Cleft Registry and Audit Network (CRANE)

Outlier Policy: Identification and management of outliers

Contents

1. Introduction 1
2. Performance Indicators 2
3. Expected Performance 2
4. Data quality 3
5. Case-mix 4
6. Detection of a potential negative outlier (Consent Verification and Outcomes) 4
7. Management of a potential negative outlier 6
8. Management of “alert” and “outlier” triggers. 9
9. Detection of and response to positive outliers 11
10. The role the CRANE Database Team 13

1. Introduction

This document describes the outlier policy for the Cleft Registry and Audit Network (CRANE). It details the process for assessing the performance of participating NHS Trusts in England, as well as Health Boards in Scotland, Wales, and Northern Ireland. It also explains the steps the CRANE Database Team will take when a cleft service’s performance falls outside the expected range. The policy is based on established principles and aligns with the Department of Health and HQIP’s outlier management policy[1] [2]. Its primary aim is to support quality improvement and promote learning from clinical excellence.

The NHS mandate and “Good Medical Practice” require clinicians to provide accurate, up-to-date information about their clinical practice to ensure patient safety. In addition, revalidation requires doctors to demonstrate acceptable clinical performance. National NHS Medical Directors have emphasised that the responsibility for maintaining and providing accurate data rests with individual clinicians, both in terms of the coding of their work and the submission of clinical data to national

[1] https://www.hqip.org.uk/outlier-management-for-national-clinical-audits/ - Previous guidance for England and Wales, updated 2/9/21

[2] https://www.hqip.org.uk/outlier-management-for-national-clinical-audits/ - Current guidance for England and Wales, updated 3/1/24

datasets, where available. To support clinicians in this requirement, NHS England, Scotland, Wales and Northern Ireland have commissioned The Cleft Registry and Audit Network (CRANE) to register children born with a cleft lip and/or palate (CL/P) and audit the outcomes of their care. This Audit is run by the CRANE Database Team, based at the Clinical Effectiveness Unit (CEU) of the Royal College of Surgeons (RCS) of England. The work of CRANE is overseen by the Cleft Development Group (CDG). CRANE ensures the clinical community is regularly updated on its activity through published Annual Reports, reports to the Council of the Craniofacial Society of Great Britain and Ireland, and through presentations at their annual Scientific Conference.

2. Performance Indicators

CRANE uses a number of process and outcome indicators to evaluate the quality of care received by individuals born with CL/P. These indicators are drawn from relevant clinical guidelines and are based on recommendations (or standards of care) related to the management of individuals born with CL/P and are agreed with the CDG who have oversight of CRANE activity.

Information on the various indicators are publicly available and are included in CRANE Annual Reports, and supplementary tables, which can be found on the CRANE Website (www.crane-database.org.uk). NHS organisations providing cleft care can benchmark their performance against their peers using these indicators. This outlier policy is used in conjunction with those specific indicators for which performance outside the expected range raises concerns about the care provided or highlights exceptional care. Not all data submitted to CRANE are analysed within the scope of this policy.

CRANE will periodically review the scope of this policy with its Clinical Steering group (The CDG) and will communicate with NHS providers any change in policy that applies to performance indicators prior to publishing this information.

3. Expected Performance

CRANE uses established benchmarks or standards to determine whether an organisation meets expected performance levels. These benchmarks are based on external sources, such as research evidence, or clinical consensus. The average performance of all providers meeting a benchmark or standard is used to assess whether an organisation's performance is within the expected range.

4. Data quality[3]

An important part of the assessment process is ensuring that data is of sufficient quality to support robust analysis. The outlier process includes evaluating the following aspects of data quality:

- **Consent Verification:** This refers to the proportion of cases where consent has been verified, relative to the total number of registered cases. Since cleft-related outcomes can only be collected and reported for CRANE-consented children, services must achieve high levels of verified consent to ensure the generalisability of results.
- **Data Completeness:** This refers to the proportion of eligible, CRANE-consented cases for whom data has been reported. Incomplete data can also affect the generalisability and reliability of the outcomes reported.

Data from services that do not meet the agreed/expected standards for consent verification (see Section 6: Consent and Data Completeness) or outcome data completeness will be excluded from relevant analyses. Specifically:

- If consent verification falls below the agreed threshold, all data from that service will be excluded from the calculation of means and standard deviations for consent-dependent indicators.
- If individual outcome data completeness is inadequate, the outcome data from that service will be excluded from the relevant calculations for that particular indicator.

