



## SAFETY AND QUALITY PROTOCOL

41 Madison Avenue, 28th Floor • New York, NY 10010, USA • T +1.212.689.9199 • F +1.212.689.9299 • info@smiletrain.org • www.smiletrain.org

**Purpose:** This document describes the requirements that must be met by health care organizations performing cleft surgeries funded by Smile Train. Patient safety is always our # 1 priority. This Safety and Quality Protocol outlines the basic elements needed to ensure safe surgeries and to provide for the ongoing review and improvement of the quality of care.

### PART 1: THE QUALITY REVIEW PROCESS

#### **Requirement 1.1: Keep complete, organized and accurate records of care received by patients funded by Smile Train, by:**

- Using the Patient Medical Record for all patients undergoing Smile Train-sponsored cleft surgeries. The health care facility agrees that these patient records will be used as part of Smile Train Express, a free, global, cleft care database ([www.smiletrainexpress.org](http://www.smiletrainexpress.org)).
  - Charting should be legible and performed as soon as clinical events occur.

#### **Requirement 1.2: Have an organized process for the review of the results of surgeries by clinical staff, by:**

- Having a regularly scheduled meeting at which members of the medical staff (surgeons, anesthesiologists or participating anesthesia providers, pediatricians, and critical care staff) review all patient records (see Requirement 1.1) no less than every 3 months, and discuss surgical outcomes and results. Sentinel events (see Requirement 1.3), if any, should be discussed within a 2-week period of the event so that opportunities for improvement in quality of care can be identified and action plans initiated.
- Keeping minutes of these meetings to periodically assess the quality review process.

#### **Requirement 1.3: Promptly review all sentinel events. A sentinel event is an unexpected event involving death or serious physical or psychological injury. 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 room, by:**

- Reporting the occurrence of all sentinel events to the Smile Train country manager within 24 hours of the event's occurrence, by telephone or email. Country managers will report these events to Smile Train headquarters in New York, by telephone or email, within 24 hours. Country managers will be responsible for obtaining confirmation from Smile Train that this notification has been received.
- Completing and submitting Smile Train's Initial Sentinel Event Form (Part One of the Sentinel Event Report) to the country manager within five (5) working days of the event. The country manager will immediately forward this form to Smile Train headquarters in New York.
- Reviewing the circumstances surrounding the sentinel event in order to understand causes, and developing system changes to educate involved personnel in order to improve patient care and safety and to prevent a repeat occurrence. In conducting this review, the facility will follow the format of Smile Train's Event Analysis Form (Part Two of the Sentinel Event Report). The facility will submit the Event Analysis Form and a complete copy of the patient's chart (containing all pre- and post-operative records, including the anesthesia record, recovery room record, all physician and nursing progress notes, lab reports, operative reports, and preoperative history/physical) with optional additional narrative, to its country manager within 30 calendar days of the event. The manager will forward the Sentinel Event Report (Parts One and Two) to Smile Train headquarters in New York within 24 hours.
  - A member of 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 receipt and discussion of this information.

## **PART 2: THE SELECTION OF PATIENTS FOR CLEFT SURGERY**

### **Requirement 2.1: Have a process in place to ensure patients selected for surgery are healthy enough to undergo the surgery safely, by:**

- Ensuring that every patient undergoing cleft surgery has received a complete history and physical exam and health clearance from a primary care physician (pediatrics or family practice) familiar with the average health status and common health problems of the locality in which the health care facility is located. A careful and thorough preoperative evaluation is designed to identify and exclude areas of risk.
- Including basic lab work to rule out anemia and active respiratory or urinary tract infection. Severely underweight children should be examined for gastrointestinal parasites and treated preoperatively if possible. A child presenting with a recent upper respiratory infection (URI) should be deferred for 4-6 weeks if possible and health status optimized, as these cases are essential. Consideration should be given to preoperative malaria screening and prophylaxis in endemic areas.
- Smile Train will not sponsor surgery for any patient who, during history and physical exam, is found to be at high risk of developing perio-post-operative problems, surgical or anesthetic. Smile Train will not sponsor surgery for any patient under three months of age for lip surgery or under six months for palate surgery. Further, patients should be of the appropriate weight for their age and Smile Train will not sponsor surgery for any patient who is less than 5kg. It is recommended that patients should have a hemoglobin level of at least 10g/Hb to ensure safe surgery. It is mandated that no Smile Train patient should undergo a pre-operative blood transfusion to increase hemoglobin level.
- All patients undergoing Smile Train-funded surgeries must be American Society of Anesthesiology (ASA) physical status class 1 or class 2. [ASA 1 patients have no organic, physiologic, biochemical, or psychiatric disturbance and the disease for which the operation is to be performed is localized and does not entail a systemic disturbance. ASA 2 patients are those with mild to moderate systemic disturbance caused either by the condition to be treated surgically or by other pathophysiologic processes, including the otherwise healthy child with cleft lip or palate]. All patients should be carefully examined pre-operatively by a qualified and experienced clinician for age related body weight, hemoglobin count, absence of infections and systemic anomalies including syndromes.
- Additionally, no Smile Train partner hospital or surgeon should perform a Smile Train sponsored surgery on the same patient within 90 days. This directive is intended to allow for proper healing time following a Smile Train sponsored surgery. If a follow up surgery is deemed medically necessary, it must take place at least 90 days after the initial surgery.

