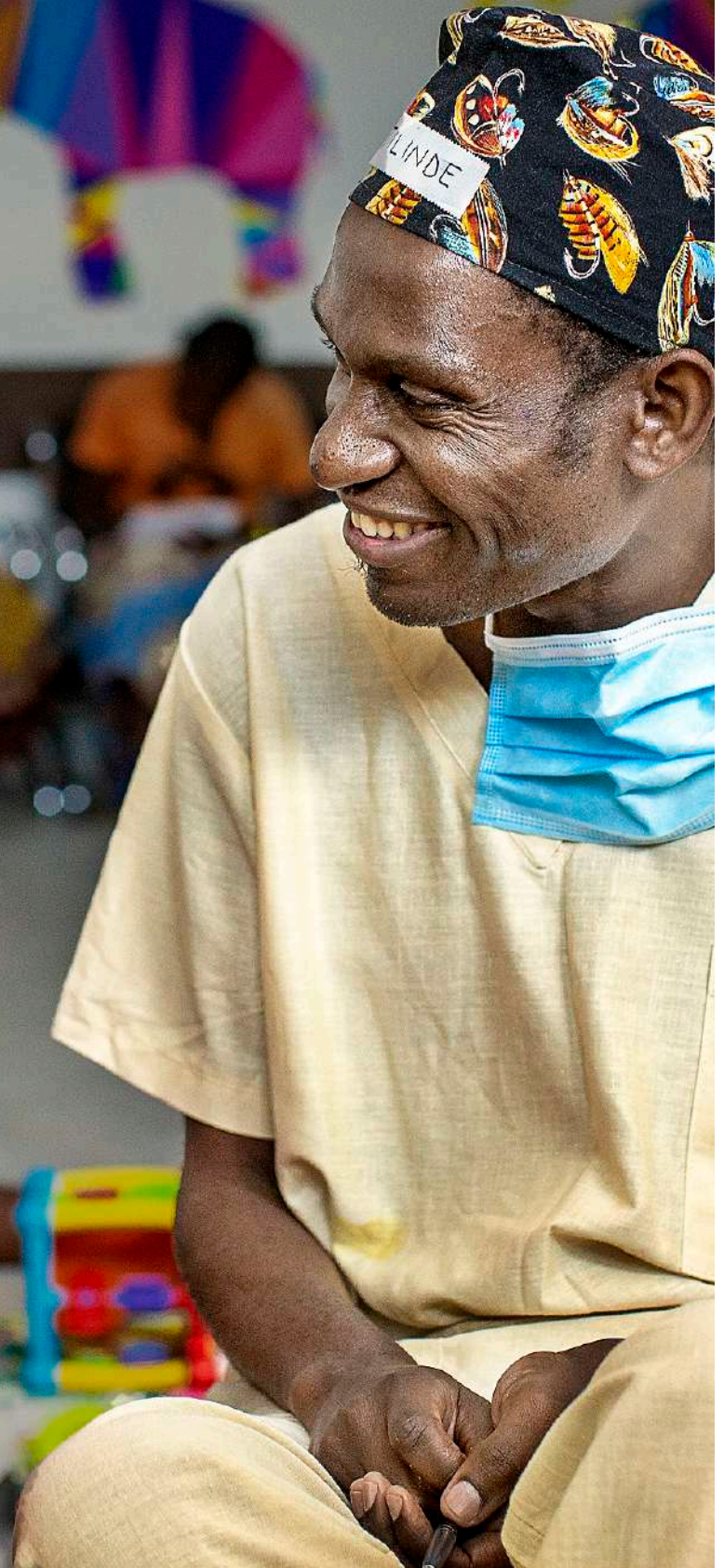


MEDICAL GLOBAL STANDARDS 2020

Operation  Smile



These Global Standards represent the efforts of our dedicated volunteers and staff. We would appreciate requests to use these materials. For permission to use the materials please contact Operation Smile's Medical Oversight Department.

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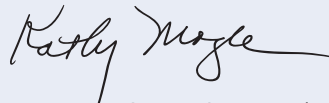
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INTRODUCTION

“ For almost 40 years, Operation Smile has provided care to hundreds of thousands of patients born with cleft lip, cleft palate, or other facial differences. Operation Smile’s global network of patients, families, staff, donors, and volunteers has extended to more than 80 countries where it provides services, raises funds, and recruits volunteers. This global network is the source of strength and fuel which enables Operation Smile’s work. ”



Bill Magee Jr., D.D.S., M.D.
Operation Smile
Co-Founder and CEO



Kathy Magee, B.S.N., M.S.W., M.Ed.
Operation Smile
Co-Founder and President

Today, Operation Smile believes the volume of patients who require cleft and essential surgical care is very large and growing. Current health systems are not setup to provide all the care required and the unmet need is so large that traditional services will never be enough to reach all patients. Addressing the entirety of the problem will require an increase in programs and operations, plus a disruptive level of innovation.

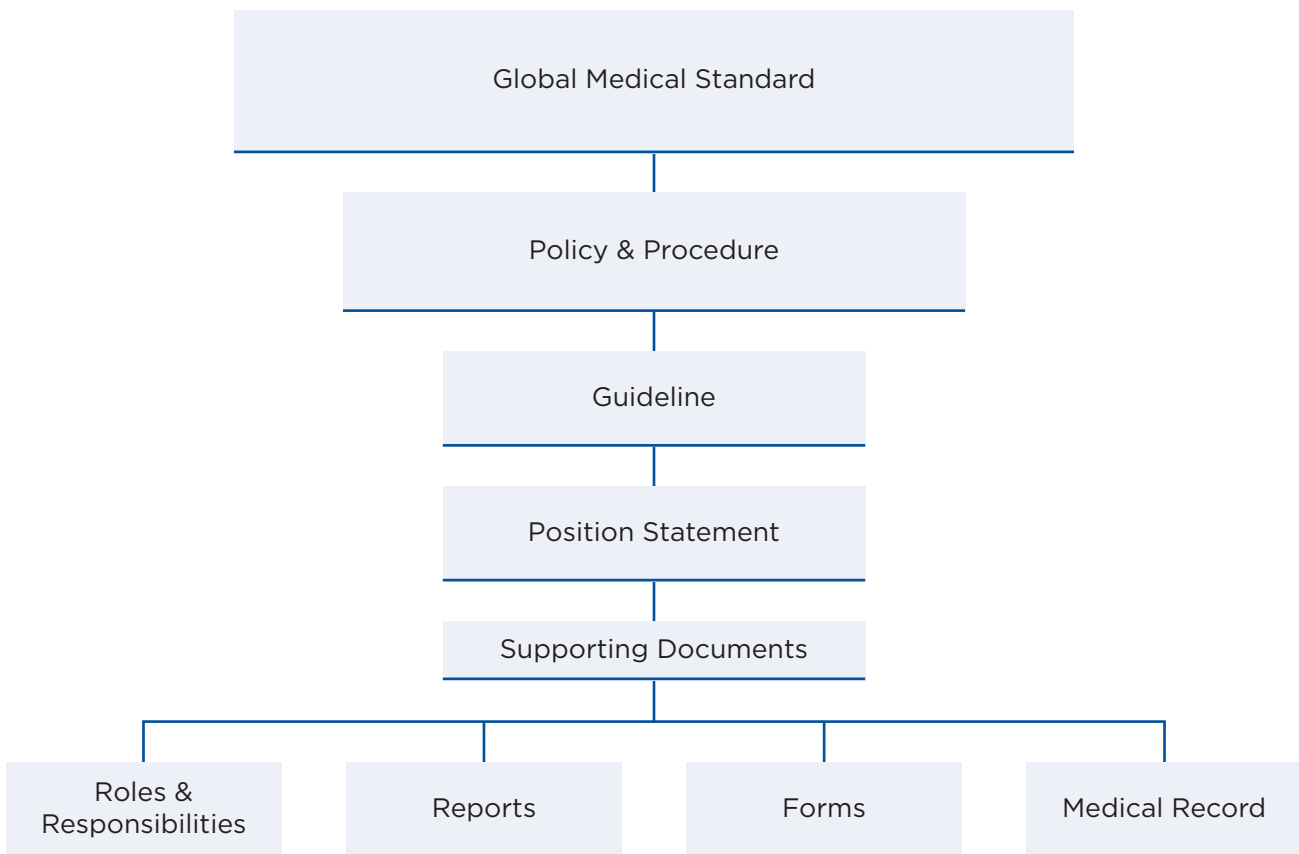
Operation Smile’s Medical Global Standards are a critical pillar in our response to the needs of patients, and to the requirements of innovation and health systems strengthening. The 2020 standards reflect the diversity of care delivery and capacity building programs our community of professionals have developed and implemented in the communities where we work. We continue to place emphasis on the expansion of safe, effective, and timely care. Our primary focus is always on patients, whose integration into family and societies is enabled through the inclusion of multiple disciplines working together in their care.

