review their RSPRT plot on a quarterly basis. The interpretation and action required by PICUs are based on three possible scenarios which are detailed in "PICANet's RSPRT guidance for units" document (6).

RSPRT plots provide an indication that a provider may be heading towards becoming an outlier (positive or negative), but do not mean that a provider will necessarily be identified as a potential outlier in the formal outlier analysis which is based on standardised mortality ratios. Providers can access RSPRT plots at any time via PICANet Web and additionally the plots are reviewed by PICANet and sent to units every quarter and are categorised into: satisfactory; cause for close monitoring; or, cause for concern indicating internal review. RSPRT plots may be published in the PICANet State of the Nation Report or associated Tables and Figures in specific cases; providers will be notified prior to publication via email if this is the case.

3.2.2 Standardised Mortality Ratios (SMRs)

Risk-adjusted standardised mortality ratios (SMRs) are estimated for each PICU on an annual basis; risk-adjustment is undertaken via a recalibrated Paediatric Index of Mortality Version 3 (PIM3) (7).

Risk-adjusted SMRs compare the number of observed deaths in PICU with the number of deaths expected based on the specific case-mix for that unit. An SMR of one indicates that the number of observed deaths were equal to the number of expected deaths; an SMR of greater than one indicates more deaths were observed than expected; and, an SMR of less than one indicates fewer deaths were observed than expected.

The SMRs are presented graphically via funnel plots (8), which, in brief, plot the risk-adjusted SMRs on the y-axis against the number of admissions on the x-axis. Control limit lines show the range of expected values for each unit's SMR assuming mortality is within the expected range and taking into account the inherent variability in mortality and the precision of each SMR estimate. Points falling outside of the control limits indicate either unusual excess mortality (for those falling above the upper limit), or unusual low mortality (for those falling below the lower limit). Control limits of 99.9% are set around the target performance (an SMR of one) for each provider on the associated funnel plot; these take into the account the number of admissions each unit has and the increased uncertainty a small number of admissions brings inherently into the calculations. PICANet do not present 95% control limits due to the impact of multiplicity on false identification rate (see Appendix B for further detail).

3.3 Formal outlier analysis

Detection and management of potential outliers is undertaken for all Level 3 PICUs providing data to PICANet (i.e. NHS and private PICUs in England, and PICUs in Wales, Scotland, Northern Ireland, and the Republic of Ireland) following the process outlined in this policy and is based on risk-adjusted standardised mortality ratios and associated funnel plots.

The formal outlier analysis includes admissions to participating PICUs for children aged 0-15 years within the three-year reporting period unless otherwise stated; patients aged 16+ or of unknown age are excluded from this analysis as PIM3 (7) was devised and validated on this 0-15 year old population.

Details of sensitivity analyses performed on the formal outlier analysis can be found in the Statistical Analysis Plan.

4 Identification and management of potential outliers

Whilst the identification of negative outliers is of utmost immediate importance, it is also necessary to identify positive potential outliers in order to acknowledge excellent performance where appropriate and to enable sharing and identification of best practice. Bodies like the CQC can use positive outliers as examples of good practice and to inform inspections.

4.1 Identification of a potential negative outlier – 'alarm' status

Any provider which falls above the upper control limit would be considered a potential negative outlier. This would trigger an 'alarm' status requiring further investigation through PICANet's potential negative outlier management process. The process is adapted from HQIP guidance (1) but is applicable to all Level 3 PICUs regardless of location; PICANet will work with the PICU to confirm via data quality assurance and understand the negative outlier status as well as inform any relevant bodies as detailed in Appendix C Tables 1 and 2.

4.2 Identification of a potential positive outlier

Any provider which falls below the lower control limit would be considered a potential positive outlier and PICANet will work with the PICU as detailed in Appendix D Table 1 to confirm and understand the positive outlier status and identify any potential good practice underpinning this for knowledge sharing as detailed in Appendix D Table 1; again this process applies to all Level 3 PICUs regardless of location.