## **PART 3: THE SURGERY**

### **Requirement 3.1: Be capable of providing safe anesthesia to young children, by:**

- Having an anesthesiologist or participating anesthesia provider with current certification, experience, and familiarity in caring for small children as documented by frequent cases done during the preceding 24 months.
- Using anesthesia machines and (or preferably, with) end-tidal carbon dioxide monitors or having, at a minimum:
  - Vaporizers for halothane or preferably sevoflurane
  - A functioning oxygen supply
  - A sufficient drug formulary including antibiotics, I.V. hypnotics (e.g., thiopental, propofol, or ketamine), I.V. and oral analgesics, muscle relaxants (e.g. succinylcholine) and emergency drugs (e.g., epinephrine, atropine, lidocaine, and dexamethasone)
  - An up-to-date reference book on pediatric anesthesia, including pediatric/adult resuscitation algorithms
- Using ECG and pulse oximeters with appropriately sized probes for children during surgery and having appropriately sized blood pressure cuffs and precordial stethoscopes and having temperature monitoring capability.
- Having and using other anesthesia equipment (including endotracheal tubes, oral airways, face masks, laryngoscopes and blades, masks, stylettes, airway circuits, suction catheters, IV catheters and tubing, disposable needles and syringes) sized appropriately for the young child.
- All of this equipment must be in good working order. If any of the specified equipment is not functioning properly, surgeries sponsored by Smile Train must be deferred or suspended.

- Medications and fluids should be charted concurrently as they are given, with vital signs (heart rate, blood pressure, oxygen saturation, ventilatory data, and temperature). Entries should be made every five minutes while the patient is in surgery and in post-operative recovery.

**Requirement 3.2: Have surgeons qualified to perform cleft surgery, by:**

- Using qualified credentialed surgeons to perform the cleft surgery who are trained and have ongoing experience in surgery for cleft lip and palate. They should be currently certified in their country and registered on Smile Train Express.

**Requirement 3.3: Perform cleft surgeries as a regular part of an ongoing surgical program, by:**

- Demonstrating that cleft surgeries occur regularly by sharing of patient lists and surgical schedules and volume.
- Demonstrating that the facility has experience in cleft surgery by having performed cleft surgeries in the previous six months.

**Requirement 3.4: Provide a safe surgical environment, by:**

- Using the World Health Organization Surgical Safety Checklist to insure that each surgical team verbally confirms that necessary safety steps have been completed. A copy of the checklist is attached to this protocol.
- Having experienced operating room personnel
- Having staff familiar with sterile technique and access to functional sterilizing machines.
- Having ability to coagulate bleeders intraoperatively.
- Having blood transfusion capability if needed.
- Having adequate water and electrical power supplies and lighting.
- Schedule surgery for young patients and palate cases as early as possible in the surgery schedule for the day.
- Having the anesthesia capability described under Requirement 3.1.

**PART 4: POST-SURGICAL AND EMERGENCY CARE**

**Requirement 4.1: Provide safe post-anesthesia care, by:**

- Having a policy and procedure where anesthesiologists or participating anesthesia providers extubate patients when they are awake enough to have a return of normal upper airway reflexes.
- Having the surgeon immediately available in the operating room suite until the patient is breathing spontaneously, is extubated, and has a clear airway.
- Having a designated unit for post-anesthesia care which is adjacent to or in the operating room suite.
- Having a clearly delineated medical chain of command, communication and responsibility for care of children in the first 24 hours after cleft surgery. This includes the ready availability of a physician capable of recognizing and treating any complications that might occur.
- Having and using pulse oximeters (appropriately sized for children) to monitor patients in recovery.
- Staffing the post-anesthesia care unit with providers trained in recovery care and airway management. They should have post-anesthesia care as a regular part of their job. Recovery care training must include how to recognize bleeding, hypo/hypertension, airway obstruction, respiratory depression and hypoxemia as detected by a pulse oximeter.
- Having enough skilled ward or recovery room staff that individualized observation is possible the first night after surgery. Specifically, all patients in the recovery area must be monitored by a nurse until they are fully awake and crying. All patients must be assessed at regular, frequent intervals for post-operative bleeding.
- Monitoring ward patients at least every 60 minutes for the first six to eight hours and not left in the care of untrained family members. Night staff should be fully oriented to regular cleft care routines and able to recognize problems as they occur.
- Having post-operative oral feeding protocols in place that are implemented and supervised by knowledgeable and trained staff.
- Having post-operative pain management protocols with monitoring to avoid respiratory depression.

**Requirement 4.2: Be able to intervene and provide intensive care if required, by:**

- Having written protocols in place and known by the staff for emergency care, triage, CPR, and blood transfusions. The use of regular emergency drills is encouraged.
- Having on-site and immediately available a suctioning machine, resuscitative medicines, an oxygen delivery system and oxygen supply, an ECG, pulse oximeter, blood pressure monitors, and resuscitation equipment (defibrillator, cricothyrotomy kit, intraosseous needle) are desirable.
- Having the ability to re-intubate children and support their breathing with mechanical ventilators and provide 24-hour monitoring by trained clinical staff; **or by**
- Having a current, functioning transfer agreement for Smile Train sponsored surgeries with a nearby health care facility that can provide this type of intensive care. The health care facility which is providing the intensive care must agree to document and share all medical information with the referring hospital in a timely manner.

**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.**

**Signed** \_\_\_\_\_ **Name** \_\_\_\_\_

**Title** \_\_\_\_\_ **Date** \_\_\_\_\_