This approach ensures that audit parameters are based only on patient populations from services with acceptable levels of consent verification and data completeness. It also safeguards the integrity of the analysis and the governance processes for participating NHS Trusts and Health Boards.

Inadequate data completeness may result in provider outcomes that are not representative of actual practice. In such cases, data will still be published, but with a clear caveat stating that benchmarking is not possible, and comparisons with other providers should be interpreted with caution.

Individual providers are expected to have internal validation and quality control procedures in place before submitting data to CRANE. Although providers may amend entries prior to the review deadline,

[3] In the rare circumstances in which information provided to CRANE could reasonably suggest the presence of very serious issues with clinical practice or system failure that presents a risk of harm to patients, the CRANE project team will implement an escalation process that mirrors the HQIP approach described in Table 3 in the following guidance published January 2024: https://www.hqip.org.uk/wp-content/uploads/2024/02/HQIP-NCAPOP-Outlier-Guidance_21022024.pdf

once the deadline passes, CRANE will extract data for analyses, and no further changes will be accepted for that reporting year.

The responsibility for the accuracy and completeness of data lies with the submitting NHS organisations. In line with HQIP guidance, regulatory bodies (Care Quality Commission (England), Care Inspectorate (Scotland), Health Inspectorate Wales and Regulation and Quality Improvement authority (Northern Ireland)) may use evidence on data quality and submission to inform their assessments of providers.

5. Case-mix

When comparing outcomes across NHS providers, it is important to account for differences in the patient populations by adjusting for known, measurable patient characteristics that are associated with the outcome indicator.

Over recent years, CRANE has worked to identify such determinants using the data collected. Several factors influencing speech and dental outcomes have been identified and reported through peer-reviewed publications and previous CRANE reports. Such factors include cleft type, extent of hard palate involvement, additional diagnoses, sex, and socio-economic status. Risk adjustment should be performed using an up-to-date model. Judgment as to the adequacy of a model will depend on the performance indicator selected and the clinical context.

CRANE will risk adjust both speech and dental outcomes from 2025 and will continue to investigate determinants of other outcomes as data allow.

6. Detection of a potential negative outlier (Consent Verification and Outcomes)

The first step in the process to identify potential outliers will be to assess whether the indicator value falls within the expected level of performance. In order to do this the data must be of sufficient quantity and quality for assessment to take place. Without consent from patients, CRANE cannot fulfil its governance role for cleft services in the UK. Consent for data to be analysed by CRANE is obtained by each submitting unit. To have confidence in the data supplied by each unit a minimum level of consent requests must be achieved. As a service CRANE would prefer to have a minimum level of consent verification (e.g.90%) to allow all to have confidence that data analysed and conclusions drawn are valid. CRANE however realises that there will be variability in consent verification achieved each year and this would therefore be impracticable. Therefore, in consultation with the CDG, CRANE has decided to institute outlier parameters (2SD and 3SD of the mean) based on three subsequent reporting years for registration and outcome data. CRANE will actively engage with the cleft clinical community during this time to champion good practice and help explore barriers to consent verification where they exist.

If consent verification is not obtained / recorded on the CRANE Database, cleft services will not be able to enter outcome data meaning that the CRANE team will not be able to include these individuals in subsequent analyses. CRANE is only able to report on data completeness by comparing number of 'visible data points' on patient registrations for each unit by year of birth. Where Consent Verification data completeness levels are out-with accepted levels, CRANE cannot comment on the quality of the services provided by such units. The clinical lead of the service and medical director / Chief Executive of the health board/Trust in question will be written to, to inform them that they lead / host a service for which CRANE cannot provide a governance report for the years in question. Outcome results for the years in question will be shared with the unit with the caveat that benchmarking against the rest of UK practice cannot be achieved due either to less than adequate consent verification, less than adequate data completeness, or both. While CRANE is not prescriptive on the process of acquiring consent, CRANE would advocate that consent is obtained as early as possible so that data beyond simple registration details can be entered onto the system at the earliest opportunity.

Data completeness for each outcome will be analysed on the basis of nationally reported data for the period of analysis. Appropriate levels of data completeness will be defined using statistically derived control limits which lie either side of the mean outcome. The assessment will be based on the most recent audit period (e.g. the last three years of data) and indicator values will be produced for this specified period. The indicator values will be typically shown on a funnel plot. Two and three standard deviation control limits will be included on each funnel plot. The first (inner) limit will indicate whether an indicator value for an NHS provider is more than two standard deviations from the expected performance level. The second (outer) limit will indicate whether the value for a provider is more than three standard deviations from the expected level.

