# Application of Outcome Measures in International Humanitarian Aid: Comparing Indices through Retrospective Analysis of Corrective Surgical Care Cases

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#### Abbreviations:

BCL = bilateral cleft lip
CDC = Centers for Disease Control and Prevention
CP = cleft palate
EMR = electronic medical records
NGO = non-governmental organization
OR = operating room
OSI = Operation Smile International
UCL = unilateral cleft lip

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### Abstract

It is common for international organizations to provide surgical corrective care to vulnerable populations in developing countries. However, a current worsening of the overall surgical burden of disease in developing countries reflects an increasing lack of sufficient numbers of trained healthcare personnel, and renders outside volunteer assistance more desirable and crucial than ever. Unfortunately, program evaluation and monitoring, including outcome indices and measures of effectiveness, is not measured commonly. In 2005, Operation Smile International implemented an electronic medical record system that helps monitor a number of critical indices during surgical missions that are essential for quality assurance reviews. This record system also provided an opportunity to retrospectively evaluate cases from previous missions. Review of data sets from >8,000 cases in 2005 and 2006 has provided crucial information regarding the priority of surgery, perioperative and operative complications, and surgical program development.

The most common procedure provided was unilateral cleft lip repair, followed closely by cleft palate. A majority of these interventions occurred for patients who were older than routinely provided for in the western world. The average child treated had an age:weight ratio at or below the [US] Centers for Disease Control and Prevention (CDC) 50th percentile, with a small percentage falling below the CDC  $20^{\text{th}}$  percentile. A majority of children had acceptable levels of hemoglobin, but the relative decreased age:weight ratio nonetheless can reflect mild malnutrition. Complications requiring medical intervention were seen in 1.2% of cases in 2005 and 1.0% in 2006. Thirty percent were reported as anesthesia complications, and 61% reported as surgical complications. One death was reported, but occurred after discharge outside the perioperative period. Complication rates are similar to rates reported in the US and UK and emphasizes the importance of standardization with uniform indices to compare quality performance and equity of care. This study offers an important example of the importance of collecting, analyzing, and reporting measures of effectiveness in all surgical settings.

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### Introduction

For decades, humanitarian aid organizations, non-governmental organizations (NGOs), and volunteer groups have provided short-term surgical interventions for ophthalmologic conditions, trauma, congenital abnormalities, and birth trauma to underserved areas of the world.<sup>1–3</sup> The provision of such care rarely is documented in peer-reviewed journals, and outcome indices and measures of effectiveness, while generally applied to medical interventions, have not been applied to these settings.<sup>4–6</sup> Recently, the World Health Organization (WHO) reported a severe shortage of healthcare workers in 57 developing countries. For example, Sub-Saharan Africa has 11% of the

Surgical Procedure	2005	2006
Bilateral cleft lip	229	251
Unilateral cleft lip	823	1,306
Cleft palate	766	898
Combination	206	134
Revision	663	838
Other	941	1,096
Total	3,628	4,523

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 Table 1—The electronically reported surgical

procedures performed on international surgical missions during 2005 and 2006

Age Group (years)	Males	Females	Average Weight (kg)	Hgb (gm/dl)
0 to 1	307	190	7.7 ±2.08	10.4 ±1.65
1–7	1,179	802	13.7 ±6.06	11.1 ±1.70
>7	1,005	915	49.3 ±18.24	12.9 ±1.85
Totals	2,485	1,907	28.7 ±22.33	11.8 ±1.95

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Table 3—Stratification of sex, average weight, and hemoglobin concentration (Hgb) for age groups <1 year, 1–7 years, >7 years in the year 2006. Weight and hemoglobin are expressed as the mean  $\pm$ standard deviation. This excludes 131 cases in which there was no information available for either the sex of the patient (78 patients) or the age of the patient (53 patients).

world's population, but 24% of the world's burden of disease, and only 3% of the health workers.<sup>7</sup> Evidence suggests that the reported burden of intentional and unintentional injuries, particularly in Sub-Saharan Africa and the Middle East, is rising.<sup>8</sup> In some areas of the developing world, the burden of disease, usually dominated by preventable infectious diseases and malnutrition, has shifted to surgically related causes that now approaches 50% of overall mortality.<sup>9-11</sup>

