2. Global Standards of Care

This chapter is largely based on the work entitled, "Operation Smile Resource Manual (2014)," produced by Operation Smile. This document can be found and downloaded from the Operation Smile website: www.operationsmile.org

Operation Smile Global Standards of Care		
1	Requierements for preoperative patient screening and assessment	Appropiate equipment, laboratory support, and trained personnel will be available to perform comprehensive screening and evaluation in order to properly assess our candidates' indications for any possible risks of surgery.
2	Requiered anesthesia equipment and supplies	Only state-of-the-art, currently calibrated anesthetic delivery and support equipment, supplies, and pharmaceuticals will be used by our medical professionals to provide the safest in reliable anesthesia.
3	Requiered surgical equipment	Comprehensive, well maintained surgical instruments, sutures, and supplies will be provided for each patient, customized to the particular operative procedure received by each of our patients.
4	Requierements for the recovery room - PACU	All our patients will receive specialized recovery care as they awaken from anesthesia, in an environment fully equipped with specialized instrumentation, personnel, and pharmaceuticals.
5	Postoperative intense care	Any of our patients requiring additional postoperative care to support ther successful recovery will be managed in a suitable, well-staffed intensive care environment.
6	Patient consent	All of our patients and their families will recieve understandable information and education in their native language, allowing them to make an informed decision about surgery.
7	Surgical Priority	Our patients will receive sugery based on appropiate, well-tested, and proven priority sytems, developed to maximize the expected benefit with primary consideration to safety and the allocation of time and resources.
8	Preventing transmission of blood-borne pathogens	Universal precaution protocols will be followed to help minimize infection, transmission of disease, and wrong-site surgey.
9	Pain management	Allevation of pain and anxiety during every phase of our perioperative care is of primary concern. Each patient will recieve the safest, most effective analgesic medication under strict monitoring from our doctors and nurses.
10	Operation Smile team	Operation smile believes a team approach to the care of our patients provide the highest level of care and safety. Team compositions are comprehensive, deep, and broad in their expertise; drilled in fluid teamwork and effective communication; and most importantly unified by the single desire to achieve the very best outcome for each of our patients.
11	Volunteer credentials	Each of our volunteers is extensively interviewed, credentialed, and proctored prior to joining and operative team. Skills required from each of our specialists meet or exceed those of his/her core discipline. Ongoing mentoring, evaluation, performance review, and professional growth are central to maintaing a top volunteer corps.
12	Minimum patient follow-up	Effective postoperative care is essential for a good surgical result and effective planning for further treatment. Postoperative care requires good documentation and extensive education of parents and clinicians to be effective. When and wherever possible, our patients will receive short, intermediate, and long-term follow-up and care.
13	Proper translation	Operation Smile missions will have sufficiently qualified translators to ensure proper communication among team members, support personnel, families, and patients. Proper translation is considered to be a matter of safety, quality and respect of our patient´s rights.
14	A standard of documentation	The purpose of documentation is to protect the patient, protect the health care personnel, and provide and accurate record for the basis of outcome assessment. Each of our patients will be monitored through a well- documented and protected medical record, whether paper or electronic.

Table 2-1. Operation Smile - Global Standards of Care.

Adapted from Operation Smile Resource Manual 2014.

INTRODUCTION

- Operation Smile's Global Standards of Care were initially developed and agreed on by the global medical leadership in 2006. Subsequent meetings have been held to review and refine these standards, which establish minimum and absolute requirements for any Operation Smile surgical program.
- The 2014 Operation Smile Global Standards of Care is the most recent update and was ratified by medical leaders at the Global Standards Summit in May, 2014.
- These standards are supported by medical policies and procedures which are developed, reviewed, refined and approved by the Operation Smile Medical Oversight team and which are referenced in each standard as appropriate. Underlying all standards and policies is the Operation Smile Charter of Patient Rights and Responsibilities.

STANDARD 1: PREOPERATIVE SCREENING AND ASSESSMENT

- *Global Best Practice* - Organizations employ comprehensive preoperative screening and assessment to optimally select patients and establish a plan for provision of medical care of the highest safety, quality and effectiveness.
- Operation Smile's commitment to screen and assess all patients regardless of specific condition requires flexibility and readiness. Operation Smile's field experience and practice recognizes that proper preparation of patients and planning of medical care in areas where the organization operates requires specific personnel, equipment and infrastructure.
- O peration Smile will ensure the following minimal essentials are in place for patient screening and assessment:
    - Equipment for accurately measuring vital signs, oxygen saturation, weight and height.
    - Equipment and personnel for recording medical histories and performing physical examinations.
    - Equipment and personnel for the psychological preparation

of the patient and family.
- P hotographic equipment for preoperative imaging.
- A speech pathologist should be available for missions performing secondary palate surgery to perform a perceptual and/or objective (nasopharyngoscopic) evaluation.
- Equipment and personnel to obtain all blood specimens.
- Hematocrit and/or hemoglobin will be measured in all surgical patients.
- A clinical laboratory and blood bank capable of supporting the mission goals.
- Personnel and an orderly system to perform postoperative evaluations on Operation Smile returning patients.

