

IDEAS AND INNOVATIONS

Use of Safety Measures, Including the Modified World Health Organization Surgical Safety Checklist, During International Outreach Cleft Missions

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International surgical outreach missions have become increasingly common within the surgery community. Untoward events in this setting, although rare, can be prevented by careful planning and the use of quality assurance guidelines designed to prevent such complications. The surgical safety checklist is widely accepted in most developed health care practices, but is used variably by international mission groups. This article outlines the quality assurance guidelines used, including a modified World Health Organization safety checklist and illustrated patient instruction forms, to provide a standardized means of delivering sound surgical care in the setting of short-term international cleft lip and/or palate missions.

KEY WORDS: *cleft lip, cleft palate, international mission, safety checklist, WHO checklist*

The increasing need for quality medical care throughout the developing world, along with the increasing ability to export surgical services, has led to the expansion of international mission groups. More than 500 groups are now dedicated to short-term medical missions, with expenditures of more than \$250 million (Maki et al., 2008). With a large number of operations performed in this unfamiliar international setting, untoward events can occur and mar the perspective of involved practitioners and the international medical community (Dupuis, 2004). Given the concern for patient safety on such missions, organizations such as the World Health Organization (WHO), the Global Smile Foundation (GSF), and other groups have proposed quality assurance guidelines to be used in the development and execution of medical missions (Eberlin et al., 2008; Politis et al., 2011). These protocols focus on the provision of quality care during such missions and the ability to foster future sustainable medical care from local physicians.

In 2009, the WHO published data establishing a statistically significant reduction in patient mortality and morbidity through the use of a surgical safety checklist (Haynes et al., 2009). This international study, performed at eight hospitals across the globe and encompassing 3733 consecutive patients of various socioeconomic statuses,

reported a significant decline in mortality from 1.5% to 0.8% and a decline in inpatient complications from 11.0% to 7.0%. These “time out” safety checklists have become the standard of care in U.S. hospitals (Semel et al., 2010) and have since been accepted by the overall international medical community (Weiser et al., 2010; Borchard et al., 2012; Fudickar et al., 2012). Despite the pervasiveness of such checklists in American hospitals, a number of mission groups from the United States do not use safety checklists on international surgical outreach missions.

Quality improvement interventions such as the surgical safety checklist are imperative within international cleft mission trips to developing countries, where language barriers can confound communication among the mission group, the patient, and the local staff (Yeow et al., 2002). The GSF, a nonprofit organization composed of a multi-specialty medical volunteer team that provides global outreach cleft care, is an advocate of stringent safety measures in international outreach initiatives. We have proposed quality assurance guidelines to ensure the provision of safe, standard care (Eberlin et al., 2008) and have described our emergency response and code simulation protocols for such missions to ensure optimal patient safety (Vyas et al., 2013). Our group has made a concerted effort to incorporate safety protocols within our missions and to involve the local medical communities in this effort. Fundamentally, we believe that the surgical safety checklist is especially beneficial in unfamiliar settings and surroundings, such as those encountered on an international mission.

This article describes the importance of safety measures including safety checklists and instructional patient forms in the setting of short-term, international cleft lip and/or palate missions and the experience of the GSF in implementing these objectives.

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Patient Surgical Safety Checklist

