



## Surgical Outreach Safety Audit Checklist

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The goal of the Surgical Outreach Safety Audit Checklist is to ensure that outreach hospitals are delivering safe, high-quality cleft surgery, by upholding the detailed requirements outlined in Smile Train's Safety and Quality Protocol. Audits are an important resource for quality assurance/improvement and are not meant to be punitive in nature. Safety in pediatric surgery is multidimensional and this Safety Audit Checklist focuses on three important areas to patient safety:

- i) Infrastructure and facilities
  - Instrumentation and equipment within and outside the operating theater
  - Emergency intervention devices and facilities
  - Reliability of medical equipment and hardware
- ii) Qualifications, experience and technical competence of medical personnel
  - Treating cleft surgeons and anesthesia providers
  - Other involved medical specialists
  - Paramedical staff
- iii) Systems, protocols and practices
  - Record keeping/surgical outcomes evaluation
  - Morbidity and mortality reporting and sentinel event review systems
  - Existence of clearly outlined, pre-, intra- and postoperative systems; including demonstrated understanding and compliance
  - Quality management in safety related areas

## Hospital Overview

<b>Outreach Hospital:</b>	<b>Notes:</b>
Name of hospital: Address:	
<u>Type of Hospital:</u> <input type="checkbox"/> Public <input type="checkbox"/> Private	
Number of hospital beds (total):  Number of pediatric beds:	
Number of operating theaters:	
Total number of surgery admissions/year:	
Total number of surgery admissions/year under general anesthesia:	
Number of pediatric surgeries/year:	

The following audit sections are based on a scoring system. Please follow these instructions:

- **Complete compliance of a mandatory item should be assigned a score of 2**
- **Partial compliance of a mandatory item should be assigned a score of 1**
- **Presence of an optional item should be assigned a score of 1**

## General Hospital Infrastructure & Facilities

Does the surgical outreach hospital:	Mandatory	Optional	Score	Notes
Have a separate pediatric surgery operating room?				(If yes, please indicate the number of operating tables)
Have a Post Anesthesia Care Unit (PACU) to monitor patients postoperatively?				(A PACU is a unit where patients are temporarily admitted after surgery to safely regain consciousness from anesthesia and receive appropriate post-operative care.)
Have a designated ward for cleft patients?				(If yes, please note number of beds)
Have a separate pediatric ward?				(If yes, please indicate the number of beds)
Have a regularly scheduled daily operating schedule?				(If no, how many days a week are cases scheduled?)
Have high dependency care capabilities (e.g. intensive care unit (ICU)) or a transfer facility in place for patients in need of intensive care?  For hospitals without ICU,  Is there access to ambulance service with life support measures and monitoring facility?				(If no, how far is the nearest ambulance service area?)
Have access to blood?				(If no, how far is the blood bank from the hospital? Please note the distance in kilometers and time it takes to access blood)

Does the surgical outreach hospital:	Mandatory	Optional	Score	Notes
Have a 24-hour lab with Arterial Blood Gas capability?				(If no, is there a facility nearby? Please note the distance in kilometers)
Have a backup generator in case of power failure?				

**TOTAL SCORE**\_\_\_\_\_

## Patient Medical Record

### Requirement 1.1: Documentation Standards

Does the surgical outreach cleft team:	Mandatory	Optional	Score	Notes
Use Smile Train's Patient Medical Record for all patients undergoing Smile Train sponsored cleft surgeries?				
Keep clear, legible and contemporaneous records of all preoperative surgical assessments and preoperative anesthetic evaluations?				
Keep clear, legible and contemporaneous records of the intraoperative period including: <ul style="list-style-type: none"> <li>▪ Anesthesia intraoperative record and notes?</li> <li>▪ Surgeon operative record and notes?</li> </ul>				
Record timings of all drugs administered, and vital signs monitored in the intraoperative anesthesia record?				
Have standard intra-operating monitoring and recording of vital signs at least every 5 minutes?				
Keep clear, legible and contemporaneous ward nursing records?				

**TOTAL SCORE**\_\_\_\_\_

## Requirement 1.2: Evaluation of Surgical Outcomes

Does the surgical outreach cleft team:	Mandatory	Optional	Score	Notes
Have regularly scheduled meetings where members of the cleft team review all patient records to discuss surgical outcomes and treatment results no less than every 3 months?				
Review the circumstances surrounding sentinel events (surgical complications and patient death) to understand causes?				
Develop system changes to educate medical personnel involved in sentinel events (surgical complications and patient death) to improve patient care and safety?				

