NHS UK Cleft Development Group

Terms of Reference

The Origins of the Cleft Development Group (CDG)

The NHS Cleft Development Group was formed in November 2004 out of the previous Cleft Registry and Audit Network(CRANE)/Cleft Levy Board, the CRANE Management Group and their Advisory bodies. These groups and bodies had been responsible for the national cleft database, CARE and then CRANE. The implementation of the Department of Health's (DoH's) guidance regarding the re-organisation of cleft services in the United Kingdom (UK), which stemmed from the DoH Clinical Standards Advisory Group report into the care of patients with Clefts of the Lip and/or Palate (1998) was the responsibility of the Cleft Implementation Group (CIG). When this group was terminated by the DoH, a new body took over its role, the Cleft Monitoring Group. When that body was terminated, the Cleft Development Group (CDG) was asked to take over its role too.

The Roles of the CDG

The CDG has three distinct roles which arise from its origins.

1. The CDG is responsible for guidance on all aspects of the delivery of re-organised cleft care in England and Wales and, when asked, by Scotland and Northern Ireland. It gives advice to the cleft centres, to bodies, trusts, boards, commissioning groups and consortia and to the Departments of Health in England and the devolved administrations. It represents all stakeholders in cleft care and works with all to ensure the highest quality of cleft care in the UK to all patients who need it. It inherits the responsibilities of the Cleft Implementation Group and the Cleft Monitoring Group which were largely advisory.

2. The CDG is responsible for the commissioning of, the strategic governance of and is ultimately responsible for the national cleft database which used to be called CARE and is now called CRANE. It must negotiate and agree a contract for the running of CRANE and have operational oversight of the implementation of that contract. It is responsible for funding of the CRANE Register and is responsible for ensuring that the agreed levy is collected annually through the NHS Specialist Commissioners. It will approve an annual

budget and business plan for CRANE drawn up with the contract holders and will review income and expenditure and ensure that the terms of reference are implemented. It will determine the location of the register and will appoint the Clinical Director/Project Leader who will be accountable to the Group.

The CDG's responsibility stems from Health Services Circular 1998/238, which states that "A CARE Register, with which all patients should be registered, will be maintained by the Craniofacial Society of Great Britain – this will form the basis for national audit".

The database was UK wide when run by the Craniofacial Society of Great Britain and Ireland and before it became the responsibility of the CRANE Levy Board. Devolution of government in the UK resulted in 4 distinct health services and as a result CDG came to be responsible for a national database for the recording of all children with clefts of the lip and/or palate born and treated in England and Wales, as the health service in Wales indicated its support for this development at an early stage. It has since then successfully sought to include in its work strong relationships also with the cleft services in Scotland, Northern Ireland and the Irish Republic.

The CDG is responsible for providing data for cleft births and cleft treatment for England and Wales and it also endeavours, with the cooperation of the health services in Scotland and Northern Ireland, to do so for the whole of the UK.

The national CRANE database has three primary functions:-

a. the recording of all birth, demographic and epidemiological data related to children born in England and Wales with the congenital abnormality of clefting of the lip and/or palate, and where possible extending this to the whole of the UK and Ireland

b. the recording of all treatment of children and adults in England and Wales with clefts of the lip and/or palate and the outcome of such treatment, and where possible extending this to the whole of the UK and Ireland

c. Providing data on agreed national outcomes for clinical audit purposes

The data from (a) will provide the same kind of information as other congenital anomaly registers and will be the basis for reports, audit and research in that area. The data from (b and c) will provide the basis for national cleft audit, which is intended to be a major and integral role of CRANE.

The relationships between the bodies involved in the national cleft database, CRANE, are defined by a Tripartite Agreement (2007) between the Cleft Development Group, the NHS Specialist Commissioners and the Craniofacial Society of Great Britain and Ireland.

3. The CDG is responsible for the "CDG Quality Monitoring and Improvement Committee(QMIC)" whose purpose is to support the UK Cleft Community to:
   a. Assure Quality
   b. Improve the quality of care
   c. Support Patient Choice

The committee will provide a safe, non-mandated, multidisciplinary, multicentre collaborative learning environment in which the process and outcome data collated by CRANE / NHS Dashboard can be peer reviewed and opportunities for building on good practice to improve outcomes created.

