

# Foundation-Based Cleft Care in Developing Countries

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**Background:** Cleft deformities of the lip and palate affect nearly one in 500 to 700 births, and lead to increased morbidity and mortality if untreated. Nevertheless, significant global disparities in access to timely and appropriate care still exist. The relatively basic infrastructure required to surgically correct these deformities and large unmet disease burden have resulted in a significant number of foundation-based cleft care initiatives focused on developing countries. In this study, the authors evaluate the peer-reviewed literature generated by these foundations in an attempt to assess their clinical, scientific, educational, and economic impact.

**Methods:** A comprehensive review of the literature was performed using key search terms, and the level of evidence of identified articles was determined. Data were then analyzed to determine the different models of foundation-based cleft care in developing countries, and their clinical, scientific, educational, and economic impact.

**Results:** A total of 244 articles were identified through the authors' search and reviewed. Foundation-based cleft care initiatives in developing countries have significantly contributed to a better understanding of disease epidemiology, barriers to care, safety considerations, complications and outcomes, and international and local cleft surgery education. The cleft care center model is more cost-effective than the surgical mission model and provides more sustainable care.

**Conclusions:** Foundation-based cleft care prevents significant morbidity in developing countries and has provided valuable resources for capacity building. The surgical mission model should be considered as a transitory conduit for establishing the more effective and sustainable cleft care center model of care. (*Plast. Reconstr. Surg.* 143: 1165, 2019.)

Congenital cleft lip and/or palate anomalies affect approximately one in 500 to 700 births, with varying global rates<sup>1,2</sup>; have an estimated incidence of 250,000 per year in low- to middle-income countries<sup>3</sup>; and, if untreated, result in significant morbidity and mortality.<sup>4</sup> For these patients, the goal is to repair the cleft lip within the first year of life and, if present, repair the cleft palate by the age of 18 months.<sup>5</sup>

The large unmet surgical burden, relatively basic infrastructure required for correction, and its dramatic impact on quality of life have made

cleft surgery in low- to middle-income countries an attractive target for foundation-based initiatives over the past four decades.<sup>6-9</sup> The care provided by these foundations varies widely in geographic location, delivery models, services, and sustainability. The literature would suggest that certain care delivery models may work better than others and that each model has benefits

**Disclosure:** *None of the authors has a financial interest to declare in relation to the content of this article.*

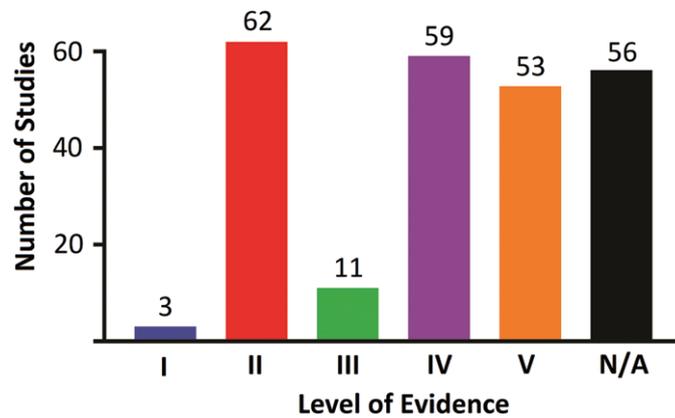
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*Received for publication June 20, 2018; accepted September 10, 2018.*

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DOI: 10.1097/PRS.0000000000005416



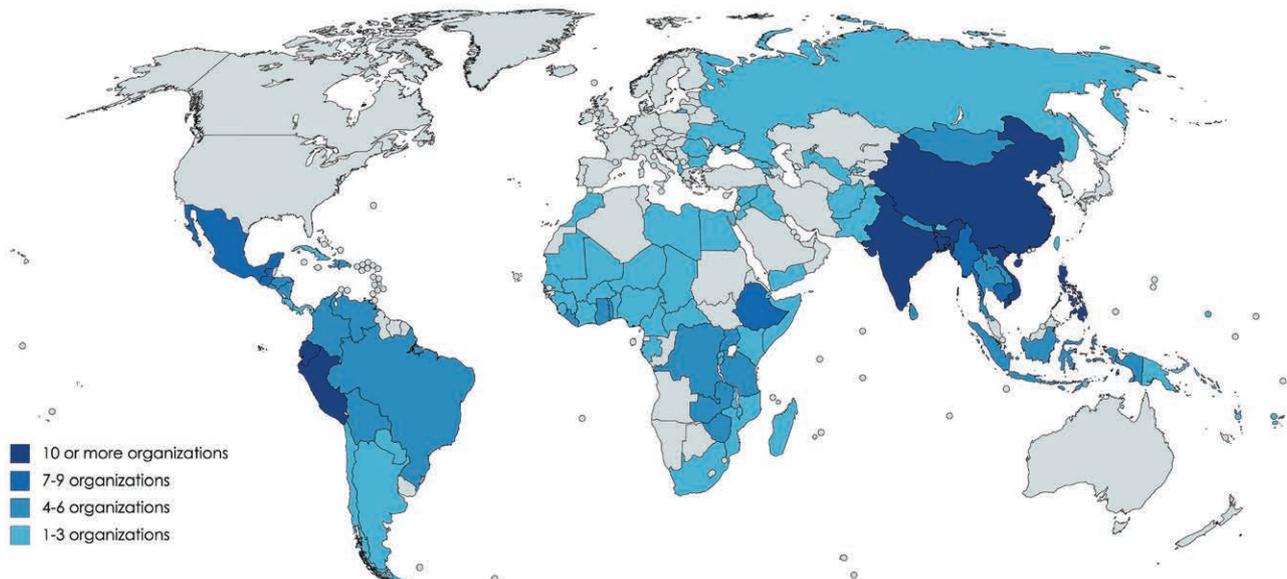
**Fig. 1.** Level of evidence of identified studies. All 244 studies identified in the peer-reviewed literature were evaluated by two raters according to the Oxford Centre for Evidence-Based Medicine classification.

and limitations.<sup>10-12</sup> To capture and evaluate the impact and limitations of cleft foundations, we evaluated the peer-reviewed literature generated by these foundations in an attempt to define their clinical, scientific, educational, and economic impact on cleft care in developing countries.