Patients with Adverse Blood Conditions:

POLICY: Mission environments are likely to include patients presenting with seemingly low hematocrit (Hct) and/or hemoglobin (Hgb) levels.

PROCEDURE: Transfusion is reserved for urgent/emergent needs. Pre-surgical transfusion is NOT to be given in order to improve a patient's condition for standard mission surgery. Patients with low levels should be referred to in-country resources for treatment of anemia prior to surgery.

STANDARD 2: ANESTHESIA EQUIPMENT AND SUPPLIES

- *Global Best Practice:* Organizations deliver safe anesthesia through effective training and accessibility of equipment and materials for patient monitoring, in order to maximize appropriate outcomes.
- Operation Smile's has adapted WHO (World Health Organization) and ASA (American Society of Anesthesiologists) standards to enable delivery the safest surgical care. Operation Smile's field experience and commitment to the highest levels of effectiveness point to specific equipment necessary for successful outcomes.
- Operation Smile will ensure the following essential equipment/ supplies (in age appropriate sizes, where applicable) medications, and blood products for delivery of anesthesia:
  - Anesthesia machine capable of delivering medicinal oxygen; administering sevoflurane or halothane; serviced annually

and mounted with a vaporizer calibrated according to manufacturer's recommendations; equipped with a backup battery if the machine requires electricity to deliver fresh gas and volatile anesthesia, if power fails; oxygen concentration monitor to test the purity of tank or wall oxygen prior to commencing surgery; secure oxygen supply with an alarm for oxygen supply failure and for hypoxic mixture and a backup oxygen supply for each anesthetizing location; fresh gas outlet that allows connection to a Mapleson or circle breathing system; mechanism for waste gas scavenging.

- Ventilation masks; Endotracheal tubes with stylets; oral and nasopharyngeal airways; anesthesia breathing systems, such as Mapleson D or F circuits or circle systems.
- Laryngoscope blades with handles; equipment to manage unanticipated difficult airway.
- Self-inflating bag-valve-mask system for emergency positive pressure ventilation.
- Suction catheters/tips and suction devices with battery backup.
- Isotonic intravenous (IV) solutions including normal saline and lactated ringers.
- All necessary equipment for administration of IV fluids to include pediatric volumetric administration devices.
- Noninvasive monitoring equipment for intermittent measurement of electrocardiogram, pulse oximetry, capnography, temperature and blood pressure.
- Immediate access to defibrillator/cardioverter with pediatric and adult paddles.
- Medications required for administration of advanced cardiac life support along with code sheet in medical record with calculated doses per weight for each medication/intervention. Equipment to establish intraosseous access.
- Sevoflurane or halothane whenever sevoflurane is unavailable.
- Dantrolene in sufficient quantity to treat malignant hyperthermia.
- Equipment and soaking solutions for the sterilization of

non-disposable anesthesia equipment.

Monitoring During Anesthesia:

POLICY: Monitoring of certain fundamental physiological variables during anesthesia is essential. Clinical monitoring by a vigilant anesthetist and appropriate devices to assist the anesthetist is the basis of safe patient care during anesthesia.

PROCEDURE:

Circulation must be monitored at frequent and clinically appropriate intervals.

- Every patient-receiving anesthesia shall have the electrocardiogram continuously displayed from the beginning of anesthesia until they leave the anesthesia location.
- Every patient-receiving anesthesia shall have arterial blood pressure and heart rate determined and evaluated at least every five minutes.
- Every patient receiving general anesthesia shall have, in addition to the above, circulatory function continually evaluated by at least one of the following: palpation of a pulse, auscultation of heart sounds, monitoring of a tracing of intra-arterial pressure, ultrasound peripheral pulse monitoring, or pulse oximetry.

Oxygenation values must be interpreted in conjunction with clinical observation of the patient. Adequate lighting must be available to aid in the assessment of patient color.

- Inspired Gas: During every administration of general anesthesia using an anesthesia machine, the concentration of oxygen in the patient breathing system shall be measured by an oxygen analyzer with a low concentration limit alarm in use.
- Blood Oxygenation: During all anesthetics, a quantitative method of assessing oxygenation such as pulse oximetry shall be employed. Adequate exposure of the patient is necessary to assess color.

Ventilation must be monitored continuously by both direct and indirect methods.

