
Strategies to Optimize Global Cleft Care

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Abstract

Orofacial clefts represent the most common congenital craniofacial anomaly worldwide. This condition is best managed by an interdisciplinary team of specialists, often with gratifying results for both the patient and the care providers. Despite recent advances in the management, it remains a challenge today to provide cleft care in low- and middle-income countries (LMIC) due to the lack of basic health care infrastructure and long-term follow-up. International cleft mission trips have traditionally been successful in providing reconstructive plastic surgery to communities with limited resources. More recently, there has been a global effort in the cleft care community to facilitate development of sustainable local cleft care centers that are capable of providing longitudinal, comprehensive care to the indigenous population. This chapter focuses on the elements that are necessary for running a successful international cleft mission and a local cleft care facility, which include the essential personnel, operational protocols, equipment, logistics, patient selection, and follow-up. The challenges and future directions of providing cleft care in LMIC are also discussed.

Keywords: cleft, craniofacial, global health care, international missions, sustainable health care models

1. Introduction

Orofacial clefts represent the most common congenital craniofacial anomaly, with an estimated prevalence of 1.2 per 1000 people worldwide [1, 2]. Although the treatment of orofacial clefts and other craniofacial anomalies has improved dramatically in developed countries, this is not true for most low- and middle-income countries (LMIC), where the capacity of cleft treatment facilities is lacking and the overall care remains insufficient [3, 4]. More than 160,000 new patients with orofacial clefts are born globally each year [5], placing a significant

economic and psychosocial burden on the individual and the families involved. The burden of care for children with orofacial clefts in LMIC is disproportionately immense due to the severely limited access to basic care. People in these resource-limited regions regularly live with untreated clefts their entire lives, battling with prejudice and social ostracism [6]. A large number of humanitarian cleft care missions have provided corrective treatments to patients in LMIC who would not otherwise have had access to such care. However, it remains difficult to provide global care to these patients due to a number of obstacles, including security issues, logistical obstruction, lack of reliable social service facilities, unsustainable or short-lived local cleft care centers, less qualified local personnel, and long-term follow-up [7].

Until recently, there had not been a set of commonly accepted standards for cleft care in less developed countries. Aiming to fill this gap, in 2006, the Volunteers in Plastic Surgery Committee of the American Society of Plastic Surgeons/Plastic Surgery Educational Foundation undertook the project of creating universal guidelines to improve quality and safety for providing reconstructive plastic surgeries in developing countries. Experienced international cleft surgeons along with representatives from Society for Pediatric Anesthesia created and published a set of guidelines, and the final document has been reviewed and approved by the boards of both organizations [8]. During the same year, Operation Smile, the largest American international cleft organization, independently convened its own conference of experts from each specialty around the world to ensure that every child receives the same first world standard of care in an international mission. The product of the conference was “Operation Smile’s Global Standards of Care,” which was adopted by over 60 member countries within Operation Smile network [9]. Both documents included comprehensive outlines for each aspect of cleft treatment, including site preparation, team make up, equipment, logistics and traveling, and safety standards so that every cleft child and their family can expect the same level of quality care no matter where they live [8, 9]. They have also provided foundation to the new paradigm of international cleft care, which is the creation of free-standing, sustainable cleft centers around the world, staffed, and operated year-round by both local and international personnel [10–13].

This chapter will briefly focus on the strategies that can help optimize global standards for cleft care, which should be followed when planning a cleft mission or building a self-sufficient cleft care facility to provide optimal and longitudinal care to patients with craniofacial anomalies.

2. Multidisciplinary team building

A multidisciplinary team of qualified healthcare professionals is the foundation to achieve proper cleft care anywhere in the world, as the management of orofacial cleft requires expertise from providers in various fields of medicine and dentistry.

Given the complexity and life-threatening risks inherent in performing surgical procedures, it is crucial that all team members be highly skilled and well trained in the patient care of cleft anomalies. The educational and experience requirements of each specialist on the cleft team

are determined by individual specialty board, various professional associations, state licensing board, etc. These requirements change over time. The professional members should be encouraged to stay updated on all the current teachings in their respective fields by actively participating in continuing educational activities and attending professional meetings. This not only ensures that they possess appropriate and current credentials but also have the requisite experience in evaluation and treatment of patients with craniofacial anomalies [1, 7, 10].