**TOTAL SCORE** \_\_\_\_\_

## Preoperative Assessment

### Requirement 2.1-2.2: Patient Selection & Evaluation

Does the surgical outreach cleft team:	Mandatory	Optional	Score	Notes
Adhere to ASA physical status requirements for Smile Train patient selection?				(All patients undergoing Smile Train sponsored surgery must be ASA Class 1 or 2)
Adhere to Smile Train's minimum weight requirement for patient selection?				(Patients must be at least 5 kg and age-appropriate weight)
Adhere to Smile Train's minimum age requirement for patient selection?				(Patients must be 3 months or older for cleft lip surgery and 6 months or older for cleft palate surgery)
Have a pediatrician, medical officer or primary care provider assessing all cleft patients by taking a thorough preoperative history, conducting a physical exam, and issuing health clearance before surgery?				

Understand that Smile Train will only fund surgery for patients who are found to be at low risk of developing surgical or anesthetic perioperative complications during history and physical exam?				
Have a designated staff member obtaining patient informed consents prior to cleft surgery?				

**TOTAL SCORE**\_\_\_\_\_

**Requirement 2.3: Scheduling of Patients**

<b>Does the surgical outreach cleft team:</b>	<b>Mandatory</b>	<b>Optional</b>	<b>Score</b>	<b>Notes</b>
Adhere to Smile Train’s requirements on scheduling of cleft surgery?				(Pediatric patients under 2 years of age early in the surgery day and in no case later than 14:00)
Adhere to Smile Train’s advisory on combined lip and palate surgical procedures?				(Smile Train will not fund these procedures for children under 1 year of age)
Adhere to the mandatory gap of 90 days between two Smile Train-sponsored surgeries to allow time for proper healing following surgery?				

**TOTAL SCORE**\_\_\_\_\_

**Specific Preoperative Requirements**

**Requirement 3.1: Patient Evaluation**

<b>Does the surgical outreach cleft team’s preoperative assessment include documentation on:</b>	<b>Mandatory</b>	<b>Optional</b>	<b>Score</b>	<b>Notes</b>
History of Present Illness?				
Medical history including birth history and congenital anomalies?				
Patient’s known allergies (e.g. medications and reactions)?				

<b>Does the surgical outreach cleft team's preoperative assessment include documentation on:</b>	<b>Mandatory</b>	<b>Optional</b>	<b>Score</b>	<b>Notes</b>
Surgical history including any complications?				
History of previous anesthetic complications?				
Detailed physical exam for congenital anomalies and airway abnormalities?				
Detailed physical exam for heart and lung abnormalities				
Chest x-ray (CXR) or electrocardiogram (ECG) if patient presents with heart and pulmonary abnormalities?				
Laboratory workup including complete blood count (CBC) and bedside clotting time for cleft palate?				
PT/PTT cleft palate patients?				

**TOTAL SCORE**\_\_\_\_\_

**Requirement 3.2: Preoperative Anesthesia Evaluation:**

<b>Does the anesthesia provider on the surgical outreach cleft team:</b>	<b>Mandatory</b>	<b>Optional</b>	<b>Score</b>	<b>Notes</b>
Conduct preoperative anesthetic evaluations prior to surgery?				(These assessments should take place a day before the surgery and not in the operating theater on the day of surgery)
Review the pediatrician's patient history/physical exam and document any previous anesthetic complications?				
Discuss any new medical issues the patient presents with after the pediatrician's /medical				



<b>Does the anesthesia provider on the surgical outreach cleft team:</b>	<b>Mandatory</b>	<b>Optional</b>	<b>Score</b>	<b>Notes</b>
officer's preoperative assessment?				
Document the patient's known allergies (e.g. medications and reactions)?				
Conduct a directed patient physical exam that includes recording current vital signs including oxygen saturation and weight?				
Review lab data?				
Discuss general anesthetic plan and review NPO guidelines for surgery with patient and/or parents?				(Please confirm that cleft team understands Smile Train's NPO guidelines)
Document patient clearance for surgery?				

**TOTAL SCORE** \_\_\_\_\_

### Requirement 3.3: Day of Surgery

<b>Does the anesthesia provider on the surgical outreach cleft team:</b>	<b>Mandatory</b>	<b>Optional</b>	<b>Score</b>	<b>Notes</b>
Ensure that patients are afebrile and demonstrate appropriate vital signs?				
Ensure that patient has no signs of respiratory tract infection				
Verify appropriate NPO status for cases and ensure patients are not dehydrated?				
Use premedication as part of the routine care of preoperative pediatric patients?				

<b>Does the anesthesia provider on the surgical outreach cleft team:</b>	<b>Mandatory</b>	<b>Optional</b>	<b>Score</b>	<b>Notes</b>
Monitor patients with a functional pulse oximeter when premedication is used?				