The 2020 standards are supported by medical policies and procedures developed, reviewed, refined, and approved by the Operation Smile Medical Oversight team. Operation Smile’s Medical Global Standards embody the commitment of our global family to levels of performance in care that can be consistently and uniformly expected by all patients, volunteers, staff, and supporters in all Operation Smile Programs.

Our sincere recognition and thanks to the creators and pioneers of the first Global Standards of Care developed in 2006/2007, revised in 2010 and 2014. The Medical Global Standards 2020 continue to build on the early efforts to ensure safe, high quality, efficient care to every Operation Smile patient worldwide.

We extend our eternal gratitude to all who participated in the creation and updating of Operation Smile’s Medical Global Standards 2020. We know that this is much more than a medical exercise; it represents your pledge to our patients’ safety and wellbeing. Adhering to the 2020 standards is how we honor all who support us and believe children should receive excellent care, no matter how much money they have or where they are born.

ORGANIZATION HIERARCHY OF DOCUMENTS



GOVERNANCE OF MEDICAL DOCUMENTS

The Operation Smile Medical Oversight Team is tasked with maintaining the integrity over medical standards, policies, procedures, guidelines, and position statements. These documents are created with input from medical leaders representing Operation Smile partner and program countries.

Medical Oversight documents adhere to Operation Smile Inc.'s operational guidelines.

Operation Smile's medical standards, policies, procedures, guidelines, and position statements provide the framework for all care delivery.

We understand as programs grow, local regulations change, and healthcare systems are strengthened there may be legitimate reasons to localize or vary from the current organizational medical documents. Should a deviation be needed, a foundation should submit their proposed variation for joint review with the Medical Oversight Team.

Medical Global Standard 1 – Facility

Approval Date: June 26, 2020	Replaces: 2015 GS 4-6,16
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All facilities used for an Operation Smile program should be verified safe and appropriate for the intended use.

1.1 Patient Lodging

A facility may be made available by the local foundation to temporarily house patients. Safety and medical considerations should be adhered to when choosing and augmenting a facility for these purposes. Communication between shelter staff and the medical team leadership is essential to successful care delivery.

1.2 Fact Find: Facility Assessment

A proper site assessment should be performed and approved by the Operation Smile Quality Team prior to patient care or as part of periodic reviews of centers which should occur no less frequently than every 2 years. Facility assessments should be completed by a program coordinator accompanied the following credentialed volunteers:

- Anesthesiologist
- Biomedical Technician
- Clinical Coordinator (recommended)



1.3 Patient Screening

A safe and appropriate facility for patient screening should include:

- Adequate physical space and setup that allows controlled patient flow.
- Adequate lighting, electrical outlets, and furniture.
- Quiet screening areas for those who must perform pulmonary and cardiac auscultation, speech assessment and those who need to communicate sensitive information.

1.4 Surgical Environment

A safe and appropriate facility for delivery of surgical care should include:

- A clean environment with washrooms and toilets in all patient care areas.
- A consistently adequate supply of water and electricity, including a backup electrical generator or other power source that allows a safe plan for completing any surgery that is ongoing at the time of a power outage.
- A supply of oxygen that is reliable and enough for the planned surgeries.
- Adequate lighting, electrical outlets, furniture (including beds), and physical space in all patient care areas.
- A post-anesthesia care unit (PACU) that has adequate space and proximity to operating rooms (ORs) and ward, so that safe transportation can occur from the ORs to the PACU, and from the PACU to the post-operative ward.
- Adequate space to set up instrument cleaning and sterilization adjacent to the ORs.
- A designated emergency bed space on the post-operative ward, only to be used for patients who need monitoring and/or emergency care.
- Adequate physical space for Speech, Psychosocial, Dental, Biomedical, Patient Imaging, and other ancillary services.
- Dedicated space for biomedical waste as stated in the policy.
- Secure, environmentally controlled space for storage of equipment, pharmaceuticals, and consumables.
- Support services:
 - Laboratory available 24/7 (or point-of-care device available and capable of supplying the same)
 - Blood access 24/7
 - Radiology service able to perform a chest-x-ray 24/7
 - Intensive care unit (ICU) in the hospital or, if nearby, plans in place for stabilization and transportation to that ICU.
 - Cardiology services including ECG and ultrasound (recommended)

1.5 Non-Surgical Facility

A safe and appropriate center that provides consultations and/or procedures without general anesthesia or monitored anesthesia should include:

- Physical area with adequate space and controlled patient flow to achieve objective.
- A stable supply of water and electricity.
- Adequate lighting, electrical outlets, and furniture.
- Quiet screening space for those who must perform pulmonary and cardiac auscultation, speech assessment and those who need to communicate sensitive information.
- Dedicated space for biomedical waste as stated in the policy.
- Secure environmentally controlled space for storage of equipment, pharmaceuticals, and consumables.

Supporting Operation Smile Standard 1 – Policies & Procedures:

1. Fact Find Policy



Supporting Operation Smile Standard 1 – Forms

1. Fact-Find Form
2. Rapid Fact-Find Form
3. Dental Fact-Find Form
4. Center Fact-Find Form

Supporting Operation Smile Standard 1 – References

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Medical Global Standard 2 – Team

Approval Date: June 26, 2020	Replaces: 2015 GS-11, 12
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Last Review Date: 2015	Review Schedule: 4 years

Operation Smile offers a multidisciplinary team approach to the care of all patients. In order to deliver safe, optimal care, different variables including patient population characteristics, care-provider qualifications, location, equipment, and local healthcare infrastructure should be considered when staffing teams.

2.1 Fact Find: Team Assessment

During a Fact Find Assessment, it is important to verify the human resources available to assist in the care of Operation Smile patients. The assessment of hospital resources should be performed prior to care delivery and/or as part of periodic reviews of centers. These support resources should also be discussed with hospital and department leadership in advance of any short-term program taking place, or on an as-needed basis for an on-going program format such as a center or clinic. Specific areas/human resources to confirm include:

- Intensive Care Unit staffing
- General patient care staffing
- Operating Room staffing



2.2 Team Members

Each team should consist of medical professionals and others practicing in the following disciplines:

Cleft Surgical Care

- Surgery
- Anesthesia
- Nursing
- Post Anesthesia Care
- Pediatrics
- Dentistry
- Medical Records
- Patient Imaging
- Biomedical
- Speech
- Psychosocial

The care team can be further enhanced by the inclusion of the following specialty providers:

- Ear, Nose & Throat specialist
- Audiologist
- Orthodontist
- Nutrition Specialist
- Geneticist

Non-Cleft Surgical Care

Operation Smile's safe surgical delivery platform has offered opportunities for addressing surgical needs other than cleft lip and cleft palates. Operation Smile may partner with other organizations to enhance surgical care opportunities.

Operation Smile requires its partners who are administering surgical care in conjunction with Operation Smile to adhere to the current Operation Smile's Medical Global Standards while acknowledging and adhering to partner standards and practices as agreed upon in organizational agreements or memorandums of understanding. All volunteers from other organizations functioning on Operation Smile programs must meet the same Operation Smile competency and review requirements.

Additional partnership staffing and positions may be considered and approved on a case by case basis by Medical Oversight and Volunteer Management.

Operation Smile educational programs such as visiting professorships and/or educational rotations typically take place within a host's home hospital environment and may involve non-cleft surgical, anesthetic, critical, and general care. Those educational programs may adhere to hospital practice standards rather than Operation Smile standards in order to optimize teaching.

Non-Surgical Care

Additional services, such as consultations, therapy, orthodontic, and other procedures should be staffed according to the patient services provided.

2.3 Team Leaders

Medical Programs

Medical Specialty Team Leaders should be assigned for all short-term surgical programs, including:

- Surgery Team Leader
- Anesthesia Team Leader
- Clinical Coordinator (nursing leader)
- Post Anesthesia Care Unit (PACU) Physician
- Pediatrician

Medical Specialty Team leaders should be assigned in consultation with Medical Oversight and Regional Medical Officers based on Operation Smile experience, previous training, or experience as a team leader and overall practice experience. Anesthesia team leaders will be physician anesthesiologists.

Centers and Non-Cleft Programs

Specialty Team Leaders should be assigned based on center services and program needs.

2.4 Staffing

Operation Smile programs, which could include short-term cleft, dental, and/or orthognathic surgery programs, and center activity should be staffed according to minimum requirements below:

All positions listed below will be filled by Operation Smile credentialed volunteers.

