



SAFETY AND QUALITY PROTOCOL

Purpose: Patient safety is our #1 priority. The following protocol outlines required policies and procedures for Smile Train partner treatment centers.

PART 1: PATIENT MEDICAL RECORDS

Requirement 1.1: Documentation Standards:

- ❖ The Smile Train Patient Medical Record and Smile Train Express (www.smiletrainexpress.org) must be used for all patients undergoing Smile Train-sponsored cleft surgeries.
- ❖ The patient medical record must include all medical documents relevant to the Smile Train supported procedure including admission notes, preoperative assessment by a pediatrician or medical officer, preoperative anesthesia evaluation and intraoperative anesthetic record, surgeon preoperative, intraoperative and postoperative notes, post anesthesia care unit and ward nursing notes with clear handover records for the whole duration of care.

Requirement 1.2: Evaluation of Surgical Outcomes:

- ❖ The cleft team must have meetings at least once every 3 months where members (surgeons, anesthesia providers (physician and non-physician), pediatricians, medical officers, speech services providers, orthodontists, and other comprehensive care specialists) review Smile Train funded patient records including treatment plans and surgical outcomes.

PART 2: PREOPERATIVE ASSESSMENT

Requirement 2.1: Patient Selection:

- ❖ Surgical patients must be,
 - \geq 3 months of age for cleft lip repair
 - $>$ 9 months for cleft palate repair
 - *If born preterm, please adjust to appropriate gestational age.
 - At least 5kg and demonstrates appropriate age for weight, height and/or length
- ❖ All Smile Train supported surgical patients must be American Society of Anesthesiology (ASA) physical status class 1 or class 2.
 - ASA 1 children are healthy (no acute or chronic disease), normal weight for age.
 - ASA 2 children with mild to moderate systemic disturbance caused either by the condition to be treated surgically or by other pathophysiologic processes. For example, children with asymptomatic congenital cardiac disease, well controlled dysrhythmias, asthma without exacerbation, well controlled epilepsy, non-insulin dependent diabetes mellitus, abnormal BMI percentile for age, mild/moderate OSA, oncologic state in remission, autism with mild limitations.

- As a reference, an otherwise healthy child with cleft lip or palate with no other medical problems would typically fall into an ASA 1 or 2 classification. Children with symptomatic congenital heart disease and underlying syndromes often fall into an ASA 3 classification or higher.
- Regardless of ASA status, high risk patients such as those with potentially difficult airways (Pierre Robin, Treacher Collins syndromes, Tessier clefts etc) should be referred to a center with the expertise and resources to manage the potential complications associated with the increased risk including ICU facilities, such as a Comprehensive Cleft Center. If unsure, please review the Smile Train advisories or email medical@smiletrain.org for further clarification.
- ❖ Informed consent for the surgical procedure must be obtained by a surgeon from the cleft team.
- ❖ Informed consent for anesthesia for the procedure must be obtained and documented by the anesthesia provider at least a day prior to the scheduled surgery.
- ❖ All patients previously referred to nutrition clinic must have the nutrition team clear patient to proceed with surgery.

Requirement 2.2: Scheduling of Patient to receive Smile Train financial support.

- ❖ All children less than 2 years of age must have their surgery scheduled and **started** before 14:00 hrs.
- ❖ Combined lip and palate surgical procedures (both procedures are performed as a single surgical case), are **NOT** allowed for patients under 1 year of age.
- ❖ A gap of 90 days is required between Smile Train-sponsored surgeries to allow adequate time for healing. This directive does not apply to emergencies requiring an urgent return to the operating theater.

PART 3: SPECIFIC PREOPERATIVE REQUIREMENTS

Requirement 3.1: Patient Evaluation

- The patient must be medically cleared for surgery by a pediatrician or medical officer prior to being scheduled for surgery. The clearance process must include a detailed history and physical examination. The healthcare provider doing the assessment should be familiar with local health and cleft-related problems. The assessment must include:
 - History of Present Illness.
 - Past medical history including birth history (estimated gestational age and any known complications at birth that might complicate anesthesia care) and congenital anomalies.
 - Known allergies (e.g., medications and reactions).
 - Past surgical history including any complications.
 - Previous anesthetic complications including any family history of adverse reactions to anesthesia.
 - A detailed physical exam must be performed and documented. Special attention must be paid to congenital anomalies, and obvious airway abnormalities. A detailed cardiac exam and respiratory exam must be performed to assess for any abnormalities.
 - Chest x-ray (CXR), Echocardiogram and Electrocardiogram (ECG) must be obtained if the patient's history or physical exam suggests cardiac or pulmonary abnormalities. (If available, review by a cardiologist would be ideal).
 - Laboratory work:
 - ALL patients must receive a complete blood count (CBC).
 - ALL patients must have a minimum preoperative hemoglobin level of 10g/dL. Patients must **NOT** have received a blood transfusion prior to surgery in order to meet the operative hemoglobin requirement.
 - Patients with cleft palate should have PT/PTT or bedside bleeding and coagulation time if their history is suggestive of bleeding tendencies.