- Every patient receiving general anesthesia shall have the adequacy of ventilation continually evaluated. While qualitative clinical signs such as chest excursion, observation of the reservoir bag and auscultation of breath sounds may be useful, quantitative monitoring of the carbon dioxide content is strongly encouraged.
- When inserting an endotracheal tube or laryngeal mask is inserted, correct positioning must be verified by clinical assessment and identification of carbon dioxide in expired gas.
- Continual end-tidal carbon dioxide (ETCO2) analysis, from the time of endotracheal tube laryngeal mask placement until extubation / removal or initiating transfer to a postoperative care location, shall be performed using a quantitative method such as capnography, capnometry or mass spectroscopy.

Temperature shall be measured during anesthesia, and when changes in body temperature are intended, anticipated or suspected, the temperature shall be measured.

Blood Supply:

POLICY: An emergency supply of blood must be immediately available at all times.

PROCEDURE: The clinical coordinator confirms prior to the start of any surgery day that the required minimum blood supply is on hand or easily accessible. The CC will notify the program coordinator of any incident during which the blood supply drops below the required level. The PC will in turn coordinate with the hospital for additional blood products.

REQUIREMENTS: Two (2) units of O negative blood will be available upon request. If O negative is not available in the area, two (2) units of O positive blood will serve as the required minimum. Storage of blood should be in the range of 1-60 C.

Clinical Pathway for Administration of Blood Products:

If the need to transfuse blood arises, the clinical coordinator or designee will obtain the blood from the blood bank and blood tubing will be brought to the bedside. The blood label will be checked by two clinicians for contents and expiration date. Establish condition of existing IV or start another as directed by the treating physician.

Infusion started within 15 minutes of retrieval from blood bank and completed within four hours. Documentation includes the time infusion started, baseline vital signs including temperature. Vital signs repeated within a minimum of 15 minutes after infusion started, any signs of adverse reaction, time infusion completed, vital signs at the completion of the infusion. Determine the need for additional labs (type and cross, hematocrit, hemoglobin). Dispose of blood bag in a biohazard bag. Keep the blood label with the chart.

Oxygen Reserve:

POLICY: A reserve oxygen supply must be available for the entire duration of the Operation Smile mission. The required reserve oxygen supply for an operating room table is defined as that which is sufficient to complete an entire surgery for the patient being placed on the table. In certain cases, an E-cylinder oxygen tank (approximately 650 liters) is shared between two operating tables with a T connector. A reserve supply, an average one oxygen tank per 2 – 3 beds, must also be available in the PACU and a reserve supply of oxygen must also be in each postoperative area.

PROCEDURE: The program coordinator and anesthesia team leader are to confirm that primary and reserve oxygen is available in the hospital prior to the start of surgery and that suitable portable oxygen tanks for patient transport. Biomedical technicians confirm that flow regulators, adapters for all oxygen sources, and reserve supplies are present and working.

Difficult Airway Management:

POLICY: The Difficult Airway Policy addresses the delivery of safe care in the situation of an airway complication during surgery.

PROCEDURE: When a patient is identified during screening as having potential of a difficult airway, all team leaders must be in agreement that the patient can safely receive surgery in a mission setting. Identified patient should not be scheduled during the same time as another potential difficult airway patient. Pediatric patients with a difficult airway should be scheduled with a pediatric anesthesiologist. The Difficult Airway Box (DAB) must be at the patient's table during the entire surgery and any use of DAB items must be recorded on the Medical Incident form. The DAB inventory list will be completed and DAB resupplied before the next mission.

Medication Administration:

POLICY: To ensure that all team members are familiar with the approved medications administered to any patient within the Operation Smile mission setting. Medication administration should be limited to medications as outlined in the Operation Smile's Pharmacopeia. Additional drugs or substitutes must be approved by the Operation Smile Medical Officers.

PROCEDURE: Operation Smile approved medications are administered using the eight rights of medication administration:

Circulation must be monitored at frequent and clinically appropriate intervals.

1. Right Patient - Verify the patient name using ID band and chart; confirm the presence or absence of allergies; verify the medication order as written; for verbal orders there should be a repeat back to verify the order.Every patient-receiving anesthesia shall have arterial blood pressure and heart rate determined and evaluated at least every five minutes.
2. Right Medication - Check the medication label and expiration date; check the order.
3. Right Dose - Check the dose; confirm the appropriateness of the route; calculate the dose based on patient weight as indicate; verify dose with another clinician as needed.
4. Right Route - Check the order for appropriateness of ordered route; verify that patient can take the medication by the ordered route.
5. Right Time - Check the frequency of the ordered medication; confirm the timing of the previous dose as documented.
6. R ight Documentation - Document medications AFTER they are given; documentation should include time, route, and injection site, if applicable.
7. Right Reason - Confirm the rationale for the ordered medication; involve the patient / family in the discussion of the use, effects, and potential side effects of medications as they are given; for pain medication, consider the use of other comfort measures to potentiate the effect of the drug.
8. Right Response - Verify that the medication has had the desired effect; document the response to the medication and other interventions that are applicable.

