A Guide to Developing Safety Protocols for International Craniofacial Outreach Programs During the COVID-19 Era

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Abstract: The ongoing COVID-19 outbreak has created obstacles to health care delivery on a global scale. Low- and middle-income countries (LMICs), many of which already suffered from unmet surgical and medical needs, are at great risk of suffering poor health outcomes due to health care access troubles brought on by the pandemic. Craniofacial outreach programs (CFOP)—a staple for craniofacial surgeons—have historically provided essential care to LMICs. To date, there has not been literature discussing the process of resuming CFOP mission trips. Herein, we propose a roadmap to help guide future journeys, as well as summarize practical considerations.

Key Words: Cleft, coronavirus, COVID-19, craniofacial, global surgical outreach, mission trips, pandemic, pediatric, public health, SARS-CoV-2, virus

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The ongoing COVID-19 pandemic has led to humanitarian and health care crises, transforming the lives of millions globally. Although the fight is far from over, recent discourse has focused on how to transition from "shelter-in-place" and emergency-only

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procedures to the "new normal." One important area of health care delivery that merits attention is the future of craniofacial outreach programs (CFOP) in the COVID-19 era.

CFOP provide an essential service to low- and middle-income countries (LMICs). 1-3 Even before the COVID pandemic, the surgical needs of LMICs were unmet by existing nongovernmental organizations (NGOs). Hence, the pandemic will likely exacerbate LMICs' surgical needs. In particular, CFOP are a staple for craniofacial surgeons (which include facial plastic and reconstructive surgeons, plastic surgeons, otolaryngologists-head and neck surgeons, and oral-maxillofacial surgeons). Although not life-threatening, patient outcomes from craniofacial surgeries (eg, cleft lip/palate surgeries) are often time-sensitive. 5,6

The state of affairs regarding craniofacial surgeons (CS) and COVID has recently been reviewed broadly. Yet, to our knowledge, there has not been literature discussing the process of resuming CFOP mission trips. As international travel restrictions, federal, state, and local "shelter in place" policies, and surgical procedure limitations ease, it is imperative that CS consider how to resume international craniofacial outreach in a safe, responsible manner in the post-pandemic world.

Herein we propose a roadmap to help guide future missions, as well as summarize practical considerations. Several authors of this manuscript (USH, ABJ, BA) were in the midst of a scheduled craniofacial mission trip in Ecuador when the World Health Organization (WHO) officially declared the COVID-19 outbreak a global pandemic. After the announcement, numerous safety measures were quickly adopted to ensure the safety of both patients and volunteers. Although Ecuador has since become one of the hotspots for the COVID outbreak in South America, none of the mission trip's volunteers, patients, or patients' families have tested positive or shown symptoms of the virus since the trip. Moreover, other authors of this manuscript (BR and NP) were about to embark on a craniofacial mission trip to the Philippines, days before COVID-19 was officially declared a pandemic. After numerous, detailed conversations with mission volunteers and local community leaders regarding the risks and benefits of continuing with the trip, the mission was ultimately cancelled a few days before the scheduled departure date. Thus, the following suggestions were crafted using both available guidelines^{9–15} and personal experiences.

Of note, as the scientific community learns more about COVID-19, specific guidelines and recommendations will continue to evolve. Therefore, the following recommendations should be considered in the context of the most up-to-date information that is available at the time of reading.

BEFORE DEPARTING HOME COUNTRY

- Check international travel regulations regarding travel to and from the intended nation.
- Investigate epidemiology of COVID-19 cases in the local community. What is the rate of community spread?¹¹