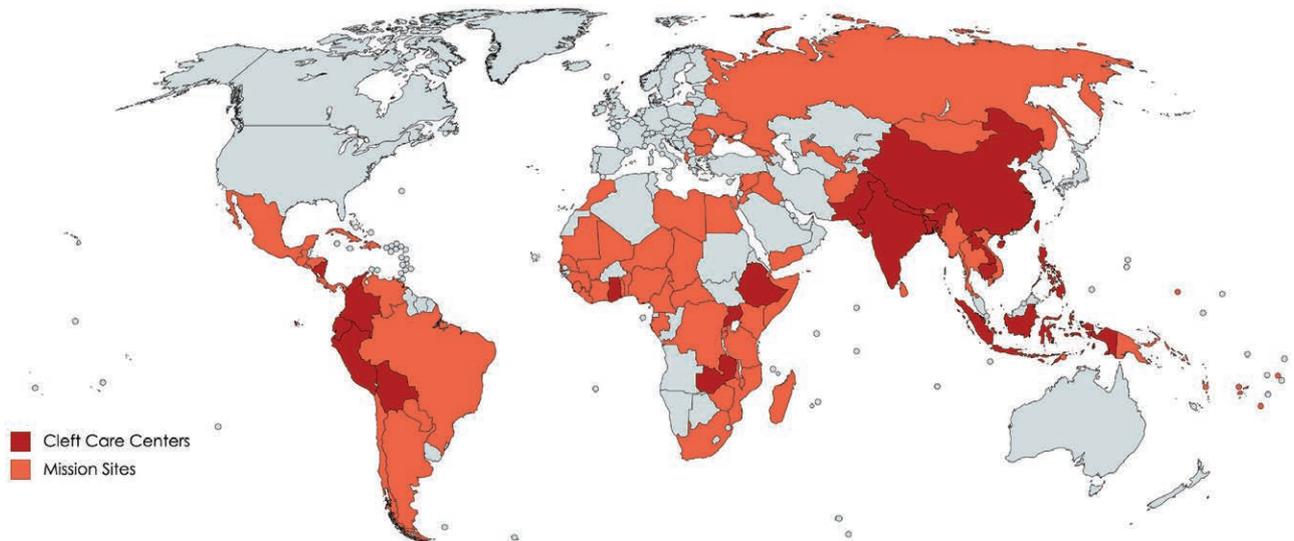
**METHODS**

For this review, the following PubMed search terms were used: “cleft,” “cleft care,” “cleft surgery,” “cleft lip,” “cleft palate,” “developing countries,” “low income country,” “middle income country,” “LMIC,” “surgical missions,” “medical missions,” “non-governmental organizations,” “foundations,”

“humanitarian,” and “volunteerism.” Only English language articles were included. The references in articles identified through this search strategy were also reviewed. Low- to middle-income countries were defined based on the World Bank 2017 classification of countries by income.<sup>13</sup> The level of evidence of the 244 identified articles was determined by two raters through consensus according to the Oxford Centre for Evidence-Based Medicine classification (Fig. 1).<sup>14</sup> In addition to the evaluated articles, websites of identified cleft foundations were reviewed for clarification of missions and cleft center sites. Collected data were subsequently analyzed and used to generate Figures 2 and 3 and Table 1. The variability in the outcomes



**Fig. 2.** Number of cleft organizations per country. The number of cleft organizations operating in each country was determined by analyzing 244 articles from the literature review and reviewing the websites of the cleft foundations identified in these articles.



**Fig. 3.** Distribution of cleft care centers and mission sites. The locations of cleft care centers and mission sites were determined by analyzing all 244 articles from the literature review and reviewing the websites of the cleft foundations identified in these articles.

reported by these studies prevented us from performing a systematic review or meta-analysis.

### CLEFT CARE DELIVERY MODELS

Foundation-based cleft initiatives in low- to middle-income countries are broadly classified as vertical, horizontal, or diagonal.<sup>15</sup> Vertical initiatives are exemplified by surgical mission trips, where teams travel to areas with limited access to cleft care along with necessary equipment and medications. These initiatives can provide service delivery in areas with an untreated backlog of cases, provide expert consultation, and deliver surgical equipment.<sup>16</sup> However, they have often been criticized for the following: lack of sustainability,<sup>11</sup> focusing on patient volume rather than quality,<sup>12</sup> disrupting host country infrastructure,<sup>17</sup> and not being cost-effective.<sup>18</sup>

Horizontal initiatives focus on investing in the host country infrastructure and collaborating with local health authorities.<sup>10</sup> The strength of this model lies in capacity building and sustainability.<sup>19</sup> Although this is critical to achieve cleft care autonomy, horizontal systems often need a significant amount of time to instill noticeable change, and may fail in areas that are completely deprived of surgical expertise.<sup>20</sup> These initiatives focus on expansion of service delivery in areas where basic infrastructure and human resources are already available.