First name: _____

Last name: _____

Medical record: _____

Date: _____



TO BE COMPLETED BY PERIOP PERSON	TO BE COMPLETED BY OR NURSE	BEFORE PATIENT LEAVES ROOM
SIGN IN – NURSE AND ANESTHESIA <input type="checkbox"/> PATIENT IDENTIFICATION VERIFIED <input type="checkbox"/> ID Band Applied <input type="checkbox"/> Consent Form Complete NPO <input type="checkbox"/> LAST FOOD/MILK AT _____ <input type="checkbox"/> LAST WATER AT _____ DOES THE PATIENT HAVE A KNOWN ALLERGY? <input type="checkbox"/> NO <input type="checkbox"/> YES THE CHILD IS WELL TODAY <input type="checkbox"/> YES <input type="checkbox"/> NO	TIME OUT – TEAM <input type="checkbox"/> INTRODUCE SELF BY NAME AND ROLE <input type="checkbox"/> INTRODUCE LOCAL TEAM <input type="checkbox"/> VERBALLY CONFIRM <ul style="list-style-type: none"> • PATIENT • SITE • PROCEDURE SURGEON VERIFIES <input type="checkbox"/> WHAT ARE THE CRITICAL /UNEXPECTED STEPS <input type="checkbox"/> OPERATION DURATION ANESTHESIA VERIFIES <input type="checkbox"/> ANTIBIOTICS GIVEN WITHIN 60 MINUTES OF INCISION DIFFICULT AIRWAY /ASPIRATION RISK? <input type="checkbox"/> NO <input type="checkbox"/> YES, AND EQUIPMENT/ASSISTANCE AVAILABLE RISK OF >500ML BLOOD LOSS (7ML/KG IN CHILDREN)? <input type="checkbox"/> NO <input type="checkbox"/> YES WT_____X7 = _____ PHOTOS/ IMAGES DISPLAYED? <input type="checkbox"/> YES <input type="checkbox"/> NOT APPLICABLE ANY QUESTIONS/CONCERNS FROM TEAM?	SIGN OUT –TEAM SURGEON VERIFIES <input type="checkbox"/> NAME OF THE PROCEDURE NURSE VERIFIES <input type="checkbox"/> NEEDLES ARE ACCOUNTED FOR <input type="checkbox"/> INSTRUMENT COUNT FOR INVENTORY TEAM VERIFIES <input type="checkbox"/> THROAT PACK REMOVED <ul style="list-style-type: none"> ○ YES ○ NOT APPLICABLE <input type="checkbox"/> KEY CONCERNS FOR RECOVERY AND MANAGEMENT OF THIS PATIENT

05/01/2011

Based on the WHO Surgical Safety Checklist, URL <http://www.who.int/patientsafety/safesurgery/en>, © World Health Organization 2008 All rights reserved.

FIGURE 1 The Global Smile Foundation surgical safety checklist, which is a modification of the World Health Organization safety checklist. This list has been tailored for the treatment of patients with cleft lip and/or palate.

GSF SURGICAL SAFETY CHECKLIST

The GSF has modified the surgical safety checklist designed by the WHO and has tailored it to operations involved in the treatment of patients with cleft lip and/or palate (Fig. 1). Alterations of the WHO surgical checklist involved input by medical members of the GSF in the specialties of nursing, surgery, and anesthesia; these members are active leaders in quality assurance within their own teaching institutions in the United States. Although the modifications are subtle, they were designed to make the checklist more applicable to the setting of outreach cleft mission work. During exit interviews for the mission trips, input was collected from the team members using the safety checklist to confirm ease of use. Maintaining a user-friendly checklist was a priority for ensuring continued use in future trips, as was encouraging and training the local medical teams to implement it.

The Global Smile Foundation checklist provides three safety checkpoints during the perioperative period. The first checkpoint occurs in the preoperative holding area and is completed by the operating room nurse and anesthesia staff. The second checkpoint is completed prior to induction of anesthesia within the operating room and requires the participation of the entire team. The last checkpoint occurs at the completion of the operation and again requires the attention of the entire operative team.

Checkpoint 1: Preoperative Holding Area (Performed by Nurse and Anesthesia Staff)

1. Patient name(s) and identification are confirmed: This is an essential step, especially at sites where patients have multiple last names (many of which are similar) and where dates of birth are sometimes unknown.
2. An identification band with the patient's information is placed on the patient. In addition, GSF codes the armbands with different colors according to Brose-low color codes (Armstrong Medical Industries, Inc., Lincolnshire, IL). The colors of the Broselow code facilitate identification of medications needed in the event that advanced cardiopulmonary resuscitation is required (Fig. 2).
3. Completion of the surgical consent form, with required signatures, is confirmed.
4. Nothing *per os* (NPO) status is confirmed, and date and time of last food is recorded.
5. The patient's allergies are confirmed.
6. The patient's satisfactory overall health status and suitability for surgery are confirmed by the perioperative nurse and anesthesiologist.