Requirement 3.2: Preoperative Anesthesia Evaluation

- ❖ A preoperative anesthesia assessment must be performed and documented by the anesthesia provider.
- ❖ This assessment must occur the day before surgery and should not be obtained once the patient has entered the operating theater.
- ❖ The anesthesia provider must:
 - Review the pediatrician's patient history and physical exam, noting specifically:
 - Past surgical history including any complications.
 - Previous anesthetic complications including any family history of adverse reactions to anesthesia.
 - Review of any implications of prematurity if present.
 - Review the child's nutritional status based on weight, height, and age.
 - Discuss with the parent (legal guardian) and patient the pediatrician's assessment and any new medical issues since the patient's last visit with the pediatrician.
 - Review and document the patient's current list of medications.
 - Document patient's known allergies (e.g., medications and reactions).
 - Document current vital signs (BP, HR, RR, O2 saturation, weight)
 - Conduct a focused physical exam. Particular attention should be focused on the patient's airway, cardiac and respiratory status.
 - A child identified to have an active lower respiratory infection (LRI) or upper respiratory infection (URI) with constitutional symptoms (e.g., fever or malaise) must have surgery delayed by 4-6 weeks until their health status is optimized. A child identified to have a URI but no constitutional symptoms should be evaluated by an anesthesia provider on a case-by-case basis regarding the appropriateness for surgery. These cases may need to be delayed by 2 weeks until the URI symptoms have resolved.
 - Review lab results.
 - Discuss the anesthetic plan with the patient and/or parents. Patient and/or parents and anesthesia provider should sign informed consent.
 - Review NPO guidelines for surgery with patients and parents.
 - Encourage the patients to drink non-carbonated clear fluids

Fluid:	Recommended fasting time:
Clear fluids	2 hours
Breast milk	4 hours
Cow's milk/ formula	6 hours
Solids	6hours

- Anesthesia clearance must be obtained prior to surgery.

Requirement 3.3: Day of Surgery

- ❖ Prior to surgery, a member of the team (nurse,) must
 - Ensure patient is afebrile and has age-appropriate vital signs.
 - Verify appropriate NPO status and confirm patient is not dehydrated.
 - Alert the anesthesia provider and surgeon if there are any concerns with the patient

Requirement 3.4: Operating Theater Equipment & Supplies

The following equipment and supplies must be available in each operating theater:

- Adequate lighting
- Well-maintained and sterilized cleft set and related surgical instruments.
- Supply of oxygen (oxygen concentrator, cylinders, or pipeline)
- Airway management equipment:
 - Appropriately sized oropharyngeal and nasopharyngeal airways
 - Appropriately sized facemasks

- Appropriately sized laryngoscope and blades
- Appropriately sized endotracheal tubes
- Intubation aids, e.g., Magill forceps, bougie, stylet
- Adult and pediatric self-inflating resuscitation bags
- Tracheostomy tray
- A well-organized difficult airway trolley
- All functional anesthesia machines should include:
 - Inspired oxygen concentration monitor.
 - Oxygen supply failure device to prevent delivery of a hypoxic gas mixture.
 - System to prevent misconnection of gas sources (e.g., tank yokes, hose connectors)
 - Should be checked daily and documentation available.
 - Should be regularly serviced and documented.
- Monitoring equipment:
 - Electrocardiogram (ECG)
 - Defibrillator (at least one functioning defibrillator should be available in the operating room area)
 - Stethoscope
 - Pulse oximeter
 - Non-invasive blood pressure monitor with appropriately sized cuffs.
 - Temperature probes
 - ETCO₂ where available
- Suction device and suction catheters
- Equipment for IV infusions and injection of medications (including burette sets, if available).
- Patient warmers

All equipment and supplies must be in good working order. If any of the specified equipment is not functioning properly, surgeries must be delayed until repaired or replaced.