Diagonal initiatives provide vertical care through surgical missions, and invest in horizontal capacity building and transition to autonomy.<sup>15,20</sup> This approach has allowed numerous

foundations to translate initial surgical mission trips into sustainable cleft care centers,<sup>16,21–25</sup> such as Operation Smile in India<sup>23</sup> and Resurge International (formerly Interplast) in Nepal.<sup>21,22,24</sup> The Guwahati Comprehensive Cleft Care Center in India is a self-sustainable, comprehensive surgical center, which focuses on cleft care, education, and outcomes research.<sup>23</sup> In Nepal, Resurge International successfully launched a cleft care center with an emphasis on patient safety, preservation of local culture, and the teaching of local surgeons.<sup>24</sup> Their model progresses through the initial stages of “observation” and “integration,” with the ultimate goal of eliminating their program during the final “independence” stage.<sup>24</sup>

It is important to note that although the classification of foundation-based cleft initiatives in low- to middle-income countries into vertical, horizontal, or diagonal is useful in describing the convergence of horizontal and vertical models of care, it does not fully capture the dynamic nature of these initiatives, their evolution over time, and the specific setting in which they were launched. Although some surgical mission trips were ultimately labeled as surgical safaris, many were launched by well-intentioned physicians and philanthropists responding to a clinical deficit. With time, increasing experience, local collaborations, and the establishment of appropriate follow-up mechanisms, foundation-based cleft initiatives are able to metamorphose into internationally renowned centers providing high-quality care such as the Noordhoff Craniofacial Center at Chang Gung Memorial Hospital; or even broaden

**Table 1. Cleft Foundations in Low- to Middle-Income Countries\***

Foundation	Headquarters	Founded	Mission/Partner Site	Cleft Care Center
ReSurge (Interplast)	Sunnyvale, Calif.	1969	Missions: Bangladesh, Bolivia, Cambodia, China, Ecuador, Ghana, India, Mali, Nepal, Nicaragua, Uzbekistan, Vietnam, Zambia, Zimbabwe	Bangladesh, Ecuador, Ghana, India (2), Nepal, Nicaragua, Peru (2), Zambia
Healing the Children (HTC)	Spokane, Wash.	1979	Missions: Bangladesh, Bolivia, Colombia, El Salvador, India, Peru	—
Terres des Hommes Programa San Francisco de Asis	Lausanne, Switzerland St. Paul, Minn.	1980 1981	Missions: Benin, Togo Missions: Peru	— —
Operation Smile	Virginia Beach, Va.	1982	Missions: Bolivia, Brazil, Cambodia, China, Colombia, Democratic Republic of the Congo, Dominican Republic, Ecuador, Egypt, Ethiopia, Ghana, Guatemala, Haiti, Honduras, India, Iraq, Jordan, Kenya, Laos, Liberia, Madagascar, Malawi, Mexico, Morocco, Myanmar, Nicaragua, Panama, Paraguay, Peru, Philippines, Russia, Rwanda, South Africa, Thailand, Venezuela, Vietnam	Bolivia, Colombia, Ethiopia, India, Nicaragua, Vietnam
Interplast Aust./ANZ	Melbourne, Australia	1983	Missions: Bangladesh, Bhutan, Cambodia, Fiji, Indonesia, Kiribati, Laos, Mongolia, Myanmar, Nepal, Papua New Guinea, Philippines, Samoa, Solomon Islands, Sri Lanka, Tonga, Vanuatu, Vietnam	Laos
Operation San Jose Mission Trip	Houston, Texas	1983	Missions: Ecuador, Honduras, Mexico, Nicaragua, Peru, Venezuela	—
Sri Lankan Cleft Lip and Palate Project	London, England	1984	Missions: Sri Lanka	—
Austin Smiles	Austin, Texas	1987	Missions: Brazil, Cuba, Dominican Republic, Ecuador, El Salvador, Guatemala, Mexico, Micronesia, Philippines	—
Smiles International Foundation	Carlsbad, Calif.	1987	Missions: Costa Rica, India, Ivory Coast, Mexico, Ukraine	—
Operation of Hope	Lake Forest, Ill.	1988	Missions: Ecuador, Zimbabwe	—
Duang-Kaew Foundation	Bangkok, Thailand	1988	Missions: Bhutan, Cambodia, China, India, Laos, Myanmar, Sri Lanka, Vietnam	—
Interethnos Interplast Italy	Bologna, Italy	1988	Missions: Albania, Bangladesh, Bhutan, Bolivia, China, Honduras, India, Iraq, Kurdistan, Morocco, Myanmar, Nepal, Peru, Tanzania, Thailand, Tibet, Togo, Uganda, Vietnam, Zambia	—
Noordhoff Craniofacial Foundation	Taipei, Taiwan	1990	Missions: Cambodia, China, Dominican Republic, Indonesia, Laos, Mongolia, Myanmar, Philippines, Vietnam	Cambodia, China, Indonesia, Philippines, Taiwan
Philippine American Group of Educators and Surgeons	Manila, Philippines	1990	Missions: Philippines	—
Hands Across the World Rotaplast International	Natick, Mass. San Francisco, Calif.	1991 1992	Missions: Ecuador Missions: Argentina, Bangladesh, Bolivia, Brazil, Chile, China, Colombia, Dominican Republic, Ecuador, Egypt, El Salvador, Ethiopia, Guatemala, India, Liberia, Mexico, Myanmar, Nepal, Peru, Philippines, Romania, Tanzania, Togo, Venezuela, Vietnam	— —
Japanese Cleft Palate Foundation	Tokyo, Japan	1992	Missions: Bangladesh, China, Indonesia, Laos, Myanmar, Vietnam	—
Cirplast Adventist Development and Relief Agency	Lima, Peru Tokyo, Japan	1995 1995	Missions: Peru Missions: Nepal	— —

(Continued)

