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Adapting Elements of Cleft Care Protocols in Low- and Middle-income Countries During and After COVID-19: A Process-driven Review With Recommendations

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#### Abstract

*Objective*: A consortium of global cleft professionals, predominantly from low- and middle-income countries, identified adaptations to cleft care protocols during and after COVID-19 as a priority learning area of need.

Design: A multidisciplinary international working group met on a videoconferencing platform in a multi-staged process to make consensus recommendations for adaptations to cleft protocols within resource-constrained settings. Feedback was sought from a roundtable discussion forum and global organizations involved in comprehensive cleft care.

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Results: Foundational principles were agreed to enable recommendations to be globally relevant and two areas of focus within the specified topic were identified. First the safety aspects of cleft surgery protocols were scrutinized and COVID-19 adaptations, specifically in the pre- and perioperative periods, were highlighted. Second, surgical procedures and cleft care services were prioritized according to their relationship to functional outcomes and time-sensitivity. The surgical procedures assigned the highest priority were emergent interventions for breathing and nutritional requirements and primary palatoplasty. The cleft care services assigned the highest priority were new-born assessments, pediatric support for children with syndromes, management of acute dental or auditory infections and speech pathology intervention.

*Conclusions*: A collaborative, interdisciplinary and international working group delivered consensus recommendations to assist with the provision of cleft care in low- and middle-income countries. At a time of global cleft care delays due to COVID-19, a united approach amongst global cleft care providers will be advantageous to advocate for children born with cleft lip and palate in resource-constrained settings.

#### **Keywords**

comprehensive cleft care, low- and middle-income countries, COVID-19, circle of cleft professionals

# Introduction

Cleft lip and/or palate (CL/P) is the most common craniofacial congenital anomaly, occurring in approximately 1/700 live births worldwide (Mossey et al., 2009). If untreated, CL/P is highly problematic for children and their families as it gives rise to functional difficulties with speech, eating, social interaction and child development. It is well established that the best way to treat a child born with CL/P is a multidisciplinary team (MDT) of specialized professionals following a protocol of comprehensive cleft care (Kassam et al., 2020). Unfortunately, global inequalities exist, with provision and access to comprehensive cleft care differing depending on geographical location of birth (Sharratt et al., 2020). Low- and middle-income countries (LMICs) face unique challenges due to the existence of constrained resources (Ma et al., 2020) and data collected in 2014 estimated the backlog of untreated CL/P in LMICs to be more than 600,000 cases (Carlson et al., 2016).

On March 11<sup>th</sup> 2020 the World Health Organization (WHO) declared COVID-19 to be a global pandemic. This had a major impact on healthcare systems and services were accordingly reprioritized, with emergency and trauma services continuing but many elective procedures being delayed or postponed (American Cleft Palate-Craniofacial Association, 2020a, 2020b; Cleft Development Group, 2020). The pandemic has undoubtedly exacerbated the backlog of healthcare interventions for children born with CL/P, as they are for the most part regarded as planned elective procedures, although the magnitude of these delays on a global scale is yet to be fully appreciated (Stoehr et al., 2021). Projections using data from 67 LMICs estimated 25,000 fewer cleft operations performed during 2020 compared to 2019 (Vander Burg et al., 2021). In Peru, children born with CL/P were having primary reconstructions at a significantly older age during the pandemic when compared to a prepandemic cohort, with delays most marked in primary cleft lip and nose reconstruction (Rossell-Perry and Gavino-Gutierrez, 2021). Prioritizing cleft care in an overcrowded healthcare system when the pandemic ends will be challenging, even in high resource settings (Breugem et al., 2020). LMICs are likely to face additional barriers to reinstating elective cleft services, which may include access to COVID-19 testing, treatment, vaccines, personal protective equipment (PPE) and travel restrictions impacting most upon patients living in remote rural locations (Ramanathan et al., 2021; Stoehr et al., 2021).

