

GLOBAL STANDARDS OF CARE

Updated March 5, 2015

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. 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*.

The 2014 Operation Smile Global Standards of Care below reflect the work at the Global Standards Summit convened in May 2014, and review processes which preceded and followed that meeting. The current structure of each standard has evolved to include the following:

GLOBAL STANDARD OF CARE STRUCTURE

- **Standard Title**
A descriptive title which accurately captures the subject of the standard.
- **Global Best Practice**
A short statement capturing the currently recognized best practice around the standard area, supported, where possible, with cited standards, codes and peer-reviewed literature.
- **Operation Smile Context**
A short statement which identifies an important or unique dimension to this standard which derives from Operation Smile experience and practice from its field mission or center activity which warrant discussion and which may bridge between the global best practice and the specific Operation Smile commitments which follow.
- **Operation Smile Global Commitments**
This is the core section which lists the specific commitments Operation Smile makes as “minimum” requirements but which may be surpassed in some or many contexts. These commitments will often reflect both the global best practice, and more specifically, operational specifics which derive from Operation Smile's operational practice.
- **Supporting Policies/Procedures**
This section identifies and links to all current, relevant Operation Smile medical policies and procedures which support and articulate the standard. This section may also include a “statement of direction” which identifies new policies in development or issues under review which may result in a new or revised policy.
- **Supporting Evaluation Practices/Documentation**
This section identifies and links to all current evaluation strategies and practices which Operation Smile employs to measure its performance against and compliance with this standard and associates policies/practices. This section may also include a “statement of direction” which identifies issues under review and new evaluation strategies and practices in development.

STANDARD 1: PREOPERATIVE PATIENT SCREENING & 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 Context:

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.

Operation Smile Global Commitments:

(Minimums which may be surpassed in some contexts)

Operation Smile will ensure the following essentials are in place for patient screening and assessment:

- 1.1 Equipment for accurately measuring vital signs, oxygen saturation, weight and height.
- 1.2 Equipment and personnel for recording medical histories and performing physical examinations.
- 1.3 Equipment and personnel for the psychological preparation of the patient and family.
- 1.4 Photographic equipment for preoperative imaging.
- 1.5 A speech pathologist should be available for medical missions performing secondary palate surgery to perform a perceptual and/or objective (nasopharyngoscopic) evaluation.
- 1.6 Equipment and personnel to obtain all blood specimens.
 - 1.6.1 Hematocrit and/or hemoglobin will be measured in all surgical patients.
- 1.7 A clinical laboratory and blood bank capable of supporting the medical mission goals.
- 1.8 Personnel and an orderly system to perform postoperative evaluations on Operation Smile returning patients.

Supporting Policies/Procedures:

Operation Smile continues to review and will develop appropriate policies to support this standard. Specific current policies include:

- *Blood Supply*
- *Pre-Surgical Blood Transfusion*
- *Patients having surgery under local anesthesia*
- *Age Minimums and Scheduling*
- *Surgical Priorities*
- *Surgical Deviation*

Supporting Evaluation Practices/Documentation:

Operation Smile continues to develop and review prospective and retrospective data collection and analysis approaches for this standard. Specifically evaluation of preoperative screening and assessment are addressed in:

- *Fact-finding Checklist (pre- medical mission)*
- *Quality Assurance Outcome Objectives (post- medical mission)*

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 Context:

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 points to specific equipment necessary for successful outcomes.