4.3 'Alert' status

The formal outlier analysis will be repeated including admissions to participating PICUs for children aged 0-15 years within the most recent year of the reporting period only. This analysis is likely to include smaller numbers of admissions (given only one year's worth of data is considered) and hence lower precision will be seen in SMR estimates, therefore confidence intervals should be considered in conjunction with control limits.

Any provider which falls outside the upper control limit in this analysis would have an 'alert' status raised and would be informed of this. The provider will be advised to review the completeness and quality of their PIM and discharge status data and will be advised to closely review and monitor mortality within their unit. If any NHS PICU in England is identified as having an 'alert' status then PICANet will inform the CQC and HQIP (using details in Appendix C Table 2) in line with HQIP guidance (1).

5 Publication of outlier analysis results

Results from outlier analysis are published each year in the PICANet State of the Nation Report which is freely available online. These results will identify providers including confirmed positive and negative outliers and whether providers had insufficient data quality for inclusion in the formal outlier analysis. For providers in England, results from the outlier analysis will also be published as part of the NCAB programme (4).

6 References

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7 Related documents

1. PICANet RSPRT Guidance for units
2. PICANet Statistical Analysis Plan

8 Appendix A – Performance indicator consideration

Appendix A Table 1: Assessment of key metrics as performance indicators for outlier detection[3]

	Metric	Target (expected performance)	Benefits	Drawbacks	Conclusions
1	Risk adjusted in PICU mortality	Observed mortality = expected mortality (i.e. SMR=1)	• Risk adjustment model available via Paediatric Index of Mortality (7) • Unadjusted mortality is an objective, robust outcome measure which can be externally verified if required. • 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	• 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). • 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.	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).

[3] The published version of the Specialised Services PICU Quality Dashboard 2022/23 at the time of writing does not include targets therefore targets referenced in this document are based on the 2021/22 Dashboard. Correspondence with NHS England identified that revisions to information presented on the NHS England Website are expected and future versions of this document will use more concurrent references.

	Metric	Target (expected performance)	Benefits	Drawbacks	Conclusions
2	Case ascertainment	100%	• Clear target	• Measure not based on quality of care but on quality of reporting • Estimated value across whole of audit based on a subsample of PICUs each year	Considered unsuitable for outlier analysis as does not meet the criteria in terms of clear relationship between indicator and quality of care.
3	Timeliness of data completeness	Within 2 months of discharge from PICU	• Standard exists (within England): NHS England Specialised Services PICU Quality Dashboard 2021/2022 target 100% (PIC010a) (9)	• Measure not based on quality of care but on quality of reporting • Can be skewed by technical issues out of PICU staff's control	Considered unsuitable for outlier analysis as does not meet the criteria in terms of clear relationship between indicator and quality of care.

	Metric	Target (expected performance)	Benefits	Drawbacks	Conclusions
4	Critical care emergency transport mobilisation time	Starting journey within 30 minutes of clinical decision that PIC transport is required* *Please note prior to April 2016 the target was 1 hour	• Standard exists (within England): NHS England Specialised Services PICU Quality Dashboard 2021/2022 target for 95% of cases achieving the standard (PIC14i) (9)	• 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 • Measure of system capacity more than quality of care • The DEPICT study found no evidence that reducing time to bedside would improve survival (with mobilisation being one component of time to bedside) • Risk adjustment not accounted for in standards • Starting the journey is only one part of timely access	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 (10). To reassess suitability of this or a similar measure in future following full consideration of the results from the DEPICT study.

