NICOR
STANDARD OPERATING PROCEDURE

NCAP Outlier Policy SOP03

Version 1.5

17th December 2025

REVISION CHRONOLOGY

VERSION	DATE	AUTHOR	REVISION DETAIL
0.1	09/05/2017	Tracy Whittaker	First draft.
0.2	21/06/2017	Tracy Whittaker	Second draft following comments and publication of updated guidance following first submission.
0.3	15/12/18	Mark de Belder and PLG/NOM	Revision in line with current agreed process.
0.4	23/01/19	James Chal	Revision in line with current agreed process.
0.5	07/06/19	Mark de Belder and PLG/NOM	Revision to address issue of individuals operating in more than one hospital.
0.6	11/09/19	Mark de Belder and PLG/NOM	Revision to anonymised funnel plots.
0.7	22/11/19	Sam McAlister, Mark de Belder and PLG/NOM	Correction to index page and removal of workflow diagram and reformatting; inclusion of new role for PM.
0.8	05/02/2020	Sam McAlister, Mark de Belder and PLG/NOM	Clarification of process of contacting individual hospitals or operators.
0.9	30/06/2021	Anthony Bradley	Clarification on page 5 about which domains the outlier process applies to.

1.0	15/12/2022	Mark de Belder, NOM and PLG	Clarification of process of contacting individual hospitals or operators; clarification of roles and responsibilities; modification of host organisation.
1.1	16/10/2023	Mark de Belder and PLG	Further amendments to reflect transition to NHS Arden & Greater East Midlands Commissioning Support Unit and other recommendations of PLG members.
1.2	31/10/2024	Mark de Belder and PLG	Updated to include additional registries.
1.3	29/11/2024	James Chal	Updated to align it with new Guidance from NHS England, CQC and HQIP.
1.4	11/07/2025	NCAP Delivery Group	Updated to align to new NCAP management structure.
1.5	17/12/2025	NCAP Delivery Group	Minor detail amendments.

NICOR
STANDARD OPERATING PROCEDURE (SOP)

Identification and Management of Outliers

Effective date	8th January 2026
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CAG/Service	
Document owner	Anthony Bradley

Accountable Board *(operational ownership of the SOP)*	NCAP Oversight Group
Approving committee(s)	NICOR PLG and NOM Group
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Related policies (to be read in conjunction with)	

Contents

Section 1: Executive summary

The Healthcare Quality Improvement Programme (HQIP) has recently issued updated guidance on the detection and management of outliers in comparing providers and individuals using batches of data collected over an appropriate defined period and in both outcome and process measures of performance. NICOR is hosted by the NHS Arden & GEM Commissioning Support Unit.

These recommendations have been based on advice from an expert group of statisticians and a review of existing management protocols used by national clinical audits.

The definition of an outlier is based on setting a target for an indicator, and then defining what level of variation from that target is acceptable, based on theories of statistical probability and/or clinical judgement. The recent guidance also recommends that hospital providers that do not participate in the audit are classified as outliers.

Based on the definition, this SOP applies currently or may apply to the following clinical domains of the National Cardiac Audit Programme (NCAP) or aligned programmes:

- National Congenital Heart Disease Audit
- Myocardial Ischaemia National Audit Project
- National Audit for Percutaneous Coronary Intervention
- National Adult Cardiac Surgery Audit
- National Heart Failure Audit
- National Audit of Cardiac Rhythm Management
- UK Transcatheter Aortic Valve Implantation (TAVI) Registry
- The Transcatheter Mitral and Tricuspid Valve (TMTV) Registry
- The Left Atrial Appendage Occlusion (LAAO) Registry
- The Patent Foramen Ovale Closure (PFOC) Registry
- The National Audit of Cardiac Rehabilitation (NACR)

This SOP applies to both positive and negative outliers. The SOP will however be relevant to all appropriate analyses on datasets held by NICOR.

Currently there are three domains that undergo the outlier process, National Adult Cardiac Surgery Audit (NACSA), National Congenital Heart Disease Audit (NCHDA) and National Audit of Percutaneous Coronary Interventions (NAPCI). The outlier indicator for these three domains relates to mortality, both positive and negative outlier status.

NACSA – in-hospital survival rate lower than expected beyond the approximate two and three standard deviation levels.
NCHDA – 30-day post-operative survival beyond the 98% confidence limit.
NAPCI – 30-day survival rate lower than expected beyond the approximate two and three standard deviation levels.

Risk models for the National Audit of Heart Failure and the Myocardial Ischaemia National Audit Project (MINAP) have been developed and will be implemented in the NCAP to allow outlier analyses after an initial exploratory phase. A new risk model for application to the UK TAVI Registry is being explored.

This SOP reflects the responsibilities of both NCAP (as a national clinical audit provider) and those of the provider organisations.

The SOP will be applied to mortality outcomes and on agreed individual analyses of metrics that have a significant relationship with mortality.

For a healthcare provider whose data completeness or quality is insufficient to draw a conclusion about its outlier status, this will be made evident to the provider and the necessary regulatory bodies.

Section 2: Purpose and scope

The purpose of this SOP is to standardise the process of identifying and managing a potential outlier, in accordance with recommended guidance from the original Department of Health (DH) and updated HQIP guidance. This SOP will detail the detection methods and the processes to follow from the point of detection of a potential outlier to an endpoint of resolution (no outlier confirmed) or confirmation of outlier status.

Any identification of 'outlier' status indicates a statistically significant value and does not necessarily mean outlying performance by a consultant or organisation. Judgements on performance can only be made after a full examination of all the issues involved in the delivery of care, and this may be multi-factorial and complex. This is not part of the NCAP remit and not covered in this SOP.

Section 3: Background

An increasing number of national clinical audits publish quantitative data that allow comparisons of processes and outcomes. These audits flag up providers that have results which do not seem to be in line with expected results compared to other providers or to existing benchmarks. The 2024 Guidance, developed by the HQIP for use within the NHS, builds upon earlier versions initially published by the Department of Health in 2011 and updated in 2017. This Guidance offers recommendations for identifying and managing potential outliers in healthcare provider and individual consultant performance, whether underperforming or exceeding expected levels.
The recommendations are based on original advice provided by an expert group of statisticians and a review of existing management protocols used by national clinical audits. The recommendations apply to:

- Comparisons of providers (general practices, hospitals, trusts, clinical networks) using batches of data collected over an appropriate defined period.

- Comparisons of individual practitioners using batches of data collected over an appropriate defined period.
- Volume, processes and outcomes of performance (referred to as 'performance indicators').

The NICOR paper on Statistical Methodology* outlines the statistical principles used to identify poor performance in the national clinical cardiovascular audits. These principles were defined by the National Clinical Audit Advisory Group (NCAAG), which provided policy and strategic guidance to the Department of Health on clinical audit.

*Pavlou M, Ambler G, Omar RZ, Goodwin AT, Trivedi U, Ludman P, de Belder M. Outlier identification and monitoring of institutional or clinician performance; an overview of statistical methods and application to national audit data. BMC Health Serv Res 2023 Jan 10:23(1):23

The denominator used for the outlier process as applied to each metric will be the total case mix that NICOR receives for the appropriate time period.

The NCHDA applies the Outlier SOP to established graphical outputs following risk-adjustment of both paediatric and adult surgical procedures, as well as funnel plots derived from non-risk-adjusted mortality data after a number of specific procedures. These plots are published and are available in the public domain. Unlike other analyses, it has been determined that Alert status, as well as Alarm status results may be included in some of these published reports.