**Table 1. Continued**

Foundation	Headquarters	Founded	Mission/Partner Site	Cleft Care Center
Smile for Children Smile Train	Seoul, Republic of Korea New York, N.Y.	1996 1998	Missions: Vietnam Partners: Afghanistan, Argentina, Bangladesh, Benin, Bolivia, Brazil, Bulgaria, Burkina Faso, Burundi, Cambodia, Cameroon, Central African Republic, Chad, Chile, China, Colombia, Democratic Republic of the Congo, Djibouti, Dominican Republic, Ecuador, Egypt, El Salvador, Ethiopia, Georgia, Ghana, Guatemala, Guinea, Haiti, Honduras, India, Indonesia, Iraq, Jordan, Kenya, Lebanon, Liberia, Madagascar, Malawi, Mali, Mauritania, Mexico, Mongolia, Mozambique, Myanmar, Nicaragua, Niger, Nepal, Nigeria, Pakistan, Panama, Peru, Philippines, Rwanda, Senegal, Sierra Leone, Somalia, Sri Lanka, Tanzania, Thailand, Togo, Uganda, Ukraine, Uzbekistan, Venezuela, Yemen, Zambia, Zimbabwe	—
Children's Surgical Centre	Phnom Penh, Cambodia	1998	Missions: Cambodia	Cambodia
Comprehensive Rehabilitation Services in Uganda	Kisubi, Uganda	1998	Uganda	Uganda
Transforming Faces Worldwide	Toronto, Ontario, Canada	1999	Missions: Argentina, Chile, Costa Rica, Ethiopia, India, Myanmar, Peru, Thailand	—
Overseas Specialist Surgical Association of Australia	Melbourne, Australia	2000	Missions: East Timor	—
Medical Missions for Children	Woburn, Mass.	2000	Missions: Cambodia, China, Ecuador, Guatemala, Peru, Philippines, Rwanda, Tanzania, Ukraine	—
Northern Cleft Foundation	Lancashire, England	2001	Missions: India	—
FACES Foundation	Portland, Ore.	2001	Missions: Peru	—
Children's Surgery International	Minneapolis, Minn.	2001	Missions: Bangladesh, Ethiopia, Ghana, Haiti, Liberia, Mexico, Peru, Vietnam	—
Smile Network	Minneapolis, Minn.	2001	Missions: Guatemala, Haiti, India, Mexico, Peru, Philippines	—
International Changing Children's Lives	New Haven, Conn.	2007	Missions: China, Colombia, Thailand, Uganda, Vietnam	—
Emergenza Sorrisi Onlus	Rome, Italy	2007	Missions: Afghanistan, Armenia, Bangladesh, Benin, Burkina Faso, Democratic Republic of the Congo, Ethiopia, Gabon, Georgia, Haiti, Indonesia, Iraq, Ivory Coast, Libya, Mozambique, Pakistan, Senegal, Syria, Tanzania, Uganda, Yemen	—
Global Smile Foundation	Norwood, Mass.	2008	Missions: Brazil, Burkina Faso, Ecuador, El Salvador, Guatemala, Ivory Coast, Lebanon, Mali, Peru, Senegal	Brazil, Ecuador, Lebanon
Free to Smile Foundation	Columbus, Ohio	2008	Missions: Ethiopia, Guatemala, Niger, Philippines, Zimbabwe	—
Smile Bangladesh	Mountainside, N.J.	2010	Missions: Bangladesh, Sri Lanka	—
JP Clawson Medical Missions Foundation	Longview, Wash.	2010	Missions: Cameroon, Ecuador, Ethiopia, Democratic Republic of the Congo, Philippines, Zambia, Zimbabwe	—

\*The cleft foundations were identified by evaluating all 244 articles identified in the peer-reviewed literature, while the foundation headquarters, year of foundation, mission or partner sites, and cleft care center sites were determined by reviewing the 244 articles and the websites of identified cleft foundations.

their health focus, such as the Flying Doctors, and providing safe anesthesia and drinking water to areas in need.<sup>26,27</sup> Furthermore, although the goal of all surgical initiatives to developing countries should be to promote local sustainability, simply providing financial resources to support the creation of a local cleft center is insufficient, as high-quality cleft care and optimal patient outcomes rely on highly qualified and appropriately trained surgeons. In these areas with a deficit in trained surgical personnel, the surgical mission model should act as a conduit toward the establishment of sustainable long-term cleft care centers.

### CLINICAL IMPACT

The high volume of patients encountered by foundation-driven initiatives as a result of the large unmet burden of disease<sup>2,28–30</sup> has resulted in epidemiologic,<sup>2</sup> clinical outcomes,<sup>30</sup> and randomized controlled studies.<sup>31–33</sup>

#### Epidemiology

The establishment of patient databases has contributed to a better understanding of the epidemiologic nuances of cleft lip and palate.<sup>2,29,30,34–39</sup> Review of 352,191 cleft operations showed a positive correlation between country income and frequency of cleft palate repair.<sup>2</sup> Classically, the cleft lip-to-cleft lip and palate-to-cleft palate ratio is reported to be 1:2:1, with 2:1 unilateral-to-bilateral and left-to-right ratios and male predominance.<sup>40</sup> More than 260,000 surgical procedures performed in India showed a cleft lip–cleft lip and palate–cleft palate ratio of 1.5:4.7:1, a unilateral-to-bilateral ratio of 2.5:1, a left-to-right ratio of 2:1, and a male-to-female ratio of 1.6:1.<sup>29</sup> In China, a retrospective analysis of 205,679 patients with orofacial clefts showed a cleft lip–cleft lip and palate–cleft palate ratio of 1:1.7:1.3, with male predominance.<sup>30</sup> Data from 36,384 cases performed in 33 African countries identified a cleft lip–cleft lip and palate–cleft palate ratio of 5.1:8.8:1, a unilateral-to-bilateral ratio of 2.93:1.0, a left-to-right ratio of 1.69:1.0, and an overall male-to-female ratio of 1.46:1.<sup>35</sup> Although the global prevalence of orofacial clefts is estimated to be approximately two of 1000 to 1.43 of 1000,<sup>1</sup> global variations do exist, with rates of 0.5 of 1000 births in Nigeria,<sup>36</sup> 0.44 of 1000 in Ethiopia,<sup>37</sup> 1.91 of 1000 in Pakistan,<sup>38</sup> and 1.94 of 1000 in the Philippines.<sup>39</sup> Importantly, although these studies offer insight into the global variations of cleft lip and palate incidence and help shed light on cultural and socioeconomic nuances that affect cleft care in

different settings, they may be underrepresentative because of significant mortality in children with unrepaired palates, estimated to be as high as 91 percent in Uganda.<sup>41</sup> Furthermore, parents of children born with cleft lip were significantly more likely to seek care compared with parents of children born with isolated cleft palate, because of the less visible nature of the palatal defect.<sup>41</sup>

