**Draft Minutes of a Meeting of the National UK NHS Cleft Development Group**

Venue- Research Boardroom at the Royal College of Surgeons of England

Date & Time- Friday 17th May, 11am-3pm

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| **Present** | Simon van Eeden (SvE) Chair  Victoria Beale (VB)  Lorraine Britton (LB)  Claire Cunniffe (CC)  Sinead Davis (SD)  Scott Deacon (SDC)  Helen Extence (HE)  Toby Gillgrass (TG)  Norman Hay (NH)  Peter Hodgkinson (PH)  Toni Kitchingham (TK)  David Landes (DL)  Kate le Marechal (KM)  Ailbhe McMullin (AM)  Ginette Phippen (GP)  Sandip Popat (SP)  Helen Robson (HB)  Ian Sharp (IS)  Jackie Smallridge (JS)  Norman Hay (pm)  **In Attendance**  Catherine Foster |  |
| **Apologies, absence and welcome to new members** | Alex Cash  Mechelle Collard  Yvette Edwards  Vanessa Hammond  Kanwal Moar  Jason Neil-Dwyer  Susan Parekh  Jules Scott  Alistair Smyth  Marc Swan |  |

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| Item | Notes | Actions |
| **2. Minutes of the Cleft Development Group Meeting, November 2018** | Amendments to the draft minutes from 22.11.18 were suggested by the committee. |  |
| **3. Matters arising** | * CC has identified some individuals for lay representation for South Wales. CC felt that it may be beneficial to establish a CDG lay representation Job Description document to give some guidance to the potential candidates. The CDG does not currently have such document, but IS suggested using a standardised NHS lay representation JD alongside the CDG ToR as a framework. CC suggested using these documents to draft a JD, of which she will then circulate to the group. * Patrick McGuiness has confirmed KM as BAOMS representative. * ToR changes have been made, with the addition of a sentence regarding representation from Ireland. The next step is to embed the conversation around the quality improvement paper, as prepared by LB and JND, into the document. * IS is to discuss dissemination at local, regional and national levels with Sir Bruce Keogh next week and will report back via email. * CRANE service review is predicted to be completed by the next CRG meeting, from there on, CRANE funding may be discussed. SDC is regularly contacting Joanna Reid, but with little success. CRANE have received a funding letter prior to the next financial year, but a contract is yet to be established. * Applicants for CRANE Clinical Project Leads have been shortlisted, with interviews due to take place on Monday 20th May 2019. * Conversations regarding Scotland’s CRANE involvement have taken place, with Scotland ready to move forward. * The ICHOM Memorandum of Understanding to being rewritten to fulfil its requirements, specifically those regarding the GDPR. Once this document has been received, SDC will circulate for the CDG for review. | 3.1 CC to draft CDG lay representation Job Description and circulate to the group for feedback. |
| **4. Terms of Reference** | **4.1 Quality Paper**  As discussed in the previous meeting, LB and NJD have produced a discussion paper regarding CDG role in supporting quality improvement in cleft care. This document was circulated prior to the meeting, and was introduced to the group by LB.  The paper proposed that the CDG could be used to provide a multidisciplinary, multicentre collaborative learning environment in which the process and outcome data collected by CRANE and NHS dashboard could be scrutinised, and opportunities for building on good practice to improve outcomes created.  LB highlighted the Ben Bridgewater (2013) 5 stages of governance, which have been used to outline the work in cleft care to date. LB noted that the CRG are currently involved in stage 1-3 (defining standards, Infrastructure to support and measure standards, Agree acceptable variance / define unacceptable variance), but there is currently no national work to date towards stages 4 and 5 (Identifying learning from outlying performers, Advise and facilitate local quality improvement processes. It is suggested that at agreed CDG meetings, the whole group could look at the CRANE Annual Report and the NHS dashboard, identify any outliers (positive or negative), and discuss any potential action required. The services would then be invited to discuss this with the CDG. Positive outliers would be able to share their protocols for the benefits of others, whilst negative outliers could share their action plans in the aim of potentially seeking help from other centres, in a formalised process.  SDC noted that this proposal will need some support from CRANE, particularly from a team member with a methodological background. DL echoed this, suggesting that a Clinical Epidemiologist will need to look at the case mix to determine if the results are robust enough.  SDC raised his concerns regarding Clinical Directors potentially performing service reviews, as this could be seen as a conflict of interest from an outsider’s perspective. SDC suggested that the subgroup should not include CDs of a service. IS suggested a discussion with the outlier CD outside of the group, and then inviting the CD back to work collaboratively towards facilitating the local improvement process. IS further highlighted that this reviewing process will need to be considered by commissioners and a representative from NHS England will need to attend, if only once a year. LB added that the committee would need to be multidisciplinary.  IS mentioned that they have just commissioned a BCH review of their Orthodontic service. They have asked the West Midlands Quality service to carry out this peer review, but are considering that this could be a complicated process. IS asked the group to consider their opinion on peer review for cleft services. SvE raised that Rona Slater had previous explored this and found it to be both expensive and time consuming. He further suggested that the interest (and funding) for a peer review across the cleft services would need to originate from commissioners.  SDC suggested the group needs to be piloted with the CRANE annual report. It was further suggested that the Craniofacial Society be involved in compiling and interfacing into the group. SvE added that CRANE will need to sit within the group in some shape or form.  It was considered how this group could be written into the ToR. It was concluded that the aim would be to have one CRANE representative and one representative from each CEN on the monitoring and evaluating committee. LB is to draft a summary document for the ToR to be reviewed at the next CDG meeting.  The Chair thanked LB and JND for their valuable work. | 4.1. Each CEN is to write to their CEN asking for a representative to sit in the quality monitoring and evaluating committee.  4.2 LB to draft a summary of the quality paper and role of committee to fit within the ToR, to be reviewed at the next meeting. |
