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Sustainable Cleft Care: A Comprehensive Model Based on the Global Smile Foundation Experience

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Abstract

Introduction: Clefts of the lip and palate are leading congenital facial anomalies. Underserved patients with these facial differences lack access to medical care, surgical expertise, prenatal care, or psychological support. Moreover, the disease results in significant economic strains on patients and their families. While surgical outreach programs have attempted to fill this void, significant challenges facing international comprehensive cleft care persist.

Objective: Propose a path toward international sustainable cleft care based on the Global Smile Foundation experience.

Results: International sustainable comprehensive cleft care can be achieved by regulating surgical outreach programs. Regulation of these missions would ensure standardized care and encourage stakeholders to cooperate and adequately allocate funding and resources. Capacity building can be achieved through "diagonal" cleft care delivery models, multidisciplinary workshops, fellowship programs, research and quality assurance, as well as leveraging emerging technologies such as Augmented Reality.

Conclusion: International comprehensive cleft care requires continuous collaborative efforts between visiting and local teams as well as international and national organizations. Standardizing and regulating current practices as well as promoting capacity building initiatives can contribute to sustainable cleft care.

Keywords

cleft lip and palate, outreach programs, missions, global surgery, sustainability, capacity building, cleft workshops, augmented reality

Introduction

Clefts of the lip and palate are leading congenital defects, affecting 1 in 700 births (Mossey and Castilla, 2001). The prevalence, however, varies significantly by geographical region and population (Dixon et al., 2011). If left untreated or if treatment is delayed, patients with cleft lip and/or palate are at increased risk of morbidity and mortality (Magee et al., 2010). Launched in 2014, the Lancet Commission on Global Surgery highlights the necessity of addressing the unmet burden of surgical diseases as well as the need to improve access to surgical care in low- and middle-income countries (LMICs), where access to basic surgical care is lacking (Meara et al., 2016). Patients in these countries face several challenges including shortages in medical and surgical expertise, deficient prenatal testing and psychosocial support, limited financial resources, long travel distances, and geopolitical conflicts (Corlew, 2010; Massenburg et al., 2016). Although nongovernmental organizations (NGOs) contribute significantly to the delivery of cleft care in LMICs, significant challenges persist

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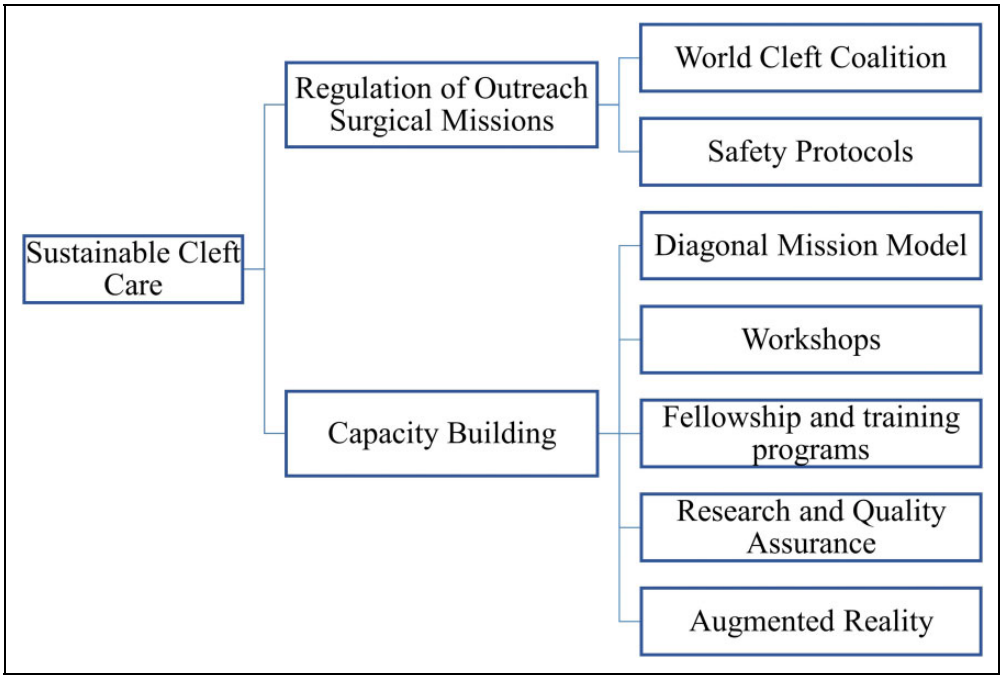

Figure 1. Roadmap to sustainable cleft care.

for the widespread implementation of comprehensive cleft care in these countries. Moreover, surgical outreach programs have often been scrutinized due to the lack of regulations, raising ethical concerns about quality of care. These programs should not be "surgical safaris" and should not be designed for "medical tourism." Surgical outreach programs should also abandon practices that emphasize quantity over quality of care that is being delivered (Dupuis, 2004). In this manuscript, we propose potential solutions (Figure 1) for widely disseminating comprehensive cleft care delivery in LMICs based on the experience of our organization, Global Smile Foundation (GSF), that encompasses more than three decades of fieldwork.

