Operation Smile is committed to providing safe, high quality and timely care for patients and their families in resource limited settings. Operation Smile’s Global Standards of Care, policies and practices are a compilation of years of experience, knowledge and expertise of our global medical leaders and volunteers. The content in this resource manual speaks of a commitment and pledge to serve with the highest degree of preparedness and integrity. It is our promise of hope and humane care to our patients, whose simple and unquestionable right to live with dignity fuels our endless desire to come together and act as one.
# TABLE OF CONTENTS

## PATIENT RIGHTS AND RESPONSIBILITIES

4

## OPERATION SMILE GLOBAL STANDARDS

8

STANDARD 1: PREOPERATIVE PATIENT SCREENING & ASSESSMENT 10
STANDARD 2: ANESTHESIA EQUIPMENT AND SUPPLIES 11
STANDARD 3: SURGICAL EQUIPMENT 13
STANDARD 4: POST ANESTHESIA CARE UNIT (PACU) 14
STANDARD 5: POSTOPERATIVE INTENSIVE CARE 15
STANDARD 6: POSTOPERATIVE WARD 16
STANDARD 7: PATIENT CONSENT 17
STANDARD 8: SURGICAL PRIORITY 18
STANDARD 9: PREVENTING TRANSMISSION OF BLOOD BORNE PATHOGENS 19
STANDARD 10: PAIN MANAGEMENT 20
STANDARD 11: OPERATION SMILE TEAM 21
STANDARD 12: QUALIFICATIONS FOR VOLUNTEERS 22
STANDARD 13: PATIENT FOLLOW-UP 25
STANDARD 14: TRANSLATION 26
STANDARD 15: DOCUMENTATION 27
STANDARD 16: HOSPITAL FACILITY 28
STANDARD 17: QUALITY ASSURANCE 29

## POLICIES AND PROCEDURES

30

1. MEDICAL RESOURCES AND SUPPLIES 31

BLOOD SUPPLY 32
PRE-SURGICAL BLOOD TRANSFUSION 33
CLINICAL PATHWAY FOR ADMINISTRATION OF BLOOD PRODUCTS 34
BLOOD BORNE EXPOSURE 36
PEP FOLLOWING OCCUPATIONAL EXPOSURE 38
OXYGEN RESERVE 40
EMERGENCY PREPAREDNESS 41
MEDICAL CRISIS NOTIFICATION PLAN 42
NON-MEDICAL CRISIS NOTIFICATION PLAN 43
PATIENT CODE SHEET 45
DIFFICULT AIRWAY MANAGEMENT 46
MEDICATION ADMINISTRATION 47
MEDICAL WASTE MANAGEMENT 49
2. CLEFT LIP AND PALATE MISSION

TEAM COMPOSITION
ADDITIONAL TABLE POLICY
ADDITIONAL TABLE – LOCAL ANESTHESIA FORM
ADDITIONAL TABLE – GENERAL ANESTHESIA FORM
SURGICAL PRIORITIES
SURGICAL DEVIATION
SURGICAL DEVIATION FORM
AGE MINIMUMS & SURGICAL SCHEDULING
AGE DEVIATION FORM

3. SCREENING

PATIENT INFORM CONSENT
PATIENT SURGICAL CONSENT

4. INTRA-OPERATIVE

SURGICAL SAFETY CHECKLIST
SURGICAL SAFETY CHECKLIST FORM
THROAT PACK
SURGICAL SITE INFECTION PREVENTION
STERILIZATION
GUIDELINES FOR STERILIZATION
DISPOSAL OF SHARPS
MONITORING, DURING ANESTHESIA

5. POST-OP

NIGHT NURSING

6. VOLUNTEER SAFETY AND PREPAREDNESS

VOLUNTEER VACCINATIONS
CREATING AND DISSEMINATING NEW MEDICAL POLICIES

7. QUALITY ASSURANCE

INCIDENT REPORTING
INCIDENT REPORTING FORM
CODE ARREST FLOW SHEET
PATIENT RIGHTS AND RESPONSIBILITIES
OPERATION SMILE
Rights and Responsibilities

Operation Smile has, through a consensus of its preeminent medical experts from around the world, set forth the following charter of patient rights and responsibilities. It is the intention of Operation Smile to adhere to this charter in order to provide patients with the best possible care by both acknowledging and respecting those patients’ basic rights.

The charter is divided into two sections. The first section outlines the rights that every patient holds. The second section outlines the responsibilities that each patient holds. Together, these sections form the basis for what every patient can expect from any given treatment event held by Operation Smile, regardless of the size, location or organizer of the event.

Charter of Patient
Patient Rights

All patients treated by Operation Smile are to be afforded rights as described below. These rights and responsibilities constitute a Charter of Patients’ Rights and Responsibilities and should be adhered to with respect to any and all medical care provided by Operation Smile and its volunteers and staff. The patient is not necessarily limited to the rights described below.

General rights include:
• The right to:
  o Justice
  o Equality
  o Beneficence
  o Non-malfeasance
• The right to be treated with both dignity and respect
• The right to have the opportunity to be treated without any restrictions regarding the conditions of the institution
• The right to religious beliefs respected
• The right to freedom from discrimination
• The right to quality healthcare regardless of race, creed, age, sex, or nationality
• The right to quality medical and surgical care by qualified healthcare providers
• The right to a high standard of healthcare
• The right to full consideration to respect of privacy concerning any medical care program
• The right to be informed in her or his original language
• The right to have an interpreter/translator should one be necessary
• The right to free treatment
• The right to know about Operation Smile, its commitment to safety, and of this charter
• The right to respect and make decisions with the patient’s psychological well-being in mind
• The right to love
• The right to understanding
Charter of Patient
Patient Rights (cont.)

Pre-treatment medical rights include:
- The right to treatment that gives due respect to both function and aesthetics
- The right to know and understand the projected treatment plan, from pre-treatment through the medical care event, and post-operative care
- The right to be informed of treatment to be rendered with regards to the risks and benefits of said treatment
- The right to participation in decision making during education and counseling
- The right to consent to or refuse of treatment
- The right to be informed about alternative treatments
- The right to discuss expectations with physician(s) providing care
- The right to know persons managing and providing her or his treatment
- The right to be educated about patient’s rights regarding privacy and confidentiality
- The right to receive education and counseling regarding his or her diagnosis, including:
  - The right to be educated about access to his or her medical records
  - The right to be educated about potential outcomes of care
  - The right to be educated about possible limitations of the plan of care
  - The right to be educated about possible side effects or complications as a result of the plan of care
- The right to access medical records
- The right to information regarding any costs/fees that are not provided by Operation Smile

Treatment rights include:
- The right to have good conditions for all medical care, including surgery and post-operative care. (i.e. surgeon, medical equipment)
- The right to a safe surgical environment
- The right to guarantee medical care regardless of participation in research or photography
- The right to receive treatment for both pain relief and psychological distress
- The right to have trained and compassionate health providers

Post-operative rights include:
- The right to access follow-up care with all specialties that make up a standard cleft team (as defined by Operation Smile), including but not limited to:
  - Speech pathologist
  - Orthodontist
Patient Responsibilities

With the granting of any rights comes the need to also outline responsibilities, so that Operation Smile may fulfill their obligation to honor patient rights. Should the patient be a minor or otherwise incapable of fulfilling these responsibilities, the responsibility then falls to the parent, guardian, or other patient representative. The patient’s responsibilities are outlined below.

- The patient must be honest about medical history during screening, hospitalization and post-operative care, including disclosures about allergies, pre-existing conditions, etc.
- The patient must provide accurate contact information
- The patient must understand the nature of his/her condition, and ask for clarification about anything that is not understood, beginning at screening and continuing through treatment and post-operative care
- The patient must follow medical instructions
- The patient must attempt to be punctual for all care events, before, during and after primary treatment
- The patient must respect the rules of Operation Smile and its medical care teams
- The patient must respect other patients
- The patient must respect the medical care site and its rules, regulations and requirements
- The patient must respect medical and non-medical staff of the care event
- The patient must report any significant changes in the symptoms
- Any representative of the patient must accurately disseminate information to the potential patient
- The patient must be responsible for adhering to her or his follow-up care plan
- The patient must obey medical rules that were explained to him or her before, during and after treatment
- The patient must follow medical orders to the best of his or her ability
- The patient must make concerns known at each step of treatment
- The patient must prepare mentally and physically for surgery
- The patient must take full responsibility for right of refusal
OPERATION SMILE GLOBAL STANDARDS
GLOBAL STANDARDS OF CARE

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 (see Appendix A).

- **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 Smiles 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 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 mission goals.
1.8 Personnel and an orderly system to perform postoperative evaluations on Operation Smile returning patients.

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

- Blood Supply
- Pre-Surgical Blood Transfusion
- Age Minimums and Surgical Scheduling
- Surgical Priorities
- Age Deviation
- 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-mission)
- Quality Assurance Outcome Objectives (post-mission)
- Age Deviation Form
- Surgical Deviation Form
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.
   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 is the only acceptable anesthetic gas.
2.15 Dantrolene in sufficient quantity to treat malignant hyperthermia.
STANDARD 2: ANESTHESIA EQUIPMENT AND SUPPLIES (cont.)

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 Operation Smile policies:
Operation Smile continues to review and will develop appropriate policies to support this standard. Specific current policies include:
- Additional Table
- Additional Table – Local Anesthesia Form
- Additional Table – General Anesthesia Form
- Oxygen Reserve
- Monitoring During Anesthesia
- Blood Supply
- Difficult Airway Box
- Pre-Surgical Blood Transfusion
- Disposal of Sharps
- Medical Waste Management
- Medication Administration
- Surgical Site Infection Prevention
- Sterilization
- Guidelines for Sterilization
- Throat Pack
- 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-mission)
- Quality Assurance Outcome Objectives (post-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 Operation Smile policies:**
Operation Smile continues to review and will develop appropriate policies to support this standard. Specific current policies include:

- Additional Table
- Surgical Site Infection Prevention
- Sterilization
- Guidelines for Sterilization
- Throat Pack
- 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-mission)
- Quality Assurance Outcome Objectives (post-mission)
- Additional Table – Local Anesthesia Form
- Additional Table – Local Anesthesia Form
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 surgical mission:
   4.1.1 PACU space and beds should be of a suitable number to support the surgical 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 Operation Smile policies:
Operation Smile continues to review and will develop appropriate policies to support this standard. Specific current policies include:

- Blood Supply
- Oxygen Reserve
- Throat Pack
- Medication Administration
- Difficult Airway Box
- 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-mission)
- Quality Assurance Outcome Objectives (post-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 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 mission site.

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

- Medication Administration
- Difficult Airway Box
- Blood Supply
- 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-mission)
- Quality Assurance Outcome Objectives (post-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.

- Medication Administration
- Difficult Airway Box
- Oxygen Reserve
- 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-mission)
- Quality Assurance Outcome Objectives (post-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 Operation Smile policies/documentation:
Operation Smile continues to review and will develop appropriate policies to support this standard.

- Age Minimums and Surgical Scheduling
- Surgical Priorities
- Age Deviation
- 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 patient consent is addressed in:

- Fact-finding Checklist (pre-mission)
- Quality Assurance Outcome Objectives (post-mission)
- Patient Inform Consent Form
- Patient Surgical Consent Form
- Age Deviation Form
- Surgical Deviation Form
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 Operation Smile policies/documentation:
Operation Smile continues to review and will develop appropriate policies to support this standard.
- Age Minimums and Surgical 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 evaluation of surgical priorities are addressed in:
- Quality Assurance Outcome Objectives (post-mission)
- MOC reports
- Surgical Outcome Evaluations
- Surgical Deviation Form
- Age Deviation Form
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 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-mission)
- Needle Stick Report (post-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-OP 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 Operation Smile new and current policies:
Operation Smile continues to review and will develop appropriate policies to support this standard.

- Medication Administration

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-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:  
   11.16.1.1 Ear, Nose & Throat (ENT) Surgeon  
   11.16.1.2 Geneticist  
   11.16.1.3 Occupational/ Physical Therapist  
   11.16.1.4 Nutrition Specialist  
   11.16.1.5 Specialty mission core positions may vary  
   11.16.1.6 Multiple core competencies may be covered by one individual

**Supporting Operation Smile new and current policies:**
*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 ensure 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 **Anesthesiologists**
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.
12.2.4 Recommended for participation in programs by current senior Operation Smile volunteer.
12.2.5 Currently caring for pediatric patient or has met the requirements according to medical oversight policy.

12.3 **Certified Registered Nurse Anesthetist (CRNA’s) 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 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.
STANDARD 12: QUALIFICATIONS FOR VOLUNTEERS

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 missions – local and international participation.
12.7.4 PALS will be required of nurses from resource countries who participate on any 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.
STANDARD 12: QUALIFICATIONS FOR VOLUNTEERS

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 mission.
12.11.3 Ability to educate in-country personnel.
12.11.4 Recommended by senior Operation Smile volunteer.

Supporting Operation Smile policies:
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 Operation Smile policies:
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 Form
- 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 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 Operation Smile policies:
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-mission)
- Quality Assurance Outcome Objectives (post-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 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 Operation Smile policies:
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-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-mission site visit is required to insure adequacy of the hospital facility to support the planned 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 mission.
16.3 Basic clinical laboratory and x-ray to support the planned mission.
16.4 Blood bank or means to provide blood supply adequate for the planned mission.

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

- Blood Supply
- Difficult Airway Box
- Additional Table
- Disposal Of Sharps
- Medical Waste Management
- Oxygen Reserve
- Surgical Site Infection
- Sterilization
- Guidelines for Sterilization

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
- Additional Table – Local Anesthesia Form
- Additional Table – General Anesthesia Form
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 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 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 Operation Smile policies:
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
OPERATION SMILE POLICIES & PROCEDURES
1. Medical Resources and Supplies
I. POLICY:
   A. An emergency supply of blood must be immediately available at all times during the mission.