The Circle of Cleft Professionals (CoCP) is a coalition of international nongovernmental organizations (NGOs), which aims to support healthcare workers around the globe to provide comprehensive cleft care (Circle of Cleft Professionals, 2021a). On September 17th 2020, CoCP facilitated an international virtual conference entitled "Solutions for Comprehensive Cleft Care (S4CCC): Responding to COVID." Following the conference, an online CoCP COVID-19 Survey was designed, aiming to identify challenges that cleft professionals face in light of the pandemic, particularly in LMICs, and to identify learning priorities (see Supplemental Figure 1). The survey was translated into six different languages to facilitate broad representation and disseminated internationally online in February 2021 to global cleft professionals through a network alliance of 10 global NGOs. The survey received 175 responses, 74% of which were from cleft professionals located in one of 40 LMICs. One priority area identified for further learning from the survey was "adapting COVID-19 cleft care protocols in light of evidence-based research."

A clinical protocol (also known as a plan, pathway or guideline) is a tool to guide evidence-based healthcare (Rotter et al., 2019). A protocol aims to standardize care and has the potential to streamline multidisciplinary clinical practice by detailing steps of management. CL/P is associated with a striking diversity of management protocols in common use and furthermore there is a paucity of a scientific evidence to support any of them (de Ladeira and Alonso, 2012; Hardwicke et al., 2017). The reason for this may be the complex, heterogeneous nature of the condition, with multidisciplinary care administered by a range of specialists at different stages of child development (Allori et al., 2017). There are examples of individual cleft centers, such as in Adelaide and Lima, publishing their protocols (Rossell-Perry and Luque-Tipula, 2020; Schnitt et al., 2004) and also nationwide cleft standards, which detail threshold age targets for the completion of primary operations (NHS England, 2018). It is perhaps not surprising that consensus for international standardization has not been reached for the delivery of cleft care protocols, nor for the assessment of outcomes (Weidler et al., 2021). The World Cleft Coalition, formed from several international NGOs, has published international treatment program standards with a primary focus on the delivery of ethical, safe, accessible and patient-centered care (Kassam et al., 2020). The coalition purposefully did not dwell on protocol technique and timings, due to the well documented controversies in this area, but instead attempted to make balanced recommendations to allow for the levels of resources available locally.

The need to adapt the cleft protocol during and following COVID-19 has been identified by global partners and is important in the quest towards reestablishing international comprehensive cleft care services. The CoCP platform was used to bring together cleft professionals from diverse locations to consider adaptations to elements of the cleft care protocol by pooling experience and reviewing available evidence. The overall aim was to formulate practical consensus recommendations to help providers in LMICs to deliver comprehensive cleft care protocols during and after COVID-19.

## Method

#### **Process Overview**

A multistage process was designed specifically for this context by CoCP organizers and advisors. The process was centered around the formation of working groups to consider four areas of learning priorities highlighted in the CoCP COVID-19 Survey in February 2021 and these were:

- 1. Augmenting telehealth in cleft care
- 2. Assessing patient outcomes during COVID-19
- Adapting COVID-19 cleft care protocols in light of evidence-based research
- 4. Promoting parental engagement during COVID-19

The application to participate in a working group was disseminated widely through the CoCP membership and beyond. Applicants were placed in working groups based on research interests, fluency in English or Spanish, and in an attempt to ensure diversity of professional context, discipline, geography and NGO affiliation. Working group members were orientated into the process and encouraged to consider their allocated topic area before meeting collectively on three separate occasions over a six-week period in 2021. The process culminated with a presentation of recommendations at a round table within an international virtual conference, that had free registration and was widely advertised, entitled "Solutions for Comprehensive Cleft Care (S4CCC): Covid and Beyond" on June 2nd, 2021 (Circle of Cleft Professionals, 2021b). The process is summarized in Figure 1.

