CLEFT REGISTRY & AUDIT NETWORK

Promoting excellence in cleft care

Cleft Registry and Audit NEtwork Database

Part of the Clinical Effectiveness Unit, of the Royal College of Surgeons of England

2021 Annual Report: Responses to outlier process

Results of the audit in England, Wales and Northern Ireland for children born with a cleft between January 2000 and December 2020

On behalf of the Cleft Development Group

Responses to outlier process

Documents related to this product, for reference, published separately:

Document	Published
CRANE 2021 Annual Report	December 2021
2021 Annual Report: Appendixes	December 2021
2021 Annual Report: Methods	December 2021

Responses to teams / Networks' outlier status below.

1. Newcastle cleft service

We are delighted that the Newcastle Cleft Service has been identified as an outlier for completeness of data collection. This clearly represents hard work by every member of our team and in particular the diligence and thoroughness of our data co-ordinator. It is supported by us having a fully staffed and very stable team.

Data collection was built into our service from the beginning and forms part of our care pathway. We made an active decision to audit only patients born into the new service from April 2002 so had time to fine tune our pathways. At the time we were criticised for this.

Data collection begins with our specialist nurses who identify to parents the benefits of involvement in data gathering to their child and others. Their technique is a gentle introduction and slow build of information up to the point of consent. This was the same technique used in the TOPS study and explains our high recruitment to that study.

It then becomes easy to discuss with parents the need for new data and audit collections at various stages including ongoing collection in the early years by specialist nurses and speech and language therapists.

I believe our clinic system contributes to the agreement of parents to support our audit. Clinicians work in ones or twos and parents and children move around seeing everyone in turn. There is no "scary" overwhelming large group of cleft team members altogether. In COVID times the patients sit in a room and we move round – slower but safer.

The final component of our 5 year data collection is the careful scheduling of 5 year audit clinics, with our audit coordinator identifying all patients for each cohort early every year, and then building specialist audit clinics around them over the 12 month period.

Our 10 year data is collected within our normal clinics.

Audit and data collection has become more difficult after the arrival of COVID-19, now that even our 5 year audit patients are scheduled with our normal reviews, but we hope to maintain our high standards.

Provided by Peter Hodgkinson, Clinical Lead/Director, Newcastle Cleft Service, November2021.

2. Leeds cleft service

Thank you for your recent letter sent on behalf of the Crane Database Team identifying the Leeds Cleft Lip and Palate Service as a positive outlier with regards to:

- Consent verification
- Child growth - data completeness
- Dental health - data completeness
- Speech - data completeness
- Psychological wellbeing - data completeness

We have discussed these positive outlier data items within our Clinical Team and in response, would identify the following reasons as to why we believe we have achieved this level of performance:

1. Our Cleft Team includes a dedicated Cleft Audit Coordinator. This role has been provided by Rachel Dalton since the inception of the Leeds Service as a Specialist Centre in 2002. Rachel is dedicated to her role and is assiduous in terms of ensuring maximal data completeness and Crane consent verification wherever possible. Much of the credit and responsibility for achieving these high levels of data submission onto Crane is due to Rachel's efforts and other members within the Cleft Administrative Team including Andrea Nye, Cleft Clinic Coordinator.

2. As a Cleft Service, we always prioritise the importance of Audit Clinics and plan for these well in advance often over the forthcoming year and try to ensure that patients attend the Audit Clinics well within the patient age time frame, such as before 6 years of age. This often allows a second appointment to be provided if on those rare occasions a patient does not attend the Audit Clinic. All Clinicians also felt it important to explain that when our patients do attend for audit record collection they are also attending for a multidisciplinary clinical review and management. Therefore it is apparent to those patients and families that the Hospital attendance is not only for record collection but also essential clinical review and management.

3. As the Audit Coordinator has responsibility for requesting this data from individual Clinicians and subsequently analysing and recording that data on Crane, individual Lead Clinicians within Clinical Nursing, Paediatric Dental Health, Clinical Psychology and Speech and Language Therapy also play a large part in monitoring the levels of data collection and ensuring that this is collected in a timely and efficient manner with minimal burden placed on the patient and their family.

4. I would also like to think that my role as Clinical Lead of the Team has had some beneficial influence on maintaining the importance of audit data collection and encouraging high levels of data completeness and submission of that data on to the National Crane Database. Our audit processes are regularly discussed at Team Meetings and where appropriate, changes introduced to make that process more efficient, achievable and complete.

On behalf of the Leeds Cleft Team we would like to thank you for your congratulations offered to our Service and hope that this response is of some assistance and of course if required, our Team would be willing to receive external review to assist learning from good practice.

Provided by Alistair Smyth, Lead Clinician, Leeds Cleft Lip and Palate Service, October 2021.

3. Liverpool cleft service

We are notifying you that the Liverpool Cleft Service has been identified as a negative outlier with regards to child growth - data completeness: We have identified weaknesses in both resources and the process of collection of height and weight data for 5 year old patients attending audit clinics that account for the poor performance in this domain. Moving forward the process will be reviewed by the Liverpool cleft team to ensure better compliance with collection of height and weight data and entry of this data onto the CRANE database. The resource limitation has been highlighted to the relevant manager at Alder Hey who has been asked to ensure that the appropriate equipment to record height and weight is readily available and easily accessible for patients attending cleft clinics.

We would also like to take this opportunity to congratulate the Liverpool Cleft Service for being identified as a positive outlier with regards to psychological wellbeing – data completeness: Following the publication of the CRANE 2020 Annual Report, we were concerned about the level of possible missing data/data without a valid reason for missing/incorrect data for our service. We therefore undertook a review of all our records for the 2011-2013 birth cohorts and re-submitted these to CRANE prior to this year's report. We are now confident that our data completeness report correctly reflects our performance in this area. This process was very labour intensive and involved considerable resource commitment from the clinical psychology team. We confirm our willingness to receive external review to learn from good practice (as per Table 2, step 3 of the Outlier Policy).

Provided by Victoria Beale, Clinical Director, North West, Isle of Mann & North Wales Cleft Network, November 2021.