| **5. Feedback from CENs** | **Lead Nurses**   * Lead nurses continue to meet four times a year, with the next meeting taking place in London in June. There are two CEN meetings per year, with the last in April receiving good attendance. * Jenny Williams and Nicola Hudson have stepped down from running the Cleft Course. The names for their replacements are yet to be confirmed, therefore the Cleft Course is not currently running. * The SLUMBRS study has been declined by NIHR as there was not sufficient literature to back the study. Iian Bruce is going to challenge this and an update will be provided at the next meeting.   **Orthodontics**   * The group have met twice since the last CDG meeting. * The CEN thanked Norman Hay (orthodontic nomination as President) for his role as President of the CFSGBI and for the successful craniofacial conference. * There is an issue with specialist training in cleft and consultant recruitment. There are several positions left empty nationwide –trying to improve engagement with trainees and this should hopefully improve consultant recruitment. * CEN is looking to facilitate calibration of new consultants * Decision needs to be made about the collection of 5 and 10 year old data * `CEN planning to look at longitudinal data   **Psychology**   * Psychology are continuing to engage with several different research projects, with several Psychology presentations taking place at the Craniofacial Conference. They continue to work with the Cleft Collective and the Bristol Research Psychologists, to ensure that the research is clinically based, rather than academically based, and also continue to collaborate with CSG, to ensure that research includes a clinical Psychology perspective. * Psychology continue to work with CLAPA, and will be nominating individuals to contribute towards the adults leavers pack. A CEN representative will also be taking back on one of CLAPAs online discussions addressing self-esteem. * Planning is taking place with regard to Psychology’s involvement in the Edinburgh 2021 conference. * Staffing across centres varies. There has been some discussion regarding sharing patients across centres. There are some concerns about how patients can have access to all disciplines, but still have the support of holistic care. This may be an issue that is brought to the CDG in the future.   **Speech and Language Therapy**   * The Lead Speech and Language Therapy group have not met since the last meeting of the CDG, so little to report. * As suggested by VB, S&LT have sent a formal letter to the Craniofacial Society, regarding CAPS-A training. * The CEN had a successful day at the Craniofacial conference, with presentations from Debbie Sell, Valerie Pereira and Anette Lohmander. * VB noted that CAPS-A funding has been discussed at the Craniofacial Society Council meeting and that they should be expecting some feedback from NH. Issues raised were buying the rights to the training and the ongoing costs of supporting speech therapist from different units attending trainings. The view of the CFS is that these costs should be provided by the individual networks. VB noted however that the costs for buying the training rights could receive some backing from the CFS. VB advised LB to await feedback from NH and report back at the next CDG meeting.     **Restorative Dentistry**   * A successful training day took place at GOSH on 1st March 2019. It was well attended and is to become part of the ISFE training. * RD are continuing to increase its profile within cleft care via presentations and collaborations. * RD were not present at the Craniofacial Conference. * Adults returning to care - work is ongoing.   **ENT & Audiology**   * The CEN met in April, where presentations made at the Craniofacial Society were discussed. The group decided that they were interested in retrospectively collecting data on PRS. * The group are looking to update ENT & Audiology information for CLAPA. * There are some concerns about the robustness of the data uploaded to the Quality Dashboard; some centres may not be using the same data i.e. different cohorts of patients. They are now looking to check what data each of the centres are using. * Only three centres were represented at the last meeting, so they are looking to have contact details for each of the centres. SD requested that all CDs pass the details of lead ENT & Audiologists to her, so that she can contact them regarding involvement.   **Surgical**   * SvE presented the surgical CEN update as the lead CEN was not present. * During the CEN day, cleft collective was discussed; Michael Mars presented on the predictability of 5year index outcomes and growth, Chris Leopold presented on 5 year nasolabial aesthetics: Duncan Atherton gave a presentation on MRA in 22q11 patients prior to pharyngoplasty.; Brian Sommerlad presented on PPAP; Tariq Ahmad gave a presentation on a difficult pharyngeal stenosis case and VB gave a presentation on a difficult bilateral case, prompting a discussion around re starting the bilateral protocols study |  |
| **6. Audit** | **CRANE (SD)**  **Staff**  The interview for the new Clinical Project Lead is to take place on Monday 21st May. SDC will remain in post until the new Lead is available, and from there onwards will job share during the handover period. SDC will complete the Delphi before stepping down.  Min Hae Park, Assistant Professor started with the Project in April 2018 and has started her maternity leave and is due back in Spring 2020.  **Funding**  CRANE have been approached and had an initial response from Joanna Reid, Lead Commissioner, NHS England. They are awaiting a formal response to their questions over a long term contract and financial stability. This is being hampered by a proposed review of all clinical registers and databases which has been discussed/planned by NHS England for over 2 years.  **Reporting**  CRANE presented at the CFSGBI conference in April 2019 with the following presentations:   * CRANE Report and potential data usage in the future – **Scott Deacon** * MH Park, **K Fitzsimons**, S Deacon, J Medina, K Fitzsimons, J van der Meulen. Longitudinal educational attainment among children with isolated orofacial cleft. Annual Conference of the Craniofacial Society of Great Britain and Ireland, London, April 2019 * Marie Pegelow; Sara Rizell; Agneta Karsten; Hans Mark; Jan Lilja; Midia Najar Chalien; Mathias Lemberger; Petra Peterson; Kate Fitzsimons; Scott Deacon; Jibby Medina; Mary Calvert; Michael Mars. Predictive validity of dental arch relationships and by inference facial growth in unilateral cleft lip and palate. A longitudinal study of 119 patients at 5, 8, 10, 15, and 19 years using the 5 Year Index and Goslon Yardstick. Annual Conference of the Craniofacial Society of Great Britain and Ireland, London, April 2019 * J Medina, K Fitzsimons, MH Park, J van der Meulen, S Deacon. Consultation on older children outcomes: Update on a multiphase Delphi method approach. Poster presentation. Annual Conference of the Craniofacial Society of Great Britain and Ireland, London, April 2019   CRANE also has a paper “School absence and its impact on academic attainment in children born with a cleft in England.” for peer reviewed journal for submission on school attendance and outpatient appointments as described at the CFSGBI 2018 conference.  **CROWN**  CRANE have extended the contract of delivery with CROWN informatics for 1 years – until September 2019. They met with CROWN Informatics Limited in February to review their current situation and contract. They may choose to extend further, but this would reduce the scope for further development due to the limitations of the platform provided by a subcontractor that CROWN originally used.  