#### Focus and Composition of This Working Group

This working group considered the topic "Adapting COVID-19 cleft care protocols in light of evidence-based research." The group was composed of seven individuals; six healthcare professionals and one nonhealthcare professional in an administrative role (see Table 1). There was representation from seven countries in four continents and inclusion of three speciality areas from the cleft MDT. Working group members had a range of experience in the delivery of comprehensive cleft care within their own countries and overseas and were affiliated with different global cleft care organizations.

#### Making and Testing Recommendations

The working group met virtually on three occasions using a videoconferencing platform. The first session entitled "exploring" involved open discussion of the assigned topic and highlighting areas in which to focus. The action plan from the first meeting was to identify available guidance through literature searches in combination with personal experience and organizational contacts. Literature was categorized according to levels of evidence (Burns et al., 2011) and shared between group members in the interim period to stimulate discussion via a blended mode of online platforms to facilitate ease of interaction. The second meeting entitled "consolidating" involved consideration of the identified evidence and the creation of preliminary consensus recommendations. The final meeting entitled "Recommending" consisted of reviewing and refining the group consensus recommendations. At the culmination of this process, the working group presented their recommendations at conference round table and attendees were encouraged to comment and provide feedback. The round table enabled a pilot test of the recommendations and an opportunity for feedback from the attending audience. Further feedback was sought from leading cleft professionals allied to the CoCP NGO network. The feedback was used to help understand the global implications of the recommendations and refine them as needed.

The structure of this report was inspired by the World Cleft Coalition publication (Kassam et al., 2020) as it was considered a rare example of an international collaborative endeavor in global cleft care and the benefit of a similar format for end user interpretation and application was recognized.

## Results

This working group considered adaptations to the cleft care protocol during and after COVID-19. A consensus was reached on foundational principles and recommendations made in two focus areas that were felt to warrant the greatest

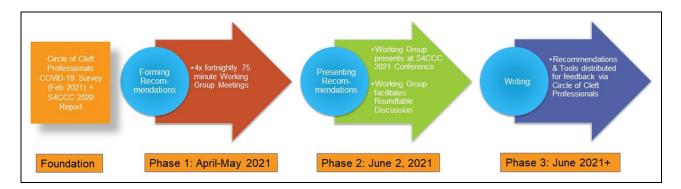


Figure 1. A flow diagram to describe an overview of the process used.

need: first, surgical safety and second, prioritization of surgical procedures and cleft care services.

### Foundational Principles

The working group agreed that recommendations for cleft protocol adaptations, supported by a body of identified scientific evidence, could be beneficial to help coordinate and unify the international lobbying of policy makers regarding the need for comprehensive cleft care provision during and after the COVID-19 pandemic in LMICs. The target audience were global cleft care providers in resource-constrained settings, which includes health care professionals and/or management teams at a regional, national or international cleft service delivery level. The aim was to create a document that would be a helpful aid to global lobbying efforts in LMICs, with an appreciation that recommendations could neither be comprehensive nor specific to reflect the needs of each individual healthcare system and setting.

Potential pitfalls were recognized with recommendations relating to global cleft care protocols. First, it was clear that cleft protocols would vary enormously in resource-constrained settings, with influencing factors including the setup of local healthcare services, the socioeconomic context, the availability of MDT care and dependance on external teams for the provision of cleft care. Each nation has its own government, healthcare laws and potential existence of crises in addition to COVID-19, such as civil war, which would have a significant impact on the delivery of any healthcare protocol. There was an endeavor to make protocol recommendations that would be broadly applicable, nonjudgemental and evidence-based by referring to relevant literature and guidance. Second, the contentious nature of many aspects of the cleft care protocol was acknowledged, especially with regard to timings, sequences and techniques in use. Prescriptive statements were avoided, with recommendations made instead according to widely accepted principles. The hope was that the recommendations would facilitate the provision of cleft care during and after COVID-19 in LMICs, rather than adding restrictive measures for healthcare providers.