4. Manchester cleft service

We are notifying you that the Manchester Cleft Service has been identified as a negative outlier with regards to dental health - dmft >5 indicating experience of extensive dental decay in a relatively high percentage of children: We regularly review the dental health data within the unit at Manchester and with the Paediatric Dental CEN. We always compare our data with the regional dmft data from the NHS Dental Epidemiology Programme review of 5 yr olds. Their data from 2017 shows that Greater Manchester has the highest dmft in the country. The North West has a dmft of 1.3 and Manchester has a dmft of 1.9, Oldham 1.4 and Rochdale 1.9. In those with dmft>0 this increases to 4.3, 4.1 and 4.0. As you have highlighted we are a positive outlier for completeness of data collection for dental health and we had a consultant in Paediatric dentistry start in 2016 so would expect a greater rate of detection of decay. Analysing the data in more depth the treatment index for the cleft patients in Manchester is 48% i.e. almost half of the caries is treated by either extraction or restorations. This is in comparison with treatment index of 21% Manchester, 14% Oldham and 11% Rochdale so this suggests we are detecting caries early and managing it proactively. We have been auditing our 3 yr olds dmft and picking up high caries risk patients and providing dental treatment, preventive advice and reviewing them within the cleft unit more frequently (every 3-6 months). The results of this should start to increase the treatment index but community wide dental public health measures such as water fluoridation and the North West programme Smile4Life will be needed to reduce the regional decay rate. The COVID 19 pandemic will have an effect on the results for the next few years as children have been unable to access their local dentists for preventive care and early detection of caries. This will be an issue country wide.

We would also like to take this opportunity to congratulate the Manchester Cleft Service for being identified as a positive outlier with regards to consent verification: We have reliable systems in place

for consent verification. This is managed by the cleft coordinator who immediately updates CRANE when consent is given and highlights any patients attending clinic who need consent updating.

We would also like to take this opportunity to congratulate the Manchester Cleft Service for being identified as a positive outlier with regards child growth – data completeness: We have reliable systems in place to collect and enter child growth data onto CRANE. The dental nurses collect and record height and weight data for 5 year old cleft patients attending audit clinics. There is a system in place to make sure this is not missed and appropriate equipment is available and accessible during cleft clinics. The cleft coordinator enters this data onto CRANE immediately after the audit clinics.

We would also like to take this opportunity to congratulate the Manchester Cleft Service for being identified as a positive outlier with regards to dental health - data completeness: The Manchester cleft unit has a consultant paediatric dentist 2 sessions per week and a dental therapist 4 sessions a week. There is always a member of the paediatric dental team present in the 5 year audit clinics and where possible this is a consultant paediatric dentist to comply with the CRANE requirements for audit data collection. There is an efficient system in place to ensure that dental health data is entered onto CRANE.

Provided by Victoria Beale, Clinical Director, North West, Isle of Mann & North Wales Cleft Network, November 2021.

5. Trent cleft service

The Trent Regional Cleft Network received an outlier status letter from CRANE indicating that the service has an outlying performance metrics on submitted audit data in comparison to the National performance across all NHS contracted cleft services in England, Wales and Northern Ireland. The performance metrics highlighted were negative outlier with regards to:

- Dental health - data completeness
- Psychological Well-being - data completeness

Trent regional Cleft Network confirms that we have reviewed the data submitted to the CRANE database for Dental Health and Psychological Well-being, and are satisfied that it is accurate and correct for the reference period.

The current state and action plans proposed by the Trent Regional Cleft Network and Nottingham University Hospitals NHS Trust to improve performance for these metrics and move the service out of negative outlier performances are below:

Dental Health

i. <u>Current State</u>
Trent Regional Cleft Network is not been staffed to provide a full paediatric dental service as described the service specification and service standards in the D07/S/a NHS Standard Contract For Cleft Lip and/or Palate Services including Non-Cleft Velopharyngeal Dysfunction (VPD) (All Ages). The service currently has a 0.12 WTE Paediatric Dentist employed as Regional Paediatric Dental Lead. This is used to provide strategic planning to address the shortfall in paediatric dental services across the Trent Regional Cleft Network and a limited clinical service. The limited clinical service is provided at our spike clinics at Sheffield and Nottingham which represents approximately 47% of our entire patient population. There is no specialist paediatric dental clinical service routinely provided at clinics in Leicester, Derby, Lincoln and Doncaster. The limited clinical service provides the data on dental health that is currently submitted to CRANE, the lack of clinical provision is reflected in the data completeness.

The Midlands Specialised Commissioning Team lead for Children has been involved in discussions around the shortfall in Paediatric Dental provisions in the Trent regional Cleft Network which partly reflects a wider issue in discussion with the commissioners and Nottingham University Hospitals NHS Trust around the examining the funding footprint for the entire regional service which by the latest national estimate data from 2017 is one of the lowest per cleft lip and /or palate birth in the UK.

The healthcare commissioning environment in the East Midlands contributes to the shortfall in Paediatric Dentistry as across the healthcare systems in Nottinghamshire, Lincolnshire, Derbyshire and Leicestershire there is no Paediatric Dental specialist consultant clinics in any of the hospitals for any service. This implies the situation the service is in partly reflects systemic issues with the provision of paediatric dentistry specialist services across the East Midlands. There has recently been a small increase in the number of specialists and consultants in paediatric dentistry within the East Midlands from only one specialist in 2019, to two specialists and one consultant. However, these specialists/consultants work within primary care and do not receive funding to attend secondary or tertiary care services. The provision of paediatric dental specialist services in South Yorkshire is via the Charles Clifford Dental Hospital and this is reflected in the provision of Paediatric Dentistry for patients in the Trent Regional Cleft Network for our South Yorkshire patients.

ii. Action Plan

a. Nottingham University Hospitals NHS Trust as Nottingham Children's Hospital is liaising with the Charles Clifford Dental Hospital, a part of Sheffield Teaching Hospitals NHS Foundation Trust, to scope the shortfall in provision of specialist paediatric dentistry for patients treated under Nottingham Children's Hospital, and to produce a business case for the creation of a specialist paediatric dental service at Nottingham Children's Hospital. This would include the requirements to meet the specification and standards across the cleft patients Nottingham Children's Hospital is responsible for from D07/S/a NHS Standard Contract for Cleft Lip and/or Palate Services. This work is at the scoping meeting stage, the timelines have not been set. A conservative estimate would be 2 years to delivery.
b. The Trent regional cleft Service is working to establish Service Level Agreements for attendance at the multidisciplinary cleft clinics with the Community Dental Services in each clinic area. This will provide access to more specialist dental care in the community for cleft patients and provision of appropriate oral health advice. The aim is for this to be an add-on to the specialist paediatric dental provision so there is a good communication and linkage of the clinical care children receive around their dental health with referral for specialist input when needed. This work should be complete by the end of 2022.

