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Promoting excellence in cleft care

CLEFT REGISTRY & AUDIT NETWORK



Cleft Registry and Audit Network Database

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

2022 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 2021

On behalf of the Cleft Development Group

Responses to outlier process

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

Document	Published
CRANE 2022 Annual Report	December 2022
2022 Annual Report: Supplementary tables (Appendices) (Excel Workbook)	December 2022
2022 Annual Report: Methods (Appendices)	December 2022

Responses to cleft services' outlier status below.

1. Newcastle cleft service

This cleft service was notified of their outlier status for the following indicators on 27-28 October 2022:

We congratulated the Newcastle Cleft Service for being identified as a positive outlier with regards to:

- consent verification,
- dental health - data completeness, and
- child growth – data completeness,
- psychological wellbeing – data completeness.

The cleft service, and leadership team, were not obliged to respond to this notification.

This was in accordance with agreement by the Cleft Development Group (CDG) on 10 November 2022, in responses to: (a) Services' ongoing pressures navigating recovery from the impact of the waves of the COVID-19 pandemic. As well as (b) to allow the [Outlier Policy](#), piloted and introduced in 2021, to become embedded in practice.

From 2025, Clinical Leads will be expected to provide full responses to outlier notifications. These will be published in a document such as this, alongside the CRANE 2025 Annual Report.

2. Leeds cleft service

This cleft service was notified of their outlier status for the following indicators on 27-28 October 2022:

We congratulated the Leeds Cleft Service for being identified as a positive outlier with regards to:

- consent verification,
- child growth – data completeness, and
- psychological wellbeing – data completeness.

The cleft service, and leadership team, were not obliged to respond to this notification.

This was in accordance with agreement by the Cleft Development Group (CDG) on 10 November 2022, in responses to: (a) Services' ongoing pressures navigating recovery from the impact of the waves of the COVID-19 pandemic. As well as (b) to allow the [Outlier Policy](#), piloted and introduced in 2021, to become embedded in practice.

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3. Liverpool cleft service

No Outliers

4. Manchester cleft service

This cleft service was notified of their outlier status for the following indicators on 27-28 October 2022:

We would congratulate the Manchester Cleft Service for being identified as a positive outlier with regards to:

- consent verification,
- child growth – data completeness, and
- facial growth (5-year-index) – data completeness.

The cleft service, and leadership team, were not obliged to respond to this notification.

This was in accordance with agreement by the Cleft Development Group (CDG) on 10 November 2022, in responses to: (a) Services' ongoing pressures navigating recovery from the impact of the waves of the COVID-19 pandemic. As well as (b) to allow the [Outlier Policy](#), piloted and introduced in 2021, to become embedded in practice.

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5. Trent cleft service

This cleft service was notified of their outlier status for the following indicators on 27-28 October 2022:

The Trent Cleft Service was identified as a negative outlier with regards to:

- psychological wellbeing - data completeness.

We congratulated the Trent Cleft Service for being identified as a positive outlier with regards to:

- facial growth (5-year-index) – data completeness, and
- speech – data completeness.

The cleft service, and leadership team, were not obliged to respond to this notification **in full**.

This was in accordance with agreement by the Cleft Development Group (CDG) on 10 November 2022, in responses to: (a) Services' ongoing pressures navigating recovery from the impact of the waves of the COVID-19 pandemic. As well as (b) to allow the [Outlier Policy](#), piloted and introduced in 2021, to become embedded in practice.

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Response with regards to **Speech – data completeness**:

In Trent we have a rolling system of collecting and analysing speech audits. The specialist SLTs in the team are proactive in collecting speech audit recordings for their area and as Lead SLT I am proactive in identifying any cases who have not been seen and chasing this. We hold monthly listening days throughout the year with 2 CAPSA trained listeners ... Our stable listening group and rolling system of listening also helped our performance.

Provided by Lorraine Britton, Lead Speech and Language Therapist, Trent Regional Cleft Network, November 2022

6. West Midlands cleft service

This cleft service was notified of their outlier status for the following indicators on 27-28 October 2022:

The West Midlands Cleft Service was identified as a negative outlier with regards to:

- child growth – data completeness,
- psychological wellbeing – data completeness,
- psychological wellbeing – face-to-face psychosocial screening before age 6,
- psychological wellbeing – with low rates of children identified as having a Tiers of Involvement Measure (TIM) of 1a+ (seen by or having had input from a psychologist), and
- psychological wellbeing – high/very high Strengths and Difficulties Questionnaire (SDQ) total scores indicating difficulties.