Few international organizations and NGOs focus their programs on the surgical treatment of congenital or chronic disease, but recently, several academic programs have revisited the importance of surgery to population health.<sup>12,13</sup>

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Age Group (years)	Males	Females	Average Weight (kg)	Hgb (gm/dl)
0 to 1	292	187	8.0 ±6.16	11.0 ±1.60
1–7	795	670	14.8 ±6.81	11.7 ±1.73
>7	797	745	40.4 ±18.04	13.4 ±1.84
Totals	1,884	1,602	27.8 ±21.06	12.3 ±2.00

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Table 2—Stratification of sex, average weight and hemoglobin (Hgb) for age groups <1 year, 1–7 years, >7 years in the year 2005. Weight and hemoglobin are expressed as the mean ±standard deviation. This excludes 142 cases in which there was no information available for either the sex of the patient (22 patients) or the age of the patient (120 patients).

An unknown number of surgical interventions are provided throughout the developing world by personnel from charitable and religious organizations, volunteer aid organizations, and well-established, funded organizations. The impact of these procedures on healthcare outcome and relief of the overall surgical burden of disease is largely unknown. However, recent WHO studies suggest that contributions of limited access to surgical interventions by NGOs, volunteer organizations, and even individuals has made an impact on chronic health conditions and traumatic injuries that can be treated, palliated, or cured by surgical intervention.<sup>7</sup> Because the primary mission of these organizations is the delivery of health care, few have paused to collect data, and even fewer have evaluated any data or statistics they have collected.<sup>14</sup>

In 2005, Operational Smile International (OSI) implemented an electronic medical record (EMR) system to track and evaluate new surgical cases. This system allows for retrospective analysis of past cases. Operation Smile International is a NGO committed to the surgical correction of congenital facial abnormalities in remote and austere environments for >25 years. This retrospective review covers data collected over two years, reviewing 8,151 surgical interventions in 35 medical volunteer missions in 18 countries. The evaluation process included documentation of outcomes and data points that impact indices and anesthetic and surgical complications.

### Methods

In 2005, the EMR began inputting data in Excel format [Microsoft, Inc., Redmond, WA] from international medical missions. Prior to surgical screening and evaluation, a universal consent form was signed by the parent or guardian for each patient that included use of surgical information for research.<sup>15</sup> Surgical and anesthetic incident reports were



Figure 1-Weight-for-age plot for girls (ages 1-20) compared with CDC data



Figure 2-Weight-for-age plot for boys (ages 1-20) compared with CDC data

stored in a separate database and reviewed by the OSI Chief Medical Officer and his assistant. In 2007, with OSI Institutional Review Board approval, all collected EMR data for years 2005–2006 were de-identified and re-organized into an Excel format that was reviewed and statistically processed for specific patient information and perioperative complications. Age groups were designated by <1 year, 1–7 years old, and >7 years old. The groups were compared internally for the following variables: age, weight, surgical priority, surgical procedure, and surgical and anesthetic complications noted in the post-operative period. Subsequently, this perioperative incident report database was de-identified and each critical incident was reviewed and compared to the surgical and anesthetic details of the case in the original database. The significant anesthesia and surgical complications were reviewed and catalogued. Pooled standard error calculations and the Z-statistic were applied to compare outcomes and a *p*-value was generated to evaluate statistical significance ( $p \leq 0.05$ ).