Psychological Well-Being

i. Current State

Trent Regional Cleft Network has not been staffed to provide a full cleft psychology service as described in the service specification and service standards D07/S/a NHS Standard Contract for Cleft Lip and/or Palate Services including Non-Cleft Velopharyngeal Dysfunction (VPD) (All Ages). The service currently has a 0.2 WTE Band 8c Clinical Psychologist employed as Regional Clinical Psychology Lead. This is used to provide strategic planning to address the shortfall in cleft psychology services across the Trent Regional Cleft Network and a limited clinical service. The limited clinical service is provided at the point that the Lead Team perceives the greatest clinical need which is across the adolescent and young adult group where there is a clinical burden related to their cleft at this life stage which has the potential for significant mental well-being issues. Therefore there is no Cleft Psychology service routinely provided at multidisciplinary clinics or in age groups below adolescent, and no capacity for the preventive contacts suggested in the service

specification. The limited clinical service is purely at the point of clinical need in a minority of the cleft population of our region, and therefore collects no audit data, and therefore no data is currently submitted to CRANE.

The Midlands Specialised Commissioning Team lead for Children has been involved in discussions around the shortfall in Clinical Psychology provisions in the Trent regional Cleft Network which partly reflects a wider issue in discussion with the commissioners and Nottingham University Hospitals NHS Trust around the examining the funding footprint for the entire regional service which by the latest national estimate data from 2017 is one of the lowest per cleft lip and /or palate birth in the UK.

A 2 year scoping project by a Band 8c clinical psychologist was undertaken in 2014-2016, this examined in depth the regional clinical psychology resources available to support patients and mapped out the resources required to provide a full service based on an examination of several of the UK regional cleft services with advice of the then, Cleft Clinical Psychology Special Interest Group and the national Cleft Clinical Psychology Lead Group. This work suggested the service required 0.4 WTE Band 8c and 1.6 Band 8a to meet the requirements of D07/S/a NHS Standard Contract For Cleft Lip and/or Palate Services including Non-Cleft Velopharyngeal Dysfunction (VPD) (All Ages). This was submitted to the Midlands NHS England Commissioning Group for Children. At a subsequent meeting, the commissioners declined to fund individual aspects of a service, but agreed to look at the whole service commissioning footprint as it appeared it potentially was not able to meet the full service specification in its current form. This work was paused during COVID-19, but has now been relaunched.

The position of the Trent regional Cleft Network for Clinical Psychology provisions reflects a wider systems issue that Clinical Psychology is underprovided across Nottingham Children's Hospital in a variety of areas, this is a recognised as one of the major clinical risks held on the Trust's risk register, and is subject of a business case written to address the whole Nottingham Children's Hospital Clinical Psychology needs including those of the Trent Regional Cleft Network.

ii. <u>Action Plan</u>

a. Nottingham University Hospitals NHS Trust has recently approved a phased 3 year business case for Nottingham Children's Hospital to expand its Paediatric Psychology services. The first year of funding has been released and the Trent regional Cleft Service is preparing to advertise for 1 WTE Band 8a Cleft Clinical Psychologist.
b. On appointment of the 1 WTE Cleft Clinical Psychologist the service will review its ability to both meet the direct clinical need and undertake preventive and audit work with this provision. It is envisaged that some data will be submitted following this to the CRANE database. This is likely to start in 2022, but will not be complete. It is difficult to be clear on whether this will bring the service out of outlier status.
c. As the full 3 year staged funding plan is delivered it is envisaged that the Trent Regional Cleft Service will get a further 0.4 WTE Band 7, at which point the service will be able to deliver the full requirements as per Clinical Psychology on D07/S/a NHS Standard Contract For Cleft Lip and/or Palate Services including Non-Cleft Velopharyngeal Dysfunction (VPD) (All Ages).

Provided by Jason Neil-Dwyer, Clinical Director, Trent Regional Cleft Network, November 2021

6. West Midlands cleft service

Further to the letter sent on 9th September regarding the outlier status of the West Midlands Regional Cleft Service, I am writing a written response as requested to outline potential reasons for the negative and positive outlier items identified. I have asked the lead clinicians in each area to provide information regarding this as a local review has not been carried out due to there being no current clinical director/clinical service lead to follow this up.
The following is the information I have gathered:

- **Negative outlier on child growth** - data completeness

  As far as I am aware there was not a robust system in place in 2018 – 2019 to collect the growth data and enter it onto CRANE due to a number of workforce issues and no data coordinator role within the team. The team will no doubt review the inclusion of measurements of height and weight at 5 year audit as a standard practice and will also need to ensure, with the support of the Trust, that there is a recognised role within the admin team for the coordination of collection and entering of data onto CRANE.

- **Negative outlier for psychological wellbeing** - face-to-face psychosocial screening before age 6.

  The Specialist Cleft Clinical Psychology Service (part of the Health in Mind Team at BCH) for the West Midlands Cleft service saw 90.9% of children for psycho-social screening, face to face, before their 6th birthday, which is slightly lower than the national average of 91.4%. There have been a number of factors contributing to this slight difference:

  - There have been significant staffing related issues across the Health in Mind team (maternity, sickness, vacancy, recruitment difficulties) which has reduced the dedicated support to the Cleft Service to 0.5 wte Clinical Psychologist, with only ad hoc support from Assistant Psychologists.
  - Paediatric Psychology staffing levels are currently logged on the Hospital Trust risk register.
  - Cover arrangements for planned annual leave are made when possible but cover for unplanned leave is often not possible
  - In addition to the screening contacts, the psychologist (and assistants) would also be seeing those who have requested psychological support or responding to clinical need identified by the team; clinical need will always be prioritised, sometimes resulting in less flexibility during the time when families are present in clinic
  - The West Midlands Cleft Service is also an outlier for children scoring higher levels of symptoms on the SDQ, which may suggest higher levels of need, often requiring more time, liaison, etc
  - Since the West Midlands Cleft Service Clinics are not organised around age cohorts therefore having to target those appropriate for screening in every clinic can result in competing demands upon psychology time.