They have met with an alternative IT firm, Netsolving, used to develop this type of product (Register and national audit tools) and the current estimate of costs for development would be £33,100.00 + VAT with annual support costs of £9000.00 VAT per year, not including the server services of approximately £6,000.00 + VAT.  SDC and the CEU will be having conversations to determine which would be the best option to resolve the issue.  **CRANE Database: Consultation on older children outcomes**  CRANE are undertaking a Delphi like approach to identifying consensus on records and data collection for older children and young adults. This is a multi-step approach, which will take some time but hopefully provide a solid foundation for future years of national audit and service evaluation. They are currently completing the second phase of the process. This was presented via poster at the CFSBGI annual conference this year. CRANE have received feedback around communication for the online survey and are looking to establish links with CENs and others to improve their ability to undertake this type of work. They are looking to partially rerun stage 2 to ensure a wider participation from the community. KLM raised that during the Psychology CEN, most individuals had not received this consultation request.  **Additional Data Sources & Outcome Measures**  **Newborn Hearing Screening Programme (NHSP)**  CRANE have received permission (again) for the following linkage to receive some hearing data one the children from the Newborn Hearing Screening Programme with Public Health England (PHE), subject to resourcing at PHE which prevented CRANE receiving data, despite the appropriate approvals in 2017. However, they are still awaiting the costs of this linkage.  **NHS Digital (HES Data)**  CRANE have undertaken an approval process for linkage to HES Data with NHS Digital. This has an increased level of governance over previous arrangements (DARS-NIC-124104). The estimate of costs for linkage to in-and outpatient aspects for our cohort and some data cleaning around postcodes is estimated at £18,870 + VAT. This cost is going prove challenging under CRANE’s current funding envelope.  **Department of Education**  CRANE are currently drafting their submission to become an “accredited researcher” with access to the data through a portal.  **Ongoing Developments**  **CRANE data collection by Scotland**  CRANE had agreed with management in Scotland to start collecting data from April 1st 2019. This has now been provisionally timetabled for 2020. To cover the whole of the UK for the first time will no doubt strengthen the ability of the project to provide robust data that informs practice and service delivery. It will also provide UK wide benchmarking which can only be a positive step forward.  **Cleft Collective**  CRANE has agreed to provide a data extract for the Cleft Collective (CC) for a collaborative project using phenotypic data. The Data Sharing Agreement (DSA) for this work, currently being reviewed by the CC, is close to being agreed.  The Health Foundation Insight Research Programme 2019 collaborating with Lead applicant Yvonne Wren for initial outline proposal for funding linkage for CC with CRANE and other data resources.  **Other research groups:**  The Health Foundation Insight Research Programme 2019 are collaborating with Lead applicant Bruce Richards for initial outline proposal Infrastructure for enhancement of CRANE through: digital upload of photos and other new audit data and linkage to other Systems, Computer based facial aesthetic measure development and Computer based infant model data mining development.  **Quality Dashboard**  CRANE are due to provide the last extract to Methods for the 2018-19 financial year (Fri 17/Mon 20). CRANES’s capacity to do this for the 2019-20 financial year is subject to review; considering the current constraints of our current funding arrangement.  **ICHOM**  *Memorandum of Understanding agreement*  Scott Deacon had a teleconference with Monika Jain and Oluwakemi Okunade from ICHOM on the Tuesday 2nd April to discuss this further. In light of GDPR and some other information governance issues a new memorandum is be produced. This will need to be reviewed before any engagement with this process, if approved by CDG.  **European Cleft Palate Craniofacial Association Congress (ECPRA 2019), Utrecht, Netherlands from 12-15 June**  Crane are presenting their experience on collecting data in the UK:  Friday 8:50 am – Scott Deacon: What and when to measure in cleft care: my experiences in the UK. |  |
| **7. Quality Dashboard** | **Proposed changes by Methods**  A Cleft Quality Dashboard Table to look at the proposed by Methods and CDG changes for discussion was circulated prior to the meeting. Changes for discussion were annotated for each indicator.  The proposed changes were discussed within the group and noted by IS. The proposed changes will be sent to Methods and SvE will await a response. |  |
| **8. Research** | **Report from Bristol (JS)**  (*See appendix 1.)*  **Report from Clinical Studies Group, Cleft Multi-Disciplinary Collaborative (David Sainsbury) and Early Career Research Group (Stephanie Van Eeden)**  *(See appendix 2. & 3.)*  **Manchester, CTG & Young Researchers Group** |  |
| **9. Feedback from Cleft Centres (UK)** | **West Midlands (IS)**  The surgical team are currently at full strength, having appointed a new full time surgeon. Despite having stability for 9 years, the centre is about to lose almost their full Psychology team. They will be replaced on an internal rotation but this may bring some challenges. Nursing is currently also challenged. However the centre is financially stable and hitting the required targets.  **Bristol (SDC)**  Bristol have recruited a new surgeon but have one surgeon on long term sick leave requiring surgery. Full bed lists are being cancelled. This is a frustrating period for the Centre, as beds cannot be provided for patients. The Clinical Coordinator is due to retire in the current month (May 2019); she may come back part-time, but it is predicted that full retirement fill follow shortly after. The head CNS and Psychologist are also due to retire shortly.  SDC is currently trying to restructure the outpatient service, as several spokes are located 5/6 hour drives away.  **Spires (GP)**  Spires have had a large amount of bed cancellations, with some occurring on the day of surgery.  In Salisbury, financial issues are the main challenge, but the budget for this year has been matched to the outgoing from the previous year.  A Succession planning meeting is due to take place in September; the centre hopes to recruit some of the next generation of nurses.  The centre are currently undertaking a service review for Guernsey, looking at the challenges of providing care to an island.  **CleftNet East (JS)**  CleftNet East have had issues with bed cancellations. The manager for the MDT his on maternity leave and is yet to be replaced. Half of the Paediatric Dentistry Team have left, causing knock on effects. Funding for the research assistant has been maintained.  **Trent (LB)**  There has been a 20% drop in cleft births in the East Midlands. Trent are now having to cancel lists due to a lack of operative patients.  DS reported that Scotland had seen a 15% drop in cleft births.  **Wales (HE)**  Thomas O’Neil, the replacement surgeon, started on 1st May and completed his first list on 16th May. The centre have had success in their WHISC funding, securing a bid for 6 years. They have received investment for the MDT, one session of Paediatric dentistry, one session of ENT, 5 session of a surgeon, administration, non-cleft EPD and a CNS. Wales are now looking to recruit a second surgeon within the next 6 months. There are some difficulties with the adult case load and the current job plan does not accommodate for adult work; an adult surgeon is required.  **South Thames (KlM)**  South Thames have had had increased but predicted demands across all services in both adult and paediatrics, resulting in some outsourcing within the network. Staffing pressures are easing due to investment across all specialities. A fourth surgeon is now in place and a MDT business case has been produced for a fifth surgeon, psychology and speech and language therapy. The CNS and psychology team have expanded. A FY3 Junior support is due to start in the summer. The centre have an OMFS STR on rotation from KSS in training. Their recent TIG has been appointed to Birmingham, leaving the centre available for the next round of TIGS. Two long serving CNSs have retired, but recruitment to fill these posts has already taken place. Access to local Speech and Language therapy services remains a challenge.  **Northern and Yorkshire**  **Newcastle (PH)**  The new CEO is keen on promoting nursing staff and non-medical staff, there is some concern that the medical staff are feeling excluded. The cleft service are thinking about the proximity and travelling distance for some of their spokes. Staffing has remained stable, but the team are aware that some CNS’s are coming towards retirement age. Newcastle are pushed for beds, with a few lists being cancelled. There is some suspicion that funding might be withdrawn from cleft services.  **North West, Isle of Man and North Wales(VB)**  The team appointed to their orthodontic vacancy in April, but unfortunately the individual withdrew their acceptance. The team are now recruiting again, whilst looking for alternative ways to support the orthodontic service. The cleft fellow has been in post for a month,-this is positive as it has allowed the team to think about succession planning and upcoming retirements. The Welsh commissioners have been in contact, requesting a meeting. NWIOMNW are not having any bed issues as in Manchester, the cleft beds have been moved from a long stay ward, into a short stay ward. VB suggested this model to other centres. The centre will be hosting the Norcleft event in November.  **Scotland**  Scotland’s surgical staffing is at full capacity, with three surgeons now in post. They are now looking at further coverage across Scotland for MDT clinics. The loss of administrative support in the centralised support service was raised with the commissioner, and they are now doing a report over all services. The Cleft Care Scotland Network has interviewed for a new Clinical Lead post. It is hoped that the new CL will look at the requirements for auditing, with a view to submitting data to CRANE.  **North Thames (NH)**  They have just appointed a Lead Nurse; she has gone on maternity leave but will be returning after 6 months. An additional nurse is due to start maternity leave in June. The hospital are trying to help out with other tasks to help support the service. A surgeon has dropped to half time; consultants are now filling this theatre time. In the long term, the plan is to introduce someone new into the service, whilst trying to find a replacement. Paediatric dentistry is down on consultants, having received a resignation. One calibrated clinician, whom also covers theatres, is covering the clinic. NT are struggling to get together calibrated data for the dashboard and CRANE, but patients are being seen by a PD. A member of staff is due to leave from the Psychology service. Recommendations state that there should be one Clinical Psychologist per 50 patients; North Thames are very under resourced. SLT are doing well but have some staff on maternity leave. |  |
| **10. Feedback from CLAPA** | CLAPA Fundraising Manager, Toni Kitchingham is to be interim CEO from late August, whilst CC is on maternity leave. CC is due to return n early July 2020. TK will be attending CDG meetings in CC’s absence. CLAPA will be advertising for TK’s replacement as Fundraising Manager shortly.  The team have recently moved into serviced offices in Cambridge Heath. The staff have been managing the move themselves, so subsequently are now having to play catch up with other tasks. CC invited the group to visit the new office if they wish. The team have also moved to a cloud based server.  The financial situation is improving; they are not within their reserves policy (3-6 months), but are on target to be there within 12 months.  PH stepped from the Trustee Board last year, and they have appointed two new clinician trustees; Jenny Williams and David Drake. They have also gained a new HR trustee, Emma Howles.  CLAPA will be having their annual conference in Glasgow on 14th September. CC thanked individuals who have sent their abstracts and reminded the group that the deadline for abstract submissions is 30th June 2019.  CLAPA are having to register for VAT, so buyers will soon need to fill in a form when making purchases online.  SvE questioned if it would be useful to have a referrals proforma, to be used across the country, on the CLAPA website for adult patients returning to the service. CC stated that this would be something that CLAPA are willing to do. Kenny Ardouin is in the process of meeting individual teams to discuss their adult patient situation. CC asked who would be a useful person for Kenny to speak with regarding the proforma. SvE suggested that KA could present his findings to the CDG. | 10.1 CC is to ask Kenny Ardouin to present information about adult patients at the next meeting |
| **11. Training** | No update received from Norma. Interviews for two fellows are due to take place on 28th June |  |
| **12. Data sharing** | Document circulated prior to the meeting. |  |
| **13. Any other business – CDG and dates of next meeting** | VB discussed the tricentre/quadcentre audit. Trent will be hosting their quadcentre audit in November. This will be in a non-hospital venue and they have an external speaker booked to attend, both of which have costs attached. VB raised that hosting hospitals are responsible for taking on the costs of the event, which can be a burden on the unit, and affect the quality of the day. VB asked the group their experience of this, and questioned whether it would be reasonable to approach the Craniofacial Society regarding aid with costs for tricentre/quadcentre audits. PH stated that if the costs could be justified that it is beneficial towards cleft training, then it would be reasonable to ask for help, but he felt that it would be hard to prove this as beneficial.  SDC and Bristol are turning their tricentre day into a Quality Improvement day, as it fits within their governance of running a cleft service.  NH asked about paediatric dental calibration courses and was informed by JS that the next course will be a full day in January 2020. |  |