II. PROCEDURE:
   A. Prior to the start of surgery, the Clinical Coordinator (CC) and Anesthesia Team Leader (ANTL) will visually confirm that the required minimum blood supply is on hand or easily accessible.
   B. The CC will notify the Program Coordinator (PC) of any incident during which the blood supply drops below the required level. The PC will coordinate with the hospital for additional blood products.

III. REQUIREMENTS:
   A. Two (2) units of O negative blood will be available upon request.
   B. If O negative is not available in the area, two (2) units of O positive blood will serve as the required minimum.

IV. SUPPORTING DOCUMENTS:
   A. Fact Find Form
II. POLICY:
   A. Mission environments are likely to include patients presenting with low hematocrit (Hct) and/or hemoglobin (Hgb) levels for a variety of medical reasons. The Team Leaders (TL) should take this into consideration when determining which patients should receive surgical treatment.

   B. Pre-surgical transfusion is NOT to be given in order to improve a patient’s condition for standard mission surgery.

   C. Transfusion is reserved for urgent/emergent needs.

   D. Patients with low Hct and Hgb should be referred to in-country resources for treatment.

III. SUPPORTING DOCUMENTS:
   A. Clinical Pathway for Administration of Blood Products
CLINICAL PATHWAY FOR ADMINISTRATION OF BLOOD PRODUCTS

I. PURPOSE:
   A. The clinical pathway of blood administration is a multidisciplinary guide that assists clinicians to manage patients receiving blood/blood products. The purpose is to improve continuity and coordination of care across varied disciplines and specialties involved in patient care.

II. CLINICAL PATHWAY:
   A. Pre-Mission Fact Find:
      1. Establish availability of onsite blood products (2 units of O negative blood)
      2. In the absence of blood supply onsite, initiate plan for the transport of blood to the site for the mission.
   B. Pre Mission Team Leader Call:
      1. Inform Team Leaders of blood availability as determined through the fact find information.
      2. Review the plan for transporting blood if the need arises.
   C. Screening:
      1. Team Leaders determine the plan for obtaining Type and Screen during the screening process.
      2. The Clinical Coordinator (CC) and Anesthesia Team Leader (ATL) visually verify the blood supply that is available prior to the start of surgery week.
      3. Storage of blood should be between the ranges of 1-6°C.
   D. Surgery:
      1. If the need to transfuse blood arises, the CC or designee will obtain the blood from the blood bank.
      2. Blood tubing will be brought to the bedside.
      3. The blood label will be checked by two medical provider for content accuracy and expiration date.
      4. Establish condition of existing IV or start another as directed by physician.
   E. Infusion should be started within 15 minutes of retrieval from blood bank and completed within four (4) hours. A medical provider should visually monitor the patient for the first 15 minutes of the transfusion for any adverse reaction.
      1. Document the following:
         a. Time infusion started, baseline vital signs including temperature
         b. Vital signs will be repeated and documented every 15 minutes X 4, then every 30 minutes X2, and every hour until infusion is complete.
         c. Any signs of adverse reaction, time infusion completed, vital signs at the completion of the infusion.
      2. Blood administration can be documented on the anesthesia record or on additional documentation form.
3. Determine the need for additional follow up labs (type and cross, hematocrit, hemoglobin or coagulation studies).

4. At the completion of infusion, dispose of transfusion bag in a biohazard bag.
   a. Keep the blood label with the chart.
   b. If the blood was not used, return it to the blood bank as soon as possible.

F. Documentation
   1. Utilize existing forms from each unit. Deleted
BLOOD BORNE EXPOSURE

I. POLICY:
   A. Operation Smile (OS) is committed to providing a safe delete environment for all volunteers participating on OS missions.

   B. OS has Blood Borne Exposure prophylaxis protocols available to all participating volunteers while in the field and/or on a mission.

   C. The designated team physician is equipped with a post exposure prophylaxis (PEP) kit.

II. PROTOCOL:
   A. POST EXPOSURE PROPHYLAXIS GUIDELINES FOR HIV/AIDS:

      1. If the volunteer elects for treatment, it will begin with the use of the PEP kit sent from OS. Treatment should begin as soon as possible after the exposure.

      2. Blood samples must be processed in one of two ways:
         a. If reliable testing is available on site, or in the host country, proceed at the local hospital or the nearest local facility.
         b. If in-country testing is not available, the individual shall work with OS to transport blood samples as expeditiously as possible to the closest testing site or the volunteer’s home country.
         c. The exposed individual opting for treatment will begin the approved medications as directed.
         d. The exposed individual opting for treatment must return to their home country immediately to continue care from physicians.

      3. A Rapid HIV kit has been made available in the PEP kit to provide a rapid screening if lab draw and results will be delayed.

      4. A volunteer has the right to refuse testing and treatment and will sign and date the BBP treatment/refusal form.
         a. The volunteer will be offered the right to return home within 3 days of exposure for continued evaluation and treatment by personal health care provider.

      5. The Regional Medical Officer (RMO) and OS Headquarters Medical Officers to include the Chief Medical Officer (CMO), Associate Chief Medical Officer (ACMO) and Senior VP of Medical Affairs should be contacted as soon as possible.
BLOOD BORNE EXPOSURE (cont.)

B. POST EXPOSURE PROPHYLAXIS KIT (PEP)

1. To include three (3) sets of the following:
   a. One copy of “Blood Borne Exposure” policy
   b. Rapid HIV test kit
   c. Three (3) 2 ml red top collection tubes – two for the Operation Smile volunteer and one for the patient
   d. Raltegravir (Isentress: RAL) 400 mg PO BID X 1 week
   e. Truvada - a fixed dose combination tablet 1 tablet PO QD
   f. Two (2) 21 gauge – vacutainer push button venous blood collection set with pre-attached holder
   g. Tourniquet
   h. Alcohol prep (1 box)
   i. Gloves – size 7, 7-1/2
   j. Band-Aids (1 box)

2. Blood samples need to be labeled with:
   a. Patient/Health care provider name
   b. Identification number
      • Volunteer’s social security number (or identification number)
      • Operation Smile (OS) chart number of the OS patient.
   c. Date/Time of sample collection

3. The following tests will be selected on the lab requisition forms:
   a. Patient – Hepatitis C, Hepatitis B, HIV
   b. Volunteer – Hepatitis C, Hepatitis B, HIV

4. Recommended follow-up testing for antibodies against HIV should be drawn at 4 weeks, 3 months and 6 months after exposure by volunteer’s personal medical practitioner.

5. The following medication dosages should be taken for 4 weeks post-exposure:
   a. Raltegravir (Isentress: RAL) 400 mg PO, BID plus
   b. Truvada (a fixed dose combination tablet) x1, PO, QD
      • Truvada = (Tenofovir DF [Viread; TDF] 300mg + Emtricitabine [Emtriva; FTC] 200

III. SUPPORTING DOCUMENTS:
   A. PEP Following Occupational Exposure
   B. Supporting Evidence
PEP Following Occupational Exposure

Offer exposed worker first dose of PEP while evaluation of exposure is underway.

Source patient HIV STATUS UNKNOWN

Obtain consent for rapid HIV testing of source patient

Source tests NEGATIVE

Has the source patient been at risk for HIV exposure in previous 6 weeks?*

YES

Obtain HIV RNA assay from source patient; continue PEP until results are available.

HIV RNA NEGATIVE

STOP PEP

Source tests POSITIVE

STOP PEP. PEP not indicated.

Source patient does not have capacity to consent

Source patient refuses HIV testing

COMPLETE 28-DAY REGIMEN:
Recommended PEP Regimen

Tenofovir 300 mg PO qd
+ Emtricitabine\textsuperscript{a} 200 mg PO qd

PLUS

Raltegravir 400 mg PO bid

■ Perform baseline confidential HIV testing of the exposed worker and refer to experienced clinician within 3 days of initiating PEP.
SUPPORTING EVIDENCE

A. **HIV** – the overall rate of HIV transmission through percutaneous inoculation (i.e. by means of needle or other instrument piercing the skin), is widely reported to be 0.3%. Splashes of infectious material to mucous membranes (e.g. conjunctivae or oral mucosa) or broken skin also may transmit HIV infection (estimated risk per exposure, 0.09%).

1. The decision whether or not to pursue treatment is entirely left to the exposed health care provider.
2. It is important to remember that all studies indicate the medical prophylaxis should be sought as soon as possible (ideally within 2 hours) after exposure to HIV.
3. Although PEP is not a guaranteed prevention, studies indicate that an 80% decreased HIV seroconversion rate is possible if PEP is administered rapidly.
4. Prophylaxis should be reserved for exposures that are associated with a credible possibility of HIV transmission, or a source patient whose serologic status is unknown but who is at high risk for HIV infection.
5. If medical prophylaxis is sought by the volunteer, OS strongly recommends that the volunteer return to his/her country of residence for medical supervision.

B. **Hepatitis B** – both an immune gamma globulin and a recombinant vaccine are available for Hepatitis B prophylaxis, thereby nearly eliminating the contagious potential of hepatitis B.

1. Although post exposure prophylaxis is possible with immune gamma globulin, OS insists on all volunteers undergoing appropriate prophylaxis against hepatitis B prior to potential exposure.
2. No immune gamma globulin for hepatitis B is available in the PEP kit. Therefore all volunteers must either receive hepatitis B immune gamma globulin prior to the mission or undergo therapy with the recombinant vaccine.
3. In persons who have been exposed recently (within 1 week) to an hepatitis B surface antigen (HBsAg) positive source patient and who are negative for hepatitis B surface antibody, treatment with immune globulin for HBV infection should be considered.

C. **Hepatitis C** - No prophylaxis currently exists for hepatitis C. Therefore OS urges all volunteers to follow universal precautions.

IV. REFERENCE:


B. Updated US Public Health Service Guidelines for the Management of Occupational Exposures to Human Immunodeficiency Virus and Recommendations for Post exposure Prophylaxis Infection Control and Hospital Epidemiology September 2013, Volume 34, Number 9

OXYGEN RESERVE

I. POLICY:
   A. A reserve oxygen supply must be available for the entire duration of the Operation Smile mission.
      1. 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.
      2. The required reserve oxygen supply for a recovery bed or Postoperative ward is defined as at least an E-cylinder (approximately 650 liters) of medical grade oxygen.

II. PROCEDURE:
   A. The Program Coordinator (PC) and Anesthesia Team Leader (ANTL) are to confirm that primary and reserve oxygen are available in the hospital prior to the start of surgery.
   B. The ANTL is responsible for identifying satisfactory supply levels.
   C. Biomedical Technicians confirm that flow regulators, adapters for all oxygen sources, and reserve supplies are present during surgery.
   D. The PC and ANTL will ensure availability of suitable portable oxygen tanks for patient transport.
   E. The ANTL will confirm prior to the start of any surgery day that an adequate oxygen supply is in place for each operating table:
      1. In certain cases, an E-cylinder oxygen tank is shared between two operating tables with a T-connector.
      2. A reserve supply, an average one oxygen tank per 2 – 3 beds, must also be available in the Patient Acute Care Unit (PACU).
      3. A reserve supply of oxygen must also be available close to the observation bed in each Postoperative area.
   F. The PC activates the Crisis Notification plan whenever the reserve oxygen supply is utilized or becomes unavailable as a “Non-Critical Medical Incident”.

III. SUPPORTING DOCUMENTS:
   Crisis Notification Plan
   Fact Find Form
EMERGENCY PREPAREDNESS

I. POLICY:
   A. To ensure that all team members are familiar with how to manage any patient or hospital emergency situation within the mission setting.

II. PROCEDURE:
   A. After prior discussion with all Team Leaders (TL), the Patient Acute Care Unit (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 to participate in a procedural review.
      1. The brief review should include all OR and PACU staff.
      2. Translators should be available for any need of interpretation.
         The review must be performed immediately prior to bringing the first patient to the OR on the first day of surgery.
      3. The Pediatrician will have a parallel review in the Postop area with Post op team members to include Pre and Postop staff, Medical Records, Speech, Dental and Child Life
   B. The review should include:
      1. Who will lead the code, notify others, designate roles and ultimately be responsible?
         a. Who will notify the family?
      2. The location of emergency equipment to include:
         a. Ambu bag, crash box (with emergency medications and equipment), oxygen, suction and defibrillator.
            i. This should include how to open the crash box, internal organization of the box and how to use the defibrillator.
      3. Familiarizing everyone with the pre-printed "Patient Code Sheet" in the Operation Smile patient’s chart.
      4. Discuss the procedure for patient emergencies outside the OR area, such as in the Pre and Postop wards and other patient areas.
         a. 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.
         b. Use of the hospital’s emergency room, as a back-up if necessary.
      5. Response to the likelihood of potential threats and hospital infrastructure failure (water, electricity, oxygen, central suction).

III. SUPPORTING DOCUMENTS:
   A. Patient Code Sheet
   B. Crisis Notification
MEDICAL CRISIS NOTIFICATION PLAN

Crisis Notification Plan
Updated May 2015

YES

Incident Managed by Team:
- FMD, PSTL, ANTL, CC, PACU Physician

Green Incidents

Incident Report completed by PC & Team

Program Coordinator Notification of Incident:
1. Medical Director
2. Regional Medical Officer
3. Associate Chief Medical Officer (Richard Berlin, Richard.Berlin@operationsmile.org, (c): 305-440-9944)
4. Sr. Director of Quality Assurance (Cindi Raglin, craglin@operationsmile.org, (c): 757-491-9055)

**Refer to Incident Reporting Policy**
6. AVP of Intl Programs (Meredith Donegan, mdonegan@operationsmile.org, (c): 757-806-9558/fo: 757-321-3277)

Amber/Red Medical Incidents
Program Coordinator (PC) Notes & Sends:
Patient’s Name & Age, Procedure, Description of Incident

OS Headquarters
Foundation

EVENT OCCURS

MEDICAL INCIDENT?