- **Negative outlier for psychological wellbeing** - high/very high Strengths and Difficulties Questionnaire (SDQ) total scores indicating difficulties.

  The West Midlands Cleft Service is also an outlier for children scoring high or very high on the SDQ, we will explore this data further. Initial exploration of data suggest that high SDQ scores found here are consistent with previous SDQ scores from patients in this locality. We recognise and acknowledge that within the West Midlands we have very diverse populations, with a wide range of socio-economic challenges, not limited to high levels of poverty and deprivation. All of which can

impact on a family's access to services and support, as well as the appropriateness of those available supports to help and the resources to sustain change.

- **Positive outlier for dental health** - data completeness.

  The Consultant Dentist in the West Midlands Cleft Service is extremely experienced and has, over the past 20 years, developed the service with dental nurses who support with data collection in clinic. The dmft data is inputted directly into the cleft data base, chair side, by dental nurses. There are no paper data collection sheets. The data base has been developed collaboratively with BCH IT, nurses and clinicians to make it an easy process for data entry. The Consultant Dentist and the dental therapist are both calibrated in caries identification and enamel defects every two years to ensure the data collected is accurate and comparable nationally. Sophie Mutter, our cleft coordinator, was given specific time out of her role to transfer the data from our Cleft database onto CRANE. This is very time consuming and not sustainable without having an identified data coordinator role for the cleft admin team. The MDT approach to seeing patients helps with reducing burden of care of parents by attending multiple appointments in one day and reducing the number of WNB appointments.

I hope this information helps explain the positive and negative outlier status for these factors. The West Midlands Cleft Service continues to be committed to national audit and data collection at 5 years and will endeavour to work with CRANE to ensure data completeness is achieved going forward as this is the only way we can reliably measure clinical outcomes and improve our services.

Provided my Imogen Underwood, Lead Speech and Language Therapist, West Midland Cleft Palate Team, October 2021

7. Cleft Net East cleft service

No Outliers

8. North Thames cleft service

On Friday the 24-9-2021, I as the clinical director for the North Thames Cleft Network, was informed by Mr Craig Russell, Clinical Project Lead, The Crane Database, The Clinical Effectiveness Unit, RCS England, that the North Thames cleft team, was designated as outliner status for 3 of our clinical outcome measures registered with crane.

As a team we recognise the importance of reporting on clinical outcomes as a means of driving improvements for the patients that we look after. As such we acknowledge the importance of this process and the ultimate aims of its directive.

On receipt of this notification, I then e-mailed the relevant specialties' identified as "outlier" (paediatric Dentistry, Psychology and speech and language therapy) along with the cleft data co-ordinator, the chief of service for surgery (including cleft) and the general manager for surgery (including cleft). This was to highlight the areas of concern so that the leads for these areas would be able to feed back on the data for the years being reported. I followed up on this on return from my annual leave (4-10-21) to request feedback from the specialties concerned and arranged a meeting to discuss in detail the data for the years date of birth 2011, 2012 and 2013.

Difficulties establishing the position at the time of the notification included:

The cleft data coordinator is relatively new to the role and unfortunately a short time after her appointment her direct supervisor left for a period maternity leave. A successor to this supervisory role has not yet been appointed. In addition, the cleft service has been without a substantive service manager for the last 3 months. Unfortunately, this person helps monitor and coordinate data collection exercises and their absence has made this process more complicated.

The cleft data coordinator has contacted the clinical contact for our trust, at CRANE (RCS) in order to identify those patients on the database which are deemed to be outliers and contributing to the "incomplete data". The CRANE clinical contact was able to help us identify the missing data for SLT but unfortunately was unable, due to time constraints, to furnish us with a list for the psychology and paediatric dental outliers.

We have since, we think, successfully identified those patients with apparent missing data for the psychology and evaluated these and the speech outcomes.

We will now report on each one in turn following a line by line evaluation of each of the patients.

Psychology Outcomes

This written summary is taken from and supported by associated data spreadsheets which can be supplied if required.

From 2011-2013 – North Thames team outcomes with rectified data and TIM scores: Of the total number of patients with a TIM of 0 from combined sites = 32, and total patients with TIM 1+ = 262. Total number of patients together =294.
262 patients with TIM 1+ divided by the total number of patients 294 = 89% of patients now have a TIM score 1+ (0-6 tier code). This means that 10.8% patients had a TIM of 0. Therefore, r analysis of the data shows the overall calculation from the crane report has increased TIM scores of 1+ from 85.6% to 89%, this is an increase of 3.4%.

Explanation of increase % - How the data has changed since the report:
From GOSH:

- For 15 patients, Assistant psychologist (AP) entered wrong code if only AP present at review appointment as they thought only qualified psychologists could assign a TIM score, or were followed up by CP – **used the psychologist under resourced code (TIM 4 or 0d tier code) in error**
- For 2 patients, incorrectly inputted and were seen during follow up - **used the psychologist under resourced code (TIM 4 or 0d tier code) in error- human error**
- For 11 patients, **under-resourced due to psychologist maternity leave for 2012 patients**
- For 8 patients with SDQ scores but missing TIM scores, **due to crane unable to hold the data/or inputted incorrectly.**
- For 18 patients had no **explanatory outcome codes** entered (previous versions of crane did not allow clinicians to include data for the 1st screen and not the audit (with a missing data code) and vice versa as including any missing data code, **meant no data could be entered**.
- For 19 patients had 1st screen dates added as these **had not been uploaded** due to entering **outcome code for audit** meant that date of 1st screen data was lost.

From Broomfield Hospital:

- 2 previously missing scores were entered in wrong clinical database – now entered as TIM 0c - psych off sick– **human error**
- 5 patients with a 1a+ TIM score not entered on database (**human error** – not rated after audit and assistant did not ask the psychologist, just left blank in database)

- 24 patients had no explanatory outcome codes entered (**previous versions of crane** did not allow clinicians to include data for the 1st screen and not the audit (with a missing data code) and vice versa as including any missing data code, **meant no data could be entered**.
- 6 patients had 1st screen dates added, as these had not been uploaded due to entering an **outcome code for** audit meant that date of 1st screen data was lost.