Operation Smile Global Commitments:

(Minimums which may be surpassed in some contexts)

Operation Smile will ensure the following essential equipment/supplies (in age appropriate sizes, where applicable) medications and blood products for delivery of anesthesia:

- 2.1 An Anesthesia Machine with the following capabilities/qualifications:
 - 2.1.1 Capable of delivering medicinal oxygen.
 - 2.1.2 Capable of administering sevoflurane or halothane when sevoflurane is unavailable.
 - 2.1.3 Serviced annually and mounted with a vaporizer calibrated according to manufacturer's recommendations.
 - 2.1.4 Equipped with a backup battery if the machine requires electricity to deliver fresh gas and volatile anesthesia, if power fails.
 - 2.1.5 Oxygen concentration monitor to test the purity of tank or wall oxygen prior to commencing surgery.
 - 2.1.6 Secure oxygen supply with an alarm for oxygen supply failure and for hypoxic mixture and a backup oxygen supply for each anesthetizing location.
 - 2.1.7 Fresh gas outlet that allows connection to a Mapleson or circle breathing system.
 - 2.1.8 A mechanism for waste gas scavenging.
- 2.2 Ventilation masks.
- 2.3 Endotracheal tubes with stylets.
- 2.4 Oral and nasopharyngeal airways.
- 2.5 Laryngoscope blades with handles.
- 2.6 Equipment to manage unanticipated difficult airway.
- 2.7 Anesthesia breathing systems, such as Mapleson D or F circuits or circle systems.
- 2.8 Self-inflating bag-valve-mask system for emergency positive pressure ventilation.
- 2.9 Suction catheters/tips and suction devices with battery backup.
- 2.10 Isotonic intravenous (IV) solutions including normal saline and lactated ringers.
 - 2.10.1 All necessary equipment for administration of IV fluids to include pediatric volumetric administration devices.
- 2.11 Noninvasive monitoring equipment for intermittent measurement of electrocardiogram, pulse oximetry, capnography, temperature and blood pressure.
- 2.12 Immediate access to defibrillator/cardioverter with pediatric and adult paddles.
- 2.13 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.
- 2.14 Sevoflurane or halothane whenever sevoflurane is unavailable.
- 2.15 Dantrolene in sufficient quantity to treat malignant hyperthermia.
- 2.16 Equipment and soaking solutions for the sterilization of non-disposable anesthesia equipment.
- 2.17 Sufficient quantity and types of blood products for planned procedures with products screened for Hepatitis B and C and HIV.

Supporting Policies/Procedures:

Operation Smile continues to review and will develop appropriate policies to support this standard. Specific current policies include:

- *Additional Table*
- *Oxygen Reserve*
- *Administration of antibiotics for all patients*
- *Monitoring during Anesthesia*
- *Administration of IV Fluids in Pediatric Patients*
- *Blood Supply*
- *Difficult Airway Box*
- *Pre-Surgical Blood Transfusion*
- *Donated Used Equipment*
- *Disposal of Sharps*
- *Medical Waste Management*
- *Pediatric Medication Guidelines*
- *Sterilization*
- *High Level Disinfection*
- *Throat Packs*
- *Surgical Safety Checklist*

Supporting Evaluation Practices/Documentation:

Operation Smile continues to develop and review prospective and retrospective data collection and analysis approaches for this standard. Specifically evaluation of preoperative screening and assessment are addressed in:

- *Fact-finding Checklist (pre- medical mission)*
- *Quality Assurance Outcome Objectives (post- medical mission)*
- *Biomedical technician report/equipment status log sheets*
- *Equipment maintenance guidelines for biomedical technicians*

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 Context:

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 Global Commitments:

(Minimums which may be surpassed in some contexts)

Operation Smile will ensure the following essential equipment/supplies for the delivery of surgical care:

- 3.1 Sufficient quantities of well-maintained instruments and sutures, with type and quantity appropriate for the planned procedure.
- 3.2 Equipment, medications and environment for providing local anesthesia.
- 3.3 Suction machine.
- 3.4 Electrocautery machine and equipment.
- 3.5 Adequate lighting for illumination of the surgical field.
- 3.6 Equipment for proper sterilization of surgical equipment.