Program Coordinator (PC) Files an Incident Report with:
- Country Executive Director
- Regional Office
- AVP of IP (Meredith Donegan, mdonegan@operationsmile.org, (c): 757-806-9558)

AVP, IP

NO

Incident Report & medical record sent to:
1. Regional Medical Officer
2. Sr. Director of Quality Assurance (Cindi Raglin, craglin@operationsmile.org)
3. Kelly Roenker

Notification of Incident to:
1. Local Executive Director
2. HQ Regional Office
3. Foundation Manager
4. National Board Chairman

Associate CMO

Notifies:
- OS CEO (Bill Magee, bmagee@operationsmile.org, (c): 757-377-4777)
- OS COO (Wayne Zinn, wayne.zinn@operationsmile.org, (c): 757-401-0789)
- SVP of Medical Affairs (Ruben Ayala, rayala@operationsmile.org, (c): 757-819-3320)
- Public Relations (Sabrina Zimring, sabrina.zimring@operationsmile.org, (c): 757-338-7731)

CEO activates Crisis Management Team, if needed
## NON-MEDICAL CRISIS NOTIFICATION PLAN

### CRISIS NOTIFICATION PLAN

Please refer to the Crisis Notification Plan when reporting non-medical incidents to pertinent individuals. Please submit this form to the headquarters security specialist/representative.

### WHAT? A brief description of the problem (person missing, kidnapped, arrested, civil unrest, terrorism, natural disaster)

- Type of Incident:  
  - ☐ Criminal
  - ☐ Terrorism
  - ☐ Civil Unrest
  - ☐ Missing Person
  - ☐ Natural Disaster
  - ☐ Other

- Details: 

### WHO? The victims (if any) with details (age, country of origin, etc.) The culprit (if any), known, suspected, or unknown

- 

### WHERE? The setting of the occurrence with available details

- 

### WHEN? The date and time of the incident

- 

### WHY? Why did the incident occur? Motives? Unknown?

- 

### INCIDENT REACTION AND NEXT STEPS

- Is your volunteer team aware of the incident?  
  - ☐ Yes
  - ☐ No

- If yes, what do they know? What was their reaction?

- Who has been notified? Who knows outside of the organization? Who is involved?

- What actions are currently underway?

- Other relevant information:

---

PROGRAM COORDINATOR SIGNATURE:  
PRINT:  
DATE:
## Non-Medical Crisis Notification Plan

### Incident Tracking and Further Notes

<table>
<thead>
<tr>
<th>Date</th>
<th>Mission Site/Country</th>
<th>Mission Coordinator</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

**Non-Medical Incident Initial Report**

<table>
<thead>
<tr>
<th>Date</th>
<th>Mission Site/Country</th>
<th>Mission Coordinator</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

**Operation Smile**

**Mission Form**

---

**NON-MEDICAL INCIDENT INITIAL REPORT**

**Operation Smile**

**Mission Form**

---

**INCIDENT TRACKING AND FURTHER NOTES**

---

MO: 5.13.15
## PATIENT CODE SHEET

### Chart #: Patient Name:

### Weight: kg  Age: years months

### Synchronized Cardioversion

<table>
<thead>
<tr>
<th>Defibrillation</th>
<th>Initial Shock joules</th>
<th>Subsequent Attempts joules</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adenosine</td>
<td>0.1 mg/kg 1st dose mg</td>
<td>0.2 mg/kg 2nd dose mg</td>
<td>IV/IO Rapid Push (Max. 6mg) followed by 10 mL saline bolus</td>
</tr>
<tr>
<td>Amiodarone</td>
<td>5 mg/kg mg</td>
<td></td>
<td>Max Bolus Dose 300 mg</td>
</tr>
<tr>
<td>Atropine</td>
<td>0.02 mg/kg mg</td>
<td></td>
<td>Min. dose 0.1mg = 1mL Max / Dose 0.5mg Child, 1mg Adolescent</td>
</tr>
<tr>
<td>Ca Chloride 10%</td>
<td>20 mg/kg mg</td>
<td></td>
<td>Slow IV Push, Adult Dose 5-10 mL Give no faster than 1mL/min</td>
</tr>
<tr>
<td>Sodium Bicarbonate</td>
<td>1 mEq/kg mEq</td>
<td></td>
<td>Infuse slowly and only if ventilation is adequate</td>
</tr>
<tr>
<td>Lidocaine 2%</td>
<td>1 mg/kg mg</td>
<td></td>
<td>IV infusion 20-50 mcg/kg/min</td>
</tr>
<tr>
<td>Epinephrine 1:10,000 IV/IO</td>
<td>0.01 mg/kg mg</td>
<td></td>
<td>0.1mL/kg. (1:10,000 1st dose Repeat every 3-5 minutes)</td>
</tr>
</tbody>
</table>

### CONTINUOUS INFUSION

| Epinephrine 3mcg/mL | 0.1 mcg/kg/min mL | Add 1.5 mL of 1mg/mL vial (1:1000) to 48.5mL D5W. Range 0.01 - 0.1mcg/kg/min |
| Dopamine 3.2mcg/mL=3,200mcg/mL | 5 mcg/kg/min mL/h | Use 800mcg per 250mL premixed solution (Range 2 - 30 mcg/kg/min) |

### REVERSAL AGENTS

| Flumazenil 0.1mg/mL | 0.01 mg/kg mg | mL Max Dose 0.2mg (2cc) May repeat q minute to a max cumulative Dose of 0.06mg/kg or 1mg, whichever is lower |
| Naloxone 0.4mg/mL | 0.01 mg/kg mg | mL Max 1.0 mg, may repeat q 2 min PRN |
| Neostigmine 1mg/mL | 0.07 mg/kg mg | mL Neostigmine Max 5mg per dose Must be given with Glycopyrrolate |
| Glycopyrrolate 0.2mg/mL | 0.2 mg/ml mg | mL |

### 1 Pre-Induction Medication

| Atrazine 0.01 mg/kg | | |
| Lidocaine 1 mg/kg | | |

### 2 Analgesia

| Nalbuphine 0.1 mg/kg | | |
| Fentanyl 2 mcg/kg | | |

### 3 Sedation

| Ketamine 1 mg/kg IV | | |
| Midazolam 0.1 mg/kg | | |
| Propofol 2 mg/kg | | |
| Remifentanil 0.2 mg/kg | | |

### 4 Paralytic

| Rocuronium 0.6 mg/kg | | |
| Vecuronium 0.1 mg/kg | | |
| Succinylcholine 1.5 mg/kg | | |
DIFFICULT AIRWAY MANAGEMENT

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

II. PROTOCOL:
   A. During Screening:
      1. If a patient has the potential of a difficult airway, all team leaders must be in agreement that the patient can safely receive surgery in a mission setting.
   B. During Scheduling:
      1. Patients identified with a potential difficult airway should not be schedule at the same time.
      2. Pediatric patients with a difficult airway should be scheduled with a pediatric anesthesiologist, if possible.
   C. During Surgery:
      1. The Difficult Airway Box (DAB) must be at the patient’s table during the entire surgery.
      2. Any use of DAB items must be recorded on the Medical Incident form.
   D. At Completion of Mission:
      1. DAB inventory list will be completed and remain inside the box.
      2. The foundation will contact OSI Logistics for replacement equipment and resupply the DAB before the next mission.

III. REQUIREMENTS:
   A. Operation Smile Responsibilities:
      1. OSI Logistics will provide one (1) Difficult Airway Box to each Foundation
         a. Each box will contain:
            • Ring-bound laminated pictures of the included equipment
            • Inventory sheet
      2. OS Headquarters Logistics will replace any items used from the box as indicated on the inventory sheet and/or by the Foundation.

IV. SUPPORTING DOCUMENTS:
   A. Medical Incident Form
   B. DAB Inventory Sheet
   C. DAB Laminated Flip Chart
I. POLICY:
   A. To ensure that all team members are familiar with approved medications administered to any patient within the Operation Smile mission setting.
   
   B. Medication administration should be limited to medications as outlined in Operation Smile’s Pharmacopeia.
   
   C. Additional drugs or substitutes must be approved by the Operation Smile Medical Officers.

II. PROCEDURE:
   A. Operation Smile approved medications are administered using the eight (8) rights of medication administration:
      
      1. Right Patient:
         a. Verify the patient name using ID band and chart.
         b. Confirm the presence or absence of allergies.
         c. Verify the medication order as written.
         d. For verbal orders there should be a repeat back to verify the order.
      
      2. Right Medication:
         a. Check the medication label and expiration date.
         b. Check the order.
      
      3. Right Dose:
         a. Check the dose.
         b. Confirm the appropriateness of the route.
         c. Calculate the dose based on patient weight as indicate.
         d. Verify dose with another clinician as needed.
      
      4. Right Route:
         a. Check the order for appropriateness of ordered route.
         b. Verify that patient can take the medication by the ordered route.
      
      5. Right Time:
         a. Check the frequency of the ordered medication
         b. Confirm the timing of the previous dose as documented.
      
      6. Right Documentation:
         a. Document medications AFTER they are given.
         b. Documentation should include time, route, and injection site, if applicable.
      
      7. Right Reason:
         a. Confirm the rationale for the ordered medication.
         b. Involve the patient/family in the discussion of the use, effects, and potential side effects of medications as they are given.
         c. For pain medication, consider the use of other comfort measures to potentiate the effect of the drug.
MEDICATION ADMINISTRATION (cont.)

8. Right Response:
   a. Verify that the medication has had the desired effect.
   b. Document the response to the medication and other interventions that are applicable.

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

C. Patient Education:
   1. Patient and family education related to postoperative and take home medications should be initiated as early as possible.
   2. Medications given in the postoperative setting should be thoroughly explained and family involvement encouraged.
   3. 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.

III. SUPPORTING DOCUMENTS:

   A. Global Standard 15 - Documentation
   B. Operation Smile Pharmacopeia
   C. Medical Health Records
      1. Patient Order Sheets (PACU and Post-Op)
      2. Anesthesia Flow Sheet
      3. Medication Administration Record
MEDICAL WASTE MANAGEMENT

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

II. PROCEDURE:
   A. International, national and local regulations governing the shipment of equipment and medical supplies will be observed.
   B. Proper handling of contaminated equipment will be utilized to eliminate potential contamination and infection related to medical waste.
      1. Sharps must be collected in puncture-proof containers.
      2. Containers for infectious waste must be collected as frequently as required and properly marked with information to include date of collection, type of waste and location in hospital where it was collected.
      3. Trained personnel, with proper protection, will handle the storage and disposal of waste.
      4. Equipment in contact with patients and/or health care workers will be thoroughly disinfected and dried prior to packing.
   C. Pharmaceuticals will be properly disposed of according to policy.
   D. Expired pharmaceuticals or consumables will NOT be donated to other entities.

III. SUPPORTING DOCUMENTS:
   A. Use of OR Sharps Disposal (TBD)
   B. Pharmaceutical Disposal Policy (TBD)
2. Cleft Lip and Palate Mission
TEAM COMPOSITION

I. POLICY:
   A. To ensure the safety and quality of care for all patients being treated during Operation Smile medical missions. All standards for qualified personnel must be maintained at all times.

II. PROCEDURE:
   A. 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.
   B. The guidelines are to be used in conjunction with the Additional Table Policy.
   C. Any surgical table employing sedation is to be considered a general anesthesia table and should be staffed accordingly.
   D. The team composition should be adjusted when higher patient objectives are planned.
      1. External factors such as patient objectives, hospital layout (postop divided into multiple areas not in the same proximity) need to be taken into consideration.
   E. Team Composition For General Anesthesia Tables:

<table>
<thead>
<tr>
<th></th>
<th>1 GA</th>
<th>2 GA</th>
<th>3 GA</th>
<th>4 GA</th>
<th>5 GA</th>
<th>6 GA</th>
<th>7 GA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgeons</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>Anesthesiologists</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>Pediatrics</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>PACU Physician</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Pediatrician</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Clinical Coordinator</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>OR Nurses</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>PACU Nurses</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Pre/Post-Op Nurses</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>4</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Post-Op Night Nurses</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Child Life/Psychosocial Care Provider</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Speech Pathologist</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Orthodonist/Dentist</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Biomed</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>
ADDITIONAL TABLE

I. POLICY:
   A. To ensure the safety and quality of care for all patients being treated during Operation Smile medical missions. The following requirements for equipment and qualified personnel must be maintained when additional tables are added during the mission.

II. PROCEDURE:
   A. The Clinical Coordinator (CC), in collaboration with the other team leaders, is tasked with assessing the site for the appropriate resources.

   B. The plan for the additional table, which includes the number and type of cases to be treated, is communicated to the medical records staff, pre-op ward, operating room, PACU and the post-op ward personnel by the CC prior to commencing surgery.

   C. The PC will notify the Regional Medical Officer (RMO) to confirm the deviation. If the RMO cannot be reached or the Associate Chief Medical Officer (ACMO) will be notified.

   D. Once confirmed, the “Additional Table Form” will be sent to the RMO, ACMO and the Sr. Director of Quality Assurance before the end of the mission.

   E. For multi-site missions, the opening of an additional table will be communicated to the in-country program coordinator.

   F. The Additional Table form is retained by the Program Coordinator for inclusion in post-mission reporting.

III. REQUIREMENTS:
   A. The following personnel and equipment must be documented as being present prior to commencing surgery on an additional table:

      1. Personnel - the team composition must meet the minimum requirements stated in the “Team Composition Policy”.

         a. An Operation Smile plastic surgeon.

         b. The float surgeon must NOT be utilized if the additional table is to use general anesthesia.

         c. The float surgeon may be used if the additional table is local anesthesia only.

         d. The float anesthesiologist must NOT be used for the additional table when sedation is utilized.

         e. A scrub nurse must be available dedicated solely to the additional table.

         f. An OR nurse must be available to safely cover the additional table.
ADDITIONAL TABLE (cont.)