In Conclusion:

1. Significant lack of resources in 2012 at GOSH due to Maternity leave which increased code 4 (0d)
2. 24 patient's data inputted incorrectly (human error) in crane upload
3. Previous technical and functional issue with crane during uploading data, whereby if the 'outcome_notcoll_reason_p5' column is completed, crane will automatically delete any other data in the rest of the columns for that patient; vice versa if the 1st clinic date column was completed it would delete the outcome reason column.
4. The corrections have not yet been added to the CRANE database.

Speech and Language Therapy - Speech - data completeness

For the speech data completeness, we have again identified those patients deemed missing data ("data completeness"). It appears that from just a first glance at the data, that the patients being reported as missing do not correspond with our list. Again, we have carried out a detailed analysis of data from the years 2011-2013 inclusive and the findings are as follows.

The list provided to SLT by GOSH data coordinator (supported by CRANE clinical contact) was a total of 189 patients across both the GOSH and Broomfield sites.

- 77 (GOSH) had no palate involvement (or had bifid uvula or unrepaired SMCP)
- 59 (Broomfield) had no palate involvement (or had bifid uvula or unrepaired SMCP)
- 51 (GOSH) had palate involvement
- 1 (Broomfield) had palate involvement

Broomfield:

- The 1 patient with palate involvement already had 'outcome not collected' added to CRANE – data was not missing.

GOSH:

Of the 51 with palate involvement:

- 2 haven't had their consent confirmed for CRANE so not able to enter data (CRANE IDs 35632, 43156)
- 1 was registered as UCLP but was in fact lip, alveolus and bifid uvula (Automatic LAHSAL code checker didn't tick the SMCP box, so I have amended. CRANE ID 34526)
- 1 patient (34440) had 2 parameters missing on CRANE and these have been added
- 1 patient which needed amendment (35588)
- 1 patient who isn't on EPIC, therefore not registered as GOSH patient (34977)
- 14 with no information (truly missing), now all on CRANE
- **32 all data was already submitted so shouldn't have been on the missing data list**

In summary

There are 16 that are now added on CRANE. 2 are not CRANE consented. All those with palate involvement on the list have been checked and where necessary, data entered on CRANE.

Here are the exclusions broken down by year (for both sites):

2013 babies
Not invited 1
Technical issues/lost videos 17
Clinically contraindicated/syndromic 7
Uncooperative 2
DNA/cancellation 0
Moved in/out 12
Too young 1

2012 babies
GOSH & Broomfield exclusions:
Eligible: 33
Lost samples but attended audit: 16
Did not see SLT on day due to overrunning clinic: 1
Too old at time of audit: 1
Moved away and discharged: 10

Not eligible: 11
Complex/language issues/unrepaired: 8 (5 DNA/did not respond audit)
DNA/Cancelled clinic: 4
Non-Cooperative: 1

2011 births:
Technical issues/lost videos 4
Clinically contraindicated/syndromic 2
DNA/cancellation 19
Too young/old 1

The main issue with missing data seems to be technicalities around the recording and recovery of speech samples, rather than patients not being recorded at their 5-year audit appointment. This was at a time when we were moving from video tapes to digital recording. We feel we have now eliminated this problem. In 2011 and 2012 we had a large number of DNA/cancellations, but this improved for the 2013 cohort.

Paediatric Dentistry

The recording of calibrated DMFT data for the North Thames Cleft team is unfortunately a long-standing problem and dates back to the unfortunate loss of 2 of our cleft calibrated paediatric dentists relatively close to one another. We have always had one calibrated clinician in the team but, as a result of these untimely circumstances, it meant that our paediatric dental consultant provision was effectively reduced by two thirds. This left the remaining consultant covering the needs of all the paediatric dental service for the hospital. The prioritisation of the service meant that attendance at the clinics was compromised for extended periods of time.

This was followed by the appointment first of locum consultants and then by substantive consultants without the required calibration. Further one of the newly appointed consultants went onto have 2 periods of maternity leave, meaning effectively they could not complete the calibration over this period.

This consultant then went on to resign her post after a 3-year appointment, without having ever completing a calibrated index score.

Further a new consultant was subsequently appointed to the team with the specific remit for looking after our cleft population of patients. Her appointment was made 2 months after the annual calibration training day, effectively meaning that despite attendance at the audit clinics any data collected could not be submitted to the CRANE database. This newly appointed consultant then moved to an academic position at another hospital leaving the trust three weeks before the training date for the calibration. We have since advertised twice to replace this consultant with a 10 PA cleft specific paediatric dental consultant (the first time no suitable applicants applied). The post has just again been readvertised. (The chronology of these events is listed below, Appendix 1).

From a governance perspective, it is important to highlight for the sake of the commissioners that a dentally qualified clinician in the form of a paediatric dentist (staff grade/registrar) or an orthodontist has carried out a detailed dental examination at the time of the audit appointment. All cases where dental disease has been detected have been referred to the patient's own dentist or internally for dental treatment. We are happy therefore that the dental needs of our cleft patients are being managed but we were not in a position to make a calibrated score at their audit appointment.

The North Thames cleft network recognised this failing immediately and have attempted to address the lack of calibrated clinicians. The trust has always strongly supported the cleft team and been active in the appointment of paediatric dental clinicians to the team. The issue has been on the trust risk register for 3 years.

Moving forward, within the last 6 months conditions within the department have changed so that our one calibrated clinician can now attend the audit clinics (previously she had a teaching commitment at another hospital). This has meant that for the last 6 months we have been recording calibrated DMFT outcomes, but of course this will not be reflected in our outcomes for some time to come. There is currently a cleft dedicated Paediatric dental consultant post (10 PA's) out to advert and we are hoping to appoint to this post soon.

One further general point on the recording of these outcomes is that it is important for data reassurance purposes, for CRANE to ensure that all units have a paediatric calibrated dentist recording these scores (this is definitely not the case for one unit) and that there is some sense check on the reproducibility of outcomes being recorded by clinicians in the various units.

