

Purpose: This document describes the requirements that must be met by health care organizations performing cleft surgeries funded by The Smile Train. The safety of the patient is always our # 1 priority. This Safety and Quality Improvement Protocol outlines the basic elements needed to insure 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 The 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 The Smile Train Express, a free, global, cleft care database (www.smiletrainexpress.org).

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 and anesthesiologists) review all patient records (see Requirement 1.1) no less than every 4 months, discuss surgical results and sentinel events (see Requirement 1.3), if any, and discuss opportunities for improvement in the quality of surgeries.
- The health care facility will keep minutes of these meetings which local partners will review to 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, BY:

- Reporting the occurrence of all sentinel events to local partners within 24 hours of the event's occurrence, by telephone or email. Local partners will report these events to The Smile Train main office in New York, by telephone or email, within 24 hours. Local partners will be responsible for obtaining confirmation from The Smile Train that this notification has been received.
- Completing and submitting The Smile Train's Initial Event Form (Part One of the Sentinel Event Report) to the local partner within five (5) working days of the event. The local partner will immediately forward this form to The Smile Train main office 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 The Smile Train's Event Analysis Form (Part Two of the Sentinel Event Report). The facility may, if it wishes, also submit a narrative report of the event. The facility will submit the Event Analysis Form and a copy of the patient's chart (containing all pre- and post-operative records, including the anesthesia record, the recovery room record, all physician and nursing progress notes, lab reports, operative reports, and preoperative history/physical) with optional additional narrative, to its local partner within 30 calendar days of the event. Local Partners will forward the Sentinel Event Report (Parts One and Two) to The Smile Train main office in New York within 24 hours of their receipt of the reports.

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.
- The history and physical exam should include basic lab work to rule out anemia and respiratory or urinary tract infection. Severely underweight children should be examined for gastrointestinal parasites and treated preoperatively if possible. Consideration should be given to preoperative malaria screening and prophylaxis in endemic areas.
- The Smile Train will not sponsor surgery for any patient who, in this history and physical exam, is found to be at high risk of developing anesthesia problems peri- or post-operatively. All patients undergoing Smile Train-funded surgeries must qualify for American Society of Anesthesiology (ASA) physical status class 1 or class 2. [ASA class 1 patients have no organic, physiologic, biochemical, or psychiatric disturbance and the pathologic process for which the operation is to be performed is localized and does not entail a systemic disturbance. ASA class 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.]

Part 3: The Surgery

Requirement 3.1: Be capable of providing anesthesia safely to young children, BY:

- Having anesthesia provided by an anesthesiologist with experience caring for small children as documented by the cases done by that anesthesiologist/ anesthesiologist during the preceding 24 months.

- Using anesthesia machines and (or preferably, with) carbon dioxide monitors or having, at a minimum:
 - Vaporizers for Halothane
 - A functioning oxygen supply
 - A sufficient drug formulary including antibiotics, I.V. hypnotics (e.g., thiopental), I.V. and oral analgesics, muscle relaxants (e.g. succinylcholine) and emergency drugs (e.g., atropine, lidocaine, dexamethasone)
 - An up-to-date reference book on pediatric anesthesia.
- Using pulse oximeters, appropriately sized for children, during surgery and having appropriately sized blood pressure cuffs and precordial stethoscopes.
- Having and using other anesthesia equipment (including endotracheal tubing, IV catheters and tubing, oral airways, masks, laryngoscopes and laryngoscopic blades, stylettes, circuits, suction catheters, disposable needles and syringes) sized appropriately for the age of the child.
- **All of this equipment must be in good working order. If any of the specified equipment is not functioning properly, surgeries sponsored by The Smile Train must be suspended.**
- Recording the details (heart rate, blood pressure, ventilatory data, agents and drugs administered, etc.) of each anesthetic on a standard form and filing the form for later review.

Requirement 3.2: Have surgeons qualified to perform cleft surgery, BY:

- Using surgeons to perform the cleft surgery who are trained to perform and have experience in surgery for cleft lip and palate.

Requirement 3.3: Perform cleft surgeries as one regularly-occurring part of an ongoing surgical program, BY:

- Demonstrating to the local partner that cleft surgeries occur regularly through sharing of information on surgical schedules.
- Demonstrating to the local partner that the facility has experience in the delivery of cleft surgery by having performed cleft surgeries in the past year.

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 working sterilizing machines.
- Having ability to coagulate bleeders intraoperatively.
- 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 that anesthesiologists extubate patients when they are awake enough to have a return of normal upper airway reflexes.
- Having a 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 OR 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 treating any complications that might occur.
- Having and using pulse oximeters (again, appropriately sized for children) to monitor post-anesthesia care patients.
- Staffing the post-anesthesia care unit with clinical staff with training in recovery care and who have post-anesthesia care as a regular part of their job. The training in recovery care must include how to recognize hypo/hypertension, airway obstruction, respiratory depression and hypoxemia as detected by a pulse oximeter.
- Having sufficient numbers of skilled post-anesthesia 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 and all patients must be assessed at regular, frequent intervals for post-operative bleeding.

Requirement 4.2: Be able to intervene to provide intensive care if a patient requires it, BY:

- Having written protocols in place and known by the staff for emergency care, triage, CPR, and blood transfusions.
- Having on-site and immediately available a suctioning machine, resuscitative medicines, an oxygen delivery system and oxygen supply, an ECG and blood pressure monitors, and resuscitation equipment.
- Having the ability to 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 with a health care facility that can provide this type of intensive care.

I have read the Smile Train Safety and Quality Improvement Protocol, and certify that _____ (organization/hospital) meets and will adhere to these requirements.

Signed	Name	Title	Date
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