Supporting Policies/Procedures:

Operation Smile continues to review and will develop appropriate policies to support this standard. Specific current policies include:

- *Additional Table*
- *Patients having Surgery under Local Anesthesia*
- *Sterilization*
- *High Level Disinfection*
- *Throat Packs*
- *Donated Used Equipment*
- *Disposal of Sharps*
- *Medical Waste Management*

Supporting Evaluation Practices/Documentation:

Operation Smile continues to develop and review prospective and retrospective data collection and analysis approaches for this standard. Specifically evaluation of preoperative screening and assessment are addressed in:

- *Fact-finding Checklist (pre- medical mission)*
- *Quality Assurance Outcome Objectives (post- medical mission)*

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 Context:

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 Global Commitments:

(Minimums which may be surpassed in some contexts)

Operation Smile will ensure the following essential equipment/supplies/services for the delivery of post anesthesia care:

- 4.1 To support the medical mission:
 - 4.1.1 PACU space and beds should be of a suitable number to support the medical mission.
 - 4.1.2 All Anesthesia equipment and medications specified in Standard #2 (with the exception of 2.1, 2.7 and 2.14), should be available for patients in the PACU.
 - 4.1.3 A device or laboratory will be available to measure glucose levels.
 - 4.1.4 Resuscitation medications of appropriate doses with available code sheet.
- 4.2 Every patient admitted to the PACU will have vital signs monitored.
 - 4.2.1 To include blood pressure, heart rate, oxygen saturation, respiratory rate and temperature.
 - 4.2.2 A device to record an electrocardiogram will be available.
- 4.3 Suction equipment, oxygen, and pulse oximeter monitor at each bedside.
- 4.4 A respiratory oxygen delivery system will be available for use in the transport from the operating room to the PACU when medically indicated.
- 4.5 Transportation of patients from the PACU to an intensive care facility must be available in a timely manner.

Supporting Policies/Procedures:

Operation Smile continues to review and will develop appropriate policies to support this standard. Specific current policies include:

- *Blood Supply*
- *Oxygen Reserve*
- *Throat Packs*
- *Pediatric Medication Guidelines*
- *Difficult Airway Box*
- *Disposal of Sharps*
- *Medical Waste Management*
- *Administration of antibiotics for all patients*

Supporting Evaluation Practices/Documentation:

Operation Smile continues to develop and review prospective and retrospective data collection and analysis approaches for this standard. Specifically evaluation of preoperative screening and assessment are addressed in:

- *Fact-finding Checklist (pre- medical mission)*
- *Quality Assurance Outcome Objectives (post- medical mission)*

STANDARD 5: POSTOPERATIVE INTENSIVE CARE

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 Context:

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

Operation Smile Global Commitments:

(Minimums which may be surpassed in some contexts)

Operation Smile will ensure the following essential equipment/supplies/services are available to properly respond to critical situations:

- 5.1 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 medical mission's hospital facility.
 - 5.1.1 Postoperative intensive care facilities will include electronic monitors for ECG, blood pressure, oxygen saturation, temperature.
 - 5.1.2 A respiratory ventilator will be available for any patient brought to the intensive care facility.
 - 5.1.3 These facilities will be staffed by appropriately trained nurses and doctors.
- 5.2 Whenever an appropriate ICU facility cannot be identified, Operation Smile will have all necessary equipment and personnel available at the medical mission site.

Supporting Policies/Procedures:

Operation Smile continues to review and will develop appropriate policies to support this standard. Specific current policies include:

- *Pediatric Medication Guidelines*
- *Difficult airway box*
- *Blood Supply*
- *Disposal of Sharps*
- *Medical Waste Management*
- *Administration of antibiotics for all patients*

Supporting Evaluation Practices/Documentation:

Operation Smile continues to develop and review prospective and retrospective data collection and analysis approaches for this standard. Specifically evaluation of preoperative screening and assessment are addressed in:

- *Fact-finding Checklist (pre- medical mission)*
- *Quality Assurance Outcome Objectives (post- medical mission)*

STANDARD 6: POSTOPERATIVE 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 Context:

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 Global Commitments:

(Minimums which may be surpassed in some contexts)