General recommendations to help improve the process of data collection for the North Thames Cleft team

1. It has been identified that the syndromic status of our patients is being under reported in the CRANE database. This is a recognised exclusion criteria in the CRANE database and may have contributed to what appears to be the missing data. In recognition of this we intend to examine retrospectively this section of the database so that it can be updated. In trying to identify how this may have happened It was recognised that often data entered on the crane database during infancy will need updating over time. Often a syndromic diagnosis may not be made for several months and possibly years after birth.

The team will prospectively arrange crane/dashboard data reviews every 2nd month with the lead clinicians involved for each specialty along with the data coordinator so that we can review the data for:

- New births

- CRANE consent status
- Syndrome status
- Data for the quarterly updates for NHS England submissions (CLP00 – CLP04)
- Data collection updates for our 5- and 10-year audit patients with regard to submissions to NHS England annual outcomes report (CLP05-CLP13)

This will make the data collection and submission process contemporaneous and allow updates on a regular basis throughout the year. It will help identify missing data that can hopefully still be captured.

It is felt that this measure would be relevant to improving the data completeness for reporting the NHS England outcomes on the cleft dashboard and ensuring the CRANE database is up to date.

The appointment of additional calibrated paediatric Dentists to the cleft team is essential. Despite the best efforts of the North Thames Cleft Team along with support from the trust, the appointment of a Paediatric Dental Specialty lead has proven problematic, as already noted previously. Despite the appointment of substantive and locum consultants along with junior staff, only one person (6 PA's) in the team is currently calibrated to record this data. To be calibrated, a dentist must be on the Specialist list for paediatric dentistry. The calibration courses have traditional taken place on an annual basis. If this date is missed following the appointment of a new member of staff this can significantly contribute to delay in the required calibration training. One suggestion might be to include cleft calibration training into the syllabus of all trainee paediatric dentists. This would mean that on appointment to the post, the paediatric dental specialist would already be in a position to record the calibrated data rather than having to wait for the next round of training.

It was felt that following our meeting to discuss the investigation of the missing data that a report from crane identifying those individuals on crane database deemed as missing would make the investigation of those particular individuals much more efficient. Certainly, for our team, with one relatively inexperienced data coordinator, this caused a significant delay in trying to establish those patients requiring investigation. It is recognised that crane resources are limited and if this is not possible then perhaps consideration could be given to producing a webinar explaining how this process takes place. We feel that this would certainly help new members of the team to train during the process on induction.

In Summary

The North Thames Cleft Team fully embraces the importance of recording good quality outcomes for all our patients, for whom it is possible.

Having highlighted these apparent deficiencies it has given us the opportunity to review our data and answer as fully and completely as possible what we consider is a true reflection of what we feel was recorded and what was genuinely missed. We recognise that there has been some human error in the recording of our outcomes on CRANE and also that the CRANE database has apparently historically had some limitations which I gather are now rectified.

We have had some time to reflect as a team on how we might improve our processes moving forwards and have listed these in the recommendations above. We would of course appreciate any further advice from the CDG Quality Monitoring & Improvement Committee if this is deemed necessary.

Provided by Norman Hay, Clinical Director, North Thames Cleft Lip and Palate Team, October 2021

9. The Spires cleft service

Thank you for your letter dated September 9th, received by email on 24th September. This contained notification of outlier status for the Spires Cleft Service as follows:

- as a negative outlier with regards to psychological wellbeing (face-to-face psychosocial screening before age 6)
- as a positive outlier with regards to dental health (data completeness) and dental health (dmft >5 indicating experience of extensive dental decay)

In response to this notification we have undertaken a review of our patient data and an initial review of local practice in relation to data collection and submission to CRANE. Clinicians from the relevant specialties have been involved in this review along with Steven Berry our Network Service manager. Our findings are:

Psychological wellbeing

The data for 2011-2013 births relates to approximately 200 eligible cases, with Spires achieving 90% face-to-face psychosocial screening before age 6. The national average for this period is 96%, with some centres achieving 100%. We note that the funnel plot for this measure is very narrow so that a small difference in case numbers could result in outlier status whilst still achieving a relatively high percentage of screening, as in this case. Prior to your letter, we were made aware of issues with documentation of psychological screening for some patients born in the years 2012-14. This was highlighted through the Psychology CEN in response to the preliminary CRANE report 30 April 2021. Some data has already been amended and this work will now be completed to include 2011 year data in the light of your notification. We are aware that in the years 2011 and 2012 we were below average in submission of 5 year old psychology scores; 89.4% of cases were accounted for, with 61.8% having scores but also 10.6% missing data. There are workforce constraints which have contributed to this; the service has a total of 1.6wte clinical psychologists comprising three part time clinicians. On the Salisbury site there is one part time clinical psychologist and both sites have seen reduced levels of service over the last 5 years due to maternity leave, sickness and vacancies.

As you state in your letter, the status of this indicator is still under review with the Psychology CEN. We have been involved in these CEN discussions about the current options for measuring performance in the area of psychology. With centres achieving percentages of 85%+ for psychological screening before age 6, this could represent a low quality of care provided to many patients being presented more favorably than a high quality care provided to the majority of patients.

It is also somewhat confusing that CLP10 on the Specialised Services Quality Dashboard is almost always one of our positive alerts; this is reflected in the most recent dashboard with us screening 87% of patients within the specified age range (birth year 2014) with a national average of 73.3%. For 20/21 we achieved 87.5% and the national average was 77.2%, in 19/20 we achieved 95.6% and the national average was 89.5% and in 18/19 we achieved were 88.4% and the national average was 70.6%. I would welcome your comments on this.

Dental health (data completeness)

The data for 2011-13 births relates to approximately 270 cases, with Spires achieving 69% cases with documented dental data, with a national average of 58%. In spite of not having a designated paediatric dentist on either the Salisbury or Oxford site our dental health data completeness is consistently good. We have a process for capturing data at the 5 year clinical & audit review appointment with administrative support for data input. During the period 2004-12 we accounted for 78.3% of cases, with

65.4% having dmft recorded but also 21.7% missing data. We are therefore not complacent about the need to check and account for missing data and the potential for this to influence outcome data.

