



NCAPOP Outlier Guidance

Identification and management of outliers

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1.0 Introduction

The Healthcare Quality Improvement Partnership (HQIP) have developed this guidance for use in the NHS. It was last updated for English data in September 2021, following on from updates to the guidance in 2017 with an implementation guide in 2018. The latter is based on the original 2011 Department of Health guidance. The previous 2021 guidance can be found on the [HQIP website](#).

An analysis that assesses the performance of healthcare providers can identify one or more organisations with unexpectedly extreme values on the performance indicator and flag them as an outlier. These types of outlier analyses have traditionally been considered primarily a quality assurance activity. The effective operation of an outlier policy also provides opportunities for national clinical audits to support quality improvement and we are very keen that this becomes the predominant reason for the operation of this policy. HQIP is also keen that identification of positive outliers is used to celebrate clinical excellence.

Whilst other less restrictive approaches to differentiating healthcare providers (e.g. quartile ranges) provide a wider scope for supporting quality improvement, outlier-based approaches make a significant contribution and are particularly important when differences between providers on an indicator might be due to random variation. Healthcare providers need to demonstrate that they have taken timely steps to investigate and respond appropriately and proportionately to outliers, both on the negative and positive sides.

2.0 Outlier identification and management

This guidance is based on original advice provided by an expert group of statisticians (see section 7). Statistical analyses to identify organisations which are outliers should be carried out by a team with appropriate statistical expertise and experience, and medical knowledge of the clinical care being evaluated.

3.0 Choice of performance indicator

Performance indicators must provide a *valid* measure of a healthcare provider's quality of care in that there is a clear relationship between the indicator and quality of care. The metric must be based on events that occur frequently enough to provide sufficient statistical power and should relate to an important quality marker in the domain under review.

Metrics are generally categorised by structure, outcomes, and process. The National Clinical Audit and Patient Outcomes Programme (NCAPOP) tends to lean more heavily towards the latter two. In relation to outlier measures, traditionally great attention has been placed on mortality as the key indicator. However, all the national audit reports and the National Clinical Audit Benchmarking (NCAB) initiative, pioneered by HQIP, abound with additional metrics which could offer useful insight if added to outlier reporting. During 2022, HQIP reviewed the metric requirements for NCAPOP providers in a bid to keep them focused and to reduce the burden on the service.

The metrics used by clinical audits are selected for quality assurance and / or for quality improvement purposes, and hopefully they inform both activities. HQIP wishes to work with clinicians, audit providers, regulators, and commissioners (NHSE and the Welsh Government) to develop a core set of outlier metrics, aligned with a set of criteria, to ensure that there is a consistent approach across the programme. Clearly mortality would always be a key metric, but there will be others in this category. These outlier metrics might be regarded as providing important assurance to patients, the service, commissioners, and clinicians. The additional metrics, of which there will be many, will be equally important but would fall into the category of quality improvement metrics.

As these criteria which will define this core group of assurance metrics are developed, the expectation would be that these are published by each audit provider alongside their bespoke version of this outlier guidance so that there is easy reference concerning each audit's approach to this concept.

HQIP recognises that where outlier analysis is carried out for the first time by an audit, publication of the healthcare provider names may not be appropriate to allow for testing and embedding of the process. However, healthcare providers with Alarm level outliers (see section 7 for definition) should be published in subsequent years.

Another theme to be reiterated as these changes are implemented, is that emphasis also moves to celebrating organisations which are positive outliers. HQIP plans to work with our communities to see how this can best be achieved. NCAPOP audit providers have experience in doing this and it is crucial that this theme is extracted and becomes as important to all concerned as the current concept of using the negative side of outliers for assurance.

4.0 Choice of target (expected performance)

The choice of target for a metric is influenced by various factors. It may be chosen to match a standard based on external sources such as research evidence, clinical judgment, or audit data from elsewhere.

Alternatively, it might reflect an internally observed level of performance such as the average performance of all healthcare providers.

5.0 Data quality

Three aspects of data quality must be considered and reported:

- **Case ascertainment:** number of patients included compared to number eligible, derived from external data sources (where available); this impacts on the generalisability (representativeness) of the results.
- **Data completeness:** in particular, performance indicator data and data on patient characteristics required for case-mix adjustment.
- **Data accuracy:** tested using consistency and range checks, and if possible external sources.