Operation Smile will ensure the following essential equipment/supplies/services are available to properly care for patients in the postoperative ward:

- 6.1 Every patient admitted to the postoperative ward will have vital signs monitored to include blood pressure, respiratory rate, heart rate, oxygen saturation and temperature.
- 6.2 An area on the postoperative ward will be designated and equipped for resuscitation including emergency drugs.
- 6.3 Suction equipment and oxygen will be available on the postoperative ward.
- 6.4 24-hour nursing care will be provided on the postoperative ward.
- 6.5 Evidence-based, postoperative care requires ongoing assessment, planning, intervention, evaluation, and documentation.
- 6.6 Postoperative patient education programs will be administered by nursing and delivered in the local language with written instructions using words and pictographs.
- 6.7 Comprehensive discharge instructions will be administered to patients/family, including medications, feeding, etc.
- 6.8 Speech Pathologist will be available for consultation and therapy, as needed.

Supporting Operation Smile policies:

Operation Smile continues to review and will develop appropriate policies to support this standard.

- *Pediatric Medication Guidelines*
- *Difficult airway box*
- *Oxygen Reserve*
- *Administration of antibiotics for all patients*
- *Disposal of Sharps*
- *Medical Waste Management*

Supporting Evaluation Practices/Documentation:

Operation Smile continues to develop and review prospective and retrospective data collection and analysis approaches for this standard. Specifically evaluation of translation services are addressed in:

- *Fact-finding Checklist (pre- medical mission)*
- *Quality Assurance Outcome Objectives (post- medical mission)*

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 Context:

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 Global Commitment:

(Minimums which may be surpassed in some contexts)

Operation Smile will ensure that meaningful informed consent is secured from all patients in its care which will include:

- 7.1 Accurate description of surgery, anesthesia, side effects and complications by attending physician or trained volunteer.
- 7.2 Permission for picture taking for clinical and research purposes.
- 7.3 Consent for administration of blood products as required.
- 7.4 Permission to utilize personal/demographic information to Operation Smile.
- 7.5 Medical record data used in any research conducted by Operation Smile.
- 7.6 HIV /AIDS testing should a needle stick injury occur to one of the health care team.
- 7.7 Use of patient's story or picture for publication.
- 7.8 Culturally relevant materials utilized to provide orientation to the patients and families.

Supporting Policies/Procedures:

Operation Smile continues to review and will develop appropriate policies to support this standard.

- *Operation Smile's Informed Consent Form*
- *Age Minimums and Scheduling*
- *Surgical Priorities*

Supporting Evaluation Practices/Documentation:

Operation Smile continues to develop and review prospective and retrospective data collection and analysis approaches for this standard. Specifically patient consent is addressed in:

- *Fact-finding Checklist (pre- medical mission)*
- *Quality Assurance Outcome Objectives (post- medical mission)*

STANDARD 8: SURGICAL PRIORITY

Global Best Practice:

Organizations offering safe and effective surgical services utilize a structured, transparent framework which analyzes available resources and the expected benefit of the intervention.

Operation Smile Context:

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 Global Commitment:

(Minimums which may be surpassed in some contexts)

Operation Smile will ensure patients are selected for surgery following our Age minimum and Scheduling Policy:

- 8.1 Patients will receive surgery from Operation Smile based on appropriate priority systems.
- 8.2 The priority system was developed to maximize the expected benefit from surgery with consideration to safety and the allocation of time and resources.

Supporting Policies/Procedures:

Operation Smile continues to review and will develop appropriate policies to support this standard.

- *Age Minimums and Scheduling*
- *Surgical Priorities*
- *Surgical Deviation*
- *Patients having surgery under local anesthesia*

Supporting Evaluation Practices/Documentation:

Operation Smile continues to develop and review prospective and retrospective data collection and analysis approaches for this standard. Specifically evaluation of surgical priorities are addressed in:

- *Quality Assurance Outcome Objectives (post- medical mission)*
- *MOC reports*
- *Surgical Outcome Evaluations*
- *Surgical deviation*
- *Age deviation forms*

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 Context:

Operation Smile's field experience drives the need to assure all supplies, equipment and skill base are available to adhere to universal precautions in order to protect patients and volunteers from transmission of blood borne pathogens.