#### Results

All 3,628 cases from 2005 and 4,523 cases from 2006 databases were reviewed. Of the total cases for this 24-month peri-



Figure 3—Priority assignment for 2005 and 2006. No priority assignment was available for 81 cases in 2005 and 238 cases in 2006

Priority 1	Primary repair of cleft lip, age ≥6 to 1 year	Wound dehiscence, any age
Priority 2	Primary repair of cleft palate, age 1-6 years	Repair of complications of cleft palate, any age
Priority 3	Primary repair of cleft palate, age 6-adult	
Priority 4	Secondary repair of lips and palates, any age	
Priority 5	Other conditions	
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Table 4—	Description	of Operati	on Smile	International	surgical	priority	y assignment
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Serious Medical Incidents	Significant and Potentially Serious Incidents (reviewed case-by- case)	Non-Serious Incidents
Malignant Hyperthermia	Allergic Reaction	Infection requiring intervention
Cardiac/Respiratory Arrest	Bronchospasm/ Airway Obstruction	IV filtrate requiring intervention
Transfer to another facility	Aspiration	Delayed discharge
Seizure	Unplanned return to OR	Wound Dehiscence
Severe Aspiration (requiring ventilation)	Arrhythmia requiring intervention	Wound Infection
Transfusion Reaction	Equipment failure resulting in patient injury	Medication error
Death	Medication error resulting in patient morbidity	
	Transfusion	

 Table 5—Categorization of surgical and anesthetic outcomes (IV = intravenous; OR = operating room)

2005	All Facial Cases (%)	Lip/Palate (%)	Others (%)	
	1.2	1.2	1.1	
2006	All Facial Cases (%)	Lip/Palate (%)	Others (%)	
2000	1.0	1.2	0.4	

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 Table 6—Stratification of complications noted in the early post-operative period

	2005 n (%)	2006 n (%)
Unilateral cleft lip	3 (9.4)	11 (31.4)
Bilateral cleft lip	1 (3.1)	1 (2.9)
Cleft palate	14 (43.8	15 (42.9)
Combination	7 (21.9)	5 (14.3)
Revision/Fistula	3 (9.4)	2 (5.7)
Other	4 (12.5)	1 (2.9)
Total	32	35

McQueen © 2009 Prehospital and Disaster Medicine Table 7—Patients experiencing complications identified per procedural type in 2005 and 2006

	Anesthesia Complications				Surgical Cor	nplications		
	Difficult Intubation	Bronchospasm	Airway Obstruction	Cardiac/ Respiratory Arrest	Post-op Bleeding	Return to OR without noted reason	Wound Dehiscence	Transfusion
2005	0	3	5	0	15	3	1	2
2006	2	2	4	5	16	3	2	1
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Table 8-Anesthesia and surgical complications

	Drug Reaction/ Equipment Failure	Fever	Seizure	Morbidity
2005	3	0	1	1
2006	0	1	0	0

#### Table 9—Other complications

od, 6,114 were craniofacial corrections or revisions (unilateral cleft lip (UCL), bilateral cleft lip (BCL), cleft palate (CP), fistula or revision) and 2,037 cases were classified as "other" and included scar revisions, skin grafts, and minor corrective procedures (Table 1). Only cases specifically classified as craniofacial repairs, revisions, or corrections of related complications were further reviewed for patient characteristics that were deemed relevant to surgical and anesthetic outcomes.

Cases were grouped by the ages relevant to western standards for repair: age <1 year, age 1-7 years, and ages >7 years. For these groups, gender was noted, and the average weight and hemoglobin concentration were calculated for each age group (Tables 2 and 3). Of the 3,628 cases reviewed in 2005, weight was available for 3,572 cases (98.5%) and hemoglobin concentration was available for 1,915 cases (52.8%). Of the 4,523 cases reviewed in 2006, weight was available for 2,116 cases (46.8%) and hemoglobin concentration was available for 2,449 cases (54.1%). Height was not collected in the database during 2005 and 2006; however it has been included in all future data sets collected by OSI so that growth and nutrition could be assessed more accurately. The average child treated had an age:weight ratio at or below the [US] Centers for Disease Control and Prevention (CDC) 50th percentile, with a small percentage falling below the CDC 20th percentile (Figure 1 and 2). Surgical priority was analyzed where available for 2005 and 2006 (Figure 3). Material and human resources are limited when delivering surgical aid, and therefore, patients must be prioritized in order to provide the greatest good for the most children. The prioritization assignment determined which children, if medically cleared for surgery, would receive their operations as early as possible, and which children would wait for a subsequent surgical mission for repair or perhaps would not receive surgery by this organization (Table 4). The prioritization also accounts for the functional improvement that can be expected from the surgical intervention.