B. Equipment:
   1. Access to suction, sterilized instruments, electro cautery, and necessary consumable supplies (anesthesia, medications, surgical)

C. Hospital:
   1. Physical space and resources in the PACU for additional patients.
   2. Physical space and resources in the Postoperative area for additional patients.

IV. SUPPORTING DOCUMENTS:
   A. Additional Table – Local Anesthesia Form
   B. Additional Table – General Anesthesia Form
## ADDITIONAL TABLE – LOCAL ANESTHESIA FORM

**Use of sedation disqualifies a table from being considered “Local Anesthesia” and must be documented using “Additional Table Form – General Anesthesia.”**

<table>
<thead>
<tr>
<th>DATE</th>
<th>TIME</th>
</tr>
</thead>
<tbody>
<tr>
<td>dec</td>
<td>/yy</td>
</tr>
<tr>
<td>/yy</td>
<td></td>
</tr>
</tbody>
</table>

**MISSION SITE**

**# OF TABLES**

### Checklist for opening a Local Anesthesia Table

(Clinical Coordinator please confirm the presence of the following:

**Personnel:**

- Operation Smile Approved Plastic Surgeon (may be floater):

- Scrub Nurse:

- Operation Smile Approved OR Nurse available for support:

**Equipment:**

- Pulse Oximeter
- Sterilized Surgical Equipment
- Suction Machine
- Electrocautery Capability
- Consumables (Sutures, Tubes, IV fluids, etc.)

**Hospital**

- Availability/Consent of Recovery Room
- Availability/Consent of Post-Op Ward

### SIGNATURES

<table>
<thead>
<tr>
<th>SIGNATURE</th>
<th>PRINT</th>
<th>DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>SURGERY TEAM LEADER SIGNATURE</td>
<td>PRINT</td>
<td>DATE</td>
</tr>
<tr>
<td>ANESTHESIA TEAM LEADER SIGNATURE</td>
<td>PRINT</td>
<td>DATE</td>
</tr>
<tr>
<td>CLINICAL COORDINATOR SIGNATURE</td>
<td>PRINT</td>
<td>DATE</td>
</tr>
<tr>
<td>PEDIATRIC INTENSIVIST SIGNATURE</td>
<td>PRINT</td>
<td>DATE</td>
</tr>
<tr>
<td>PROGRAM COORDINATOR SIGNATURE</td>
<td>PRINT</td>
<td>DATE</td>
</tr>
</tbody>
</table>

☐ **SENT TO RMO/ACMO**

**DATE**

*dec /yy /yy*

☐ **APPROVED BY RMO/ACMO**

**DATE**

*dec /yy /yy*
### ADDITIONAL TABLE – GENERAL ANESTHESIA FORM

This table will give **general** anesthesia only.

**DATE**  **DD**  **/MM**  **/YYYY**  **TIME**

**MISSION SITE**

**# OF TABLES**

#### Checklist for opening a General Anesthesia Table (Clinical Coordinator please confirm the presence of the following:)

- **Personnel:**
  - Operation Smile Approved Plastic Surgeon (may **NOT** be floater):
  - Operation Smile Approved Anesthesiologist (if IV sedation used):
  - Scrub Nurse:
  - Operation Smile Approved OR Nurse available for support:

- **Equipment:**
  - Pulse Oximeter
  - End-Tidal CO2 Monitor
  - Sterilized Surgical Equipment
  - Suction Machine
  - Electrocautery Capability
  - Consumables (Sutures, Tubes, IV fluids, etc.)

- **Hospital**
  - Availability/Consent of Recovery Room
  - Availability/Consent of Post-Op Ward

---

#### SIGNATURES

<table>
<thead>
<tr>
<th>Role</th>
<th>Signature</th>
<th>Print</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery Team Leader</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anesthesia Team Leader</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical Coordinator</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pediatric Intensivist</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Program Coordinator</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

☐ **SENT TO RMO/ACMO**  **DATE**  **DD**  **/MM**  **/YYYY**  

* RMO, or in their absence ACMO, must be notified and all designated team members need to sign this form before any deviations can take effect.

☐ **APPROVED BY RMO/ACMO**  **DATE**  **DD**  **/MM**  **/YYYY**  

---

*Operation Smile Inc. - 3641 Faculty Boulevard - Virginia Beach, Virginia 23459 - United States  Updated: Nov 2014*
Surgical Priorities

I. Policy:

A. Operation Smile’s (OS) priority system allows for safe patient selection and optimal surgical outcomes. During the patient selection process, follow-up care, rehabilitation, and other therapies should be considered. The goal is to provide the highest standard of safe surgical care and follow up in the mission environment. Refer to “Age Minimums and Scheduling Policy”.

II. Procedure: Surgical Priorities

A. Priority 1 – Primary Repair of Cleft Lip (Ages 6 months and older) can be accomplished safely, quickly, and with near guarantee of improving the patient’s appearance. The safe minimum age and body weight of the patient depends on the setting, the equipment, and the experience level of the anesthesia staff and capability of the nursing staff to monitor the patient.

1. Patients under 3 months of age should NOT be considered for any surgery on Operation Smile medical mission.
2. Ages 3 – 6 months – refer to "Age Minimums and Scheduling Policy"
3. Any primary lip not qualifying for surgery, yet has potential for surgery in the future, are noted in the chart as Priority 1.
   a. A “not cleared for surgery” note in the chart will explain the reason – too young, weight too low, poor nutrition, low hemoglobin or stated illness.
4. Returning Operation Smile with surgical complications (dehiscence).
   a. Patients are to be screened in full to determine if their health is appropriate for surgery. This assumes the surgical treatment is expected to be successful and not expected to dehisce again due to poor tissue conditions.

B. Priority 2 – Primary Repair of Cleft Palate (Ages 1 - 10 years) has the greatest success in enabling the patient to develop normal speech. The operation can be done safely, in most children over 12 months. Younger patients have a better chance for developing normal speech even when no speech therapy is available in the country.

1. The safe minimum age and body weight of the patient depends on the setting, the equipment, and the experience level of the anesthesia staff and capability of the nursing staff to monitor the patient.
2. Any cleft palate age 1 – 10 years old not qualifying for surgery, yet has potential for surgery in the future should be noted in the chart as Priority 2.
   a. A “not cleared for surgery” note in the chart will explain reason – too young, weight too low, low hemoglobin, poor nutrition or stated illness.
3. Ages 1 – 10 years refer to “Age Minimums and Scheduling Policy”
SURGICAL PRIORITIES (cont.)

4. Operation Smile patients returning with surgical complications – all ages
   a. Classified as Priority 2
   b. Surgically treated by Operation Smile, returns presenting with dehiscence/fistula of the palate or other related failures, selected for surgery accordingly.
   c. Patients are to be screened in full to determine if their health is appropriate for surgery. This assumes the surgical treatment is expected to be successful and not expected to dehisce again due to poor tissue conditions.

C. Priority 3 - Primary Repair of Cleft Palate (Ages 10+ to Adult) when possible, older children and adults should have the opportunity for surgeries. While perfect speech will not be possible, a great deal of improvement can be achieved safely and in a short period of time.
   1. Special consideration should be given in scheduling for patients identified by the Speech Language Pathologist (SLP).
   2. Psychosocial benefits to the patient are enormous.
   3. Patients will require good follow-up care and must be told that additional surgery may be necessary.

D. Priority 4 – Secondary Repair of Lip or Palate (all ages) if time allows, and priority 1, 2 and 3 patients have been accommodated, secondary repairs can be scheduled.
   1. Each case should be considered on its merits and the benefits compared to competing cases.
   2. Returning OS patients with secondary repairs not due to complications.

E. Priority 5 – Other Conditions (all ages) despite the temptation to try to help patients with severe deformities and burn contractures, cases should be avoided requiring prolonged anesthesia, extensive grafting, or prolonged complicated follow-up care or rehabilitation.
   1. For cases requiring > 4 hours, refer to “Surgical Deviation Policy”
   2. If for political or other reasons these cases cannot be avoided, be very selective in what is done and advise the patient and family on the potential for no improvement.
   3. Parental and patient expectations may be beyond the goals of the scheduled procedure.
   4. Expectation management is essential and requires procedures performed to be clearly defined, and patient/parent informed the condition may require further surgery and Operation Smile cannot make a commitment to further surgery.

F. Not a Candidate
   1. Patient’s condition does not fall within any of the above categories treated by Operation Smile and is not a candidate for the current mission, any future mission, nor World Care.

G. Potential World Candidate
   1. Candidate for surgery whose condition is too complex to be treated during an Operation Smile mission or are unable to receive surgery due to mission time or resource constraints.
   2. NO PROMISES should be made to any potential World Care candidates.
   3. Final evaluations are done in coordination with Operation Smile headquarters and the Chair of the World Care program.
SURGICAL PRIORITIES (cont.)

H. Surgeries not done on Operation Smile missions
   1. The focus of Operation Smile is on the social acceptance of the patient, by repairing the cleft lip/cleft palate and restoration of normal speech. Most other congenital and acquired deformities fall outside our scope and developed expertise.
   2. Often we are tempted to try to help patients with other conditions, but it must be realized, that in a one-week mission, with only three more days for follow-up, and possibly little chance for the patients to be helped locally, the majority of health care needs cannot be addressed by Operation Smile.

I. No Further Surgical Intervention Needed
   1. Successfully operated on patient that cannot be improved with further surgery.
I. POLICY
   A. To ensure the delivery of safe care when surgical cases other than cleft lip and/or cleft palate or other routine procedures (i.e., syndactyly, frenulectomy, keloids, and minor releases) are requested to be considered during a mission.

II. PROTOCOL:
   A. During Screening:
      1. If a patient is identified as a surgical deviation, the case must be discussed and agreed upon for potential surgery by all team leaders.
         a. Any surgical deviation procedures requiring greater than three (3) hours, must be agreed upon by all team leaders.
      2. The Surgical Deviation form must be completed and approved by the Regional Medical Officer (RMO) prior to scheduling.
   B. During Scheduling:
      1. Essential supplies, personnel, available intensive care support and plan for follow-up care must be identified and secured before the surgery is scheduled.
   C. At Completion of Mission:
      1. Prior to Operation Smile staff transferring care of the patient over to the local medical personnel, post-op plan of care and processes must be clearly identified and discussed.

III. SUPPORTING DOCUMENTS:
   A. Surgical Deviation Form
**SURGICAL DEVIATION FORM**

<table>
<thead>
<tr>
<th><strong>OPERATION SMILE</strong></th>
<th><strong>SURGICAL DEVIATION</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>CLEFT LIP &amp; PALATE MISSION</td>
<td></td>
</tr>
<tr>
<td><strong>PATIENT FAMILY / LAST NAME</strong></td>
<td><strong>DATE</strong> / / <strong>CHART NUMBER</strong></td>
</tr>
<tr>
<td><strong>PATIENT FIRST NAME</strong></td>
<td><strong>MISSION SITE</strong></td>
</tr>
<tr>
<td><strong>PROPOSED</strong></td>
<td><strong>MISSION SITE</strong></td>
</tr>
<tr>
<td>LIP</td>
<td>NO</td>
</tr>
<tr>
<td>NOSE</td>
<td>NO</td>
</tr>
<tr>
<td>PALATE</td>
<td>NO</td>
</tr>
<tr>
<td>Fistula</td>
<td>NO</td>
</tr>
<tr>
<td>OTHER</td>
<td>NO</td>
</tr>
<tr>
<td><strong>PROPOSED</strong></td>
<td><strong>ALLERGIES</strong></td>
</tr>
<tr>
<td><strong>PROCEDURE</strong></td>
<td><strong>WEIGHT</strong> KG</td>
</tr>
<tr>
<td><strong>LENGTH OF SURGERY</strong></td>
<td><strong>HEIGHT</strong> CM</td>
</tr>
<tr>
<td><strong>BIRTHDATE</strong> / / <strong>AGE</strong></td>
<td></td>
</tr>
</tbody>
</table>

**LAB RESULTS**

- [ ] HEMATOCRIT/HEMOGLOBIN (H/H) DONE (REQUIRED):
  - HCT ________
  - HB ________

- [ ] ADDITIONAL TESTS (AS NEEDED):
  - PT
  - PTT
  - TYPE AND SCREEN
  - OTHER:

**ADDITIONAL ORDERS & NOTES (PLEASE HIGHLIGHT SPECIFIC PARAMETERS & ADJUSTMENTS)**

Please explain the circumstances prompting the team leaders to consider scheduling this case:

Required supplies to complete the case:

Appropriate instrumentation:

Personnel required:

Intensive care or additional hospital support:

Plan for follow up post-operative care:

**SIGNATURES**

- **SURGERY TEAM LEADER SIGNATURE:**
  - PRINT:
  - DATE:

- **ANESTHESIA TEAM LEADER SIGNATURE:**
  - PRINT:
  - DATE:

- **CLINICAL COORDINATOR SIGNATURE:**
  - PRINT:
  - DATE:

- **PEDIATRIC INTENSIVIST SIGNATURE:**
  - PRINT:
  - DATE:

- **PROGRAM COORDINATOR SIGNATURE:**
  - PRINT:
  - DATE:

- [ ] SENT TO RMO/ACMO **DATE** / / **YYYY**

- [ ] APPROVED BY RMO/ACMO **DATE** / / **YYYY**

* RMO, OR IN THEIR ABSENCE ACMO, MUST BE NOTIFIED AND ALL DESIGNATED TEAM MEMBERS NEED TO SIGN THIS FORM BEFORE ANY DEVIATIONS CAN TAKE EFFECT.