NCAPOP audit providers should describe how they will approach data quality challenges. This might include the use of thresholds to determine statistical significance or the use of imputation to compensate for missing data.

It is recognised that challenges around data quality frequently present barriers in terms of applying an outlier policy to the analysis of a specific metric. If these barriers are absolute (e.g. they prevent any meaningful outlier analysis from being undertaken) there would be an expectation that a metric associated with data quality itself should be considered for outlier analysis to facilitate improvement.

The Care Quality Commission (CQC) consider how English healthcare providers manage data quality and data submission including participation in national clinical audits. They are currently transforming their approach to regulation where it is anticipated that evidence on data quality and submission could be used to form judgements about providers. As well as responding to formal data quality outliers, the CQC will also consider additional activities in partnership with audit providers seeking to improve data quality. Where NCAPOP providers have specific concerns about the robustness of an analysis that flags a healthcare provider as an outlier for an individual metric, they should discuss this and any important contextual information with the CQC or Welsh Government as appropriate.

6.0 Case-mix (risk) adjustment

Comparison of healthcare providers must take account of the differences in the mix of patients by adjusting for known, measurable patient characteristics that are associated with the performance

indicator. These are likely to include age, sex, disease severity, co-morbidity, socio-economic status, and ethnicity.

Adjustment should be carried out using an up-to-date statistical model. The model should have been rigorously tested with regard to its performance. For a binary outcome, this could be in terms of its power of discrimination and its calibration. Measures of model performance should be publicly reported alongside details of the model. Judgment as to the adequacy of a model will depend on the performance indicator selected and the clinical context, so universal, absolute values cannot be provided.

7.0 Identification of a potential outlier: alarms, alerts, and non-participants

Statistically derived limits around the target (expected) performance should be used to define if a healthcare provider is a potential outlier. Limits approximate to more than two standard deviations (SD) (but less than 3 standard deviations) from the target are normally defined as an 'alert'. A difference between the indicator value for a provider and the target of more than three standard deviations is defined as an 'alarm'. Funnel plots can be used to take into account the size (volume of activity) of a healthcare provider meaning that larger providers, with larger numbers of patients, have narrower confidence limits.

Note that these definitions of statistically significant differences from expected performance may not indicate clinically significant differences if the indicator value for a provider is based on large numbers of patients.

The table in Appendix A provides some definitions of non-participation in an audit, where a healthcare provider is eligible for the audit but does not participate, or supplies incomplete data. Beginning in 2024, cases of complete non-participation will be reported as outliers.

8.0 NCAPOP audit providers

8.1 Notification of alert level outliers (England)

The process for notification of alert level outliers is set out in Table 1. Reporting of alert level outliers to CQC, NHSE and HQIP will be limited to metrics relating to mortality, however this is subject to review in line with changes to CQC processes.

8.2 Notification of alarm level outliers and non-participation outliers (England)

Following notification to the CQC, NHSE, and HQIP by the NCAPOP audits, the CQC will follow the process stated in Table 2 and take any necessary regulatory action deemed appropriate. It should be noted that use of audit outlier in the CQC's regulatory model is subject to review (see <https://www.cqc.org.uk/about-us/how-we-will-regulate>). The CQC will send a routine quarterly high-level summary to NHSE of alarm and alert level outliers.

When an audit provider has problems with a poorly engaged healthcare provider, this should be escalated to the HQIP medical director who will discuss with audit provider colleagues and with relevant colleagues in the CQC and NHS England. The CQC will then assume responsibility for the subsequent management. NHS England will also be involved when there are concerns about poor engagement via the established outlier reporting schedules set out below.

8.3 Individual NCAPOP provider outlier policies

NCAPOP audits are required to have a project specific outlier policy that describes how they operationalise this national outlier guidance. The audit outlier policy should be approved at audit provider project board level (or equivalent) and be reviewed for each round of analysis (i.e. annually). Where these policies refer to CQC procedures, the policy should be shared with CQC to confirm that they align with current practice. NCAPOP audits should make the project specific outlier policy publicly available on their audit website. NCAPOP audits should include a link to their updated outlier policy when notifying CQC of outliers.