Of the craniofacial cases reviewed, complications requiring medical intervention were identified in 1.2% of cases in 2005 and 1.0% of cases in 2006. Using the OSI complicaMcQueen © 2009 Prehospital and Disaster Medicine

tions designation (Tables 5 and 6), seven (10%) of the critical incidents were designated as serious, and 29 (43%) were designated as significant and potentially serious.

Complications varied by procedural type (Table 7), which is expected in any clinical setting. Of the complications recorded during this two-year period, 21 (30%) were due to anesthesia (Table 8), 43 (61%) due to surgical repair, and six (9%) were due to allergic reaction, fever of unknown etiology, seizure, and one death after discharge (Table 9). In some cases, more than one complication occurred.

Surgical complications were observed significantly (p =0.006) more frequently than anesthetic complications. The total complications and surgical complications were not different (p = 0.842 and p = 0.267 respectively) when the age groups were compared as <l year of age and ≥1 year of age. While anesthesia complications occurred less often than those designated as surgical complications, they did occur more often (p =0.072) in children <1 year of age. Both anesthesia and surgical complications were observed in significantly (p = 0.0004) greater frequency in patients receiving surgical correction for cleft palate than for those receiving cleft lip correction. Anesthesia and surgical complications were more frequent in patients receiving a combined palate/lip procedure compared to patients receiving palate surgery alone (p = 0.034). Patients receiving a primary surgery were observed to have a greater incidence of complications than were patients receiving a surgical revision or secondary repair (p = 0.0024).

#### Discussion

Cleft lip occurs in 1 in 750 live births and cleft palate occurs in 1 in 2,000 live births. In half of all reported cases, these abnormalities occur together.<sup>16,17</sup> The etiology of these anomalies is multi-factorial.<sup>18,19</sup> The overall incidence is increasing and together, they represent the most common congenital abnormalities are not life threatening, they impact nutrition, speech, and socialization.<sup>20,21</sup> The overall contribution to the global surgical burden of disease and its consequences on health and social development in developing countries is unknown.

Foreign agencies, including non-governmental organizations and military physicians have been providing surgical care for these patients since the Vietnam era.<sup>22</sup> In recent decades, several international organizations have organized to focus on the exclusive provision of reconstructive surgery in dozens of countries. Thousands of procedures have been completed, but until recently these surgical corrections were not tracked or reviewed and only the surgical team providing care and the patients' families knew their outcomes. While it is assumed that many lives have been positively impacted, the effectiveness of the surgical intervention has not been evaluated.

Operation Smile International is the first international organization known to implement an EMR for tracking patients and evaluating outcomes for the purpose of quality assurance. Operation Smile International has provided surgical intervention for cleft lips and palates for >100,000 children in >25 countries for 25 years. Providing these services has not been without challenge or criticism.<sup>23–26</sup> The OSI has responded to these issues by attempting to ensure a standardized approach to the anesthesia, surgery, and post-operative care by creating an EMR, promoting *Global Standards* and following outcomes for the purpose of quality improvement.<sup>27</sup>

The data points collected have provided program coordinators and medical personnel with invaluable information on quality control and mission success. Each data point collected related specifically to surgical intervention, anesthetic management, or programmatic logistics. Gender, age, weight, hemoglobin concentration, surgical lesion, and priority were routinely collected in sites with the EMR in place. Cleft lip and palate are noted to occur with some gender variation-cleft lip occurs more commonly in males, whereas cleft palate occurs more commonly in females.<sup>16,17</sup> Age is important when considering the optimal time for repair and avoidance of nutritional, speech, and psychosocial impact of the abnormality.<sup>20</sup> However, age alone cannot dictate optimal surgical repair due to an increased risk of surgical complications in very small or nutritionally compromised children. Therefore, weight and hemoglobin concentration are essential data points as they are estimates of overall nutritional (malnutrition and micro-nutrient) adequacy. Finally, the surgical type and priority are considerations when reviewing surgical and anesthetic complications. Surgical priority differs in the US and Europe from the priority systems used in the field. Operation Smile International considers age, surgical type, and available resources when creating a priority list of surgical cases. The OSI Priority scale is a based on the optimal time for repair:

