PICANet detecting and management of potential outliers

Final v2.0

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Authors:

Hannah Buckley, PICANet Senior Statistician, University of Leeds

Contents

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.

This policy is reviewed and updated biennially as a minimum; it is recommended that the policy be reviewed on an annual basis prior to the analysis for the PICANet Annual Report.

Next review date	Reviewed by	Date
Oct 2021	HB	14/10/2021
Oct 2023		

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. 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). This policy details the identification and management of potential outliers for healthcare providers who submit data to PICANet.

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 2021/2022 (6), 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 currently reports annually on the following key metrics in relation to healthcare provider performance:

- Case ascertainment and timeliness of data completeness
- 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 extubation is also an outcome of interest within the clinical community, in terms of quality of care, but not yet included as one of the key metrics.

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[1] *Please note that the Paediatric Critical Care Society use to be called Paediatric Intensive Care Society (PICS).*

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 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, and will be publically available through documentation in the PICANet Annual 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 (3). 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 an 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. Providers are prompted to review their RSPRT plot on a quarterly basis. The interpretation and action required by PICUs based on four possible scenarios which may be seen on the plots are detailed in Appendix B.

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. From 2022, RSPRT plots may be published in the PICANet Annual Report; 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) (4).

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 (5), 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 C for future detail).

3.3 Formal outlier analysis

Detection and management of potential outliers is undertaken for all PICUs providing data to PICANet (i.e. NHS and private PICUs in England and Wales, and PICUs in Scotland, Northern Ireland, and the Republic of Ireland) following the processes 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 (4) was devised and validated on this 0-15 year old population.

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

Any provider which falls above the upper control limit would be considered a potential negative outlier and would trigger an 'alarm' status requiring further investigation through our outlier management plan (see Section 5).

3.3.2 Identification of a potential positive outlier

Any provider which falls below the lower control limit would be considered a potential positive outlier and additional data cleaning would be undertaken to confirm this status (see Section 4); no 'alert' or 'alarm' status is associated with a confirmed or potential positive outlier status.

3.3.3 'Alert' status

The 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. Any provider which falls above 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. 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.

3.4 Notification of HQIP and CQC

HQIP should be notified of any NHS England providers with **confirmed** negative outlier or **confirmed** 'alert' status, via the HQIP project manager and associate director. The CQC should be notified of any providers within England (private or NHS) with confirmed negative outlier or confirmed 'alert' status, via clinicalaudits@cqc.org.uk copying the HQIP project manager and associate director.

4 Management of potential positive outliers

It is important to identify positive potential outliers in order to acknowledge excellent performance and bodies like the CQC can use these examples in discussions of good practice and to inform inspections.

Providers identified as a potential positive outlier will be asked to confirm that data relating to PIM variables and discharge status are accurate, as complete as possible, and to provide any reason(s) why they may have better than expected performance outcomes.

Following this, positive outlier status will be confirmed and the provider's performance highlighted in the PICANet Annual Report. All potential positive outliers are required to have confirmed status before publication; the management steps for confirmation are detailed in Table 1. This process should be followed for all providers identified as a potential positive outlier.

Table 1: Potential positive outlier management details

Stage	What action?	Who?	Guide Timelines
1	**PICANet internal checks** Providers identified as potential positive outliers require scrutiny of 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) *Potential positive outlier status not maintained* - potential positive outlier status is not confirmed, data and results are updated and details formally recorded. *Potential positive outlier status maintained* – potential positive outlier status remains. Proceed to Stage 2.	PICANet	Within 10 working days
2	**Provider notified of potential positive outlier status** The Lead Clinician at the provider organisation should be informed by phone of the potential positive outlier status, where possible. This must be followed up by a letter formally notifying the provider. The letter will notify the provider of the potential positive outlier status, detail the steps required to confirm the status and where the results will be made publically available. The formal letter will include a request for a written response (Stage 3) to:	PICANet Co-PIs & Senior Statistician	Within 5 working days

	- Confirm the accuracy and completeness of data submitted to PICANet - Identify any policies or changes in practice which might have led to the positive outlier status			
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 possible explanations for the potential outlier status - Any other information deemed relevant or pertinent	Provider Lead Clinician	Within 25 working days
4	**PICANet review of response** PICANet to undertake review of Lead Clinician's response to determine whether the potential positive outlier status to be confirmed. *Potential positive outlier status not maintained* - original data confirmed as containing inaccuracies and re-analysis no longer indicates potential outlier status. In this case, data and results are updated and details formally recorded by PICANet and the Lead Clinician is notified in writing. 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.	PICANet	Within 20 working days

	Potential positive outlier status maintained – **Confirmation of statistical positive 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.		