Section 4: Standard operating procedure

a. NCAP staff involved with the SOP

This SOP applies to the following NCAP personnel:

- NICOR Clinical Director (tbc)
- NICOR Chief Operating Officer (COO)
- Chair of the NCAP Operational and Methodology (NOM) Group
- NCAP Domain Clinical Lead
- Head of Systems Development, Data Services & Analysis
- Senior Delivery Manager
- Principal Information Analyst
- Delivery Managers
- Higher Information Analysts

b. Key operational relationships

i. NCAP Domain Clinical Leads and relevant Professional Society Officers (Presidents, Clinical Standards leads etc.)

ii. Inter-department relationships
NHS England / NHS Wales NCAP Oversight Group, NHS England NCAP Commissioning Group, NICOR-AGEM NCAP Risk Group

iii. External stakeholders
Trust / Hospital Lead Clinician for relevant audit
Trust / Hospital Medical Director / Responsible Officer
Trust / Hospital Chief Executive

NHS England / NHS Wales – NCAP Commissioners (via Richard Arnold, NCAPOP)
Care Quality Commission
General Medical Council

c. Responsible personnel

i. National Clinical Audit (NCA) supplier (the team responsible for running and managing the audit nationally **– i.e. the National Cardiac Audit Programme (NCAP))**

The NCAP is responsible for confidential data handling and statistical analysis, determining whether any potential outliers exist, and the management processes associated with outliers.

Within NICOR:

- Higher Information Analyst. The Higher information analyst is responsible for the data analysis and the following activities:
    - If a potential outlier is detected the Higher Information Analyst is responsible for reporting this to the NCAP Principal Information Analyst, relevant Delivery Manager and Senior Delivery Manager.
    - If there is a 'case to answer' the Higher Information Analyst will be responsible for re-analysing the revised data submitted by the provider organisation.
    - Updating the relevant sections of the Outlier Log.

- NCAP Principal Information Analyst. The Principal Information Analyst is responsible for scrutinising the data and analysis methodology and the following activities:
    - Assigning a reference number to the potential outlier and creating a log of the process.
    - Allocation of an analyst to work on analyses or re-analyses as required and to ensure that the work is performed in collaboration with the statistician.
    - Confirming the finding and informing the relevant Delivery Manager and Senior Delivery Manager.
    - Overseeing any statistical review of updated data relevant to the process and confirming the outlier status if it is concluded there is a 'case to answer';

confirming this with the relevant Delivery Manager and Senior Delivery Manager.

- Updating the relevant sections of the Outlier Log.

- Delivery Manager (DM). The DM is responsible for:
  - Informing the Senior Delivery Manager, the Chair of the NOM Group, the Domain Clinical Lead and the NICOR COO of the finding.
  - Collating the appropriate information and, when instructed, sending the relevant prepared letter (signed by the NICOR Clinical Director, Professional Society President and Domain Clinical Lead) to the Medical Director/Lead Clinician of the provider hospital (copying to the database manager and others as outlined).
  - Ensuring that the names and email addresses of all parties receiving letters from the NCAP are correct and up to date.
  - Ensuring the process and documentation (log) is completed in a timely manner.
  - Updating the relevant sections of the Outlier Log.

- Senior Delivery Manager (SDM). The SDM is responsible for:
  - Monitoring progress and ensuring updates are discussed at Senior Management Team Meetings and in key governance documentation.
  - Ensuring the SOP is followed and undertaking an annual review.
  - Working with the NICOR COO and Chair of the NOM Group to ensure that all sections of the SOP are followed and for liaising with regulatory bodies as agreed.
  - Updating the SOP as necessary.

- Head of Systems Development, Data Services & Analysis (HSDDSA). If the Principal Information Analyst is absent, the HSDDSA will take on the Principal Information Analyst's responsibilities.

- NCAP Domain Clinical Lead. The NCAP Domain Clinical Lead will be responsible for:
  - Ensuring due process is followed to determine whether the outlier status is confirmed.

- Discussing the process to be followed with the Chair of the NCAP Operational and Methodology Group and/or NICOR Clinical Director.

- Liaising with the President of the relevant Professional Society and ensuring that agreed processes are followed to inform the relevant provider or individual clinician.

- Co-signing the outlier letters, along with the President or Senior Officer of the relevant Professional Society.

- Liaising with the Principal Information Analyst, the Chair of the NOM and the statistical advisors about the need for recalibration of risk models or other issues related to methodology.

- The Chair of the NOM Group. The Chair of the NOM Group will be responsible for:

  - Ensuring that due process is followed to confirm outlier status, discussing possible explanations with the Domain Clinical Lead, and ensuring that an appropriately worded letter to the provider or clinician is prepared in collaboration with the relevant Domain Clinical Lead and Society President.

  - Ensuring that agreed processes will be followed in collaboration with the relevant Domain Clinical Lead and Professional Society.

  - Ensuring that the NICOR Clinical Director is informed.

  - Ensuring that the NICOR Clinical Director has co-signed all outlier letters together with the Domain Clinical Lead and/or a senior member of the relevant Professional Society and ensuring, where relevant, that telephone calls are made to the hospital or individual prior to the letters being sent.

  - Ensuring that all problems that arise are addressed in collaboration with all relevant individuals.

- NICOR Chief Operating Officer (COO). The NICOR COO will be responsible for:

  - Ensuring the NCAP staff follows due process in a timely manner and completes all relevant documentation.

  - Ensuring the NICOR Delivery Group follows due process and updates the SOP as necessary.

  - Providing anonymized updates at the various NHS Arden & GEM / NHS England / NHS Wales Oversight, Commissioning and Risk Group meetings.

- Liaising with NHS Arden & GEM/NHS England/NHS Wales or Welsh Government if the Chief Executive/Medical Director or Responsible Officer of a provider hospital fails to comply with stages 8 and 9.

- Notifying the Care Quality Commission (CQC) if the Chief Executive/Medical Director or Responsible Officer of a provider hospital fails to comply with stages 6 and 9 (Trust level outlier).

- Notifying the General Medical Council (GMC) if the Chief Executive/Medical Director or Responsible Officer of a provider hospital fails to comply with stages 6 and 9 (COP only).

- Updating NHS England regional directors about alert and alarm status of providers within the NCHDA (Congenital Domain).

- Informing CQC of relevant alert and alarm outlier status (Trust level).

- The NICOR Clinical Director. The NICOR Clinical Director will be responsible for:

  - The appropriate management of the process to identify outlier status and to ensure that due governance is followed. When absent, responsibility will fall to the NICOR COO and the Chair of the NOM Group.

  - Co-signing letters to Trusts or individuals informing them of their outlier status.

  - Ensuring that relevant issues are discussed with the NHS England / NHS Wales NCAP Oversight Group, the NHS England NCAP Commissioning Group, NHS Wales or Welsh Government (where relevant) and the NICOR Senior Management Team.

ii. NCAP Provider (Trusts participating in the audits)

The NCAP provider Lead Clinician (i.e. the clinical audit lead for the audit at the hospital) is responsible for:

- Providing written confirmation of the accuracy of data underpinning the analysis following initial notification.

- Correcting the live data if the underlying the outlier analysis is inaccurate.

- Discussing with the NCAP Domain Clinical Lead/ NICOR COO if a potential outlier is detected and there is a ‘case to answer’.

- Providing the NCAP team with the reasons why the original data were inaccurate and outlining changes that have been made to prevent a recurrence.

- Discussing the findings with the local clinical and governance leads.

The provider Medical Director or Responsible Officer/ Chief Executive are responsible for:

- Acknowledging the receipt of the letter in all cases.
- In the case of an 'alarm', informing relevant bodies about the NCAP concerns. These include Integrated Care Boards, relevant Professional Society/Association, the Care Quality Commission and, potentially, the GMC Employment Liaison Advisor (ELA).
- In the case of an 'alarm', initiating a local review of the NCAP information and triangulation with other governance information to assess if further action is required.

d. Equipment requirements

Equipment	Quantity
Published risk model	1
Data extract	1

e. Procedures

The following SOP is based on original guidance published by the Department of Health and subsequently by HQIP and NHS England on the detection and management of outliers. The SOP indicates nine stages that need to be followed. This SOP translates the guidance into NCAP operational guidance and sets out the roles and responsibilities for staff and external stakeholders. Table 1 sets out the stages, actions and timelines for the process. The table below provides guidance for optimal running of the process, accepting that some flexibility is required to accommodate periods of annual or professional leave requirements, etc.

The following two Tables outline the actions required for managing the Alert and Alarm outliers for either at Unit (Trust) or individual clinician (operator) level.

