

# The Cleft Multidisciplinary Collaborative: Establishing a network to support cleft lip and palate research in the United Kingdom

## Abstract

*Background:* As a growing paradigm of health research, trainee collaboratives can influence clinical practice through the generation of cost-effective multicentre audit and research projects. The aims of the present article are to outline and discuss the establishment of a multidisciplinary collaborative in the context of cleft lip and/or palate (CL/P).

*Methods:* The Cleft Multidisciplinary Collaborative (CMC) was formed in April 2016 under the overarching supervision of the National Institute for Health Research. Membership of the CMC is open to all members of the CL/P multidisciplinary team, who are encouraged to submit ideas for new research projects which will benefit clinical practice.

*Results:* To date, 48 clinical participants are involved in the CMC. These participants represent all 17 cleft teams from the UK and encompass a wide range of disciplines. [The CMC has undertaken two major projects thus far. The first involved collection of phenotype data to support a national cohort study. The second, still in progress, is a systematic review investigating factors associated with outcomes for velopharyngeal competence following cleft palate repair.](#)

*Conclusions:* The concept of a multidisciplinary collaborative in CL/P has been demonstrated, through the generation of a UK-wide network of committed clinicians and researchers, and the effective [undertaking](#) of two large research projects. As the CMC gathers momentum, it hopes to attract funding to support its activities, to promote more involvement from the allied health and nursing professions, to encourage a more ingrained research culture within the CL/P community, and to promote the wider ambition of a global collaborative.

*Key words:* trainee, collaboration, multicentre, research, audit, multidisciplinary

## 28 Introduction

29 The first trainee collaborative, the West Midlands Research Collaborative (<http://wmresearch.org.uk>), was  
30 established in 2007 by a group of general surgical trainees, with the aim of changing clinical practice through the  
31 generation of multicentre audit and research projects. Their success has been recognised, and other collaboratives  
32 have been established in the last decade, both across a range of surgical disciplines and within other medical  
33 specialities (Kolias et al., 2013; Skerrit and Hall, 2015). Through these supportive networks, clinical trainees are  
34 able to design, organise and disseminate both small and large scale collaborative projects across a wide  
35 geographical area (Nepogodiev et al., 2017).

36 As a growing paradigm of healthcare research, several studies have sought to evaluate the range of activity of  
37 trainee collaboratives (Bhangu et al., 2014; Dowswell et al., 2014; Skerrit and Hall, 2015; Jamjoom et al., 2016;  
38 Mehta et al., 2017; Nepogodiev et al., 2017). One large observational study of 24 surgical trainee research  
39 collaboratives in the United Kingdom (UK; Jamjoom et al., 2016) identified more than 80 projects, 41 percent of  
40 which had been completed and 59 percent of which were currently running or under development. Of these  
41 projects, the most common type of project was clinical audit (46%). However, a wide range of other projects  
42 were also identified, including randomised trials, surveys, cohort studies, and systematic reviews. A total of 35  
43 publications attributed to the collaboratives were retrieved. These ranged from peer-reviewed journal articles to  
44 case reports, and had achieved 181 citations in all, with a median impact factor of 2.1 and a median h-index of 5.  
45 The median number of authors on each publication was seven. These findings demonstrate the wide-ranging  
46 outputs and potential impact of trainee collaboratives.

47 Several advantages of trainee collaboratives have been identified. First, and from a methodological standpoint,  
48 a multicentre approach limits bias and increases the external validity of results (Bhangu et al., 2014). Second,  
49 trainee collaboratives offer the opportunity for high quality research to be carried out with few setup or running  
50 costs, and with minimal infrastructure (Mehta et al., 2017; Nepogodiev et al., 2017). While the level of input  
51 required from consultants is low, they may also benefit from adopting trainee projects into their portfolio (Skerrit  
52 and Hall, 2015). Third, high relevance to clinical practice is assured, increasing the likelihood that findings will  
53 be translated into practice and have an impact on patient outcomes (Dowswell et al., 2014; Skerrit and Hall,  
54 2015). Finally, there are many benefits for the trainees themselves. Collaborative models make research  
55 opportunities more accessible to trainees at an earlier stage of their career, and offer trainees experience in

56 protocol writing, gaining ethical approvals, contributing to funding applications, interaction with professionals  
57 from other disciplines, and involvement in peer-reviewed publications (Bhangu et al., 2014; Dowswell et al.,  
58 2014; Skerrit and Hall, 2015). Equally, trainees can gain a sense of greater project ownership and widespread  
59 recognition for their efforts (Mehta et al., 2017). In combination, these strategies may serve to engrain a research  
60 culture into routine clinical practice (Bhangu et al., 2014).