Labeling of Medications:

- Medications that have been drawn from another container/vial must be labeled for drug name, concentration, and dose.
- All solutions and medications on the surgical field must be labeled.

Patient Education:

- Patient and family education related to postoperative and take home medications

should be initiated as early as possible.
- Medications given in the postoperative setting should be thoroughly explained and family involvement encouraged.
- Medications sent home with the patient need to be labeled with instructions for dosing, route, and timing. Confirmation of the patient/family understanding of the medication use needs to be demonstrated and documented.

STANDARD 3:
SURGICAL EQUIPMENT

- *Global Best Practice* - Organizations delivering safe and effective surgical interventions assure the availability and proper utilization of appropriate equipment, materials, and instrumentation and sterilization practices.
- Operation Smile's field experience and commitment to the highest levels of surgical effectiveness has supported definition of a robust complement of equipment staged and shipped in support of all surgical programs along with associated practices for use.
- Operation Smile will ensure the following essential equipment/ supplies for the delivery of surgical care:
    - Sufficient quantities of well-maintained instruments and sutures, with type and quantity appropriate for the planned procedure.
    - Equipment, medications and environment for local anesthesia.
    - Suction machine; electrocautery machine and equipment; adequate lighting for illumination of the surgical field.
    - Equipment for proper sterilization of surgical equipment.

Surgical Safety:

POLICY: To ensure the safety and quality of care for all patients treated on all OS medical missions during the perioperative phase, the following surgical safety items will be implemented.

PROCEDURE:

Surgical Safety Checklist - The Operation Smile surgical safety checklist will be completed by perioperative team members. By signing this form, the team member is verifying that each step was taken in the proper order before progressing with surgery and taking the patient to PACU.

Antibiotic Administration - The prophylactic administration of antibiotics within one hour

of incision helps reduce and/or prevent surgical site infections. All Operation Smile surgical patients will receive this prophylactic dose of antibiotic. Team leaders will discuss and determine the antibiotic preference.

Throat Pack - Throat packs will be used on a case by case basis as determined by the surgeon to prevent aspiration and protect the airway. Throat packs are available in Operation Smile Custom Surgical Packs. If Custom Surgical Packs are not available they will be constructed using the Guideline or Throat Pack Construction. Placing or removal of throat packs should be announced to the OR staff and a throat pack sign made visible to all. Removal of throat pack will be documented on the anesthesia flow sheet.
Sharps Disposal - Operation Smile promotes a safe environment for all staff and volunteers. It is essential for staff and volunteers to practice safe and appropriate handling and disposal of sharps and needles.

Medical Waste Management:

POLICY: To ensure the adequate handling of medical waste in order to avoid health consequences and impact on the environment. To eliminate the possibility of inadvertent contact with blood or other potentially infectious materials by personnel not prepared or trained to handle medical waste.

PROCEDURE: Follow international, national and local regulations governing the shipment of equipment and medical supplies.

- Proper handling of contaminated equipment to eliminate potential problems of contamination and infection related to medical waste.
    - Sharps must be collected together in puncture-proof containers.
    - Bags and containers for infectious waste must be collected as frequently as required and properly marked with information to include date of collection, type of waste, place in hospital where it was collected.
    - Trained personnel, with proper protection, will handle the storage and disposal of waste.
    - All equipment in contact with patients and/or health care workers will be thoroughly disinfected and dried prior to packing.
- Proper disposal of pharmaceuticals.
- No expired pharmaceuticals or consumables will be donated to other entities.

Sterilization:

POLICY: To ensure the adequate handling of medical waste in order to avoid health consequences and impact on the environment. To eliminate the possibility of inadvertent contact with blood or other potentially infectious materials by personnel not prepared or trained to handle medical waste.

- All critical items such as instruments, supplies and equipment used during surgical procedures must be sterile. Critical items are those that enter sterile tissue or the vascular system. This includes surgical instruments utilized in cleft lip and cleft palate surgery, craniofacial surgery, microsurgery, orthopedic surgery, burns and dental procedures.
- Items are considered sterile that have undergone one of several sterilization methods including steam sterilization, gamma radiation or ethylene oxide.

- Manufactured items must have sterility status printed on the package and the outer packing must be dry and intact to be considered sterile.
- Items that have been processed within the facility must have a positive external and internal chemical indicator reading denoting adequate exposure to sterilization processes.
- All facility processed re-useable critical items will be considered unsterile after being packed and moved to another location.
- All manufactured sterile supplies must be stored within a closed container in a temperature controlled facility. Extreme temperatures and humidity compromise the outer package and can render an item unsterile.
- During missions saturated steam under pressure will be the method of sterilization for reusable critical items. Single use items should not be sterilized for reuse.