The committee will:

- Review the CRANE Annual Report and NHS England Dashboard reports on agreed outcome measures and key performance indicators.
- Identify outliers who fall outside the 99.8% confidence limits (3 standard deviations) from the agreed National Outcomes (HQIP, 2017). The outliers may be positive or negative.
- Facilitate outlying units / centres to review their data to look for explanations for the difference in their performance.
- Offer cleft services the opportunity to discuss their quality improvement plans or share their lessons in excellence via CDG.

See appendix 1 for the Terms of Reference for the QMIC and appendix 2 for the CRANE outlier policy.

Composition of the Cleft Development Group.

The composition of the Cleft Development Group should reflect all stakeholders involved in cleft care. Consequently, its composition (and consequently these Terms of Reference) will need to be changed from time to time. The Members of the Cleft Development Group will normally and primarily be active clinical members of a designated Cleft Team, public health consultants, commissioners of cleft care and representatives of parent/patient organisations. Membership of the Group will be for a term of three years which can be extended at the behest of the nominating organisation, except for members ex-officio who will be members during their terms of that office whether it be less or more than 3 years. The Group will elect its own Chair, who will remain in office for 3 years. The Group will also elect a Vice Chair. The Group may decide to re-elect the holders of these offices.

The composition will be:

1. Commissioners of Cleft Care. A commissioner from England *(nominated by the National Specialist Commissioning Group for England)*, Wales, Scotland and Northern Ireland *(each nominated by their equivalent national specialist commissioning body)* will be invited to attend CDG meetings. It is intended that there should be no more than six specialist commissioners in total to be agreed and appointed by the bodies which contribute data to the database (in the case of Scotland by sharing its data with CDG). Only those commissioning groups which, pay the levy may vote on issues relating to CRANE.

2. Public Health Consultants. These should include representatives of commissioning areas who are actively involved in cleft commissioning and will normally be Consultants in Dental Public Health. There should be at least two *(to be nominated by the BASCD Consultants in Dental Public Health Group).*

3. *A CLAPA representative.*

4. A Lay representative from a Parent Support Group (1) *(to be nominated by CLAPA)*

5. Cleft surgeons (2) *(presently one nominated by BAOMS and one by BAPRAS)*

6. The President of the Craniofacial Society of Great Britain and Ireland

7. The Chair of the Cleft Surgery Training Interface Group

8. A Speech & language therapist (1) *(to be nominated by the Lead Cleft Speech and Language Therapy Group)*

9. An Orthodontist (1) *(to be nominated by the Cleft Orthodontic CEN).*

10. A Specialist Cleft nurse (1) (*to be nominated by the Cleft Nurses CEN)*

11. A Psychologist (1) *(to be nominated by the Cleft Psychologists CEN)*

12. A Paediatric Dentist (1) *(to be nominated by the Cleft Paediatric CEN)*

13. An ENT surgeon or audiological physician/audiologist (1) (to be *nominated by the ENT/Audiolgical SIG)*

14. A Restorative Dentist (1) (to be nominated by the Restorative Dental CEN)

15. The Co-ordinator/Chair of the UK Cleft Centres Clinical Directors' Group (1)

16. A Cleft Co-ordinator (1) (*to be nominated by the Cleft Coordinators Special Interest Group).*

17. A Representative from the group of 'other' specialities involved in cleft care (1) *(to be nominated by CFS Council).*

18. A Clinical representative from Northern Ireland (1) / Scotland (1) / Wales (1) / England (as appropriate, if not already represented) *(to be nominated by those countries)*

19. There may be representation, as determined by CDG to be appropriate, of any national bodies representative of Audit (1) and Research (1)

20. Clinical Directors/Clinical Leads of UK Cleft Centres not otherwise represented on CDG shall be invited to attend and become voting members so that all centres will be represented.

21. The Clinical Director/Project Leader of the CRANE service will be in attendance at Group meetings to which he/she will report, except when required to be absent because their own position is being discussed/decided. This individual will not be a voting member of the Group unless in another capacity and will not be eligible to become Chair.