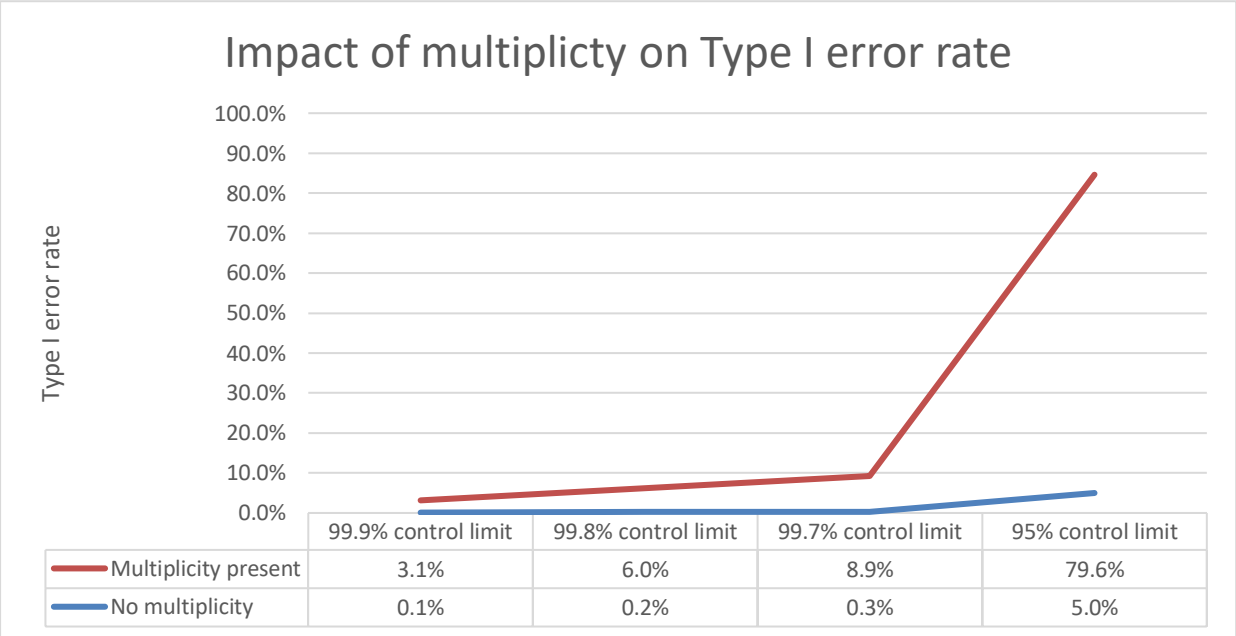
	Metric	Target (expected performance)	Benefits	Drawbacks	Conclusions
5	Emergency readmission within 48 hours (to same PICU)	<2%	• Emergency readmissions are an established metric both for PICU and other specialities across the NHS • Standard exists (within England): NHS England Specialised Services PICU Quality Dashboard 2021/2022 target <2% emergency readmissions to PICU (PIC04) (9)	• Approximately 93% of patients discharged from PICU are discharged to another ward within the same hospital or to another hospital (11). 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. • Rare event which affects 1.7% of all admissions (12) so may not occur frequently enough to give statistical power • Ongoing research work is investigating the impact of the various contributory factors on emergency readmissions	Considered unsuitable for outlier analysis as does not meet the criteria in terms of clear relationship between indicator and quality of care.

	Metric	Target (expected performance)	Benefits	Drawbacks	Conclusions
6	Unplanned extubations in PICU	<5 per 1,000 ventilated days	• Within unit measure which is not impacted by wider organisational influence • Interest within the clinical community as most commonly occurring adverse event • NHS England Specialised Services PICU Quality Dashboard 2021/2022 target <5 per 1,000 ventilated days (PIC08a) (9)	• 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 • Rare event with 4.4 unplanned extubations per 1,000 intubated days (12) so may not occur frequently enough to give statistical power • May be linked to the sedation policy of the PICU.	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. To be reviewed once target has been defined.