The policy should describe, for each of the measures, how the metrics perform in relation to the criteria contained within the statistical principles for identifying poor performance in National Clinical Audits (i.e. with respect to statistical power, validity, objectivity and fairness). NCAPOP audits should also ensure their project specific outlier policy aligns with the following checklist.

Does the policy describe:

1. Which specific patient cohort the policy applies to (e.g. xx audit round, patients diagnosed from year 20xx-20xx, frequency of data collection/refreshes)?
2. Where the results of the outlier analysis will be published (e.g. on-line, the annual report)?
3. Which metrics will be subject to an outlier analysis?
4. An explanation of what each measure is, the rationale for inclusion and how to interpret?
5. Whether the terms 'alert' and 'alarm' will be adopted?
 - i. If 'yes', does the policy use $\sim > 2SD$ and $\sim > 3SD$ to define alerts and alarms respectively?
 - ii. If 'no', does the policy explain how limits of expected performance will be defined and the reasoning for an alternative approach?
6. What will happen when issues with data quality or completeness prevent a healthcare provider from having a conclusion drawn about its outlier status? (See appendix A which has more detail concerning non-participation)?
7. The timescales, notification and escalation steps for running the outlier process (which in some cases may need to deviate from those set out in the HQIP Outlier Guidance)?
8. Of the additional metrics collected, has consideration been given to applying an outlier analysis to them and if not has this been explained?

Table 1 outlines the actions required for outliers at the alert level (greater than two standard deviations but within three standard deviations of expected performance).

Table 1: Actions required for outliers at the alert level			
> 2 standard deviations from expected performance			
Step	England	Wales	Owner
1	For alert level outliers relating to mortality, NCAPOP providers should inform the CQC (clinicalaudits@cqc.org.uk), using the outlier template , and include a copy of the project specific outlier policy, NHSE (england.clinical-audit@nhs.net), HQIP associate director and project manager (www.hqip.org.uk/about-us/our-team/) and HQIP NCAPOP Director of Operations, Jill Stoddart (jill.stoddart@hqip.org.uk).	NCAPOP audit providers should inform the Welsh Government (wgclinicalaudit@gov.wales) and HQIP of all outliers at the alert level. NCAPOP audit providers will need to ensure that in their regular local level Health Board performance reports, it is clear if a Health Board is an outlier at the alert level.	NCAPOP audit providers

Table 1: Actions required for outliers at the alert level			
> 2 standard deviations from expected performance			
Step	England	Wales	Owner
	The healthcare provider lead clinician should also be informed by the NCAPOP provider of any alert level outliers. However, unlike for alarm level outliers (see below) the CQC, NHSE, and HQIP are not mandating a formal notification and escalation process for alert level beyond notification of the relevant clinical team.		
	The expectation is that NHS Trusts should use 'alert' information as part of their internal quality monitoring process. They should review alerts in a proactive and timely manner, acting accordingly to mitigate the risk of care quality deteriorating to the point of becoming an alarm level outlier.	The expectation is that Health Boards should use 'alert' information (available within local Health Board reports) as part of their internal quality monitoring process. They should investigate alerts in a proactive and timely manner, acting accordingly to mitigate the risk of care quality deteriorating to the point of becoming an alarm level outlier.	England = Healthcare provider lead clinician Wales = Health Boards

Table 2 sets out the actions required for outliers at the alarm level (greater than 3 standard deviations from expected performance) and for non-participation in the audit. It aims to be feasible for those involved, fair to healthcare providers identified as outliers, and sufficiently rapid so as not to unduly delay the disclosure of comparative information to the public.

NCAPOP audit providers will need to ensure that in their regular local level NHS Trust performance reports / Welsh Board reports, it is clear if a Trust / Board is an outlier at the alarm level. It should also be clear when a Trust / Board which should be contributing data and is not, is identified as such. More information is provided concerning differing degrees of non-participation in Appendix A.