61 Existing evidence suggests that trainee collaboratives can provide a valuable contribution to knowledge through  
62 the collection of multicentre research data, and supports the case for collaborative-led audit and research to be  
63 trialled within the field of cleft lip and/or palate (CL/P). Research within the field of CL/P has long been  
64 criticised for its lack of multicentre studies (Stock et al., 2018), and input from trainee collaboratives may  
65 therefore help to overcome this ongoing challenge. Trainee collaboratives have historically been medical in  
66 nature, while CL/P requires a wider multidisciplinary approach. Further, centralised organisation of CL/P  
67 services in the UK and the specialist knowledge of the clinicians delivering this care lends itself well to a  
68 trainee collaborative model. Although the majority of clinicians working in the field would not necessarily  
69 describe themselves as ‘trainees’, many are still developing their specialist expertise, are keen to participate in  
70 multicentre research, and wish to gain further research experience. Most collaboratives are unfunded but  
71 productive, and therefore cost effective by contributing to the evidence base/advancing knowledge without  
72 the need for grant money. Their success relies on individuals committing their time and effort to a project  
73 unpaid but in exchange for the advantages described earlier. Dividing the work and time required between the  
74 members of the collaborative reduces the time required from any individual, making a large project  
75 manageable. In particular, a collaborative approach reduces the costs and complexities of multicentre working  
76 as individuals local to each centre can contribute rather than a single researcher or research team having to  
77 travel.

78 The aims of the present article are to outline the establishment of a multidisciplinary collaborative in the context  
79 of CL/P, to demonstrate the Cleft Multidisciplinary Collaborative’s (CMC) successes to date; and to discuss the  
80 future potential of the CMC.

## 82 **Methods**

83 The National Institute of Health Research (NIHR) funds health and care research in the UK. As part of the NIHR  
84 structure, the NIHR Clinical Research Network (CRN) Coordinating Centre manages the provision of facilities  
85 and people in 30 clinical specialties. One of these specialties (CRN: Children) manages fourteen Clinical Studies  
86 Groups (CSGs), the aims of which are to promote high quality research in conditions specifically affecting  
87 children. The Cleft and Craniofacial Conditions CSG was formed in May 2012, and later founded the Early  
88 Career Researcher Group (ECRG) to support and develop clinicians interested in building their research skills.  
89 The CMC was formed in April 2016 as a sub-group of the Cleft and Craniofacial Conditions ECRG (Figure 1).  
90 Building upon existing UK surgical trainee collaboratives, and expanding the remit to allow all clinical disciplines  
91 to contribute, the goal of the CMC was to develop a national network and infrastructure for delivering multicentre  
92 audit and research in the field of CL/P.

93 From its inception, the CMC has therefore been open to all members of the CL/P multidisciplinary team (MDT)  
94 interested in cleft-related research, including and not limited to oral and maxillofacial, Ear, Nose and Throat and  
95 plastic surgery; paediatric and restorative dentistry; orthodontics; speech and language therapy; psychology; and  
96 nursing. Additionally, clinicians with a desire to incorporate clinical research into their roles can be at any stage  
97 of their clinical career. Interested parties are advised to read and agree to the terms of reference and authorship  
98 policy. It is also recommended that if a clinician expresses an interest in becoming involved with a CMC project,  
99 they first gain the approval of their Training Programme Director and Assigned Educational Supervisor within  
00 their designated training scheme. For those invited professions who do not have this management structure in  
01 place, approval from their line manager is required. As standard, clinical participants should complete the Good  
02 Clinical Practice training provided by the NIHR prior to undertaking research.

03 Recruitment to the CMC is performed using a variety of methods. Initially, these included a direct email to  
04 potentially interested clinical participants, an email to the leads for the various CL/P specialist clinical networks  
05 who subsequently cascaded this information to their membership, advertisements at relevant meetings and  
06 conferences, notices posted in specialist information bulletins and websites (such as the Craniofacial Society for  
07 Great Britain and Ireland, the British Association of Plastic and Reconstructive Aesthetic Surgeons and the  
08 Association of Oral and Maxillofacial Surgery), and via social media (@cleft\_collab). All of the above activities  
09 were performed once at the outset of the formation of the CMC during the spring/summer of 2016. Subsequently,  
10 deliberate recruitment activity has also been delivered via oral presentation at the annual congress of the

11 Craniofacial Society for Great Britain and Ireland. Here, specific emphasis was placed on recruitment from non-  
12 medical/surgical and non-dental/orthodontic disciplines. Another important factor is likely to be word of mouth.  
13 Since the CMC is unfunded, all involvement remains entirely voluntary, and with flexible participation as a  
14 fundamental principle.