5	**Provider notified of confirmed statistical positive outlier status**
	
	Lead Clinician contacted by letter confirming statistical positive outlier status (copied to CEO and Medical Director).
	
	The formal notification will contain:
	• Confirmation of statistical positive outlier status
	• Advance notice for the CEO that PICANet will be publishing information of comparative performance that will identify providers
	• Notice that PICANet will be contacting relevant bodies (as detailed below based on location of provider)
	• Notice that PICANet may consider the following to help share good practice amongst providers:
	    o Inclusion of confirmed status in publication key messages;
	    o liaison with HQIP for inclusion in newsletters and bulletins (for NHS England providers);
	    o capturing impact on the quarterly contract review meeting Impact Forms.
	
	The provider can share the confirmed statistical positive outlier status in confidence with individuals within their regional network but not with other colleagues outside of the network until the PICANet Report is published.
		PICANet Co-PIs	Within 5 working days

	Relevant bodies informed (based on where PICU is located): England (NHS): - PICANet to inform CQC[‡] and HQIP[**] England (Private providers): - PICANet to inform HQIP[**] Wales - PICANet to inform the Welsh Government[¶] Scotland & Northern Ireland - No notification to relevant bodies currently required ROI - PICANet to inform NOCA		
6	**Publication** Public disclosure of comparative information that identifies providers (e.g. PICANet annual report, data publication online).	PICANet	N/A

[‡] CQC contacted via clinicalaudits@cqc.org.uk (email address should be checked before use);

[†] NHS Improvement contacted via nhsi.medicaldirectorate@nhs.net (email address should be checked before use);

[¶] Welsh government contacted via wgclinicalaudit@gov.wales (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 email prior to, or at the same time as, notifying CQC; via clinicalaudits@cqc.org.uk copying the HQIP project manager and associate director (personnel and email addresses should be checked before use; HQIP contact details can be found at: www.hqip.org.uk/about-us/our-team/).

[ε] NOCA contacted via Paediatric Programme Assistant Audit Manager (currently Karina Hamilton karinahamilton@noca.ie) and Head of Data Analytics and Research (currently Fionnola Kelly fionnolakelly@noca.ie); personnel and associated email addresses should be checked before use.

5 Management of potential negative outliers

If a provider is identified as a potential negative outlier in the formal outlier analysis (see Section 3.3.1), then appropriate management is required.

Table 2 shows actions, responsibilities and timelines upon detection of a potential outlier and is adapted from HQIP guidance (1). This process must be followed for all providers identified as a potential negative outlier.

Table 2: Potential negative outlier management details

Stage	What action?	Who?	Timelines

1	**PICANet internal checks**
	
	Providers with a performance indicator 'alarm' (i.e. identified as a potential negative 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 negative outlier status, errors and/or potential data collection periods of interest, for example, where there changes over the reporting period in:
	   o case-mix of patients;
	   o observed deaths;
	   o expected deaths;
	   o SMR;
	   o data quality;
	   o missing data;
	   o primary reason for PICU admission; or,
	   o age distribution of patients.
		PICANet	Within 10 working days

	Checks should be made for errors, suitability of risk-adjustment, systematic data collection issues. *'No case to answer'* - potential negative outlier status is not confirmed, data and results are updated and details formally recorded. *'Case to answer'* – potential negative outlier status remains. Proceed to Stage 2.		
2	**Provider notified of potential negative outlier status** The Lead Clinician at the provider organisation should be informed by phone of the potential negative 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 • Provide any justifiable explanation(s) for the potential negative outlier status. All relevant data and analyses will be made available to the Lead Clinician to assist with this. 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	Within 5 working days
3	**Provider response to notification** Lead Clinician to respond to the notification correspondence. The response should include:	Provider Lead Clinician	Within 25 working days

	• 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 justifiable explanations for the potential outlier status • Any other information deemed relevant or pertinent 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 to undertake review of Lead Clinician's response to determine: *'No case to answer'* - 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. *'Case to answer'* – **Confirmation of statistical negative 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

| 5 | **Provider notified of confirmed statistical negative outlier status**

Lead Clinician contacted by telephone and notified of confirmed statistical negative outlier status. This must be followed up by a letter formally notifying the provider CEO of the 'alarm' status (copied to the Lead Clinician and Medical Director).