- 1. Unilateral cleft lip and BCL are Priority 1 at any age;
- Those <1 year of age with a weight of 10 kilograms is a Priority 1;
- 3. Cleft palates are Priority 2 when >1 year and <7 years of age, as this is the time period when speech is prominently impacted;
- 4. Repairing a CP after the age of seven still may benefit the child in terms of mitigating ear infections and poor nutrition. Speech often is only minimally improved; therefore, these children are Priority 3;
- 5. Fistulas that develop as a long-term complication of cleft palate repair may cause functional difficulty; however, surgical intervention for this condition is

assigned a Priority 4, as repairing the primary palate still has more impact on the child. Similarly, any revision, functional or cosmetic, also is assigned a Priority 4 for the same reason; and

6. A patient will be considered Priority 5 if another condition that would benefit from surgery is present.

Over the 25 years of delivery of surgical interventions, many children have been prioritized as a 5 and eventually have received surgery. Most commonly, these patients have been burn patients in need of scar revision or contracture release and special burn missions have been established. For example, in 2000 in Amman, Jordan, >100 children, whose parents and guardians learned of the OSI team of surgeons coming to Jordan for the first time, registered with hypospadeus and other urological conditions. A year later, a team of urologists was coordinated by OSI to return to Jordan to provide surgical repair for these children. The prioritization of surgery is important in that, at any given time, need always exceeds the available medical and human resources. Knowing that parents and guardians may not have the resources or security to come back for a second or third time, a tenet of corrective care in these situations has been to provide as much surgical intervention to as many children in need as is safely possible.

The outcomes available in this retrospective review are perioperative complications. Complications are easily tracked and often are used worldwide as surgical and anesthesia outcome indicators. However, in Western literature, complications are considered "immediate" and "long term". This review considers only perioperative complications and immediate post-operative complications. For this reason, the most relevant outcomes assessed are anesthetic, as most anesthetic complications occur within the OR or in the immediate (<24 hours) post-operative period.<sup>28–30</sup> While some surgical complications occur in the days and weeks following discharge (infection, dehiscence, fistula formation).<sup>28,31,32</sup>

The complications tracked and reported during this two-year period are consistent with those tracked and reported in the western world in the immediate post-operative period.28-32 Most of the complications noted were surgical, and a majority of them were immediate post-operative bleeding (46%) with a return to the operating room (OR) for re-exploration and hemostasis. This represents an overall post-operative bleeding rate of 0.5%.<sup>31</sup> All patients with significant post-operative bleeding returned to the OR for treatment. Of the patients treated for post-operative bleeding, 10% (n = 3) required blood transfusion for stabilization. While postoperative bleeding is known to occur in the US and Europe following cleft lip and palate surgery and is reported in older literature to be as high as 4.3%,<sup>32</sup> more recent literature reports indicate that there was no postoperative bleeding in a moderately sized study.<sup>31</sup> While immediate post-operative bleeding rates were not readily available in the modern literature, several studies suggest that the occurrence is very low.<sup>18,19</sup> Improved techniques and the use of electric cauterization may account for fewer post-operative bleeding rates than those reported in 1966.32 However, the low reporting of

post-operative bleeding also may be due to the relatively small numbers of cases seen by any one center or community in comparison to those seen on these missions, or may be due to a patient population that is nutritionally superior and less apt to bleed. When comparing other oral procedures with similar potential for postoperative bleeding, such as surgical intervention for tonsillectomy and adenoidectomy, which are much more commonly performed, the results reveal much higher rates of immediate post-operative bleeding and may offer a point of comparison until more data exist, from overseas missions.<sup>32</sup>

The only other surgical complication of note was immediate wound dehiscence or soft tissue breakdown, which occurred 0.05% (n = 3), however only two patients were reported to have returned to the OR for surgical closure. This may be explained by the reality that mucosal dehiscence is the most common dehiscence in the immediate post-operative period, and may not require surgical reclosure. The western literature reports early mucosal dehiscence<sup>28,31,32,34</sup> in very low numbers as observed in this study population. The most recent study reporting surgical complications reports a soft tissue breakdown rate of 0.8%.<sup>31</sup> Other "unexpected return to the OR" was noted in an additional six cases, but the reason for return to the OR was not explained in the EMR.