Regulation of Outreach Surgical Missions

The World Cleft Coalition (WCC) is a collaborative initiative launched by prominent NGOs dedicated to international comprehensive cleft care (World Cleft Coalition, 2020), including Global Smile Foundation, Smile Train, Operation Smile, the American Cleft Palate Association, Transforming Faces, and the European Cleft Organisation. The WCC does not present itself as a legal entity but rather as a collaboration of organizations that intend to solicit and engage the discussion of inconsistent standards of care (Kassam et al., 2020). The goal of the WCC is to develop an approved set of international treatment program standards based on the evolving experience of the contributing bodies that include both core practice guidelines and best practice guidelines. The main objectives of the WCC are to encourage the delivery of comprehensive cleft care in a standardized way as well as emphasize surgical safety, quality of care as well as patient and provider education. The WCC also promotes sustainability and local capacity building through partnerships with host nations. This allows the delivery of long-term comprehensive cleft care and prolonged patient follow-up as well as promotes the autonomy of local providers. Through strong partnerships between the involved NGOs, the WCC has also developed a comprehensive database of all current cleft lip and palate surgical volunteers programs (Patel et al., 2018).

These efforts strive for the development and delivery of the highest standards of care that should be delivered during surgical outreach programs. As a result, many NGOs have developed and implemented protocols to maximize patient safety. Examples of such protocols include GSF's emergency response protocol (Vyas et al., 2013) and the modified World Health Organization surgical safety checklist, designed and implemented by GSF (Patel et al., 2014), quality assurance guidelines developed by Medical Missions for Children (Eberlin et al., 2008), and the anesthetic guidelines developed by Smile Train and Operation Smile (Kulkarni et al., 2013). Since implementation of the modified World Health Organization surgical safety checklist in 2010, we have operated on more than 1800 patients and have completed, among other craniofacial procedures, 803 primary cleft lip repairs, 505 primary cleft palate repairs, and 505 cleft lip revisions. While no direct assessment of the complication rates since implementation of such safety protocols has yet been evaluated, no mortalities have been reported.

In order to provide the highest standards of care, visiting teams should aim to include qualified professionals and volunteers. Global Smile Foundation cleft care teams include pediatric craniofacial plastic surgeons, facial plastic surgeons, pediatric otolaryngologists, maxillofacial surgeons, pediatricians, pediatric anesthesiologists, dentists, orthodontists,

perioperative nurses, OR nurses, PACU nurses, nutritionists, psychologists, speech therapists, biomedical engineers, and administrative personnel. This approach aspires to reproduce as closely as possible the multidisciplinary approach to cleft care implemented in developed countries. Volunteers participating in GSF surgical outreach programs are required to have current credentials and significant experience in cleft care to ensure adequate care delivery and to optimize surgical outcomes on a mission. Psychologists are an essential part of the team as they provide much needed psychological services to both patients and parents, including anxiety management, coping skills, and discrimination management. This support is critical in underserved countries, where such support is often lacking and patients are commonly ostracized from societies, discriminated against, stigmatized, or even considered cursed (Chung et al., 2019)