The formal notification will contain:
• Confirmation of statistical negative outlier status
• All relevant data and statistical analyses, including previous response from the Lead Clinician
• Advance notice for the CEO that PICANet will be publishing information of comparative performance that will identify providers
• 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

The provider can share the confirmed statistical negative outlier status in confidence with individuals within their regional network but not with other colleagues outside of the network until the PICANet Report is published.

Relevant bodies informed (based on where PICU is located):
<u>England:</u>
• PICANet to inform CQC[‡] and HQIP[**] (as per Section 8) | PICANet Co-PIs | Within 5 working days |

	- PICANet advise provider CEO to inform commissioners, NHS Improvement[†] and Royal College of Paediatrics and Child Health. Wales - PICANet to inform the Welsh Government[¶] - PICANet advise provider CEO to inform commissioners, NHS Improvement[†] and Royal College of Paediatrics and Child Health. Scotland & Northern Ireland - PICANet advise provider CEO to inform commissioners, NHS Improvement[†] and Royal College of Paediatrics and Child Health. ROI - PICANet to inform 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 (copying in the CQC if provider located within England[‡] or the Welsh Government[¶] if provider located within Wales[¶]). 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	Provider CEO*	Within 10 working days

	Advisory Group (CAG) is consulted. Ideally, the investigation would be independent of the provider and undertaken by an expert panel of clinicians. 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 may wish to share findings from the review with Commissioners (and, either the CQC[‡] or Welsh Government[¶] if the provider is located within England or Wales respectively). 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 CQC[‡] if provider located within England or the Welsh Government[¶] if provider located within Wales). If no response is received within 5 working days of the reminder letter, then notification of non-compliance should be reported to: • HQIP[**], CQC[‡] and NHS Improvement[†] for providers located within England • Welsh Government[¶] for providers located within Wales, • NOCA[ε] for providers located within the Republic of Ireland	PICANet	Within 5 working days
8	**Publication**	PICANet	N/A

Public disclosure of comparative information that identifies providers (e.g. PICANet annual report, data publication online).		

‡ CQC contacted via clinicalaudits@cqc.org.uk (email address should be checked before use);

† NHS Improvement contacted via nhsi.medicaldirectorate@nhs.net (email address should be checked before use);

¶ Welsh government contacted via wgclinicalaudit@gov.wales (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 email prior to, or at the same time as, notifying CQC; via clinicalaudits@cqc.org.uk copying the HQIP project manager and associate director (personnel and email addresses should be checked before use; HQIP contact details can be found at: www.hqip.org.uk/about-us/our-team/).

ε NOCA contacted via Paediatric Programme Assistant Audit Manager (currently Karina Hamilton karinahamilton@noca.ie) and Head of Data Analytics and Research (currently Fionnola Kelly fionnolakelly@noca.ie); personnel and associated email addresses should be checked before use.

6 Publication of outlier analysis results

Identifiable results from outlier analysis are published each year in the PICANet Annual Report which is freely available online. If any providers had insufficient data quality for inclusion in the formal outlier analysis then the provider will also be identified in the PICANet Annual Report. For providers in England, results from the outlier analysis will also be published as part of the NCAB programme.

As stated in Section 3.2.1, from 2022, RSPRT plots may be published in the PICANet Annual Report; providers will be notified prior to publication via email if this is the case.

7 References

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11. PICANet. *Paediatric Intensive Care Audit Network: Annual Report 2018.* [Online]. 2018. [Accessed 03/09/2021]. Available from: https://www.picanet.org.uk/annual-reporting-and-publications/annual-report-archive/

8 Appendix A – Performance indicator consideration

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

Metric	Target (expected performance)	Benefits	Drawbacks	Conclusions
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.
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) (6)	• 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.
Critical care emergency transport mobilisation time	Starting journey within 30 minutes of clinical decision that PIC transport is required*	• Standard exists (within England): NHS England Specialised Services PICU Quality	• On occasion transport may be strategically delayed due to appropriate risk-based triaging which would mean the mobilisation target is	Considered unsuitable for outlier analysis as does not meet the criteria in terms of clear relationship between indicator and quality of care.