9 Appendix B – Multiple testing

An important statistical consideration when looking at multiple PICUs is the impact of multiplicity on the number of providers identified as potential negative outliers due to chance alone (i.e. a false detection). Multiple testing (also called multiplicity or the multiple comparison problem) occurs when a number of statistical tests are performed simultaneously, as is the case when many providers are compared in the PICANet 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. 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



	99.9% control limit	99.8% control limit	99.7% control limit	95% control limit
Multiplicity present	3.1%	6.0%	8.9%	79.6%
No multiplicity	0.1%	0.2%	0.3%	5.0%

Footnote: Calculated using $\alpha_{FWER} = 1 - (1 - \alpha)^m$, where α_{FWER} is the family-wise error rate (or overall Type I error rate, α 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 detected as a potential negative 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 detections than find a falsely reassuring result (i.e. missing identification of a true outlier), and so our approach is conservative.

Multiplicity is the reason that PICANet do not employ an ‘alert’ status based control limits set to two standard deviations. 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 is clearly impractical and uninformative.

10 Appendix C – Management process for potential negative outlier

Appendix C Table 1: Management process for potential negative outliers

Stage	What action?	Who?	Timelines
1	**PICANet internal checks** Providers with a performance indicator 'alarm' (i.e. identified as a potential outlier) require careful scrutiny of the data handling and analyses performed by PICANet. Internal checks should include, but are not limited to: • Validation of statistical programs to check for bugs and/or programming errors; • Review of provider data quality and completeness for relevant fields (including PIM variables and unit discharge status); • Review of data to identify any potential drivers for the potential outlier status such as errors, data completeness, systematic data completion issues, suitability of risk adjustment, differences compared with national averages and/or changes over the reporting period. Analyses may include: o case-mix of patients; o proportion of admissions discharged for palliative care; o highest level of care provided during admissions as defined by HRG grouping; o observed deaths; o expected deaths; o SMR; o data quality; o missing data; o clinical characteristics of the PICU population, for example, primary reason for PICU admission;	PICANet	Within 10 working days

Stage	What action?	Who?	Timelines
	○ descriptive characteristics of the PICU population, for example, age distribution of patients; ○ key data of interest, for example, healthcare associated infections (HCAI), unplanned extubations, emergency readmissions, length of stay, ventilation status; ○ any other analyses deemed pertinent. <u>*Outlier status not maintained*</u> - potential outlier status is not confirmed, data and results are updated and details formally recorded. <u>*Outlier status maintained*</u> – potential outlier status remains. Proceed to Stage 2.		
2	**Provider notified of *potential* outlier status** The Lead Clinician at the provider organisation should be informed by phone of the potential outlier status. This must be followed up by a letter formally notifying the provider. The formal letter will include a request for a written response (Stage 3) to: • Confirm the accuracy and completeness of data submitted to PICANet (this is required in order to ensure the statistical validity of the outlier status); • Comment on the analyses provided in the notification; • Provide any explanation(s) for the potential outlier status. Relevant data and analyses from Stage 1 will be made available to the Lead Clinician to assist with this. These may include, but will not be limited to:	PICANet Co-PIs & Senior Statistician	Within 5 working days

Stage	What action?	Who?	Timelines
	• Sensitivity analyses as detailed in the Statistical Analysis Plan; • A description of case-mix compared with national averages; • Details of palliative care discharges compared with national averages; • PIM score completeness and explanation of how this may influence the potential outlier status; • PIM score summaries and a list of event IDs for cases with low PIM scores where the patient died in PICU for further exploration. A copy of the letter should be sent to the provider organisation CEO and Medical Director (after the Lead Clinician has been informed) as well as the Chair of the PICANet Clinical Advisory Group and the PICANet Clinical Advisor.		
3	**Provider response to notification** Lead Clinician to respond to the notification correspondence. The response should include: • Details of data checks undertaken, whether inaccuracies or missing data were found and any action taken to address data issues; • Confirm that data submitted was complete, accurate and validated (specifically in relation the PIM variable and discharge status); • Any comments on the statistical analyses provided, for example, whether the negative outlier status may be driven by case-mix, palliative care discharge practice, etc.; • Any explanations for the potential outlier status; • Any other information deemed relevant or pertinent.	Provider Lead Clinician	Within 25 working days