Table 1: NCAP actions in managing ALERT outliers for Trusts or individual clinicians.

Please note:

a. the guidance applies to both Trusts and individuals unless otherwise stated at the relevant stage;

b. validated NCAP data must be available prior to Stage 1;

c. the suggested templates for letters and logs are for guidance only and can be adapted according to circumstances.

STAGE				NICOR		
Stage	**What action?**	**Who?**	**Within how many working days?**	**What additional action?**	**Who?**	**Within how many working days?**
1	Careful scrutiny of the data handling and analyses performed is required if hospitals and individuals are flagged up with one or more of their performance indicators as a positive or negative outlier at **an 'alert'** level, to determine whether there is:	NCAP team	11	○ If a potential outlier is detected the Higher Information Analyst refers to the Principal Information Analyst in writing (email: Template 1).	Higher Information Analyst	1
				○ The Principal Information Analyst must acknowledge receipt of the email. If no response is received within 1 working day, the Higher Information Analyst must inform the DM in writing (email: Template 1).	Principal Information Analyst / Higher Information Analyst	1
				○ The DM must assign a reference number to the potential outlier and commence a log of the process (Log 1).	Delivery Manager	3
	'No case to answer' • potential outlier status not confirmed			○ The Principal Information Analyst (or other analyst as assigned by the Principal Information Analyst) must check the data/methodology.	Principal Information Analyst	3
	• data and results revised in NCAP records • details formally recorded.			○ If 'no case to answer', log this. No further action is needed.	Principal Information Analyst / DM	1
	'Case to answer' • potential outlier status persists			○ If 'case to answer', prior to proceeding to stage 2, the Principal Information Analyst (or analyst assigned by the Principal Information Analyst) informs the DM.	Principal Information Analyst	1
	• *proceed to stage 2*			○ The DM informs the following via email (Template 2) ○ Senior Delivery Manager ○ Domain Clinical Lead ○ NICOR COO ○ Chair, NOM Group	Delivery Manager	1
		Domain Clinical Lead / Professional Society / DM	17	○ The Domain Clinical Lead will inform the President of the relevant Professional Society, the data will be reviewed for any obvious data discrepancies, but thereafter plans will be made to inform the hospital or individual. The Domain Clinical Lead and President of the relevant Professional Society will determine whether a secondary validation process is followed.	Domain Clinical Lead and President of the relevant Professional Society	5
				○ The hospital or individual will be informed by a telephone call prior to	Domain Clinical Lead	7

				notification by letter (stage 2**, to be sent by the DM by post and email**); the call will be made by a senior member of the Professional Society; this call should be confirmed to the NICOR COO and Chair of the NOM Group. o The NICOR Clinical Director, together with the President of the relevant Professional Society and/or the Audit Clinical Lead, will co-sign the notification letters (see section 2). (Template 3, which should be adapted if no secondary validation process is undertaken). If no secondary validation process is undertaken, proceed to stage 5.	and Professional Society representative / Delivery Manager NICOR Clinical Director, President of the relevant Professional Society and/or Domain Clinical Lead / Delivery Manager	5
2	The Medical Director / Responsible Officer and Hospital Lead Clinician in all relevant provider organisations and the individual (if applicable, COP) involved should be informed by phone and follow up letter about the potential outlier status and requested to confirm, again, that the data submitted were complete, accurate and validated. They are asked to identify any data errors or justifiable explanation for a negative outlier status and reasons why the result might be better than average for a positive outlier. All relevant data and analyses should be made available to the Responsible Officer(s), Hospital Lead Clinician(s) and (if applicable) individual clinician. Trust / Hospital level: Following the call, the letter should be sent by the DM to the Medical Director/Responsible Officer of the provider organisation and copied to the Hospital Lead Clinician. Individual letter: Following the call, the letter should be sent to the Medical Director/Responsible Officer(s) and CEO(s) and copied to the Hospital Lead Clinician as well as the individual clinician.	NCAP Domain Clinical Lead or Officer of the relevant Professional Society The Letter(s) are coordinated and sent by post and email by the DM.	5	o If a secondary validation process is likely, the DM will ensure that the 'notification of potential outlier status' letters are sent **by post and email** to the Medical Director / Responsible Officer(s), Hospital Lead Clinician(s) and the individual clinician (if applicable). With respect to outlier status of an individual clinician, these letters will be sent to all hospitals where the individual is known to practice. o The Domain DM to send a copy of the letter to the Hospital Medical Director / Responsible Officer(s), clinical governance lead(s) and/or CEO(s) of the provider organisation(s), as outlined. o All addresses should be checked by the Domain Delivery Manager before letters or emails are sent out. Letters should be posted, in confidence, to the Medical Director or Responsible Officer, whose titles should be included on the envelope for posted correspondence. o The Domain DM to update the NCAP Outliers Log. o The Domain DM to update the NCAP contact database.	Delivery Manager	5

3	The Medical Director / Responsible Officer(s) or Hospital Lead Clinician(s), in conjunction with the individual clinician (if applicable) should provide a written response to the NICOR Clinical Director, the Senior Officer of the relevant Professional Society and/or Domain Clinical Lead (depending on the co-signatures of the original notification letter).	Provider Medical Director / Responsible Officer(s) or Hospital Clinical Lead(s)	25	If no response is received, NICOR will uphold the original data submission and follow the course of action in step 4 for a 'case to answer'.		25
4	Review of Medical Director's / Responsible Officer's / Hospital Lead Clinician's response to determine: '**No case to answer'** • It is confirmed that the data originally supplied by the provider contained inaccuracies. Re-analysis of accurate data no longer indicates outlier status. • Data and results should be revised in the NCAP records. Details of the provider's response and the review result recorded. • Medical Director / Responsible Officer(s) and Hospital Lead Clinician(s) and individual clinician (if appropriate) notified in writing. • Request made to the Hospital Lead Clinician at the NCAP provider as to why the original data were inaccurate and what has been put in place to prevent a recurrence. '**Case to answer'** • It is confirmed that although the data originally supplied by the provider were inaccurate, analysis still indicates outlier status; or	NCAP team	20-25	○ If no secondary validation process is considered/actioned, move to stage 5. ○ Where necessary, the Higher Information Analyst will re-run the analysis on the data, confirm with the Principal Information Analyst and provide results to the DM. ○ The DM emails the following (Template 2), attaching draft letters for sign off within 2 working days to: ○ Senior Delivery Manager ○ Domain Clinical Lead ○ NICOR COO ○ Chair, NOM Group ○ NICOR Clinical Director. ○ NICOR Clinical Director, Officer of the relevant Professional Society and/or Audit Clinical Lead to sign off letters. If '**no case to answer'** the DM to send the prepared and signed letter **by post and email** to the Medical Director / Responsible Officer(s), Hospital Lead Clinician(s) and Individual clinician (Template 4i). If a **'case to answer'** the DM ensures the necessary letters are prepared but awaits confirmation that the notification telephone call has been made prior to sending the prepared and signed letter **by post and email** to either the Hospital Medical Director/Responsible Officer and Hospital Lead Clinician (Hospital outlier) or Medical Director/Responsible Officer(s) and individual clinician (Templates 4ii-4iv). See stage 5. In some circumstances it may be concluded that the results arise from an unusual case mix or confounders that are	 Higher Information Analyst / Principal Information Analyst Delivery Manager NICOR Clinical Director, Officer of the relevant Professional Society and/or Domain Clinical Lead Delivery Manager Delivery Manager Domain Clinical Lead, NICOR	 10 2 5 3 3 5

