

NICOR
STANDARD OPERATING PROCEDURE
NCAP Outlier Policy SOP03

Version 1.1

16 October 2023

REVISION CHRONOLOGY

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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.
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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.

**NICOR
STANDARD OPERATING PROCEDURE (SOP)**

Identification and Management of Outliers

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Contents

Section 1: Executive summary 5

Section 2: Purpose and scope 6

Section 3: Background 6

Section 4: Standard operating procedure 7

Section 5: Local approval 19

Section 6: SOP review and monitoring compliance/audit requirements 19

Section 7: Templates and logs 19

Section 8: SOP dissemination, training and competency assessment 28

Section 9: Acronyms, glossary and definitions. 29

Section 1: Executive summary

The Department of Health and HQIP have previously issued 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 now 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.

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

- 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 TAVI Registry

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) are in development and will enable outlier analyses.

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 Healthcare Quality Improvement Partnership (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. Guidance published by the Department of Health (2017)¹ and the Healthcare Quality Improvement Partnership (revised 2017)² provided recommendations on how potentially outlying (under or over) performance of healthcare providers and individual consultants can be identified and managed.

The recommendations in both documents are based on 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* details the statistical principles for identifying poor performance in national clinical audits, as defined by the National Clinical Audit Advisory Group (NCAAG).

*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.

Section 4: Standard operating procedure

a. NCAP staff involved with the SOP

This SOP applies to the following NCAP personnel:

- NICOR Director
- Chief Operating Officer (COO)
- Chair of the NCAP Operational and Methodology (NOM) Group
- NCAP Domain Clinical Lead
- National Clinical Audit Services Manager
- Senior Project Manager
- Principal Information Analyst (statistician)
- Domain Project Managers
- Information Analysts

b. Key operational relationships

- i. Audit Clinical Leads and relevant Professional Society Officers (Presidents, Clinical Standards leads etc.)
- ii. Inter-department relationships
NHS England NCAP Oversight Group, NHS England NCAP Commissioning Group, NICOR-AGEM NCAP Risk Group
- iii. Other departments
None
- iv. External stakeholders
Trust Lead Clinician for relevant audit
Trust Medical Director / Responsible Officer
Trust Chief Executive
Care Quality Commission
General Medical Council

c. Responsible personnel

i. **National Clinical Audit (NCA) supplier (the team responsible for managing and running 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:

- Information Analyst. The information analyst is responsible for the data analysis and the following activities:

- If a potential outlier is detected the information analyst is responsible for reporting this to the NCAP Principal Information Analyst (statistician), relevant Project Manager and Senior Project Manager.
 - If there is a 'case to answer' the 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 (statistician). The Principal Information Analyst (statistician) 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 Project Manager and Senior Project 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 Project Manager and Senior Project Manager.
 - Updating the relevant sections of the Outlier Log.
- Domain Project Manager (PM). The PM is responsible for:
 - Informing the Senior Project Manager, the Chair of the NOM Group, the Audit Clinical Lead and the NCAP COO of the finding.
 - Collating the appropriate information and, when instructed, sending the relevant prepared letter (signed by the NICOR Director, Professional Society President and Audit Clinical Lead) to the Medical Director/Lead Clinician of the provider hospital (copying to the database manager and others as outlined).
 - Ensuring that 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 Project Manager (SPM). The SPM 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 Chief Operating Officer 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.

- National Clinical Audit Services Manager (NCASM). If the Principle Information Analyst is absent, the NCASM will take on the Principal Information Analyst's responsibilities.

- NCAP Domain Clinical Lead. The NCAP Audit 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 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, unless this responsibility is undertaken by the President or Senior Officer of the relevant Professional Society.
 - Liaising with NICOR senior staff, 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 Clinical Lead, and ensuring that an appropriately worded letter to the provider or clinician is prepared in collaboration with the relevant Audit Clinical Lead and Society President.
 - Ensuring that agreed processes will be followed in collaboration with the relevant Audit Clinical Lead and Professional Society.