For this purpose, large and fully articulated cleft care teams must be designed to deliver an entire range of care to the patients. This is essential in building long-term, sustainable, and self-sufficient cleft care centers. Such a team should include the following members [6, 7, 14–16]:

1. Pediatrician
2. Cleft/craniofacial surgeon
3. Cleft/craniofacial orthodontist
4. Anesthesiologist
5. Nursing staff
6. Speech pathologist
7. Psychologist
8. Medical record specialist/research coordinator
9. Other surgical specialties

If a cleft care center recruits international professionals once or twice a year during special cleft surgery camps and cleft missions, the presence of a skilled translator also becomes important because language barrier can hinder full team performance and potential. Therefore, qualified interpreters should be provided to ensure proper verbal and written communication among the team members, patients, and families. The team needs to work in a coordinated manner to provide appropriate care to any patient that comes with a cleft anomaly [10, 17].

Some cleft care centers are not able to provide all types of examinations and services required by the patients. The team in such facilities should have a mechanism for referral to the required professionals, who will be able to provide the necessary service to the patient [11].

Lastly, it is important that all members of the team are monitored regularly and their performance reviews are maintained, so that the quality of care provided to the patients is not compromised.

3. Protocols

Generally, competent surgeons, anesthesiologists, craniofacial orthodontists, and nursing staff each have their own particular way of doing things. This is especially true for professionals who work in different parts of the world. This presents a unique challenge when the

team is composed of healthcare providers with diverse backgrounds. In these circumstances, setting priorities and following protocols during different phases of care can help focus the personnel into a more coherent group. Protocols also ensure consistency and decrease the margin of error in most circumstances. For instance, operative protocols could recommend certain procedures to be used by all surgeons for patients with cleft lip and palate (e.g., assuming acceptable blood reports, primary lip repair at age 10 weeks, followed by Furlow double opposing Z-plasty at the age of 10 months). Nasoalveolar molding, craniofacial orthodontic, and dentofacial orthopedic protocols could be standardized in terms of biomechanics and timing of treatment. The anesthesiologists might suggest protocols on intra- and post-operative pain management. The nursing team might recommend certain staff to patient ratio in the post-operative recovery ward. Compliance with these protocols is imperative to the success of a mission trip or permanent craniofacial care facility, and should be well articulated to each team member from the start. However, it is important to keep in mind that changes in the protocol are permissible under circumstances where it does not apply properly.

4. Equipment

In general, the equipment and supplies needed in a developing world hospital are not different from the ones needed in a modern hospital. Acquisition, preparation, shipping (in case of cleft mission), deployment, and maintenance of equipment are a big challenge for both permanent craniofacial care centers and organizations that aim to provide cleft missions. At minimum, complete surgical trays, sutures and dressings, reliable anesthesia equipment, resuscitation packs, perioperative monitors, and sterile materials are necessary for the cleft repair operations regardless of the practice setting. Care should be taken when using medications and instruments purchased in the host countries, especially if the instructions are not in English or if they are unfamiliar pharmaceutical formulations. A partial list of recommended supplies and equipment for orofacial cleft care centers are listed in **Table 1**.

Screening and assessment

- Vital sign monitors
- Camera
- Lights, tongue blades, and other examination material
- Medical records
- Lab facility for blood tests

Anesthesia

- Anesthesia machine
- Resuscitation boxes with updated, unexpired drugs and dosage schedules
- Airway equipment including masks, endotracheal tubes, airways, laryngoscopes, positive pressure ventilation systems, suction devices, non-invasive monitors, difficult airway management items, anesthetic agent

Post-anesthesia care

Nasoalveolar molding

- Blood supply
- Defibrillator and other appropriate emergency equipment
- Intravenous fluids and fluid administration sets
- Equipment and soaking solutions for the sterilization of non-disposable anesthesia equipment
- Full resuscitation medications of appropriate doses
- Arrangements for glucose level measurement
- Oxygen and suction equipment at each bedside
- Vital sign monitors with pulse oximetry
- Suction equipment
- Documentation system
- Slow speed dental hand piece

Surgery

- Hard acrylic
- Soft acrylic
- Water bath
- Boley gauge
- Orthodontic spatula
- Utility wax
- Three-prong plier
- Light wire plier
- College plier
- Scalpel
- Orthodontic wire
- Dental impression material and cast
- Surgical instrument trays
- Appropriate suture material
- Sterilization material
- Illumination
- Suction machine
- Electrocautery capability

Post-operative intensive care

- An appropriate ICU facility and a plan for critical patient transfer when the ICU is not within the hospital facility
- Electronic monitors
- Respiratory ventilators

Post-operative ward

- 24 hour nursing staff
- Appropriate dressing and cleaning materials
- Medications for pain management, antisepsis, nausea, and other nursing needs
- Vital sign monitoring equipment
- Oxygen availability

Table 1. List of minimum supplies and equipment required for proper cleft care [8, 9].