- Cleft Surgeons: 1 cleft surgeon for each general anesthesia table and 1 for each local anesthesia table, plus at least 1 additional float surgeon (no more than 5 surgical tables to be covered by 1 float surgeon). Surgery team leader is included in the ratio above.
- Physician Anesthesiologists and Non-Physician Anesthesia Providers: 1 physician or non-physician anesthesia providers for each general anesthesia table and 1 for each local anesthesia table whenever sedation is planned, plus at least 1 additional float physician anesthesiologist (no more than 5 surgical tables to be covered by 1 floater). The anesthesia team leader is included in the ratio above and should be the float physician anesthesiologist.
 - Minimum of 1 physician pediatric anesthesiologist for each team; additional pediatric anesthesiologists or physician anesthesiologists who regularly care for infants may be needed whenever there are plans to operate on large numbers of infants.
 - No more than 2 total non-physician anesthesia providers plus first-time Operation Smile physician anesthesiologists per team providing anesthesia at any point in time.
 - Supervision ratio is 1 physician anesthesiologist to 2 non-physician anesthesia providers/first-time Operation Smile physician anesthesiologist. The supervising physician anesthesiologist may be the float physician anesthesiologist or another physician anesthesiologist who is available to circulate and is not concurrently providing anesthesia.

- Post Anesthesia Care Unit Physician: 1 Post Anesthesia Care Unit physician for 5 surgical tables or less. Additional staffing may be required for 6 or more surgical tables.
- Pediatrician: 1 pediatrician for 5 surgical tables or less. Additional staffing may be required for 6 or more surgical tables.
- Clinical Coordinator (CC): At least 1 clinical coordinator per team; increased number may be required for special programs.
- Surgical Circulating Nurse: 1 nurse per operating room. If more than 2 surgical tables in a room, 1 nurse per two surgical tables.
- Surgical Scrub Personnel: 1 per surgical table.
- Post Anesthesia Care Unit Nurse: 1 nurse per 1.5 surgical tables.
- Pre/Post-Operative Day-Shift Nurses: Minimum of 2 nurses for 1-2 surgical tables, 3 nurses for 3 surgical tables, 4 nurses for 4-5 surgical tables, 5 nurses for 6-7 surgical tables.
- Pre/Post-Operative Night-Shift Nurses: Minimum of 2 nurses for up to 3 surgical tables, 3 nurses for 4-6 surgical tables; 4 nurses for 7 surgical tables.
- Psychosocial Provider: Minimum of 1 per team; 2 recommended when when 4 surgical tables or more.
- Speech Language Pathology Provider:
 - 2 speech providers on surgical programs with 4 surgical tables or more and/or programs with projection of high volume of secondary palate repairs.
 - One of the speech providers should be a credentialed speech language pathologist.
 - 1 speech provider for centers and programs with 3 surgical tables or less.
 - If there is only 1 speech provider on a surgical program, it should be a credentialed speech language pathologist.
 - 1 credentialed speech language pathologist for education programs/rotations when applicable.
- Dental Provider: Minimum of 1 dental provider with maxillofacial prosthesis and pre-surgical molding experience; addition of 1 dental provider recommended for 7 surgical tables or more.
- Biomedical Technician: Minimum of 1 biomedical technician per program, with no more than 6 surgical tables per biomedical technician.
- Medical Records: Minimum of 1 trained medical records volunteer to manage the medical records for 1 – 2 surgical tables, 2 trained medical records volunteers (1 may be an assistant) for 3 – 4 surgical tables, and 3 trained medical records volunteers (1 or 2 may be assistants) for 5 or more surgical tables.
 - If an electronic system is being used, at least 1 medical records volunteer trained to use the electronic system should be on the team or the use of the electronic system may need to be omitted.
- Patient Imaging Technician: Minimum of 1 trained patient imaging technician for 1-2 surgical tables, 2 trained patient imaging technicians for 3- 5 surgical tables, 3 trained patient imaging technicians for 6 or more surgical tables.

Operation Smile carries out a variety of care delivery and education/training programs. Staffing standards may be adjusted to match programmatic needs with the prior approval of the Regional Medical Officer and/or Medical Oversight.

2.5 Team Qualifications

Medical volunteers with Operation Smile will provide evidence as defined by Medical Oversight Policy of the following:

- Graduation from an academic or training program.
- Certification and/or licensure as required by specialty practice in home country.
- Current professional experience as defined by specialty.
- Demonstrated expertise in specialty.
- Life support certification if applicable.

All medical and non-medical volunteers must remain current and in good standing according to specialty qualifications and volunteer management.

Supporting Operation Smile Standard 2 - Policies & Procedures:

1. Volunteer Qualifications Policy
2. Staffing Policy



Supporting Operation Smile Standard 2 – Forms

1. Skills Evaluation Form
2. Team Leader Evaluation of Team Leaders Form
3. Team Leader Evaluation of Team Members Form
4. Team Leader Evaluation of Program Form

Supporting Operation Smile Standard 2 – References

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Medical Global Standard 3 – Equipment, Supplies, and Pharmaceuticals

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Last Review Date: 2015	Review Schedule: 4 years

All Operation Smile surgical and non-surgical services should have an equipment and supply management program to promote the availability and integrity of equipment, supplies, and pharmaceuticals. The organization endeavors to strengthen medical supply management.

3.1 Fact Find: Equipment, Supplies, and Pharmaceuticals Assessment

As part of the Fact Find, an equipment, supply, and pharmaceutical assessment should be performed and approved by the Operation Smile Quality Team prior to patient care or as part of periodic reviews of centers which should occur no less frequently than every 2 years.

Pharmaceuticals and supplies will be available in enough quantity and age appropriate sizes for patient objectives.



3.2 Integrity of Equipment, Supplies and Pharmaceuticals

Operation Smile strives to promote the integrity of equipment, supplies, and pharmaceuticals for the benefit of enhancing safety and quality patient care by:

- Enhanced awareness of the threats posed by substandard, falsified, and counterfeit medical products.
- Sourcing pharmaceutical supplies and medical equipment from reputable manufacturers and distributors.
- Enhanced deterrence of substandard, falsified, and counterfeit medical products by maintaining awareness of the supply chain, and by requesting distributors to provide information on immediate sources of these products.
- Partaking in pharmacovigilance efforts to detect, assess, understand, and prevent adverse effects.
- Promptly responding to recalls and notifying Operation Smile’s Quality Department of proper disposal of substances and/or supplies and disposition of devices in question.
- Storing and managing equipment, supplies, and pharmaceuticals in accordance with the product labels/packaging.

3.3 Screening – Equipment, Supplies, and Pharmaceuticals

Preparation for screening of patients should include the following:

- Equipment for the psychological preparation of the patient and family.
- Equipment and consumables for medical screening and patient assessment.
- Equipment for measuring vital signs, oxygen saturation, weight, and height.
- Equipment for recording medical histories and physical examinations.
- Photographic equipment for patient imaging and identification.
- Equipment to obtain and process needed laboratory analyses.
- Equipment and supplies for patient tracking and scheduling.

3.4 Surgical – Equipment, Supplies, and Pharmaceuticals

Delivery of surgical care requires the following:

- Appropriate type and quantity of surgical instruments for the planned procedures.
- Surgical instruments inventoried, checked, and maintained at routine intervals.
- Sterile sutures and consumables in type and quantity appropriate for the planned procedures.
- Equipment, medications, and treatment environment for providing nerve blocks or local anesthetic infiltration.
- Functioning suction machine with associated supplies.
- Functioning electrocautery machine and associated supplies.

- Adequate lighting for illumination of the surgical field.
- Supplies and equipment for proper cleaning high level disinfection and sterilization.
- Placement of a suture or tag (that extrudes from the mouth) attached to any packing material placed in the oropharynx, according to the Operation Smile Throat Pack/Retained Surgical Items Policy.
- Palatal evaluation of patients seeking optimal secondary surgical procedures, preferably by nasal endoscopy for location of velopharyngeal gap.

3.5 Anesthesia – Equipment, Supplies, and Pharmaceuticals

Delivery of anesthetic care requires the following (in age appropriate sizes where applicable):

- An anesthesia machine with the following capabilities/qualifications:
 - Delivery of medical oxygen.
 - Oxygen analyzer.
 - Oxygen supply failure alarm at the anesthesia machine.
 - Available mount for agent specific vaporizer for sevoflurane or other locally available volatile agent if approved by Medical Oversight. Agent specific vaporizers must only be used with the volatile agent for which they are designed.
 - Ability to deliver fresh gas and volatile anesthesia without electrical power.
 - Fresh gas outlet that allows connection to a Mapleson breathing system, or a machine that can be used with a circle-system.
 - Available mechanism for waste gas scavenging.
- Backup oxygen cylinder(s).
- Face masks.
- Endotracheal tubes with stylets.
- Oral and nasopharyngeal airways.
- Laryngoscope blades with handles.
- Equipment to manage unanticipated difficult airway (Difficult Airway box).
- Anesthesia breathing systems, such as Mapleson D circuits (preferred Mapleson circuit for Operation Smile practice) or circle circuit if circle-system used.
- Adult and pediatric self-inflating bag-valve-mask systems for emergency administration of positive pressure breathing.
- Functioning suction machine with all associated supplies.
- Isotonic Intravenous (IV) solutions including Ringers lactate (Hartmann’s solution) and normal saline.
- Equipment for administration of IV fluids to include pediatric volumetric administration devices.
- Medication in type and quantity appropriate for the planned procedures. Sevoflurane is the preferred volatile anesthetic agent and use of other volatile agents requires Medical Oversight approval.