PROCEDURE: Full sterilization procedures are available in the Operation Smile Resource Manual.

STANDARD 4: POST ANESTHESIA CARE UNIT (PACU)

- *Global Best Practice* - Organizations delivering safe and effective post anesthesia care assure the availability and proper use of appropriate equipment, materials, pharmaceuticals along with supporting services and trained personnel.
- Operation Smile's field experience has helped define a globally uniform commitment to the highest level of effectiveness through specific equipment and personnel necessary for successful outcomes.
- Operation Smile will ensure the following essential equipment, supplies, and services for the delivery of post anesthesia care:
    - PACU space and beds should be of a suitable number to support the surgical mission.
    - Anesthesia equipment and medications specified in Standard #2 (with the exception of anesthesia machine, breathing systems, and general anesthesia gases) should be available for PACU patients.
    - A device or laboratory will be available to measure glucose levels.
    - Resuscitation medications with available code sheet and dosing.
    - Every patient admitted to the PACU will have vital signs monitored to include blood pressure, heart rate, oxygen satura-

tion, respiratory rate and temperature.
- A device to record an electrocardiogram will be available.
- Suction equipment, oxygen, and pulse oximeter monitor at each bedside.
- A respiratory oxygen delivery system will be available for use in the transport from the operating room to the PACU when indicated.

Emergency Preparedness:

POLICY: : To ensure that all team members are familiar with how to manage any patient or hospital emergency situation within the mission setting.
PROCEDURE: After prior discussion with all Team Leaders, the PACU physician will notify all OR and PACU staff to a central point, usually where the defibrillator and crash box are located outside of the operating rooms. The Pediatrician will have a parallel discussion in the Postop area with team members in the Postop area to include Pre and Postop staff.

REQUIREMENTS: The presentation should include:
- Who will lead the code, notify others, designate roles and ultimately be responsible? Who will notify the family?
- Where is the emergency equipment to include ambu bag, crash box (with emergency medications and equipment), oxygen, suction and, defibrillator. This should include how to open the crash box, internal organization of the box and how to use the defibrillator.
- Familiarize everyone with the pre-printed "Patient Code Sheet" in the Operation Smile patient's chart.
- Discuss the procedure for patient emergencies outside the OR area, such as in the Pre and Postop wards and other patient areas. This should include the method of communication for first responders and if the patient will be immediately transferred to the PACU or the Postop area.
- Based on the environment comment on the potential likelihood of hospital infrastructure failure (water, electricity, oxygen, central suction) and response.

STANDARD 5:
POST OPERATIVE INTENSIVE CARE UNIT

- *Global Best Practice* - Organizations delivering safe and effective post-operative intensive care assure the availability and proper use of appropriate equipment, materials, pharmaceuticals along with supporting services and trained personnel.
- Operation Smile's field experience demonstrates the importance of establishing effective plans of action to respond to critical care situations. Operation Smile teams prepare for such events by mak-

ing postoperative intensive care units available, either in partnership or as a temporary stand-alone unit.

- Operation Smile will ensure that the following essential equipment, supplies, and services are available to properly respond to critical situations.
    - Intensive Care Unit (ICU) support may be required due to complications of surgery. An appropriate ICU facility should be identified prior to initiating surgery, and a plan for patient transfer should be developed whenever the ICU is not within the mission's hospital facility.
    - Postoperative intensive care facilities will include electronic monitors for ECG, blood pressure, oxygen saturation, temperature.
    - A respiratory ventilator will be available for any patient brought to the intensive care facility.
    - Facilities will be staffed by appropriately trained nurses and doctors.
    - Whenever an appropriate ICU facility cannot be identified, Operation Smile will have all necessary equipment and personnel available at the mission site.

STANDARD 6: POST OPERATIVE WARD

- *Global Best Practice* - Organizations offering effective, evidence-based, postoperative care utilize personnel and infrastructure to assure ongoing assessment, planning, intervention, evaluation and documentation of care.
- Operation Smile's field experience demonstrates the importance of postoperative care in facilitating patient's full recovery as well as educational materials and preparation for discharge including materials in multiple languages and in pictorial formats.
- Operation Smile will ensure the following essential equipment, supplies, and services are available to properly care for patients in the postoperative ward:
    - Every patient admitted to the postoperative ward will have

vital signs monitored to include blood pressure, respiratory rate, heart rate, oxygen saturation and temperature.
    - An area on the postoperative ward will be designated and equipped for resuscitation including emergency drugs.
    - Suction equipment, oxygen, and 24-hour nursing care will be available on the postoperative ward.
    - Evidence-based, postoperative care requires ongoing assessment, planning, intervention, evaluation, and documentation.
    - Postoperative patient education programs will be administered by nursing and delivered in the local language with written instructions using words and pictographs.
    - Comprehensive discharge instructions will be administered to patients and family, including medications, feeding, etc.
    - Speech pathologist available for consultation and therapy, as needed.