**The next meeting of the Cleft Development Group will take place on Monday 11th November 2019 at the Royal College of Surgeons of England**

**Appendices**

***Appendix 1.***

# Cleft Development Group 17th May 2019

Summary of key milestones since the November 2018 CDG Meeting**.**

* All sixteen cleft teams have now joined the study and are actively recruiting. To date these teams have recruited 7910 (November 2018: 7129) individuals from 2812 (previously 2536) families have been recruited (as of 16/04/2019).

Number of antenatal participants = 354 (previously November 2018: 262)

Number of antenatal families = 136 (108)

Number of postnatal participants = 5068 (4599)

Number of postnatal families = 1765 (1603)

Number of 5-year participants = 2487 (2268)

Number of 5-year families = 911 (825)

* All sites are now recruiting, however there have been staff changes at Salisbury, Manchester and Birmingham which has caused some disruption. New staff have been retrained and supported by the operations team. Despite this recruitment rates have remained consistent. Birmingham will be monitored as research nurse time has recently been reduced which may affect recruitment rates going forward.
* Antenatal recruitment is totally surpassing our expectations. The collection of cord blood from the mother at time of delivery allows measurement of the exposures of the mother and infant with cleft during pregnancy. We have now received 105 (previously 83) samples of cord blood. We currently have 100+ maternity units approved for this across the UK. These are all ready to collect cord blood and there are more to follow.
* We have received ethical and HRA approval to enable participants to complete follow-up questionnaires online. We are currently in the final development stages of the questionnaires and plan to make them available online in the summer.
* We continue to be pleased with completion rates for the surgical forms and appreciate the work that many of the teams undertake in this area. Our surgical form return rate for first surgery is now 92% (1256/1361).
* There are increasing costs and ever-changing goal posts being set by NHS Digital. We have therefore decided to put our application for NHS Digital mortality, cancer and tracking data on hold. We can obtain updated address data (tracking data) directly from the cleft teams and numbers previously obtained for cancer and death data were extremely small. It was therefore agreed we should focus efforts elsewhere for the time being. Following the new criteria set by the National Pupil Database (NPD) and the Office of National Statistics (ONS) to obtain education data we are working closely with the university to develop a “Data Safe Haven”. This will enable us and other researchers across the university to access NPD data in a secure environment which meets NPD and ONS guidelines. Before an application can be submitted, Safe Researcher training must be undertaken. Kerry Humphries and Amy Davies will attend a training session in May 2019. We continue to use a range of approaches to determine phenotype data, including linking to medical records held by cleft teams, obtaining extracts from cleft databases or visiting the cleft teams and collecting the data from the medical records. To date we have successfully completed our annual collection of phenotype data at four cleft teams, have set up processes with another eight cleft teams and will continue to work with the other four teams to establish linkage to their cleft records. Although extremely time consuming, it has been necessary for us to obtain phenotype data in this way because of the slow progress in linking to the CRANE database. A response to CRANE’s letter was sent in December 2018 asking for a breakdown of charges. We have yet to receive a response. Scott Deacon has recently agreed to do a “one off” (free of charge) collaborative project to validate phenotype data held within the Cleft Collective and CRANE.
* The Collective Speech and Language Study (CC-SL) is nested within the Birth Cohort study. Twelve sites are currently recruiting, a further two have approval to recruit but are unable to do so at this stage because of limited research nurse capacity. We are currently progressing the approvals process with Belfast and they hope to start recruiting soon. The research and development team for the one remaining site have declined to be involved despite interest from the clinical team. The CC-SL study is also impacted by the changes in staffing at Salisbury, Manchester and Birmingham with regards to recruitment. The CC-SL study was developed with the SLTs and all were involved in agreeing what data would be collected and when. The study was also designed around existing clinical care pathways to reduce patient burden and to maximise the opportunities for data collection. Recruited to date: 713 (633) individuals from 356 (316) families. Two hundred and thirty recordings have been captured with the LENA recordings of children’s vocalisations and interactions with parents at age 13 months. Two hundred and sixteen assessments have been returned for children aged 18 or 24 months and 108 have been returned for children aged 36 months. Recruitment and data collection are going well, and so far, attrition is minimal.
* Data are continually being cleaned and prepared ready for analysis to enable researchers to use the resource. A detailed dictionary explaining the data that is available online and updated monthly (<http://www.bristol.ac.uk/dental/cleft-collective/professionals/access/>). The Cleft Collective Project Management Group have received and approved six proposals to use Cleft Collective data in the last 6 months. All approved research proposals are now logged on the website: <http://www.bristol.ac.uk/cleft-collective/professionals/access/projects/>. See appendix for research proposals received to date.
* Team members are continuing to engage in ongoing PPI and public engagement activities (e.g. in relation to the development of questionnaires, the content of the website, through conferences, social media, participant feedback and newsletters). As part of their efforts to involve real people personally affected by cleft throughout the development of their research, the Cleft Collective have worked with CLAPA to put together a consultation group made up of people from our community. The [CLAPA Cleft Collective Consultation Group](https://www.clapa.com/treatment/research/the-cleft-collective/) gives people affected by cleft a chance to feed their own ideas and experiences directly into this project, which will impact the lives of families like theirs around the world. Their interest in research together with their personal experiences and knowledge give a unique perspective to the researchers and ensure the programme continues to value and consider the interests of both the research and cleft communities. On Saturday 23rd March, The Cleft Collective welcomed CLAPA’s Cleft Collective Patient Consultation Group to Bristol for a day of presentations and discussions around the next phase of this exciting initiative. The report is well worth reading and reflects the healthy relationship we have developed on this important aspect of the project. <https://www.clapa.com/news-item/a-day-at-the-cleft-collective/>

