1. Surgical Care in Developing Regions

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INTRODUCTION

- Orofacial clefts are a major public health problem affecting 1 in every 500 to 1000 births worldwide.
- 85-95% of these children are in the developing world, where access to proper care is severely limited.
- Cleft lip and cleft palate remain a stark example of the global burden of surgical disease, with millions of untreated patients worldwide.
- Untreated cleft patients suffer from neglect, prejudice, and isolation throughout the entirety of their lives.
- The burden of suffering for a child with a cleft affects the entire family unit.
- Governments, funding agencies, and professionals are becoming increasingly drawn to the idea of sustainable global surgical care.
- Cleft surgery has been the largest most sustained humanitarian global surgical effort to date, helping to overcome the misconception that surgery is too difficult and costly in resource poor regions.

HISTORY

- International surgical relief traditionally limited by several factors.
    1. Unstable social infrastructure on the receiving end of aid.
    2. Logistics and security of transporting medical supplies.
    3. Outdated medical knowledge and surgical procedural safety.
    4. Limited ability to safely and reliably administer anesthesia.
    5. Difficulty traveling to remote locations.
- The International Red Cross was chartered at Geneva Convention (1864) to protect human life and health, to ensure respect for all human beings, and to prevent and alleviate human suffering.
- The evolution of medical knowledge, as well as surgical procedural safety and effectiveness, began its rapid acceleration in the 1950s and 1960s, leading to modern international surgical missions.
    - African Medical and Research Foundation (AMREF, Flying

Doctors Service) founded in 1957 to provide medical care to remote regions of East Africa.

- Interplast (now ReSurge) formed in 1969 by Donald Laub at Stanford University and began the modern era of mission-based cleft care. Interplast deployed focused, fully manned and equipped surgical teams to targeted locations with the specific intention of delivering safe, effective, and high quality cleft care.
- Operation Smile founded by Bill and Kathy Magee in 1982 and provides free cleft lip and palate surgeries to children worldwide through mission-based care and its global network of cleft centers. Operation Smile additionally concentrates on services, education and training, research and outcomes, and development of sustainable programs.
- Smile Train was founded in 1999 to train and support local doctors to provide cleft surgery and provides education, equipment, and funding to hospitals and professionals for the procedures.
- Transforming Faces was founded in 1999 and advocates strongly for comprehensive cleft care by working in partnership with local cleft specialists and funding community-based medical teams.
- The Chang Gung Craniofacial Center in Taiwan was developed by American plastic surgeon Dr. Samuel Noordhoff is now recognized as one of the leading cleft centers in the world. The Noordhoff Craniofacial Foundation started international medical missions in 1998 and devoted to helping to establish centers of excellence in other countries in need.
- The Plastic Surgery Foundation established Volunteers in Plastic Surgery (VIPS). VIPS is a volunteer mission resource center and functions as a forum for discussing common issues and providing solutions to the many challenges inherent to international care missions.
- Numerous teams from universities, foundations, and private partnerships have developed ongoing relationships with individual communities they support through periodic missions and support of local professionals.

SURGICAL MISSIONS

Today's international voluntary surgical charity movement works to correct facial deformities, build and equip facilities, train competent local surgeons, develop comprehensive cleft care teams, and secure ongoing funding.

- Standards for volunteer missions are essential to the safe and effective execution of these trips.
- Regardless of the type of care, the overriding goal always is the safety of the child. Patient safety can be optimized by careful selection of patients, facilities, procedures, equipment, and staff and through close coordination with host professionals and officials.
- Although the nature of voluntary organizations is to provide maximum service with minimum expenditures, organizations must be measured by using objective criteria to ensure the best quality of care to all patients.

Identification of Need and Host Country Partners

- Mission sites may be identified by local contacts on the basis of personal contacts, proximity to patients, relationships with funding organizations, and affiliation with religious groups or other mutual benefit societies
- For any chance of success, the host country and local community must play a supportive, welcoming role.
- The principal goals of the trip (provision of service, education, training) should be mutually clear to the participants from both the visiting organization and the host site.
- Understanding whatever healthcare system is in place is extremely valuable. Local champions usually emerge from within the medical community no matter how sparse.
- Alliances with motivated laypeople are necessary and allow critical access to patients, facilities, transportation, and media.