	• It is confirmed that the originally supplied data were accurate, thus confirming the initial designation of outlier status. • *proceed to stage 5*			not included in the risk model used to identify outlier status. In these circumstances, the Domain Clinical Lead should formulate an appropriate response with the NICOR Clinical Director and the President of the relevant Professional Society, accepting the explanation but confirming that monitoring will continue. o All addresses should be checked by the Delivery Manager before letters or emails are sent out. Letters should be posted, in confidence, to the Medical Director or Responsible Officer, whose full names, titles and address should be included on the envelope for posted correspondence.	Clinical Director, President of the relevant Professional Society	
5	**Hospital outlier:** Contact Medical Director / Responsible Officer and Hospital Lead Clinician by telephone, prior to written confirmation of potential **alert** outlier status; letter addressed to the Hospital Medical Director / Responsible Officer and copied to the Hospital Chief Executive and Hospital Lead Clinician. **Individual outlier:** Contact individual clinician and Hospital Medical Director / Responsible Officer of all relevant provider organisations. In the case of a negative outlier, include all relevant data and statistical analysis, including previous response to Medical Director / Responsible Officer(s) and Hospital Lead Clinician(s), and copied to the Chief Executive(s). In the case of a positive outlier, discussion should follow as to possible explanations and whether the Hospital Lead Clinician and individual clinician would be available to mentor others at the less good end. In the case of a **Trust** or **Hospital** level 'alert' NICOR COO to notify CQC and NHS England and/or, where applicable, to the Welsh	Domain Clinical Lead or Officer of the relevant Professional Society	5	o The Domain Clinical Lead will liaise with the Chair of the NOM Group and/or President of the relevant Professional Society to ensure that the Medical Director / Responsible Officer and Lead Clinician(s) at the provider organisation(s) are contacted by telephone. o The DM will send the prepared notification letter **by post and email** on behalf of the NICOR Clinical Director, informing them that NCAP will proceed to publish information of comparative performance that will identify the provider and individual (if relevant). All relevant data and statistical analyses, including previous response from the Hospital Lead Clinician(s) should be referenced and attached in the letter. The letter will be copied to the Hospital Lead Clinician(s) and Chief Executive(s) of the provider(s). (Template 4i-4iii: Negative Outlier; Template 4iv: Positive Outlier). o All addresses should be checked by the DM before letters or emails are sent out. Letters should be posted, in confidence, to the Medical Director or Responsible Officer, whose titles should be included on the envelope for posted correspondence. o For individual outliers, a copy of the BCS/SCTS Working Group document around the recommended responses to individual outlier status will be enclosed with such letters. o The NICOR COO to notify CQC and NHS England or the Welsh Government regarding the alert level outliers using the CQC Audit Outlier Notification template (Template 5i) with	Domain Clinical Lead, Chair of the NOM Group, and/or Officer of the relevant Professional Society Delivery Manager Delivery Manager Delivery Manager NICOR COO	3 2

	Government (wgclinicalaudit@gov.wales). . In the case of an 'alert' the Medical Director / Responsible Officer and Hospital Lead Clinician would be expected to initiate a local review and triangulate this information with other governance information to see if further information is required. **Additional requirements:** In the case of NCHDA outliers NHS England has requested the following roles are also copied into the letter: ○ Programme Director (Congenital Heart Disease Programme) ○ NHS England Regional Director			a covering email (Template 5ii) using the following email addresses: ○ CQC (clinicalaudits@cqc.org.uk) ○ NHS England (england.clinical-audit@nhs.net) ○ Welsh Government (wgclinicalaudit@gov.wales) NHS England will share outlier information with National Clinical Directors, Spec Comm Commissioners, Policy Leads and another internal stakeholder as appropriate. On a quarterly basis an aggregated report of outliers across all NCAPOP topics (including NCAP) is shared across the wider NHS England system (RMD's, CNO's Mortality Boards, Quality Surveillance Groups, ICS, etc. NHS England will also advise the Welsh Government about the outliers. These organisations should confirm receipt of the notification. ○ NICOR COO to provide summary 'outlier' update at NHS England / NHS Wales NCAP Oversight Group, NHS England NCAP Commissioning Group, NCAP Delivery Group. NOTE: NCAP does NOT publish the alert outliers (except with some outputs in the NCHDA domain). However, the expectation is that a Trust 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.	NHS England CQC and NHS England or Welsh Government NICOR COO	
6	The Hospital(s) is(are) required to: - Acknowledge receipt of the letter	Provider Medical Director / Responsible Officer(s) or Chief Executive(s)	10	DM updates the Outlier log and files letter. DM notifies COO of non-compliance with stage 6.	Delivery Manager	10
7	If no acknowledgment received, a reminder letter should be sent to the Medical Director / Responsible Officer(s). Trust / Hospital level only: letter to be copied to CQC. If no response is received within 5 working days, CQC	NICOR COO/ Delivery Manager	5	DM to send a reminder letter and update the outlier log. NICOR COO notifies CQC and NHS England or NHS Wales / Welsh Government of non-compliance.	Delivery Manager COO	5 of deadline expiry 5

	and NHS England / NHS Wales or Welsh Government notified of non-compliance.					
8	Alert level outliers are NOT publicly disclosed, except for some outputs in the NCHDA domain.					
9	Failure of the Chief Executive(s) / Medical Director / Responsible Officer(s) to comply with point 6 (for negative outliers only), would lead NCAP to notify the following organisations: - CQC - NHS England / NHS Wales or Welsh Government - GMC (individual operator only), following discussion with the NHS England National Clinical Director for Heart Disease (NCD).	NCAP team Individual only - NCAP in consultation with NHSE's NCD.	5	NICOR COO to notify CQC, NHS Arden & GEM/ NHS England or NHS Wales / Welsh Government (Template 5i and 5ii). NICOR COO to update log and file correspondence.	NICOR COO	5

Table 2: NCAP actions in managing ALARM outliers for Trusts or individual clinicians.

See section 4f for definition of outlier status for non-compliance with the audit and Template 7.

STAGE				NICOR		
Stage	**What action?**	**Who?**	**Within how many working days?**	**What additional action?**	**Who?**	**Within how many working days?**
1	Careful scrutiny of the data handling and analyses performed is required if hospitals and individuals are flagged up with one or more of their performance indicators as a positive or negative outlier at an '**alarm**' level, to determine whether there is: **'No case to answer'**	NCAP team	11	○ If a potential outlier is detected the Higher Information Analyst refers to the Principal Information Analyst in writing (email: Template 1). ○ The Principal Information Analyst must acknowledge receipt of the email. If no response is received within 1 working day, the Information Analyst must inform the Delivery Manager (DM) in writing (email: Template 1). ○ The Delivery Manager must assign a reference number to the potential	Higher Information Analyst Principal Information Analyst/ Higher Information Analyst Delivery Manager	1 1 3

	• potential outlier status not confirmed			outlier and commence a log of the process (Log 1).		
	• data and results revised in NCAP records • details formally recorded.			○ The Principal Information Analyst (or an Information Analyst as assigned by the Principal Information Analyst) must check the data/methodology.	Principal Information Analyst	3
	'Case to answer' • potential outlier status persists			○ If 'no case to answer', log this. No further action is needed.	Principal Information Analyst / DM	1
	• *proceed to stage 2*			○ If 'case to answer', prior to proceeding to stage 2, the Principal Information Analyst (or an Information Analyst assigned by the Principal Information Analyst) informs the DM.	Principal Information Analyst/ Information Analyst	1
				○ The DM informs the following via email (Template 2) ○ Senior Delivery Manager ○ Domain Clinical Lead ○ NICOR COO ○ Chair, NOM Group	DM	1
		Domain Clinical Lead / Professional Society / DM	17	○ The Domain Clinical Lead will inform the President of the relevant Professional Society, the data will be reviewed for any obvious data discrepancies, but thereafter plans will be made to inform the hospital or individual. The Domain Clinical Lead and President of the relevant Professional Society will determine whether a secondary validation process is followed.	Domain Clinical Lead and President of the relevant Professional Society	5
				○ The hospital or individual will be informed by a telephone call prior to notification by letter (stage 2**, to be sent by post and email**); the call will be made by a senior member of the Professional Society; this call should be confirmed to the NICOR COO and Chair of the NOM Group.	Domain Clinical Lead and Professional Society representative / Delivery Manager	7
				○ The NICOR Clinical Director, together with the President of the relevant Professional Society and/or the Audit Clinical Lead, will co-sign the notification letters (see section 2). (Template 3, which should be adapted if no secondary validation process is undertaken). If no secondary validation process is undertaken, proceed to stage 5.	NICOR Clinical Director, President of the relevant Professional Society and/or Domain Clinical Lead / Delivery Manager	5
2	The Medical Director / Responsible Officer and Hospital Lead Clinician in all relevant provider organisations and the individual (for COP)	Domain Clinical Lead or Officer of the relevant	5	○ If a secondary validation process is likely, the DM will ensure that the 'notification of potential outlier status' letters are sent **by post and email** to the Medical Director / Responsible Officer(s), Hospital	Delivery Manager	5