- Monitoring equipment capable of continuous monitoring of electrocardiography (EKG), pulse oximetry, capnography, temperature, and intermittent noninvasive blood pressure (NIBP) measurement.
- Point of care (POC) device capable of measuring glucose (recommended).
- Point of care (POC) device capable of measuring hemoglobin (recommended).
- Immediate access to defibrillator/cardioverter with pediatric and adult paddles.
- Medications required for administration of advanced life support.
- Emergency code sheet in medical record of each patient, indicating calculated doses per weight for each medication and intervention.
- Equipment to establish vascular access.
- Dantrolene in adequate quantity to treat an adult malignant hyperthermia case.
- Equipment and soaking solutions for the high-level disinfection and/or sterilization of non-disposable anesthesia equipment.
- Type-Rh specific blood if available; if not available, two (2) units of O negative or O positive blood screened for Hepatitis B, C and HIV.

3.6 Dental – Equipment, Supplies, and Pharmaceuticals (Dental and Surgical Mission)

Delivery of dental services should include the following:

- Appropriate type and quantity of dental instruments for the planned procedures.
- Dental instruments inventoried, checked, and maintained at routine intervals.
- Equipment, medications, and treatment environment for providing safe local anesthesia.
- Basic monitoring equipment including intermittent blood pressure measurement and pulse oximetry.
- Consumables appropriate to patient procedures.
- Functioning suction device with associated supplies.
- Functioning suction machine with air compressor recommended.
- Mobile table recommended.
- Access to X-ray machine and lead apron when indicated.
- Equipment for proper cleaning, high level disinfection, and sterilization.
- Medications and equipment for administration of basic life support and emergency response i.e., allergic reactions (Dental Emergency Box).
 - Glucometer (recommended).

3.7 Speech – Equipment, Supplies, and Pharmaceuticals

Delivery of speech services should include the following:

- Consumables appropriate to patient therapy services.
- Nasal endoscope and topical anesthetic (recommended).
- Voice recording device (recommended).

3.8 Audiology / Ear, Nose & Throat – Equipment, Supplies, and Pharmaceuticals

Delivery of audiology and ENT services should include the following:

- Consumables appropriate to patient therapy services.
- Otoscope (recommended).
- Tympanometer / Audiometer (recommended).

3.9 Psychosocial – Equipment, Supplies, and Pharmaceuticals

Delivery of psychosocial support services should include the following:

- Supplies and consumables relevant to psychological preparation of the patient and family during the entire spectrum of treatment and to integration into home and social settings.

3.10 Post Anesthesia Care Unit (PACU) – Equipment, Supplies, and Pharmaceuticals

Delivery of post anesthesia care requires the following (in age appropriate sizes where applicable):

- One (1) post anesthesia care unit bed for each general anesthesia table.
- Isotonic intravenous (IV) solutions.
- Equipment for administration of IV fluids to include pediatric volumetric administration devices.
- Monitoring equipment with size appropriate accessories capable of continuous monitoring of electrocardiography, pulse oximetry, temperature, and intermittent noninvasive blood pressure measurement should be available in the following ratio:
 - 1 machine for 1-2 post anesthesia care unit beds.
 - 2 machines for 3-4 post anesthesia care unit beds.
 - 3 machines for 5-6 post anesthesia care unit beds.
- Immediate access to defibrillator/cardioverter with pediatric and adult paddles.
- Medications and equipment for administration of advanced life support (Code Box and Malignant Hyperthermia Box).
- Bag-valve-mask for infant, child, and adult.
- Small volume nebulizer and Metered Dose Inhaler (MDI).
- Emergency code sheet in medical record with calculated doses per weight for each medication and or intervention.
- Point of care device capable of measuring glucose (recommended).
- Point of care device capable of measuring hemoglobin (recommended).

- Oxygen source with associated supplies available for each post anesthesia care unit bed and for transport if needed.
- Functioning suction machine with associated supplies available for each post anesthesia care unit bed.
- Medication and consumables in type and quantity appropriate for the planned procedures.
- Access to laboratory and radiology services.
- Ability to transport patients from post anesthesia care unit to an intensive care facility in a timely manner.

3.11 Intensive Care – Equipment, Supplies, and Pharmaceuticals

Delivery of intensive care requires the following:

- Ability to provide directly or through a partnership with a hospital facility to have Intensive Care Unit services available for all Operation Smile patients.
- The Intensive Care setting should provide:
 - Adult and pediatric ventilatory management.
 - Immediate access to defibrillator/cardioverter with pediatric and adult paddles.
 - Monitoring equipment to include cardiac monitoring, respiratory rate, capnography, oxygen saturation, temperature, and blood pressure measurements.
 - Oxygen and oxygen administration supplies.
 - Functioning suction machine with associated supplies.
 - Medications for administration of advanced cardiac life support.
 - Emergency code sheet in medical record with calculated doses per weight for each medication and or intervention.
- Consumables in type and quantity appropriate for planned procedures.
- Whenever the above required services are not rapidly obtainable in an actual hospital intensive care setting, then plans should be in place to provide those services in the post anesthesia care unit.

3.12 Pre/Post-Operative Wards – Equipment, Supplies, and Pharmaceuticals

Delivery of pre- and post-operative care should include the following:

Pre-operative Ward:

- Equipment with size appropriate accessories capable of measuring pulse oximetry, blood pressure, and temperature.
- Consumables for pre-surgical bathing.
- Clean gown for each surgical patient.
- Operation Smile Patient Care Booklet.

Post-operative Ward

- One (1) bed for each surgical patient.
- One (1) designated emergency bed **for emergency monitoring only (required)**.
- Equipment with size appropriate accessories capable of measuring pulse oximetry, blood pressure, and temperature.
- Intravenous (IV) solutions such as D5% ¼ NS, normal saline, and Ringers lactate.
- Equipment for administration of IV fluids to include pediatric volumetric administration devices.
- Access to defibrillator/cardioverter with pediatric and adult paddles.
- Medications and equipment for administration of advanced cardiac life support (Code Box).
 - Oxygen and suction with associated supplies at emergency bed.
 - Bag-valve-mask device for infant, child, and adult.
 - Emergency code sheet in medical record with calculated doses per weight for each medication and or intervention.
- Medications and consumables in type and quantity appropriate for the planned procedures.
- Small volume nebulizer/aerosolizer.
- Point of care device capable of measuring glucose (recommended).
- Point of care device capable of measuring hemoglobin (recommended).

In a non-surgical setting, equipment, supplies, and medications will be available for basic life support.

3.13 Biomedical – Equipment and Supplies

Provision and support of equipment and supplies should include the following:

- Operation Smile should provide or have signed vendor agreements to set up, calibrate, and maintain required and recommended equipment.
- An active inventory, maintenance, and repair program.
- A climate-controlled area for consumables and pharmaceuticals.
- Availability of backup oxygen.
- Availability of a backup generator.
- Oxygen tanks which have a safety collar or chain to prevent accidental tipping of the tank.

Supporting Operation Smile Standard 3 – Policies & Procedures

1. Storage Space Requirements Policy
2. Medical Equipment Maintenance Policy
3. Surgical Instrument Maintenance Policy
4. Oxygen Reserve Policy
5. Use and Maintenance of Point of Care Equipment Policy
6. Pharmaceutical Integrity, Substitutions and Storage Policy
7. Medical Waste Management Policy
8. Throat Pack and Retained Surgical Items Policy

Supporting Operation Smile Standard 3 – Forms

1. Difficult Airway Box Inventory
2. Code Box Inventory
3. Malignant Hyperthermia Box Inventory
4. Post-Program Instrument Report
5. Instrument Set Check List
6. Dental Emergency Box Inventory



Supporting Operation Smile Standard 3 – References

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Medical Global Standard 4 – Patient Selection

Approval Date: June 26, 2020	Replaces: 2015 GS-1,8,7
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Current Revision Date: March 2, 2020	Responsible Party: Chief Medical Officer
Last Review Date: 2015	Review Schedule: 4 years

Operation Smile utilizes population and patient data to recruit, screen, and select patients to optimize well-timed surgery and related care. All Operation Smile surgical procedures are elective and therefore general health status must be considered to determine eligibility for anesthesia and surgery.

4.1 Pre-Screening

Pre-screening of patients is recommended to assess and prepare patients for potential surgical treatment or additional therapies. This may be done 2 to 12 weeks before surgery. Pre-screening should include:

- Screening for nutritional deficiencies.
- Screening for medical conditions.
- Anthropometric measures must include:
 - Length/height for age Z-score (standard deviation) taking possible prematurity into account.
 - Weight for length/height Z-score (standard deviation).
 - Middle upper arm circumference (MUAC) (recommended).
 - Body mass index (BMI) (recommended).
- Screening for immunization status; recommending vaccination when applicable.
- Physical examination.
- Appropriate laboratory tests, when available.