STANDARD 7: PATIENT CONSENT

- *Global Best Practice* - Health interventions and associated research proceed only after securing meaningful and documented informed consent from patients directly or from legally-authorized representatives through culturally and literacy-appropriate information. Additional informed consent may be indicated depending on health intervention outcomes or research protocols.
- Operation Smile's field experience has included a wide array of cultural, language, socioeconomic and educational contexts resulting in a two-tier informed consent practice involving a global consent process which is implemented wherever appropriate with local, country-level consent processes as may be legally or otherwise required or indicated.
- Operation Smile will ensure that meaningful informed consent is secured from all patients in its care which will include:
    - Accurate description of surgery, anesthesia, side effects and

complications by attending physician or trained volunteer.
  - Permission for picture taking for clinical and research purposes.
  - Consent for administration of blood products as required.
  - Permission to utilize personal and demographic information.
  - Medical record data used in any research.
  - HIV /AIDS testing should a needle stick injury occur to one of the health care team.
  - Culturally relevant materials utilized to provide orientation to the patients and families.
  - Use of patient's story or picture for publication.

STANDARD 8: SURGICAL PRIORITY

- *Global Best Practice* - Organizations offering safe and effective surgical services utilize a structured and transparent framework that analyzes available resources and the expected benefit of the intervention.
- Operation Smile's field experience has evolved a framework to carefully analyze and assess maximization of effectiveness and safety of the interventions after careful and thoughtful assessment of available resources, infrastructure and the presenting population. This knowledge is embodied in our surgical priorities policy.
- Operation Smile will ensure patients are selected for surgery following our age minimum and scheduling policy
  - Patients will receive surgery from Operation Smile based on appropriate priority systems.
  - The priority system was developed to maximize the expected benefit from surgery with consideration to safety and the allocation of time and resources.

Surgical Priorities:

POLICY: : Operation Smile has developed priorities for patient selection as a means to address primary concerns of safe surgery and healthy recovery of patients. During the selection process, follow-up care, rehabilitation, and other therapies should be considered.

Goal is to provide highest standard of care, safety and professionalism for the mission environment.

PROCEDURE: Surgical Priorities

Priority 1 – Primary Repair of Cleft Lip (Ages 6 months and older)
Priority 2 – Primary Repair of Cleft Palate (Ages 1 - 10 years)
Priority 3 – Primary Repair of Cleft Palate (Ages 10+ to Adult)
Priority 4 – Secondary Repair of Lip or Palate
Priority 5 – Other Conditions

- Additional possibilities include Not a Candidate, Potential World Candidate, and No Further Surgical Intervention Needed.
- Returning Operation Smile patients with complications are classified as Priority 1.

Cleft Age Minimums and Surgical Scheduling:

POLICY: : To ensure the safety and quality of care for all patients being treated during Operation Smile medical missions. The policy outlines the minimum age acceptable for surgery of a cleft lip or palate and the procedure required to deviate from the established age. Patients under the age of 3 months should NOT be considered for any surgery on an Operation Smile medical mission.

PROCEDURE:

- Cleft lip repair: >6 months of age is the minimum age standard for patients eligible for surgery at most Operation Smile mission sites. Patients aged 3-6 months may be scheduled only with total agreement from ALL team leaders*
- Cleft Palate repair: >12 months of age is the minimum age standard for patients eligible for palate surgery at most Operation Smile mission sites. Patients aged 9-12 months of age may be scheduled only with total agreement from ALL team leaders*
- Combination lip and palate repairs should be considered only for patients >1 year old.

*Team leaders include: Field Medical Director (FMD), Anesthesia Team Leader (ANTL), Plastic Surgery Team Leader (PSTL), Clinical Coordinator (CC), and PACU Physician.

STANDARD 9: PREVENTING TRANSMISSION OF BLOOD BORNE PATHOGENS

- *Global Best Practice* - Organizations delivering optimal health care take measures to prevent transmission of blood borne pathogens, following WHO and CDC recommendations.
- Operation Smile's field experience drives the need to assure all supplies, equipment and skill base are available to adhere to uni-

versal precautions in order to protect patients and volunteers from transmission of blood borne pathogens.

- Operation Smile will ensure protocols are followed to limit exposure to blood borne pathogens. Universal precautions protocols will be followed
- Universal precautions protocols will be followed.
- The following strategies should be considered in limiting exposure to blood borne pathogens:
    - Appropriate handling and disposal of sharps.
    - Appropriate intervention in needle stick injuries.
    - When available, the use of needle safe IV systems.