- Consider the COVID testing capacity, as well as availability of treatments/vaccines, in the local community.
- Implement screening of all volunteers before departure including COVID PCR and antibody testing, if available.
- Volunteers with co-morbidities and risk factors known to impact COVID-19 outcomes should consider forgoing travel with the team.
- Create a comprehensive training program for all volunteers, including local volunteers, regarding COVID-19 symptoms¹⁶ and screening protocols.
- Work with local public health agencies and community leaders to create protocols regarding social and physical distancing, contact tracing, quarantine logistics, and workflow—for both patients and volunteers.¹¹
- Inspect digital infrastructure capabilities of the destination (eg, telehealth capacities, broadband connectivity, and so on).
 Consider supplying patients with equipment that may facilitate telemedicine care.
- 9. Review personal protective equipment (PPE) needs. This should be done after careful review of planned procedures and patient interactions. PPE used during the trip should reflect published guidelines, 10,13-15 including procedure-based risk assessments (eg, higher-level PPE for aerosol-generating procedures). Decisions regarding PPE should be made prudently to maximize the safety of staff and patients, while being considerate of the global PPE shortage. 5,15 PPE allocation and planning should also consider the safety of accompanying anesthesiologists and nonphysician personnel.
- Careful appraisal of necessary equipment including hand sanitizer, soap, face shields, and face masks for mission volunteers, local volunteers, patients, and patients' families.
- 11. In coordination with local volunteers, attempt to triage and schedule as much patient care as possible before departure. This includes triaging care through telemedicine visits when able. This will not only help guide the necessary equipment to bring, but also minimize unnecessary patient/volunteer exposures.
- 12. Have volunteers obtain clear communication on quarantine protocols for their state of residence and home hospital before embarkment. All volunteers should be aware of local ordinances and have a possible quarantine plan in place before returning home from the expedition.

PRE-VISIT PATIENT SCREENING

- Each patient and family member should receive a "pre-visit wellness check" via telehealth within 24 hours of their scheduled visit, including screening for active COVID symptoms, recent COVID symptoms, possible COVID exposures, travel history of patient and family, and recent contacts (including their travel history). 11,16 One important consideration is that, in some cases, this questioning may not yield accurate information. Families may be incentivized to not provide valid information to avoid having the patients' procedures cancelled.
- When possible, volunteer clinicians should leverage telemedicine capabilities to perform the history and physical examination before the in-person examination. Maximizing data collection before the in-person visit may help minimize office visit duration and incidental exposures.
- Triage care to maximize patient outcomes, while minimizing patient contacts and exposure risks.
- Thoughtfully update patients on new COVID-based protocols for their upcoming in-person visit. Patients should be reminded of physical distancing procedures, visitation policies, face covering requirements, and so on.¹¹

Patients should also be reminded to remain home if they are experiencing any viral symptoms or have had a possible COVID exposure.

IN-PERSON SCREENING

- Limit family members accompanying patients. In pediatric cases (eg, craniofacial, cleft lip/palate), we recommend allowing only a single family member to accompany the patient to the visit. Although this may be a significantly different experience for patients accustomed to traveling as a family unit, the importance of limiting visitors should be emphasized and discussed with the patient, in a culturally appropriate context.
- Adjust examination and waiting room layouts to maximize physical distancing. Physical space should be arranged to manage movement of patients through screening and patient care areas, with the goal of limiting interactions with both nonessential personnel and other patients/familes.¹¹
- 3. We recommend a second round of COVID screening upon arrival to the hospital/medical facility. In the aforementioned recent mission trip to Ecuador, volunteers set up a screening area outside of the hospital for this second assessment. The screening area included a hand sanitizing station, temperature check, and repeat COVID symptom and exposure questionnaire. All equipment contacted by the patient/family member was sanitized after use. Patients and families were not permitted to enter the hospital until passing this screening station.
- Enforce strict hand sanitization protocols for all clinicians, volunteers, patients, and family members upon entering and leaving rooms/facilities.
- 5. Adoption of rigorous cleaning protocols to disinfect patient care areas and equipment between patient visits.

SURGERY AND PROCEDURE CONSIDERATIONS

- Limit procedures and surgeries to an as needed basis. Ideally triaging necessary surgical interventions and office-based procedures should be performed before the patient visit. Specifically, clinicians should limit aerosolizing procedures, such as dental procedures and nasopharyngoscopy.
- When possible, perform COVID testing before surgical interventions and/or admission to the hospital.
- 3. Specific PPE employed during surgeries and procedures should reflect the risk-level of the case, in accordance with published guidelines. ^{10,11,13–15} CS have already been documented to be at greater risk of viral transmission^{5,7}; thus PPE decisions should be made thoughtfully to protect surgeons, staff, volunteers, and patients. For instance, for procedures involving the oral cavity, oropharynx, nasopharynx, and/or airway appropriate PPE, at minimum, should include an N95 mask or powered airpurifying respiratory, eye protection, waterproof gown, surgical cap, shoe covers, and 2 sets of gloves. ¹³
- 4. Emphasize conservative PPE use and distribution.⁵
- 5. The number of personnel in the operating room should be limited to the minimum number necessary.¹³ Minimizing staff in the operating room will help both conserve PPE and limit possible viral exposures.
- Utilize a surgical checklist for both COVID-negative¹⁷ and COVID-positive or COVID-suspected patients.¹⁸