Table 2: Actions required for outliers at alarm level and for non-participation				
>3 standard deviations from expected performance start from step 1				
Non-participation outliers are included from step 5				
Step	England	Wales	Owner	Within working days
1	<p>Healthcare providers with a possible performance indicator at alarm level require scrutiny of the data handling and analyses performed (in some cases this may not be possible for the audit provider and details of this can be included in the individual NCAPOP provider Outlier Guidance, see section 8.2) to determine whether:</p> <p><i>'Alarm' status not confirmed:</i></p> <ul style="list-style-type: none"> • Data and results revised in national clinical audit (NCA) records • Details formally recorded, and process closed <p><i>'Alarm' status confirmed:</i></p> <ul style="list-style-type: none"> • Potential 'alarm' status: <p>> <i>proceed to step 2</i></p>		NCAPOP audit provider team	10
2	<p>Healthcare provider lead clinician informed about potential 'alarm' status and asked to identify any data errors or justifiable explanation(s). All relevant data and analyses should be made available to the lead clinician.</p>		NCAPOP audit provider clinical lead	5
3	<p>Healthcare provider lead clinician to provide written response to NCAPOP audit provider team.</p>		Healthcare provider lead clinician	25
4	<p>Review of healthcare provider lead clinician's response to determine:</p> <p><i>'Alarm' status not confirmed:</i></p> <ul style="list-style-type: none"> • It is confirmed that the data originally supplied by the healthcare provider contained inaccuracies. Re-analysis of accurate data no longer indicates 'alarm' status • Data and results should be revised in NCAPOP audit provider records including details of the healthcare provider's response <p><i>'Alarm' status confirmed:</i></p> <ul style="list-style-type: none"> • Although it is confirmed that the originally supplied data were inaccurate, analysis still indicates 'alarm' status, or • It is confirmed that the originally supplied data were accurate, thus confirming the initial designation of 'alarm' status 		NCAPOP audit provider clinical lead	20

Table 2: Actions required for outliers at alarm level and for non-participation				
>3 standard deviations from expected performance start from step 1				
Non-participation outliers are included from step 5				
Step	England	Wales	Owner	Within working days
	> proceed to step 5			
5	<p>Contact healthcare provider lead clinician by telephone, prior to sending written notification of confirmed 'alarm' 3SD outliers and/or non-participation outliers to healthcare provider CEO and copied to healthcare provider lead clinician and medical director. For 3SD outliers, all relevant data and statistical analyses, including previous response from the healthcare provider lead clinician should be made available to healthcare provider medical director and CEO.</p> <p>For England, the outlier confirmation letter should also include the details in Step 7 below, and a request that the Trust engage with their CQC local team.</p> <p>The relevant NCAPOP project specific outlier policy should be provided to healthcare provider colleagues.</p> <p>Notify the CQC (clinicalaudits@cqc.org.uk), using the outlier template, and include a copy of the project specific outlier policy, NHSE (england.clinical-audit@nhs.net), HQIP associate director and project manager (www.hqip.org.uk/about-us/our-team/), and HQIP NCAPOP Director of Operations, Jill Stoddart (jill.stoddart@hqip.org.uk) of confirmed 'alarm' status.</p> <p>All three organisations should confirm receipt of the notification.</p> <p>The CQC will provide NHS England with a quarterly report of all alarm and alert level outliers that have been notified to CQC.</p>		NCAPOP audit provider clinical lead/ team	5
	For Welsh providers, notify wgclinicalaudit@gov.wales and HQIP associate director and project manager (www.hqip.org.uk/about-us/our-team/) of confirmed 'alarm' status.			
6	New (2024)	Acknowledge receipt of	England =	England =