5. Logistics and transportation

Transportation of the team and equipment is an important part of cleft care during international mission trips, and should not be overlooked. Travel to and from sites can be a costly endeavor, and the logistics must be planned out well before the trip for any hope of coordinated arrival and departure of equipment and personnel. A week-long trip may require months of meticulous planning, including arrangements of passports and visas, housing, meals, social events, and security. If the mission is planned by an international healthcare organization, it is beneficial to have local partnerships or contacts to help navigate the custom regulations when bringing equipment into the host country. The equipment should also be acquired and tested prior to shipping time. Drugs and expendables should be checked for expiration dates and evidence of mishandling or breach in packaging. To further ensure successful transportation, all items should be inventoried and documented.

6. Patient screening and assessment

One of the most crucial elements in cleft care is to determine surgical priority through proper patient screening and assessment. Children in LMIC are often undernourished, and many have concomitant medical illnesses and infectious diseases, all of which can lead to a lowered healing reserve compared to children normally encountered in developing countries. Therefore, when a cleft patient first contacts a healthcare facility for treatment, he/she needs to be properly assessed by a multidisciplinary team. Blood tests should be ordered to evaluate any metabolic abnormalities and the presence of anemia. Low hemoglobin level may be a marker for poor nutrition, and thus associated with high surgical risk. Traditionally, hemoglobin value of 10 g/dl is considered the lower limit of acceptable surgical candidate; however, the data to support this are lacking [8]. During the first phase of screening, risk factors such as poor nutrition, low hemoglobin, significant airway anomalies, and young age should be considered to disqualify a child as a potential candidate for surgery. A number of studies have identified age as a significant risk factor for surgery in children using death or cardiac arrest as primary end points. These studies suggest that neonates (0–30 days) are at a risk as high as 40 times compared to older children or adults, whereas infants (1–12 months) have a 4- to 5-fold increased risk compared to older children [18–20].

For patients that have passed the initial screening phase, a final assessment and evaluation occurs before the operation, which consists of two parts. A team of surgeons first determine surgical priority of the procedure and its estimated duration. If there are any surgical contraindications to the operation, they are identified at this point and the patient will not be scheduled for surgery. Second, the pediatric anesthesiologist team determines the American Society of Anesthesiologists (ASA) patient classification and provides a second independent opinion on the suitability of patient for the surgery. Most importantly, the cardiac and respiratory status of the patient is carefully evaluated at this time [12]. A patient who has satisfied the criteria for each of these phases is selected for surgery. When indicated, a course of preoperative nasoalveolar molding therapy is advised.

Such a comprehensive and lengthy selection procedure is important to ensure patient safety, as well as to maximize the expected benefits from surgery and proper usage of time and resources. **Figure 1** shows an outline of the steps involved in patient selection.