	involved should be informed by phone and follow up letter about the potential outlier status and requested to confirm, again, that the data submitted were complete, accurate and validated. They are asked to identify any data errors or justifiable explanation for a negative outlier status and reasons why the result might be better than average for a positive outlier. All relevant data and analyses should be made available to the Responsible Officer(s), Hospital Lead Clinician(s) and (if applicable) individual clinician. Trust / Hospital level: Following the call, the letter should be sent to the Medical Director / Responsible Officer of the provider organisation and copied to the Hospital Lead Clinician. Individual letter: Following the call, the letter should be sent to the Medical Director / Responsible Officer(s) and CEO(s) and copied to the Hospital Lead Clinician as well as the individual clinician.	Professional Society The Letter(s) are coordinated and sent by post and email by the DM.		Lead Clinician(s) and the individual clinician (for COP). With respect to outlier status of an individual clinician, these letters will be sent to all hospitals where the individual is known to practice. ○ The DM to send a copy of the letter to the Hospital Medical Director/ Responsible Officer(s), clinical governance lead(s) and/or CEO(s) of the provider organisation(s), as outlined. ○ All addresses should be checked by the DM before letters or emails are sent out. Letters should be posted, in confidence, to the Medical Director or Responsible Officer, whose titles should be included on the envelope for posted correspondence. ○ The DM to update the NCAP Outliers Log. ○ The DM to update the NCAP contact database.		
3	The Medical Director / Responsible Officer(s) or Hospital Lead Clinician(s), in conjunction with the individual clinician (if applicable) should provide a written response to the NICOR Director, the Senior Officer of the relevant Professional Society and/or Domain Clinical Lead (depending on the co-signatures of the original notification letter).	Provider Medical Director / Responsible Officer(s) or Hospital Lead Clinician(s)	25	If no response is received, NICOR will uphold the original data submission and follow the course of action in step 4 for a 'case to answer'.		25
4	Review of Medical Director's / Responsible Officer's / Hospital Lead Clinician's response to determine: '**<u>No case to answer'</u>** • It is confirmed that the data originally supplied by the provider	NCAP team	20-25	○ If no secondary validation process is considered/actioned, move to stage 5. ○ Where necessary, the Higher Information Analyst will re-run the analysis on the data, confirm with the Principal Information Analyst and provide results to the DM.	Higher Information Analyst / Principal Information Analyst	10

	contained inaccuracies. Re-analysis of accurate data no longer indicates outlier status. • Data and results should be revised in the NCAP records. Details of the provider's response and the review result recorded. • Medical Director/ Responsible Officer(s) and Hospital Lead Clinician(s) and individual clinician (if appropriate) notified in writing. • Request made to the Hospital Lead Clinician as to why the original data were inaccurate and what has been put in place to prevent a recurrence. '**Case to answer'** • It is confirmed that although the data originally supplied by the provider were inaccurate, analysis still indicates outlier status; or • It is confirmed that the originally supplied data were accurate, thus confirming the initial designation of outlier status. • *proceed to stage 5*			○ The DM emails the following (Template 2), attaching draft letters for sign off within 2 working days to: ○ Senior Delivery Manager ○ Domain Clinical Lead ○ NICOR COO ○ Chair, NOM Group ○ NICOR Clinical Director ○ NICOR Clinical Director, Officer of the relevant Professional Society and/or Domain Clinical Lead to sign off letters. If '**no case to answer'** the DM to send the prepared and signed letter **by post and email** to Medical Director / Responsible Officer(s), Hospital Lead Clinician(s) and Individual clinician (Template 4i). If a **'case to answer'** the DM ensures the necessary letters are prepared but awaits confirmation that the notification telephone call has been made prior to sending the prepared and signed letter **by post and email** to either the Hospital Medical Director / Responsible Officer and Hospital Lead Clinician (Hospital outlier) or Medical Director / Responsible Officer(s) and individual clinician (Templates 4ii-4iv). See stage 5. In some circumstances it may be concluded that the results arise from an unusual case mix or confounders that are not included in the risk model used to identify outlier status. In these circumstances, the Domain Clinical Lead should formulate an appropriate response with the NICOR Clinical Director and the President of the relevant Professional Society, accepting the explanation but confirming that monitoring will continue. ○ All addresses should be checked by the DM before letters or emails are sent out. Letters should be posted, in confidence, to the Medical Director or Responsible Officer, whose titles should be included on the envelope for posted correspondence.	Delivery Manager NICOR Clinical Director, Officer of the relevant Professional Society and/or Domain Clinical Lead Delivery Manager Delivery Manager Domain Clinical Lead, NICOR Clinical Director, President of the relevant Professional Society	2 5 3 3 5
5	**Hospital outlier:** Contact Medical Director / Responsible Officer and	Domain Clinical Lead or	5	○ The Domain Clinical Lead will liaise with the Chair of the NOM Group and/or President of the relevant	Domain Clinical Lead, Chair of the NOM Group,	3

	Hospital Lead Clinician by telephone, prior to written confirmation of potential outlier **alarm** status; letter addressed to the Hospital Medical Director / Responsible Officer and copied to the Hospital Chief Executive and Hospital Lead Clinician. **Individual outlier:** Contact individual clinician and Hospital Medical Director / Responsible Officer of all relevant provider organisations. In the case of a negative outlier, include all relevant data and statistical analysis, including previous response to Medical Director / Responsible Officer(s) and Hospital Lead Clinician(s), and copied to the Chief Executive(s). In the case of a positive outlier, discussion should follow as to possible explanations and whether the Hospital Lead Clinician and individual clinician would be available to mentor others at the less good end. In the case of a **Trust** or **Hospital** level **'alarm'** NCAP to notify CQC and NHS England and/or, where applicable, the Welsh Government (wgclinicalaudit@gov.wales) In the case of a **Trust** or **Hospital level 'alarm'**, the Provider CEO will be advised to inform the commissioners: NHS England or NHS Wales / Welsh Government and the relevant Royal Colleges. In the case **of an individual level 'alarm',** the hospital Medical Director / Responsible Officer(s) / Chief Executive(s) to be advised to consider informing the GMC Employment Liaison Adviser (ELA).	Officer of the relevant Professional Society			Professional Society to ensure that the Medical Director / Responsible Officer and Lead Clinician(s) at the provider organisation(s) are contacted by telephone. ○ The DM will send the prepared notification letter by post and email on behalf of the NICOR Clinical Director and President of the Professional Society, informing them that the NCAP will proceed to publish information of comparative performance that will identify the provider and individual (if relevant). All relevant data and statistical analyses, including previous response from the Hospital Lead Clinician(s) should be referenced and attached in the letter. The letter will be copied to the Hospital Lead Clinician(s) and Chief Executive(s) of the provider(s). (Template 4i-4iii: Negative Outlier; Template 4iv: Positive Outlier). ○ All addresses should be checked by the DM before letters or emails are sent out. Letters should be posted, in confidence, to the Medical Director or Responsible Officer, whose titles should be included on the envelope for posted correspondence. ○ For individual outliers, a copy of the BCS/SCTS Working Group document around the recommended responses to individual outlier status will be enclosed with such letters. ○ The NICOR COO to notify CQC and NHS England or Welsh Government regarding both alarm and alert level outliers using the CQC Audit Outlier Notification template (Template 5i) with a covering email (Template 5ii): ○ CQC (clinicalaudits@cqc.org.uk) ○ NHS England (england.clinical-audit@nhs.net) ○ where applicable, Welsh Government (wgclinicalaudit@gov.wales) NHS England will share outlier information with National Clinical Directors, Spec Comm Commissioners, Policy Leads and another internal stakeholder as appropriate. On a quarterly basis an aggregated report of outliers	and/or Officer of the relevant Professional Society Delivery Manager Delivery Manager Delivery Manager NICOR COO NHS England	2