15 Initial support and guidance is provided by senior academics and NHS consultants, with the day-to-day  
16 leadership and running of the CMC managed by a consultant 'guide' (DS). The CMC is also supported by the  
17 ECRG, which holds biannual face-to-face meetings allowing like-minded clinicians and researchers to discuss  
18 ongoing and potential projects, and to be given advice from experts on topics such as Patient and Public  
19 Involvement, gaining ethical approval and performing systematic reviews. The CMC generally operates as a  
20 project based, virtual group/network. For each project the project leaders use email, phone and web  
21 conferencing to develop the strategy and to keep in touch. Potential collaborators who have expressed interest  
22 are contacted using email to confirm their involvement and / or telephone if further discussion is required. This  
23 demonstrates that it is possible to perform multi-centre collaborative studies without direct meetings; such  
24 methodology potentially enables global initiatives. Other external support to date has been received from the  
25 Reconstructive Surgery Trials Network ([www.reconstructivesurgerytrials.net](http://www.reconstructivesurgerytrials.net)); the UK-based charity, the Cleft  
26 Lip and Palate Association ([www.clapa.com](http://www.clapa.com)); and the Cleft Collective research programme  
27 ([www.bristol.ac.uk/cleft-collective](http://www.bristol.ac.uk/cleft-collective)). Ideas for new projects can be submitted by any member of the CMC to  
28 stimulate discussion, and to collect useful feedback from the ECRG and the CSG. Ideas driven by the findings  
29 of the UK James Lind Alliance Research Priority Setting Exercise (Petit-Zeman and Cowan, 2013) for CL/P are  
30 particularly encouraged. The CMC also sits within the broader registry of the National Research Collaborative  
31 ([www.nationalresearch.org.uk](http://www.nationalresearch.org.uk)).

32 The core aims of the CMC are as follows: 1) To inspire clinicians to become involved in cleft related research;  
33 2) To establish a clinical specialist-led national network of those disciplines involved in cleft care to conduct high  
34 quality, multi-centre research, audit and quality improvement projects; 3) To provide a channel of communication  
35 and continuity allowing clinical participants to develop their involvement in research and audit projects as they  
36 undertake their training or develop their clinical careers; 4) To provide opportunities to develop research skills  
37 for the educational benefit of its members; 5) To attract national funding for research and audit work; 6) To foster

a collaborative spirit for national and international cleft-related projects; and 7) To keep clinical participants up to date with the latest research developments from the international community.

## Results

To date, 48 clinicians have expressed an interest in being involved in the CMC. These clinical participants represent all of the 17 specialist cleft teams in the UK, and encompass the following disciplines: plastic surgery ( $n = 16$ ), oral and maxillofacial surgery ( $n = 15$ ), restorative dentistry ( $n = 7$ ), paediatric dentistry ( $n = 4$ ), orthodontics ( $n = 3$ ), research nursing ( $n = 1$ ), speech and language therapy ( $n = 1$ ) and general medicine ( $n = 1$ ).

The CMC has been involved in two major projects thus far. The first of these was the collection of CL/P phenotype data to support the Cleft Collective Cohort Studies. The Cleft Collective is the world's largest CL/P research programme, an initiative of the Scar Free Foundation and supported entirely by voluntary donations. At the core of the Cleft Collective programme are two national cohort studies, with the overarching aim of investigating the biological and environmental causes of CL/P, the best treatments for CL/P, and the psychological impact of CL/P on those affected and their families (Stock et al., 2016). With data being collected from a variety of sources, and across a wide geographical area, some gaps in data collection are unavoidable. The CMC therefore took the opportunity to assist the Cleft Collective to collect phenotype data for those participants who had explicitly consented to their data being collected from medical records. This project will enable the Cleft Collective to backfill missing baseline phenotypes, and will help to validate phenotypic data already collected from different sources. The Cleft Collective developed a secure online method of entering and transferring this missing data, which were retrieved directly from medical records by members of the CMC. Following a pilot conducted in two UK cleft teams, this project was rolled out nationally across ten CL/P surgical sites, and achieved a data collection rate of between 68 and 100 percent. Due to the phased set-up of the Cleft Collective cohort studies, the amount of data requested at each surgical site varied. Data collected from this project will be cross-referenced with those data already held by the Cleft Collective to ensure accuracy. It is hoped that data collected by other relevant organisations can also be cross-referenced.

The CMC's second major project is a systematic review of factors influencing outcomes for velopharyngeal competence following cleft palate (CP) repair (PROSPERO project number: 51624). Velopharyngeal competence that supports normal speech production and the absence of fistula formation are early principal

66 outcome measures following CP repair (Smith and Losee, 2014). The objective of this systematic review is  
67 therefore to identify which pre-operative factors may support or hinder velopharyngeal competence following the  
68 primary CP surgery. This review is currently in process and will be documented soon.