Checkpoint 2: In the Operating Room, the Surgical Time Out (Performed by Team)

Equipment	GRAY* 3-5 kg	PINK Small Infant 6-7 kg	RED Infant 8-9 kg	PURPLE Toddler 10-11 kg	YELLOW Small Child 12-14 kg	WHITE Child 15-18 kg	BLUE Child 19-23 kg	ORANGE Large Child 24-29 kg	GREEN Adult 30-36 kg
Resuscitation bag		Infant/child	Infant/child	Child	Child	Child	Child	Child	Adult
Oxygen mask (NRB)		Pediatric	Pediatric	Pediatric	Pediatric	Pediatric	Pediatric	Pediatric	Pediatric/adult
Oral airway (mm)		50	50	60	60	60	70	80	80
Laryngoscope blade (size)		1 Straight	1 Straight	1 Straight	2 Straight	2 Straight	2 Straight or curved	2 Straight or curved	3 Straight or curved
ET tube (mm) [†]		3.5 Uncuffed 3.0 Cuffed	3.5 Uncuffed 3.0 Cuffed	4.0 Uncuffed 3.5 Cuffed	4.5 Uncuffed 4.0 Cuffed	5.0 Uncuffed 4.5 Cuffed	5.5 Uncuffed 5.0 Cuffed	6.0 Cuffed	6.5 Cuffed
ET tube insertion length (cm)	3 kg 9-9.5 4 kg 9.5-10 5 kg 10-10.5	10.5-11	10.5-11	11-12	13.5	14-15	16.5	17-18	18.5-19.5
Suction catheter (F)		8	8	10	10	10	10	10	10-12
BP cuff	Neonatal #5/infant	Infant/child	Infant/child	Child	Child	Child	Child	Child	Small adult
IV catheter (ga)		22-24	22-24	20-24	18-22	18-22	18-20	18-20	16-20
IO (ga)		18/15	18/15	15	15	15	15	15	15
NG tube (F)		5-6	5-8	8-10	10	10	12-14	14-18	16-18
Urinary catheter (F)	5	8	8	8-10	10	10-12	10-12	12	12
Chest tube (F)		10-12	10-12	16-20	20-24	20-24	24-32	28-32	32-38

Abbreviations: BP, blood pressure; ET, endotracheal; F, French; IO, intraosseous; IV, intravenous; NG, nasogastric; NRB, nonrebreathing.
^{*}For Gray column, use Pink or Red equipment sizes if no size is listed.
[†]Per 2010 AHA Guidelines, in the hospital cuffed or uncuffed tubes may be used (see below for sizing of cuffed tubes).
 Adapted from Broselow™ Pediatric Emergency Tape. Distributed by Armstrong Medical Industries, Lincolnshire, IL. Copyright 2007 Vital Signs, Inc. All rights reserved.

Pediatric Color-Coded Length-Based Resuscitation Tape

FIGURE 2 The Broselow color code system facilitates the administration of weight-based pediatric medicine and equipment for advanced resuscitation measures. Permission granted by Armstrong Medical Industries, Inc., Lincolnshire, IL. Copyright 2007, GE Healthcare Vital Signs Inc.

1. Each GSF team member introduces himself or herself and his or her role in the operating room.
2. Local team members and local operating room staff are introduced.
3. The patient, the procedure, and the surgical site are announced and confirmed.
4. The surgeon verifies the critical steps of the procedure and discusses the anticipated duration of the surgery, including the planned use of a throat pack if applicable.
5. The anesthesiologist verifies the type and time of administered intravenous antibiotics.
6. The airway is discussed regarding fire safety and aspiration risk, with confirmation of necessary available equipment.
7. Anticipated blood loss is discussed.
8. Imaging, including preoperative photography, is reviewed and confirmed for patient identification. This is another critical step on international mission trips, where names can be similar.
9. Any additional team concerns are discussed.

Checkpoint 3: In the Operating Room, at the End of the Case (Performed by Team)

1. The surgeon verifies the procedure performed.
2. Operating room personnel confirm that all sharps are accounted for.
3. The nurse confirms that the instrument count is correct.
4. The team verifies that any throat pack, if used, has been removed prior to the patient’s return to the care

- of the anesthesiologist. “Throat pack-in” and “Throat pack-out” signs, placed centrally in the operating room, are used for this purpose.
5. The team discusses key concerns in the recovery and management of the patient for the postoperative period, and these concerns are relayed to the post-anesthesia care unit (PACU) anesthesiologist and nursing staff.

The main modifications made to the WHO surgical safety checklist involved shifting the items concerning airway and blood loss into the operating suite where a fluid discussion could more readily be performed between the surgery and anesthesia teams. Often times the holding area contains family members and other patients who can distract from discussions of these topics within international missions. Minor changes included the omission of marking the surgical site because the cleft deformity is obvious and, therefore, marking is not indicated. An additional checkpoint for placement of the identification band was included because this process also served as the hospital check-in for the patient. A key component for monitoring quality of delivered health care by international cleft missions is through photo documentation. Therefore, the checklist allowed an opportunity to ensure preoperative photo documentation is being performed. Last, the use of throat packs is highly surgeon-dependent and can pose a serious safety threat if not removed at the end of the operation; therefore, the team members of GSF felt it imperative to include the documented use and disuse of this item on the checklist as well.