Site Visit

- Any new mission location should receive a site visit by professionals with experience working in developing regions.
- Assessments made on facilities, staff, and equipment to under-

stand available infrastructure and what will need to be imported for the mission.
- Local professionals should be identified and recruited to participate and assist in the care of the patients before, during, and after the mission
- Evaluation of logistical support including food, housing, and transportation available for the team and for the patients and families. Safety of the location must also be confirmed.
- Understanding of any similar services provided in the area by local or international organizations.
- Local governmental support and alliances with the healthcare system, non profit sector, educational institutions, and local corporations are important for success of the mission and establishing long term sustainability.

Healthcare Personnel

- Professionals providing perioperative care of children should be competent and qualified to provide similar duties in their country of origin.
- Patients seen in developing regions are especially vulnerable and more complicated to treat due to lack of general health care, poor nutrition, and significant deformity. This makes it even more important for the surgical team to consist of highly skilled individuals who are knowledgeable about the challenges and pitfalls of treating patients in developing regions.
- Each individual professional must be credentialed, qualified, and current in the general body of knowledge and experience of his or her specialty.
- Teams can be as small as a plastic surgeon and anesthesiologist supported by familiar and trusted local healthcare providers with the plan of simply repairing presenting deformities.
- Modern cleft care is often provided by fully articulated cleft care team designed to deliver an entire care package with the eventual plan of building sustainability and self-sufficiency over a multi-year interval.

Cleft Surgeon(s)	Anesthesiologist(s)
Pediatric Intensivist	Pediatrician(s)
Clinical Coordinator	Operating Room Nurses
Recovery Room Nurses	Ward Nurses
Dentist	Medical Records Specialist
Photo Imaging Technician	Biomedical Technician
Speech Therapist	Child Life Specialist
Patient Coordinator(s)	Logistics Coordinator(s)

- Volunteers must commit to additional responsibilities including overseas travel, time away from jobs and families, appropriate health and vaccinations, knowledge regarding professional expectations and responsibilities, and understanding of local customs.
- It is best for organizations to thoroughly educate each volunteer about its core values, repeatedly making them aware of the mission rules. This should be reinforced frequently and distributed in print and verbally before, during, and after the mission.

Facilities and Equipment

- Facilities must provide the space, equipment and support necessary to provide a high standard of care for all patients.
- Electrical power should be dependable and continuous, with clear plans for contingencies of power failure.
- Mission teams import the supplies and equipment necessary to meet basic standards if not available at the host site. This includes acquisition, preparation, shipping, deployment, and maintenance of equipment.
- The operational layout of a mission site must be well planned in advance to maximize patient flow and the efficient use of human resources and materials. The operating room, recovery area, and intensive care region should be co-located to the maximum extent possible. This allows surgeons and anesthesiologists to monitor patients in all perioperative phases.
- Complete surgical trays, sutures and dressings, reliable anesthesia equipment, resuscitation packs, perioperative monitors, and sterility materials are necessary to proceed with operations. (Table 1).

Medical Mission Supplies	
Screening and assessment	Vital sign monitors Camera Oto-ophtalmoscope Lights, tongue blades, and other examination equipment Medical records Laboratory facilities for blood and electrolyte analysis
Anesthesia	Anesthesia machine (with capabilities equivalent to those used un volunteer´s home environments) Resuscitation boxes with current, unexpired drugs and pediatric dosage schedules Airway equipment for pedriatic patients including, but not limited to, masks, endotracheal tubes, airways, laryngoscopes, positive pressure ventilation systems, noninvasive monitors, difficult airway management items, Sevoflurane anesthesic agent, and Dantrolene. Blood matching and blood for transfusion Defibrillator and other appropriate emergency equipment Intravenous fluids and fluid administration sets
Sugery	Appropriately constructed surgical instrument trays for cleft lip, cleft palate, burn, or hand care. Appropriate suture material Sterilization materials whit barrier devices, gowns, and gloves Electrocautery capability Illumination
Postanesthesia care	Full resuscitation packs Oxygen and suction equipment at each bedside Vital signs monitors with pulse oximetry Documentation system
Postoperative intensive care	Either built-in capability in host hospital or provision made for transport of critical patients
Ward nursing units	Appropiate dressing and cleaning materials Medication for pain, antisepsis, nausea, and other nursing needs Vital sign monitoring equipment

Table 1-1. Medical Mission Supplies. Adapted from "Global Aspects of Cleft Care," by R. Sherman and A. Campbell in Losee JE, Kirschner RE (Eds.), Comprehensive Cleft Care 2nd Ed. New York: McGraw-Hill Medical.