We congratulated the West Midlands Cleft Service for being identified as a positive outlier with regards to:

- dental health - data completeness.

The cleft service, and leadership team, were not obliged to respond to this notification.

This was in accordance with agreement by the Cleft Development Group (CDG) on 10 November 2022, in responses to: (a) Services' ongoing pressures navigating recovery from the impact of the waves of the COVID-19 pandemic. As well as (b) to allow the [Outlier Policy](#), piloted and introduced in 2021, to become embedded in practice.

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7. Cleft Net East cleft service

This cleft service was notified of their outlier status for the following indicators on 27-28 October 2022:

The Cleft Net East Service was identified as a negative outlier with regards to:

- speech – data completeness.

We congratulated the Cleft Net East Service for being identified as a positive outlier with regards to:

- child growth – data completeness, and
- psychological wellbeing – data completeness.

The cleft service, and leadership team, were not obliged to respond to this notification.

This was in accordance with agreement by the Cleft Development Group (CDG) on 10 November 2022, in responses to: (a) Services' ongoing pressures navigating recovery from the impact of the waves of the COVID-19 pandemic. As well as (b) to allow the [Outlier Policy](#), piloted and introduced in 2021, to become embedded in practice.

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8. North Thames cleft service

This cleft service was notified of their outlier status for the following indicators on 27-28 October 2022:

The North Thames Cleft Service was identified as a negative outlier with regards to:

- dental health - data completeness,
- speech – data completeness, and
- psychological wellbeing – with low rates of children identified as having a Tiers of Involvement Measure (TIM) of 1a+ (seen by or having had input from a psychologist).

Their full response is provided below:

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.

As previously, on receipt of this notification, the relevant specialties were contacted 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. We met the next day to strategize the formulation of our response and I have attached the investigations for each of the specialties.

Further to the explanation last year we have had an experienced member of the team return which made sourcing the data more straight forward and the data co-ordinator has now been in post for one year which again helped with the mining of data.

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

	2012		2013		2014	
	GOS	CHELMS	GOS	CHELMS	GOS	CHELMS
Total patients (consented)	105	39	83	45	85	47
Total patients recorded with a Tier score	74	32	66	32	61	30
No. with TIM 1a	43	13	42	8	12	11
No. with TIM 2+	19	18	20	21	33	18
% total TIM 1a+	84%	97%	94%	91%	74%	97%
No. and % TIM 0	12 (16%) <i>9 (9%) = 0d, staff under resourced</i> <i>1 (1%) = 0a, with another patient</i> <i>2 (2%) = 0b, staff on AL</i>	1 (3%) <i>1=0a, with another patient</i>	4 (6%) <i>3 = 0d, staff under resourced</i> <i>1 = 0e psychology declined by patient</i>	3 (9%) <i>3= 0c, psychologist off sick</i>	16 (26%) <i>4 (5%)= 0c, staff sickness</i> <i>7 (8%) = 0d, lack of staff resource during vacancy gap</i> <i>HOWEVER, 5 (6%) entered incorrectly as Zero D were actually seen by a psychologist</i>	1 (3%) <i>1 = 0e, psychology declined by patient</i>

					<i>and were therefore 1A+</i>	
% total TIM 1a+						
% TIM missing with reason code *	31 (explained in previous report/ could not find patient data)	7 (explained in previous report/ could not find patient data)	17 (explained in previous report/ could not find patient data)	13 (explained in previous report/ could not find patient data)	24 8 (9%)= <u>clinic cancelled</u> due to covid-19 10 (12%)= <u>DNA</u> suspected due to Covid-19	17 6 (13%)= <u>clinic cancelled</u> due to covid-19 4 (9%)= <u>DNA</u> suspected due to Covid-19

* explained using the outcome codes entered correctly onto crane:

1= Patient deceased or emigrated

2= Patient transferred in or out of area

3= Syndromic Diagnosis

4= Clinically contraindicated (other than syndromic) - this record type for this patient

5= Lack of staff / facilities / equipment

6= Patient DNA / cancelled / did not consent / cooperate

9= Other reason

As you can see the updated table attached shows the breakdown of our Tier score data for each of the three years, including a breakdown of our Tier 0 scores. If we adjust for the staff vacancy in 2014 at GOSH where 7 patients weren't seen and 5 patients were seen but the data was incorrectly entered as Zero D and should have been 1A+ our percentage would maybe have been within the norms, and we wouldn't have been an outlier. There was also a significant number not seen in 2012 at GOSH due to maternity leave with no cover which also affects our outlier status.