Capacity Building

Diagonal Model of Care Delivery

Several cleft care delivery models exist, each with noteworthy advantages and disadvantages. ***Vertical Care*** *Delivery* provides a transitory increase in workforce that helps decrease the burden of disease and helps address health care deficits temporarily. Visiting teams provide host countries with needed supplies, equipment, and workforce. While the vertical model of surgical missions serves as a transient solution, it has been criticized for lack of sustainability, potential disruption of local healthcare systems and infrastructure, additional financial strain on LMICs, and possible alienation or dependence of host countries on the visiting teams (Hughes et al., 2012; Patel et al., 2012; Carlson et al., 2015; Kantar et al., 2019a). The ***Horizontal Care Delivery*** model focuses on developing and strengthening existing infrastructures. Advantages of the horizontal model include potential sustainability of care and empowerment of local teams. However, this model involves long-term investment and requires continuous follow-up until transition to autonomy can be achieved (Patel et al., 2012). The ***Diagonal Care Delivery*** model combines advantages of the vertical and horizontal models. It provides the temporary workforce and resources needed on surgical missions while empowering and investing in local teams and infrastructures (Patel et al., 2012). The *diagonal care delivery* model has gained popularity and is believed to be used by 50% of surgical organizations providing cleft lip and palate care (Patel et al., 2018). Global Smile Foundation endorses the diagonal model of cleft care delivery during its surgical outreach programs as it facilitates the transition to sustainable cleft centers. Through these programs, GSF has had a considerable impact both on a clinical and economical level. Over the last decade, GSF completed more than 2,000 craniofacial procedures, among which were 951 primary cleft lip repairs and 558 primary cleft palate repairs. The primary cleft lip and primary cleft palate repair procedures have averted 12,922 years of disability (Disability-Adjusted Life Years) and contributed to an economic gain of US$42,844 to US$82,175 per patient, with a total economic gain between US$64,651,261 and US$124,001,435 (Kantar et al., 2020b). Another approach for classification of charitable global surgery programs is through surgery platforms that focus on methods of delivery rather than diseases. It differentiates between temporary surgical platforms—which include short-term surgical trips and self-contained surgical platforms, and specialty surgical hospitals — that rely on establishment of a treatment center for a certain surgical condition. This model emphasizes that the only platform suitable for sustainability of care and the most cost-effective model is development of specialty surgical hospitals. Many of the specialty surgical platforms mature and expand from temporary, short-term platforms (Shrime et al., 2015). Prominent examples include the establishment of the Guwahati Comprehensive Cleft Care Center in India by Operation Smile, and the cleft care center in Nepal by Resurge International (Campbell et al., 2014). Other similar efforts include the establishment of GSF Comprehensive Cleft Care Centers in Guayaquil, Ecuador, and Beirut, Lebanon, in collaboration with GSF Ecuador and GSF Middle East/North Africa, respectively (Global Smile Foundation—Education, 2017). These centers allow continuous follow-up of patients and ensure year-round availability of comprehensive cleft care as they provide dental, orthodontics, psychosocial, speech therapy, and surgical services. Since its establishment in 2014, our comprehensive cleft care center in Guayaquil has provided care for 2,629 patients, 735 of whom underwent cleft-related surgeries. Our dental team has provided care for 3,048 patients. Our speech pathologists and psychosocial team also evaluated most of the patients as part of the screening process and provided the necessary care.

Comprehensive Cleft Care Workshops

Challenges to sustainable cleft care include lack of universal surgical expertise as well as scarce qualified practitioners. To address these issues, efforts ought to be made to empower practitioners through educational initiatives. Global Smile Foundation hosts yearly comprehensive, multidisciplinary cleft care workshops that aim at providing didactic lectures and hands-on training while encouraging intellectual exchange and networking (Kantar et al., 2019b). The workshops are replicated in areas of need around the world (Figure 2) with emphasis on tailoring the educational content delivered based on regional needs. These workshops are achievable through strong partnerships between GSF and other cleft care organizations and health care institutions. The workshops have received endorsement from key organizations including the American Cleft Palate Association, the European Association of Plastic Surgeons, the American Society of Plastic Surgeons, European Cleft Organization, and Latin American Craniofacial Association (Comprehensive Cleft Care Workshop, 2018). The first simulation-based comprehensive cleft care workshop held in the Middle East and North Africa (MENA) region was shown to be well received among participants, with all 97 participants from 18 countries reporting that they would recommend it to colleagues and would participate in similar workshops again (Kantar et al., 2019b). Similar results were obtained from the second comprehensive