Operation Smile Global Commitments:

(Minimums which may be surpassed in some contexts)

Operation Smile will ensure protocols are followed to limit exposure to blood borne pathogens:

- 9.1 Universal precautions protocols will be followed.
- 9.2 The following strategies should be considered in limiting exposure to blood borne pathogens:
 - 9.2.1 Appropriate handling and disposal of sharps.
 - 9.2.2 Appropriate intervention in needle stick injuries.
 - 9.2.3 When available, the use of needle safe IV systems.

Supporting Policies/Procedures:

Operation Smile continues to review and will develop appropriate policies to support this standard.

- *Blood Supply*
- *Pre-Surgical Blood Transfusion*
- *Blood Borne Contagions and Post-Exposure Prophylaxis*
- *Disposal of Sharps*
- *Medical Waste Management*
- *Team Vaccination*
- *Sterilization*
- *High Level Disinfection*

Supporting Evaluation Practices/Documentation:

Operation Smile continues to develop and review prospective and retrospective data collection and analysis approaches for this standard. Specifically prevention of transmission of blood borne pathogens are addressed in:

- *Volunteer Health Information Sheet (pre- medical mission)*
- *Needle Stick Report (post- medical mission)*

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 Context:

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 Global Commitments:

(Minimums which may be surpassed in some contexts)

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.

10.1 Intra-Operative Pain Management:

10.1.1 Multi modal analgesia will be used for pain relief including local blocks, local infiltration, per-rectal and intravenous titration of appropriate medications.

10.1.2 Morphine will not be used in pediatric cleft lip and palate patients.

10.2 Recovery Room Pain Management:

10.2.1 Analgesia will be maximized with due consideration for a smooth emergence from anesthesia

10.3 Post-Operative Ward Pain Management:

10.3.1. Oral and rectal analgesia will be the preferred routes of administration under the direction of a physician.

10.3.2. Analgesia will be maximized with due consideration for adequate control of procedure related pain through discharge home.

10.4 Non-Pharmacological Pain Management:

10.4.1. 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.

Supporting Policies/Procedures:

Operation Smile continues to review and will develop appropriate policies to support this standard.

- *Pediatric Medication Guidelines*

Supporting Evaluation Practices/Documentation:

Operation Smile continues to develop and review prospective and retrospective data collection and analysis approaches for this standard. Specifically evaluation of surgical priorities are addressed in:

- *Quality Assurance Outcome Objectives (post- medical mission)*
- *Operation Smile's Pharmacopeia*

STANDARD 11: OPERATION SMILE TEAM

Global Best Practice:

Organization offering effective surgical services assign proper personnel ensuring the highest level of care and safety.

Operation Smile Context:

Operation Smile draws more than 5000 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 Global Commitments:

(Minimums which may be surpassed in some contexts)

Operation Smile will offer a multidisciplinary team approach to the care of all patients, providing the highest level of safety and quality. The following roles will be integrated as appropriate to support specific programs:

- 11.1 Program Coordinator
- 11.2 Clinical Coordinator
- 11.3 Cleft Surgeon
- 11.4 Anesthesiologist
- 11.5 Operating Room Nurses
- 11.6 Preoperative/Postoperative Nurses
- 11.7 PACU Nurses
- 11.8 Pediatrician
- 11.9 PACU Physician
- 11.10 Dentist
- 11.11 Medical Records Specialist
- 11.12 Medical Photographer
- 11.13 Biomedical Technician
- 11.14 Speech Pathologist
- 11.15 Certified Child Life Specialist/Psychosocial Care Provider
- 11.16 The team care provided by the team listed above can be further enhanced by the inclusion of the following team members:
 - 11.16.1 Ear, Nose & Throat (ENT) Surgeon
 - 11.16.2 Geneticist
 - 11.16.3 Occupational/ Physical Therapist
 - 11.16.4 Nutrition Specialist
 - 11.16.5 Specialty medical mission core positions may vary
 - 11.16.6 Multiple core competencies may be covered by one individual

Supporting Policies/Procedures:

Operation Smile continues to review and will develop appropriate policies to support this standard.