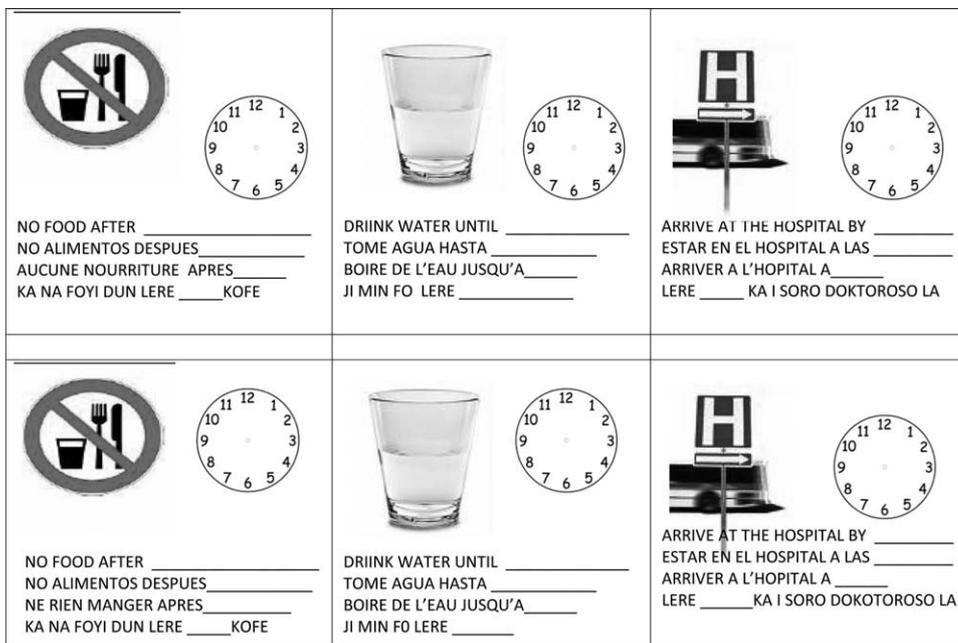


FIGURE 3 Instruction sheets for the family designed to provide written and diagrammatic instructions for preoperative preparation and postoperative care. **A:** Informs the family when the patient must stop eating food prior to surgery, stop drinking water prior to surgery, and what time to arrive to the hospital. The instructions are written in English, Spanish, French, and a West African dialect (Bambara). **B:** Provides specific details in English on the administration of postoperative medication, feeding, and wound care, as well as the postoperative follow-up appointment time. **C:** Provides the same information listed in Figure 3b but in Spanish.

(continued on next page)

PURPOSE OF SAFETY MEASURES

Improving Team Familiarity, Camaraderie, and a Unified Purpose

Checklists and surgical protocols create uniformity for medical personnel working in unfamiliar surroundings. In their home institutions, surgeons often work with the same teams with whom everyone is familiar and all have well-established functions within the operating arena. During international medical mission trips, however, team members often have not worked together and may not be completely familiar with the local surroundings and roles of team members. The confirmation of NPO status, allergies, and the health of the patient might be performed by different medical personnel at the various home medical institutions. Establishing a checklist ensures that these critical steps are performed for every patient.

Techniques among surgeons often vary when repairing cleft lip and palates. Confirming the presence or absence of a throat pack at the beginning and conclusion of the operation is imperative for patient safety and to prevent postoperative airway obstruction. On an international mission, an unfamiliar environment and the absence of a surgical routine could make it more likely for this to be overlooked, and as such GSF policy

is for the throat pack to be placed with a silk suture tied to the gauze and brought out the mouth adjacent to the endotracheal tube. The suture provides a visible reminder of the throat pack and ensures easy removal at the end of the case. By documenting this on the surgical checklist, the entire team is held accountable for throat pack safety at the end of the case.

Optimizing the Relationship Between GSF Volunteers and the Local Team

During medical missions, the relationship between the GSF surgical team and the local medical staff, volunteers, and patients is in a constant state of flux. Language barriers often exist; the surgical checklist and other safety measures are performed to ensure uniformity in care delivery both in and out of the operating room.