ADDITIONAL PAGE

OPERATION SMILE INC. 3641 FACULTY BOULEVARD VIRGINIA BEACH, VIRGINIA 23451 UNITED STATES UPDATED JUNE 2014 AGE DEVIATION
CLEFT AGE MINIMUMS & SURGICAL SCHEDULING

I. POLICY:
A. 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.

II. PROCEDURE:
A. Cleft lip repair:
   1. Over 6 months of age:
      a. Operation Smile expects team leaders will use 6 months as the minimum age standard for patients eligible for surgery at most Operation Smile mission sites.
      b. However, each patient should be discussed individually, and team leaders must agree ahead of time if the standard age should be elevated to 1 year depending on hospital or country conditions.
   2. 3 to 6 months of age:
      c. A patient in the 3 to 6 month age range may be scheduled only if there is total agreement from the team leaders who consist of:
         • Field Medical Director (FMD), Anesthesia Team Leader (ANTL), Plastic Surgery Team Leader (PSTL), Clinical Coordinator (CC), and PACU Physician on patient health and hospital facilities.
      d. Patients in this age range selected for surgery should be documented on an Age Deviation form.
      e. Patients should have no comorbidities that would compromise care in the perioperative period.

B. Cleft palate repair:
   1. Over 12 months of age:
      a. The standard practice for Operation Smile missions is to select for palate surgery patient over 12 months of age.
   2. 9 to 12 months of age:
      a. A patient in the 9 to 12 month age range may be scheduled only if there is total agreement from the team leaders on patient’s health and hospital facilities.
      b. Patients in this age range selected for surgery should be documented on an Age Deviation form.
      c. Patients should have no co-morbidities that would compromise care in the perioperative period.
CLEFT AGE MINIMUMS & SURGICAL SCHEDULING (cont.)

C. Combination lip and palate “Combo” repairs:
   1. Combination operations should be considered only for patients over 1 year of age.
      a. All team leaders plus the operating surgeon must agree to the combo surgery before
         scheduling and appropriate post-operative care must be assured in advance.

D. Considerations:
   1. All patients in consideration for surgery must be in good general health, as agreed on by
      the PSTL, ANTL, CC, PACU Physician, and FMD.
   2. Special attention should be taken to children with asthma, gastro-esophageal reflux or
      who are malnourished or emaciated.
   3. Special concern must also be given to scheduling patients that may present as difficult
      intubations such as microstomia, small mandibles, wide bilateral clefts and children with
      syndromes or cardiac problems.

E. Hospital Facility
   1. When considering the surgical schedule and patient age, the FMD and the PACU Physician
      must ensure that the mission site hospital is equipped with an appropriate pediatric
      intensive care unit (PICU), and that appropriate equipment is in working order and
      available (blood gas machine and pediatric ventilator).
   2. If the mission hospital is not equipped with an appropriate PICU, the FMD, PACU Physician,
      Program Coordinator and an in-country foundation representative must identify another
      local hospital that is equipped with an appropriate PICU.
      a. Arrangements must be formally agreed upon with that hospital director for the facility’s
         use along with patient use.
      b. See Transportation of Patients – 5.11 policy

F. Scheduling Requirements:
   1. The surgical schedule should be arranged so that the ANTL can assign a pediatric
      anesthesiologist or an experienced Operation Smile anesthesia provider for all children
      under the age of 2 years.
   2. Patients under the age of 2 years should be scheduled as early as possible in the day.
   3. Do not schedule any cleft palate repairs for the last day of surgery.
   4. The Regional Medical Officer (RMO) must approve all deviations prior to finalizing the
      schedule.
# AGE DEVIATION FORM

<table>
<thead>
<tr>
<th>OPERATION SMILE</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLEFT LIP &amp; PALATE MISSION</td>
</tr>
</tbody>
</table>

**PATIENT FAMILY / LAST NAME**

**DATE** / ____ / ________ **CHART NUMBER** ________

**PATIENT FIRST NAME**

**MISSION SITE** ________

**PROPOSED**

- [ ] LIP
- [ ] NOSE
- [ ] PALATE
- [ ] FISTULA
- [ ] OTHER

**ALLERGIES**

- [ ] NO
- [ ] YES

**WEIGHT** ___ KG  **HEIGHT** ___ CM  **SEX** [ ] M  [ ] F

**LENGTH OF SURGERY**

**BIRTHDATE** / ____ / ________ **AGE** ________

---

## LAB RESULTS

- [ ] HEMATOCRIT/HEMOGLOBIN (H/H) DONE (REQUIRED):
  - HCT ______
  - HG ______

- [ ] ADDITIONAL TESTS (AS NEEDED):
  - [ ] PT
  - [ ] PTT
  - [ ] TYPE AND SCREEN
  - [ ] OTHER:

---

## ADDITIONAL ORDERS & NOTES (*PLEASE HIGHLIGHT SPECIFIC PARAMETERS & ADJUSTMENTS*)

---

---

## SIGNATURES

- [ ] SURGERY TEAM LEADER SIGNATURE:  PRINT:  DATE:

- [ ] ANESTHESIA TEAM LEADER SIGNATURE:  PRINT:  DATE:

- [ ] CLINICAL COORDINATOR SIGNATURE:  PRINT:  DATE:

- [ ] PEDIATRIC INTENSIVIST SIGNATURE:  PRINT:  DATE:

- [ ] PROGRAM COORDINATOR SIGNATURE:  PRINT:  DATE:

- [ ] SENT TO RMO/ACMO  DATE:  DD / MM / YYYY

**RMO, OR IN THEIR ABSENCE ACMO, MUST BE NOTIFIED AND ALL DESIGNATED TEAM MEMBERS NEED TO SIGN THIS FORM BEFORE ANY DEVIATIONS CAN TAKE EFFECT.**

- [ ] APPROVED BY RMO/ACMO  DATE:  DD / MM / YYYY

**ADDITIONAL PAGE**  OPERATION SMILE INC. *3441 FACULTY BOULEVARD* VIRGINIA BEACH, VIRGINIA 23451 UNITED STATES  UPDATED JUNE 2014  AGE DEVIATION

---

MO: 5.13.15  63 | P a g e
3. Screening
# PATIENT INFORM CONSENT

## OPERATION SMILE

### CLEFT LIP & PALATE MISSION

**PATIENT FAMILY / LAST NAME:** ____________________________  **DATE:** ____________________________  **CHART NUMBER:** ____________________________

**PATIENT FIRST NAME:** ____________________________  **MISSION SITE:** ____________________________  **LOCAL CHART NUMBER:** ____________________________

---

**MEDICAL ASSESSMENT PRIOR TO SELECTION FOR SURGERY**

- I consent to physical examination(s), X-rays, imaging and other diagnostic procedures as may be deemed necessary by Operation Smile to evaluate my case for possible surgery. .......................................................... ☐ YES ☐ NO

- I consent to the photographing, video and voice recording of any aspect of treatment including screening, operation(s), post-operative care for identification and medical purposes. .......................................................... ☐ YES ☐ NO

- I authorize Operation Smile to retain or preserve any specimens or tissues taken from my body as part of this assessment or additional medical procedures conducted on me if selected for surgery, and to manage these specimens and to assure their responsible disposal. .......................................................... ☐ YES ☐ NO

- I further consent to the use of specimen or products of those procedures for scientific and educational purposes. .......................................................... ☐ YES ☐ NO

- I understand any additional surgical or medical procedures will result in Operation Smile generating and managing medical records associated with my case. I further understand that these records will be managed with the highest levels of anonymity, security and patient confidentiality. I consent for the use of these records for educational or research purposes. .......................................................... ☐ YES ☐ NO

---

**ADDITIONAL CLAUSES (INFORMATION RELEASE & PHOTOGRAPHY)**

- I hereby give my consent to the photographing, video and voice recording of myself to Operation Smile for public relations, advertising, fund raising or other business purposes - regardless of whether I am selected for surgery and without further approval. I understand that images or video segments in which I can be identified and which are used by Operation Smile for any purpose, that my name will be identified and properly associated with these images or video segments. .......................................................... ☐ YES ☐ NO

- I hereby give my consent to the photographing, video and voice recording of myself to Operation Smile for identification, medical, scientific or educational purposes. .......................................................... ☐ YES ☐ NO

- I consent to the admittance of observers approved by Operation Smile at any stage of this assessment in the operating room if I am selected for surgery for the purpose of advancing medical education, research and the understanding of Operation Smile’s mission and goals. .......................................................... ☐ YES ☐ NO

- I also grant Operation Smile, unrestricted, exclusive rights and usage of these photographs, voice recordings, videos and likenesses. These photographs and/or recordings may be used singularly or in conjunction with other photographs and/or recordings. .......................................................... ☐ YES ☐ NO

- I hereby release Operation Smile and any of its associated or affiliated companies, their directors, officers, agents, employees, customers and the organization's appointed advertising agencies, officers, directors, agents and employees, from all claims of any kind on account of such use. .......................................................... ☐ YES ☐ NO

* I understand that my refusal to any of the last five statements will NOT affect my potential for being selected as a candidate for medical treatment and that my acceptance will not increase my ability to receive such medical care. .......................................................... ☐ YES ☐ NO

My signature below acknowledges that I have read and understand the foregoing statements:

---

**SIGNATURE OF PATIENT (IF OVER 18) OR PARENT/GUARDIAN:** ____________________________  **PRINT:** ____________________________  **DATE:** ____________________________

**SIGNATURE OF OPERATION SMILE VOLUNTEER/TRANSLATOR/READER:** ____________________________  **PRINT:** ____________________________  **DATE:** ____________________________

---

PAGE 3  OPERATION SMILE INC. • 3641 FACULTY BOULEVARD • VIRGINIA BEACH, VIRGINIA 23453 • UNITED STATES  UPDATE AUGUST 2014  PATIENT INFORMATION CONSENT
PATIENT SURGICAL CONSENT

OPERATION SMILE
CLEFT LIP & PALATE MISSION

PATIENT FAMILY/LAST NAME: ____________________________ DATE: __/__/____ CHART NUMBER: ____________________________

PATIENT FIRST NAME: ____________________________ MISSION SITE: ____________________________ LOCAL CHART NUMBER: ____________________________

ATTENTION: THIS DOCUMENT DOES NOT GUARANTEE THE SIGNATORIES AN OPERATION

SURGICAL, POST-OPERATIVE & DISCHARGE MEDICAL INFORMATION

- I consent to any operation(s) and/or procedure(s), and to the administration of such anesthetics, as have been described to me and which may be considered necessary or advisable by Operation Smile Medical Volunteers.

- I realize that if chosen for an operation, every effort will be made to perform the surgery that was outlined at the initial evaluation. However I understand that in unique cases the physician’s judgment may change regarding the procedure once in the operating room.

- I have been given no guarantee or assurance of the results that may be obtained with the proposed operation(s) and/or procedure(s).

- I consent to samples of blood being collected and screened for blood borne pathogens (including HIV, Hepatitis A, Hepatitis B, Hepatitis C) as may be indicated during surgical or post-operative procedures.

- I hereby authorize the administration of blood or blood products as deemed necessary by the attending physician. I understand that there are risks involved with blood transfusions.

- The proposed operation(s) and/or procedure(s), the nature and purpose of the specific treatment, the alternative methods of treatment, the risks including death, brain injury and paralysis, and the benefits involved have been satisfactorily explained to me by the physician. I have all the information I desire, and my questions have been answered satisfactorily.

- I have received an orientation as to the range of Operation Smile surgical intervention which may apply to my case and understand the orientation which I have received.

LIST OF PROPOSED PROCEDURE(S) explained to the patient/parent/guardian: ____________________________

LENGTH OF PROCEDURE(S): _______ Hours _______ Minutes

☐ The nature, known risks and purpose of the operation(s) to be performed on this patient have been explained to him/her (if the patient is over 18), or his/her parent/guardian (if the patient is under 18).

SIGNATURE OF SURGEON AT SCREENING PRINT: ____________________________ DATE: __/__/____

My signature below acknowledges that I have read and understand the foregoing statements:

SIGNATURE OF PATIENT (IF OVER 18) OR PARENT/GUARDIAN PRINT: ____________________________ DATE: __/__/____

SIGNATURE OF WITNESS/TRANSLATOR/READER PRINT: ____________________________ DATE: __/__/____

- Is the Final Procedure the same as the Proposed Procedure ABOVE? ____________________________ YES NO
- Does the Patient Understand the RISKS of the FINAL Procedure? ____________________________ YES NO

SIGNATURE OF OPERATING SURGEON PRINT: ____________________________ DATE: __/__/____
4. Intra-Operative
SURGICAL SAFETY CHECKLIST

I. POLICY:
   A. The World Health Organization (WHO) Surgical Safety Checklist tool is designed to improve the communication of surgical teams. The policy is intended for use in all Operation Smile surgical settings to ensure the safety of the patients.

II. PROCEDURE:
   A. Before Induction of Anesthesia – **Sign In**
      1. Completed before the induction of anesthesia to confirm the safety of proceeding.
      2. Each step on the checklist should be performed aloud and in conjunction with other team members in the OR.
      3. Confirmation of every step is essential to avoid omission of errors.
   B. Before Skin Incision – **Time Out**
      1. Defined as a momentary pause taken by the OR team just before skin incision in order to confirm that several essential safety checks are undertaken.
      2. The Time Out must involve every member of the team, including the surgeon.
      3. The critical time for team introductions is prior to the first case of the day.
      4. Confirm that each team member has introduced themselves by name and role.
   C. Before the patient leaves the Operating Room – **Sign Out**
      1. Ideally performed just before or during wound closure.
      2. Facilitates the transfer of important information to the clinical teams responsible for the care of the patient after surgery.
      3. The surgeon, anesthetist and the nurse should review the postoperative recovery and management plan, focusing in particular on intraoperative and/or anesthetic issues that might affect the patient in the recovery phase.