	In the case of an 'alarm' outlier the Medical Director / Responsible Officer and Hospital Lead Clinician would be expected to initiate a local review and triangulate this information with other governance information to see if further information is required. The Trust / Hospital should be informed that the NCAP will publish information of comparative performance at an 'alarm' level that will identify individuals and providers. **Additional requirements:** In the case of NCHDA outliers NHS England has requested the following roles are also copied into the letter: - Programme Director (Congenital Heart Disease Programme) - NHS England Regional Director			across all NCAPOP topics (including NCAP) is shared across the wider NHS England system (RMD's, CNO's Mortality Boards, Quality Surveillance Groups, ICS, etc. NHS England will also advise the Welsh Government (DHCW) about the outliers. These organisations should confirm receipt of the notification. ○ NICOR COO to provide summary 'outlier' update at NHS England / NHS Wales NCAP Oversight Group, NHS England NCAP Commissioning Group, NCAP Delivery Group.	CQC and NHS England or Welsh Government NICOR COO	
6	The Hospital(s) is(are) required to: - Acknowledge receipt of the letter - Confirm that local investigation will be undertaken (Alarm only) - In the case of a requirement to inform the GMC ELA (individual clinician only), confirmation that this has taken place.	Provider Medical Director / Responsible Officer(s) or Chief Executive(s)	10	DM updates the Outlier log and files letter. DM notifies NICOR COO of non-compliance with stage 6.	Delivery Manager	10
7	If no acknowledgment received, a reminder letter should be sent to the Medical Director / Responsible Officer(s). Trust / Hospital level only: letter to be copied to CQC. If no response is received within 5 working days, CQC and NHS England / NHS Wales or Welsh Government notified of non-compliance.	Delivery Manager/ NICOR COO	5	DM to send a reminder letter and update the outlier log. NICOR COO notifies CQC and NHS England (and NHS Wales / Welsh Government where appropriate) of non-compliance.	Delivery Manager COO	5 of deadline expiry 5
8	Public disclosure of comparative information that identifies providers and	NCAP team	As per Standard	This is part of the reporting cycle. The DM to update log on publication.	Delivery Manager and others	As per NCAP

	individuals (if relevant) in applicable publications. To date these are limited to: • Annual Report • Professional Societies' websites. The current agreement with CQC/NHSE is that providers falling in the alarm zone will be disclosed.		Reporting Procedure			report timelines
9	Failure of the Chief Executive(s) / Medical Director / Responsible Officer(s) to comply with point 6 (for negative outliers only), would lead NCAP to notify the following organisations: - CQC - NHS England / NHS Wales or Welsh Government - GMC (individual operator only), following discussion with the NHS England NCD.	Trust level – NCAP team Individual only - NCAP in conjunction with HQIP Medical Director.	5	NICOR COO to notify CQC, NHS Arden & GEM/NHS England or NHS Wales (Templates 5i and 5ii). If applicable, NICOR COO to write to the GMC (Template 6). NICOR COO to update log and file correspondence.	NICOR COO NICOR COO NICOR COO	5

f. Alert status because of non-compliance with the audit.

	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.
3	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, NHS Wales or the Welsh Government and HQIP. Letters to Trusts will be adjusted accordingly but using Template 7. Trusts will be expected to respond and failure to do so will require action as per step 9 in Table 2.

g. Contingencies

The NCAP is required to implement the outlier policy if outliers are identified.
In the absence of personnel listed in the SOP, responsibility would be allocated to alternative NCAP staff by the NICOR COO/SDM.

h. Level of evidence and references

HQIP's Outlier Guidance: identification and management of outliers for National Clinical Audits. https://www.hqip.org.uk/wp-content/uploads/2024/02/HQIP-NCAPOP-Outlier-Guidance_21022024.pdf

Section 5: Local approval

The SOP has been reviewed by NICOR staff including the NICOR Clinical Director, NICOR COO, Senior Delivery Manager, Head of Systems Development, Data Services & Analysis, Chair of the NOM Group and Domain Clinical Leads and discussed at the Professional Liaison Group and NOM Group.

Section 6: SOP review and monitoring compliance/audit requirements

a) The NCAP Delivery Group is responsible for Policies, SOPs and Guidance and will review the SOP on an annual basis or before if required (e.g. due to changes in national guidance or the result of known risks or issues).
b) The NCAP Delivery Group will monitor progress as part of fortnightly meetings.
c) The Outlier log and Outlier documentation will be reviewed throughout this period to ensure the SOP is followed.
d) NCAP will audit compliance with the policy on an annual basis.

Section 7: Templates and logs

1. TEMPLATES AND LOGS ASSOCIATED WITH THE SOP

Please note that these templates are for guidance and may have to be adapted, especially if no secondary validation process is intended.

a. Template 1: Email from Higher Information Analyst to Principal Information Analyst or Delivery Manager informing of potential outlier

Subject: POTENTIAL OUTLIER DETECTED; 'INSERT NAME OF NCAP DOMAIN'

Text:

Dear 'INSERT NAME'

A potential outlier has been detected in the 'INSERT NAME OF NCAP DOMAIN'. Please can the methodology and analysis be checked to determine if there is a possible 'case to answer'?

Please can you confirm your findings by [date *+3 working days*]?

Please note that this information is confidential and must not be circulated outside of the recipients of this email.

Kind regards

'INSERT NAME'

b. Template 2: Email from Delivery Manager to Senior Delivery Manager, Domain Clinical Lead, NICOR Chief Operating Officer and Chair of the NOM group (and NICOR Clinical Director where necessary)

Subject: POTENTIAL OUTLIER DETECTED: POSSIBLE CASE TO ANSWER

Text:

Dear All,

This is to inform you that the following outlier(s) has/have been detected in the 'INSERT NAME OF NCAP DOMAIN', fulfilling the conditions for progression to the next stage of the managing outliers SOP. Please find attached a draft letter to the Medical Director / Responsible Officer and Hospital Lead Clinician in the relevant provider organisation(s) and the individual clinician(s) (if relevant). Please could you review and authorise sign off by [date *+ 3 working days]*.

Details of the outlier are attached.

Please note that this information is confidential and must not be circulated outside of the recipients of this email. Failure to comply will be deemed to be a breach of NCAP security policy.

Kind regards
'INSERT NAME'

c. Template 3: Letter to Medical Director / Responsible Officer and/or Hospital Lead Clinician of provider and/or individual clinician relating to outlier (to be sent by post and email after confirmation of contact and address details). The wording, who the letter is addressed to and those copied in will vary depending on whether this relates to a hospital or individual outlier.

*This letter must be on appropriate **NICOR letter headed** paper*.

Do not include NHS Arden & GEM or NHS England logo on external documents. The template may be modified so that the letter can be tailored to the specifics of the issue.

'INSERT DATE'

Insert Full name, title and role of the recipient, the full postal address of the Department and the hospital. Include the email address of the recipient.

Dear 'INSERT NAME OF HOSPITAL LEAD CLINICIAN AND INDIVIDUAL CLINICIAN (COP) AT PROVIDER ORGANISATION'

Re: Notification of potential outlier status reference 'INSERT REF'

Analysis of the data submission for the 'INSERT NAME OF NCAP DOMAIN' for the period 'INSERT TIME PERIOD' has identified your hospital/you [delete as necessary] as a [potential] [delete as necessary] outlier in the following areas:

'INSERT DETAILS OF DATA AND ANALYSES'

At this first stage of the outlier process we need confirmation that the data on which these analyses are based are correct. Please could you review your data and either confirm that the data submitted are complete and accurate, or that there are discrepancies. If there are discrepancies the data must be amended within the timeline below.

The deadline for responding is [insert date +25 working days]. If we do not receive a response, the NCAP will uphold the original data submission.