- Working, modern anesthesia machines should be recently checked and calibrated. Dependable oxygen supply is provided for all care areas, including sufficient backup.
- Fully functional monitoring is required for all patients in the operating rooms including continuous evaluation of electrocardiography, blood pressure, arterial oxygen saturation, end-tidal carbon dioxide, and temperature. Pulse oximetry should be used, at least initially, for all children in the recovery area. Electrocardiography,

noninvasive blood pressure, and pulse oximetry should be available in all care areas.
- Working suction should be present at each operating room table and in the recovery area and patient ward.
- Basic laboratory and radiology services should be available.
- The capability to transfuse either properly cross-matched, type-specific blood or O-negative fresh whole blood or packed red blood cells should be available when the possibility of significant blood loss exists (palates).
- Organizations or teams intending to care for complex pediatric patients or to perform complex procedures may require a fully staffed and equipped pediatric intensive care unit, comprehensive on-site laboratory and radiology services, and blood banking.

Logistics

- Personnel recruitment, local licensure and visas, equipment acquisition, and travel must be coordinated long before a mission to place resources in the position to achieve safe, quality, and cost effective care.
- Local travel arrangements, housing, meals, social events, and security all play a crucial role in mission success and require meticulous planning.
- Patient identification, mobilization and logistics require sufficient local preparation and action.
- All equipment should be acquired and tested well before shipping time.
- Drugs and expendables should be checked for expiration dates and evidence of mishandling or breech in packaging. Drugs should be tightly controlled and their access and distribution monitored.
- Successful passage through customs requires all shipped items to be accurately inventoried and documented. Those components that are intended to return to the home base should be inventoried separately and differentiated from those that will remain behind. On arrival, cargo and supplies should be inventoried again.

- The host medical leaders should be given a clear explanation about the supplies that will stay versus the supplies that will return with the team.

Patient Assessments

- All surgical and anesthetic procedures are accompanied by recognized risks, which are affected by a variety of patient factors.
- Several factors are widely recognized as contributing to risk and these cases should be considered complex.
  - Age younger than 1 year.
  - Coexisting disease - American Society of Anesthesiologists Physical Status of 3 or greater
  - Previous illness – Upper respiratory infection, lower respiratory infection, fevers.
  - Poor nutrition - Children that are obviously malnourished with height, weight, or head circumference well below that expected for age.
  - Hemoglobin value less than 10 g/dl (greater at altitude).
  - Significant airway anomalies.

American Society of Anesthesiologists Physical Status Classification System

Physical Status	Definition
1	A normal healthy patient.
2	A patient with mild systemic disease.
3	A patienr with severe systemic disease.
4	A patient with severe systemic disease that is a constant threat to life.
5	A moribund patient who is not expected to survive without the operation.
6	A declared brain-dead patient whose organs are being removed for donor purposes.

Table 1-2. ASA Physical Status Classification System.

- Volunteers must commit to additional responsibilities including overseas travel, time away from jobs and families, appropriate health and vaccinations, knowledge regarding professional expectations and responsibilities, and understanding of local customs.
- It is best for organizations to thoroughly educate each volunteer about its core values, repeatedly making them aware of the mission rules. This should be reinforced frequently and distributed in print and verbally before, during, and after the mission.

Protocols

- Competent surgeons, anesthesiologists, and nurses will each have a particular way of doing things.
- Standards, policies, and protocols help focus the mission volunteers into a more coherent group in order to ensure consistency and decrease the margin of error.
- Total compliance with these protocols is imperative to the trip's success and should be well articulated to the group before the mission.
- The Operation Smile Resource Manual / Global Standards of Care assimilates more than 30 of years of organizational experience and the knowledge of global medical leaders from all disciplines with special expertise in caring for children.
    - Patient Rights and Responsibilities
    - Operation Smile Global Standards
    - Operation Smile Policies and Supporting Documents

Documentation

- Medical record forms (written or electronic) should be explicit and clearly designed, and identical throughout the organization. Medical history, physical examination, and all aspects of treatment and follow up care should be clearly documented.
- All patients or guardians must read and sign a consent form. These forms should be equivalent in content to those used in the United States. They must be comprehensive and translated using a skilled interpreter. They must, at least, include the nature of the operation and its attendant risks, the use of anesthesia and potential blood transfusions, the taking of pictures, and HIV and hepatitis testing in the case of a needle stick.
- Preoperative and postoperative photographs are a key factor in analyzing results. They should be taken of all patients in standard, well-lit poses and properly labeled to identify the patient.