Stage	What action?	Who?	Timelines
	A copy of the response should be sent to the provider organisation CEO and Medical Director by the Lead Clinician.		
4	**PICANet review of response** PICANet will provide a copy of the letter from Stage 3 to the Chair of the PICANet Clinical Advisory Group and the PICANet Clinical Advisor. With clinical input as required, PICANet to undertake review of Lead Clinician's response to determine: <u>*Outlier status not maintained*</u> - original data confirmed as containing inaccuracies and re-analysis no longer indicates outlier status. In this case, data and results are updated and details formally recorded by PICANet and the Lead Clinician is notified in writing, copying in provider organisation CEO and Medical Director. Lead Clinician is asked to respond with reasons why the original data was inaccurate and what processes have been put in place to mitigate the risk of this occurring again in the future. <u>*Outlier status maintained*</u> – **Confirmation of statistical outlier status** Original data confirmed as containing inaccuracies but re-analysis still indicates outlier status <u>OR</u> original data confirmed as accurate confirming the initial designation of outlier status. Proceed to Stage 5.	PICANet	Within 20 working days

Stage	What action?	Who?	Timelines
5	**Provider notified of *confirmed* statistical outlier status** Lead Clinician contacted by telephone and notified of confirmed statistical outlier status. This must be followed up by a letter formally notifying the provider CEO of the status (copied to the Lead Clinician and Medical Director as well as the Chair of the PICANet Clinical Advisory Group and the PICANet Clinical Advisor). The formal notification will contain: • Confirmation of statistical negative outlier status; • A summary of the response from the Lead Clinician provided in Stage 3 including any potential explanations for the status; • All relevant data and statistical analyses, including previous correspondence; • Advance notice for the CEO that PICANet will be publishing information of comparative performance that will identify providers; • Notification of the date of PICANet publication and permission to share the confirmed statistical outlier status in confidence with individuals within their regional network before publication but not with other colleagues outside of the network until the PICANet Report is published; • Notice that PICANet will be contacting relevant bodies (as detailed below based on location of provider); • Advice on which relevant bodies the CEO needs to inform (as detailed below based on location of provider); • Advice that the Medical Director and Lead Clinician should initiate a review; • A request for acknowledgement of receipt of the letter and confirmation that a review will be undertaken.	PICANet Co-PIs	Within 5 working days

Stage	What action?	Who?	Timelines
	Relevant bodies informed (based on where PICU is located): <u>England:</u> • PICANet to inform CQC and HQIP* • PICANet advise provider CEO to inform commissioners, NHS England (NHS Impact) and Royal College of Paediatrics and Child Health. N.B. For non-NHS PICUs, PICANet would not inform HQIP <u>Wales</u> • PICANet to inform the Welsh Government, the Welsh Health Specialised Services Committee and Healthcare Inspectorate Wales. • PICANet advise provider CEO to inform commissioners, Improvement Cymru and Royal College of Paediatrics and Child Health. <u>Scotland</u> • PICANet to inform National Specialist and Screening Directorate (NSD), NHS National Services Scotland and Healthcare Improvement Scotland. • PICANet advise provider CEO to inform commissioners, and Royal College of Paediatrics and Child Health. <u>Northern Ireland</u> • PICANet to inform Health and Social Care (HSC) Strategic Planning and Performance Group of the Department of Health (SPPG) and The Regulation and Quality Improvement Authority (RQIA). • PICANet advise provider CEO to inform commissioners, Health and Social Care Quality Improvement (HSCQI) and Royal College of Paediatrics and Child Health.		