The optimal pre-screening team from the local community may include:

- Nurse experienced in pediatric growth and development.
- Nutritionist.
- Pediatrician.
- Surgeon and/or Anesthesiologist.

4.2 Screening

Operation Smile aims to provide a full medical screening of all presenting patients. A multidisciplinary approach is utilized to determine general health status, anthropometric measures, and readiness for surgery and to provide psychosocial preparation. To determine the specific cleft surgical or non-surgical procedure(s), collaboration between Surgery, Speech Language, and Dental/Orthodontic providers is recommended. More complex procedures (e.g., orthognathic and facial clefts) require advanced planning and preparation.

Medical screening of patients will include:

- Screening for malnutrition should use the World Health Organization (WHO) and/or national anthropometric growth charts and middle upper arm circumference (MUAC).
- Screening for medical conditions by obtaining a thorough patient history.
- Screening for physical conditions by performing a thorough physical examination.
- Screening for hematologic conditions, including anemia, by performing laboratory tests:
 - Serum hemoglobin.
 - Blood type and Rh factor for patients having surgeries with risk for substantial blood loss, including palatoplasty.
 - Evaluation of coagulation may be considered for patients having surgeries with risk for substantial blood loss, including palatoplasty.

The following specialties should evaluate patients:

- | | |
|------------------|--------------------------|
| • Surgery | • Speech |
| • Anesthesiology | • Dental/orthodontic |
| • Pediatrics | • Psychosocial |
| • Nursing | • Other(s) as applicable |

4.3 Surgical Classification System

The selection of patients for surgical intervention is guided by Operation Smile's Screening, Classification, and Selection Policy. Operation Smile's Surgical Classification System is designed to guide the selection of eligible patients for surgery.

Operation Smile's Screening, Classification, and Selection Policy emphasizes the following:

- Patients must be selected after confirming that there is nothing in the medical history and current general health status to contra-indicate anesthesia and surgery.

- Cleft surgical interventions should be appropriately timed and sequenced to enhance the benefits for patients.
- Palate repairs are time sensitive for cleft palate patients as it relates to normal speech development.
- Alveolar bone graft and revision palate surgery (including surgery for velopharyngeal insufficiency and fistula) should be considered specialized surgery, performed only when appropriate expertise is present and, ideally, in patients selected and prepared in advance.
- Patients needing palate surgery for speech improvement should be given high consideration for scheduling when the right expertise and environment for care are available.
- Patients who have had presurgical orthodontics should receive high consideration for scheduling given the specific time frame surgery must be completed.
- Options for care, rehabilitation, and other therapies should be considered during the surgical patient selection/scheduling process.
- Eligible surgical patients previously not selected for surgical intervention can be given a higher level of consideration for scheduling within their classification group.
- Operation Smile may offer non-cleft surgical interventions in places where there is need and teams are properly qualified, prepared, and resourced to successfully carry out such interventions and post-operative care.

Surgical Classification System

Category 1: Primary lip repair, age three months through seven (7) years (up to 8th birthday). Priority to patients who have both cleft lip and palate. This category also includes repeat surgery for complete lip dehiscence when timing is appropriate. See age deviation for infants between 3 and 6 months of age.

Category 2: Primary palate repair, age nine (9) months through seven (7) years (up to 8th birthday). Revision palate surgery in this age group. Speech surgery including palate lengthening, pharyngeal surgery, and repair of fistulas when speech is affected. *Pharyngeal surgery for speech shall only be considered under appropriate conditions in cleft centers or tertiary care settings**. See age deviation policy for infants between 9 and 12 months of age.

Category 3: Primary lip repair from age (8) years and older.

Category 4: Primary palate repair from eight (8) years and older (as prioritized by speech language pathologist).

Category 5: Secondary cleft lip. Can include minor nasal revisions (one element significantly off or two elements with minor asymmetries. May include tip plasty.

Category 6: Additional cleft procedures (**alveolar bone graft, rhinoplasty, ***orthognathic surgery, etc.)

Category 7: Other (syndactyly, ****frenulectomy, nevi removal, burns etc.).

Note: Patients in categories 1-4 who have been denied care previously are prioritized within each category.

Not a candidate: A patient's condition does not fall within any of the above categories treated by Operation Smile and is not a candidate for the current program, any future program, nor world care.

Potential World Care Candidate: Candidates for surgery whose condition is too complex to be treated during an Operation Smile program or are unable to receive surgery due to time or resource constraints.

* These include a qualified team of surgeons, speech language pathologists and dentist/orthodontists to evaluate and plan care. See Surgical Classification Policy for further detail on requirements. With respect to closure of fistulas, priority is given to fistulas that affect speech.

**Alveolar bone grafts should be considered specialized surgery that is performed only when appropriate expertise is present. Ideally, these patients should have been selected and prepared in advance. Patients that have had presurgical orthodontics should also receive high priority on the surgical schedule because we have committed to complete these operations within a specified time frame.

***Orthognathic surgery is only to be performed on designated orthognathic programs.

****Frenulectomy for feeding difficulties may be scheduled.

4.4 Patient Selection and Scheduling

Patient selection should be based on cleft surgical classification, overall anthropometric and general health status, laboratory values, and consent to treat. Patients with medical conditions and syndromes should be carefully screened and a decision to proceed with surgery on those patients should be agreed upon by team leaders.

For education purposes or non-cleft patients, selection may differ according to overall goals and objectives of the program.

All patients who will receive surgery should have a hemoglobin level of **9 or greater**.

States of malnutrition where **weight for length/height is below -2 SD should not be scheduled**. Length/height for age and other anthropometric measures may be considered by all team leaders to reaffirm readiness for surgery or suggest other therapeutic measures.

For cleft programs, team leaders from anesthesia, surgery, and nursing, as well as the PACU physician, pediatrician, dentist, and speech provider collaboratively consider the following points during patient selection and scheduling:

- Length of surgical day should be limited to 10 hours from the first patient on the surgical table to the last patient off the surgical table.
- Anesthetic care for children under 1 year of age (infants) should be provided by a pediatric anesthesiologist or another anesthesiologist who also regularly provides anesthesia for infants.
- Infants should be scheduled as early in the day as possible.
- Palate surgeries should be scheduled as early in the day as possible.

All patients have the right to receive feedback on the results of their screening evaluations. Whether a patient is selected for surgical treatment and multidisciplinary care by Operation Smile or whether a candidate for referral and care by another team, facility or entity, information should be delivered by a medical provider in a respectful and considerate manner.

4.5 Informed Consent

Patients and caregivers (if the patient is a minor) should be well informed and involved in decisions regarding their own care or the care of their minor children. Treatment will only be provided after the proper informed consent has been obtained from the patient (if of legal age) or from the patient's caregivers (if the patient is a minor). Consent should be "knowing" which involves clear explanations of care, including multifaceted staged treatment such as orthognathic care.

Consent for Examination and Treatment

- This consent gives permission for photo imaging, physical examination, psychosocial evaluation, blood sampling, and other testing needed to assess whether the patient is a candidate for surgery and should be obtained when the medical record is initiated.

Consent for Surgical Treatment

- This consent gives permission for administration of anesthesia, administration of blood products, and performance of a designated surgical procedure and should be obtained prior to surgery.

Consent for Dental Treatment

- This consent gives permission for performing dental procedures and treatment and should be obtained prior to treatment.

4.6 Surgical Deviations

All cases requiring deviations related to age, surgical tables, surgical time, or surgical procedure must be reviewed and approved by all team leaders and by the applicable Regional Medical Officer prior to scheduling those cases.

Age Deviation

A cleft lip patient less than 3 months is NOT safe for an Operation Smile surgical program and will not receive surgery. A cleft lip patient between the ages of 3 months and 6 months is considered an **Age Deviation** and may be scheduled for a cleft lip repair only if the child has no medical conditions, is currently healthy and well nourished, and has normal serum hemoglobin as outlined in Operation Smile policy.

A cleft palate patient less than 9 months is NOT safe for an Operation Smile surgical program and will not receive surgery. A cleft palate patient between the ages of 9 months and 1 year is considered an **Age Deviation** and may be scheduled for a cleft palate repair only if the child has no medical conditions, is currently healthy and well nourished, and has normal serum hemoglobin as outlined in Operation Smile policy.

A non-cleft patient under 1 year of age will be considered an age-deviation for general anesthesia.

Surgical Procedure Deviation

Any unplanned advanced or complex procedures, including but not limited to flaps, bone grafts, complex maxillofacial defects such as facial clefts, are considered a **Surgical Procedure Deviation** and must be approved as noted above.

Any unplanned advanced or unusually complex procedure beyond Operation Smile's typical scope of practice is considered a **Surgical Procedure Deviation** and must be approved as noted above.