Following receipt of your written response, the NCAP will undertake a review of the response/new data submission within the subsequent 20 working days. You will be notified after this period whether the potential outlier status persists.

If you identify data inaccuracies, please provide the reasons for the poor data quality and outline any changes that have been made to prevent a recurrence.

This process is in accordance with the following documents:

Healthcare Quality Improvement Partnership Outlier management for national clinical audits. Guidance for Identification and management of outliers (2024). https://www.hqip.org.uk/wp-content/uploads/2024/02/HQIP-NCAPOP-Outlier-Guidance_21022024.pdf

Yours sincerely,

[Name] Clinical Director, NICOR on behalf of the NCAP
[Name] Officer, Professional Society
+/- [Name] Domain Clinical Lead

Cc: Medical Director / Responsible Officer [Trust / Hospital]
Cc: Clinical Governance Lead
Cc: Chief Executive Officer

d. Template 4: Letter from the NCAP to Hospital Medical Director / Responsible Officer, Hospital Lead Clinician and Chief Executive to inform of outlier status (to be sent by post and email after confirmation of contact and address details).

This letter must be on appropriate NICOR headed notepaper

Do not include NHS Arden & GEM/NHS England Logo on external documents. This template may be modified so that the letter can be tailored to the specifics of the issue.

Letters should be modified depending on whether the outlier status is at the 'Alert' or 'Alarm' level.

i): 'no case to answer'

'INSERT DATE'

Dear 'INSERT NAME OF HOSPITAL LEAD CLINICIAN AT PROVIDER ORGANISATION'

Re: Notification of potential outlier status reference 'INSERT REF'

Thank you for your letter dated 'INSERT DATE' in response to the potential outlier notification you received from the NCAP. It has been confirmed that the data originally submitted by 'INSERT HOSPITAL NAME' contained inaccuracies and reanalysis of the accurate data no longer indicates outlier status. The data and results will be revised in the NCAP records. Please find enclosed the revised analysis.

Please submit a summary of the reasons for the inaccurate data submission and what measures have been put in place to prevent a reoccurrence. The deadline for submitting the response is [*date within 10 working days*]

Yours sincerely

[Name], NICOR Clinical Director, on behalf of the NCAP
[Name] Officer, Professional Society
[Name] Domain Clinical Lead

Cc: Medical Director / Responsible Officer [Trust / Hospital]
Cc: Clinical Governance Lead
Cc: Chief Executive Officer

ii) 'Case to answer' – Negative outlier original data incorrect (to be sent by post and email after confirmation of contact and address details)

'INSERT DATE'

Dear 'INSERT NAME OF CEO AT PROVIDER ORGANISATION'

Re: Notification of potential outlier status reference 'INSERT REF'

Thank you for your letter dated 'INSERT DATE' in response to the potential outlier notification you received from NICOR. It has been confirmed that although the originally supplied data were inaccurate, analysis still indicates outlier status. Please find enclosed related correspondence and statistical analyses. The NCAP will proceed to publishing information of comparative performance that will identify providers [*provide date if available*]. Your status as an 'Alert' outlier will not be published / Your status as an 'Alarm' outlier will be published. [*Delete whichever does not apply*] As per the national guidance, you are now required to undertake the following steps:

i. Provide acknowledgement of receipt of this letter within the next 10 working days. The letter also needs to include the following information:
ii. In the case of an Alarm status, please confirm that a local investigation will be undertaken with independent assurance of the validity of this exercise. [*Delete for ''Alert' level letters*]
iii. A summary of the reasons for the inaccurate data submission and what measures have been put in place to prevent a recurrence. The deadline for submitting the response is *[date within 10 working days*].
iv. In the case of an 'Individual operator 'alarm' status you may wish to consider informing the GMC Employment Liaison Adviser (ELA). Please confirm that this has taken place in your acknowledgment letter if applicable. [*Delete for 'Alert' level letters*]

Please send a copy of this letter to the Care Quality Commission (clinicalaudits@cqc.org.uk). In the case of a Trust / Hospital level 'alarm' status it is also advisable to notify commissioners, NHS England or NHS Wales / Welsh Government and the relevant Royal College(s). [*Delete last sentence for 'Alert' level letters*]

This process is in accordance with the previous guidance from the Department of Health (2011 and 2017), which has been recently updated by NHS England and Healthcare Quality Improvement Partnership HQIP: https://www.hqip.org.uk/wp-content/uploads/2024/02/HQIP-NCAPOP-Outlier-Guidance_21022024.pdf

In line with the agreed policy with NHS England, the NCAP is also required to report all Alarm and Alert level outliers to the Care Quality Commission and to NHS England (and where relevant to NHS Wales / Welsh Government). In relation to all NCHDA outliers, NCAP is also required to notify the Congenital Heart Disease Programme Director and NHS England Regional Director. [*Delete if not NCHDA outlier*]

You may find the attached document from a BCS/SCTS Working Group helpful in determining your response to this finding. [*Delete for organisation level outliers; this Applies only to an individual outlier*]

Yours sincerely

[Name], NICOR Clinical Director, on behalf of the NCAP
[Name] Officer, Professional Society
[Name] Domain Clinical Lead

Cc: Trust / Hospital Lead Clinician
Cc: Clinical Governance Lead
Cc: Medical Director / Responsible Officer

iii) Case to answer' – Negative outlier original data correct (to be sent by post and email, after confirmation of contact and address details)

Thank you for your letter dated 'INSERT DATE' in response to the potential outlier notification you received from NICOR. It has been confirmed that the originally supplied data were accurate, thus confirming the initial designation of outlier status. Please find enclosed related correspondence and statistical analyses. The NCAP will proceed to publishing information of comparative performance that will identify providers [*provide date if available*]. Your status as an 'Alert' outlier will not be published / Your status as an 'Alarm' outlier will be published. [*Delete whichever does not apply*] As per the national guidance, you are now required to undertake the following steps:

i. Provide acknowledgement of receipt of this letter within the next 10 working days. The letter also needs to include the following information:
ii. In the case of an Alarm status, please confirm that a local investigation will be undertaken with independent assurance of the validity of this exercise. [*Delete for ''Alert' level letters*]
iii. In the case of an 'Individual operator 'alarm' status it is advisable to inform the GMC Employment Liaison Adviser (ELA). Please confirm that this has taken place in your acknowledgment letter if applicable. [*Delete for ''Alert' level letters*]

Please send a copy of this letter to the Care Quality Commission (clinicalaudits@cqc.org.uk).In the case of a Trust level 'alarm' status it is also advisable to notify commissioners, NHS England or NHS Wales / Welsh Government and relevant Royal College(s). [*Delete last sentence for 'Alert' level letters*]

This process is in accordance with the previous guidance from the Department of Health (2011 and 2017), which has been recently updated by NHS England and Healthcare Quality Improvement Partnership HQIP: https://www.hqip.org.uk/wp-content/uploads/2024/02/HQIP-NCAPOP-Outlier-Guidance_21022024.pdf

In line with the agreed policy, the NCAP is also required to report all Alarm and Alert level outliers to the Care Quality Commission and to NHS England (and where relevant to NHS Wales / Welsh Government). In relation to all NCHDA outliers, NCAP is also required to notify the Congenital Heart Disease Programme Director and NHS England Regional Director. [*Delete if not NCHDA outlier*].

You may find the attached document from a BCS/SCTS Working Group helpful in determining your response to this finding. [*Delete for organisation level outliers; this* applies only to an individual outlier].

Yours sincerely

[Name], NICOR Clinical Director, on behalf of the NCAP
[Name] Officer, Professional Society
[Name] Domain Clinical Lead

Cc: Trust / Hospital Lead Clinician
Cc: Individual Clinician

iv) Positive outlier (to be sent by post and email, after confirmation of contact and address details)

Thank you for your letter dated 'INSERT DATE' in response to the potential outlier notification you received from NICOR. It has been confirmed that the originally supplied data were accurate, thus confirming the initial designation of outlier status. Please find enclosed related correspondence and statistical analyses. The NCAP will proceed to publishing information of comparative performance that will identify providers on [*provide date if available*]. Your status as an 'Alert' outlier will not be published / Your status as an 'Alarm' outlier will be published. [*Delete whichever does not apply*] Please provide acknowledgement of receipt of this letter within the next 10 working days.