**TOTAL SCORE** \_\_\_\_\_

**Requirement 3.4: Operating Theater Equipment & Supplies:**

<b>Does the surgical outreach cleft team have the following equipment and supplies during the surgical outreach program:</b>	<b>Mandatory</b>	<b>Optional</b>	<b>Score</b>	<b>Notes</b>
Adequate lighting?				
Well-maintained and sterilized cleft set and related surgical instruments?				
Supply of oxygen (oxygen concentrator, cylinders or pipeline)?				
Appropriately sized oropharyngeal and nasopharyngeal airways?				
Appropriately sized facemasks?				
Appropriately sized laryngoscope and blades?				
Appropriately sized endotracheal tubes?				
Micro-cuffed ET tubes?				
Intubation aids, e.g. Magill forceps, bougie, stylet?				
Adult and pediatric self-inflating resuscitation bags?				
Tracheostomy tray?				

<b>Does the surgical outreach cleft team have the following equipment and supplies during the surgical outreach program:</b>	<b>Mandatory</b>	<b>Optional</b>	<b>Score</b>	<b>Notes</b>
Difficult airway trolley (for storage of above airway equipment)?				
Inspired oxygen concentration monitor when using nitrous oxide or air?				
Anti-hypoxia device to prevent delivery of a hypoxic gas mixture when using nitrous oxide?				
System to prevent misconnection of gas sources if using nitrous oxide?				(e.g. tank yokes, hose connectors)
Electrocardiogram (ECG) machine?				
Defibrillator? Please indicate how many.				(At least one functioning defibrillator should be available in the OT complex)
Precordial Stethoscope?				
Pulse oximeter?				
Non-invasive blood pressure monitor with appropriately sized cuffs?				
End tidal carbon dioxide (ETCO <sub>2</sub> ) monitoring?				
Suction device and suction catheters?				
Equipment for IV infusions and injection of medications (including burette sets, if available)?				
IV pressure infuser bag?				
Equipment to maintain normal body temperature?				

**TOTAL SCORE**\_\_\_\_\_

## Surgical and Anesthesia Care Requirements

### 4.1: Qualified Clinical Professionals:

Does the surgical outreach team:	Mandatory	Optional	Score	Notes
Have experience in the delivery of cleft surgery?				Please indicate the number of cleft surgeries performed at the hospital in the last six months.
Have qualified, credentialed cleft surgeons to perform surgery on Smile Train sponsored patients?				If yes, do they hold current certifications in their own country?
Have qualified credentialed anesthesiologists or anesthesia providers with current certification in their country and ongoing familiarity in caring for young children?				Please indicate the number of pediatric patients intubated at the hospital in the last month.
Work with anesthesia providers that have postgraduate experience in pediatric anesthesia?				Please indicate number of years of experience of working with children.
Have anesthesia providers with experience working in the intensive care unit (ICU)?				
Have an additional anesthesia provider/intensivist available within the outreach hospital in case of emergency?				
Have a medical officer or a pediatrician working with the cleft team?				

**TOTAL SCORE**\_\_\_\_\_

## Intraoperative Surgical and Anesthesia Care Requirements

### Requirement 5.1: Safe Surgical Environment:

Does the surgical outreach cleft team:	Mandatory	Optional	Score	Notes
Use the World Health Organization Surgical Safety				

<b>Does the surgical outreach cleft team:</b>	<b>Mandatory</b>	<b>Optional</b>	<b>Score</b>	<b>Notes</b>
Checklist for every Smile Train sponsored patient?				
Work with operating theater personnel experienced in cleft surgery?				
Mandate that all operating theater personnel change into clean garments before entering the operating theater?				
Have familiarity with sterile techniques, access to functional sterilizing machines, and follow sterilization protocols?				
Perform routine surgical equipment checks?				If so, is there documentation for these checks?
Have the appropriate surgical equipment that is regularly serviced to safely perform cleft lip and palate surgery?				Please list equipment and date of last service.
Perform daily anesthesia machine checks?				Is there documentation for these checks?
Regularly service anesthesia machines?				Provide date of last service.
Have an existing operating theater disinfection protocol that is regularly followed?				
Have blood and blood transfusion capabilities readily available for cleft palate surgeries?				
Have supplemental oxygen for all patients undergoing general anesthesia?				
Monitor operating theater temperature?				

**TOTAL SCORE** \_\_\_\_\_

**Requirement 5.2: Intraoperative Medication/Intravenous Fluids/Gases:**

<b>Does surgical outreach cleft team have access to the following medication/intravenous fluids, and gases during the surgical outreach program:</b>	<b>Mandatory</b>	<b>Optional</b>	<b>Score</b>	<b>Notes</b>
Ketamine?				
Diazepam or midazolam?				
Narcotic analgesia: morphine or fentanyl?				
Local anesthetic (e.g. lidocaine or bupivacaine)?				
Thiopentone or Propofol?				
Appropriate inhalational anesthetic (e.g. halothane, isoflurane, sevoflurane)?				
Suxamethonium/Succinylcholine?				
Appropriate nondepolarizing muscle relaxant?				
Neostigmine (if employing non-depolarizing muscle relaxants)				
Atropine or Glycopyrrolate?				
Tranexamic acid?				
Oxygen? Supplemental oxygen?				
Epinephrine (adrenaline)?				
Inhaled racemic epinephrine?				
Dexamethasone?				
Ephedrine or phenylephrine?				
Inhaled bronchodilators?				
Hydrocortisone?				
Dextrose?				