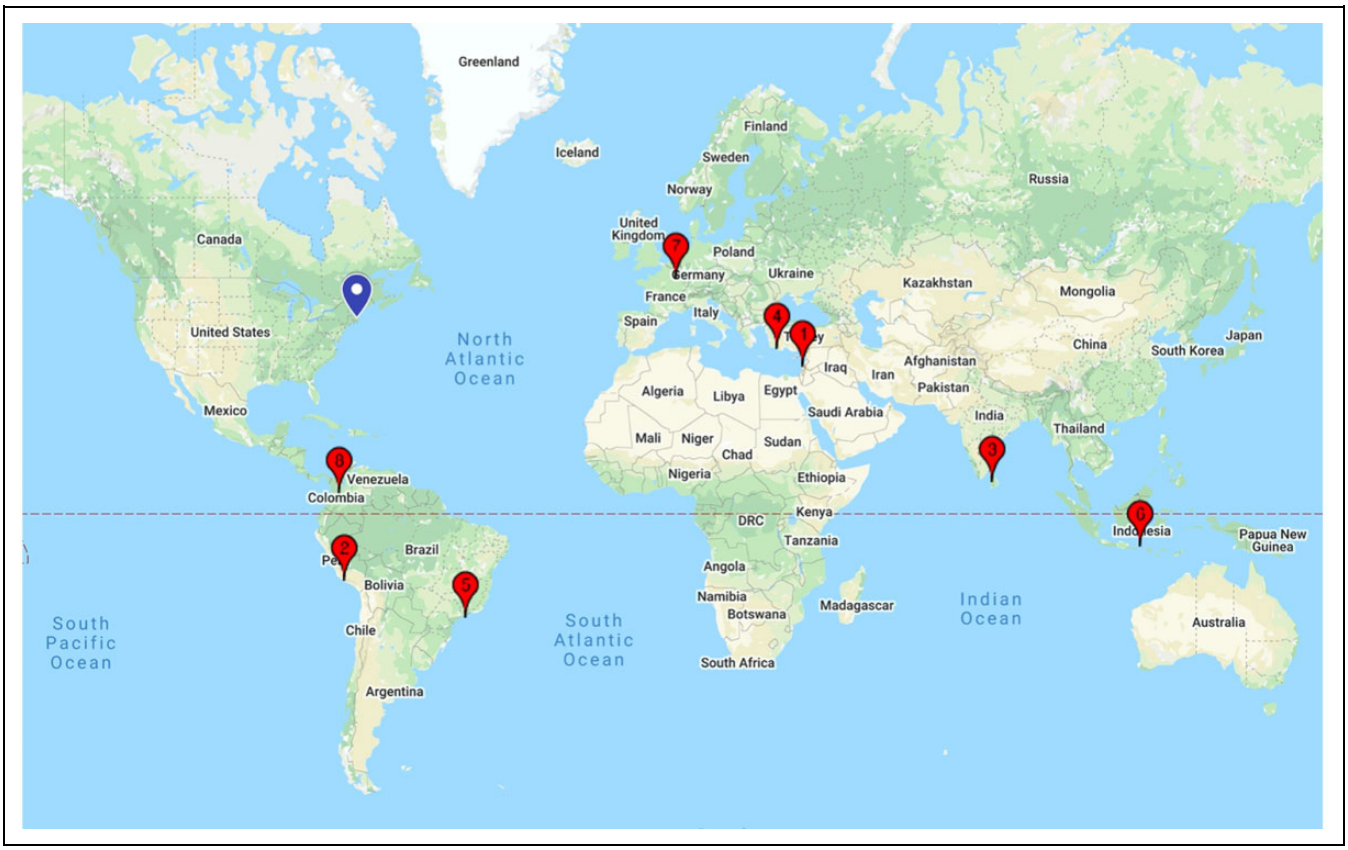

Figure 2. Comprehensive cleft care workshop locations through 2025. Blue pin: GSF headquarters—Norwood, Massachusetts. 1. Beirut, Lebanon, 2018. 2. Lima, Peru, 2019. 3. Chennai, India, 2020. 4. Istanbul, Turkey, 2021. 5. Rio de Janeiro, Brazil, 2022. 6. To be determined, South East Asia, 2023. 7. Amsterdam, the Netherlands, 2024. 8. Cartagena, Colombia, 2025.

cleft care workshop in Lima, Peru, in 2019, that hosted 180 participants from 29 countries. Additionally, participants reported a positive impact of the workshop on their competence, performance, outcomes, clinical care, and clinical practice (Kantar et al., 2020a). The simulation-based hands-on sessions are an essential and evolving component of surgical education and contributed to increased procedural confidence among participants for cleft lip and cleft palate surgery.