III. SUPPORTING DOCUMENTS:
   A. Surgical Safety Checklist
# SURGICAL SAFETY CHECKLIST

**OPERATION SMILE**

**CLEFT LIP & PALATE MISSION**

<table>
<thead>
<tr>
<th>PATIENT FAMILY / LAST NAME:</th>
<th>DATE:</th>
<th>CHART NUMBER:</th>
</tr>
</thead>
<tbody>
<tr>
<td>PATIENT FIRST NAME:</td>
<td>MISSION SITE:</td>
<td>LOCAL CHART NUMBER:</td>
</tr>
</tbody>
</table>

**EACH SECTION OF THE CHECKLIST MUST BE COMPLETED & MUST INVOLVE THE TEAM MEMBERS LISTED**

## BEFORE ANESTHESIA

WITH CIRCULATING NURSE, AND/OR ANESTHESIOLOGIST

- **HAVE THE PATIENT/PARENT/GUARDIAN & CHART VERIFIED THE FOLLOWING?**
  - [ ] CALL OUT CHART NUMBER
  - [ ] PATIENT IDENTITY
  - [ ] WEIGHT
  - [ ] SURGICAL SITE
  - [ ] PROCEDURE
  - [ ] CONSENT

- **IS THE SITE/SIDE MARKED?**
  - [ ] YES
  - [ ] NOT APPLICABLE

- **ARE THERE ANY KNOWN DRUG OR LATEX ALLERGIES?**
  - [ ] NO
  - [ ] YES, PLEASE LIST:

- **IS PULSE OXIMETRY MONITORING IN PLACE?**
  - [ ] YES

## BEFORE INCISION

WITH NURSE, SURGEON, AND/OR ANESTHESIOLOGIST

- **CONFIRM ALL TEAM MEMBERS HAVE INTRODUCED THEMSELVES**

- **TEAM VERBALLY CONFIRMS:**
  - [ ] PATIENT IDENTITY
  - [ ] SURGICAL SITE
  - [ ] PROCEDURE

- **IS THE THROAT PACK IN PLACE WITH SUTURE?**
  - [ ] YES
  - [ ] NOT APPLICABLE

- **HAS ANTIBIOTIC PROPHYLAXIS BEEN GIVEN WITHIN THE LAST 60 MINUTES?**
  - [ ] YES

- **SPECIAL CONCERNS HAVE BEEN DISCUSSED:**
  - RISK OF SIGNIFICANT BLOOD LOSS
  - AIRWAY COMPLICATIONS
  - ALLERGIES

## BEFORE PATIENT LEAVES OPERATION ROOM

WITH NURSE, SURGEON, AND/OR ANESTHESIOLOGIST

- **VERBALLY CONFIRM THE NAME OF THE PROCEDURE**

- **IS THE TONGUE SUTURE IN PLACE?**
  - [ ] YES
  - [ ] NOT APPLICABLE

- **IS THE THROAT PACK(S) REMOVED?**
  - [ ] YES
  - [ ] NOT APPLICABLE

- **DISCUSS ANY KEY CONCERNS FOR RECOVERY OR POST-OP MANAGEMENT**

- **IS THE PATIENT READY TO BE MOVED TO RECOVERY?**
  - [ ] YES

**BY SIGNING THIS FORM, YOU ARE VERIFYING THAT EACH STEP WAS TAKEN IN THE PROPER ORDER, BEFORE PROGRESSING WITH SURGERY AND TAKING THE PATIENT TO THE POST ANESTHESIA CARE UNIT**

**ANESTHESIOLOGIST OR NURSE SIGNATURE:**

**PRINT:**
THROAT PACK

I. POLICY:
   A. To ensure the safety and quality of care for patients treated on OS medical missions, throat packs will be used on all cases of cleft lip and cleft palate surgery. Throat packs are often inserted by anesthetists or surgeons to:
      B. Absorb material created by surgery in the mouth
      C. Prevent fluids or material from entering the esophagus or lungs
      D. Prevent escape of gases from around the endotracheal tubes
      E. Stabilize artificial airways

II. PROCEDURE:
   The following procedure is established regarding the construction, use, and documentation of throat packs.
   A. Materials for throat packs
      1. Sterile 4x4 gauze or sterile 4x8 surgical sponges; x-ray detectable (radiopaque) gauze.
      2. 2-0 silk suture
   B. The scrub nurses (or operating room nurse if scrub nurse is unavailable) will construct throat packs by threading 2-0 Silk suture through the end of the sponges and tying a secure knot (discarding the needle.)
   C. Place assembled throat packs on the mayo stand and additional packs on the back table. Assemble sufficient throat packs to cover the anticipated day’s procedures.
   D. The silk suture will act as a “marking” suture which must hang outside the surgical field in order to act as a visual reminder that a throat pack is in place. If more than one throat pack is used in a patient, the total number of packs will be reflected in the number of visual “marking” sutures.
   E. In addition to the “marking” suture, one additional visual aid (sign, tape on forehead, other form agreed upon by team) will be utilized to clearly indicate throat pack(s) placement.
   F. Anesthesia provider for each patient is responsible for documenting placement and removal of throat pack(s) on the anesthesia record.
   G. The circulating nurse (OR nurse) will check the appropriate box on the Post-Operative Checklist, and initial to confirm that the throat pack has been removed.
THROAT PACK (cont.)

III. SPONGE SAFETY:
   A. Only Ray-Tech sponges will be used in the OR.
   B. Only 4x4 size and larger will be available in the OR.
   C. **UNDER NO CIRCUMSTANCES SHOULD 2X2 SPONGES BE USED IN THE OR.**
   D. **UNDER NO CIRCUMSTANCES SHOULD CUT SPONGES BE USED IN THE OR.**
   E. Throat packs should be left in their original configuration and should not be cut or altered in any way
   F. Non-radiopaque gauze dressing materials should be withheld from the field until the final count

IV. RESPONSIBILITY:
   A. The entire surgical team.

V. SUPPORTING DOCUMENTS:
   A. Throat Pack signage of choice.
   B. OR Flowsheet (TBD)

VI. REFERENCES:
   A. AORN 2012 Standards, “Retained Surgical Items”
I. PURPOSE:
   A. This policy has been developed to:
      1. Help reduce and/or prevent surgical site infections (SSI) through prophylactic antibiotic therapy and surgical site preparation.

II. POLICY:
   A. To support the prevention of surgical site infections (SSI), the following components of care must be implemented:
      1. Appropriate use of prophylactic antibiotics:
         a. Selection of prophylactic antibiotics for surgical patients will be consistent with evidence based guidelines.
         b. Prophylactic antibiotics will be administered within 1 hour prior to surgical incision.
         c. Prophylactic antibiotics are recommended to be discontinued within 24 hours after surgery end time.
      2. Appropriate hair removal.

III. GUIDELINES:
   A. Appropriate use of prophylactic antibiotics:
      1. Use preprinted standing orders specifying antibiotic, timing, dose, and discontinuation.
      2. Develop protocols that include preoperative antibiotic selection and dosing based on patient-specific age, weight, allergies, renal clearance, etc.
      3. Assign dosing responsibilities to anesthesia or designated nurse to improve timeliness.
      4. Verify administration time during “surgical time-out”.
   B. Hair Removal:
      1. Remove hair at operative site unless it interferes with the patient’s surgery.
      2. Use of clippers or depilatory agent for hair removal at operative site is recommended.
   C. Use appropriate antiseptic agent and technique for skin preparation.
   D. Keep OR traffic to a minimum

IV. SUPPORTING DOCUMENTS:

V. REFERENCE:
STERILIZATION

I. POLICY:
   A. Outlines the procedures for providing quality measures in the proper cleaning, decontamination and sterilization of instruments, supplies and equipment used within the operating room.
   B. Creates and maintains an aseptic environment that reduces the risk to the patient of hospital-acquired infections (HAI).
   C. Ensures that recommended standards of practice with regards to infection control are being applied in the care of Operation Smile patients.

II. PROCEDURE:
   A. All critical items such as instruments, supplies and equipment used during surgical procedures must be sterile to include but not limited to:
      1. Critical items are those that enter sterile tissue or the vascular system.
      2. Surgical instruments utilized in cleft lip and cleft palate surgery, craniofacial surgery, microsurgery, orthopedic surgery, burns and dental procedures.
   B. Items are considered sterile that have undergone one of several sterilization methods including steam sterilization, gamma radiation or ethylene oxide.
      1. Manufactured items must have sterility status printed on the package and the outer packing must be dry and intact to be considered sterile.
      2. Items that have been processed within the facility must have a positive external and internal chemical indicator reading denoting adequate exposure to sterilization processes.
   C. All facility processed re-useable critical items will be considered unsterile after being packed and moved to another location.
   D. 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.
   E. During missions saturated steam under pressure will be the method of sterilization for re-useable critical items. Single use items should not be sterilized for reuse

III. REQUIREMENTS:

IV. SUPPORTING DOCUMENTS:
   A. Guidelines for Sterilization

V. REFERENCE:
Guidelines for Sterilization

A. Cleaning and decontamination:
   1. Items to be sterilized will be decontaminated in a controlled environment preferably a safe distance from the clean area where instruments are prepared for sterilization. During the cleaning process standard universal precautions will be followed. Personnel will wear appropriate protective attire including unsterile gloves.
   2. Instruments will be cleaned manually to be free of all bioburden by using scrub brushes and a disinfecting solution or instrument cleaner. Chemical disinfectants will be used according to manufacturer’s instructions.
   3. Extra attention will be paid to box locks and hinges as well as serrations within the jaws of the instruments.
   4. Lumens must be flushed with the chemical disinfectant by using a syringe with steady pressure to force out any debris. Follow with a water flush.
   5. Instruments must be inspected for any remaining debris and rinsed well with running water. Care must be taken to avoid splash and reduce aerosols.

B. Preparation for sterilization of unwrapped items:
   1. Items to be sterilized must be able to withstand steam under pressure without being damaged.
   2. All instrument box locks must be opened to allow steam to come in contact with surfaces.
   3. Instruments to be sterilized must be placed in an approved pan with a mesh bottom to allow for steam penetration. All items must be loosely situated to ensure complete steam contact.
   4. No towels, cloth, or paper will be used under or over the instruments during an unwrapped cycle.
   5. A chemical indicator will be placed at the center of the load near the door.

C. Use of table top steam autoclave/sterilizer:(refer to manufacturer instructions)
   1. After loading the sterilizer pull down the vent lever until water appears at the bottom to the sterilizer
   2. Close the door and tighten until secure.
   3. Set the timer for 15 minutes. This allows for a 10 minute exposure time to sterilization parameters of a temperature of 270° F/135°C and a pressure of 30. It takes 5 minutes for the sterilizer to reach these parameters.
   4. Upon completion of the cycle the buzzer will sound. Turn the buzzer slightly to the left until it stops.
   5. Press down the fill/vent lever. Lean away and to the side of the sterilizer to avoid the escape of hot steam.
   6. Once the door pops push the door handle to the right and then pull forward.
   7. The contents will be very hot. Handle with care.
   8. Check the chemical indicator for a positive reading that indicates that all parameters for sterilization have been met.
9. If instruments are to be transferred to the sterile field immediately a sterile towel must be used for the transfer.

10. If there is time for the instruments to cool you may close the door but leave it somewhat ajar so steam and moisture can continue to escape.

   *Note: Individual instruments may be flash sterilized on a 3 minute cycle (exposure time). In this case set the timer for 8 minutes.

D. Preparation of instrument sets for sterilization by the host hospital or Operation Smile nurses:

1. Instruments sets will be prepared for assembly in a clean work area.
2. Individual instruments will be inspected for cleanliness and damage.
3. Instruments sets will be reassembled with a checklist or instrument count sheet.
4. Instrument box locks will be left open to allow steam exposure to all surfaces.
5. A chemical indicator will be placed in the middle of the set.
6. Each set will be double wrapped. Wrap must be of adequate size to completely cover the item to be sterilized and to provide an aseptic field upon opening. If double-bonded wrap is available sets need only be wrapped once.
7. Linen wrap must be freshly laundered to allow the steam to adequately penetrate the fibers. Although the wrap may be clean it cannot be reused without being laundered.
8. Disposable wrap must be specifically designed for sterilization purposes. The material must not hinder the penetration of the steam and should not retain it.
9. The wrap must be durable enough to allow for normal handling in storage and distribution.
10. All wrapped sets will be secured with chemical indicator tape. The tape is labeled to identify the contents.

   *Note: Ensure that the hospital personnel have allowed for proper drying times for wrapped sets. If the wrapped sets are returned and the wrapper is damp the set must be considered unsterile.

E. Wrapping method

1. The diagonal fold method will be used to wrap sets for sterilization.
2. The use of two wrappers applied in a sequential manner will be used.
3. An appropriate size wrapper must be selected to adequately secure the contents. A square wrapper with a 6 inch border around each side will be used.
4. The square wrapper is laid flat in a diagonal fashion so it appears as a diamond. The set is placed in the center facing the user. The corner nearest the user is folded over the item and a small portion of the corner is folded back to form a tab. The tab is useful when opening the package at the time of use.
5. The left corner of the wrapper is folded over the item and a tab is formed.
6. The right corner of the wrapper is folded over the item and a tab is formed.
Guidelines for Sterilization (cont.)

7. The top corner of the wrapper is folded down over the item. The flap is tucked under the right and left folds leaving a small tab visible to aid in opening the package.
8. The second wrapper is folded in the same manner and the chemical indicator tape is applied and labeled appropriately.

F. Preparation of instruments sets for sterilization cases

1. Instruments will be prepared for sterilization according to previously stated approved standards and placed in sterilization cases with a chemical indicator in the middle of the set.
2. Manufacturer approved filter paper will be inserted into the serrated disc holder in the top and bottom of the case.
3. A closure clip will be placed through the lid and cases to ensure the security of the contents.
4. Sterilization cases will be sent to the sterile processing department within the host hospital.
5. Prior to use, on external inspection of the cases the clip will be intact. The clip indicator and the filter paper indicator will be positive.
6. Upon removing the internal rack the internal chemical indicator will be checked prior to the use of the instruments.