	*Please note prior to April 2016 the target was 1 hour	Dashboard 2021/2022 target for 95% of cases achieving the standard (PIC14i) (6)	missed but the team are providing good quality care • Measure of system capacity more than quality of care • Impact of timeliness of access to paediatric intensive care on clinical outcomes is not yet established (being assessed as part of the DEPICT study) • Risk adjustment not accounted for in standards • Starting the journey is only one part of timely access	Additionally, whilst there is currently a standard available, it is recognised that this is aspirational at present (7). To reassess suitability of this or a similar measure in future following full consideration of the results from the DEPICT study.
Number of qualified nurses and non-registered healthcare staff employed per funded level 3 bed	UK = 7.06 WTE ROI = 5.6 WTE	• Standard exists: PCCS standard 2021 for UK is 7.06 WTE (L3-207) (2) • Standard for ROI is 5.6 WTE (8, 9)	• Process measure rather than outcome measure • It is recognised that this is an aspirational target (7) which few providers currently meet • Data collected as a snapshot in November each year but not continuously. • The number of funded beds may be different to the number of open beds as demonstrated by the census data collected by PICANet	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, 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

			• 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.	accurately match reported establishment figures.
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) (6)	• Approximately 93% of patients discharged from PICU are discharged to another ward within the same hospital or to another hospital (10). 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 (affects 1.6% of all admissions (11)) so may not occur frequently enough to give statistical power • Ongoing research work at Birmingham is investigating the impact of the	Considered unsuitable for outlier analysis as does not meet the criteria in terms of clear relationship between indicator and quality of care.

			various contributory factors on emergency readmissions	
Unplanned extubations	<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) (6)	• 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 (0.4 unplanned extubations per 100 intubated days (11)) 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.
Risk adjusted in PICU mortality	Observed mortality = expected mortality (i.e. SMR=1)	• Risk adjustment model available (Paediatric Index of Mortality (4))	• 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	Despite the limitations in relation to current tools available for risk adjustment, this metric is considered

		• 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	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.	suitable for outlier analysis as clear relationship between indicator and quality of care (although interpretation must be mindful of the limitations noted).

9 Appendix B – RPSRT interpretation and action required by PICUs

9.1 Satisfactory performance

When does this occur?

Performance is said to be satisfactory when the plot remains between the two orange threshold lines in the period of interest <u>OR</u> has not crossed either orange threshold line for more than three consecutive months.

What does this mean?

This indicates that current performance appears to be in line with expected natural variation.

What action is required by the PICU?

None – continue to monitor at quarterly intervals as a minimum.

9.2 Cause for close monitoring

When does this occur?

The plot remains between upper orange and upper red lines (in the 'warning zone') for three or more consecutive months.

What does this mean?

This indicates that performance is temporarily higher than would be expected after taking into account natural variation and how sick children are at admission.

What action is required by the PICU?

It is recommend that performance is closely monitored on a monthly basis for a few months by downloading the live RSPRT plots from PICANet Web to ensure that mortality rates remain within the safe zone.

9.3 Cause for concern indicating internal review

When does this occur?

Performance is said to be cause for concern requiring internal investigation if the RSPRT plot resets due to crossing the upper red line.

What does this mean?

This indicates that the odds of mortality are higher than would be expected after taking into account natural variation and how sick children are at admission.

<u>What action is required by the PICU?</u>

Step 1: We recommend that your unit urgently checks the data submitted to PICANet Web; in particular we advise that you focus on PIM variables and discharge data to ensure that these fields are complete and accurate.

Step 2: Re-run your RSPRT plot from PICANet Web (Reports > Admissions > RSPRT Control Chart) following your data checks. If your revised RSPRT plot still resets (i.e. crossed the upper red line), then PICANet recommend an internal review of your mortality cases; PICANet are happy to provide advice on this if required (picanet@leeds.ac.uk).

Step 3: Regardless of whether your plot still resets following data checks, we recommend that you closely monitor your performance on a monthly basis over the next few months by downloading your live RSPRT plots from PICANet Web to ensure that mortality rates remain within the 'safe zone'.

<u>Why might the plot have reset?</u>

There are many reasons why an RSPRT plot may reset. These reasons fit into 3 categories:

1) Data quality (e.g. events missing from PICANet Web; PIM3 data missing or inaccurately recorded);

2) Clinical practice (e.g. actually changes in mortality performance, a run of patients who died or a change in case-mix);

3) RSPRT plot methodology (e.g. PIM3 might not be adequately capturing the risk of your patients or this trigger may be a false alarm).