- *Team Composition*
- *Night Nursing*

Supporting Evaluation Practices/Documentation: None

Operation Smile continues to develop and review prospective and retrospective data collection and analysis approaches for this standard.

- *Team Composition Review*
- *Credentialing Process and Volunteer Approval*
- *Crisis Notification Plan*

STANDARD 12: QUALIFICATIONS FOR 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 Context:

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 opportunities 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 Global Commitments:

(Minimums which may be surpassed in some contexts)

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.

The following items are considered the minimum requirements to participate as a volunteer in an Operation Smile Program:

12.1 Pediatrician

- 12.1.1 Registered in Specialty – achieved highest level of certification available and current professional license in specialty.
- 12.1.2 Graduate of specialty training in pediatrics.
- 12.1.3 Demonstrated clinical competence including current certification of Pediatric Advanced Life Support (PALS) or equivalent course.
- 12.1.4 Currently caring for pediatric patients or has met the requirements according to medical oversight policy.

12.2 Anesthesiologist

- 12.2.1 Registered in Specialty – achieved highest level of certification available and current professional license in specialty.
- 12.2.2 Graduate of specialty training in anesthesia.
- 12.2.3 Demonstrated clinical competence through observed practice. Current certification of:
 - Pediatric Advanced Life Support (PALS) and/or equivalent course is required.
 - Advanced Cardiac Life Support (ACLS) and/or equivalent course is recommended.
- 12.2.3 Recommended for participation in programs by current senior Operation Smile volunteer.
- 12.2.4 Currently caring for pediatric patient or has met the requirements according to medical oversight policy.

12.3 Certified Registered Nurse Anesthetist (CRNAs) and other non-physician providers (limited to certain countries)

- 12.3.1 Registered in Specialty – achieved highest level of certification available.
- 12.3.2 Graduate of specialty training in anesthesia.
- 12.3.3 Demonstrated clinical competence through observed practice. Current certification of
 - Pediatric Advanced Life Support (PALS) and/or equivalent course is required.
 - Advanced Cardiac Life Support (ACLS) and/or equivalent course is recommended.
- 12.3.4 Recommended for participation in programs by current senior Operation Smile volunteer.
- 12.3.5 Currently caring for pediatric patients or has met the requirements according to medical oversight policy.

- 12.4 **Cleft Surgeon**
 - 12.4.1 Registered in a relevant specialty that includes cleft lip and palate surgical training and achieved the highest level of certification available.
 - 12.4.2 Demonstrates current cleft experience and current professional training.
 - 12.4.3 Demonstrated clinical competence.
 - 12.4.4 Recommended for participation in programs by peers.

- 12.5 **Other Surgical Specialties**
 - 12.5.1 Registered in Specialty – achieved highest level of certification available.
 - 12.5.2 Graduate of specialty training in surgery.
 - 12.5.3 Current clinical experience in surgical specialty.
 - 12.5.4 Demonstrated clinical competence.
 - 12.5.5 Recommended for participation in programs by peers.

- 12.6 **Dentist**
 - 12.6.1 Currently licensed and in good standing.
 - 12.6.2 Be competent in treating children in the operating room.
 - 12.6.3 Aware of effects of extraction on the developing occlusion.
 - 12.6.4 Trained/experienced in taking impressions of patients with cleft palate, fabricating and adjustment of obturators.