22. The Director of the body which holds the contract for CRANE will be in attendance at Group meetings to which he/she will report, except when required to be absent because their own position is being discussed/decided. The Director will not be a voting member of the Board and will not be eligible to become the Chair.

23. A representative of the DH will always be invited to meetings and will receive minutes but will not be a voting member of the Board and will not be eligible to become the Chair.

24. There may be representation as determined by the CDG to be appropriate from Ireland on an ad hoc basis.

25. Such other people who from time to time would serve the interests of the Cleft Development Group may be co-opted for a period of one year at a time.

Deputies for members may be appointed from time to time provided they are done so formally in writing by the nominating body to the CDG Chair. Where an individual comes to represent two positions on CDG, that person will continue to fulfil those roles and no additional person will be elected.

Additional representation will be considered (e.g. cleft paediatricians, cleft anaesthetists, cleft genetics) as and when those disciplines have formally established national special interest groups, which genuinely represent those disciplines.

Meetings

Meetings will normally be held twice a year with administrative support provided by the body which holds the CRANE contract, or the DoH or NHS bodies.

Appendix 1: Quality Monitoring and Improvement Committee**,** Terms of Reference

Role

The Quality Monitoring and Improvement Committee (QMIC) began development in the autumn of 2019 by the National UK Cleft Development Group (CDG) to support the UK Cleft Community to:

1. Assure Quality
2. Improve the quality of care
3. Support Patient Choice

The committee will provide a safe, non-mandated, multidisciplinary, multicentre collaborative learning environment in which the process and outcome data collated by CRANE and the NHS England Dashboard can be peer reviewed and opportunities for building on good practice to improve outcomes created.

The committee aims / responsibilities are:

- To provide peer review to units / centres who fall outside the 99.8% confidence limits (3 standard deviations) from contemporaneous National Outcomes. The outliers may be positive or negative.
- To assist outlying units / centres to review their data and processes to look for explanations for the difference in their performance in line with HQIP guidance (2017).
- To offer services the opportunity to discuss their quality improvement plans or share their lessons in excellence.

Membership

- Chair of CDG who will also be chair of the improvement committee
- A cleft surgeon (nominated by the surgical Clinical Excellence Network)
- A Lead Speech and Language Therapist (nominated by the Lead SLT group)
- An Orthodontist (nominated by the Cleft Orthodontists Clinical Excellence Network).
- A Specialist Cleft nurse (nominated by the Cleft Nurses Clinical Excellence Network).
- A Psychologist (nominated by the Cleft Psychologists Clinical Excellence Network).
- A Paediatric Dentist (nominated by the Cleft Paediatric Dentist Clinical Excellence Network).
- An ENT surgeon / audiologist (nominated by the ENT / Audiology Clinical Excellence NetworkSpecialist Interest Group).
- A Restorative Dentist (nominated by the Restorative Dental Clinical Excellence Network)
- A clinical director (nominated by the Clinical Directors Clinical Excellence Network).
- A representative from CLAPA
- A representative from CFSGBI
- The Clinical Project Lead for CRANE will act as advisor to the QMIC

Members will be asked to stand for 3 years. It can then be renewed.

All members of the committee may need to step back if their unit is involved.

The committee will have the power to co-opt as required.

When investigation of outlier status is indicated at least 3 appropriate people will be identified from the full committee to form the advisory group. Where it thought appropriate wider expertise can be added by co-opting necessary individuals.

Accountability

The committee will be required to provide a report on its activities to each CDG meeting.

Review

The committee will review the relevance and value of its work and the terms of reference every 3 years.

Working methods / ways of working

- CRANE will identify outliers at the point of publishing the CRANE interim tri/quad centre audit reports. Outliers are determined if a unit is beyond the 99.8% (3 standard deviations) confidence intervals for any single measure in any one year or if they are beyond the 95% (2 standard deviation) confidence intervals for any single measure in 2 consecutive years. Where an outlier is determined the CRANE Outlier Policy Timeline commences. This follows the stages outlined in the HQIP Guidance (2017). (for full CRANE outlier timeline see document appended below)

- CRANE will notify the chair of CDG regarding any outliers.