This process begins on patient screening day; the GSF has created diagrammatic instructions in the local language to reinforce preoperative instructions and overcome potential breakdown in communication (Fig. 3A through 3C). Bilingual translators are present at screening day and during the operative week to ensure effective communication among team members, the local team, and patients and their families. The operative safety checklist helps to prevent oversight in



How to Care For Your Child

- Give child _____ in  morning AND  evening for _____ days.
- Give child the _____ colored antibiotic.
- If child has pain give _____ pain medicine every 4 to 6 hours as needed.
- Contact hospital if child has severe pain, bleeding or fever. Call _____.



Lip Care

- Keep lips and nose clean and dry for 2 weeks
- Use water to clean lips and nose
- Do not let child suck or use pacifier for 3 weeks
- Use q-tip and water **only** to remove pus or dirt
- In 6 weeks, begin circular massages over the lip scar. Do 5-6 times a day for 5-6 months.

Hands

- Do not let child touch mouth or nose for 3 weeks
- Keep restraints on arms most of the day and night
- Let child move arms 3 times a day for 20 minutes and make sure child does not touch mouth or nose



Feeding: No Solid Food for 2 Weeks

- Feed with syringe from hospital or tilted spoon
- Rinse mouth with water after feeding
- No bottles or breastfeeding for 3 weeks
- First Day: milk, juice, soup
- 2 Weeks: milk, juice, soup, mashed potatoes or carrots, yogurt

- Come back to hospital on _____ for child's first check with Doctor _____.
- Return on _____ for your child's second check with Doctor _____.

FIGURE 3B

(continued on next page)

confirming such issues as NPO status and allergies that may be more difficult to ascertain due to language barriers with the patient families. The GSF has produced an animated educational DVD that explains the process of patient screening and selection, provides perioperative and postoperative instructions, educates families as to the causative factors for clefts, and emphasizes perioperative nutrition, bottle feeding, and other psychosocial factors affecting the cleft patients and their families.

Ensuring Child Health Status Given Screening Day Limitations

Patients' families are often anxious for their child to undergo an operation by the visiting surgical team and thus can understate known medical comorbidities in the interest of this goal. During screening day, patients undergo a thorough evaluation by the surgical team, pediatric anesthesiologists, and pediatrician. This involves a comprehensive exam, with personnel noting



Como Cuidar a Su Hijo(a)

- Dele a su hijo(a) el antibiotico del color _____:

_____ en  la mañana Y _____ en  la noche por ____ días.

- Si necesita medicina para el dolor use _____ cada 4 horas (solo si tiene dolor)



Cuidado del labio

- Mantenga los labios limpios y secos por 2 semanas
- Use agua para limpiar la nariz y los labios
- No use biberón o chupón por 3 semanas
- No permita que su hijo(a) succione/chupe por 3 semanas
- En 6 semanas, _____, 201____, inicie masajes circulares sobre la cicatriz del labio 5-6 veces al día por 5-6 meses

Manos

- No permita que su hijo(a) se toque la boca o nariz con sus manos por 3 semanas
- Use los inmovilizadores de brazos constantemente durante la mayoría del día y la noche
- Permita que su hijo(a) mueva sus brazos 3 veces al día por 20 minutos. Obsérvelo cuidadosamente y no permita que se toque la boca o la nariz durante este tiempo



Alimentación

- Use la jeringuilla que le dan en el hospital o use una cuchara ligeramente inclinada
- Enjuague la boca de su hijo(a) con agua después de cada comida
- No le de el pecho a su hijo(a) por 3 semanas

NO COMIDA SOLIDA POR 2 SEMANAS

- Primer día: leche, jugo, sopa
- Por 2 semanas: leche, jugo, sopa, puré de papas o de zanahoria, cremas, batidos, coladas, yogurt.

Regrese al hospital el _____ para el primer chequeo _____
Y el _____ para el segundo chequeo con el Dr. _____

FIGURE 3C

any associated anomalies and communicating these findings among teams to further assess the patient's eligibility for general anesthesia. It is GSF policy that patients with associated congenital deformities will not be offered an operation during the mission and will be referred to the appropriate local specialists for further evaluation and management; involvement of the local team is critical to facilitate this. It is known that 8% to 45% of cleft patients possess additional congenital anomalies, such as cardiac defects, that affect the patient's safety under general anesthesia (Stoll et al., 2000).