# Focus Area 1: Surgical Safety

The primary focus of any healthcare protocol is to promote the safety of patients, their family and the healthcare providers. Following the inevitable delays in cleft care provision following COVID-19, the reinstatement of cleft services must be done safely and according to the latest available evidence. Many aspects of surgical safety were in place before the pandemic and for the most part, these would continue during or after the pandemic with some notable additions and considerations. Recommendations centered upon suggested additional adaptations to be considered during and after COVID-19 and have been categorized according to the period of operative care (pre, peri and post) as described in Table 2.

**Table 1.** The Composition of the Working Group.

| Name           | Group role  | Location                            | Clinical discipline           | Organization affiliations                      |
|----------------|-------------|-------------------------------------|-------------------------------|--|
| Fell, M        | Cochair     | United Kingdom                      | Plastic Surgery Trainee       | The Cleft Collective + CLEFT charity           |
| Goldschmied, K | Cochair     | Chile                               | Speech and Language Pathology | Hospital Dr Luis Calvo Mackenna                |
| Goldwasser, M  | Member      | USA                                 | Professor of Surgery          | Operation Smile + University of North Carolina |
| Jayanth, BS    | Member      | India                               | Cleft Surgeon                 | ABMSS Comprehensive Cleft Care                 |
| Pereira, RMR   | Member      | Brazil                              | Cleft Surgeon                 | University of Sau Paulo                        |
| Nawej, CT      | Member      | Democratic Republic<br>of the Congo | Anesthetist                   | University of Lubumbashi                       |
| Winer, R       | Coordinator | Canada                              | Nonclinical                   | Transforming Faces                             |

| Period        | Routine pre-COVID-19 safety measures   | Suggested adaptations during and after COVID-19                       |
|---------------|--|---|
| Presurgical   | Pre-op review by surgeon and anesthetist   | Monitoring regional COVID prevalence                                  |
|               | Vital signs and weight   | Virtual screening pre-op  |
|               | Blood tests  | Consider the need for pre-op isolation                                |
|               |  | COVID-19 vaccination status for patients and staff                    |
|               |  | Patient testing with RT-PCR   |
|               |  | Staff testing with RT-PCR   |
|               |  | Protocol if COVID-19 positive   |
| Peri-surgical | Multidisciplinary care by trained professionals  | Allow for time delays due to COVID-19 precautions                     |
|               | Appropriate pediatric medical and surgical facilities with adequate equipment and access to high dependency care | Skills and equipment to care for COVID-19 positive patients and staff |
|               | Hygiene and running water  | Isolation and quarantine facilities                                   |
|               | PPE for operating theater staff  | PPE for all staff, patients and families                              |
|               | Crisis notification plan   | Distancing measures within facility                                   |
|               | Emergency arrest protocol  | Consent to include COVID risk   |
|               | Pediatric anesthetic services  | Minimize family members to reduce people at risk                      |
|               | Informed consent process   |   |
|               | Safeguarding procedures for vulnerable people  |   |
|               | WHO surgical checklist   |   |
| Postsurgical  | Immediate postoperative pathways and observation   |   |
|               | Weigh risk/benefit for inpatient versus outpatient care  |   |
|               | Weigh risk/benefit for physical versus virtual follow-up   |   |
|               | Recording of outcomes and ongoing monitoring   |   |

 Table 2.
 Cleft Surgery Safety Measures That Were Routine Before COVID-19 and Specific Adaptations for Consideration During and After COVID-19.