Provider values that are more than 3 standard deviations below the expected level of performance will be deemed an 'alarm' and labelled as an 'outlier'. Those NHS providers who fall between the 2 and 3 SD limits below the expected level of performance will be flagged as an 'alert'. Two consecutive years as an 'alert' in any parameter (consent / data completeness or individual outcomes) will represent an 'alarm' and the unit labelled as an 'outlier'. The protocol outlined in Table 1 will be followed.

It is important to note that these definitions of statistically significant differences from expected performance will be based on the results achieved in the UK as a whole, over the period in question and as such represent benchmarking against peer organisations. The control limits (funnels) take into account caseload numbers, so it is possible to produce statistically robust performance indicators except when the number of cases is extremely low. UK cleft service organisation is such that this should not be an issue; however, if any unit returns appropriate but low numbers of consented / reported data

an observed minimum caseload (<10 cases) will be required for appropriate statistical methods to ensure that reliable benchmarking can take place.

7. Management of a potential negative outlier

The management of a potential outlier will involve the following people:

- The CRANE Database Team: The team responsible for managing and running the audit nationally including the clinical project lead - https://www.crane-database.org.uk/about/our-team/.
- The Cleft Development Group (CDG): The CDG includes the clinical directors of each unit in the UK, the clinical excellence networks appointed CDG representatives and the clinical project lead of CRANE. The chair of CDG will oversee strategic direction and be responsible for monitoring all aspects of delivery of the outlier policy through its sub-group the QMIC.
- The provider service's Clinical Lead will be notified and involved in responses to Outlier status.
- Consent and Data completeness alert and outlier status for Process Indicators will be escalated as per details below in a manner to encourage engagement with CRANE. Only issues relating to Consent and Clinical Outcomes will be escalated to Medical Directors and Chief Executive.
- Where no return communication is received from Medical Director and / or Chief Executives within the specified period, clinical outcome concerns will be escalated to the relevant nation's regulatory body (CQC / CI / HIW / RQIA)

Table 1 describes the seven stages that will be followed in managing a potential negative outlier, the actions that need to be taken, the people involved and the maximum time scales. It aims to be fair to NHS providers identified as potential outliers and sufficiently rapid so as not to unduly delay the publication of comparative information. The process applies to providers flagged as an "alarm" in the initial analysis. NHS providers should invest the time and resources required to review the data when identified as a potential outlier. If after a review of their data, their level of performance is still beyond the 3 SD control limit, the provider will be flagged as an outlier in the subsequent Annual Report.

Table 1. Negative Outlier Identification Process

Stage	Action	Who?	Within how many working days?
1	Providers with a performance indicator suggesting 'outlier" status will have their data reviewed and the analysis double-checked to determine whether there is: **'No concern of outlier status'** • potential outlier status not confirmed • data and results revised in CRANE records • details formally recorded • *Process ends* **'Concern of outlier status'** • potential outlier status persists • *Proceed to stage 2*	CRANE Database Team	From Annual report extract cleaning and analysis – 10 days
2	**The Clinical Lead** at the provider organisation is informed about the potential outlier status and requested to identify any data errors or justifiable explanation(s). Aggregate results to support the review of data will be made available to the Clinical Contact. **The chair of CDG** will also be informed of potential outlier status	CRANE Database Team Local Service Clinical Lead CDG Chair	5
3	**Clinical Lead** at the provider organisation to provide written response to CRANE Database Team to 1) confirm their confidence in their data, 2) share the reasons for the potential outlier status, and 3) willingness to receive external review should their medical director request it. The response should include information about the review of their patient data and an initial review of local practice.	Local Service Clinical Lead	25