POSTOPERATIVE CARE

 Postoperative care should highlight many of the abovementioned considerations, including minimizing visitors, physical distancing on rounds, use of face coverings for family

- and volunteers, judicious PPE use, implementation of telemedicine, and avoidance of aerosol-generating procedures.
- Any family member accompanying the patient should not leave the hospital premises during the inpatient period, to minimize the risks of viral exposure. This should be discussed with patients' families beforehand. Efforts should be made to accommodate the family member while they stay with the patient, including sleeping arrangements, food delivery, among others.
- Employ routine COVID monitoring of patients and their families in the postoperative setting.
- Create postoperative care information packets and use telemedicine, to minimize inpatient duration and need for inperson return visits.

THROUGHOUT THE TRIP

All volunteers should continue self-monitoring for symptoms on a twice daily basis. These "self-checks" should include temperature checks. Any volunteer endorsing COVID symptoms, ¹⁶ fever, and/or high-risk exposure should be quarantined until testing becomes available. Quarantine and screening protocols for volunteers should be well-described before departing from their home country, and reviewed periodically during the trip. These protocols should be crafted and updated with the latest guidelines published by the CDC¹⁶ (or similar health agency).

BEFORE RETURNING TO HOME COUNTRY

- Implement screening of all volunteers before returning to their home country, including COVID PCR and antibody testing, if available.
- Before returning to their home country, volunteers should confirm quarantine and self-isolation protocols for their state of residence to make sure there have been no changes in federal and state policies since their departure.

The ongoing pandemic has greatly complicated the delivery of international surgical outreach. Hence, we acknowledge that many of the aforementioned suggestions may seem unattainable, at this time. At the most basic level, CFOP will need to address the concerns, anxieties, and fears of both the underserved communities and the organizations' volunteers before resuming activities. The most critical piece to resuming the status quo for mission trips—and life in general—will likely be the development of a widely available and effective vaccine and/or treatment for COVID-19. Even before vaccines become widely available globally, vaccination of CFOP volunteers alone may enable missions to resume safely, as a successful vaccine will serve the dual purpose of protecting volunteers both from spreading COVID to local communities and from contracting the virus themselves.

Without a vaccine, the ability to safely conduct missions will be contingent on securing the appropriate PPE and accurate, timely COVID testing. Given that many developed nations, such as the United States of America, are still struggling to grow PPE and testing capacity domestically, this alone may seem like an insurmountable task. Even prior to the COVID pandemic, the lowresource settings of LMICs often meant that CFOP were functioning with PPE, operating room, and medical facility standards that were below that of developed nations. Furthermore, physical distancing initiatives may slow the operative volume of CFOP missions by decreasing both operating room and patient room capacities. Such factors should be carefully considered when planning future CFOP missions. Now, more than ever, CFOP needs to prioritize physician/volunteer safety, global health needs, and excellent patient care in a balanced manner. Together with careful planning, appropriate resource allocation, and greater scientific understanding of COVID-19, we hope that the above-mentioned suggestions will serve as a roadmap to help guide future international craniofacial surgical outreach.

In short, although the exact timing of future CFOP operations remains unclear, it is evident that CFOP provide essential care to underserved areas of the world. 1-3,19 Despite the many unknowns created by the COVID-19 contagion complicating international surgical outreach, CFOP will eventually resume activities. Our hope with the aforementioned suggestions is to spur discussion and encourage the creation of an efficient, safe, and economical path forward. Now is the time for CS to work together to consider what the future of CFOP international trips look like. Global health programs and CFOP have a remarkable opportunity to collaborate with NGOs, infectious disease experts, public health officials, and global leaders to build evidence-based guidelines directing future international humanitarian work. The focus of such guidelines should be to not only protect volunteers, but, more importantly, to protect and serve patients and their local communities in-need.

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