Sustainability

- Charitable surgery involves shifting of costs away from the patient to provide care that is otherwise unattainable, and requires signifi-

cant resources and financial support.
  - Lost income to medical volunteers during their time of service.
  - Travel, food, and housing for volunteers.
  - Equipment, supplies, and pharmaceuticals.
  - Administration and organizational infrastructure.
- Fundraising, grant writing, and other development strategies must continually bring in money to sustain and grow organizations providing charitable surgery. Income is largely derived from grants, gala events, media campaigns, private donors, and annual fund drives.
- This requires dedicated administrative specialists to oversee these operations, and investment in development efforts.
- It is wise to invest in local foundations in host countries, who then share in development of local professionals, infrastructure and funding.
- Ideally host countries mature to become self-sufficient, and are then able to contribute to the supporting the needs of poorer sites in their regions.

Education

- Providing educational opportunities and building sustainable capacity for care is where surgical charity work, medical training, modern communications, and globalization come together.
- On-site education is effective in transmitting small, focused, and discrete areas of knowledge and competencies, like Basic Cardiac Life Support (BCLS), ACLS, PALS, or sterilization techniques. It can also result in meaningful mentoring opportunities in surgery and other specialties.
- Visiting educator programs take skilled international surgeons to a host hospital and teach and train local surgeons.
- Long term partnerships increase impact through educational investments.
- Visiting scholar programs bring a limited number of host country participants to educational program opportunities in various resource locations, including Canada, the United States, Taipei, Singapore, and Europe for time periods varying from 2 weeks

to 2 years.
- Additional training opportunities are now emerging in developing countries, which are leveraging expertise and infrastructure gained through local development efforts to expand the number of skilled providers in regions of need.

Follow Up and Quality Assurance

- Trip planning should anticipate the need for follow-up of patients postoperatively to monitor surgical outcome, address surgical complications, and track all perioperative complications. This should include a physician and at least one medical support professional that are present with the team and that understand postoperative management.
- Personnel located in the local region with appropriate skills for following up postoperative care should be identified and trained to report all postoperative outcomes to the sponsoring agency's medical supervisors.
- Standardized photos should be taken of all postoperative patients.
- Data monitored for quality assurance should include the following:
    - Critical events, such as cardiac arrest, respiratory failure, and death; unanticipated escalation in level of care (postoperative ventilatory support, intensive care unit or equivalent care), unanticipated need for transfusion, life-threatening emergencies, or return to the operating room to manage complications.
    - Anesthesia quality markers should be recorded such as unanticipated difficult intubation, laryngospasm requiring reintubation, postanesthesia care unit reintubation, bronchospasm, cancellation after induction of anesthesia, postoperative nausea and vomiting, and post operative pain control.
    - Early surgical complications to be recorded include return to surgery for bleeding, infection, dehiscence, fistula and others. Surgical complications seen in follow up include infection, dehiscence, fistula, poor cosmetic result, and others.
- Organizations should have a readily available written plan for managing adverse outcomes and crisis.

THE SURGICAL SPECIALTY HOSPITAL

- Governments, funding agencies, foundations, and professionals are increasingly drawn to the notion of sustainable global surgical care.
- Many organizations advocate the use of high-volume hospitals for complex surgical procedures and for those requiring comprehensive multidisciplinary care.
- Specialty surgical centers have been suggested by numerous authorities as the optimal approach to cleft care in both wealthy and developing nations.

Case Study: The Guwahati Comprehensive Cleft Care Center: Scalable, Sustainable, and Cost Effective Surgical Care

I. Challenge and Commitment

- India is facing a crisis in cleft care, with 1 million estimated untreated cases.
- The state of Assam in Northeast India exemplifies this seemingly insurmountable cleft burden: 1000 children are born every year with cleft lip and cleft palate, and the backlog of untreated patients in the region is estimated at 30,000.
- Through observations made during mission trips, Operation Smile identified this region as an area with a large burden of cleft disease.
- A unique strategy was used in Guwahati to effectively evolve from mission-based care to a sustainable specialty cleft center. This involved a transition from vertical inputs through missions to horizontal investments in permanent infrastructure and human capital. This represents a diagonal model of care delivery, which can help

a greater portion of the underserved population.

- The Guwahati Comprehensive Cleft Care Center (GCCCC) is the result of a unique partnership between government, charity, and private enterprise and charged with the mission to provide safe, quality, comprehensive, and cost-effective surgical care to a highly vulnerable patient population.
- A state-of-the-art surgical facility was constructed that includes a modern integrated operating suite with an open layout, advanced surgical equipment, sophisticated anesthesia and monitoring capabilities, central medical gases, and sterilization facilities.