Taken overall this would mean that the overall percentage of those with a tier score of 1a+ between 2012-2014 would increase to 89% (instead of the current 87%). It is not known if this would have improved the score to be within 2 standard deviations, but it is certainly closer to that level.

The previous errors in data entry for 2012 and 2013 have already been corrected on the CRANE database. We have yet to correct the data for the 2014 entries but will do so soon.

Speech and Language Therapy - Speech - data completeness

Having reviewed the data set of the missing outcomes a number of patients attended for audit but were unable to co-operate or undertake a speech assessment (25 pts. 43%). In addition, a number of patients listed on CRANE were no longer known to the service with a closed referral (15%) or had transferred out of the North Thames Network. There is also a small number who DNA or declined assessment. Sadly, a number had passed away and this should have been updated on to the CRANE database. It is acknowledged that all these factors should have been recorded on the CRANE database and we intend to update the CRANE dataset in the coming months.

The outlier report has provided us with an opportunity to review our systems across the North Thames Regional Network and we aim to provide 100% data completeness for the 2016 cohort. In addition, we will cross check our 2016 data set against the CRANE database to ensure we are capturing all our patients within the Network. We have established a monthly meeting with our Data Manager and Audit Lead to ensure we continue to meet our obligations to CRANE and the patients we serve. Our thanks to CRANE for enabling us to reflect and seek solutions for the service.

Across the 3-year period 2012 – 2014 here is a summary of the missing data set

Reason for Missing data	Percentage
Attended for audit but unable to cooperate or recording taken	43
Cancelled	14
DNA	7
Transferred to another unit	9
Deceased	7
Seen in MDT but no recording	2
No referral to Cleft	15
Unrepaired	3

Paediatric Dentistry

The problems with the provision of a cleft calibrated paediatric dentist within the team persist with just one person able to record the necessary outcomes at 5 years. The post of consultant in paediatric dentistry, specifically covering the cleft service, has been advertised 3 times but unfortunately any applicants applying have not been appointable. We are about to advertise for a fourth time and are hopeful that there are candidates interested in the post.

As previously reported 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.

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 12 months conditions within the department have changed so that our one calibrated clinician can now attend the audit clinics (previously they had a teaching commitment at another hospital). This has meant that for the last 12 months we have been recording calibrated DMFT outcomes, and we are hopeful this will be reflected in our outcomes moving forwards.

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

1. With regard to psychology, we seem to have identified unforeseen absences in staff and incorrect data entry as the main culprits. The introduction of new members of staff to the team can occasionally be delayed due to trust processes. This has led to occasional gaps in the provision of psychology support which is evident from the above. Secondly, we recognise that sense checking the data is important as we have identified some mistakes in the data entered. Since first recognising this, we have introduced quality assessment of each birth year to ensure the diagnoses are correct for each of our babies and that they have been entered correctly on crane. As we move into the successive years we were expecting to see the benefit of these quality improvements.
2. With regard to the SLT outcomes we have identified a problem with our Epic electronic patient entry system where patients can effectively be lost follow-up. This is listed above as “no referral made to cleft”. Similarly, following the QI mentioned above, we should be in a much better position to ensure that no patients are missed from our audit recall clinics as we will have verified the database for the required year in advance.
3. 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 Cleft Paediatric Dental Specialty lead has proven problematic, as already noted previously. We have partially addressed this with a change to the job plan of our 1 calibrated clinician but recognise that in the long term this is not sustainable, hence the need to appoint new consultant as soon as possible.

In Summary:

We have put in quality improvement measures to help ensure that we capture as much data as possible through our cleft audit clinics. We absolutely recognise the importance of the completeness of data entry and the beneficial affects this has on accurately measuring treatment outcomes, which in the long term will introduce changes for the benefit of our patients. 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, November 2022

9. The Spires cleft service

This cleft service was notified of their outlier status for the following indicators on 27-28 October 2022:

The Spires Cleft Service was identified as a negative outlier with regards to:

- psychological wellbeing - face-to-face psychosocial screening before age 6.

We congratulated the Spires Cleft Service for being identified as a positive outlier with regards to:

- dental health **and** psychological wellbeing – data completeness, and
- dental health - dmft >5 indicating experience of extensive dental decay. Your cleft service fell outside the lower 99.8% control limit on the funnel plot, indicating they had a relatively low percentage of children with >5 dmft; suggesting good outcomes/practice that could be learned from.

The cleft service, and leadership team, were not obliged to respond to this notification.