Stage	Action	Who?	Within how many working days?
4	Review of Clinician Lead's response to determine: '**No concern of outlier status'** • Evidence is provided to show the data originally analysed contained sufficient inaccuracies to produce the unexpected performance value. • Details of the Trust / provider's response will be recorded and shared with CDG Chair / vice chair. • The CRANE Clinical Contact Provider and chair of CDG notified in writing of this conclusion. • *Process ends* **Ongoing concern that there is outlier status'** • There is insufficient evidence to conclude the data originally supplied were so inaccurate to suggest this was the only reason the level of performance was beyond the 3 SD control limits; or • It is confirmed that the originally supplied data were accurate, thus confirming the initial designation of "outlier" status. • *Proceed to stage 5*	CRANE Database Team	20
5	5a. • CRANE to contact Clinical lead by telephone, prior to written confirmation of outlier status 5b. • Written confirmation sent to clinical lead and copied to Medical Director and Chief Executive. • Medical Director and Chief Executive will be requested to undertake a local investigation in line with HQIP "Detection and management of outliers" document. 5c. • Chief executive advised to inform relevant bodies about CRANE's concerns including commissioners, NHS Improvement bodies and relevant Royal Colleges. 5d. • CRANE will prepare information of comparative performance that will identify providers. Unedited written response from Outlier unit will be included in the annual report, adjacent to performance of concern.	CRANE Database Team Local Service Clinical Lead Chair of CDG CDG QMIC	30 *Continued on next page…*

Stage	Action	Who?	*Within how many working days?*
5	5e. • Chair of CDG Quality Monitoring & Improvement Committee will identify 3 most relevant members with necessary expertise whose names and qualification will be made available to the outlying unit senior management (clinical lead) / medical director / chief executive for input at their discretion • All relevant statistical analyses, including previous response from the CRANE's clinical contact, made available. At the discretion (and on the timeline) of the local service: • CDG Quality Monitoring and Improvement Committee will support the local service to help them to review their data to look for explanations for the difference in their performance and, where appropriate, recommend actions to improve performance.		*…continued from previous page.*
6	• Public disclosure of comparative information that identifies providers (e.g. CRANE Annual report).	CRANE Database Team	
7	• **Provider Chief Executive** or appointed representative will acknowledge receipt of the letter, confirming that a local investigation will be undertaken with independent assurance of the validity of this exercise, copying in the regulators (e.g. CQC/CI/HIW/RQIA) • **CRANE Database Team** will send a reminder within 5 days if not received within 10-day timeframe. The CQC / regulator will be notified of non-compliance if no response is received to this reminder.	Provider Chief Executive CRANE Database Team	10

8. Management of "alert" and "outlier" triggers.

Clinical teams and governance leads need to understand the meaning of these terms and the responses that they will be required to undertake.

An "alert" indicates that the hospital site has a value that is between 2 and 3 Standard Deviations from the expected level in the poor direction of performance. Providers flagged as "alerts" will not be subject to the review process as outlined in Table 1 above unless this is the second consecutive year of alert status in the identified parameter when the unit would be upgraded to an 'Alarm' and the process above commenced and followed. An "outlier" indicates that a hospital site has an indicator value that is more than 3 Standard Deviations from the expected level of performance. As outlined in Table 1 above,

the Trust/Health Board should invest the time and resource required to reviewing data and providing updated data to CRANE. In addition, consideration will be given to whether it is necessary to recommend suspension of performance of certain activities. This will be more likely if poor performance is leading to significant patient harm. It is important to understand that these measures exist for patient safety and that such a recommendation to suspend certain activities will be immediately withdrawn if it can be demonstrated after reviewing the revised data that performance was within the "outlier" line.

Hospital sites should be aware that while CRANE has a duty to report on the data it holds, CRANE is not responsible for the accuracy and completeness of the data submitted. This responsibility rests with the clinical teams/sites/NHS Trusts/Health Boards providing the cleft service. Issues with clinical audit data (either case ascertainment or data quality) must be addressed by the unit/trust/board concerned. The role of CRANE is to provide impartial, consistent analysis and case mix adjustment of data received from hospitals and to make reports on the process and outcome of care publicly available.

From 2025 CRANE (as mandated by CDG) will report to service Clinical Directors where; 1. Consent verification levels,2. Process and outcome data completeness levels and 3. Actual process and outcomes are determent as alerts (between 2 and 3 Standard deviations of national mean) or alarms (when either between 2 and 3 Standard deviations for two consecutive reporting periods, or when beyond 3 standard deviations in any one reporting period).

Only where 'Alarm' outlier status is confirmed for 1. Consent verification and 2. Clinical outcomes (after service response and CRANE confirmation of validity of response) will CRANE escalate communication to those with ultimate governance responsibility for a service (e.g. Medical Directors / Chief Executive Officers. In communication with such persons CRANE will provide details of evidence of used to determine 'Alarm' status, response of local team, confirmation of alarm status after review of service response and HQIP Guidance document on "Detection and management of outliers". CRANE will indicate that investigation of Local practice and outcomes is warranted and seek reassurance that such timely investigation will be undertaken. Where no response is received to such primary or secondary communication CRANE will escalate concerns regarding poor performance to the relevant national regulatory body. (CQC/CI/HIW/RQIA).