Preoperative safety protocols exist to assess whether the patient is safe to proceed with a procedure and often incorporate a consultation and basic tests. Post-COVID-19, preoperative assessments need to be expanded to judge the risk of the virus causing harm to patients, families and providers. The extent of preoperative modifications (such as frequency of COVID-19 testing and the need for isolation strategies) can be adapted in response to regional COVID-19 prevalence, which has been classified as low (<0.5%), medium (0.5-2%) and high (>2%)(Royal College of Paediatrics and Child Health, 2020). Whilst an in-person consultation with the patient, surgeon and anesthetist remains vital, virtual screening for COVID-19 symptoms can be successfully utilized (Royal College of Paediatrics and Child Health, 2020). COVID-19 testing, performed as close to the time of care as possible, is an important adaptation of the preoperative protocol, whilst recognizing the need for flexibility due to access to testing facilities. Establishing vaccination status is important but vaccine availability will likely be a challenge in LMICs due to global inequity and therefore an emphasis on PPE for patient, families and staff may be required (Ma et al., 2020; Stoehr et al., 2021).

Perioperative safety protocols exist to maintain patient wellbeing whilst under the care of health professionals. Healthcare systems are well accustomed to protocols relating to safety during this period and should have training and equipment in place to deal with adverse events (Operation Smile, 2020; Smile Train, 2018.). The WHO has published guidance on equipment and facilities required to run a safe surgical service (World Health Organisation, 2003). Securing adequate stocks of PPE has always been an important element of creating a safe working environment, but the need is now extended to patients and their families, which may present a challenge amongst other resource shortages in LMICs (Ma et al., 2020). Adaptations are required to factor in the space, facilities and time to address COVID-19 risk reducing precautions such as social distancing and isolation (Cai et al., 2021). Specifically, consent for procedures should detail the risk of contracting COVID-19 during the hospital stay and emphasize the importance of following current COVID-19 guidance (Ramanathan et al., 2021).

Postoperative safety protocols exist to ensure that the surgical care episode was successful and that the patient does not develop complications that require intervention. The decision to follow-up patients in person or remotely is made on the merits and practicalities of both options and has many influencing factors, of which COVID-19 is just one. Irrespective of COVID-19, it remains important that operative outcomes are accurately assessed and recorded and indeed the advances in telemedicine during the COVID-19 pandemic may ultimately make this easier. Arguably, there may not be any specific safety adaptations required in this postoperative phase of the protocol during or following COVID-19 but maintaining levels of follow-up surveillance when resources are restricted may be a challenge.

## Focus Area 2: Prioritization

There is a need for prioritization within the cleft protocol despite each element of comprehensive cleft care having

| Priority | Surgical procedures   | Cleft care services   |
|----------|---|---|
| High     | Respiratory access if required in PRS   | New-born cleft babies need to be assessed regarding breathing, feeding and hearing, and families need to be counseled appropriately |
|          | Primary cleft palate repair (+- middle ear tubes)                                   | Ongoing pediatric and nutritional support care (especially for syndromes)<br>Dental or ENT Infections (otitis media)                |
|          | Mandible distraction if required for nutrition (if<br>integrated in local protocol) | Speech Pathology intervention   |
| Medium   | Primary cleft lip reconstruction  | Routine Speech, Audiology, Dental, Orthodontic Psychosocial and Surgical assessment and advice                                      |
|          | Secondary speech surgery  | Presurgical orthopedics (if used within local protocol)   |
|          | Symptomatic fistula repair  |   |
|          | Secondary alveolar bone grafting  |   |
| Lower    | Orthognathic surgery  |   |
|          | Secondary rhinoplasty and revisional cleft lip surgery                              |   |
|          | Routine dental procedures   |   |

Table 3. Recommended Time-sensitive Prioritisation of Surgical Procedures and Cleft Care Services.

equal importance, because some elements are time-sensitive and linked to functional outcomes, therefore their delay would lead to irreversible harm (Rossell-Perry and Gavino-Gutierrez, 2021). Prioritization of care according to clinical urgency has been widely encouraged as a vital part of reestablishing elective services amidst the backlog of untreated cases (Royal College of Paediatrics and Child Health, 2020). Elements of the cleft protocol were prioritized primarily based on time-sensitive functional outcomes, whilst also recognizing the importance of esthetic and psychosocial outcomes (See Table 3).