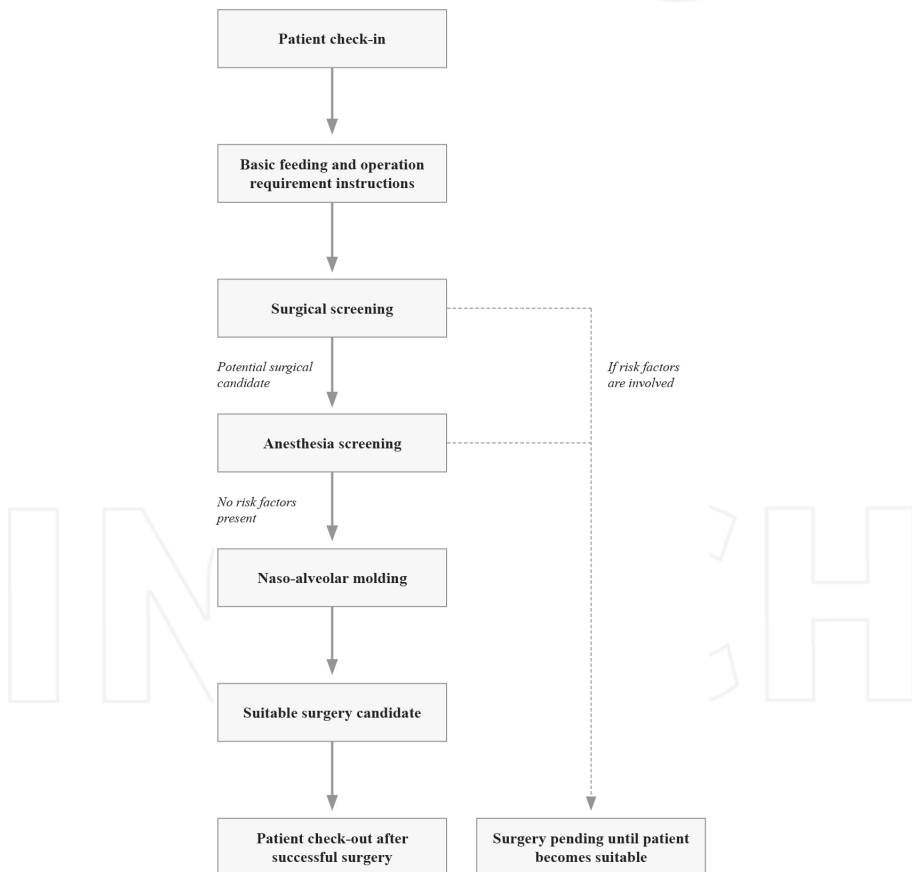


Figure 1. Steps involved in patient selection.

7. Documentation

As in all other endeavors, if it is not written it has not been done. Organizations offering optimal care ought to create detailed documentation and provide an accurate and secure record for the basis of ongoing care and outcome assessments. Documenting details of a patient at every stage makes developing the treatment plan easier for cleft patients. As shown in **Figure 2**, documentation can be divided into five vital areas.

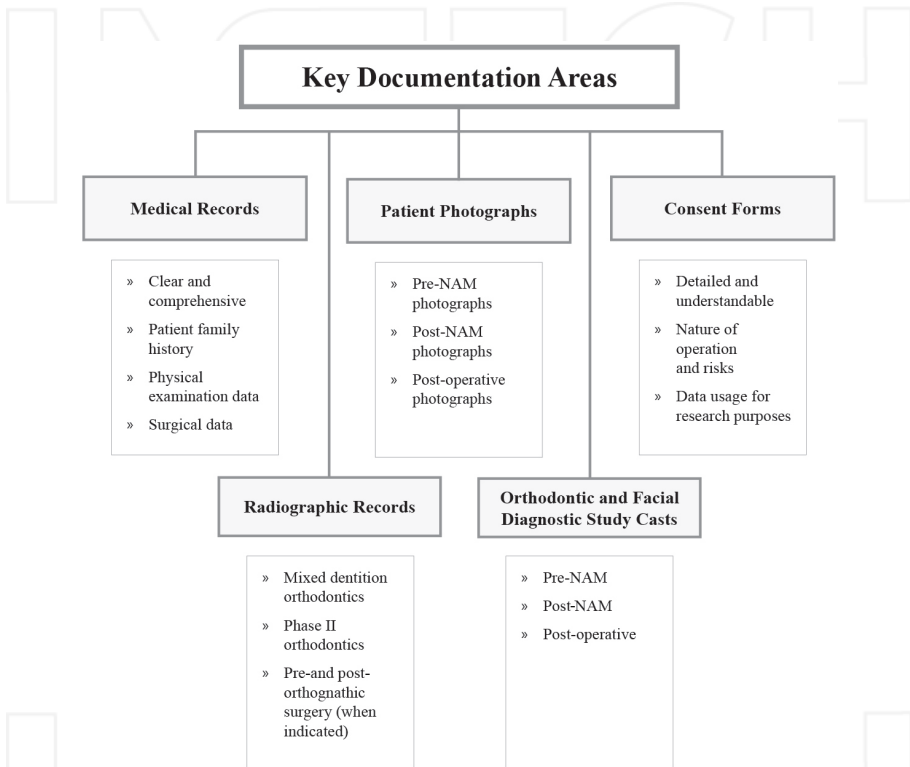


Figure 2. Key documentation areas.

• Medical records

These forms, whether written or electronic, should be identical throughout the organization. They should be comprehensive, explicit, and clear. The history section should include family background, demographic details, and previous history of cleft in the family. A complete record of physical examination and medical diagnosis of data must be entered. Multiple copies should be made for each file. This allows one copy to be left with patient's medical chart in the host country, and another copy to be used for tracking and future analysis.