While little can be concluded from the percentage of surgical complications reported for these cases without similar comparison within the peer-reviewed literature, there is some objective certainty that the incidence of postoperative bleeding and dehiscence is not grossly different from that reported within the western literature or that reported for procedures studied to a greater degree.<sup>28,31,33</sup> However, these represent estimates and should not be assumed as normative. The current study documents a reexploration rate of 0.3%, which compares favorably with a reported complication rate of 0.5%. Immediate dehiscence rate is 0.8% overall and 100% of these are seen in palate surgery.<sup>31</sup> The dehiscence rate in this 2005–2006 study was 0.05%. Low-grade fever is reported as 2.4% in the peer reviewed literature in the immediate post-operative period; however, only one fever occurred in this group of 6,114 cases, 0.02% of patients. This may represent under-reporting or may be influenced by acetaminophen (30mg/kg) that OSI uses for pain relief in the immediate post-operative period.

Anesthesia complications accounted for 31% of the overall reported complications in the data reviewed during 2005–2006. Difficult intubation, bronchospasm, and airway obstruction account for a majority (76%) of these reported study anesthetic complications, which is consistent with reported complications.<sup>28-30,34,35</sup> Airway complications are the most common incidents witnessed in the OR and postoperative period<sup>29,30</sup> and are more common during surgical procedures involving the mouth and airway.<sup>28-30,33,34</sup> These events routinely are treated by anesthesia providers, diagnosed rapidly, appropriately treated, and do not result in long-term morbidity. Of the patients treated by OSI during 2005-2006, 3% were reported to have an airway complication. Significantly, children <1 year of age experienced more airway/anesthesia complications than did children  $\geq 1$  year of age (p = 0.027). These findings are consistent

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with those in the literature.<sup>34,35</sup> Of these complications, 31% were secondary to bronchospasm and 56% were due to airway obstruction, one of which was a retained throat pack. Thirteen percent of these patients were reported to be difficult intubations. Five (0.08%) respiratory arrests were reported in this population and all but one of these arrests was resuscitated successfully. All of these complication rates fall within the normal range.<sup>29,30,33,34</sup> However, many airway complications, such as laryngospasm, are especially transient if quickly recognized and treated; the numbers reported in this study data actually may be spuriously low.

While the literature demonstrates little for comparison in similar patients, several publications illustrate the challenges of providing anesthesia in the developing world.<sup>35,36</sup> By providing *global standards*,<sup>27</sup> OSI has attempted to provide the same standard of care on medical missions as it does while providing surgical intervention for these congenital conditions in the US. The literature supports that respiratory and surgical complications are common during and following repair of cleft lip and palate, especially in infants.<sup>33,34</sup>

Unexpected perioperative death is unusual. The perioperative death rate for otherwise healthy patients (ASA I or II) is very low in Europe and the US.<sup>29</sup> Most of the patients operated on by OSI fall into an ASA Class I or II category, and patients who have serious syndromes often are taken to the US where appropriate monitoring is more readily available. However, even with excellent pre-surgical screening by pediatricians, intensivists, and anesthesiologists, there are times when underlying co-morbidity is missed. One death was reported in this 2005-2006 case review. The death occurred during a 2005 mission after the child underwent an uncomplicated anesthetic and surgical revision of a cleft palate that had been surgically corrected by OSI a year earlier. The patient did well post-operatively and was discharged home with his mother 48 hours later. While the circumstances at home are unclear, the mother returned to the mission site 24 hours after discharge (72 hours post-operative) with a lethargic and severely dehydrated child who she reported was not taking fluids. The surgical repair was intact and the child was not bleeding. There was no evidence of infection. Shortly after being seen by the mission team, the patient suffered a cardiac arrest, and while every effort was made at resuscitation, the child died. Retrospectively, it was revealed that the patient might have had an underlying heart condition that was intentionally or inadvertently omitted by the mother from the medical history during screening. Nonetheless, it bears emphasis, since while providing medical care overseas, communication and translation often are difficult and cultural variation often necessitates ethnographic-specific efforts to communicate medical information.