Table 2: Actions required for outliers at alarm level and for non-participation				
>3 standard deviations from expected performance start from step 1				
Non-participation outliers are included from step 5				
Step	England	Wales	Owner	Within working days
	<p>NCAPOP audit providers will proceed to public disclosure of comparative information that identifies healthcare providers as Alarm level outliers or non-participation outliers (e.g. NCAPOP provider annual report, data publication online).</p> <p>Healthcare providers who have an alarm status outlier investigation, that they or others have performed, will be published by the NCAPOP audit provider as an addendum or footnote.</p> <p>Publication will not be delayed whilst waiting for such investigation to be completed. This can be added, online, when and if it subsequently becomes available.</p> <p>Conversely, if there has been no response from the healthcare provider concerning their alarm outlier status, that will be documented on the NCAPOP audit provider's website where this information is presented.</p>	<p>the written notification confirming that a local investigation will be undertaken with independent assurance of the investigation's validity for 'alarm' level outliers, copying in the Welsh Government.</p> <p>Healthcare provider CEO informed that the NCAPOP audit provider team will publish information of comparative performance which will identify healthcare providers.</p>	<p>NCAPOP audit provider team Wales = Healthcare provider CEO</p>	<p>NCAPOP audit provider report publication date Wales = 10</p>
7	<p>The CQC advise that during their routine local engagement with the providers, their inspectors will:</p> <ul style="list-style-type: none"> Encourage Trusts to identify any learning from their performance and provide the CQC with assurance that the Trust has used the learning to drive quality improvement Ask the Trust how they are monitoring or plan to monitor their performance 	<p>The Welsh Government monitors the actions of organisations responding to outliers and takes further action as and when required. The Healthcare Inspectorate Wales (HIW) does not act as regulator and cannot take regulatory action in relation to NHS providers. However, HIW</p>	<p>England = CQC Wales = Healthcare Inspectorate Wales</p>	<p>Determined by the CQC and HIW</p>

Table 2: Actions required for outliers at alarm level and for non-participation				
>3 standard deviations from expected performance start from step 1				
Non-participation outliers are included from step 5				
Step	England	Wales	Owner	Within working days
	<ul style="list-style-type: none"> Monitor progress against any action plan if one is provided by the trust. 	can request information on the actions undertaken by organisations to ensure safe services are being delivered. The Welsh Government can share information with HIW where appropriate and advise on the robustness of plans in place to improve audit results and outcomes.		
	If an investigation has been conducted in the Trust into an alarm outlier status, it is required that the CQC and audit provider would be provided with the outcome and actions proposed.	N/A	Trust medical director	
	<p>This would be published by the audit provider alongside the annual results. Further if there were no response, the audit provider would publish this absence of a response.</p> <p>The CQC are not prescriptive concerning any such investigations but there needs to be a degree of independence so that the validity of the findings is acceptable.</p>	N/A	NCAPOP audit provider team	
8	N/A	If no acknowledgement received, a reminder letter should be sent to the healthcare provider CEO, copied to Welsh Government and HQIP. If not received within 15 working days, Welsh Government notified of non-compliance in	NCAPOP audit provider team	Wales = 15

Table 2: Actions required for outliers at alarm level and for non-participation				
>3 standard deviations from expected performance start from step 1				
Non-participation outliers are included from step 5				
Step	England	Wales	Owner	Within working days
		consultation with HQIP.		
9	N/A	Public disclosure of comparative information that identifies healthcare providers (e.g. NCAPOP audit provider annual report, data publication online).	NCAPOP audit provider team	NCAPOP provider report publication date

Appendix A: Non-participation

The following is proposed as the starting point for types of non-participation and how they may be regarded as part of the outlier process.

	Issue	Healthcare provider is responsible for non - participation?	Reporting of results	Outlier process applied to metrics where provider is non-participant?
1	Healthcare provider is not eligible for any metrics of the audit. (Complete non-participation)	No	Nothing is published in relation to this provider for the specific audit. Provider is not included in the published non-participant list.	No
2	Provider is eligible for at least one metric (and had eligible cases in the cohort) but has not participated in the audit at all. (Complete non-participation)	Yes	Included in reporting with results flagged with 'Data not submitted by the healthcare provider'. Provider is included in the published non-participant list.	Yes* Provider should be treated as an alarm level outlier for all eligible metrics and followed up via standard processes with a note clarifying that status is due to non-participation.
4	Provider eligible for more than one metric (and had eligible cases in the cohort) but for one or some of these metrics has submitted no data. (Partial non-participation)	Yes	Included in reporting with specific metric results flagged with 'Data not submitted by the healthcare provider'. Provider is not included in the published non-participant list.	Yes* Provider should be treated as an alarm level outlier for all eligible metrics where non-participant, and followed up via standard processes with a note clarifying that status is due to non-participation.

*For non-participation, the Outlier process as outlined in Table 2 will start at step 5 with the healthcare provider lead clinician being notified by telephone that their non-participation is to be flagged up to the Trust CEO and Medical Director and the Outlier process followed with notification of CQC, NHS England and HQIP.