Cleft Registry and Audit Network (CRANE)

Outlier Policy

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1. Introduction

This document describes the outlier policy for the Cleft Registry and Audit Network (CRANE). It sets out the process by which participating English NHS Trusts / Welsh, Northern Irish Health Boards' performance will be assessed and the process the CRANE Database Team will follow to manage any hospital that is found to fall outside the expected range of performance and therefore flagged as an outlier. The principles on which the policy is based follow established practices and are consistent with the DH/HQIP outlier management policy[1].

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 datasets, where available. To support clinicians in this requirement, NHS England, Wales, Northern Ireland have commissioned The Cleft Registry and Audit Network (CRANE) to register cleft births and audit the outcome of care for persons born with an oro-nasal cleft. This Audit is run by CRANE Database Team based at the Clinical Effectiveness Unit (CEU) of the Royal College of Surgeons of England and is overseen by the Craniofacial Society of Great Britain and Ireland(CFSGB&I) through the Cleft Development Group.

2. Performance Indicators

CRANE uses a variety of process and outcome indicators to evaluate the quality of care received by patients born with oro-nasal clefts. These indicators were drawn from relevant clinical guidelines and are based on recommendations (or standards of care) related to the management of patients born with an oro-nasal cleft and are agreed with the Cleft Development Group who have oversight of CRANE activity.

[1] http://www.hqip.org.uk/resources/detection-and-management-outliers-national-clinical-audits/

Information on the various indicators are publicly available and are included in CRANE Annual Reports and 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. Not all data submitted to CRANE are analysed annually and therefore are not within the scope of this policy.

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

Details of process and outcome indicators are published on the CRANE website along with the corresponding dataset for the prospective audit (www.crane-database.org.uk). Copies of Previous years CRANE Annual Reports are also available on the website.

3. Expected Performance

There are two potential approaches to determine whether an organisation is meeting expected levels of performance for an indicator. The first is to use an established benchmark or standard. Examples of this are the agreed time points and standards associated with first contact within 24hours of diagnosis (antenatal or postnatal) / Lip repair by 6 months etc. The second approach is to compare local performance against national level of performance. The former is acceptable for process monitoring while outcome monitoring (which will vary year on year – with hopefully a trend towards improvement) is better assessed using the latter approach. National outcomes will be assessed against peer data and will be derived from the data provided to CRANE by each submitting unit.

4. Assessing performance and data quality[2]

An important part of the assessment process is to ensure that the data are of sufficient quality for an analysis to meet adequate standards of completeness and accuracy. CRANE is provided with data by each commissioned cleft unit in England and the Health Boards treating cleft patients in Wales, Northern Ireland. Published outcomes are therefore essentially self reported with CRANE only having an analysis and interpretation role. It is therefore essential to the integrity of the audit process that regular analysis of patient consent to analyses levels and data completeness levels are published alongside treatment outcomes. Data from units not achieving acceptable levels of consent verification

[2] 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 will implement an escalation process that mirrors the HQIP approach described in Table 3 in the following guidance published January 2019: https://www.hqip.org.uk/wp-content/uploads2019/02/NCAPOP-cause-forConcern-Final-Eand-W-Feb-2019.pdf

(see section in consent / data completeness) or individual outcome data completeness will either have all data excluded from mean and standard deviation calculations (consent levels out-with agreed standard) or data excluded from individual outcome mean and standard deviation calculations (outcome data-completeness levels out-with agree standard). This ensures that the Audit results reflect patient populations only from services with acceptable levels of consent verification and process/outcome data return levels and in so doing ensures robustness of interpretation/ governance for Trusts/ health boards satisfactorily returning data. In summary, while gaps in submitted data can result in the indicator values for NHS providers not being representative of actual practice, data will still be published for such providers but with a caveat that benchmarking for said units is not possible and comparison with other providers should be undertaken with significant caution.

Individual providers should have in place internal checking and quality control processes before supplying the data to CRANE. On receipt by CRANE, the data are further checked and prepared for statistical analysis. Once data are received by CRANE it is still possible for the submitting provider to change entries on the database but once review deadlines are passed, CRANE will extract data for analyses and subsequent corrections are not possible for that year's report. **The responsibility for the accuracy and completeness of the patient data rests with the NHS organisations that submit records to CRANE.**

5. Risk-adjustment to remove the effect of differences in patient case-mix

The comparison of outcomes across NHS providers must take into account differences in the mix of patients treated and other factors that can potentially influence outcome so that there can be confidence that any variation in provider outcomes (observed and reported) are real and not unduly influenced by variations in rates of know outcome modulators. Those involved in cleft care will understand that few robust data exist in relation to individual patient differences and their potential effect on outcomes. The CRANE Database Team is currently working with information previously collected to develop early risk stratification models for the clinical outcomes currently reported on. If the identified contributors to the risk of adverse outcome stand up in multi-variant analysis, it is CRANE's aim to incorporate appropriate weighting of results in future reports, however this will not happen until risk stratification scoring systems have been accepted for use by the Cleft Development Group. Until that time un-risk stratified data will continue to be presented in published reports.