- Ensuring that the NICOR Director is informed.
 - Ensuring that the NICOR Director has co-signed all outlier letters together with either the Audit Clinical Lead for the relevant domain 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.
- NCAP 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 Team follows due process and updates the SOP as necessary.
 - Providing anonymized updates at the various NHS Arden & GEM/NHS England Oversight, Commissioning and Risk Group meetings.
 - Liaising with NHS Arden & GEM/NHS England 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 audit).
 - Informing CQC of relevant alert and alarm outlier status (Trust level).
 - The NICOR Director. The NICOR 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 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 NCAP Oversight Group, the NHS England NCAP Commissioning Group and the NICOR/NHS Arden & Gem Risk Group.

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.
- Amending the live data if the data underpinning the outlier analysis are inaccurate.
- Discussing with the NCAP Audit Clinical Lead/COO if a potential outlier is detected and there is a 'case to answer'.
- Providing NCAP 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 Clinical Commissioning Groups, relevant Professional Society/Association, the GMC Employment Liaison Advisor (ELA) and the Care Quality Commission.
- 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

e. Procedures

The following SOP is based on guidance published by the Department of Health and HQIP 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. The SOP should be read in conjunction with the original guidance^{1,2}. 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.

Table 1: DH and HQIP Guidance and NCAP actions in managing outliers for both Trusts and individuals.

Please note the guidance applies to both unless otherwise stated at the relevant stage.

Please also note that the agreed NCAP validation process should have taken place prior to Stage 1.

Please note that 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' or 'alarm' level, to determine whether there is: 'No case to answer' • potential outlier status not confirmed	NCAP	10	<ul style="list-style-type: none"> If a potential outlier is detected the Information Analyst refers to the Principal Information Analyst (Statistician) in writing (email: Template 1). The Principal Information Analyst (Statistician) must acknowledge receipt of the email. If no response is received within 1 working day, the Information Analyst must inform the PM in writing (email: Template 1). The Principal Information Analyst (Statistician) or PM must assign a reference number to the potential outlier and commence a log of the process (Log 1). The Principal Information Analyst (Statistician) (or other analyst as assigned by the Principal Information Analyst (Statistician)) must check the data/methodology. 	Information Analyst Statistician/information Analyst Principal Information Analyst (Statistician) Principal Information Analyst (Statistician) / Domain Project Manager	1 1 3 3 1

	<ul style="list-style-type: none"> • data and results revised in NCAP records • details formally recorded. <p>'Case to answer'</p> <ul style="list-style-type: none"> • potential outlier status persists • <i>proceed to stage 2</i> 			<ul style="list-style-type: none"> • If 'no case to answer', log this. No further action is needed. • If 'case to answer', prior to proceeding to stage 2, the Principal Information Analyst (Statistician) (or analyst assigned by the Principal Information Analyst (Statistician)) informs the Domain PM. • The Domain PM informs the following via email (Template 2) <ul style="list-style-type: none"> ○ Senior Project Manager ○ Audit Clinical Lead ○ COO ○ Chair, NOM Group • The Audit 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 NCAP Audit Clinical Lead and President of the relevant Professional Society will determine whether a secondary validation process is followed. • 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 COO and Chair of the NOM Group. • The NICOR Director, together with the President of the relevant Professional Society 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. 	<p>Domain Project Manager</p> <p>Principal Information Analyst (Statistician)/ Information Analyst</p> <p>Domain Project Manager</p> <p>Audit Clinical Lead and President of the relevant Professional Society</p> <p>Audit Clinical Lead Professional Society representative</p> <p>NICOR Director, Audit Clinical Lead and/or President of the relevant Professional Society.</p>	<p>1</p> <p>1</p> <p>5</p> <p>7</p> <p>5</p>
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	NCAP Clinical Lead or Officer of the relevant Professional Society	5	<ul style="list-style-type: none"> • If a secondary validation process is likely, the Domain Project Manager (PM) 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. • The Domain PM to send a copy of the letter to the Hospital Medical Director / Responsible Officer(s), 	Domain Project Manager	5