- 12.7 **Nursing**
 - 12.7.1 Graduate from an accredited nursing school.
 - 12.7.2 Clinical competence.
 - 12.7.3 Basic Life Support (BLS) or equivalent course, with current active license where applicable, required for all medical missions – local and international participation.
 - 12.7.4 PALS will be required of nurses from resource countries who participate on any medical missions.
 - 12.7.5 Eventual attainment of PALS will be required of all nurses.
 - 12.7.6 At least 2 years current experience in their specialty relevant to Operation Smile.

- 12.8 **PACU Physician**
 - 12.8.1 A physician trained and experienced in pediatric perioperative care, pain management, the recognition of postoperative complications and cardiopulmonary resuscitation.
 - 12.8.2 PALS certification or its equivalent is required.

- 12.9 **Speech Pathologist**
 - 12.9.1 Hold a degree and licensure in Speech Language Pathology or its equivalent certification within a country.
 - 12.9.2 Clinically competent in cleft lip and palates and other craniofacial syndromes.
 - 12.9.3 Ability to educate counterparts.
 - 12.9.4 Recommended by senior Operation Smile volunteer.

- 12.10 **Child Life Specialist /Psychosocial Care Provider**
 - 12.10.1 Hold a degree in child life, child development, psychology or closely related field; and hold certification in child life or an equivalent disciplinary credential.
 - 12.10.2 Clinically competent in provision of developmentally appropriate therapeutic interventions based on stress vulnerability assessment, teaching, emotional support and the provision of patient and family centered care.
 - 12.10.3 Ability to educate counterparts about psychosocial care.

- 12.11 **Physical or Occupational Therapist**
 - 12.11.1 Hold a degree and licensure in Physical or Occupational Therapy or its equivalent certification within a country.
 - 12.11.2 Clinically competent in the area of the specialty medical mission.
 - 12.11.3 Ability to educate in-country personnel.
 - 12.11.4 Recommended by senior Operation Smile volunteer.

Supporting Policies/Procedures:

Operation Smile continues to review and will develop appropriate policies to support this standard.

- *Discipline and Dismissal*
- *Team Vaccination*

Supporting Evaluation Practices/Documentation: None

Operation Smile continues to develop and review prospective and retrospective data collection and analysis approaches for this standard.

- *Volunteer Evaluations*
- *Team Leader Reports*
- *Volunteer Orientation*

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 Context:

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 Global Commitments:

(Minimums which may be surpassed in some contexts)

Operation Smile will offer ongoing care through its network of global volunteers to all patients returning during the established follow up periods.

- 13.1 Effective postoperative care is essential for good surgical results and effective planning for further treatment.
- 13.2 Postoperative care requires good documentation and extensive education of parents and clinicians to be effective.
- 13.3 Postoperative care from an Operation Smile organized team should review patients at the following intervals:
 - 13.1.1. **One week after surgery (4 – 7 days post-op).** The goal is to recognize and manage immediate surgical results and complications.
 - 13.1.2. **Six months – 1 year.** Team evaluation for documenting outcomes of surgeries and planning for future treatment.

Supporting Policies/Procedures:

Operation Smile continues to review and will develop appropriate policies to support this standard.

Supporting Evaluation Practices/Documentation:

Operation Smile continues to develop and review prospective and retrospective data collection and analysis approaches for this standard.

- *Patient Care Booklet*
- *Post-Operative forms*
- *MOC Report*
- *Surgical Outcome Review*

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.

Operation Smile Context:

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 Global Commitments:

(Minimums which may be surpassed in some contexts)

- 14.1 Operation Smile medical missions will provide qualified interpreters to ensure proper communication amongst team members, patients and families.
- 14.2 Operation Smile will provide orientation for interpreters and training for team members to effectively use interpreters.
- 14.3 Operation Smile will place interpreters with the most skill in critical areas.

Supporting Policies/Procedures:

Operation Smile continues to review and will develop appropriate policies to support this standard.