Global variations in the severity of cleft lip deformities also exist, with patients in the Asian region—specifically, in the Philippines and Vietnam—presenting with more severe unilateral cleft lip deformities than patients in the Middle East, North Africa, and sub-Saharan African regions.<sup>34</sup> Future genome analyses will provide a better understanding of these global variations, and recent genetic studies have identified a positive association between *MSX1* CA polymorphism and cleft lip with or without cleft palate in a Colombian population.<sup>42</sup>

#### Barriers to Care

Barriers to cleft care are geographically diverse and unique to different patient populations.<sup>43</sup> There is a strong correlation between national income and delayed access to primary cleft palate surgery, with a 70 percent increase in the odds of late surgery for every \$1000 decrease in Gross Domestic Product per capita in low- and lower-middle-income countries specifically.<sup>44</sup> The most commonly reported barriers to access were travel costs, followed by lack of awareness, then lack of financial support.<sup>43</sup> Patient travel cost was the major barrier to cleft care in sub-Saharan Africa, the Middle East, North Africa, South Asia, and Southeast Asia, whereas lack of financial support was the most common barrier in the Americas, Eastern Europe, and East Asia.<sup>43</sup> Importantly, a survey of patients seeking cleft care with Operation Smile in Vietnam reported cost, mistrust of medical providers, and lack of supplies and trained physicians as the most significant barriers to care.<sup>45</sup> In a cross-sectional, multisite study of families seeking care in Vietnam through the same group, regression analysis showed that higher paternal educational level and male patient sex were significantly associated with timely cleft care, whereas distance and cost of travel were not associated with timing of access.<sup>46</sup>

#### Safety, Quality Assurance, and Ethical Considerations

Outcomes collection and auditing systems have proven essential for analyzing risk factors

**Table 2. Level I Evidence Studies Performed by Cleft Foundations in Low- to Middle-Income Countries**

Reference	Study Design and Patients	Patients	Location	Intervention	Sample Size	Results
Rossell-Perry et al., 2014 <sup>31</sup>	PRDB	1-yr-old with cleft palate	Outreach Surgical Center, Lima, Peru	New technique of uvular repair during PCPR	Conventional technique, <i>n</i> = 30; new technique, <i>n</i> = 30	Better uvular position and shape with new technique without an increased rate of fistula and/or VPI
Aznar et al., 2015 <sup>32</sup>	PRDB	Aged 1–43 yr (median, 9 yr) with cleft palate	GC4, Guwahati, India	5-day regimen of oral postoperative amoxicillin after PCPR	Antibiotics, <i>n</i> = 270; placebo, <i>n</i> = 276	Postoperative antibiotics decreased the incidence of fistulae from 17.1% to 10.7% without reaching statistical significance
Rossell-Perry et al., 2017 <sup>33</sup>	PRDB	1-yr-old with unilateral cleft lip and palate, with lip repaired at 3 mo	Outreach Surgical Center, Lima, Peru	One-flap palatoplasty with relaxing incisions versus two-flap palatoplasty	One-flap palatoplasty group, <i>n</i> = 70; two-flap palatoplasty group, <i>n</i> = 72	No statistically significant differences in maxillary and dental arch dimensions between the two groups, using the 5-yr-old's index

PRDB, prospective, randomized, double-blind; VPI, velopharyngeal insufficiency; PCPR, primary cleft palate repair; GC4, Guwahati Comprehensive Cleft Care Center.

associated with postoperative adverse events.<sup>47</sup> Consequently, many foundations have developed standardized perioperative protocols in low- to middle-income countries. Anesthetic guidelines developed and implemented by Smile Train<sup>48</sup> and Operation Smile<sup>49</sup> represent examples of such efforts. Similarly, the Global Smile Foundation emergency response protocol is another illustration of efforts to optimize patient safety in underresourced settings and to adapt to the uncertainties of providing surgical cleft care in low- to middle-income countries.<sup>50</sup> The same group<sup>9</sup> and Operation Smile<sup>51</sup> have developed a set of perioperative quality assurance guidelines, including a modified version of the World Health Organization safety checklist, as a roadmap to standardizing care in cleft surgery missions. Anesthetic and airway considerations are particularly important in underresourced countries, as patients with orofacial clefts are known to be at an increased risk for airway and respiratory complications, and necessary equipment or personnel to provide optimal general anesthesia for all patients might not be available.<sup>52</sup> Consequently, cleft foundations have reported performing cleft lip repair in adolescents and adults successfully under local anesthesia,<sup>53</sup> and using nerve blocks for effective perioperative pain control and the reduction of postoperative opioid use in children.<sup>54</sup> Ethical issues associated with cleft care initiatives in low- to middle-income countries, including informed surgical consent, patient vulnerability, long-term sustainability, and appropriate follow-up, are also critical considerations and have been the focus of extensive discussions.<sup>17</sup>