Stage	What action?	Who?	Timelines
	<u>ROI</u> • PICANet to inform National Office of Clinical Audit (NOCA). • PICANet advise provider CEO to inform commissioners and relevant Royal Colleges.		
6	**Provider CEO to provide acknowledgement of receipt** Acknowledgement of receipt sent from provider CEO to PICANet. For NHS England PICUs, the provider CEO must copy in the CQC in line with HQIP guidance [REF]. The acknowledgement should confirm that: • Relevant bodies will be informed as required based on location of provider; • An investigation will be undertaken. As a minimum, the investigation should be local with independent assurance of the validity of this exercise; it is strongly recommended that a member of the PICANet Clinical Advisory Group (CAG) is consulted. Ideally, the investigation would be independent of the provider and undertaken by an expert panel of clinicians. It is desirable that the investigation is concluded prior to publication of the next State of the Nation Report; therefore the investigation should be commissioned within three months of being confirmed a statistical outlier, and completed within six months of commissioning. It is the responsibility of the organisation involved to obtain and fund this review and to ensure that the information governance surrounding the exercise is in place. The provider should share the findings of the review with PICANet and may also share it with Commissioners, relevant regulators and Quality Improvement bodies based on location of provider.	Provider CEO**	Within 10 working days

Stage	What action?	Who?	Timelines
	Proceed to Stage 8 If no acknowledgement of receipt provided to PICANet within 10 working days proceed to Stage 7.		
7	**Reminder letter sent to CEO (if required)** If no acknowledgement is received within 10 working days, a reminder letter should be sent to the CEO copying in the national organisations that PICANet notified in Stage 5 based on location of provider. If no response is received within 5 working days of the reminder letter, then notification of non-compliance should be reported by PICANet to the national organisations in Stage 5 based on location of provider.	PICANet	Within 5 working days
8	**Publication** Public disclosure of comparative information that identifies providers (e.g. PICANet State of the Nation Report, data publication online).	PICANet	N/A

* Inform HQIP via email prior to, or at the same time as, notifying CQC.

** 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.

See Appendix C Table 2 for the contacts for notifying of confirmed statistical outlier status and / or notification of non-compliance.

Appendix C Table 2: Contacts for confirmed statistical outlier status and / or notification of non-compliance[4]

Location of participating organisation	**Organisations and their contact details** *Personnel and email address should be checked before use*
England (NHS)	HQIP: Notify the HQIP project manager and associate director. HQIP contact details can be found at: www.hqip.org.uk/about-us/our-team/).
	CQC: clinicalaudits@cqc.org.uk
	NHS England (NHS Impact) england.improvementdelivery@nhs.net and/or the previous contact address for NHS Improvement nhsi.medicaldirectorate@nhs.net
England (non-NHS)	CQC: clinicalaudits@cqc.org.uk
Wales	Welsh government: wgclinicalaudit@gov.wales Welsh Health Specialised Services Committee: kimberley.meringolo@wales.nhs.uk, kevin.francis@gov.wales and Caroline.Lewis@gov.wales
	Healthcare Inspectorate Wales: hiw@gov.wales
	Improvement Cymru: (029) 2022 7744 or Dr. John Boulton, Director of NHS Quality Improvement and Patient Safety / Director, Improvement Cymru John.Boulton2@wales.nhs.uk
Scotland	National Specialist and Screening Directorate (NSD), NHS National Services Scotland: Sarah McKnight, Programme Manager nss.specialistservices@nhs.scot
	Programme Lead for the National Hub for Reviewing and Learning from the Deaths of Children and Young People, NHS Healthcare Improvement Scotland his.cdrnationalhub@nhs.scot
Northern Ireland	Health and Social Care (HSC) Strategic Planning and Performance Group of the Department of Health (SPPG): SPPGcommunications@hscni.net
	The Regulation and Quality Improvement Authority (RQIA) RQIA, Belfast: 028 9536 1111 or info@rqia.org.uk
	Health and Social Care Quality Improvement (HSCQI): ihub@hscni.net

[4] This list will be updated by PICANet on an ongoing basis as Governance and staffing change

Republic of Ireland	NOCA contacted via Paediatric Programme Assistant Audit Manager (Karina Hamilton karinahamilton@noca.ie) and Head of Data Analytics and Research (Fionnola Kelly fionnolakelly@noca.ie)