PART 4: SURGICAL AND ANESTHESIA CARE REQUIREMENTS

Requirement 4.1: Qualified Clinical Professionals:

- ❖ Only qualified, credentialed cleft surgeons registered in Smile Train Express are permitted to perform surgery on Smile Train-sponsored patients. These surgeons must be trained, have current certification in their country, and have ongoing experience in surgery for cleft lip and palate. Qualified surgeons must:
 - Demonstrate they regularly perform cleft surgeries occur regularly by sharing of patient lists, surgical schedules, and volume.
 - Demonstrated that the facility has experience in cleft surgery by having performed cleft surgeries in the previous six months.
 - Surgical trainees must be supervised **DIRECTLY** by the credentialed cleft surgeons
 - Registered in Smile Train's online patient database Smile Train Express.
- ❖ Only qualified credentialed anesthesiologists or non-physician anesthesia providers who are registered in Smile Train Express with current certification in their country and have ongoing experience and familiarity in caring for infants and young children may provide anesthesia for Smile Train patients.
- ❖ Smile Train-sponsored patients must be transferred from the theatre to the recovery room by a fully trained provider and appropriately handed over to the PACU staff. Prior to transfer to the ward, the patients must be signed out by the anesthesia provider. The PACU nurse will then be responsible for appropriately handing the patient over to the ward nurses.

PART 5: INTRAOPERATIVE SURGICAL AND ANESTHESIA REQUIREMENTS

Requirement 5.1: Safe Surgical Environment:

- ❖ The World Health Organization Surgical Safety Checklist (or and adapted version) should be used for every surgery

performed to enhance patient safety and documented in the patient's chart (this may be a copy of the checklist if available or documentation that the process was completed).

- ❖ Appropriately trained operating theater personnel experienced in cleft surgery.
- ❖ All operating theater personnel must change into clean scrubs before entering the operating theater.
- ❖ Staff familiar with sterile techniques and access to functional sterilizing machines must be available.
- ❖ During general anesthesia, care must be taken to protect patient's eyes to avoid corneal injuries.
- ❖ Appropriate surgical equipment to safely perform cleft lip and palate surgery.
- ❖ During use of electrocautery, care must be taken by the team for proper use to avoid burns to the patient.
- ❖ For cleft palate surgeries, blood and blood transfusion capabilities must be readily available.
- ❖ Modalities and devices for temperature regulation should be available in the operating theater.

Requirement 5.2: Intraoperative Medication/Intravenous Fluids/Gases:

- ❖ The following medications must be always available in the operating theater:
 - Ketamine
 - Diazepam or midazolam
 - Analgesia: Paracetamol, NSAIDs, Narcotics e.g., morphine, pethidine or fentanyl, regional blocks (where applicable) Local anesthetics (e.g., lidocaine or bupivacaine)
 - Thiopentone or propofol
 - Appropriate inhalational anesthetic (e.g., halothane, isoflurane, sevoflurane)
 - Nondepolarizing muscle relaxant
 - Neostigmine
 - Naloxone
 - Dexamethasone and hydrocortisone
 - Tranexamic acid
- ❖ These resuscitation medications must be always available in the operating theater:
 - Oxygen (supplemental oxygen must be available for all patients undergoing anesthesia)
 - Epinephrine (adrenaline)
 - Ephedrine or phenylephrine
 - Atropine
 - Succinylcholine
 - Inhaled racemic epinephrine
 - Inhaled bronchodilators
 - Dextrose for management of *diagnosed* hypoglycemia.
- ❖ Normal saline or Ringer's lactate must be always available in the operating theater.
- ❖ Hypotonic IV solutions should be avoided perioperatively.
- ❖ All medications and IV fluids must be clearly labeled and dated
- ❖ If procurable, dantrolene sodium should be available for treatment of cases of malignant hyperthermia.

Requirement 5.3: Standard monitoring intraoperatively:

- ❖ Monitoring by a trained anesthesia provider intraoperatively, present throughout the surgery and with standard monitoring as referenced in 3.4 above.
- ❖ An intraoperative anesthetic record must be used. All medications administered (including time and dosage administered) must be documented. Vital signs must be recorded contemporaneously (every 5 minutes).

PART 6: POSTOPERATIVE SURGICAL AND ANESTHESIA CARE REQUIREMENTS

Requirement 6.1: Safe Postoperative Environment:

- ❖ It is expected that the operating surgeon will remain in the operating theater suite until the patient is extubated and breathing spontaneously with stable vital signs.
- ❖ All patients must be awake, breathing spontaneously, and administered supplemental oxygen by facemask when transported from the operating theater to the post anesthesia care unit (PACU).
- ❖ The anesthesia provider should oversee all patient care until he/she is moved to the ward.
- ❖ A well-stocked crash cart should be easily accessible to the PACU, and ward. Care should be taken to regularly replenish materials after use.