- **Patient photographs**

Pre- and post-operative photographs of patients are also important as they are a key factor in analyzing results. These photographs can be further used for outcome assessment and research purposes.

- **Orthodontic and facial diagnostic study casts**

Pre-, progress, and post-nasoalveolar molding (NAM) facial and orthodontic diagnostic study casts are imperative for the fabrication of NAM appliances, orthodontic appliances, and orthopedic appliances. Additionally, they are required to evaluate treatment progress, outcomes assessment, and for research purposes.

- **Radiographic records**

Pre-, progress, and post-orthodontic and surgical imaging should be taken as indicated in order to aid in the diagnosis and treatment planning of craniofacial orthodontics, dentofacial orthopedics, and orthognathic surgery. Like photographs and diagnostic study cases, they are also useful for research purposes.

- **Consent forms**

Lastly, consent forms are an integral part of the documentation process. All patients and guardians must read and sign a consent form, which should be comprehensive and clear. The form must include the nature of the operation and its risks, use of anesthesia, potential blood transfusion, HIV, and hepatitis testing in the case of needle stick and permission for taking photographs. The families should also be informed, and oral or written consent should be taken if the data are to be used for research purposes. When language difference exists, professionals should utilize interpreters to assure informed consents are properly documented prior to delivery of care and surgery.

All members of the multidisciplinary cleft care team are responsible for documentation. The cleft care facility should work systematically to ensure that documentation tools are readily available to all health care providers, while at the same time respecting and maintaining patient confidentiality.

8. Sustainable cleft care facility

International organizations have long provided cleft care through surgical missions to selected areas in LMIC with shortage of resources and experienced personnel. The drawback of this practice model is that these health missions often provide short-term relief, making treatment available to limited amount of people for a short time period [3]. The mission trips are dependent on proper funding, grants, and resources. This model of intervention is ideal for urgent humanitarian response to disasters or epidemics, where a substantial amount of resources can be mobilized quickly for disease-specific use in LMIC. However, it is less effective for sustaining long-term care to the indigenous population and for conducting educational/preventive endeavors. This type of practice has been criticized for operating outside of the existing health

care systems and structures, doing little to strengthen the primary care systems in LMIC, and compromising countries' autonomy and participation in health care initiatives [6]. Finally, most of the mission trips are not designed to deal with the complex socioeconomic disease determinants many patients face, and lack the capacity to maintain prolonged post-operative follow-up and therapy.

It has become increasingly clear that one of the most important strategies that can help optimize and increase cleft care globally is to establish effectively run, high-volume, indigenous centers of excellence, capable of serving large and wide spread populations in the LMIC [6]. The ideal long-term goal for international groups should be to prepare local surgical teams to provide the same quality care for their population without outside medical assistance [8]. Once established and maintained, such local cleft care facilities not only provide services throughout the year to its region but can also contribute to the funding needs of much poorer sites in the future.

In order to offer effective surgical and orthodontic/orthopedic interventions, these facilities must develop and maintain an environment that meets world class minimums on proper workforce, access to supplies, instrumentation, infection control, and supporting infrastructure. See **Table 2** for a list of basic requirements.

Physical space	An adequate space should be present for patient screening, assessment, operating rooms, preoperative, and post-operative wards
Laboratory	A basic clinical laboratory to perform regular blood and electrolyte tests
Equipment	The minimum number of instruments required for patient examination, anesthesia, surgery, orthodontics, nasolabial molding, and ward care
Staff	Administrative, management, nursing, and permanent or visiting expert surgery staff to run the facility
Donors	Various funding agencies and/or private donors to run and maintain the cleft center as well as support patients that cannot afford the treatment otherwise
Quality control	A system that ensures that quality of cleft care provided is according to international standards, assures patient/family satisfaction, conducts staff performance reports, and develop guidelines to address the problems faced in the facility

Table 2. Basic requirements for a sustainable cleft care infrastructure/facility.

9. Patient follow-up

Whether it is a cleft mission or a permanent cleft care facility, arrangements for adequate follow-up are important to maximize treatment effectiveness, access the available options for future treatment, and monitor outcomes. As shown in **Figure 3**, a basic post-operative follow-up has two intervals.