11 Appendix D – Management process for potential positive outliers

Appendix D Table 1: Management process for potential positive outliers

Stage	What action?	Who?	Timelines
1	**PICANet internal checks** Providers identified as a potential outlier (either positive or negative) require careful scrutiny of the data handling and analyses performed by PICANet. Internal checks should include, but are not limited to: • Validation of statistical programs to check for bugs and/or programming errors • Review of provider data quality and completeness for relevant fields (including PIM variables and unit discharge status) • Review of data to identify any potential drivers for the potential outlier status such as errors, data completeness, systematic data completion issues, suitability of risk adjustment, differences compared with national averages and/or changes over the reporting period. Analyses may include: o case-mix of patients; o proportion of admissions discharged for palliative care; o highest level of care provided during admissions as defined by HRG grouping; o observed deaths; o expected deaths; o SMR; o data quality; o missing data; o clinical characteristics of the PICU population, for example, primary reason for PICU admission;	PICANet	Within 10 working days

Stage	What action?	Who?	Timelines
	○ descriptive characteristics of the PICU population, for example, age distribution of patients; ○ key data of interest, for example, healthcare associated infections (HCAI), unplanned extubations, emergency readmissions, length of stay, ventilation status; ○ any other analyses deemed pertinent. If a unit has been a positive outlier in the previous consecutive year then data analyses may be expanded to include a focus on whether the clinical and demographic characteristics of patients admitted in the most recent year is comparable with admissions in the two years prior. <u>*Outlier status not maintained*</u> - potential outlier status is not confirmed, data and results are updated and details formally recorded. <u>*Outlier status maintained*</u> – potential outlier status remains. Proceed to Stage 2.		
2	**Provider notified of *potential* outlier status** The Lead Clinician at the provider organisation should be informed of the *potential* outlier status; this may be by letter or phone, if by phone then this will be followed up by letter. The letter will include a request for a written response (Stage 3) to:	PICANet Co-PIs & Senior Statistician	Within 5 working days

Stage	What action?	Who?	Timelines
	• Confirm the accuracy and completeness of data submitted to PICANet (this is required in order to ensure the statistical validity of the outlier status)[5]; • Comment on the analyses provided in the notification; • Provide any insights into the positive outlier status which may be useful to share as good practice. Relevant data and analyses from Stage 1 will be made available to the Lead Clinician to aid with the provision of insights into good practice which may be underpinning the positive outlier status. This may include, but is not limited to: • Sensitivity analyses as detailed in the Statistical Analysis Plan; • A description of case-mix compared with national averages; • Details of palliative care discharges compared with national averages; • PIM score completeness and explanation of how this may influence the potential outlier status; • PIM score summaries and a list of event IDs for cases with high PIM scores where the patient survived PICU for further exploration. A copy of the letter will be sent to the Chair of the PICANet Clinical Advisory Group and the PICANet Clinical Advisor.		

[5] If the unit was a positive outlier in the previous year's report then this can focus on the most recent year as data from the earlier years in the reporting period will already have been confirmed complete and accurate.

Stage	What action?	Who?	Timelines
3	**Provider response to notification** Lead Clinician to respond to the notification. The response should include: • Confirmation of the accuracy and completeness of data submitted to PICANet, specifically in relation to PIM variables and discharge status;[6] • Any comments on the statistical analyses provided, for example, whether the positive outlier status may be driven by case-mix, palliative care discharge practice, etc.; • Any insights into the potential positive outlier status which may be useful to share as good practice (e.g. systems or procedures in place; unit culture; or, specific skills and knowledge within the team); • Any other information deemed relevant or pertinent.	Provider Lead Clinician	Within 25 working days
4	**PICANet review of response** PICANet will provide a copy of the letter from Stage 3 to the Chair of the PICANet Clinical Advisory Group and the PICANet Clinical Advisor.	PICANet	Within 20 working days

[6] If the unit was a positive outlier in the previous year's report then this can focus on the most recent year as data from the earlier years in the reporting period will already have been confirmed complete and accurate.