STANDARD 10: PAIN MANAGEMENT

- *Global Best Practice* - Organizations deliver optimal pain management through proper assessment and application of pharmacological and culturally appropriate non-pharmacological means to minimize pain and anxiety.
- Operation Smile's field experience has evolved a framework to carefully assess and effectively manage pain and anxiety, including the development of a global pharmacopeia to assure that locally available alternatives can be integrated into pain management strategies.
- The organization has also adapted non-pharmacological techniques as an important tool in the provision of effective pain management.
- Operation Smile will offer the safest, most effective alleviation of pain and anxiety during every phase of perioperative care, under strict monitoring from Operation Smile physicians and nurses.
- Intra-Operative Pain Management:
    - Multi modal analgesia will be used for pain relief including local blocks, local infiltration, per rectal and intravenous titration of appropriate medications.
    - Morphine will not be used in pediatric cleft lip and palate patients.

- Recovery Room Pain Management:
  - Analgesia will be maximized with due consideration for a smooth emergence from anesthesia
- Post-Op Ward Pain Management:
  - Oral and rectal analgesia will be the preferred routes of administration under the direction of a physician.
  - Analgesia will be maximized with due consideration for adequate control of procedure related pain through discharge home.
  - Pain management will include alternative non-pharmacological measures such as parental presence, alternate focus techniques, and psychological support and comfort positions will be used for pain management as appropriate.

STANDARD 11: OPERATION SMILE TEAM

- *Global Best Practice* - Organizations offering effective surgical services assign proper personnel ensuring the highest level of care and safety.
- Operation Smile draws more than 5,000 volunteers from over 90 countries, maximizing available medical skills for provision of the highest level of safety and quality.
- These volunteers function as effective multidisciplinary teams offering language, cultural and technical skill diversity helping assure safety and quality for every program around the world.
- Operation Smile will offer a multidisciplinary team approach to the care of all patients, providing the highest level of safety and quality.
  - Cleft surgeon(s)
  - Anesthesiologist(s)
  - PACU Physician
  - Pediatrician(s)
  - Clinical Coordinator
  - Operating Room Nurses
  - Recovery Room Nurses
  - Pre / Post Operative Nurses
  - Dentist
  - Medical Records Specialist
  - Medical Photographer
  - Biomedical Technician
  - Speech Therapist
  - Child Life Specialist
  - Clinical Coordinator(s)
  - Program Coordinator(s)

- Team compositions need to provide for an effective number of medical personnel and specialties in relation to the number of general anesthesia tables planned and/or added. The team composition should be adjusted according to patient volume, hospital layout, and additional factors

Operation Smile Mission Team

Surgeons	2 GA	3 GA	4 GA	5 GA	6 GA	7 GA
Anesthesiologists	3	4	5	6	7	8
Peds Anesthesiologists	2	3	5	6	8	9
Pacu Physician	1	1	1	1	1	2
Peditrician	1	1	1	1	2	2
Clinical Coordinator	1	1	1	1	1	1
OR Nurses	2	3	3	4	5	6
PACU Nurses	2	2	3	3	4	5
Post-op Nurses	2	2	3	4	5	5
Night Nurses	2	2	2	2	2	3
Child Life	1	1	1	1	1	2
Speech Therapy	1	1	1	1	2	2
Dentist	1	1	1	1	1	2
Biomed	1	1	1	1	1	1

Table 2-2. Mission Team Members.

Adapted from Operation Smile Resource Manual 2014.

STANDARD 12: QUALIFICATIONS OF VOLUNTEERS

- *Global Best Practice* - Organizations delivering optimal global surgical care assure all health professionals are properly trained and credentialed, and have mechanisms for continuing assessment of competencies and performance.
- Operation Smile has evolved processes for the inclusion of providers from around the world, based on the review of core competencies, the enhancement of skills through specific training opportu-

nities and a system of ongoing support by peers and monitoring to ensure all health providers are able to deliver safe and effective care. The organization has also developed mentoring and professional growth opportunities to maintain a strong core of professional volunteers.

- Operation Smile will ensure teams working on all its programs are comprised of qualified providers. All volunteers will be extensively interviewed, credentialed and proctored prior to joining an operative team. Skills required from each of our specialists will meet or exceed those of his/her core discipline.
- Operation Smile will offer a mentoring evaluation, performance review and opportunities for professional growth as a central strategy to maintaining its volunteer core.
- Minimum requirements for all specialties are listed in the Operation Smile Resource Manual.