Fellowship and Training Programs

Education and training can also be promoted through fellowship programs. Fellows are directly trained and mentored by experts in the field and are provided with the needed expertise in cleft care and confidence to provide surgical care in underserved countries. The GSF Cleft Surgery Training program (GSF-CSTP) promotes education, leadership, and research through a multidisciplinary approach. Training includes didactic lectures and seminars as well as hands-on training. This program aims at developing surgical skills, cultural competence, and communication skills required to provide compassionate care to patients and their families. To this day, three plastic surgery fellows have benefitted from this training program: one from Brazil and two from Ecuador. Additionally, GSF recognizes the importance of training opportunities during surgical outreach programs and has partnered with several US-based hospitals to strengthen and consolidate residency and fellowship training. Since 2011, GSF has participated in the training of eighteen fellows (5 anesthesiologists, 7 otolaryngologists, 3 pediatricians, 3 plastic surgeons) and sixty-nine residents (41 anesthesiologists, 7 otolaryngologists, 4 OMF, 2 pediatricians, 5 plastic surgeons, and 10 general surgeons) in nine outreach countries. While most residents and fellows were pursuing their training in the United States, some of them were pursuing their training in Brazil, Ecuador, Lebanon, Peru, and Puerto Rico. Similarly, the advanced Nasoalveolar Molding (NAM) program in outreach settings, developed by GSF, aligns with the vision of providing year-round comprehensive cleft care through education and empowerment. Since 2012, we have trained fourteen international providers in NAM from five different countries: Ecuador (7), Nicaragua (2), Egypt (1), Peru (3), and El Salvador (1). The program aims to provide fellows with adequate academic knowledge and clinical skills to incorporate NAM technique in diagnosis, management, and treatment of patients with cleft lip and/or palate (Global Smile Foundation—Education). Since March 2012, a single trained provider has treated 192 patients with NAM and 38 patients with DynaCleft. She now has a full-time position in our cleft center in Guayaquil and provides year-round NAM and dental care to new and follow-up patients.

Figure 3. Unilateral cleft lip repair with augmented reality. A. International operating room setup: video camera mounted above the operating table transmitting audio and video in real time to remote surgeon. B. US-based surgeon guides international team through correct cleft lip surgical marking.

Research and Quality Assurance

Global Smile Foundation recognizes the importance of outcomes evaluation and continuous quality assessment, both of which constitute stepping stones for sustainable outreach cleft care. Hence, efforts have been directed into the development of our own electronic medical record (EMR). Advantages of the EMR include consistent patient documentation and collection of substantial patient data on a clinical level but also facilitation of research conduction and adequate patient follow-up on a societal level. We anticipate that the EMR will allow us to quantify and strengthen our long-term commitment to our patients.

Augmented Reality

Global Smile Foundation also supports local team autonomy and education through the use of emerging technologies to demonstrate procedures and empower surgeons. Augmented reality (AR) is a promising tool that has gained popularity in surgical education and training over the past several years. It allows superposition of a virtually generated image on a three-dimensional environment in real time (Ayoub and Pulijala, 2019; Cao and Cerfolio, 2019). Through AR, US-based GSF surgeons are able to remotely assist and provide guidance to their on-site colleagues during surgery (Figure 3). In this "win-win situation," US-based GSF surgeons can ascertain their commitment to sustainable international cleft care by maintaining *virtual* year-long presence as well as availability to their overseas colleagues. Similarly, on-site professionals have year-long support to strengthen and reinforce skills they have learned during GSF outreach programs. A thirteen months curriculum combining site visits and remote sessions was developed and implemented in Trujillo, Peru, to evaluate the use of such technology as an emerging teaching modality in terms of feasibility, efficacy, safety, and continuity of partner surgeons training. Augmented reality was used in 17 of 43 primary cleft lip repairs. Overall, both the remote and overseas surgeons reported a positive trend in preoperative counseling and diagnosis as well as operative design, anatomy, decision-making and efficiency, and principles and techniques of cleft lip repair (Vyas et al., 2020). In doing so, GSF aspires for continuity of training and reinforcement of its commitment to sustainable cleft care.

Conclusion

Cleft lip and palate are leading congenital deformities that require multidisciplinary treatment. In LMICs, a majority of patients and their families lack access to medical and surgical care. To achieve universal, sustainable, comprehensive cleft care, efforts should be focused on capacity building initiatives, as well as regulating and standardizing the care delivered by surgical missions. Capacity building should be implemented through diagonal cleft care delivery, educational initiatives such as workshops and fellowship programs, research, and quality assessment as well as harnessing emerging technologies. While we recognize that the establishment of this proposed path to sustainable cleft care is a task of great magnitude that requires collaboration of all stakeholders involved, we hope that this manuscript will initiate discussions and encourage organizations to strive for delivery of sustainable comprehensive cleft care.

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