Stage	What action?	Who?	Timelines
	With clinical input as required, PICANet will undertake review of Lead Clinician's response to determine: *Positive outlier status maintained* – **Confirmation of positive statistical outlier status** Original data confirmed as accurate OR original data confirmed as requiring updates but re-analysis still indicates positive outlier status confirming the initial designation of outlier status. Proceed to Stage 5. *Positive outlier status not maintained* - original data required updates and re-analysis no longer indicates positive outlier status. In this case, data and results are updated and details formally recorded by PICANet and the Lead Clinician is notified in writing. A copy of the letter will be sent to the Chair of the PICANet Clinical Advisory Group and the PICANet Clinical Advisor.		
5	**Provider notified of confirmed statistical outlier status** Lead Clinician contacted by letter to confirm positive outlier status. The letter will contain: • Confirmation of statistical positive outlier status; • A summary of the response from the Lead Clinician provided in Stage 3 including any good practice identified by the unit; • All relevant data and statistical analyses including previous correspondence; • Notification of the date of PICANet publication and permission to share the confirmed statistical outlier status in confidence with individuals within their regional network	PICANet Co-PIs	Within 5 working days

Stage	What action?	Who?	Timelines
	before publication but not with other colleagues outside of the network until the PICANet Report is published; • If good practice has been identified, an invitation to meet with the PICANet team to discuss how PICANet can support dissemination of findings and therefore assist other PICUs in quality improvement as well as discussing knowledge sharing to be included in the PICANet report. A copy of the letter will be sent to the provider organisation CEO and Medical Director, the Chair of the PICANet Clinical Advisory Group and the PICANet Clinical Advisor. If the provider is an NHS England PICU, then HQIP will also be informed of the confirmed status.		
6	**Publication** Public disclosure of comparative information that identifies providers (e.g. PICANet State of the Nation Report, data publication online) and, if good practice has been identified, wider dissemination of findings and the incorporation of these into PICANet's quality improvement processes.	PICANet	N/A

12 Appendix E – Document and review history

Appendix E Table 1: 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
2.0	Hannah Buckley	14/03/2022	Expansion of management of potential positive and negative outliers section to add clarity and ensure is in line with minimal national standards. Numerous updates, and minor corrections / clarifications to phrasing / typography. Removal of some extraneous detail (such as on case ascertainment) either entirely or to Appendices. 'Alert' status updated to be based on SMR and funnel plot analysis for most recent single year of data. Notification that RSPRT plots may be presented in the Annual Report from 2022. Updating of PICU metric targets in Appendix A Table 1 to be based on 2021/2022 PICU Metric Definitions and/or PCCS Standard 2021 as appropriate.
2.1	Chris Leahy	27/09/2022	Management of SMR positive potential outliers brought in line with process established in v2.0 for managing negative outliers. Updated

			management process for UK nations and ROI and key metrics.
3.0	Hannah Buckley	10/07/2023	Updated introduction to refer to devolved nations and ROI in addition to England. Specifying throughout and in title that policy applies to Level 3 designated units only. Cross-reference to the statistical analysis plan incorporated. Addition of notification to HQIP and CQC of 'alert' level in line with HQIP guidance. Positive outlier process reviewed, simplified and separated out from negative outlier process. Additional information added to Stage 1 checks for potential outliers. Additional consideration for repeated positive outliers in consecutive years. Reorganisation of Sections 3 and 4 including tables detailing outlier management moved to Appendices. Update to devolved nations contacts for negative outlier management process. Inclusion of CQC into acknowledgement from provider CEO in Stage 6 of the negative outlier management process in line with HQIP guidance.

			Updated references to NHS Improvement to NHS England (NHS Impact) and corresponding contact details. Movement of document and review history to Appendix. Updating unplanned extubations rate reference to the PICANet State of the Nation Report. Updating from PICANet Annual Report to PICANet State of the Nation Report throughout.

Appendix E Table 2: Review history

Next review date	Reviewed by	Date completed
Oct 2021	HB	14/10/2021
Sep 2022	CL	27/09/2022
Mar 2023	HB	10/07/2023
Mar 2024		