II. Program Development and Quality Care

- GCCCC is open year round and offers full-time services and follow-up care.
- A team of international professionals from various disciplines served in Guwahati full time to oversee patient care and train the local surgeons.
- Recruitment of local professionals in all disciplines began early in the scheme of the program and led to gradual expansion of all medical teams.
- Local medical providers participated in a model of graded responsibility commiserate with individual skill and progress. Gradually local providers assumed all leadership positions and 100% of the workforce.
- The GCCCC took a needs-based approach to care and provides world-class care to the most needy patients. This required development of innovative programs in patient mobilization, patient care services, patient education, nutrition, and follow up.
- The GCCCC placed emphasis on achieving optimal outcomes for

each patient treated rather than treating the maximum number of patients.

- Along with surgery, GCCCC provides speech therapy, child life counseling, dental care, otolaryngology, orthodontics, and nutrition services for their cleft patients under one roof.
- These institutional infrastructure improvements positioned and empowered teams of skilled local health care professionals while implementing systemized perioperative processes.
- This helped to further optimize quality and safety of all clinical care through expanded formalization of education and training, quality assurance, infection control, and patient education.

III. Impact and Sustainability

- Operation Smile carried out six international missions in Guwahati, treating more than 3000 patients between January 2009 and February 2011.
- Since opening in May 2011, the GCCCC has provided surgical care to an additional 10,000 patients while building local capacity, improving outcomes, and achieving sustainability.
- The GCCCC developed into a regional referral center and center of education and research, providing world-class care to the most needy of patients while contributing to the evolution of global cleft care.
- Governments of surrounding states have contracted the GCCCC to provide care for their citizens with cleft lip and cleft palate, and teams from the center travel to regional hospitals on outreach missions to provide surgery and multidisciplinary care to exceptionally remote populations.

Key Acomplishements

- Patient mobilization programs penetrated all 27 districts and 149 blocks in the state, educated 34,000 community health workers, and mobilized more than 10,000 patients for free surgery.
- Patient care programs assist patients and families with food, transportation, and shelter and guide them through the treatment process. More than 15,000 patients and family members have received these services, with 95% satisfaction rates on regular patient surveys.
- Evolution of surgical technique and perioperative care processes has decreased complications by 85%. Despite the vulnerability of patients and complexity of cases, outcomes at the GCCCC are comparable to those published in North America and Europe.
- A specialized nutrition team identifies malnourished patients and provides integral interventions. More than 500 nutrition patients have received successful surgery after care by the nutrition team.
- Patient follow-up programs have led to a 360% increase in patient follow-up and a total of more than 15,000 follow-up examinations. This has led to improved analysis of care as well as expanded provisions for speech therapy; dental work; ear, nose, and throat (ENT) treatments; and future surgical services.
- Delivery of multidisciplinary services was enhanced. Dental care is provided to all patients, and orthodontic services were initiated. Speech therapists provided 4000 evaluations and

treatment sessions per year. Child life specialists provided perioperative services and counseling to 100% of patients and their families.

- Education and training were been prioritized in all divisions. A robust visiting professor program hosted distinguished professionals from around the world, and agreements were formalized with numerous universities for collaboration and exchange. More than 150 visiting fellows from 20 countries have rotated in Guwahati, and formalized training programs were created in cleft surgery, anesthesia, and nursing.
- Emergency preparedness is vigorous. Local teams regularly participate in training. All physicians and nurses achieved accreditation through the American Heart Association (AHA) in basic life support (BLS) and PALS.
- Research centered at GC4 has produced more than 100 presentations at national and international conferences and more than 30 publications in academic journals.
- The GCCCC created three programs to define and improve the quality of care: (1) the quality assurance program, (2) the surgical outcomes program, and (3) division of research and outcomes were established to define and improve the quality of care. An institutional review board was created to oversee all research projects, and numerous university partnerships facilitated collaboration and combination of complementary resources.
- When compared with the costs of international missions, the cost per surgery decreased by 40% while greatly increasing investment into the institution and the community.
- Several large reviews recently determined that care provided

by GCCCC was cost effective while averting significant disability. The center has been cited as an effective model for surgical care in resource-poor settings.

- The President of India, the Health Minister of India, and a Nobel Laureate in economics have cited the GCCCC as a role model for surgical care in developing regions.

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