Supporting Evaluation Practices/Documentation:

Operation Smile continues to develop and review prospective and retrospective data collection and analysis approaches for this standard. Specifically evaluation of translation services are addressed in:

- *Fact-finding Checklist (pre- medical mission)*
- *Quality Assurance Outcome Objectives (post- medical mission)*

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 Context:

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 medical 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 Global Commitments:

(Minimums which may be surpassed in some contexts)

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.

15.1 Adequate Medical Records.

- 15.1.1 Demographic detail must be recorded; with special care to clarify family name, given name, and unique Operation Smile identifier.
- 15.1.2 Patient/family history.
- 15.1.3 Physical examination.
- 15.1.4 Medical/surgical diagnosis.
- 15.1.5 Operation Intended/Operation Performed (must have a prominent place)
- 15.1.6 Documentation of care through the entire clinical pathway (Screening, Pre-Op, OR, Anesthetic record, Photographic documentation, PACU, Post-op, Discharge).
- 15.1.7 All team members are responsible for documentation.
- 15.1.8 Operation Smile will work to ensure that documentation will be available to caregivers.
- 15.1.9 Management of documentation will respect patient confidentiality.

Supporting Policies/Procedures:

Operation Smile continues to review and will develop appropriate policies to support this standard.

Supporting Evaluation Practices/Documentation:

Operation Smile continues to develop and review prospective and retrospective data collection and analysis approaches for this standard.

STANDARD 16: HOSPITAL FACILITY

Global Best Practice:

Organizations offering effective surgical interventions assure an environment which meets world class minimums on proper personnel, access to supplies, equipment, infection control and supporting infrastructure.

Operation Smile Context:

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- medical 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 Global Commitments:

(Minimums which may be surpassed in some contexts)

Operation Smile is committed to conducting a pre- medical mission site visit is required to insure adequacy of the hospital facility to support the planned medical mission, including presence of the following:

- 16.1 Adequate physical space for screening, operating rooms, post anesthesia care unit, preoperative and postoperative care.
- 16.2 Infrastructure able to support the planned medical mission.
- 16.3 Basic clinical laboratory and x-ray to support the planned medical mission.
- 16.4 Blood bank or means to provide blood supply adequate for the planned medical mission.

Supporting Policies/Procedures:

Operation Smile continues to review and will develop appropriate policies to support this standard.

- *Blood Supply*
- *Difficult Airway Box*
- *Additional table*
- *Blood Supply*
- *Disposal of Sharps*
- *Medical Waste Management*
- *Oxygen Reserve*
- *Sterilization*
- *High Level Disinfection*

Supporting Evaluation Practices/Documentation:

Operation Smile continues to develop and review prospective and retrospective data collection and analysis approaches for this standard.

- *Fact Finding Checklist*
- *Biomed Report*

STANDARD 17: QUALITY ASSURANCE

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 Context:

Operation Smile's experience 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 Global Commitments:

(Minimums which may be surpassed in some contexts)

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:

- 17.1 Collection of quality improvement data, including standard quality indicators, adverse events, monitor performance and identify areas needing improvement.
- 17.2 Evaluation of adverse events identified as "critical events" to determine causes and prevention.
- 17.3 Performance of quality improvement projects to address items identified in Standard 17.1 and 17.2.
- 17.4 Interfacing with organizational leaders to develop guidelines and policies that address items identified in Standard 17.1 and 17.2.
- 17.5 Interfacing with Credentialing Coordinator to insure providers meet qualifications outlined in Standard 12.

Supporting Policies/Procedures:

Operation Smile continues to review and will develop appropriate policies to support this standard.

- *Incident Reporting*
- *Surgical Safety Checklist*

Supporting Evaluation Practices/Documentation:

Operation Smile continues to develop and review prospective and retrospective data collection and analysis approaches for this standard.

- *Quality Assurance Audit Checklist*
- *Team Leader Reports*
- *MOC Reports*
- *Crisis Notification Plan*
- *Morbidity & Mortality Procedure*