However, such a simplified follow-up regimen is rarely adequate for most cleft patients. From birth throughout childhood and adolescence, a cleft patient requires coordinated care among surgeons, orthodontists, and other health care providers. Even after surgery, most cleft patients require regular ear examinations during infancy. Approximately 75% of cleft patients require two to three additional orthodontic/dentofacial orthopedic interventions and continued speech therapy throughout childhood and adolescence to achieve satisfactory growth, speech, and language competence. Coordination of various dental procedures is crucial from the period of mixed dentition through adolescence. Furthermore, overall health and the psychosocial impact of having a cleft also need to be monitored routinely [1, 12, 21].

To achieve such a prolonged follow-up plan, it is the responsibility of the cleft team to maintain communication with the patients and families, extensively educate them on the importance of follow-up and maintain appropriate documentation and record keeping.

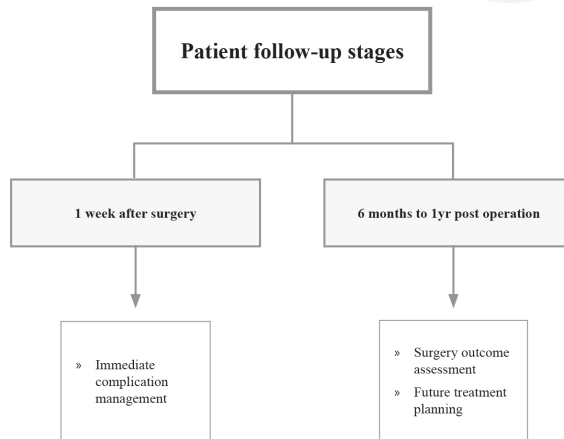


Figure 3. Patient follow-up stages.

10. Education and research

Finally, education and awareness regarding orofacial clefts are key factors in achieving better long-term global access to cleft care. Education in cleft care is conducted at two levels:

(a) Education of parents and caregivers

Educating the care givers of cleft patient is crucial in achieving proper care and satisfactory future outcomes. On the initial visit, caretakers of the children should be given instructions on feeding assistance, airway maintenance, and other basic cleft care information to help the patient prepare for surgical intervention. After the operation, families should be given strict instructions regarding the remainder of their post-operative care at home prior to discharge. Families must

be educated on the need for follow-up after operations and the importance of regular visits to the craniofacial orthodontist, pediatrician, speech therapist and feeding specialist for the long-term.

(b) Training and education of local professionals

It has long been the aim of global health care organizations to provide educational and training opportunities to health care professionals of LMIC, who can thereafter deliver high quality, team-based care in their local regions. A number of approaches have been outlined and proven to be effective in accomplishing this goal:

- **On-site education**

Delivering knowledge to local professionals on-site during cleft missions is effective in transmitting small, focused, and discrete areas of knowledge and experience. Although enormously enriching, such short-term programs provide a rather limited introduction to cleft care and surgery to local professionals present at the time [6].

- **Long-term education and training**

Long-term partnerships between local hospitals and academic institutions in wealthy countries help to provide proper, professional education, and experience. This can either be achieved by allowing fully credentialed visiting surgeons to stay with a host hospital and teach for an extended period of time or by bringing a limited number of host country participants to educational programs in regions with well-established craniofacial centers. More robust academic partnerships can also promote local academic leaders and would enhance training for health care providers in other fields, including speech pathology and surgical technicians. Such training programs aim to provide much needed local cleft care experts, who can contribute to the development of sustainable, self-sufficient cleft care centers.

(c) Clinical research

Collection of prospective, standardized data can yield high quality information that can be used to improve overall knowledge, cleft care processes, and outcomes. In addition to contributing to the field, research results can be presented to local health care professionals and the general population. Research can broadly be categorized as: epidemiological, genetic, prevention/risk factors, clinical presentation, outcomes assessment, and quality of life.

11. Conclusion

Orofacial clefts are a correctable condition with proper treatment resulting in a dramatic improvement of function and quality of life. Providing universal cleft care in LMIC still faces numerous challenges today due to a lack of basic health care infrastructures [22]. Traditionally, international health missions have been very successful in providing reconstructive plastic surgery to people in resource-limited regions. Largely due to the success of

cleft missions, the cleft care community is now in position to increase surgical capacity and promote development of sustainable local cleft care centers that are capable of providing comprehensive, longitudinal care to the indigenous population [6]. With the shift in global cleft care delivery, many organizations have started to incorporate efforts to expand local facility, increase human capital, and foster interdisciplinary quality health care by local providers [22]. As we move toward the future of accessible, sustainable cleft care in LMIC, it will continue to rely on concerted efforts from both international aid groups and local governments to invest in the local health care system.

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