	<p>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.</p> <p>Trust 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.</p> <p>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.</p>			<p>clinical governance lead(s) and/or CEO(s) of the provider organisation(s), as outlined.</p> <ul style="list-style-type: none"> All addresses should be checked by the Domain Project 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. The Domain PM to update the NCAP Outliers Log. The Domain PM to update the NCAP contact database. 		
3	<p>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 Audit Clinical Lead (depending on the co-signatures of the original notification letter).</p>	<p>Provider Medical Director / Responsible Officer(s) or Clinical Lead(s)</p>	25	<p>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'.</p>		25
4	<p>Review of Medical Director's / Responsible Officer's / Hospital Lead Clinician's response to determine:</p> <p><u>No case to answer'</u></p>	NCAP	20	<ul style="list-style-type: none"> If no secondary validation process is considered/actioned, move to stage 5. Where necessary, the information analyst will re-run the analysis on the data and provide results to the Domain PM. 	Information Analyst	10

	<ul style="list-style-type: none"> 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 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. <p><u>Case to answer</u></p> <ul style="list-style-type: none"> It is confirmed that although the data originally supplied by the provider were inaccurate, analysis still indicates outlier status; <p>or</p> <ul style="list-style-type: none"> It is confirmed that the originally supplied data were accurate, thus confirming the initial designation of outlier status. 			<ul style="list-style-type: none"> The Domain PM emails the following (Template 2), attaching draft letters for sign off within 2 working days to: <ul style="list-style-type: none"> Senior Project Manager Audit Clinical Lead COO Chair, NOM Group Director, NICOR Director, NICOR, Officer of the relevant Professional Society and/or Audit Clinical Lead to sign off letters. <p>If <u>no case to answer</u> the Domain Project Manager 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 4a).</p> <p>If a <u>case to answer</u> the Domain Project Manager 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 4b-d). See stage 5.</p> <p>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 NCAP Audit Clinical Lead should formulate an appropriate response with the NICOR Director and the President of the relevant Professional Society, accepting the explanation but confirming that monitoring will continue.</p> <ul style="list-style-type: none"> All addresses should be checked by the Domain Project 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. 	<p>Domain Project Manager</p> <p>Director, NICOR, Officer of the relevant Professional Society and/or Audit Clinical Lead</p> <p>Domain Project Manager</p> <p>Domain Project Manager</p> <p>NCAP Audit Lead, NICOR Director, President of the relevant Professional Society</p>	<p>2</p> <p>5</p> <p>2</p> <p>3</p> <p>5</p>
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	• <i>proceed to stage 5</i>					
5	<p>Hospital outlier: Contact Medical Director / Responsible Officer and Hospital Lead Clinician by telephone, prior to written confirmation of potential outlier status (alert or alarm); letter addressed to the Hospital Medical Director / Responsible Officer and copied to the Hospital Chief Executive and Hospital Lead Clinician.</p> <p>Individual outlier: Contact individual clinician and Hospital Medical Director / Responsible Officer of all relevant provider organisations.</p> <p>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).</p> <p>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.</p> <p>In the case of a Trust level 'alert' or 'alarm' NCAP to notify CQC and, where necessary, GIG/Cymru (NHS Wales). In the case of a Trust level 'alarm', the Provider CEO will</p>	NCAP Clinical Lead or Officer of the relevant Professional Society	5	<ul style="list-style-type: none"> The Audit 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. The Domain PM will send the prepared notification letter by post and email on behalf of the NICOR 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 4a-c: Negative Outlier; Template 4d: Positive Outlier). All addresses should be checked by the Project 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. 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 COO to notify: <ul style="list-style-type: none"> CQC (clinicalaudits@cqc.org.uk) NICOR Director or COO to provide summary 'outlier' update at NHS England NCAP Oversight Group, NHS England NCAP Commissioning Group, NICOR/NHS Arden & GEM Risk Group. 	<p>Audit Clinical Lead, Chair of theNOM Group, and/or Officer of the relevant Professional Society</p> <p>Domain Project Manager</p> <p>Domain Project Manager</p> <p>Domain Project Manager</p> <p>COO</p> <p>NCAP Director or COO</p>	<p>3</p> <p>2</p>

	<p>be advised to inform commissioners, NHS England or NHS Wales and the relevant Royal Colleges.</p> <p>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).</p> <p>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.</p> <p>The Trust should be informed that NCAP will publish information of comparative performance at an 'alarm' level that will identify individuals and providers.</p> <p>Additional requirements: In the case of NCHDA outliers NHSE has requested the following roles are also copied in to the letter:</p> <ul style="list-style-type: none"> - Programme Director (Congenital Heart Disease Programme) - NHS England Regional Director 					
6	<p>The Hospital(s) is(are) required to:</p> <ul style="list-style-type: none"> - Acknowledge receipt of the letter 	<p>Provider Medical Director / Responsible Officer(s) or Chief Executive(s)</p>	10	<p>PM updates the Outlier log and files letter. PM notifies COO of non-compliance with stage 6.</p>	<p>Domain Project Manager</p>	