Requirement 6.2: Safe Postoperative PACU Care:

- ❖ There must be a designated PACU where all patients can be transported after surgery to recover from anesthesia. This area must be staffed by a nurse or anesthesia provider (ideally 1:2 practitioner to patient ratio) who are trained in airway management and postoperative monitoring (blood pressure, ECG, temperature, and pulse oximetry monitoring) and recognition of warning and danger signs.
- ❖ A clear handover tool from OR to PACU and onward to post-operative ward with clear instructions must be available.
 - All patients must be monitored, and vital signs recorded contemporaneously every 5 minutes on a PACU record for the first hour and then every 15 minutes until discharge from the PACU.
 - Assessment of pain
- ❖ Patients must remain in PACU until they are fully awake, pain is controlled, and there is no evidence of nausea, vomiting or postoperative bleeding. Typically, this will be one to two hours postoperatively. Before any patient is transferred to the ward, an anesthesia provider must evaluate the patient and deem that the patient is stable enough to be transferred to the ward.

Requirement 6.3: Safe Postoperative Ward Care:

- ❖ A handover document should be completed by the PACU team for the ward staff with written details of problems to anticipate, plan for pain management, whom to contact in case of an emergency/complication (including phone number) and instructions on when and how feeding may be initiated.
- ❖ All patients on the ward should have a 4 hourly pulse, respiratory rate and O₂ saturation monitored by ward staff overnight.

Requirement 6.4: High Dependency Care Provisions:

- ❖ All surgical facilities must have access to a high dependency care unit (e.g., intensive care unit [ICU] for patients with severe and life-threatening illnesses and injuries who require constant, close monitoring). These units can be within the hospital.
- ❖ If high dependency care capabilities are not available within the hospital, a current written transfer agreement with a nearby healthcare facility that can provide this type of intensive care must be in place for Smile Train-sponsored surgeries. The healthcare facility that is providing the intensive care must agree to document care provided and share all medical information with the referring hospital in a timely manner.
- ❖ An anesthesia provider, intensivist, pediatrician, or anesthesiologist must oversee ICU management and care provided to Smile Train sponsored patients.
- ❖ Nurses trained to care for critically ill patients must be available. Ideally a 1:2 nurse to patient ratio.
- ❖ Written protocols must be in place and implemented by the staff for emergency care, triage, CPR, and blood transfusions. The use of regular emergency drills is strongly encouraged.
- ❖ A handover document should be completed by the anesthesia provider for the ICU staff.

PART 7: SENTINEL EVENTS

Requirement 7.1: A sentinel event is an unexpected event that results in death, serious permanent physical or psychological injury, or severe temporary harm to a patient. Examples of sentinel events include, but are not limited to, patient death, cardiac arrest, respiratory arrest, stroke, aspiration or aspiration pneumonia, and unanticipated return to the operating theater:

- ❖ Within 24 hours of a sentinel event occurrence partner hospital must:
 - Report the occurrence of the sentinel event to Smile Train by emailing medical@smiletrain.org.
 - Complete Smile Train’s Sentinel Event Form (Part One) and email to medical@smiletrain.org.
- ❖ Within 1-3 weeks of the sentinel event occurrence
 - A safety and quality reviewer will meet with the team involved in the patient’s treatment to facilitate a mortality and morbidity meeting (virtual or physical). The aim of this meeting is to discuss the sequence of events and synthesize potential context specific recommendations and learning points from the event in a collegial setting.
 - All sentinel events must be discussed by the cleft team at the healthcare facility so that opportunities for improvement in quality of care can be identified and action plans initiated.
- ❖ Within 14 days of the sentinel event occurrence:
 - Partner hospital must complete Smile Train’s Sentinel Event Report (Part Two) and email to medical@smiletrain.org.
 - Partner hospital must prepare and send the patient’s medical record (preoperative history & physical, pre-, intra-, and postoperative records including the anesthesia preoperative assessment and intraoperative record, PACU record, all physician and nursing progress notes, lab reports, operative reports, and any additional narratives) to medical@smiletrain.org.
- ❖ Within 3-6 weeks of the Sentinel Event occurrence:
 - Smile Train’s Medical Advisory Board will review and analyze the medical records received and will provide constructive feedback to the partner hospital in the form of an analysis and memorandum.
- ❖ The partner hospital will send written confirmation of the analysis and plans for inclusion of constructive feedback and recommendations. All partner hospitals that experience a sentinel event resulting in the death of a Smile Train-sponsored patient will be required to undergo a safety and quality audit of their facility conducted by an independent pediatric anesthesiologist appointed by Smile Train.

Recognizing that patient safety is always our #1 priority, I have read Smile Train’s Safety and Quality Protocol, and certify that _____(organization/hospital) meets and will adhere to these requirements.

Signature	Name
Title	(Hospital administration) Date
Signature	Name
Title	(Head of Surgery) Date
Signature	Name
Title	(Head of Anesthesia) Date
Signature	Name
Title	(Head of Nursing) Date