Dental health (dmft >5)

The data for 2011-13 births relates to approximately 180 cases, although I am not sure why this number differs from the 270 eligible cases with dmft data at age 5 years in the same period? The rate of dmft >5 for Spires is around 7% compared to the national average of 15%. It is not entirely clear why this should be the case but we have discussed it within the MDT and reflected on the cohort characteristics and the demographics of our region as well as our service model. There are areas of socioeconomic deprivation within the Spires region but also areas of relatively high socioeconomic status which could partially explain the lower rate. We are very aware of a small number of children who present with high dmft scores and require multiple extractions due to a combination of social and medical factors. In particular, children with isolated cleft palate often have associated conditions that can place them at higher risk of dental disease. Finally, we have been highlighted in recent years as a service that does not have a specialist paediatric dentist within the workforce. This could therefore call into question the validity of the positive dmft data.
However we do have paediatric clinicians who are calibrated to measure and document this outcome on both sites. I have asked for confirmation that the calibration training is up to date for all clinicians. We also have a focus on dental health information and support that begins with our clinical nurse specialists at birth and continues through all early years and children's clinics and contacts with the multidisciplinary team, including liaison with GDP and Special Care dentistry colleagues. On the whole we have excellent primary care salaried dental device support across the region. This model has been effective for our centre but we continue to consider the potential benefits of recruiting a paediatric dentist, although the fact that we are not co-located with a dental school at either site is likely to be a barrier. We are completely open to discussions with other centres about our results and our service model.

I hope that this response adequately explains our outlier status in respect of the psychology and dental data. We are pleased to be part of this process with CRANE and welcome further feedback on our interpretation of the data and explanations given.

Provided by Ginette Phippen, Clinical Director, The Spires Cleft Service, November 2021

10. South Wales cleft service

Thank you for your letter dated the 8th September 2021 identifying the South Wales Cleft Service for being a positive outlier with regards to data completeness for child growth, dental health and psychological wellbeing.

I have discussed this with the clinical leads for psychology and paediatric dentistry and we have highlighted reasons below for why we have been successful in completing the data for these categories.

- Good administration support; the admin team go to such great efforts to ensure all the 5 year olds are seen in clinic before they are 6 years of age. Our admin staff chase patients, so they attend.
- We also have a clear Was Not Brought policy which helps patients to attend for MDT appointments.
- We have designated 5-year audit clinics. Having designated clinics allows staff to remember everything we need to collect and record.

- A Clinical Psychologist (CP) and an Assistant Psychologist (AP) attend our clinics. They can ask people to complete their SDQ if they have forgotten it, early in the clinic by the CP and then follow up or collect it in at the end of the clinic by the AP.
- We have the same dental nurse who takes height and weight measurements and also records the dmft scores and the reasons if not collected. This is documented on the clinic sheet and inputted by the cleft secretary when she is typing the clinic letters.
- In terms of inputting, it is helpful only to have one or two staff inputting the data so it is consistent. We have identified our team secretary to do this who is now very familiar with the CRANE website. She has also gone back and looked at any missing data for explanations. We input information clinic by clinic.
- Those identified to input information have received training from CRANE staff, which has been very helpful and they also have contact numbers to contact CRANE staff should difficulties arise.
- Many MDT staff have been committed to not taking leave when there are 5 year clinics.

I hope this is useful information. Please feel free to contact me should you require any further information.

Provided by Helen Extence, Clinical Director, The Welsh Centre for Cleft Lip & Palate, September 2021

11. South West cleft service

Thank you for your letter of 9th September 2021 informing us that the South West Cleft Service has been identified as a negative outlier with regards to:

1. Child growth data completeness
2. Dental health dental completeness

Whilst all medical practice has been affected by the Covid19 pandemic response, within the UK Cleft Services the South West Cleft Service based in Bristol has stood out for the degree to which the service has been compromised. The pandemic has produced problems primarily of its own but also exposed weaknesses in the support that our service relies on. Maternity leave of the paediatric dental surgery consultant in the South West Cleft Service overlapped with the pandemic response. With only approximately 2.8 whole time equivalent consultant paediatric dentists in the South West of the UK at the time, and paediatric dentistry hard pushed with the work load of the region, a regular consultant replacement was not possible during this time. Therefore the dental health data will be incomplete.

Our area covered by the South West Cleft Service is large: from Gloucester to the Isles of Scilly. We have a main hub in Bristol and run spoke clinics in five other centres (reduced from six previously). Measurements such as child growth and dental health are taken in these clinics. The pandemic response shut down our possibilities for face-to-face assessment of audit data set values. We have looked at beginning these in our main hub in Bristol after the recovery from lockdown measures, however, restrictions of numbers of clinicians in clinical spaces and now backlogs in more urgent clinical review appointments have prevented this. The position is worse with our partners throughout the South West as there were other more pressing demands of catching up from clinical backlogs and the audit clinics of an external service such as ours were not a priority. In addition to this, the team has been hit by the same isolating and sick leave that everyone else has experienced.

These difficulties have been shared with the Cleft Development Group members. We are working on a longer term plan to get back on course.

Provided by Alistair Cobb, Clinical Director, South West Cleft Service, October 2021

12. Evelina London cleft service

1. Consent Verification – data completeness

Upon investigation and performing a local audit, it was discovered that there are inconsistent multifactorial processes leading to low consent verification. Therefore, the following action plan is proposed:

- The Cleft Nurse Specialist (CNS) team was identified and designated as owning initial consent verification.
- Consent verification is being built into the existing nursing care pathway.
  Goal - all relevant patients to have a consent response prior to 6 months old.
- Lead CNS to audit performance monthly.
  Results - fed into standing agenda item at a monthly nurse meeting for discussion and accountability.
- CRANE performance metrics to be fed through the cleft service monthly Performance Review Meeting with the wider Directorate Management Team.
- CRANE policy and procedure will be formally put in place via written document used to maintain historical knowledge; for staff reference; and new staff orientation.
- Cleft service management will implement retraining, close supervision, and reporting structure for team data manager.
- Data manager to send monthly consent verification report to Lead CNS in preparation for monthly nurse meeting.
- Retrospective consent verification will continue to be divided between the multidisciplinary team members for collection.
  This process has already returned circa 80 retrospective consents to date.