Providing medical care in under-served and underresourced areas yields difficult circumstances that contribute to the challenges that a medical team faces. Primary care often is not available in many of the areas where these interventions are provided, and therefore, many conditions are under-diagnosed and under-treated. Malnutrition and occult and non-occult micronutrient deficiencies also are more common in resource-poor countries, and for this reason, children often are under-weight and have anemia and low plasma protein concentrations. For these reasons, the children treated by this and other surgical mission groups may be more prone to wound infection, wound dehiscence, and other complications.

Critically important to children worldwide is that normal socialization is crucial to healthy development. Isolation and/or embarrassment secondary to a facial deformity and speech impediment may impede an individual's ability to get an education or pursue marriage. Multicultural interpretation of the disability and its consequences must be understood by the medical, surgical, and support teams involved. While the medical realities in these situations may make the surgery and healing more difficult and perhaps add additional risk, a family seemingly may accept the increased risk for the opportunity of a potential life of social acceptance for the child. How they understand the risks deserve considerable attention to translation and retranslation.

#### Conclusions

Whereas achievement or performance indicators commonly are reported to missions in developing countries, outcome indicators are more critical to measuring effectiveness. This first documented attempt at measuring and reporting the outcomes of surgical interventions delivered by a humanitarian aid organization is an important step forward in assuring quality performance. Of note is that the complication rates reported approach those of the developed world. This occurred in the face of nutritional challenges in many of the children and logistical limitations placed on the surgical program. Barring unforeseen circumstances, quality assurance is essential and possible in developing countries for these surgical procedures. Potential funding for these crucial interventions must be based on consistently highquality care, and measuring outcome indicators is an essential first step in this process. Increased efforts made within the humanitarian aid community to mandate outcome data collection and analysis on all missions worldwide will ensure that future surgical programs will reach the expected equity in care.

#### References

- Rinsky L: Personal experiences with overseas volunteerism. Clin Orthop Related Res 2002;392:89–97.
- 2. Wurlitzer F: Volunteering in Western Africa. West J Med 1991;154(6):730-732.
- 3. Spann SJ: Family practice in the tropics. Fam Med 1986;18:84-96.
- Driftmeyer JE, Llewellyn CH: Toward more effective humanitarian assistance. *Mil Med* 2004;169(3):161–168.
- Burkle FM, McGrady K, Newett SL, et al: Complex, humanitarian, emergencies III. Measures of effectiveness. Prebospital Disast Med 1995;10(1):48–56.
- Burkle FM, Greenough PG: Measures of Effectiveness in Disaster Management. In: Ciottone GR (ed), *Disaster Medicine*. Boston: Harvard University and Mosby Publishers, 2006, pp 333–335.
- World Health Organization (WHO): The World Health Report 2006: Working together for health. Available at http://www.who.int/whr/2006/en/index.html. Accessed 05 September 2007.
- WHO: World Health Report 2004: Changing history. Available at http://www.who.int/whr/2004/cr. Accessed 30 June 2007.
- Debas, HT: Surgery: A Nobel profession in a changing world. Ann Surg 2002;236(3):263-269.
- Debas HT, Gosselin R, McCord C et al: Surgery. In: Jamison DT, Breman JG, Measham AR, et al (eds), Disease Control Priorities in Developing Countries. 2nd ed. New York: Oxford University Press, 2006, pp 1245-1260.
- Massey B, Howard A: The burden of othopaedic disease in developing countires. J Bone Joint Surg Am 2004;86A(8):1819–1822.
- Duda RB, Hill AG: Surgery in developing countries: Should surgery have a role in population-based healthcare? Bull Am Coll Surg 2007;92(5):12-19.
- Schecter WP, Farmer D: Surgery and global health: A mandate for training, research and service—A faculty perspective from UCSF. *Bull Am Coll Surg* 2006;91(5):36–38.
- Baiden F, Hodgson A, Binka FN: Demographic surveillance sites and emerging challenges in international health. Bull World Health Organ 2006;84(3):163–164.
- Operation Smile International: Consent and Release of Data Form. Available at http://www.operationsmile.org. Accessed 10 August 2007.
- 16. Davies D: Cleft lip and palate. BMJ 1985;290:625-628.
- Shah CP, Wong D: Management of children with cleft lip and palate. Can Med Assoc J 1980;122:19-25.
- Martinelli S, Scapoli L, Pezzetti F, et al: Study of four genes belonging to the folate pathway: Transcobalamin 2 is involved in the onset of non-syndromic cleft lip with or without cleft palate. *Hum Mutat* 2006;27(3):294.