### Complications and Outcomes

Cleft foundations have contributed to Level I evidence through prospective, randomized, blinded studies (Table 2). Rossell-Perry et al. from the Outreach Surgical Center Program in Peru showed that a novel method of uvular reconstruction in patients with cleft palate, resulting in improved uvular appearance, does not increase the rate of fistulae or velopharyngeal insufficiency as compared to conventional reconstruction, and does not affect velopharyngeal competence.<sup>31</sup> The same group showed that the use of palatal relaxing incisions in patients undergoing primary unilateral cleft lip and palate repair is not associated with maxillary growth impairment.<sup>33</sup> Importantly, although statistical significance was not reached, the results of a prospective, randomized, blinded, controlled trial conducted at the Guwahati Comprehensive Cleft Care Center showed that the use of postoperative antibiotic prophylaxis reduced the incidence of fistulae from 17.1 percent to 10.7 percent following primary cleft palate repair.<sup>32</sup>

Rates of adverse events in foundation-based cleft care vary widely from 0.88 to 57.0 percent.<sup>6,29</sup> Evaluation of series of 709 and 1408 patients undergoing cleft palate repair at the Guwahati Comprehensive Cleft Care Center showed palatal fistulae rates ranging from 3.9 to 13.6 percent.<sup>55,56</sup> Data from the same center also showed that procedures performed by visiting surgeons were associated with a higher risk of early postoperative complications.<sup>32</sup> Although low complication rates have been reported in international cleft surgery missions,<sup>57</sup> existing data are conflicting. Maine et al. showed a significant higher fistula rate in the

mission setting in Ecuador (56 percent) as compared to that reported in major craniofacial centers in the United States (2.6 percent),<sup>58</sup> with no difference between local Ecuadorian (57 percent) and visiting American surgeons (54 percent). Similar findings were observed in children undergoing palatoplasty performed by international teams in China compared with children treated at a major U.S. center, with fistula rates of 35.4 percent and 2.5 percent, respectively.<sup>59</sup> The same study showed that the rate of fistulae in children treated at a tertiary hospital in China (12.8 percent) was also significantly lower than that reported in children treated by international teams (35.4 percent). Furthermore, retrospective comparison of cleft care delivered through the Outreach Surgical Center in Peru, by means of surgical missions or the referral center model of care provided by the same team, showed significantly higher rates of postoperative wound dehiscence (22.9 percent versus 9.8 percent), hemorrhage (17.2 percent versus 2.3 percent), and palatal fistulae (25.0 percent versus 3.8 percent) in the missions.<sup>60</sup> Although these findings highlight the importance of ensuring that the quality of cleft care delivered by these foundations is equivalent to that delivered in developed countries, they may also reflect the unfortunate reality of practicing in low- to middle-income countries. Nutritional optimization, application of presurgical infant orthopedics, and postoperative follow-up are often difficult to achieve for many of these patients, which might predispose them to an increased risk of complications.<sup>22,28</sup> Further complicating the treatment of patients in low- to middle-income countries is delayed presentation, which may lead to suboptimal outcomes in areas such as speech.<sup>61</sup> However, there is evidence to suggest that foundation-based cleft initiatives in low- to middle-income countries have significantly decreased the age at which patients present for cleft lip and/or palate care. The average or median age of patients presenting for cleft care has decreased by 0.8 year per trip in Zimbabwe,<sup>6</sup> from more than 70 months to 28 months or less in a Nepalese cohort,<sup>62</sup> from 3.8 years to 3 months in India,<sup>63</sup> from 14 years to 1.3 years in southern Vietnam,<sup>64</sup> and from 11.6 years to 1.8 years in Laos.<sup>57</sup>

### CLEFT SURGERY EDUCATION

Given the high volume of surgical cases encountered,<sup>65</sup> cleft surgery missions and care centers in developing countries provide an opportunity for the education of surgeons worldwide.

### International Education

In 2007, Operation Smile established the Regan/Stryker Fellowship program for plastic surgery, pediatrics, or anesthesia trainees.<sup>7,66</sup> The fellowship provides an accredited international clinical experience, with substantial exposure to operative and perioperative care, and opportunities for global health research.<sup>67</sup> Nearly all participants reported significant personal growth, greater cultural competency, and promotion of the six core competencies outlined by the Accreditation Council for Graduate Medical Education.<sup>67</sup> The majority of trainees planned to participate again,<sup>68</sup> and fellowship experiences predicted future involvement in international cleft care.<sup>66</sup> Similarly, the Tsao Fellowship in Global Health was developed as part of a multi-institutional partnership between the University of Southern California, the Children's Hospital of Los Angeles, and Operation Smile in 2011.<sup>69</sup> The fellowship provides plastic surgery residents with opportunities to perform research, pursue a master's degree, and gain operative experience procedures through overseas missions.<sup>69</sup> Fellowship participants are assigned mentors who provide guidance in the setting of graded responsibility, and are integrated into the training of local residents.<sup>70</sup>

### Pitfalls

Although well intentioned, surgical missions may inadvertently ignore the needs of local trainees and prioritize surgical quantity over quality,<sup>11</sup> leading to a practice that has been described as "safari surgery."<sup>71</sup> Risks of such practice include disrupting local infrastructure and demoralizing local surgeons who may already perform cleft surgery but lack necessary resources.<sup>15</sup>

### Local Education

To address these issues, several cleft foundations have embraced a "maturational shift" toward sustainability<sup>19,24,66</sup> and training local surgeons.<sup>69</sup> Riviello advocates that local skills development in low- to middle-income countries takes priority until local cleft teams can independently manage community health care needs.<sup>72</sup> Similarly, the Resurge center in Nepal,<sup>24</sup> and Operation Smile Guwahati Comprehensive Cleft Care Center in India,<sup>23</sup> have integrated training local surgeons as part of their model. To evaluate the training of local surgeons, Operation Smile launched a competency-based education pilot program in five international mission sites and noted improvements of general technical scores by local surgeons, and greater

specific competency scores for both cleft lip and palate repairs.<sup>65</sup> The same group has developed a visiting fellows program at the Guwahati Comprehensive Cleft Care Center, where local individuals constitute 90 percent of the full-time staff,<sup>66</sup> and a Physicians Training Program that invites 20 to 30 international physicians to the Operation Smile Headquarters in Norfolk, Virginia, for training in cleft care.<sup>67</sup> In a survey of 14 Smile Train partner hospitals, Purnell et al. found that international partnerships yielded more cleft surgeons and multidisciplinary teams in 75 percent of hospitals,<sup>19</sup> demonstrating the success of their “teach a man to fish” strategy.<sup>10</sup>