2. Child Growth – data completeness

- Inconsistent process was revealed leading to incomplete data entry. In addition to creating a written policy and procedure and creating a systematic process for monitoring as outlined above, the following action plan is proposed:
- Intake nurses present for clinics will take height and weight measurements for all patients attending 5- year audit clinics in-person.
- Intake nurses will prepare and “check-in” patients attending virtual visits to obtain current height and weights from parents (via recent GP appointment and/or Red Book).
- Collection of retrospective child growth data (5 years old) will need to be divvied between multidisciplinary team members.
- Data manager will audit completeness of this data point and report monthly.

3. Dental Health – data completeness

In reviewing our processes for gathering 5-year-old dental health outcome data for the birth cohort 2011 to 2013, it was noted that the data available at this time was collected by our then newly appointed part-time Consultant in Paediatric Dentistry.

Our service Consultant was appointed to a part-time position in 2016 and had significant clinical backlogs to address which took up the majority of their working hours at that time. However, new data collection processes were put in place at that time, to enable the collection of as much data as possible.

Further staffing level increases within cleft Paediatric Dentistry have subsequently been made and additional Consultant sessions were appointed to in late 2019. This has brought our establishment up to 1 WTE and increases our confidence that our service is now in a better position to gather data going forward. There do remain challenges, however.

These are particularly related to CRANE consent gathering, which has a knock on to all aspects of our outcome data publishing, and to the fact that we do not have paediatric dental provision in our outreach clinics – an area where we do not have overarching control of local resources.

4. Psychological Wellbeing - outcome indicator

(Strength and Difficulties Questionnaire, Percentage of patients with high /very high scores)

The Evelina London (South Thames) Cleft Service have been shown be negative outliers for one of the Clinical Psychology measures - specifically the proportion of SDQ scores being in the 'high' or 'very high' range which would indicate that significantly more 5-year-olds in our region experience psychological difficulties compared to other regions in England and Wales.

We have reviewed the Clinical Psychology data submitted for the 2011, 2012 and 2013 birth cohorts and have identified that significant errors were made in the calculation of SDQ scores – particularly for the 2011 and 2012 cohorts - and that when the raw data (questionnaire scores) is recalculated correctly, the correct data appears to be in line with national averages (see Appendix 1).

The Strengths and Difficulties Questionnaire (SDQ) contains 25 questions which are divided between 5 scales: (1) emotional symptoms, (2) conduct problems (3) hyperactivity / inattention (4) peer relationship problems (5) prosocial behaviour. For the first 4 scales, a low score is better and means that the child is showing fewer difficulties in these areas. For the 5th scale (prosocial behaviour) a higher score is better and indicates that the child has positive social skills. The SDQ Total score is the sum of scales 1-4 and does not include the prosocial score. Again, for the total score, a lower number is better. It is the SDQ Total Score that is reported to CRANE.

Unfortunately, for a substantial number of the Evelina London Cleft Service data entered into CRANE for the birth years in question, the member of staff responsible for calculating the scores incorrectly included the prosocial scale in the child's total score (thus significantly inflating the total score). This is the main error that we uncovered and affects many of the data points entered. Other errors also occurred including not reversing scores where the SDQ scoring metric requires this.

We have undertaken a review of our local practice in respect to the calculation of SDQ scores and will ensure that, in future, we perform a range of checks on our data to ensure that no further errors of these types occur. We have already checked all the original SDQ forms and rescored them. At the end of this document, we have attached tables to compare the data that was (erroneously) entered onto CRANE with the accurate data (see Appendix 1).
We are grateful to CRANE for having highlighted this problem with our data and are glad that we can report that - most importantly of all - our patient cohort do not appear to be experiencing significantly poorer outcomes in terms of their psychological presentation at age 5 compared to other areas of England and Wales.
We are hopeful that the response provided, and our corrected data will allow CRANE to feel satisfied that there is now 'No concern of outlier status' when compared to the data from other centres. We are able to provide evidence to show that the data originally analysed contained sufficient inaccuracies to produce the unexpected performance value and we are optimistic that the negative outlier process can now conclude for the Clinical Psychology data.

Provided by, Alex Cash, Clinical Director, Evelina London Cleft Service, November 2021

13. Northern Ireland cleft service

In response to the notification dated 9th September that the Northern Ireland Cleft Service has been identified as a negative outlier with regards to two areas, we provide the following information:

- Child growth – data completeness

The data collection period was 2016 – 2018 for the birth cohort identified (2011-2013 births) and during this time we had 1 WTE Cleft Nurse Specialist (CNS), a combination of factors including staffing, patients failing to attend and children attending out of standard contributed to an incomplete data set. In order to address this issue in the future a second WTE CNS has been appointed and they will endeavour to ensure complete child growth audit outcomes are submitted to CRANE.

- Psychological wellbeing – data completeness

For the time period 2016 – 2018 we had limited psychology input in Cleft Service. The service was allocated 1 psychologist with 3 sessions per week to cover MDT clinics, audit data collection, individual therapeutic support, CPD, supervision, team meetings and frequently this meant that when leave is also considered audit records were not taken and returns to CRANE were incomplete. In order to address these shortcomings we have funding for a 1 WTE Cleft Psychologist and this will be advertised for interview shortly.

The NI Cleft Palate team have had staffing issues in the past however this is being addressed and staff are committed to ensuring we have 100% data completeness for all areas moving forward. We have put in place a system where the Cleft Coordinator will now meet with each discipline and internal cross checking and quality control processes will be completed prior to submitting data to CRANE.

To respond to the identification of positive outlier status, we provide the following information:

- Consent verification

CRANE have been clear that without initial consent at diagnosis then any further data cannot be included on CRANE, therefore the CNS is extremely diligent about discussing CRANE consent with families as soon as possible after making contact and it is appropriate to do so. She identifies and endeavours to follow up any families who have yet to provide consent by telephone. The CNS and Cleft coordinator continue to work tirelessly to identify any families who do not initially consent to inclusion on CRANE to ensure NI data can be as complete as possible.

- Dental health – data completeness

The Cleft Coordinator has always worked closely with the Consultant Dental Surgeon on submitting returns to CRANE, therefore they have a robust process in place which ensure high levels of data completeness. This involves cross checking and meeting regularly to upload CRANE records once completed.

Provided by Chris Hill, Clinical Director, Northern Ireland Cleft Service, October 2021