STANDARD 13: PATIENT FOLLOW UP

- *Global Best Practice* - Organizations offering optimal surgical care make provisions for adequate follow up to maximize treatment effectiveness, assess options for future treatment and monitor outcomes.
- Operation Smile has established processes to periodically make available health care providers to orient patients, document and evaluate outcomes, plan future interventions and offer additional assistance.
- Operation Smile will offer ongoing care through its network of global volunteers to all patients returning during established follow up periods.
- Effective postoperative care is essential for good surgical results and effective planning for further treatment.
- Postoperative care requires good documentation and extensive education of parents and clinicians to be effective.
- Postoperative care from an Operation Smile organized team should review patients at the following intervals:

- One week after surgery (4–7 days post-op). The goal is to recognize and manage immediate results and complications.
- Six months to 1 year. Team evaluation for documenting outcomes of surgeries and planning for future treatment.

STANDARD 14: TRANSLATION

- *Global Best Practice* - Effective and appropriate written and verbal translation services are an integral part of surgical delivery and post-operative care to assure safety and quality, optimize positive outcomes, and respect patient rights including informed consent.
- Extending the above, Operation Smile's field experience and practice recognizes the importance of and utilizes translation services and translated documentation which are critical to its medical programs and essential to its volunteers' ability to contribute.
- Operation Smile will provide qualified interpreters to ensure proper communication amongst team members, patients and families.
- Operation Smile will provide orientation for interpreters and training for team members to effectively use interpreters. Operation Smile will place skilled interpreters in critical áreas.

STANDARD 15: DOCUMENTATION

- *Global Best Practice* - Organizations offering optimal care create detailed documentation (including medical records) capturing the life cycle of patient interactions. They effectively utilize this documentation to inform patient assessment and health interventions and manage it under the highest standards of security and confidentiality.
- Operation Smile's experience in delivering surgical care in diverse and challenging settings has resulted in robust strategy for creating, utilizing and managing documentation including medical records. The diverse geography and environments in which missions are conducted and the associated legal requirements and cultural

sensitivities have helped define Operation Smile's documentation solutions. In the near future, these solutions will also integrate various technologies including electronic health records, encryption and other digital strategies.

- Operation Smile is committed to protecting the patient, health care personnel, and to provide an accurate and secure record for the basis of ongoing care and outcome assessment.
- Adequate medical records include the following:
  - Demographic detail must be recorded; with special care to clarify family name, given name, and unique Operation Smile identifier.
  - Patient/family history.
  - Physical examination.
  - Medical/surgical diagnosis.
  - Operation performed
  - Documentation of care through the entire clinical pathway (Screening, Pre-Op, OR, Anesthetic record, Photographic documentation, PACU, Post-op, Discharge).
- Operation Smile will work to ensure that documentation will be available to caregivers. All team members are responsible for documentation.
- Management of documentation will respect patient confidentiality.

STANDARD 16: HOSPITAL FACILITY

- *Global Best Practice* - Organizations offering effective surgical interventions assure an environment which meets minimums on proper personnel, access to supplies, equipment, infection control and supporting infrastructure.
- Extending the above, Operation Smile's field experience and the broad diversity of settings in which it operates has resulted in the development and use of extensive pre-mission fact-finding processes to assure all minimums are in place prior to any surgical intervention. In many settings, Operation Smile strengthens the health care infrastructure in place to meet these minimums.

- Operation Smile is committed to conducting a pre-mission site visit, which is required to insure adequacy of the hospital facility to support the planned mission, including presence of the following:
    - Adequate physical space for screening, operating rooms, post anesthesia care unit, preoperative and postoperative care.
    - Infrastructure able to support the mission.
    - Basic clinical laboratory and x-ray.
    - Blood bank or means to provide adequate blood supply.

STANDARD 17: QUALITY ASSURRANCE

- *Global Best Practice* - Organizations in the health services which have effective quality assurance practices focus on individual performance against ethical and professional standards. Additionally, appropriate monitoring of that performance, along with other aspects such as services and infrastructure are critical to delivery of high quality medical services.
- Operation Smile's experienced in delivering surgical care in diverse and challenging settings has resulted in a tier oversight system at country, region and global levels. The resulting quality mechanism, assures the organization's commitment to world-class safety and quality.
- Operation Smile will maintain a quality assurance task force and processes and recognizes ongoing monitoring as a crucial mechanism to fulfill the organization's pledge to provide care of the highest caliber.
- Quality assurance mechanisms include the following:
    - Collection of quality improvement data, including standard quality indicators, adverse events, monitor performance and identify areas needing improvement.
    - Evaluation of adverse events identified as "critical events" to determine causes and prevention. Performance of quality improvement projects.
    - Interfacing with organizational leaders to develop guidelines

and policies that address items identified.
- Interfacing with Credentialing Coordinator to insure providers meet qualifications outlined in Standard 12.

KEY READING

1. Operation Smile Resource Manual (2014).