This was in accordance with agreement by the Cleft Development Group (CDG) on 10 November 2022, in responses to: (a) Services' ongoing pressures navigating recovery from the impact of the waves of the COVID-19 pandemic. As well as (b) to allow the [Outlier Policy](#), piloted and introduced in 2021, to become embedded in practice.

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10. South Wales cleft service

This cleft service was notified of their outlier status for the following indicators on 27-28 October 2022:

We congratulated the South Wales Cleft Service for being identified as a positive outlier with regards to:

- child growth – data completeness,
- dental health - data completeness, and
- psychological wellbeing – data completeness.

Their full response is provided below:

Thank you for your letter indicating that our unit is a positive outlier for dental, growth and psychology data completeness.

As a team we have worked hard to identify gaps in our data completeness and to rectify this. This has involved going back through the medical notes for some patients which has been time consuming. In order to avoid this for 2015 data and for the future, we have implemented a proforma at the designated 5 year old clinics.

This has enabled us to record dental results and growth directly onto the proforma at the time of the clinic rather than searching through the medical note entries. If we are unable to obtain the information, a reason is given at the time. The data from the proforma is inputted onto the CRANE database by our designated secretary, responsible for recording the data. We hope this will continue to support data completeness for our unit.

Provided by Helen Extence, Clinical Director, The Welsh Centre for Cleft Lip & Palate, November 2022

11. South West cleft service

This cleft service was notified of their outlier status for the following indicators on 27-28 October 2022:

The South West Cleft Service was identified as a negative outlier with regards to:

- child growth – data completeness,
- dental health – data completeness, and
- facial growth (5-year-index) – data completeness.

The cleft service, and leadership team, were not obliged to respond to this notification.

This was in accordance with agreement by the Cleft Development Group (CDG) on 10 November 2022, in responses to: (a) Services' ongoing pressures navigating recovery from the impact of the waves of the COVID-19 pandemic. As well as (b) to allow the [Outlier Policy](#), piloted and introduced in 2021, to become embedded in practice.

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12. Evelina London cleft service

This cleft service was notified of their outlier status for the following indicators on 27-28 October 2022:

The Evelina London Cleft Service was identified as a negative outlier with regards to:

- consent verification,
- child growth – data completeness, and
- dental health - data completeness.

Their full response is provided below:

Overall, we are pleased to see how well Evelina compares to the other 12 regional services in terms of our ability to collect the required data and for the quality of our outcomes. On the whole we compare very favourably to the other national services and I am proud of the team and the work of the Evelina London Cleft Service. It is pleasing to see how our outcomes demonstrate what excellent, multidisciplinary, patient-centred care we provide.

You have identified that the Evelina London Cleft Service appears as a negative outlier with regards to three of the data items collected by CRANE and I note that these three aspects relate to process rather than clinical outcome. The areas where we remain outliers in this year's report represent a historical struggle to complete all checks at pre-defined time points (considered appropriate in the patient journey) but do not suggest that our patients are receiving inadequate clinical care or poorer outcomes – the data show that this clearly is not the case.

The three areas where we are found to be negative outliers for the 2022 CRANE report are discussed below.

1. Consent Verification – data completeness

For babies born in 2012-2014, our consent verification figure (the number of families where we have obtained their consent to be registered on the CRANE database) is reported as 67% (246 out of 367 births). This is disappointingly low and our local investigations and audit demonstrate that there are a

number of reasons why at the time when these children were born (between 8 and 10 years ago), consent was not collected. We are tackling this issue with both a retrospective and prospective strategy and are seeing some good results – certainly of the new processes put in place for gathering consent for babies born from 2021 onwards. Consent verification is now firmly built into the existing Cleft Clinical Nurse Specialist pathway with a goal of all relevant patients having had consent established (through contact with parents) within the first 6 months of life, and certainly by 12 months. The data on CRANE show that, for babies born in 2021 and 2022, our service is consistently achieving positive results for registrations – in fact, whilst eleven out of thirteen cleft services registered a lower number of children born with a cleft in 2021 (in comparison to the yearly average number of registrations across the 2018-20 period), Evelina London showed a substantially higher number of children than all other services for that birth year.

In addition, as a service we are committed to collecting retrospective consent for all children under our service where this was not, unfortunately, collected in this early period. Our Audit and Information Officer is taking a lead on identifying all unconsented patients. The MDT are alerted when any unregistered child attends an MDT or unidisciplinary clinic appointment and all clinicians take responsibility for explaining about CRANE and collecting consent. And, in addition to this process, our Audit and Information Officer (and other members of the team) are making direct contact with other families by phone, post and email, where consent has not yet requested. We are following the CRANE protocol for consent collection and will focus our efforts now on ensuring that children born between 2013 and 2015 (those who will be discussed in the 2023 CRANE report) will be prioritised for registration. Once registration has been achieved, our Audit and Information Officer is overseeing the process of gathering and uploading the clinical outcome information that was collected at the 5 year review time point.