*Prioritization of Surgical Procedures.* Surgical emergencies for patients born with CL/P, such as airway or nutritional compromise, require potentially life-saving surgical interventions and are therefore an obvious priority. The airway can be compromised in Pierre Robin Sequence, primarily due to glossoptosis and emergent surgical procedures to secure the airway, although rare, may be required (Breugem et al., 2016). The utilization of mandibular distraction osteogenesis for children with micrognathia to improve breathing and eating is more controversial, with long-term outcomes in facial development yet to be determined (Breik et al., 2016), but was prioritized because of its aim to improve vital functions, with the proviso that it formed a part of the agreed local protocol (Ramanathan et al., 2021).

Primary palatoplasty was considered a high priority due to the body of literature identified to demonstrate its relationship with both speech and maxillary growth outcomes (see Supplemental Tables 1 and 2). Evidence suggests the palate needs to be functional when sounds are first learned in order to avoid the development of compensatory speech patterns (Chapman et al., 2008). The optimal primary palatoplasty regime is a source of continued debate (Lohmander et al., 2012; Rohrich and Byrd, 1990) and randomized control trials currently in process aim to define the optimal timing for palatoplasty (Conroy et al., 2021). The SCANDCLEFT trials found that both good and poor functional outcomes can be achieved by a variety of palatoplasty techniques, sequence and timings and concluded that it was probably the operator skill and familiarity with the protocol that was most important (Shaw and Semb, 2017). Therefore, primary palatoplasty should be performed as a priority according to the accepted techniques, and within the scheduled timeframe, of the local cleft care protocol.

Primary cleft lip repair was categorized as a medium priority as earlier lip repairs have been shown to benefit motherinfant interactions and bonding (Murray et al., 2007). Secondary speech surgery, symptomatic fistulae repair and secondary alveolar bone grafting were medium priorities due to their time-sensitive association with functional outcomes of speech and maxillary growth, although they occur at an older age and with a wider window of opportunity when compared to primary palatoplasty (Breugem et al., 2020). Secondary speech surgery and the repair of symptomatic fistulae may be warranted before the child enters primary education with an aim to achieve normal speech to help optimize educational performance (Sell et al., 2015). Secondary alveolar bone grafting is commonly timed according to the decent of the deciduous canine tooth at approximately 8-12 years of age and aids the functional development of the alveolar arch to provide support for facial structures (Semb, 2012).

Orthognathic surgery, secondary rhinoplasty, revisional lip procedures and routine dental procedures were categorized as a lower priority, not to undermine their importance, but because they are not as acutely time-sensitive.

*Prioritization of Cleft Care Services.* New-born babies with CL/P need to be assessed regarding breathing, feeding and hearing and this is a priority, both for the health of the baby and to provide support for parents during this critical neonatal period. Some children with CL/P, especially those with

syndromes, will require ongoing input from medical professionals with pediatric experience. Acute dental infections or otitis media were prioritized because efficient treatment reduces the likelihood of permanent damage to dentition and hearing (Kuo et al., 2013).

Speech pathology intervention was categorized in the highest priority to reflect the importance of speech outcomes and evidence to suggest that speech interventions reduce speech errors commonly observed in children with cleft (Sell et al., 2017). Innovations in telemedicine during COVID-19 have shown promising signs of the efficacy of delivering speech therapy remotely and this may be a great opportunity in LMICs going forward, especially for patients living in remote rural locations (Camden and Silva, 2021; Law et al., 2021; Pamplona and Ysunza, 2020).

Routine MDT assessments in dentistry, audiology, orthodontics, speech, psychology and surgery, as available within the local cleft team, were categorized as a medium priority because of the ability of these services to be delivered over a greater timescale without compromising outcomes. Presurgical orthopedics was also categorized as a medium priority because despite its aim to improve tissue position and ultimately functional outcomes, it is not utilized universally, partly due to availability and partly due to the controversies surrounding efficacy (Hathaway and Long, 2014).