In addition, we are seeking novel ways to engage the public in our research findings and are planning a series of YouTube videos to achieve this.

* We have also developed a further animation which will be the backbone for specific information we would want to disseminate to the public. This provides simple and clear explanations on complex subjects such as the value of epigenetics in the Cleft Collective study. We will create a library of these animations if further core funding is obtained to extend the study.
* We have published and disseminated our Spring 2019 Newsletter where we have several achievements to celebrate.

<http://www.bristol.ac.uk/dental/cleft-collective/news/2019/spring19newsletter.html>

* There are ongoing collaborations with the various cleft Clinical Excellence Networks (CEN), including surgeons, psychologists, nurses, speech and language therapists and orthodontists. Members of the team meet with clinicians on a regular basis for the purpose of ensuring that data collection is capturing all clinically important variables and is feasible within clinical practice.
* Team members continue to progress the research funding strategy and to develop initial funding applications which will both expand the dataset and use it to address clinically relevant research questions. With regards to obtaining funding to expand the dataset, we are preparing a bid to the MRC Partnership Grant scheme and are very clear that we cannot simply put a bid forward to extend the study. Rather, we are entering a new phase with three vital and interconnected elements to this:

1. Collection of long-term outcomes which are vital to understanding clefting. The first phase of the Cleft Collective is limited to a study of aetiology and initial parent responses to having a child with a cleft. We need to collect the outcome data for these children at ages 3,5,10 and beyond.
2. It has become clear from our published work which shows that methylation patterns for the three main subtypes of cleft are different. We need to build a sufficient sample size to allow sub-phenotype analysis. For example, bilateral clefting of the lip and palate comprise 10% of all clefts and at best we would only expect to see 100 of these children born in the UK each year. Other aspects such as laterality and other rare types of clefting need to be analysed separately. All the future analyses that we do will need to consider cleft type as fundamental.
3. Developing systems for ensuing accessibility to the resource for the international cleft clinical, academic and patient communities This will mean that we have the systems in place to enable access and respond to requests for data. We will also develop partnerships to promote the resource. Ultimately this is what will make the resource self-sustaining and we need to show MRC that we can do that by the end of the funding period.