9. Detection of and response to positive outliers

Audit and benchmarking are not only about identifying negative issues relating to individual or unit performance. Perhaps more important is identifying excellence in performance so that this can be learned from, disseminated and incorporated into practice elsewhere. CRANE will undertake the same rigour in analysis of positive performance as it does negative performance to ensure that there is confidence in such a result that others will want to learn from and incorporate into their own processes and practice. When a unit either performs above 3 standard deviations, or consistently performs (two or more consecutive reporting years) above 2 standard deviations of the national mean, the process detailed in Table 2 will be followed:

Table 2. Positive Outlier Process

Stage	Action	Who?	Within how many working days?
1	Providers with a performance indicator suggesting positive 'outlier" status will have their data reviewed and the analysis double-checked to determine whether there is: **'No Evidence of Outlier Status'** • potential positive outlier status not confirmed • data and results revised in CRANE records • details formally recorded • *Process ends* **'Evidence of Outlier Status'** • potential positive outlier status persists • *Proceed to stage 2*	CRANE Database Team	10
2	The **Clinical Lead** at the provider organisation is informed about the potential positive outlier status. They will be requested to ensure that their data is correct and they are happy to receive external review to learn from good practice. Aggregate results to support the positive review of data will be made available to the Clinical Lead.	CRANE Database Team Local Service Clinical Lead	5
3	**CRANE Clinical Contact** to provide written response to CRANE Database Team to 1) confirm their confidence in their data, 2) share the reasons for the potential outlier status, and 3) willingness to receive external review to learn from good practice. The response should include information as to why the local team believe they have achieved outstanding performance and initial potential learning points.	Local Service Clinical Lead	25

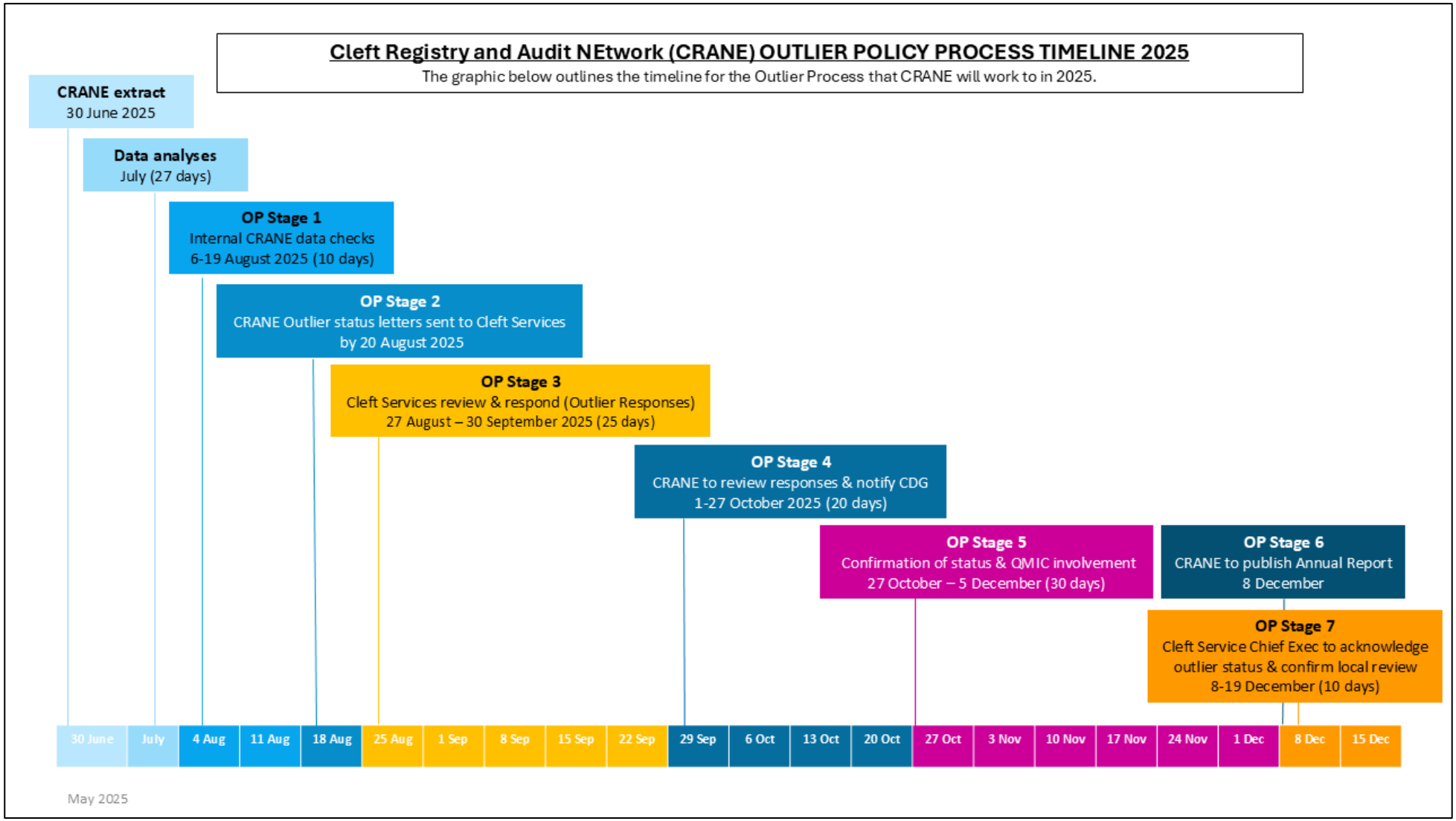
Stage	Action	Who?	Within how many working days?
4	**CRANE Clinical Lead** to write to CDG chair indicating that positive data outlier status identified/confirmed and Clinical Director of the service confirms validity of the data and willingness to receive external review group to learn from the good practice. This letter will also include the information as to why the local team believe they have achieved positive outlier status to help CDG determine how best to direct learning exercise • *Proceed to stage 5*	CRANE Database Team	20 .
5	• **Chair of CDG Quality Monitoring & Improvement Committee** will identify 3 most relevant members with necessary expertise whose names and qualification will be made available to the positively outlying unit senior management (clinical lead) for approval for learning review At the discretion (and on the timeline) of the local service: • **The CDG Quality Monitoring and Improvement Committee** will work with the local service with the aim of identifying key features of local practice that may explain the positive difference in their performance • The findings of the review will be discussed within the Quality Monitoring and Improvement Committee and a report provided to CDG Opportunity for full CDG membership to review report recommendations and discuss within forum of next CDG meeting	Chair of CDG CDG QMIC	30
6	Public disclosure of outstanding performance in CRANE annual report Letter to host organisations Medical Director and Chief Executive highlighting the outstanding performance of the clinical team and the wider learning from such performance that has been achieved.	CRANE Database Team	