Any patient with an expected difficult mask airway or an expected difficult intubation to the degree that a video laryngoscope or fiberoptic scope is likely to be required for intubation is a **Surgical Procedure Deviation** and must be approved as noted above.

Surgical Time Deviation

Any surgical procedure with a duration of more than 3 hours is considered a **Surgical Time Deviation** and must be approved as noted above.

Surgical Table Deviation

Any addition or adjustment in the number of planned local anesthesia or general anesthesia surgical tables during a surgical program is considered a **Surgical Table Deviation** and must be approved as noted above. Adequate equipment, supplies, pharmaceuticals, beds, and staff must be confirmed prior to approving a **Surgical Table Deviation**.

Surgical Table Deviations include:

- Adding a general anesthesia surgical table.
- Adding a local anesthesia surgical table.
- Converting a local anesthesia surgical table to a general anesthesia surgical table.

Supporting Operation Smile Standard 4 – Policies & Procedures

1. Patient Screening, Classification, and Selection Policy
2. Age, Table, Procedure, and Time Deviation Policy

Supporting Operation Smile Standard 4 – Forms

1. Pre-Screening Form
2. Age Deviation Form
3. Surgical Procedure and Surgical Time Deviation Form
4. Surgical Table Deviation Form
5. WHO weight to length growth chart for gender/age

Supporting Operation Smile Standard 4 – References

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Medical Global Standard 5 – Medical Patient Management

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Last Review Date: 2015	Review Schedule: 4 years

Operation Smile is committed to safe and comprehensive treatment for patients and families. A multidisciplinary team approach allows for a thorough assessment, diagnoses, and treatment plan. We aim for full integration of the patient into family and society.

5.1 Pre-admission

Patients may be admitted from home or a patient shelter/village before screening.

Operation Smile may organize patient lodging and arrange for additional support as part of its strategies to expand access and affordability of care. Such accommodations should be designed to minimize the risk of spread of infection by observing infection prevention measures.

Patient lodging should be maximized to provide supporting services and patient education by nursing (highly recommended), pediatrics, psychosocial care, dental, speech, nutrition, and others. Support may include surgical and non-surgical services to patients who may or may not be receiving surgery prior to and following discharge from the hospital/clinic.



5.2 Patient and Caregiver Education

Patients and caregivers are an integral part of the medical team. Patient centered decision making should be incorporated to facilitate understanding of screening through after-care, procedure expectations, and physical/psychologic care.

Evidence based, standardized materials that consider patient/caregiver literacy and language needs should be used for education.

Patient preparation and education concerning surgery or other procedures should be provided by the multi-disciplinary team to include:

- Etiology, condition.
- Procedure description, expectations, and/or follow up therapy.
- Food and fluid restriction before surgery.
- Post-operative diet following surgery and after discharge.
- Warning signs and complications to report to medical staff.
- Medication use and administration.
- Pain management.
- Wound care and infection prevention.
- Discharge and follow-up care.

5.3 Surgical Admission

All Operation Smile patients will be assigned an Operation Smile medical record number. The Operation Smile medical record should include the full name, address, contact information, date of birth using day/month/year (**dd/mm/yyyy**) format, next of kin, and other demographic information. An identification photo should be in the medical record.

On admission to the hospital or center for surgery an identification band will be placed on the patient's wrist or ankle. The identification band will contain at minimum:

- The patient's name.
- The patient's Operation Smile medical record number.

At least 2 unique identifiers will be used for all patients when receiving any care, medication, or surgery. Other unique identifiers, in addition to the above, that may be used include:

- Identification photo in the medical record.
- Date of birth.
- Name and address or contact information of the parent/caregiver or guardian.

Pre-operative

A safe holding space should be provided for patients before entering the surgical area. Psychosocial providers may facilitate therapeutic play and patient education while awaiting surgery.

Prior to a patient being taken to the operating room or dental treatment area, the medical record should be reviewed to check patient identity, surgical procedure, and side/site of surgery.

The following team members will use the chart to confirm patient identification and validate the following:

- Operative surgeon/dentist assuring there is a signed consent and operative plan.
- Anesthesia/pediatrician to assure health and required *nil per os* (NPO) status are acceptable for surgery.
 - 6 hours for non-clear liquids and solids.
 - 4 hours for breastmilk.
 - 1 hour for clear glucose fluids.
- Surgical circulating nurse and clinical coordinator will confirm a signed consent, laboratory values, vital signs, and an appropriate emergency code sheet.

The surgeon and anesthesia provider or dental provider should:

- Introduce his/herself to the patient/caregiver.
- Examine patient and verify identification.
- Verify the planned procedure with the patient/caregiver.
- Ask the patient/caregiver if there are any questions.

5.4 Surgical Process

The Operative Area

Verification of the care team, equipment, and processes should occur before taking any patient to the operating room.

Patient imaging photographs should be secured at designated points:

- Pre-surgical patient image: after induction and prior to application of skin disinfection solution.
- Post-surgical patient image: before extubation with mouth gag still in place (palates) and after surgical site is cleaned (lips).

Surgical Safety Check

A three-step surgical safety “Time-Out” is required for ALL patients. This occurs at:

- Sign In: when the patient enters the operating room before induction of anesthesia.
- Time Out: before the skin incision or dental extractions.
- Sign Out: On completion of case before the patient is extubated (timing is in order to confirm throat packs have been removed).

All items listed should be verified by the: surgeon, anesthesia provider, surgical scrub personnel, and the surgical circulating nurse. This process is usually led by an anesthesia provider or surgical circulating nurse.

Intra-Operative Management

Anesthetic induction must be attended by two credentialed anesthesia providers. An Operation Smile credentialed anesthesia provider must always remain with an anesthetized patient. Anesthetic emergence and extubation must be attended by the anesthesia provider and one other team member (circulating anesthesiologist when available, otherwise surgical circulating nurse).

For patients undergoing general anesthesia or monitored sedation, intraoperative monitoring must include: continuous capnography (not possible for monitored sedation cases that prohibit use of nasal cannula capnography), electrocardiogram (EKG), temperature, pulse oximetry, and non-invasive intermittent blood pressure (NIBP) measurements cycling every 5 minutes or less.

Fluid management should follow Operation Smile policy.

Multi-modal analgesia should utilize nerve blocks when appropriate and pre-operative and intra-operative analgesic medications of different classes.

Intravenous antibiotics will be administered within one hour prior to surgical incision. Current evidence does not support the use of postoperative antibiotics.

A tongue stitch may be placed for palatoplasty patients, with placement and time of removal at the discretion of surgical/anesthesia/pediatric teams.

Throat Pack

All palate and select lip procedures with an uncuffed endotracheal tube should have a throat pack placed with approved suture tail and signage. Throat packs may be used with a cuffed endotracheal tube at the discretion of the anesthesiologist and surgeon. Construction of gauze packing that goes into the oral cavity and placement of a suture or tag (that extrudes from the mouth) must be done according to Operation Smile policy. Insertion and removal of oral packing must be verbally acknowledged and documented on the surgical safety checklist and anesthesia record.

Local Anesthesia

Patients may receive local anesthesia, no sedation, and surgery without involvement of an anesthesia provider. Whenever local anesthesia patients receive intravenous sedation, an anesthesia provider must be present to administer sedatives and continuously monitor (according to intraoperative standard above) and care for those patients.

Care of surgical patients receiving local anesthesia **and no sedation** should include:

- An interpreter/translator (when necessary) for proper communication between the patient and the surgical team.
- Measurement of heart rate, respiratory rate, oxygen saturation, and blood pressure prior to and at the end of the procedure and, as needed, by the surgical circulating nurse.
- Documentation by surgical circulating nurse on the operating room notes should include:
 - Intravenous fluid and antibiotic administration.
 - Heart rate, respiratory rate, oxygen saturation, and blood pressure prior to and at the end of the procedure and as needed.
- Monitored in the PACU until hemodynamically stable.

Attire

Operating Room staff will wear approved attire for clean procedures to minimally include:

- Head and hair covering.
- Face mask.
- Sterile gloves (surgeons, scrub nurses).

Local regulations may have additional requirements that should be adhered to.

Case Cancellation

In the event a surgical patient needs to be cancelled, a medical provider and a psychosocial provider should explain to the patient/caregiver the cause of the cancellation and potential future therapeutic options. The medical chart should have documentation of the cancellation, the cause, and follow-up options.

5.5 Post-Surgical

Post Anesthesia Care Unit (PACU)

This critical high-observation unit is designed to provide close observation and monitoring as the patient emerges from anesthesia.

Patients should be extubated prior to entry to the post anesthesia care unit.

Hand off should occur between the anesthesia provider and a member of the post anesthesia care staff.

The following care must be provided to post anesthesia care patients:

- Continuous pulse oximetry and blood pressure measurements with availability of continuous electrocardiography to be used as needed.
- Pain and emergence delirium management using approved intravenous analgesics (judiciously), sedatives, and other non-pharmacologic modalities.