## Discussion

## **Overview of Process**

The structured process used in this study provided a positive collaborative experience, which should be encouraged in future global cleft care endeavors. The condensed six-week time period, with a preestablished "finish-line," and a platform for the working group to present its recommendations, helped to increase intensity and provide urgency to the process. It became apparent that the variety of experience in the management of both CL/P and COVID-19 provided a rich environment for discussion and mutual learning. Scheduling meetings on a videoconferencing platform at the same time and day of the week helped to provide consistency and improve attendance, especially given the working group members' multiple time zones and working commitments. It was helpful to specify focused aims from the outset of the process and to set tangible action points at the end of each group meeting. Encouraging continued discussion and the sharing of resources on virtual platforms between meetings helped to increase productivity. Consensus was achieved via identifying global areas of commonality and recognizing areas of diversity and controversy.

## Summary of Recommendations

The working group was tasked to make recommendations regarding the adaptation of cleft care protocols during and after COVID-19 to help facilitate the provision of global comprehensive cleft care in LMICs. Foundational principles were set to respect the complex multidisciplinary nature of cleft care in resource-constrained settings and the specifics of local protocols, as it has been demonstrated that familiarity with a protocol is of primary importance for the achievement of good outcomes (Shaw and Semb, 2017). Within the broad topic of cleft protocols, the two areas that were focused upon were surgical safety and prioritization. First, recommendations about adaptations to surgical safety protocols were made that were categorized into pre, peri and postoperative phases. Adaptations are most likely to be required in the pre- and perioperative phases to identify and manage COVID-19 risk. Second, recommendations to prioritize surgical procedures and cleft care services were based on time-sensitivity and functional outcomes. Primary palatoplasty was prioritized due its intimate relationship with speech and maxillary growth outcome. Infant medical services, management of acute infections and speech pathology interventions were the most highly prioritized cleft care services.

## Interpretation and Implications

The WHO has documented the far-reaching impact of the COVID-19 pandemic in terms of the widespread disruption to essential health services, but elective services are being reestablished (World Health Organisation, 2021a). Global providers of cleft care will need to be prepared to adapt protocols to enable the comprehensive delivery of this essential health service. The literature and data on CL/P and COVID-19 is unsurprisingly sparse, given the relative infancy of the pandemic. Salehi et al. (2021) have published recommendations for cleft and craniofacial outreach programs during the COVID-19 era with considerations for visiting teams before, during and after their visit away from their home country. The recommendations in this current study focus instead on two important elements of the cleft protocol, and whilst applicable to visiting teams, are aimed at a wider audience of global cleft care providers in LMICs.

Surgical safety is recognized to be of utmost importance when delivering cleft care (Kassam et al., 2020). The COVID-19 pandemic presents a safety dilemma because of the need to minimize the risk of the virus whilst balancing the risk of cleft treatment delays. The WHO has developed a useful facility assessment tool to enable rapid assessment of healthcare facilities to aid the provision of essential health services during the COVID pandemic (World Health Organisation, 2021b). More specifically for cleft, (Cai et al., 2021) reported management strategies to minimize the spread of the coronavirus during CLP treatment episodes in Shanghai. The working group looked at safety protocols in common use before the pandemic and made recommendations on adaptations to consider specifically for COVID-19. Some of these adaptations, such as COVID-19 testing, will come at an increased monetary cost, and this is likely to be problematic in LMICs, where resources were already limited (Rossell-Perry and Gavino-Gutierrez, 2021). On the other hand, some

COVID-19 adaptations represent innovations and the advances in telemedicine in particular, which has proven to be successful for preoperative COVID-19 screening and speech therapy delivery, may be well suited to LMICs (Ramanathan et al., 2021). Vaccinations provide a crucial part of the international COVID-19 response, and the current global vaccination inequity will stand to reduce access to comprehensive cleft care for children born in LMICs (Circle of Cleft Professionals, 2021c).