### Educational Tools

A free online cleft surgery educational simulator with instructional videos, intraoperative footage, and voiceover narration of more than 20 cleft-related procedures was created in 2012 through a collaboration with Smile Train, with 5-year use patterns demonstrating access in 136 countries by more than 4000 users, the majority of whom were surgeons or trainees and found the simulator to be useful.<sup>73</sup> Video broadcasting of cleft procedures from the Guwahati Comprehensive Cleft Care Center has also been reported as a potentially new method for surgical education.<sup>74</sup> Similarly, live intraoperative video feeds projected to observers in an on-site conference room allowed for discussions between visitors and the operating surgeons.<sup>74</sup>

## ECONOMIC IMPACT

Many foundations have evaluated the economic impact of cleft surgery initiatives on low- to middle-income countries and financial considerations associated with the different cleft care delivery models (Table 3).<sup>8,18,75–86</sup> Economic modeling studies have relied on the disability-adjusted life-year metric when evaluating the clinical burden of cleft lip and/or palate, whereby 1 disability-adjusted life-year represents 1 year of healthy life that is lost because of morbidity or mortality from the disease.<sup>87</sup>

### Impact

The average number of disability-adjusted life-years averted per patient following cleft surgery in low- to middle-income countries ranges from 2.67 to 9.04,<sup>80</sup> whereas the average economic gain per patient ranges from \$5510 to \$50,634,<sup>80</sup> cost per averted disability-adjusted life-year ranges from \$33.90 to \$508,<sup>78,79</sup> and cost per patient ranges

from \$219.40 to \$1590.<sup>75,86</sup> When cleft lip and palate procedures are analyzed separately, the average number of disability-adjusted life-years averted per patient ranged from 2.5 to 6.3 following cleft lip repair and from 6.7 to 16.6 following cleft palate repair.<sup>81</sup> Poenaru et al. and Corlew et al. evaluated more than half a million patients undergoing cleft lip and/or palate surgery by Smile Train partner surgeons, or through the Interplast cleft care center in Katmandu, and estimated a total number of disability-adjusted life-years averted ranging from 1.3 to 5.0 million, with an associated total economic gain ranging from \$3.0 to \$27.7 billion.<sup>8,83</sup>

### Cost-Effectiveness

The different models of cleft care delivery have previously been compared using the incremental cost-effectiveness ratio, which evaluates the difference in cost between possible health care interventions relative to their effect, and showed that cleft centers are more cost-effective, with an incremental cost-effectiveness ratio of \$190 compared with \$466 for surgical missions.<sup>18</sup> Similarly, the cost per procedure is lower when performed through a cleft care center at \$400 compared with \$677 through surgical missions.<sup>85</sup> The cost-effectiveness of cleft surgery seems to be optimal when these procedures are performed by local teams in governmental hospitals, where a cost per procedure was reported to be as low as \$219, compared with private hospitals.<sup>86</sup> Both cleft care centers and cleft surgical missions have been shown to be cost-effective methods of cleft care delivery, with the lower cost-effectiveness associated with surgical missions mostly attributable to team transport and accommodation.<sup>85</sup> Nagengast et al. compared expenditure breakdowns of four surgical missions to India by Operation Smile to data from the Guwahati Comprehensive Cleft Care Center and showed that 73.1 percent of mission expenditures were on air travel and hotel. These items accounted for 4.7 percent of Guwahati Comprehensive Cleft Care Center expenditures, whereas 77.6 percent of expenditures were on salaries, medical equipment, medications, and cleft center infrastructure.<sup>85</sup> Interestingly, the District Outreach Follow-up and Speech Therapy program launched in Assam, India, to improve patient follow-up was associated with a lower mean cost per follow-up at 304 Indian rupees compared with 1100 rupees for follow-up at the Guwahati Comprehensive Cleft Care Center.<sup>85</sup> The direct costs, number of missed workdays, and mean lost

**Table 3. Summary of Studies Evaluating the Economic Impact and Financial Considerations in Foundation-Based Cleft Care in Low- to Middle-Income Countries**