- Lidral AC, Moreno LM: Progress toward discerning the genetics of cleft lip. Curr Opin Pediatr 2005;17:731–739.
- Murray JE, Mullikan JB, Kaban LB, et al: Twenty year experience in maxillocraniofacial surgery: An evaluation of early surgery on growth, function and body image. Ann Surg 1979;190(3):320–330.
- Kahn, JP: Operations for harelip and cleft palate: The emotional complications in children. *Calif Med* 1956;84(5):333–338.
- Burkle, FM: Delta Medical: A fitting memorial. US Naval Institute Proceedings 1970;96:36–39.
- Hoover EL, Cole-Hoover G, Berry PK, et al: Private volunteer medical organizations: How effective are they? J Natl Med Assoc 2005;(97)2:270-275.
- Wolfberg AJ: Volunteering overseas: Lessons from the surgical brigades. N Engl J Med 2006;354(5):443–445.
- Einterz E: International aid and medical practice in the less-developed world: Doing it right. *Lancet* 2001;357:1524–1525.
- Dupuis CC: Humanitarian missions in the third world: A polite dissent. Plast Reconstr Surg 2004;113(1):433–435.
- Operation Smile International: Global Standards. Available at http://www.operationsmile.org. Accessed 10 August 2007.
- Lees VC, Pigott RW: Early postoperative complication in primary cleft lip and palate surgery-How soon may we discharge patients from the hospital? *Br J Plast Surg* 1992;45:232-234.
- Tiret L, Desmonts JM, Hatton F, Vourc'h G: Complications associated with anesthesia—A prospective survey in France. Can Anaesth Soc J 1986;33(3):336–344.
- Tiret L, Nivoche Y, Hatton F, et al: Complications related to anaesthesia in infants and children: A prospective survey of 40,240 anaesthetics. Br J Anaesth 1988;61:263–269.
- Canady JW: Complication outcomes based on preoperative admission and length of stay for primary palatoplasty and cleft lip/palate revision in children aged 1 to 6 years. *Ann Plast Surg* 1994;33(6):576–580.
- Wilhelmsen HR, Musgrave RH: Complications of cleft lip surgery. Cleft Palate J 1966;3:223-230.
- Crysdal WS, Russel D: Complications of tonsillectomy and adenoidectomy in 9,404 children observed overnight. Can Med Assoc J 1986;135:1139–1141.
- Fillies T, Homann C, Meyer U, et al: Perioperative complications in infant cleft repair. Head Face Med 2007;3:9.
- 35. Takemura H, Yasumoto K, Toi T, et al: Correlation of cleft lip type with the incidence of perioperative respiratory complications in infants with cleft lip and palate. Paediatr Anaesth 2003;13(7):646.
- Hodges SC, Mijumbi C, Okello M, et al: Anaesthesia services in developing countries: Defining the problems. Anaesthesia 2007;62:4–41.