- Vital signs and Post Anesthesia Recovery Score must be assessed and documented every 5 minutes until the patient is awake, then every 15 minutes until discharge to the post-operative ward.
- Discharge readiness is when:
 - The patient is conscious and hemodynamically stable, with pain and bleeding controlled.
 - The vital signs return to age appropriate baseline.
 - Supplemental oxygen is no longer needed.
 - The Post Anesthesia Recovery Score is 8 or better.
 - A minimum of 30 minutes monitoring in the post anesthesia care unit with the following exceptions:
 - Stable local anesthesia patients after a brief evaluation and vital sign check.
 - When anesthesia time is less than 30 minutes, such as in a frenulectomy.

Post-Operative Ward

Hand off should occur between the post anesthesia care staff and the receiving post-operative ward staff.

Post-operative care is provided continuously by credentialed Operation Smile staff from admission to the ward until discharge.

Elbow restraints may be used at the discretion of the post-operative staff.

Assessment, vital signs, and pain scores should be performed and documented every 4 hours (or more frequently if needed).

Additional services may be provided on the pre/post-operative ward to include but not limited to speech, psychosocial, or other services pertinent to the scheduled or performed procedure.

Pain Management on Ward

Multi-modal pain management will occur using approved oral pharmacologic and non-pharmacologic modalities. Intravenous or intramuscular analgesics are discouraged but may be necessary in cases of severe unrelenting pain, especially after bone grafts or maxillo-facial surgery. The patient and caregivers are an integral part in assessment and pain management. The medical team should work with the patient and caregivers through regular assessment and ongoing education. Pain should be assessed using valid, age appropriate scoring systems.

Length of Stay

Patient length of stay should be decided individually for each patient by the team leaders. The following variables should be considered in these decisions: patient age and health status, distance from home, local protocols and regulations, follow-up treatment, and education needs. Average length of stay may be:

- 1 night for uncomplicated surgeries.
- 2 nights for patients requiring additional observation.
- 2 hours (minimum for local anesthesia patients).

5.6 Intensive Care

Operation Smile teams will be prepared for intraoperative critical events that indicate need for ongoing intensive care and for postoperative escalation of care using advanced monitoring. Any need for intensive care must be documented as a medical event.

Return to Post Anesthesia Care Unit

Any ward patient in need of escalation of care with advanced monitoring and/or critical care interventions (including airway management) will be admitted back to the post anesthesia care unit.

Return to the Operating Room

An “on call” operating team must be available for any complication requiring a return to the operating room.

Intensive Care

Operation Smile should ensure on-site availability of a satisfactory intensive care setting, including medical staff, monitors, equipment, and supplies for patients in need of intensive care. When unavailable, a plan should be in place for transport to an off-site intensive care facility.

Intensive Care in the Post Anesthesia Care Unit

For short term monitoring or in the absence of adequate intensive care facilities at or near the mission site, a patient in need of intensive care should be moved to the post anesthesia care unit. Downsizing of the program’s surgical tables and overall plans may be necessary to safely care for other patients while allowing adequate staffing for an intensive care patient managed in the post anesthesia care unit.

Hospital Based Intensive Care Unit (ICU)

Prior to conducting surgery, a plan should be in place to provide intensive care services for patients should they be needed. Intensive care services are generally located within the hospital where the program takes place or a hospital a short distance away. The plan (to include transportation if the ICU facility is offsite) should be documented in a memorandum of understanding. A non-Operation Smile intensive care unit must have the following:

- A bed with monitoring capabilities for continuous electrocardiography, heart rate, respiratory rate, oxygen saturation, capnography, and temperature.
- Ventilator(s) capable of pediatric and adult use.
- A 24-hr. laboratory available for hematology, blood gasses, and chemistry parameters.
- Radiology and cardiology services available.
- Qualified physicians and nurses available for 24-hour care for the patient.

5.7 Discharge and Ongoing Care

Local resources should be identified for ongoing patient care after discharge.

Patient Discharge

Patient discharge is a collaborative decision between the surgeon and pediatrician with input from nursing and other disciplines as indicated. Patients should be hemodynamically stable and pain adequately managed prior to discharge.

When a patient is cleared for discharge, the discharging nurse or pediatrician should assure the patient/caregiver can verbalize the following:

- Wound care instructions.
- Nutrition/diet/hydration guidelines.
- Pain management strategies.
- Purpose and administration of medications.
- Identification and management of complications.

Patient Follow-Up

Operation Smile supports capacity building efforts to expand access to ongoing post-operative services via centers, partnerships, or integration with local health services.

Patients should return to a designated site 4-7 days following surgery to be examined by a surgeon experienced in assessing wound healing and other potential complications related to cleft surgery. The following team members should perform this assessment:

- Surgeon.
- Patient imaging technician.
- Pediatrician or nurse.
- Speech and/or psychosocial provider (recommended).

Patients should return to a designated site 6 months to 1 year after surgery to be examined for further assessment of results and needs for further services. The following team members should perform this assessment:

- Surgeon.
- Patient imaging technician.
- Pediatrician or nurse.
- Speech and/or psychosocial provider (recommended).

Patients undergoing surgical procedures other than cleft lip or cleft palate should have a defined multi-disciplinary follow-up plan of care to include timeline and procedures/treatments.

Supporting Operation Smile Standard 5 – Policies & Procedures

1. Medication Administration Policy
2. General Anesthesia: Delivery, Monitoring, and Care Policy
3. Local Anesthesia: Delivery, Monitoring, and Care Policy
4. Emergence Delirium and Post-Operative Pain Policy
5. Fluid Management Policy
6. Transfer of Patient Care Policy
7. Throat Pack and Retained Surgical Items Policy
8. Speech, Language, and Feeding Management Policy
9. Psychosocial Care Policy
10. Dental Management Policy

Supporting Operation Smile Standard 5 – Forms

1. Operation Smile Patient Chart
2. Surgical Safety Checklist
3. Operation Smile Patient Care Booklet
4. Nursing Guideline to Cleft Care Education
5. Transfer of Care Form
6. Call Team Communication Form



Supporting Operation Smile Standard 5 – References

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Medical Global Standard 6 – Safety

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Last Review Date: 2015	Review Schedule: 4 years

Operation Smile prioritizes safety for patients, caregivers, and health workers. Achieving safe, quality care is a multidisciplinary effort. Operation Smile promotes a culture of safety through the establishment of a safe environment of care, safe medical practice, availability of necessary equipment and medications, readiness for unplanned emergencies and secure handling of patient information.

6.1 Emergency Preparedness

Operation Smile provides qualified teams and processes to allow rapid and timely response to medical events or emergencies.

A Crisis Notification Plan will be in place for all Operation Smile programs and centers to ensure management of critical events.

Team members should be familiar with equipment, medications, and policies allowing rapid response to medical events or life-threatening emergencies.



The following emergency boxes, kits, and equipment must be available, fully stocked, current, and in working order as applicable:

- Code Box.
- Malignant Hyperthermia Box.
- Difficult Airway Box.
- Dental Emergency Box.
- Post Exposure Prophylaxis Kit.
- Team Kit.
- Defibrillator.

An emergency preparedness drill will be conducted to review and demonstrate equipment operation and location, and to designate team roles and responsibilities during emergencies.

- Medical Program: drill occurs on the first day of surgery before any procedure begins.
 - Night shift personnel: drill occurs at the start of the first post-op night shift.
- Dental Program: drill occurs on the first day of program before any procedures begins.
- Center-based surgical and/or dental services: drill occurs on a regular basis for existing and new personnel.

For Centers with non-surgical services:

- A basic emergency plan for response capabilities is recommended.

In any surgical setting, the following designated leaders will direct the emergency response and care:

- Surgical Area – Anesthesia Team Leader
- Post Anesthesia Care Unit – PACU Physician
- Ward – Pediatrician, with assistance from one of the above

In any dental or non-surgical setting, an identified lead medical professional will direct emergency response and care.

6.2 Blood Transfusion

Operation Smile normally performs elective surgical procedures which mandates screening, medical clearance, and selection of patients for surgery.

A blood transfusion may NOT be given to elevate an unacceptably low hemoglobin to reach the accepted threshold value. Those anemic patients should be referred to local medical services for evaluation and treatment.

A blood transfusion may be given in the course of managing an Operation Smile patient who has an unanticipated significant surgical blood loss. The blood administered should be cross-matched, type, and Rh specific whenever time allows. Whenever time is inadequate to crossmatch, type and RH specific non-cross-matched blood may be transfused. In emergent situations, O negative or O positive if O negative is unavailable may be used.

Blood Administration

Safety checks for blood administration that adhere to Operation Smile policy and procedure must be followed and include the following:

- A physician's order.
- A check by two medical providers to include the blood label and patient information prior to administering the blood.
- Close observation during the first 15 minutes of the infusion for potential reaction and continued monitoring throughout the entire transfusion.
- Use of the Operation Smile Blood Transfusion documentation form.
- Initiation of blood within 30 min of leaving the controlled blood bank refrigerator and discontinuation of blood within 4 hours.