Data submitted to PICANet Web should be urgently checked for completeness and accuracy; particular focus should be given to PIM variables and discharge data. The RSPRT plot should be re-run then an interval review of mortality cases plus close monitoring of performance on a monthly basis is recommended.

The PICANet team may be contacted via picanet@leeds.ac.uk, for any support required in validating the data. If, following data checks, your revised RSPRT plot still shows cause for concern, then PICANet recommend an internal review of your mortality cases. PICANet and the PICANet Clinical Advisory Group are happy to provide advice on this.

9.4   Recommended data review

<u>When does this occur?</u>

The plot remains between lower orange and lower red lines for three or more consecutive months OR the plot resets due to crossing the lower red line.

<u>What does this mean?</u>

This indicates that the odds of mortality are lower than would be expected after taking into account natural variation and how sick children are at admission.

<u>What action is required by the PICU?</u>

Step 1: You should checks the data submitted to PICANet Web; in particular we advise that you focus on PIM variables and discharge data to ensure that these fields are complete and accurate in order to be sure that the plot you are seeing is accurate.

Step 2: Re-run your RSPRT plot from PICANet Web (Reports > Admissions > RSPRT Control Chart) following your data checks and let PICANet know that you have reviewed your data (picanet@leeds.ac.uk).
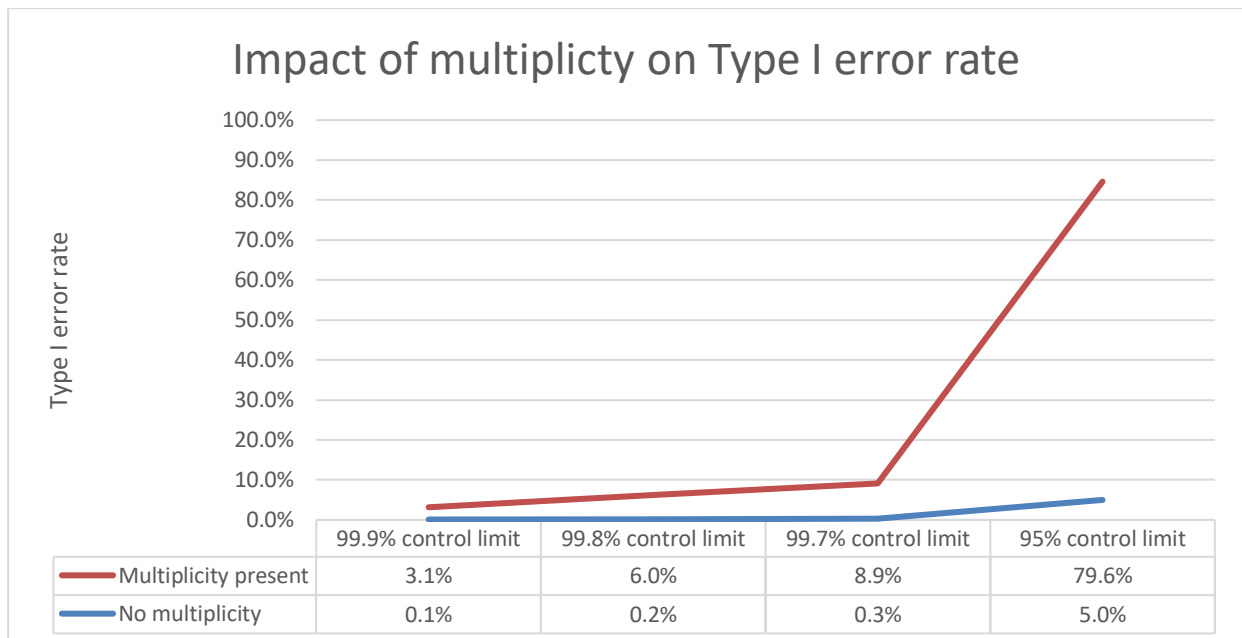
<u>Why might the plot have reset?</u>

There are many reasons why an RSPRT plot may reset. These reasons fit into 3 categories:

1) Data quality (e.g. events missing from PICANet Web; PIM3 data missing or inaccurately recorded);

2) Clinical practice (e.g. actually changes in mortality performance or a change in case-mix);

3) RSPRT plot methodology (e.g. PIM3 might not be adequately capturing the risk of your patients or this trigger may be a false alarm).

10 Appendix C – Multiplicity

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). Multiplicity (also called multiple testing 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

Impact of multiplicty 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.