	<ul style="list-style-type: none"> - 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. 					
7	<p>If no acknowledgment received, a reminder letter should be sent to the Medical Director / Responsible Officer(s).</p> <p>Trust level only: letter to be copied to CQC. If no response is received within 5 working days, CQC and NHS England / NHS Wales notified of non-compliance.</p>	COO/ Domain Project Manager	5	<p>Domain PM to send a reminder letter and update the outlier log.</p> <p>COO notifies CQC and NHS England or NHS Wales of non-compliance.</p>	<p>Domain Project Manager</p> <p>COO</p>	<p>5 of deadline expiry</p> <p>5</p>
8	<p>Public disclosure of comparative information that identifies providers and individuals (if relevant) in applicable publications. To date these are limited to:</p> <ul style="list-style-type: none"> • Annual Report • Professional Society websites. <p>The current agreement with CQC is that providers falling in the alert zone will not be disclosed, whereas alarm status will.</p>	NCAP team	As per Standard Reporting Procedure	This is part of the reporting cycle. Domain PM to update log on publication.	Domain Project Manager and others	
9	<p>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:</p> <ul style="list-style-type: none"> - CQC - NHS England / NHS Wales - GMC (individual operator only), following discussion with 	<p>Trust level – NCAP team</p> <p>Individual only - NCAP in conjunction with HQIP Medical Director.</p>	5	<p>COO to notify NHS Arden & GEM/NHS England or NHS Wales.</p> <p>COO to write to the GMC (Template 5).</p> <p>COO to update log and file correspondence.</p>	COO	

	the NHS England NCD.					
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f. Contingencies

The NCAP is required to undertake 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 COO/SPM.

g. Level of evidence and references

1. Department of Health. Detection and management of outliers' guidance prepared by the national Clinical Audit Advisory Group. 2011.
<https://www.gov.uk/government/publications/detection-and-management-of-outliers-guidance-prepared-by-national-clinical-audit-advisory-group>
2. Detection and management of outliers for National Clinical Audits. Guidance prepared by National Clinical Audit Group/HQIP (2011). Updated by HQIP in consultation with CQC, NHS England, NAGCAE, NHS Improvement (May 2017).
<https://www.hqip.org.uk/resource/detection-and-management-of-outliers-for-national-clinical-audits-implementation-guide-for-ncapop-providers/#.XEmSkVX7Rpg>
3. Bridgeman B, Keenan D, Mullan K. [online]; 2015. Healthcare Quality Improvement Partnership. Technical Manual for the Consultant Outcomes Publication 2015
<http://www.hqip.org.uk/resources/clinical-outcomes-publication-technical-manual/>

Section 5: Local approval

The SOP has been reviewed by NICOR staff including the NICOR Director, COO, Senior Project Manager, National Clinical Audit Services Manager, Chair of the NOM Group and Audit 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 change in national guidance or the result of known risks or issues).
- b) The NCAP Delivery Group will monitor progress as part of weekly 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 Information Analyst to Principal Information Analyst (Statistician) or Project Manager informing of potential outlier*

Subject: POTENTIAL OUTLIER DETECTED; 'INSERT NAME OF CLINICAL AUDIT'

Text:

Dear 'INSERT NAME'

A potential outlier has been detected in the 'INSERT NAME OF AUDIT'. 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 NCAP Project Manager to NCAP Senior Project Manager, Audit Clinical Lead, Chief Operating Officer and Chair of the NOM group (and NICOR 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 CLINICAL AUDIT', 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 headed notepaper.

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

'INSERT DATE'

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 AUDIT' 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, NCAP will uphold the original data submission.

Following receipt of your written response, 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:

1. Department of Health Guidance 'The detection and management of outliers (2011). <https://www.gov.uk/government/publications/detection-and-management-of-outliers-guidance-prepared-by-national-clinical-audit-advisory-group>
2. Healthcare Quality Improvement Partnership Technical Manual for the Consultant Outcomes Publications (2016). <http://www.hqip.org.uk/resources/clinical-outcomes-publication-technical-manual>

Yours sincerely,

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

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

d. *Template 4: Letter from 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.