* With regards to the third aim, we have a team of external co-applicants comprising Reader Fran Rice (Cardiff), Professor Stephen Richmond (Cardiff), Mr David Sainsbury (cleft surgeon), Ms Lucy Southby (speech and language therapist and NIHR Doctoral Fellow and early career researcher), Professor George Wehby (Iowa), Associate Professor John Thompson and Dr Elizabeth Leslie (both in the early stages of establishing clinical cohort studies of children born with clefts in New Zealand and the US respectively), Claire Cunniffe (CEO of CLAPA) and Ana Hobbs (parent of a child born with a cleft). This is in addition to the Bristol co-applicants. Together, this co-applicant team is developing five bids which will use Cleft Collective data to address clinically relevant research questions around mental health, face shape, outcomes from surgery, genetic basis of cleft and outcomes in education for the population of children born with clefts.
* In addition, we have secured support from the international research community who are potential future users of the dataset and who will join the wider list of named collaborators on this bid and will also be one of our major routes for developing awareness of the resource to external users. To date, we have received letters of support for this from academics at universities in Copenhagen, Pittsburgh, Oslo, Gothenburg, Bergen, Capetown, Iowa, Edinburgh, Dundee, Cardiff and Manchester as well as UWE and the Sanger Institute.
* We hope to include the remaining ‘spend out’ in our projected costings for the MRC bid and a letter of support from the Scar Free Foundation explaining this, we believe, would substantially improve our chances of success and would enable us to show we have funding to continue the work for another five years.
* We are also developing a separate bid to the Health Foundation Insight Programme to address the increasing costs associated with linkage and to address research questions around variation in cleft care across the region and associations with outcomes.
* We plan to start generating genotype data in June 2019 with funding kindly provided by the Scar Free Foundation for all the non-syndromic cases and their families within our cohort. We have been awaiting version 3 of the Global Screening Array (GSA) so that all our samples can be run on the same platform for comparison. This will be an immensely important resource for future work exploring the genetic and non-genetic causes of cleft and cleft-related outcomes.
* The New Zealand case control study (led by Dr John Thompson) has been funded ($NZ 1 million) and is using questionnaires, ethics, PIS and SOPs developed by the Cleft Collective. The data collection and recruitment has only just started and will run over four years. This delay has inevitably been caused by the difficulties with ethics and research permissions. (Dr Thompson is one of the co-applicants in the MRC bid and the New Zealand study will provide a useful source for replication.)
* Longitudinal data relating to the three themes of genetics, speech and language and psychology continue to be collected for the study. Dr Yvonne Wren and Dr Sarah Lewis continue as Speech and Language Theme and Genetics Theme leads respectively.
* We have discussed the Research Tissue Bank with the University’s research governance team and Dr Sue Ring (Head of Laboratories and Executive Director of ALSPAC). A Research Tissue Bank ethics application will be submitted when we have further funding in place.
* Sammy Berman, a Fulbright Scholar, is currently carrying out her MSc in Public Health and hopes to use Cleft Collective data for her dissertation, "Transition to school: Evaluating the psychological wellbeing and behavioral development of children with cleft lip and/or palate at age 5 and 8". Sammy will be supervised by Gemma Sharp, Evie Stergiakouli and Sarah Lewis.
* Nikolas Tasiopoulos is a Computer Scientist completing a 6-month internship with the Cleft Collective with the aim to build a database and website containing detailed information on biological factors involved in cleft.
* Christina Dardani won the Arnold Huddart Medal at the Craniofacial Society of Great Britain and Ireland with seminal work on educational attainment and genetics ‘*Cleft lip/palate and educational attainment: Cause, consequence or correlation’*. The Arnold Huddart Medal was established in 1990 for the encouragement of original and promising research papers at the Annual Scientific Conference. Christina’s project was supervised by Gemma Sharp.

# Publications and Conferences since November 2018

# Publications

1. **Howe, L.J**., Richardson, T, Arathimos, R, Alvizi, L, Passos-Bueno, MR, Stanier, P, Nohr, EA, Ludwig, K, Mangold, E, Knapp, M, Stergiakouli, E, St Pourcain, B, **Davey Smith, G, Sandy, J**, **Relton, C**, **Lewis, S.J.**, Hemani, G & **Sharp, G.C**., (2019). Evidence for DNA methylation mediating genetic liability to non-syndromic cleft lip/palate. *Epigenomics*, 11(2), 133-145. doi: <https://doi.org/10.2217/epi-2018-0091>
2. Sainsbury, D.C.G., **Davies, A., Wren, Y., Southby, L.,** Chadha, A., Slator, R., **Stock, N.M.** and the Cleft Multidisciplinary Collaborative (2019). The Cleft Multidisciplinary Collaborative: Establishing a network to support cleft lip and palate research in the United Kingdom. *Cleft Palate-Craniofacial Journal*, 56(4), 502-507.

<https://doi.org/10.1177/1055665618790174>

1. **Howe LJ, Sharp GS**, Hemani G, Zuccolo L,Richmond S, **Lewis SJ**. (2019) Prenatal alcohol exposure and facial morphology in a UK cohort. *Drug and alcohol dependence*. 197, 42-47. doi: <https://doi.org/10.1016/j.drugalcdep.2018.11.031>

# Invited Talks and Keynote Addresses

1. **Davies, A., Wren, Y.E.,** and The Cleft Collective team (2019) *‘Overview of The Cleft Collective Resource’*, Annual Conference of the Craniofacial Society of Great Britain and Ireland. Surgeons CEN. London, April 2019.
2. **Davies, A., Lewis, S.,** and The Cleft Collective team (2019) *‘Overview of The Cleft Collective Resource’*, Annual Conference of the Craniofacial Society of Great Britain and Ireland. Psychology CEN. London, April 2019.
3. **Davies, A., Lewis, S.,** and The Cleft Collective team (2019) *‘Overview of The Cleft Collective Resource’*, Annual Conference of the Craniofacial Society of Great Britain and Ireland. Orthodontists CEN. London, April 2019.
4. **Davies, A., Wren, Y.E.,** and The Cleft Collective team (2019) *‘Overview of The Cleft Collective Resource’*, Annual Conference of the Craniofacial Society of Great Britain and Ireland. Speech and Language CEN. London, April 2019.