- The chair of CDG will identify the most appropriate people (at least 3) from the quality improvement committee to work with a specific outlier at a specific time

- The committee will work with services (units/ centres) that are outliers to help them to review their data to look for explanations for the difference in their performance and, where appropriate, identify actions to improve performance. This might include supporting centres to:

o Work with CRANE to analyse the data for accuracy of reporting (e.g. data completeness)

o Work with CRANE to analyse the caseload submitted to ensure that this is not different from other centres (e.g. interpretation of exclusions, balance of cleft types)

o Examine how the results were obtained (i.e. internally/externally)

- Analyse institutional factors that might be contributing to the difference in performance (e.g. waiting times)
- Analyse individual service processes, protocols, capacities and workflow. (e.g. surgical protocols, age at repair, management of poor healing/ fistulae)
- Assist in developing an action plan, where appropriate, aimed to improve performance

• Both positive and negative outliers using 99.8% confidence limits will be invited to share their experiences with CDG for quality improvement purposes. This may involve inviting key members from the team to attend the Quality Improvement Committee / CDG meetings.

• Centres with concerns about their outcomes (e.g. those who are outliers at 95% CI in a single year) can also seek support from the Quality Improvement Committee and CDG.

• Support from CDG could include advice about the data review; personal support for the Clinical Director and any individual clinicians involved; visits between units; letters written by CDG to commissioners / Trust Managers; putting top performing units in contact with under-performing units to facilitate learning etc.

• As the work of this committee is non-mandated it will require mutual consent with the participating units.

• The QMIC chair will organise and chair the meetings of the QMIC

• Minutes will be written by a member of the committee

Role of Quality Improvement Committee Members

The members of the Quality Improvement Committee will be there to support peer review of cleft outcomes and processes published in CRANE and by the NHS Dashboard.

Their role will be as impartial “critical friend” helping teams with their own investigations of performance.

This is a non-mandated role and therefore will require mutual consent and a high level of inter / intra-professional respect based around principles of appreciative inquiry.

It is expected that committee members will be afforded time by their primary NHS employers to perform this important quality improvement role and attend committee meetings and contribute to supportive interaction with any service identified as an outlier / requesting support .

References

Health Care Quality Improvement Partnership (HQIP) (2017) “Detection and management of outliers”

Health Care Quality Improvement Partnership (HQIP) (2016) “Best Practice in Clinical Audit

Appendix 2: Cleft Registry and Audit Network (CRANE) Outlier Policy

Date of publication: 01 April 2021

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 Project 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 project 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). 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]

[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

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 (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 affect on outcomes. The CRANE project 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 consent CRANE would advocate it is obtained as early as possible so that data beyond simple registration details can be entered prospectively onto the database.

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 the table 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 Project Team: the team responsible for managing and running the audit nationally including the clinical project lead.
- The Cleft Development Group(CDG): 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 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 Project Team	10
2	The CRANE Clinical Contact (unit Clinical Director/Lead Clinician) at the provider organisation is informed about the potential outlier status and	CRANE Project Team	5

Stage	Action	Who?	Within how many working days?
	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	Local Unit Clinical Directors/ Lead Clinicians CDG Chair	
3	CRANE Clinical Contact to provide written response to CRANE Project 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
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'**	CRANE Project Team	30

Stage	Action	Who?	Within how many working days?
	• 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*		
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 project 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 Project Team / CRANE Clinical Lead Chair of CDG	30

Stage	Action	Who?	Within how many working days?
	• 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	CDG QMIC	
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 Project 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 Project Team	10

Stage	Action	Who?	Within how many working days?
7	Public disclosure of comparative information that identifies providers (e.g. CRANE Annual report).	CRANE Project 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 the table 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 the table 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 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 Project 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	CRANE Project Team Local Unit Clinical Directors/ Lead	5

Stage	Action	Who?	Within how many working days?
	will be made available to the Clinical Contact.	Clinicians	
3	CRANE Clinical Contact to provide written response to CRANE Project 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
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 Project Team	10 .
5 **6**	• 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	 CDG QMIC	10 30

Stage	Action	Who?	Within how many working days?
	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		
7	Public disclosure of outstanding performance in CRANE annual report	CRANE Project Team	

10. The role the CRANE Project Team

The primary role of the CRANE Project 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 Project 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 Project 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).