10. The role the CRANE Database Team

The primary role of the CRANE Database Team is to support clinical teams in providing high-quality, robust clinical audit data. It is anticipated that "outlier" status will be triggered rarely and that a regular reporting cycle will help to drive up clinical quality. Where such triggers are activated, the CRANE Database Team will seek to provide additional help to providers wanting to review data entry and quality.

Hospital sites or clinicians with concerns about data quality are urged to contact the CRANE Database Team at the Clinical Effectiveness Unit of the Royal College of Surgeons of England at the earliest opportunity (please e-mail crane@rsceng.ac.uk).

Where resources allow, CRANE will share positive experiences of the outlier process and will invite teams to share best practice in a webinar format (Making it Better Sessions).


Cleft Registry and Audit NEtwork (CRANE) OUTLIER POLICY PROCESS TIMELINE 2025
The graphic below outlines the timeline for the Outlier Process that CRANE will work to in 2025.
CRANE extract
30 June 2025
Data analyses
July (27 days)
OP Stage 1
Internal CRANE data checks
6-19 August 2025 (10 days)
OP Stage 2
CRANE Outlier status letters sent to Cleft Services
by 20 August 2025
OP Stage 3
Cleft Services review & respond (Outlier Responses)
27 August – 30 September 2025 (25 days)
OP Stage 4
CRANE to review responses & notify CDG
1-27 October 2025 (20 days)
OP Stage 5
Confirmation of status & QMIC involvement
27 October – 5 December (30 days)
OP Stage 6
CRANE to publish Annual Report
8 December
OP Stage 7
Cleft Service Chief Exec to acknowledge
outlier status & confirm local review
8-19 December (10 days)
30 June
July
4 Aug
11 Aug
18 Aug
25 Aug
1 Sep
8 Sep
15 Sep
22 Sep
29 Sep
6 Oct
13 Oct
20 Oct
27 Oct
3 Nov
10 Nov
17 Nov
24 Nov
1 Dec
8 Dec
15 Dec
May 2025