Risk -adjustment models will be assessed in terms of their power of discrimination (e.g. that the model correctly identifies low-risk and high-risk patients) and calibration (how well the model outputs fit with the observed data). Judgment as to the adequacy of a model will depend on the performance indicator selected and the clinical context.

6. Detection of a potential negative outlier (Consent Verification / Data Completeness 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. There has been increasing variation in consent levels verified by each unit overtime and also increasing variation in the consent verification levels achieved between units in any single year. 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 given current variability in consent verifications achieved this would be impracticable. Therefore in consultation with the CDG CRANE has decided to institute outlier parameters (2 and 3SD of the mean) based on the variability of UK consent verification achieved in the reporting year for the next 3 years (2014 -16 birth years/ 2021 to 2023 reporting years) and to then review the situation. CRANE will actively engage with the cleft clinical community during this time to champion good practice and help explore barriers to verification where they exist.

If consent verification is not obtained / recorded on the CRANE database then Cleft teams will not be able to enter outcome data meaning that the CRANE team will not be able to include these patients in subsequent analyses. CRANE is only able to report on data completeness by comparing number of 'visible data points' to patient registrations for each unit by year of birth. Where data completeness levels are out-with accepted levels, CRANE will not comment on the quality of the services provided by such units. The clinical director of the service and medial 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 year in question. Outcome results for the year in question will be shared with the unit with the caveat that they cannot be benchmarked against the rest of UK practice due either to less that 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.

Data completeness for each outcome will be analysed on the basis of nationally reported data for that year/ period of analysis. Appropriate levels of data completeness will be defined using statistically derived control limits which lie either side of the mean outcomes. 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; this might happen because of random variation every 1 in 20 occasions. The second (outer) limit will indicate whether the value for a provider is more than three standard deviations from the expected level; this might happen because of random variation every 1 in 500 occasions.

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 and protocol outlined in Table 1 below 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 numbers of cases is extremely low - UK cleft service organisation is such that this should not be an issue. If any unit returns appropriate but low numbers of consented / reported data an observed minimum caseload will be determined by appropriate statistical methods to ensure that appropriate 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.
- In addition, the provider service's Clinical Director, Medical Director and Chief Executive may need to be involved.

The following 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	10
2	• **The CRANE Clinical Contact** (unit Clinical Director/Lead Clinician) 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. • A copy of the request will also be sent to the **Clinical Governance Lead of the provider organisation**. • **The chair of CDG** will also be informed of potential outlier status	• CRANE Database Team • Local Unit Clinical Directors/ Lead Clinicians • CDG Chair	5
3	**CRANE Clinical Contact** to provide written response to CRANE Database Team about the reasons for the potential outlier status. The response should include information about the review of their patient data and an initial review of local practice.	Local Service Clinical Director / Lead Clinician	30

Table 1 continues on the next page

Stage	Action	Who?	Within how many working days?
4	Review of Lead Clinician'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 Clinical Governance Lead 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	30
5	• Contact **CRANE** Clinical Contact by telephone, prior to written confirmation of outlier status • Written confirmation copied to Provider clinical governance lead, Medical Director and Chief Executive. The team will also inform the relevant regulator such as the CQC. • Medical Director and Chief Executive will be requested to undertake a local investigation according to HQIP "Detection and management of outliers" document. • **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 to the Medical Director and Chief Executive.	• CRANE Database Team / CRANE Clinical Lead • Chair of CDG • CDG QMIC	30 *Continued on next page…*

Stage	Action	Who?	*Within how many working days?*
5	• **The 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. • Chief executive advised to inform relevant bodies about CRANE's concerns including commissioners, NHS Improvement and relevant Royal Colleges. • CRANE will proceed to publishing information of comparative performance that will identify providers. Outlier unit given option to include written unedited response adjacent to Performance of concern in the annual report	•	*…continued from previous page.*
6	• **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) • **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
7	Public disclosure of comparative information that identifies providers (e.g. CRANE Annual report).	CRANE Database Team	

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 index procedures. 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 data that performance was outside the "outlier" line because of data issues.

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 service to patients. 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 publically available.

9. Detection of and response to positive outliers

Audit and benchmarking is 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 about, 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 (2 or more consecutive years) performs above 2 standard deviations of the national mean then the following process, detailed in Table 2 below, 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 **CRANE Clinical Contact** (unit Clinical Director/Lead Clinician) at the provider organisation is informed about the potential positive outlier status. They will be requested to ensure that they are content that their data is correct and complete and 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 Contact.	CRANE Database Team Local Unit Clinical Directors/ Lead Clinicians	5
3	**CRANE Clinical Contact** to provide written response to CRANE Database Team about confirming their confidence in their data and 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 Director / Lead Clinician	30

Table 2 continues on the next page

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 local team believe they have achieved positive outlier status to help CDG determine who best to direct learning exercise • *Proceed to stage 5*	CRANE Database Team	10 .
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 • **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	10 30
6	Public disclosure of outstanding performance in CRANE annual report	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).