REFERENCES:

Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. 2008 Association for the Advancement of Medical Instrumentation (AAMI)
DISPOSAL OF SHARPS

I. POLICY:
   A. 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.

II. PROCEDURE:
   A. Sharps safety:
      1. Where sharps usage is essential, particular care should be exercised in handling and disposal. Sharps should never be left lying around.
      2. Needles, blades and other sharps are to be disposed of in a heavy plastic needle containers or sharps disposal kits provided on missions. At no time are sharp items to be placed in the regular trash as this may result in serious injuries to personnel.
      3. Sharps should be disposed of immediately after use, at the point of use, by the person who carried out the procedure.
      4. Where there are two healthcare workers working together, sharps should not be passed from one person to another. Responsibilities must be clearly defined.
      5. Needles should not be broken or bent prior to use or disposal.
      6. Needles and syringes should not be dismantled by hand before disposal and should be disposed of as a complete unit.
      7. Recapping contaminated needles should be avoided.
         a. Contaminated needles and syringes must be placed in the sharps disposal system immediately after the operation.
         b. If it is necessary to recap the needle, it may be done safely by sliding the used needle into the cap.
         c. Once the needle is safely inside the cap, pull the cap securely over the needle hub by placing the fingers along the side of the cap and pulling down.
         d. Never push the cap on from the end of the cap which is located directly over the hub by pressing the cap against a hard surface while holding the barrel of the syringe.
      8. When loading and/or unloading surgical blades, an instrument such as hemostats should be available rather than using your hands.
         a. When using an instrument, the blade should always be pointed in the downward position to avoid snapping it towards an individual, if you lose control of the instrument or the blade.

   B. Sharps containers should be available at every operating table. Hand held sharps containers are available and may be used as indicated. Sharps containers must not be filled above the 2/3 full marker line.
C. Sharps containers should never be emptied and reused.
D. If a sharps puncture should occur it must be reported to the Clinical Coordinator immediately and a needle-stick report.

III. SUPPORTING DOCUMENTS:
   A. Blood borne Exposure Policy

IV. REFERENCE:
   A. [wl.nhs.uk/.../Safe%20Use%20of%20Sharps](https://wl.nhs.uk/.../Safe%20Use%20of%20Sharps)
MONITORING DURING ANESTHESIA

I. POLICY:
   A. Monitoring of certain fundamental physiological variables during anesthesia is essential. Clinical monitoring by a vigilant anesthesia provider and use of appropriate devices is the basis of safe patient care during the delivery of anesthesia.

II. PROCEDURE:
   A. Circulation must be monitored at frequent and clinically appropriate intervals.
      1. Every patient receiving anesthesia must have noninvasive monitoring equipment for intermittent measurement of electrocardiogram, pulse oximetry, capnography, temperature and blood pressure. The monitoring equipment must be continuously displayed from the beginning of anesthesia until preparing to leave the anesthesia location.
      2. Every patient receiving anesthesia shall have monitor readings evaluated and documented on the anesthesia flowsheet at least every five minutes.
      3. 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.

   B. 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.
      1. 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.
      2. Blood Oxygenation: During administration of general anesthesia, a quantitative method of assessing oxygenation such as pulse oximetry shall be employed. Adequate visualization of the patient is necessary to assess color.

   C. Ventilation must be monitored continuously by both direct and indirect methods.
      1. 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 required.
      2. When inserting an endotracheal tube or laryngeal mask, its correct positioning must be verified by clinical assessment and by identification of carbon dioxide in expired gas.
      3. Continual end-tidal carbon dioxide (ETCO2) analysis, will be performed from the time of endotracheal tube/laryngeal mask placement until extubation or initiating transfer to a post-operative care location. Monitoring shall be performed using a quantitative method such as capnography, capnometry or mass spectroscopy.
MONITORING DURING ANESTHESIA (cont.)

D. Temperature
   1. There shall be readily available a means to continuously measure the patient's temperature.

V. SUPPORTING DOCUMENTS:

VI. REFERENCES:
5. Post-Op
NIGHT NURSING

I. POLICY
   A. Operation Smile (OS) has developed the Night Nursing policy as a means to address the delivery of safe post-operative care on a round the clock basis on all Operation Smile missions.

II. PROTOCOL
   A. Safety requirement – at least (2) nurses assigned for night shift.
   B. Additional night nurses may be required for the following reasons:
      1. Post-Op patients divided on several floors/wards.
      2. Increase in the number of scheduled OR patients.
      3. Increase in the patient acuity.
   C. The work day will be divided into two 12-hour rotations (0700 –1900 and 1900 – 0700).
   D. The Program Coordinator (PC) or In-Country Manager will be responsible for the following:
      1. Hire a security guard or ensure guaranteed safety rounds by hospital security.
      2. Provide food and water access.
      3. Make hotel arrangements for a later breakfast and earlier lunch/dinner.
      4. Secure safe transportation to and from the hospital.
      5. Purchase in-country cell phones to ensure immediate contact with team members at the hotel in the event of an emergent situation.
   E. Prior to the mission, the Clinical Coordinator (CC) will be responsible for the following:
      1. Contact the night nurses (phone/email) and review the Night Nursing policy – responsibilities of position & job description:
         a. Night nurses may need to stay in the hospital the night prior to the first day of surgery.
   F. By the end of the night shift, have the first row of scheduled patients prepared for surgery – gowned, pre-op sticker completed (on the front of the chart) and waiting to be seen by the pediatrician and pre-op nurse.
   G. Provide day shift nurses with report highlighting any changes to status of patients.
   H. Mandatory expectation – to work their shift anytime post-op patients require their expertise. This includes the night of the final party.
   I. Arrangements must be made for shift coverage with the CC and PC, if a night nurse has scheduled an early morning departure for the end of the mission.
      1. During the mission, the CC will be responsible for the following:
         a. Ensure there is patient coverage until night nurses arrive and report is complete.
b. Ensure a detailed call list with phone and hotel room numbers of team leaders, pediatrician and program coordinator is provided.

c. Provide night nurses with daily briefing from morning team meeting and any other significant information.

d. Provide a key for access to the surgical suite.

e. Ensure that adequate supplies are available for patient care for the night shift.

f. Provide translators to remain with the night nurses throughout the entire night.

III. REQUIREMENTS:

A. Night Nurses – International, Regional/Local

1. Must meet Global Standards of Care requirements for volunteer nurses-
   a. Refer to Global Standard #11 (11-5).

2. Must be credentialed through Operation Smile application process.

3. Must have Basic Life Support (BLS) or equivalent.

4. Must have Pediatric Advanced Life Support (PALS) or equivalent, to participate on an International mission.

5. Must meet qualifications for Pre/Post-Op Nurse position.
   a. Pediatric experience – required
   b. Preferred knowledge of post-operative care of patients with cleft lip (CL) and cleft palate (CP) surgery.

6. One nurse must have Operation Smile mission experience (at least 2 missions)

B. Operation Smile Responsibilities-

1. Fact find to determine Local/Regional staffing limitations & qualifications:
   a. Designate the location of Post-Op Ward(s) - single versus several post-op units.
   b. Determine the availability of Local/Regional “credentialed” nurses.
   c. Recognize cultural indicators which would limit participation of local nurses on the night shift such as:
      • No hired or volunteer “in-country” nurses available.
      • Lack of nursing infrastructure to promote education and evaluation.

2. The team composition should reflect the Night Nurse position as separate from the other Pre/Post – Op nursing positions.
   a. See Team Composition Guideline Policy.

III. EDUCATION / ROTATION MISSIONS

A. Education missions where an Operation Smile physician is responsible for surgery, and the nursing team assumes patient care, should include at least (1) OS credentialed nurse plus at least (1) local nurse available for post-op night care

B. Partnership OS missions where the nurse is there as an advisor, consultant or educator, it is not the responsibility of OS to provide night shift nursing coverage.
6. Volunteer Safety and Preparedness
Volunteer Vaccinations

I. Policy:
   A. Vaccination of medical volunteers is essential to the overall health and safety of Operation Smile missions.

II. Procedure:
   A. Prior to the mission, volunteers are required to have all vaccinations current.
      1. Volunteers must carry a copy of their vaccination record and be prepared to present it to immigration officials.
   B. Recommended vaccinations and prophylaxis for regions and areas transited during travel to and from a mission are available from the United States Department of Health and Human Services and the Centers for Disease Control and Prevention.
   C. Volunteers are encouraged to check with their places of employment and travel bureaus for additional information on which vaccinations and medical preparations may be required by the government at their mission site.

III. Supporting Documents:

IV. Reference:
   A. United States Department of Health and Human Services, Centers for Disease Control and Prevention (www.cdc.gov/travel)
CREATING AND DISSEMINATING NEW MEDICAL POLICIES

I. POLICY
   A. All Operation Smile policies and procedures are created by medical leadership, including the Quality Assurance (QA) team, Medical Advisory Council (MAC), Chief Medical Officer (CMO), Associate Chief Medical Officer (ACMO), and SVP of Medical Affairs. Approval of policies is by the Operation Smile Medical Advisory Committee. New or revised policies and procedures are distributed through the following channels:

II. PROCEDURE
   A. Identification of a policy or procedural issue.
      1. Request input from the specialty, or specialties involved.
   B. Submit to medical leadership (RMO’s, CMO, ACMO, Medical Oversight, and QA) proposed recommendations for new or revised policies and procedures.
   C. Quality Assurance is responsible for updating all planning and procedural documents. QA will then disseminate all approved policies and procedures to include the following:
      1. Regional Medical Officers
         a. Reinforce with Team Leaders during calls and on site
      2. Medical Directors of all OS foundations
         a. In-country medical leadership and volunteers
   D. International Programs will distribute to:
      1. Regional Teams (RPDs/RPMs) – Regional Program Directors/Regional Program Managers
         a. Foundation Staff
      2. International Programs managers at headquarters
         a. Operation Smile Program Coordinators

III. SUPPORTING DOCUMENTS:
   A. Process for Creating and Dissemination of New Medical Policies
CREATING AND DISSEMINATING NEW MEDICAL POLICIES

Identification of Issue(s)

Request input from specialities involved

Submit for approval to Medical Leadership
RMO’s, CMO, ACMO
Medical Oversight, Quality Assurance

Once approved – QA’s responsibility for dissemination

Senior Director
Quality Assurance

Regional Medical Officers

Medical Directors
All OS Foundations

Regional Teams
RPD’s/RMP’s

IP Managers at
OS Headquarters

Enforce with Team Leaders during calls and on site

In-country medical leadership and volunteers

Foundation Staff
(EDs and PCs)

OS Program Coordinators

Update all planning and procedural documents
7. Quality Assurance
INCIDENT REPORTING

I. POLICY:
A. To ensure accurate and timely reporting of serious medical events or complication to Operation Smile leadership. To include:

   1. Regional Medical Officers (RMO’s), SVP of Medical Affairs, Associate Chief Medical Officer (ACMO), Chief Medical Officer (CMO), Quality Assurance Senior Director.

II. PROCEDURE: All complications / incidents will be defined as either RED, AMBER or GREEN.
A. MANAGEMENT OF COMPLICATION / INCIDENT – RED
   1. Immediate priority is the medical management of the incident.
   2. Follow the Crisis Communication Plan which includes an accurate account of the incident recorded on the Medical Incident Report form from the clinicians involved. The account should contain:
      a. Patient observations including events leading up to the incident, hemodynamic and respiratory changes, medications administered, other interventions made, reasons for interventions, etc.
      b. Surgical procedures performed.
   3. If the critical incident progresses into a “code” situation, documentation on Code Arrest Flow Sheet must be completed.
   4. A meeting should occur as soon as possible after the incident and should include individuals involved in the incident, team leaders and Country Manager. The Field Medical Director (FMD) will moderate the meeting and the Program Coordinator (PC) will record the minutes of the meeting. The purpose of the meeting is to:
      a. Determine the most probable cause of the incident.
      b. Discuss management of events during incident.
      c. Obtain necessary information to complete the Operation Smile incident report which must be completed immediately after the meeting. The report must be signed by all team leaders.
      d. Create plan for ongoing patient management.
      e. Create plan for promptly debriefing patient’s family and hospital administrators. The plan must be approved by the RMO and in-country Medical Director prior to the debriefing.
      f. Create plan for debriefing of entire team.
   5. Regional Medical Officer must be notified immediately who will in turn notify the Chief Medical Officer, Associate Chief Medical Officer and Senior Vice President (SVP) of Medical Affairs.
INCIDENT REPORTING (cont.)

6. The following information pertaining to critical incidents must be emailed immediately to the Associate Vice President (AVP) of International Programs and Senior Director of Quality Assurance.
   a. Medical Incident Report
   b. A copy of the patient’s Operation Smile’s medical record and local hospital record, if requested.
   c. Minutes from the meeting leader noted above.
7. Ensure the Country Manager is aware of the incident and has been sent a copy of the meeting minutes if unable to attend.
8. The RMO, CMO, ACMO and SVP of Medical Affairs will confer and a representative from that group will contact the Field Medical Director to discuss the event, any further action required, and to discuss the plan for debriefing the patient’s family and hospital administrators.
9. On return to Operation Smile Headquarters, the Program Coordinator will give the SVP of Medical Affairs and Quality Assurance a copy of the medical incident report and a complete copy of the patient’s records.
10. The evaluation of RED incidents by the QA committee will be included in the monthly MOC report generated by the Senior Director of Quality Assurance, and in a report to the CMO, ACMO and SVP of Medical Affairs.

B. MANAGEMENT OF COMPLICATION / INCIDENT – AMBER

1. Immediate priority is the medical management of the incident.

2. An accurate account of the incident should be recorded by the clinician who was involved. See Medical Incident Report form. The account should include:
   a. Patient observations including: events leading up to the incident, hemodynamic and respiratory changes, medications administered, other interventions made, reasons for interventions, etc.
   b. Surgical procedures performed.