We are confident that, over time, the Evelina London Cleft Service will no longer be a negative outlier in this respect.

2. Child Growth – data completeness

This indicator refers to the collection of Height & Weight at 5 years. In the CRANE 2022 report (children born in 2012-2014) we were found to have reported both height and weight for 22.8% of CRANE registered, eligible children. This means that the Evelina London Cleft Service is 1 of 4 services that are negative outliers for this aspect.

This is a difficult metric to improve upon in the short term because these children turned 5 (the year in which the data should have been collected) between 2017 and 2019. We cannot retrospectively collect this data (it can only be collected when the child is 5 years old) and so cannot improve on this figure for previous years.

However, our analysis of this issue for last year's CRANE report found various reasons for the lack of data collection and we accept that our processes were inadequate at that time. We have thus improved on our protocol and now have a system in place whereby the dental nurses supporting our MDT clinics routinely take height and weight measurements for all child patients attending clinics in-person and certainly for those who are 5 years old. The heights and weights are logged on the patient's electronic patient record and our Audit and Information Officer is notified of these so that the data can be uploaded to CRANE.

The Head of Service is routinely meeting with the Audit and Information Officer and will continue to audit completeness of this data point with an expectation that our outlier status will reduce over coming years.

3. Dental Health – data completeness

CRANE records the percentage of CRANE registered and consented children with dmft (decayed, missing and filled teeth) scores in order to ascertain how many children have had a dental health check at 5 years. For our CRANE registered children born in 2012-2014, our dmft collection rate is reported as being at 35.4%

Similarly to the analysis for the child growth metric, this is an indicator that is unlikely to show dramatic improvements on CRANE in the short term since this birth cohort have now turned 5 (between 2017 and 2019) and we cannot now collect this data for this set of patients. We thus cannot expect to see dramatic improvements on this figure for some years to come.

As we reported last year, we have taken considerable time to review our processes for gathering 5-year-old dental health outcome data for the birth cohort and note that the main reason for this not having been completed to a greater degree, was due to a lack of resource within our team ie an inadequate amount of Consultant Paediatric Dentist time within our service historically. Staffing level increases within cleft Paediatric Dentistry have 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, including longterm sick leave and uncovered maternity leave cover for one of our Consultants on the St Thomas' site and we are hopeful that this issue will be resolved soon. It should be noted, however, that we do not have paediatric dental provision in our outreach clinics – an area where we do not have overarching control of local resources.

It is pleasing to see that, although collecting the dmft scores at the age of 5 has been challenging for us as a service, where we have been able to do so, we are at least in line with other cleft services in the UK in terms of our patient cohort's overall dental health. We have had issues with the process of collecting the data but not with the outcomes we are achieving in this respect.

We are hugely grateful to CRANE for the support and guidance they provide to us to collect the required data and for all the work that goes into analysing and reporting on this. We know that the intention is to help us to continue to work for patient benefit and to ensure that our cohort of individuals born with a cleft receive excellent care. We remain fully committed to this process and this report has been shared with the clinical leads within our team and also with the Clinical Director for the Children's Surgery Theatres and Anaesthesia (CSTA) Directorate within Evelina London.

Provided by, Kate le Maréchal, Consultant Clinical Psychologist and Head of Service, Evelina London (previously South Thames) Cleft Service, November 2022

13. Northern Ireland cleft service

This cleft service was notified of their outlier status for the following indicators on 27-28 October 2022:

The Northern Ireland Cleft Service was identified as a negative outlier with regards to:

- child growth - data completeness,
- psychological wellbeing - data completeness, and
- psychological wellbeing - face-to-face psychosocial screening before age 6.

We congratulated the Northern Ireland Cleft Service for being identified as a positive outlier with regards to:

- consent verification, and
- dental health - data completeness.

The cleft service, and leadership team, were not obliged to respond to this notification.

This was in accordance with agreement by the Cleft Development Group (CDG) on 10 November 2022, in responses to: (a) Services' ongoing pressures navigating recovery from the impact of the waves of the COVID-19 pandemic. As well as (b) to allow the [Outlier Policy](#), piloted and introduced in 2021, to become embedded in practice.

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