Reference	Countries	Procedures	Study Details	Metrics and Results
Tollefson et al., 2006 <sup>75</sup>	China	CLP	46 procedures in 42 patients	Cost per patient: \$1590
Corlew et al., 2009 <sup>81</sup>	Nepal	CLP	568 patients (402 cleft lip 166 cleft palate)	Cleft lip: DALYs averted: 1012.6–2550.4 Mean DALYs averted: 2.5–6.3 Economic gain: GNI per capita: \$344,283–\$2,652,434 VSL: \$22,881,627–\$57,631,770 Average economic gain: GNI per capita: \$856–\$6598 VSL: \$56,919–\$143,363 Cleft palate: DALYs averted: 1119.3–2757.8 Mean DALYs averted: 6.7–16.6 Economic gain: GNI per capita: \$380,575–\$2,868,130 VSL: \$25,293,709–\$62,318,395 Average economic gain: GNI per capita: \$2293–\$17,278 VSL: \$152,372–\$375,412
Magee et al., 2010 <sup>79</sup>	Vietnam, Nicaragua, and Russia	CLP	303 patients	DALYs averted: 3099.52 Cost per DALY averted: \$33.94 per mission
Hughes et al., 2012 <sup>77</sup>	Ecuador	CLP and other plastic surgery procedures	1142 procedures including 277 CLP	DALYs averted: 396–1042 Economic gain: \$4.7–\$27.5 million
Moon et al., 2012 <sup>84</sup>	Vietnam	CLP	2907 patients	Cost per case: \$335 Without age weighting: DALYs averted: 1508 Cost per DALY averted: \$68 Without opportunity cost: DALY averted: 296 Cost per DALY averted: \$76 With opportunity cost: DALY averted: 296 Cost per DALY averted: \$97 With age weighting: DALYs averted: 2291 Cost per DALY averted: \$56 Without opportunity cost: DALYs averted: 357 Cost per DALY averted: \$63 With opportunity cost: DALYs averted: 357 Cost per DALY averted: \$80
Poenaru et al., 2013 <sup>83</sup>	International	CLP	536,846 procedures in 364,467 patients	DALYs averted: 2.1–4.7 million Economic gain: \$196 million Mean DALYs averted: 3.8–9.0 Cost per DALY: \$72–\$134 DALYs because of advanced age at surgery: 191,000–457,000
Jansen et al., 2014 <sup>76</sup>	India	CLP	10,582 follow-up visits by 3439 patients, 2921 at GC4 and 518 in DOFAST	GC4: Cost per follow-up: 1100 IR Mean lost income: 367 IR Direct cost: 911 IR More missed workdays DOFAST: Cost per follow-up: 304 IR Mean lost income: 143 IR Direct cost: 299 IR Fewer missed workdays

(Continued)

**Table 3. Continued**

Reference	Countries	Procedures	Study Details	Metrics and Results
Nagengast et al., 2014 <sup>85</sup>	India	CLP	Expenditure breakdown of 4 surgery missions between 12/9 and 2/11 vs. GC4 between 4/12 and 3/13	Missions: Air travel: 51.5% Hotels: 21.6% Cargo: 3.8% Food: 5.5% Administration: 2.3% Medical equipment and medicines: 7.1% Salaries: 3.2% Cost per procedure: \$677 GC4: Air travel: 4.2% Hotels: 0.5% Cargo: 0.2% Local transport: 2.3% Food: 3.5% Administration: 3.3% Medical equipment and medicines: 11.5% Salaries: 46.3% Patient travel and accommodation: 8.2% Infrastructure: 19.8% Training: 0.1% Cost per procedure: \$400 DALYs averted: 5400–9600 Cost per DALY averted: \$285–\$508 Economic benefit: \$32–\$116 million
Alkire et al., 2015 <sup>78</sup>	India	CLP	1498 patients	Missions: Total cost: \$5,218,159 DALYs averted: 21,006 Incremental cost: \$2,069,794 Incremental DALYs averted: 4437 ICER: \$466 Center: Total cost: \$3,148,365 DALYs averted: 16,569 Incremental cost: \$3,148,365 Incremental DALYs averted: 16,569 ICER: \$190
Hackenberg et al., 2015 <sup>18</sup>	India	CLP	7358 patients from 17 missions and 4930 patients from care center	DALYs averted: 1,464,025–4,952,656 Mean DALYs averted: 2.67–9.04 Economic gain: \$3.0–\$27.7 billion Average economic gain: \$5510–\$50,634 Cost of procedures: \$197 million
Poenaru et al., 2016 <sup>80</sup>	International, 83 countries	CLP	548,147 patients	DALYs averted: 1,325,678–3,071,427 Average DALYs averted: 2.69–6.23 Economic gain: \$7.9–\$20.7 billion Average economic gain: \$16,133–\$42,351 Cost per DALY averted: \$149
Corlew et al., 2016 <sup>8</sup>	International, 84 countries	CLP	548,233 patients	15 CLP NGOs: Total revenue: \$912,757,996.82, 26.52% of total 160 NGOs Total expenses: \$809,238,269.93, 25.82% of total 160 NGOs Program service expenses: \$501,356,549.10 Management expenses: \$27,124,232.84 Service expense/total expense ratio: 0.782
Gutnik et al., 2016 <sup>82</sup>	International	CLP and other surgical specialties	160 NGOs including 15 CLP NGOs	Visiting international surgical teams: Cost per procedure in Palestine: \$970.79 Cost per procedure in Sudan: \$869.71 Local surgical teams working at governmental hospital: Cost per procedure in Palestine: \$476.32 Cost per procedure in Sudan: \$219.40
Sherif et al., 2017 <sup>86</sup>	Palestine and Sudan	CLP	Cost per cleft operation in different models of care	

CLP, cleft lip and/or palate; DALY, disability-adjusted life-year; GNI, gross national income; VSL, value of a statistical life method; GBD, global burden of disease; GC4, Guwahati Comprehensive Cleft Care Center; IR, Indian rupees; DOFAST, District Outreach Follow-up and Speech Therapy program; ICER, incremental cost effectiveness ratio; NGO, nongovernmental organization.

income by patients were also lower with the District Outreach Follow-up and Speech Therapy program. This initiative offers an innovative and cost-effective approach to increase patient follow-up by taking multidisciplinary teams into patients' districts for local follow-up after cleft surgery.

## CONCLUSIONS

In the past few years, there has been a growing acceptance of the fundamental role of global cleft surgery in global health.<sup>82</sup> Foundation-based cleft care initiatives are overall cost-effective, avoid significant patient morbidity, and have contributed to a better understanding of disease epidemiology. Surgical missions should be considered temporary conduits to establish more sustainable, cost-effective, multidisciplinary, comprehensive cleft care centers, and integrate into local health systems. In the meantime, establishing updated and unified global patient quality and safety assurance guidelines for international surgical teams is essential.

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