In a crowded healthcare system following delays to many areas of planned services, prioritization of care will be vital. Breugem et al. (2020) conducted a survey of cleft priorities during COVID-19 with 218 cleft professionals in Europe, Asia and the USA. The respondents viewed airway intervention for Pierre Robin Sequence to be an emergency procedure. Primary palatoplasty was similarly thought to be a priority, but there was no consensus about timing, with 70% recommending before 15 months of age and 22% before 18 months of age. Speech surgery, alveolar bone grafting, placement of ear tubes and primary cleft lip repair were viewed to be time dependent and therefore warranted prioritization.

In the United Kingdom, all surgical procedures were prioritized into four categories of urgency by the Federation of Surgical Specialty Associations in July 2020 to expediate the recovery of surgical services during COVID-19 (Federation of Surgical Specialty Associations, 2021). Primary palatoplasty and secondary speech surgery were initially categorized as priority 3 but were upgraded to priority 2 in February 2021 (see Supplemental Table 3) following advice from UK cleft professionals regarding the association with functional speech outcomes (Cleft Development Group, 2021). The recommendation in the UK was for primary palatoplasty and secondary speech surgery to be performed within 3 months of their target threshold ages specified in the national standards, whilst other cleft surgical procedures (categorized as priority 4) could be performed over a longer timescale (NHS England, 2018). In the USA, cleft operations have similarly been categorized and prioritized via a tiered system with reference to the national operative threshold guidance (Zimmerman et al., 2020).

The prioritization of surgical procedures in this study purposefully did not incorporate threshold timings but instead categorized procedures into high, medium and lower priorities to reflect the degree of time-sensitivity with respect to functional outcomes. There was a purposeful emphasis to prioritize MDT cleft care services equally alongside surgical procedures as these complete the comprehensive approach. A common theme with both strands was a prioritization of speech outcomes, in recognition of the crucial role that speech plays globally in the life and social functioning of children born with CL/ P.

## Strengths and Limitations

The main strength of this piece of work was the collaborative nature of the international working group, which was inclusive of multiple disciplines and affiliation with multiple global cleft care organizations. The working group was a favorable size in terms of productivity, but it was not inclusive of all specialties, organizations or regions and deliberations all took place in English.

The consensus recommendations were based on common principles, but this is not an exhaustive document and therefore not a comprehensive guide to delivering cleft care protocols in LMICs during and after COVID-19. It is hoped this work will help to support efforts of cleft care providers in resourceconstrained settings to present a united and coordinated case for the provision of comprehensive cleft care to policy makers and ultimately improve safety and outcomes for patients. Ideally, there should be a focus on local protocols and guidance, therefore the relevance of these recommendations in specific environments may be limited (Truche et al., 2020).

## Further Work

It is hoped that collaborative efforts such as this will galvanize the global cleft community to perform multicentre international trials to reach a consensus on cleft care protocols and outcomes. Local outcome data collection must be encouraged to drive context-specific guidance. Finally, the efficacy of innovations highlighted by this pandemic should be explored so that they can ultimately help to improve the provision of global cleft care.

# Conclusion

Comprehensive cleft care is an essential health service and every child born with CL/P deserves the opportunity to receive treatment through safe and effective cleft care protocols. The COVID-19 pandemic has had a detrimental impact on the delivery of comprehensive cleft care, which was already stretched in many areas of the world. As a global community, it is helpful for the providers of cleft care in LMICs to be able to recognize protocol adaptations during and after COVID-19 that may be needed to deliver care safely and elements that should be prioritized to maximize time-sensitive outcomes. A unified approach amongst global cleft care providers may help to lobby policy makers effectively at this crucial time of scarce resource allocation.

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#### Supplemental Material

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