# Oral conference presentations

1. **Lewis, S.** (2019) *‘Using genetics to identify causal risk factors and biological mechanisms for cleft lip and palate.’* Rīga Stradiņš University International Conference on Medical and Health Care Sciences Knowledge for Use in Practice, Riga, April 2019.
2. **Humphries, K.**  **The Cleft Collective team** (2019) *‘The Cleft Collective’* Annual Conference of the Craniofacial Society of Great Britain and Ireland. London, April 2019.
3. Dardani, C. (2019). ‘*Cleft lip/palate and educational attainment: Cause, consequence or correlation’* (Arnold Huddart winner). Annual Scientific Conference of the Craniofacial Society of Great Britain and Ireland. London, April 2019.
4. **Stergiakouli, E** on behalf of the Visigen Consotrium. (2019). ‘*Novel genetic loci affecting facial shape in humans*’. Annual Scientific Conference of the Craniofacial Society of Great Britain and Ireland. London, April 2019.
5. **Lewis, S.,** Howe, L.J., **Sharp, G.C.,** Richmond, S. (2019). ‘*Prenatal alcohol exposure and facial morphology in a UK cohort*’. Annual Scientific Conference of the Craniofacial Society of Great Britain and Ireland. London, April 2019.
6. Seifert, M., **Wren, Y.E., Davies, A.,** McLeod, S., **The Cleft Collective Team.** (2019). ‘*Parents’ ratings of intelligibility in 3-year-olds with cleft lip and/or palate using the Intelligibility in Context Scale: Findings from the Cleft Collective Cohort Studies’*. Annual Scientific Conference of the Craniofacial Society of Great Britain and Ireland. London, April 2019.
7. Baker, S., **Wren, Y.,** Cooper, F., Zhao, F. & Extence, H. (2019) *Is there a relationship between conductive hearing loss and cleft speech characteristics in children with cleft palate?* Craniofacial Society of Great Britain and Ireland Annual Conference. London, April 2019.
8. Fell, M., **Davies, A., Wren, Y.E.** (2019). ‘*Exploring current trends in cleft surgery across the UK*’. Annual Scientific Conference of the Craniofacial Society of Great Britain and Ireland. London, April 2019.

# Conference posters

1. Davies, Alex., **Davies, A., Wren, Y.E.**, Deacon, S., Cobb, A., Chummun, S. (2019). ‘*Exploring the relationship between palatal cleft type and width and the use of relieving incisions’* [Poster] Annual Scientific Conference of the Craniofacial Society of Great Britain and Ireland. London, April 2019.

# Awards and prizes

1. **Christina Dardani:** Arnold Huddart medal winner at the CFSGBI annual conference for an original and promising research paper.

# Grants

1. **Gemma Sharp:** Prenatal influences on childhood health: what role for mums and dads? (June 2019 – June 2022, MRC New Investigator Research Grant) £677,364. MR/S009310/1

# Other achievements

1. **Yvonne Wren** has been invited to join the scientific committee for the World Cleft Congress in Edinburgh 2021
2. **Sarah Lewis** has been invited to join the awards and prize giving committee for the World Cleft Congress in Edinburgh 2021
3. **Yvonne Wren** has been invited to join the Research Council for the Scar Free Foundation

***Appendix 2.***

**Update from the Cleft Multidisciplinary Collaborative- David Sainsbury**

·      ***Unrepaired Cleft Palate Project***

Data collected from Leeds, Liverpool, Manchester, South Wales, Dublin, South Thames, Newcastle

Oral presentation at recent CFSGBI 2019.

Future plans:

1.   1. Psychology and nursing collaborators to perform qualitative element of project.

2.   2. Verify current data collection via cross-referencing with locally maintained databases to identify which patients do not meet dashboard criteria for timing of lip and palate surgery eg death, associated morbidities, poor growth, non-verbal

·      ***National Review of Early Management and Speech Outcomes in Children with Robin Sequence (UK)***

Centres involved: Liverpool, Oxford, Salisbury, Belfast, Newcastle

Accepted for oral presentation at the European Cleft Palate Craniofacial Association, Utrecht, June 2019.

 ·       ***Systematic Review: Non-Interventional Factors Influencing Outcomes in Velopharyngeal Function in Initial Cleft Palate Repair (Sainsbury, Williams, Mullen, Chadha, de Blacam, Wren, Hodgkinson).***

Protocol re-submitted to the journal *Systematic Reviews* following minor revisions.

Current status:1836 articles retrieved. Levels I (title screening), level II (title/abstract screening) completed. Level III on-going (full text screening of 650 articles). Planning to start data extraction in June 2019.

***Appendix 3.***

**Update from Early Career Researchers Group (ECRG) - Stephanie van Eeden**

* New chair and vice chair – Stephanie van Eeden and Ambika.

This year we had an update from NIHR about changes to Fellowships and funding. Currently two members of the group undergoing NIHR doctoral fellowships (Stephanie van Eeden  and Lucy Southby). At least one member applying in this year’s rounds for the Pre-doctoral fellowship (Caroline Williams).

* Membership has been SLT and surgeon heavy (reflected in the NIHR fellowships – all SLTs!) but following GDPR rules we are in the process of a re-application process to the group and will actively encourage people from other disciplines.
* The group have been carrying out a systematic review into BCLP outcomes (multidisciplinary) this year; this is ongoing.
* In conjunction with the Cleft Multidisciplinary Collaborative (CMC) members of the group have also been involved in national audits/evaluations of *Purposefully unrepaired cleft palates* (presented at Craniofacial this year) and *National review of early management and  SLT outcomes in Pierre Robin Sequence* (to be presented at the European conference)

As we have developed, the roles and overlap of the ECRG group and CMC have become clearer; the ECRG deals with the process of research (including some training) and helps develop ideas and provide early support for applications for research funding; the CMC is a group that actively collects and collates data for national projects and comes together to present and/or publish these. We would expect that members of the ECRG are automatically part of the CMC and can take an active part in any projects as they wish; however, people may join the CMC for one project whilst a trainee to gain experience of working on a research project but may not necessarily be a member of the ECRG as their main work commitment may not be to cleft.