## 70 **Discussion**

71 The aims of the present article were to outline the establishment of a multidisciplinary collaborative in the context  
72 of CL/P, to demonstrate the CMC's successes to date; and to discuss the future potential of the CMC. While the  
73 CMC is still in its infancy, the authors believe that the appetite for, and the concept of a multidisciplinary  
74 collaborative in the field of CL/P has been proven, through the generation of a UK-wide network of committed  
75 clinicians and researchers, and the successful delivery of two major research projects.

76 The CMC model offers an appealing antidote to numerous research-based challenges in CL/P, including the bias  
77 inherent in single-centre research, and high running costs (Bos et al., 2007; Bhangu et al., 2014; Mehta et al.,  
78 2017; Nepogodiev et al., 2017), as well as several benefits to consultants, large research projects, clinical practice  
79 and the clinical participants themselves (Bhangu et al., 2014; Dowswell et al., 2014; Skerrit and Hall, 2015;  
80 Mehta et al., 2017). The CMC offers opportunities for clinicians to learn and develop key research skills and to  
81 complete research projects that will result in tangible outputs. Some are now undertaking formal research training  
82 via a higher degree, in order to enhance their qualifications and improve their job prospects in a competitive  
83 market. This is especially important given that research activities are often subsidiary to clinical commitments,  
84 particularly in light of recent reforms such as the European Working Time Directive (Chapman et al., 2014). Not  
85 only do the CMC's efforts have the potential to impact directly upon patient care, but they also benefit the  
86 clinician for the remainder of their career through improved critical appraisal skills, continued desire for academic  
87 enquiry and a passion for research; success which can then propagate. Additional support from initiatives such  
88 as the CSG and ECRG help to demonstrate what a clinical academic career can offer and provide several stages  
89 of peer review and quality control to projects undertaken by the CMC.

90 Establishing a wide geographical network of collaborators is not without its challenges (Skerrit and Hall, 2015),  
91 and engaged, enthusiastic participants are prerequisites for a successful collaborative (Dowswell et al. 2014). In  
92 the case of the CMC's inaugural study, which collected phenotype data for the Cleft Collective research  
93 programme, the infrastructure was already established, and a support network already in place. Dowswell and



04 colleagues (2014) describe the requirement of a “critical mass”, and similar parallels can be seen with our  
05 experience of this study. While this was a relatively simple data collection task, it was vital to the future capability  
06 of the Cleft Collective programme to deliver meaningful results. Further, this inaugural study, in addition to the  
07 second project carried out by the CMC, demonstrated a clear potential for professional development and tangible  
08 outputs.

09 An ongoing priority for the CMC will be to increase the representation of disciplines other than  
10 medicine/surgery and dentistry/orthodontics in the CMC. Speech and language therapists, psychologists,  
11 nurses, and geneticists, as well as a number of other allied professions are all vital members of the clinical  
12 teams, and would bring a more holistic approach to the investigations carried out by the CMC; a unique feature  
13 of this collaborative when compared to previous trainee collaboratives. Discussions with members of these  
14 professions who are currently working in a junior specialist capacity suggest there is no lack of enthusiasm, but  
15 that a different professional development structure exists, in which expectations of, and capacity for research  
16 activity is more limited. A move toward a more ingrained research culture and the ongoing support of  
17 managers will be needed, in order to release clinical members of staff to participate in research activity. Some  
18 representation of speech and language therapy and nursing is currently evident within the CMC, and therefore  
19 identifying the ways in which these individuals have been successful in their involvement will inform future  
20 efforts to encourage more diversity. [While the CMC works to encourage greater involvement from the other  
21 professions in the MDT, consultation/feedback on specific projects from many of these professions can be  
sought from the CSG and ECRG where they are currently better represented.](#)

As the CMC continues to gain momentum, it is hoped that funding will become available to support future  
activities. Elsewhere, trainee-led trials are beginning to attract funding from organisations such as the NIHR, and  
the CMC is determined to continue this tradition. Furthermore, the CMC hopes to utilise the current impetus  
among the CL/P community to establish a more ingrained research culture, and to inspire full MDT involvement  
in future studies. In addition, the authors hope to capitalise on the momentum generated thus far, and aspire to  
create a global collaborative of clinical participants interested in CL/P and other craniofacial research. The  
authors would therefore welcome interest from professionals around the globe who are currently developing a  
specialism within cleft and craniofacial care.



## 22 Conclusions

23 The concept of, and the enthusiasm for a multidisciplinary collaborative in the field of CL/P has been  
24 demonstrated, through the generation of a UK-wide network of committed clinicians and researchers, and the  
25 successful delivery of two major research projects to date. With ongoing support from other organisations and  
26 networks, the CMC offers a platform from which clinicians, consultants, existing research projects and patients  
27 can benefit. The development of a global collaborative is a key future ambition.

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