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

Cc: Medical Director / Responsible Officer [Trust]
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. NCAP will proceed to publishing information of comparative performance that will identify providers [*provide date if available*]. 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.
- 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.

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 and the relevant Royal College(s).

This process is in accordance with the Department of Health Guidance 'The detection and management of outliers' (<https://www.gov.uk/government/publications/detection-and-management-of-outliers-guidance-prepared-by-national-clinical-audit-advisory-group>) and Healthcare Quality Improvement Partnership Technical Manual for the Consultant Outcomes Publications <http://www.hqip.org.uk/resources/clinical-outcomes-publication-technical-manual/>

In line with this policy, the NCAP is also required to report all Alarm and Alert level outliers to the Care Quality Commission. 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 [applies only to individual outlier].

Yours sincerely
John Deanfield, Director, NICOR on behalf of the NCAP
[Name] Audit Clinical Lead
[Name] Officer, Professional Society

Cc: Trust 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 NCAP. 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. NCAP will proceed to publishing information of comparative performance that will identify providers [*provide date if available*]. 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.
- 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 it is advisable to inform the GMC Employment Liaison Adviser (ELA). Please confirm that this has taken place in your acknowledgment letter if applicable.

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 and relevant Royal College(s). This process is in accordance with the Department of Health Guidance 'The detection and management of outliers' (<https://www.gov.uk/government/publications/detection-and-management-of-outliers-guidance-prepared-by-national-clinical-audit-advisory-group>) and Healthcare Quality Improvement Partnership Technical Manual for the Consultant Outcomes Publications (<http://www.hqip.org.uk/resources/clinical-outcomes-publication-technical-manual>)

In line with this policy, the NCAP is also required to report all Alarm level outliers to the Care Quality Commission. 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 [applies only to individual outlier].

Yours sincerely
John Deanfield, Director, NICOR, on behalf of the NCAP
[Name] Audit Clinical Lead
[Name] Officer, Professional Society

Cc: Trust 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 NCAP. 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. NCAP will proceed to publishing information of comparative performance that will identify providers on [provide date if available]. 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.

This process is in accordance with the Department of Health Guidance 'The detection and management of outliers' (<https://www.gov.uk/government/publications/detection-and-management-of-outliers-guidance-prepared-by-national-clinical-audit-advisory-group>) and Healthcare Quality Improvement Partnership Technical Manual for the Consultant Outcomes Publications <http://www.hqip.org.uk/resources/clinical-outcomes-publication-technical-manual>.

Yours sincerely
John Deanfield, Director, NICOR, on behalf of the NCAP
[Name] Audit Clinical Lead
[Name] Officer, Professional Society

Cc: Trust Lead Clinician
Cc: Individual Clinician

e. *Template 5: Letter from NCAP 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 CLINICAL AUDIT'

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 ELA (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

James Chal, Chief Operating Officer, NICOR

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

OUTLIER LOG: OUTLIER REF

Insert date on completion

			Stage 1	Stage 1	Stage 2	Stage 3	Stage 4	Stage 5	Stage 5	Stage 6	Stage 7	Stage 8	Stage 9
Ref	Reporting period	Clinical Audit	Information analyst detects potential outlier and informs NCAP statistician	Statistician confirms status	Telephone call made to provider or clinician and potential outlier letter sent	Trust response received	NCAP review	Confirmation call/letter sent	CC in CQC	Acknowledgment of receipt	Reminder letter	Outlier published	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]
[NAPCI-18-002]													
etc													
etc													

SOP DISSEMINATION AND TRAINING

Section 8: SOP dissemination, training and competency assessment

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

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

1. Physical copy of the SOP contained within the departmental SOP folder.
2. Electronic copy available to all staff on the departmental shared folder.
3. 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:

- Information analysts
- Principal Information Analyst (Statistician)
- Chief Operating Officer
- Domain Project Managers and other Project Managers involved in the process
- Senior Project Manager
- Audit Clinical Leads
- Chair of the NCAP NOM Group
- Director, NICOR.

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 NCAP Senior Project 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.