As this is a positive outlier, please could you also provide a summary as to the possible explanations? In the spirit of sharing good practice, we would like to use this as a basis of a case study that can be shared with the wider cardiac community as part of the NCAP publications.

Yours sincerely

[Name], NICOR Clinical Director, on behalf of the NCAP
[Name] Officer, Professional Society
[Name] Domain Clinical Lead

Cc: Trust / Hospital Lead Clinician
Cc: Individual Clinician

e. *Template 5i: CQC and NHS England / Welsh Government Audit Outliers Notification Template*

The NICOR COO is to notify Care Quality Commission (CQC) and NHS England (and where appropriate NHS Wales / Welsh Government) by completing and submitting the embedded template of Alert or Alarm level of statistical outliers for NCAP. The completed template will be sent to the following email address for the respective organisations:

- CQC: clinicalaudits@cqc.org.uk
- NHS England: england.clinical-audit@nhs.net
- NHS Wales / Welsh Government: wgclinicalaudit@gov.wales

CQC-Audit-Outliers-Notification-Template

Template 5ii: Covering email to accompany template 5i for notifying CQC and NHS England or Welsh Government about NCAP outliers.

The email should be addressed to CQC (at the email address: clinicalaudits@cqc.org.uk) but copied to the NHS England (email address: england.clinical-audit@nhs.net) and NHS Wales / Welsh Government (email address: wgclinicalaudit@gov.wales):

Dear CQC colleague

Subject: Notification of potential outliers for NCAP (reference: 'INSERT REF')

I am writing to notify the Care Quality Commission and NHS England (and where appropriate NHS Wales / Welsh Government)* of Outlier(s) detected in the National Cardiac Audit Programme analyses at Alert and / or Alarm level. The completed template is attached.

Please acknowledge receipt.

For any queries or further information, please do not hesitate to contact me.

Your sincerely

[Name], NICOR Chief Operating Officer

* Delete as appropriate.

f. *Template 6: Letter from NICOR COO to GMC to inform of failure of a provider organisation to comply with process.*

This letter must be on appropriate NICOR headed notepaper
Do not include NHS Arden & GEM/NHS England Logo on external documents. This template may be modified so that the letter can be tailored to the specifics of the issue.

Subject: FAILURE TO COMPLY WITH NATIONAL CARDIAC AUDIT PROGRAMME PROCESS FOR THE MANAGEMENT OF A CLINICAL DATA OUTLIER STATUS; 'INSERT NAME OF NCAP DOMAIN'

Text:

Dear 'INSERT NAME'

The 'INSERT NAME OF PROVIDER UNIT' has failed to conform to the nationally agreed process for the management of an outlier as regards a key clinical audit metric. The hospital was first informed of their potential outlier status on [ENTER DATE] and the outlier status was confirmed on [ENTER DATE]. The Medical Director / Responsible Officer and Chief Executive Officer were requested to [DELETE AS NECESSARY]:

- Acknowledge receipt of the letter
- Confirm that local investigation will be undertaken (Alarm only)
- In the case of a requirement to inform the GMC Employment Liaison Advisor (individual clinician only), confirmation that this has taken place.

We requested a response within 10 working days. The hospital has failed to conform to this timetable and we are unable to determine the response the hospital has made to this notification.

Please can you confirm receipt and outline any actions you choose to undertake by [date *+3 working days*]?

Yours sincerely

[Name], NICOR Chief Operating Officer

g. Template 7: Letter from NICOR COO to Trust / Hospital Medical Director / Responsible Officer and Chief Executive Officer to inform them of failure to participate in the NCAP.

This letter must be on appropriate NICOR headed notepaper
Do not include NHS Arden & GEM/NHS England Logo on external documents. This template may be modified so that the letter can be tailored to the specifics of the issue.

Subject: FAILURE TO COMPLY WITH PARTICIPATION IN THE NATIONAL CARDIAC AUDIT PROGRAMME

Text:

Dear 'INSERT NAME'

The 'INSERT NAME OF PROVIDER UNIT' has failed to comply with the requirements of the National Cardiac Audit Programme (NCAP), as per your commissioned status with NHS England*
*delete last part of this sentence for a hospital in Wales

Your unit has either fully or partially failed to comply with the data required for the following domains within the National Cardiac Audit Programme:

[Add list of domains as appropriate]

As agreed with NHS England and NHS Wales, your Trust is therefore identified as an Alarm-level outlier. We would be grateful if you could:

- Acknowledge receipt of the letter
- Confirm that local investigation will be undertaken
- Reassure NICOR of steps to be taken to ensure full participation in the NCAP.

We request a response within 10 working days.

Please can you confirm receipt and outline any actions you choose to undertake by [date *+3 working days*]?

Yours sincerely

[Name], NICOR Chief Operating Officer

a. Log 1: Management of outliers' log and signatures form

OUTLIER LOG: OUTLIER REF

Insert date on completion

Ref	Reporting period	NCAP Clinical Domain	Stage 1 Higher Information Analyst detects potential outlier and informs NCAP Principal Information Analyst	Stage 1 Principal Information Analyst confirms status	Stage 2 Telephone call made to provider or clinician and potential outlier letter sent	Stage 3 Hospital response received	Stage 4 NCAP review	Stage 5 Confirmation call/ letter sent	Stage 5 CC in CQC	Stage 6 Acknowledgment of receipt	Stage 7 Reminder letter	Stage 8 Outlier published	Stage 9 CQC informed of failure to comply Case study (positive outlier only)
[NAPCI-18-001]	2018	NAPCI	[date]	[date]	[date]	[date]	[date]	[date]	[date]	[date]	[date]	[date]	[date]
[NAPCI-18-002]													
etc													
etc													

Section 8: SOP dissemination, training and competency assessment

a) This SOP should be disseminated via email to all NCAP staff and the NCAP Domain Clinical Leads.

a) The dissemination process for all staff will include the following:

1. Electronic copy available to all staff on the Share Point folder.
2. New staff joining the department will be informed on induction.

In addition, elements of this SOP should be included in the Data Quality Guidance with the hospitals/Trusts so that the responsibilities of the provider organisation are highlighted.
Training in this SOP within NICOR is required by the:

- Higher Information Analysts
- Principal Information Analyst
- NICOR Chief Operating Officer
- Head of Systems Development, Data Services & Analysis
- Delivery Managers and other team members involved in the process
- Senior Delivery Manager
- Domain Clinical Leads
- Chair of the NOM Group
- NICOR Clinical Director.

b) Training will consist of reading the SOP and sign-off at an individual level before any involvement in the implementation of the SOP and during the induction process for new staff.

c) Competency assessments will be conducted initially (for new staff) and periodically. Any problems / issues identified which need to be corrected will include additional task-specific training and awareness.

Competency assessments methods will include the following:

- Indirect observations – periodic checks / reviews by the Senior Delivery Manager to ensure processes outlined in this SOP are being adhered to.
- Direct observations – this will include observing techniques by staff members which will allow the observer to see if the staff member is following the SOP.
- Use of a checklist where observable items, actions and attributes outlined in section 7 are observed.
- Monitoring the recording and quality of the Outlier log. This will be reviewed on a weekly basis during the outlier period.

Section 9: Acronyms, glossary and definitions.

Outlier	Identification of 'outlier' status indicates a statistically significant value in the relevant analyses. The definition is based on setting a target for an indicator, and then defining what level of variation from that target is acceptable, based on theories of statistical probability and /or clinical judgement.
Alert and Alarm	The definition of outlier is based on a 2-sided statistical approach and threshold *p* values of 0.05 for 'alert' and 0.002 for 'alarm'.
Provider organisation	The hospital or Trust submitting the data being analysed.
Case to answer	A 'case to answer' refers to the identification of a potential outlier status.
No case to answer	'No case to answer' refers to a situation where a 'case to answer' was not identified and potential outlier status has not been confirmed following data scrutiny and analysis.