On the day of surgery, the patient's health status is reassessed as part of the checklist—both to confirm the absence of associated congenital anomalies and to exclude the development of concurrent illness. By strictly using the proposed checklist, the team is offered two separate opportunities to evaluate the patient's medical condition and to ensure that he or she is an acceptable surgical candidate.

In addition to the surgical safety checklist discussed above, the GSF has also initiated other safety protocols. These include

- A team meeting at the beginning of the mission in order to rehearse various emergency scenarios, specifically outlining the role of each team member.
- Establishment of a portable “emergency crash code” suitcase that contains essential items found within resuscitative “crash carts.” All team members are aware of the location of the code crash cart, and the location allows for access to the operating rooms, PACU, and inpatient floors (Vyas et al., 2013).
- An on-call schedule and a reliable, reproducible communication chain for each night that includes a team coordinator, surgeon, anesthesiologist, pediatrician, operating room nurse, PACU nurse, and translator.

THE GSF EXPERIENCE

We implemented the GSF surgical safety checklist in November 2009 and have since completed 785 craniofacial surgical procedures during 21 mission trips using this protocol. The checklist was first piloted during a mission to Bamako, Mali, and underwent the majority of modifications listed above in November 2010 based upon teams’ feedback from five missions conducted during a 12-month period. The use of a safety checklist was not enforced at the hosting facility prior to this time. The illustrated patient instruction forms were introduced in March 2011 and were designed to aid in overcoming the language and literacy barrier. Although it is difficult to retrospectively ascertain the number of complications prevented, we have anecdotally noted a number of cases where patients’ similar names, NPO status, and failure of throat pack removal were addressed by this checklist before an untoward event occurred.

Of note, prior to the formal checklist confirmation of preoperative photography and name identification, we had missing preoperative photographs of patients secondary to their double last names being the same. A higher-impact anecdote included an incident where surgeries were being accomplished through the joint effort of the local team and the GSF team. One operating suite was assigned to the GSF team and the other to the local team, where the checklist had not been instituted. According to the GSF protocol, any child recovering from a recent upper respiratory infection is deferred from surgery. One child had just completed a course of antibiotics and did not obtain clearance to proceed with surgery by the GSF anesthesia team. Unbeknown to the GSF team, the patient underwent the procedure by the local team but postoperatively required reintubation, and radiographic evidence suggested pneumonia.

GSF documentation of all 785 procedures reports no mortalities.

In order to ensure that our safety protocols are effective, the GSF holds a morbidity and mortality

session at the conclusion of each trip to assess the details and discuss mechanisms to prevent future complications. No direct comparison of the morbidity rate before and after the implementation of the checklist has been formally conducted; however, we feel that the data provided by the WHO are evidence that such checklists should be enforced.

DISCUSSION

Systematically using this surgical safety checklist plays an important role in international medical mission trips given the unfamiliarity of team members, the relationship between mission volunteers and local staff, language barriers, and the difficulty of overall health assessment given the limited time frame for patient screening. We have experienced a positive impact including fostering trust with the local communities, as displayed by their continued invitation for our return annually. Most important, it has ensured the safest means of providing health care to patients independent of location or situation.

One reason that many practitioners participate in international medical missions is the freedom to deliver care in a purely altruistic way, without the bureaucracy and paperwork required in most American hospitals. It is important to note that this checklist has not been a burden to GSF team members and has actually increased efficiency by standardizing preoperative and intraoperative protocols. The checklist provides a systematic means of creating multiple layers of confirmation yet has not become overbearing.

In addition to enabling improved safety for mission trips, these protocols also serve as an opportunity to introduce the checklists to the local medical teams. At the time that these surgical checklists were initiated by the GSF, the local medical teams were not using formal time-out checklists. One of the goals set forth by the GSF is to produce sustainable, safe health care for the hosting communities. By leading through example, we hope that the host communities also adopt the applicable safety protocols into their daily routine. Our future goals will include assessing the utilization and impact of these protocols on the local medical communities.

CONCLUSION

Attention to surgical safety on medical missions, along with the advent of a modified WHO patient safety checklist and illustrated patient instruction forms, has led to successful missions for GSF volunteers over the past 25 years. Ultimately, the provision of quality care on such medical missions benefits both patients and outreach groups and can help facilitate the involvement of local professionals in the provision of long-term quality care.

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