3. Regional Medical Officer must be notified immediately who will in turn notify the Chief Medical Officer, Associate Chief Medical Officer and Senior Vice President (SVP) of Medical Affairs.

4. The following information pertaining to critical incidents must be emailed immediately to the Associate Vice President (AVP) of International Programs and Senior Director of Quality Assurance.
   a. Medical Incident Report
   b. A copy of the patient’s Operation Smile medical record and local hospital, if requested.

5. The RMO, CMO, ACMO and SVP of Medical Affairs will confer and a representative from that group will contact the Field Medical Director to discuss the event and any further action required.
6. On return to Operation Smile Headquarters, the Program Coordinator will give the SVP of Medical Affairs and Quality Assurance a copy of the medical incident report and a complete copy of the patient’s records.

7. The evaluation of AMBER incidents by the QA committee will be included in the monthly MOC report generated by the Senior Director of Quality Assurance, and in a report to the CMO, ACMO and SVP of Medical Affairs.

C. MANAGEMENT OF COMPLICATION / INCIDENT – GREEN

1. The immediate priority is the management of the patient.
2. An accurate account of the incident should be recorded by the clinician who was involved. See Medical Incident Report form. The account should include:
   a. Patient observations including: events leading up to the incident, hemodynamic and respiratory changes, medications administered, other interventions made, reasons for interventions, etc.
   b. Surgical procedures performed.
3. Within 24 hours of return to the local foundation or Operation Smile headquarters, the Program Coordinator will ensure that the medical incident reports and any other pertinent documents are given to the Senior Director of Quality Assurance.
4. A review of the incident and any data collection obtained will be collated and submitted in a quarterly Medical Oversight Committee (MOC) report.

D. DATA COLLECTION

1. A Quality Assurance panel comprised of the Senior Director, QA (nurse), Director, QA (plastic surgeon), and two anesthesiologists. One anesthesiologist will always be the chairperson of the panel.
2. Initial incident reports are sent directly to the Senior Director, QA
   a. Incident report is then forwarded to the QA individual on the panel representing his/her specialty with the responsibility to gather additional information, if necessary. After investigation of circumstances, reports will be forward to the QA panel chairperson.
   b. Recommendations will be forwarded to the SVP of Medical Affairs.
3. The Chief Medical Officer, Associate Chief Medical Officer, SVP of Medical Affairs and specialty council chairpersons (as needed) will review the case and take appropriate action.
4. Medical incidents and patient complications will be discussed at
   a. Monthly Morbidity and Mortality meeting at Operation Smile headquarters.
   c. Minutes will be recorded to include conclusions and actions decided upon by the Medical Team.

E. PLEASE NOTE: All post-surgery complications (infection, wound dehiscence) are reportable medical incidents which can be found on the Postop Complication form.
INCIDENT REPORTING (cont.)

III. SUPPORTING DOCUMENTS:
   A. Operation Smile Incident Report form
   B. Code Arrest Flow Sheet

IV. REFERENCE:
   B. Haines, A. Kuruvilla, S, Borchert, M, Special Theme-Bridging the Know-Do Gap in Global Health, Implementing evidence in clinical practice, Policy and Practice, August 2004; 274-733
# Data Collection for Incident Report

<table>
<thead>
<tr>
<th>RED</th>
<th>AMBER</th>
<th>GREEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Immediately</td>
<td>Report Immediately</td>
<td>Report within 24 hrs. of return to local foundation or Operation Smile headquarters</td>
</tr>
<tr>
<td>QA panel will initiate a review of the incident within 72 hours</td>
<td>QA panel will initiate a review of the incident within 7 days</td>
<td>QA must discussed on a quarterly basis</td>
</tr>
<tr>
<td>Most serious adverse events</td>
<td>Serious adverse events leading to actual or possible harm</td>
<td>Adverse events less likely to result in harm</td>
</tr>
</tbody>
</table>

**CHECK ALL BOXES THAT APPLY TO THE INCIDENT, NOT JUST ONE BOX**

- Death
- Cardiac arrest
- Unplanned ICU admission (or equivalent)
- Critical care provided in PACU overnight
- Malignant hyperthermia
- Myocardial infarction
- Incorrect site or procedure
- Respiratory arrest outside of OR
- New stroke
- Incorrect patient in OR
- Other, specify

- Unplanned return to the OR
- Pneumothorax
- Aspiration
- Pulmonary edema
- Critical care provided in PACU for 4+ hours
- Medication error resulting in consequence to the patient
- Anaphylaxis
- Local anesthetic systemic toxicity
- Unanticipated transfusion
- Transfusion reaction
- Case cancelled after induction
- Retained throat pack
- Position injury
- Fall from OR table
- Surgical fire
- Burn injury caused by medical equipment
- Equipment problem during patient care causing patient harm
- New peripheral neurological deficit postoperatively
- High spinal
- Patient reports awareness / recall during anesthesia
- Bronchospasm requiring treatment
- Inability to secure airway
- Unplanned re-intubation
- Unanticipated difficult airway
- Unplanned respiratory arrest in OR
- Laryngospasm requiring neuromuscular blockade treatment
- New PVC’s, bradycardia, atrial fibrillation, or other dysrythmias requiring unanticipated treatment
- Myocardial ischemia (not infarction)
- Hypotension requiring unanticipated treatment with a continuous pressor infusion
- Inability to reverse neuromuscular blockers (NMB)
- Unanticipated medication reaction (not anaphylaxis)
- Medication error without consequence to the patient
- Use of sedation/narcotic reversal agents
- Failed regional block
- Unintended dural puncture
- Seizure
- Equipment problem during patient care causing potential but not actual patient harm
- Unplanned patient admission
- Abnormal blood sugar requiring treatment.
## Incident Reporting Form

**Operation Smile**

**Cleft Lip & Palate Mission**

**Incident Report**

<table>
<thead>
<tr>
<th>Incident Reporting Form</th>
<th>PATIENT FAMILY / LAST NAME</th>
<th>DATE:</th>
<th>CHART NUMBER:</th>
</tr>
</thead>
<tbody>
<tr>
<td>PATIENT FIRST NAME</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>COUNTRY/SITE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOCAL CHART NUMBER</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BIRTHDATE:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AGE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SEX M F</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SURGERY DATE:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WEIGHT:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HEIGHT:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>COMPLETED PROCEDURE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LIP NOSE PALATE FISTULA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OTHER</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ORIGINAL OPERATING SURGEON:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRIORITY:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ANESTHESIOLOGIST:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SURGERY TIME:</td>
<td></td>
<td>MIN</td>
<td></td>
</tr>
<tr>
<td>ANESTHESIA TYPE:</td>
<td></td>
<td>GENERAL</td>
<td>MAC</td>
</tr>
<tr>
<td>ASA I II III IV E</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NGO PROVIDER CARE MODEL:</td>
<td></td>
<td>MD</td>
<td>MD-CRNAA</td>
</tr>
<tr>
<td>LOCAL PROVIDER INVOLVEMENT IN CARE:</td>
<td></td>
<td>NONE</td>
<td>MD-ANESTHETIST</td>
</tr>
<tr>
<td>ANY SERIOUS INCIDENT REQUIRES IMMEDIATE NOTIFICATION OF REGIONAL MEDICAL OFFICER</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HOSPITAL</td>
<td></td>
<td>OR</td>
<td>PACU</td>
</tr>
<tr>
<td>LOCATION OF INCIDENT:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RED</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AMBER</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GREEN</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>REPORT IMMEDIATELY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>INVOLVES DEATH/PHYSICAL HARM</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>REPORT IMMEDIATELY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>THREATENS WELL BEING/COMPELLING LESSONS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>REPORT FOLLOWING THE CLOSE OF MISSION ROUTINE COMPLICATION/INCIDENTS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RED</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DEATH</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CARDIAC ARREST</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNPLANNED ICU ADMISSION (OR EQUIVALENT)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CRITICAL CARE PROVIDED IN PACU OVERNIGHT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MALIGNANT HYPERTERMIA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MYOCARDIAL INFARCTION</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>INCORRECT SITE OR PROCEDURE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RESPIRATORY ARREST (NOT IN OR)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NEW STROKE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>INCORRECT PATIENT (IN OR)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OTHER, SPECIFY:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNPLANNED RETURN TO OR</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PNEUMOTHORAX</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASPIRATION</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PULMONARY EDEMA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CRITICAL CARE PROVIDED IN PACU FOR 4+ HOURS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEDICATION ERROR RESULTING IN CONSEQUENCE TO PATIENT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ANAPHYLAXIS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOCAL ANESTHETIC SYSTEMIC TOXICITY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNANTICIPATED TRANSFUSION</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TRANSFUSION REACTION</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CASE CANCELLED(AFTER INDUCTION)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RETAINED THROAT PACK</td>
<td></td>
<td></td>
<td>ME\n\n\n</td>
</tr>
<tr>
<td>FALL FROM OR TABLE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SURGICAL FIRE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BURN INJURY CAUSED BY MED. EQPT.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EQUIPMENT PROBLEM DURING PATIENT CARE CAUSING PATIENT HARM</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NEW PERIPHERAL NEUROLOGIC DEFICIT POSTOPERATIVELY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIGH SPINAL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PATIENT REPORTS AWARENESS/RECALL DURING ANESTHESIA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BRONCHOSPASM REQUIRING Rx</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>INABILITY TO SECURE AIRWAY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNPLANNED RE-INTUBATION</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNANTICIPATED DIFFICULT AIRWAY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNPLANNED RESPIRATORY ARREST (IN OR)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LARYNGOSPASM REQUIRING NEUROMUSCULAR BLOCKADE Rx</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NEW PVCs, BRADYCARDIA, ATRIAL FIBRILLATION, OR OTHER DYSRHYTHMIAS REQUIRING UNANTICIPATED Rx</td>
<td></td>
<td></td>
<td>ME\n\n\n</td>
</tr>
<tr>
<td>HYPOTENSION REQUIRING UNANTICIPATED Rx WITH A CONTINUOUS PRESSOR INFUSION</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>INABILITY TO REVERSE NMB</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNANTICIPATED MEDICATION REACTION (NOT ANAPHYLAXIS)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEDICATION ERROR WITHOUT CONSEQUENCE TO PATIENT</td>
<td></td>
<td></td>
<td>ME\n\n\n</td>
</tr>
<tr>
<td>FAILED REGIONAL BLOCK</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNINTENDED DURAL PUNCTURE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SEIZURE</td>
<td></td>
<td></td>
<td>ME\n\n\n</td>
</tr>
<tr>
<td>UNPLANNED PATIENT ADMISSION</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| ABNORMAL BLOOD SUGAR LEVEL REQUIRING Rx |                       |       | ME\n\n**Page 1**

**Operation Smile Inc.**

**3641 Facility Boulevard, Virginia Beach, Virginia 23453, United States**

**Updated June 2014**

**Incident Report**
# CODE ARREST FLOWSHEET

<table>
<thead>
<tr>
<th>Witnessed</th>
<th>Unwitnessed</th>
<th>Center Chart #</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Last/Family/Surname</td>
</tr>
<tr>
<td>Etiology</td>
<td></td>
<td>First/Given Name</td>
</tr>
<tr>
<td>Cardiac</td>
<td>Respiratory</td>
<td>Age</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td>Weight</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date:</th>
<th>Location:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Time Code</th>
<th>Time Code Terminated</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Survived</th>
<th>Expired</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Time</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Chest Compression</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Yes X Terminated</td>
</tr>
<tr>
<td>O Stopped for Rhythm check</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ventilation</th>
</tr>
</thead>
<tbody>
<tr>
<td>M Mask ET Intubation S Spontaneous AM Ambu AS Assisted V Vent Settings</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pulse (if spontaneous, write value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>O Absent XO Present with CPR X Spontaneous Pulse</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Blood Pressure (if present, write value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>O Absent A Present Audibly/Palpation P Present</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cardiac Rhythm (attach strip)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VF V Fib VT V Tach Asys Asystole</td>
</tr>
<tr>
<td>B Bradycardia SVR Supraventricular Tach O Other</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Defibrillation (Joules)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Cardioversion (Joules)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>External Pacing (Rate)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Medications Write I.V.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adrenaline Atropine Lidocaine</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Strength/dosages</th>
</tr>
</thead>
</table>

| PHYSICIAN NOTIFIED (note: name / time) |
| CODE TEAM (Full Name) |
| Time Notified |

| TIME OF CALL FOR AMBULANCE |
| MD in Charge |

| TIME OF TRANSFER |
| RN |

| CONDITION AT TRANSFER |
| RN |

| DESTINATION |
| Other |

<table>
<thead>
<tr>
<th>Recorder Signature</th>
<th>Assigned Nurse Signature</th>
<th>Lead</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Other</td>
</tr>
<tr>
<td>Last/Family/Surname</td>
<td>First/Given Name</td>
<td>Center Chart #</td>
</tr>
<tr>
<td>---------------------</td>
<td>------------------</td>
<td>----------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(Continued from front) Time:

| Chest Compression | ✓ Yes ✗ Terminated | O= Stopped for Rhythm check |

| Ventilation | M= Mask ET= Intubation S= Spontaneous AM=Ambu AS=Assisted V=Vent Settings |

| Pulse (if spontaneous, write value) | O= Absent XO Present with CPR X= Spontaneous Pulse |

| Blood Pressure (if present, write value) | O= Absent A= Present Audibly/Palpation P=Present |

| Cardiac Rhythm (attach strip) | VF= V. Fib VT= V. Tach Asys= Asystole B= Bradycardia SVR= Supraventricular Tach O= Other |

| Defibrillation (Joules) | Cardioversion (Joules) |

| External Pacing (Rate) |

<table>
<thead>
<tr>
<th>I.V.</th>
<th>Site</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>#2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medications - Write Strength / Dosages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adrenaline</td>
</tr>
<tr>
<td>Atropine</td>
</tr>
<tr>
<td>Lidocaine</td>
</tr>
</tbody>
</table>

Summary of Event

Date & Sign