Blood Transfusion Documentation and Reporting

The medical record of a patient receiving a blood transfusion must contain:

- Signed patient consent to receive blood (found on the surgical consent).
- Blood administration order.
- Blood bank tags identifying the unit(s) administered.
- Completed transfusion record.

A medical event report will be submitted whenever a transfusion is given so that Operation Smile's quality assurance program can evaluate the event and track all transfusions.

6.3 Medications

Only non-expired, clearly labeled medications will be used.

Medication substitutions not included in the Operation Smile Pharmacopeia should be approved by the Regional Medical Officer or Medical Director.

The chain of custody and integrity of medications should adhere to Operation Smile policy and local regulation.

Eight Rights of Medication Administration should be observed:

- The right medicine – Clearly identified and labeled.
- The right patient – confirm 2 unique patient identifiers.
- The right dose – double check dose calculation.
- The right time – confirm time of last dose.
- The right route – confirm ordered route.
- The right reason – confirm correct indication.
- The right documentation – verify order before administration and document AFTER administration.
- The right effect – assess and chart patient response.

6.4 Communication

Effective communication is essential for safety. Acknowledging and addressing language and knowledge barriers are essential for clear communication.

Translation/Interpretation

Medical interpreters can bridge language and cultural divides between healthcare providers and/or patients. Whenever patients/caregivers cannot communicate clearly with an Operation Smile health care provider because they do not speak the same language, translation/interpretation should be provided.

Interpreters should be fluent in relevant languages and/or dialects for the setting.

Interpreters should be familiar with medical terminology and concepts appropriate for the setting.

Team Communication

A process for clear, concise, and continuous team communication should be established:

- Between team leaders and team members.
- Between the anesthesia team leader, post anesthesia care physician, clinical coordinator, and pediatrician to assure safe, continuous care from admission to discharge.

An agreed upon mode of secure communication between team leaders should be established and utilized for all medical programs.

A clear, consistent form of hand-off communication should be utilized when transferring patient care from one area/medical team to another. The hand off should be between medical professionals and include the following information:

- Situation.
- Background.
- Assessment.
- Recommendation.

Patient/Caregiver Communication

Operation Smile acknowledges the rights of patients and the caregivers to be informed and involved in decision making regarding their care. This is accomplished through mutual respect and communication as partners in care.

Any medical information shared with a patient and/or caregiver should be communicated by a medical professional.

Assessment of and attention to language, knowledge, and learning barriers/needs are essential for clear communication and is known to enhance patient satisfaction.

Each member of the medical care team should communicate to the patient and caregiver their name, title, and role in care.

Patients and caregivers should be empowered to ask questions and clarify information.

6.5 Medical Record Documentation

Operation Smile strives to keep an accurate and secure medical record in order to properly document ongoing medical care and assess patient outcomes. Operation Smile patients should have a paper and/or electronic record with a distinct identifier for each surgery.

The Operation Smile medical record should include:

- Patient demographic information.
- Photo identification.
- Medical assessment.
- Physical examination.
- Medical and surgical diagnoses.
- Treatment plan including all planned operations or treatments.
- Consent forms.
- Documentation of treatment and patient care.
- Discharge disposition.

Each credentialed team member is responsible for documentation.

Non-credentialed medical providers need a co-signature from a credentialed provider.

Operation Smile patients may have their medical care documented in host country medical charts by host facility personnel, as required by local regulation. Such documentation DOES NOT replace Operation Smile's own required documentation.

Operation Smile programs that utilize an existing hospital system in order to teach and care for patients, such as visiting professorships and center partnerships, will in some cases utilize host charting within their own medical records rather than creating Operation Smile medical records.

Confidentiality

Patients are entitled to privacy and the protection of their personal health information (PHI). Therefore, any patient's PHI and other confidential information that is shared with Operation Smile's providers, or placed in any patient's Operation Smile medical record is accessible only to those providers involved in that patient's medical care or in maintaining that patient's medical record, unless the patient/guardian consents to the sharing of that PHI or the disclosure of that PHI is required by law.

Confidential patient data include:

- Verbal communication with a patient.
- Medical records in either paper or electronic formats.
- Written information about a patient maintained outside the medical record.
- Photos, videos, and voice recordings.

Access to identifiable patient data should be limited to personnel involved in patient care.

Supporting Operation Smile Standard 6 – Policies and Procedures

1. Blood Transfusion Policy
2. Emergency Preparedness Policy
3. Difficult Airway Management Policy
4. Malignant Hyperthermia Policy
5. Communication Policy
6. Documentation Policy
7. Informed Consent Policy

Supporting Operation Smile Standard 6 – Forms

1. Code Box Inventory
2. Difficult Airway Box Inventory
3. Code Documentation Form
4. Malignant Hyperthermia Box Inventory
5. Malignant Hyperthermia Documentation Form
6. Malignant Hyperthermia Information Poster
7. Blood Component Transfusion Record
8. Blood Request Form
9. Surgical Safety Checklist
10. Dental Emergency Box Inventory



Supporting Operation Smile Standard 6 – References

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Medical Global Standard 7 – Quality

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Operation Smile’s culture of safety promotes and supports an environment that encourages quality care, patient safety, risk management, and transparent reporting.

Quality Assurance (QA) and Quality Improvement (QI) depend on mutual trust, transparency, collaborative engagement, data collection/analysis and sharing, thorough evaluation of medical events, and the dissection of organizational systems that may need to be altered to effect positive change.

Operation Smile’s quality management strategies include:

- Commitment to a culture of safety including patient and volunteer safety.
- Reduction of morbidity and mortality (M&M).
- Improving outcomes other than morbidity and mortality, including reduction of the inequality in availability of safe and timely surgical care.
- Empowering team members to identify unsafe care and encourage reporting.
- Tracking of medical events and other data to effect system changes.

Operation Smile respects applicable international, national, and local regulatory requirements.



7.1 Reporting

Operation Smile endeavors to collect and share accurate data in a timely manner.

Data include:

- Medical Events.
- Center Reports.
- Program Data Reports.
 - Medical Oversight Committee Reports.
 - Post-operative Patient Evaluations.
 - Age, Surgical Procedure and Time Deviations.
 - Surgical Table Deviations.
 - Biomedical and Instrument Reports.
- Surgical/Patient outcomes.

Data are used to ensure safe clinical practice, to determine quality of interventions, and to identify trends and analyze factors that facilitate planning and implementation of Quality Improvement solutions.

7.2 Medical Event Review

Operation Smile's culture of safety promotes the reporting of medical events. A medical event is anything that happens or could happen with potential or actual psychologic or physical harm to a patient, caregiver, or volunteer.

A medical event should abide by the following:

- Transparent and timely event reporting.
- Timely response of medical leaders.
- Joint engagement and quality review after the medical event.

Medical events that cause serious patient harm or death will be analyzed in a peer review process involving Operation Smile's Medical Oversight Committee and medical and surgical specialty advisors.

7.3 Quality Site Assist Visit

A quality site assist visit is a collaborative process of information gathering, observation, and analysis in order to enable discussion of findings with those involved in Operation Smile's delivery of care.

- The Operation Smile Quality Team should engage with Operation Smile Foundations in site assist visits and share findings, highlights, and recommendations.
- An after-action report provides mutually identified goals and measurements of success.
- Operation Smile's Quality and Medical Oversight Teams should collaborate with Operation Smile Foundations and use the analyses of results and trends to develop quality improvement initiatives.

7.4 Infection Control Program

Operation Smile's safety culture involves adherence to infection control practices. Operation Smile programs and centers will have defined guidelines and programs that include:

- Description and function of the surgical program/dental program/center.
- Basic infection prevention measures, including hand hygiene, disinfection and sterilization, environmental control, and isolation.
- Specific infection control measures directed at program location or program specific risk areas.
- Preventive measures to counter spread of infection to and between patients and personnel.
- Appropriate use of antibiotics.
- Infection surveillance measures.

7.5 Surgical Site Infection Prevention

Operation Smile supports the following evidence based global guidelines for the prevention of surgical site infections:

- Pre-operative hygiene measures.
- Hand hygiene.
- Protective attire – gloves, facemasks, gowns, aprons, footwear.
- Inspection, cleaning, decontamination, and sterilization of surgical instruments prior to use.
- High Level Disinfection (HLD) on any semi-critical instrument/equipment.
- Surface and environmental disinfection practices.
- Administration of prophylactic antibiotics within 1 hour of surgical incision when indicated and discontinued within 24 hours after surgery.

Supporting Operation Smile Standard 7 – Policies and Procedures

1. Quality Management Policy
2. Infection Control Policy
3. Medical Event Policy

Supporting Operation Smile Standard 7 – Forms

1. Medical Event Report
2. Quality Site Assist Assessment

Supporting Operation Smile Standard 7 – References

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