Does surgical outreach cleft team have access to the following medication/intravenous fluids, and gases during the surgical outreach program:	Mandatory	Optional	Score	Notes
Amiodarone?				
Normal saline or Ringer's lactate?				

**TOTAL SCORE**\_\_\_\_\_

**Requirement 5.3: Intraoperative Anesthesia Monitoring:**

Does the anesthesia provider on the surgical outreach cleft team:	Mandatory	Optional	Score	Notes
Adhere to Smile Train's Safety and Quality Protocol requirements and remain in the OT with the patient at all times during surgery?				
Monitor all patients for pulse rate and quality?				
Monitor all patients for tissue oxygenation and perfusion?				
Monitor all patients for respiratory rate and quality?				
Monitor all patients for breath sounds?				
Monitor all patients for heart sounds?				
Record patient vital signs contemporaneously on intraoperative anesthesia record?				

**TOTAL SCORE**\_\_\_\_\_

## Postoperative Surgical and Anesthesia Care Requirements

### Requirement 6.1- 6.3: Safe Postoperative Care:

Does the surgical outreach cleft team have the following systems in place during the surgical outreach program:	Mandatory	Optional	Score	Notes
The surgeon remains in the operating theater until the patient is extubated and breathing spontaneously with stable vital signs?				
Guidelines in place for safely transferring patients from the operating theatre to the PACU?				(Smile Train's Safety and Quality Protocol requires that all patients must be awake and breathing spontaneously and with continuous monitoring and supplemental oxygen by facemask if needed when transported to the PACU)
A PACU staffed by experienced doctors and nurses who are trained in airway management and monitoring (blood pressure, ECG, and pulse oximetry)? Ideally 1:3 clinician to patient ratio.				
Staff to continuously monitor patients in PACU for tissue oxygenation and perfusion (with a pulse oximeter), respiratory rate, pulse rate and assessment of pain?				
Protocol to keep patients in PACU until they are awake, pain is controlled, and there is no evidence of nausea, vomiting or postoperative bleeding?				(Typically for one to two hours postoperatively)
Temperature control modality in the PACU?				
Anesthesia provider to ensure that a written care plan is shared with the ward staff?				(For example, details of problems to be expected, plan for pain management and instructions on when feeding may be initiated)
Designated staff on ward monitoring patients at night and documenting pulse, respiratory rate and O2 sat levels/hr?				(Auditor should conduct a spot check in the ward to ensure that this monitoring takes place)



Does the surgical outreach cleft team have the following systems in place during the surgical outreach program:	Mandatory	Optional	Score	Notes
Patients are postoperatively assessed for pain and follow Smile Train pain management protocol?				(It is important for anesthesiologists to work with the surgeons to determine what medications should be administered to pediatric patients to appropriately manage their pain without causing respiratory compromise)
Have a crash cart accessible in the PACU and the ward?				
Crash cart have the following medications/fluids:				
<ul style="list-style-type: none"> <li>▪ Nasopharyngeal airway or oropharyngeal tubes in assorted sizes</li> </ul>				
<ul style="list-style-type: none"> <li>▪ Laryngoscope handle and assorted blades</li> </ul>				
<ul style="list-style-type: none"> <li>▪ Cuffed and uncuffed endotracheal tubes in assorted sizes &amp; stylets</li> </ul>				
<ul style="list-style-type: none"> <li>▪ Laryngeal mask airway or esophageal-tracheal tubes or laryngeal tubes in assorted sizes</li> </ul>				
<ul style="list-style-type: none"> <li>▪ Cuffed tracheostomy tubes</li> </ul>				
<ul style="list-style-type: none"> <li>▪ Cricothyrotomy kit</li> </ul>				
<ul style="list-style-type: none"> <li>▪ Resuscitation bag and pediatric/adult masks</li> </ul>				
<ul style="list-style-type: none"> <li>▪ Nasal cannula</li> </ul>				
<ul style="list-style-type: none"> <li>▪ Nebulizer kit</li> </ul>				
<ul style="list-style-type: none"> <li>▪ Availability of Oxygen</li> </ul>				
Crash cart have the following medications/fluids:				
<ul style="list-style-type: none"> <li>▪ Portable oxygen tanks</li> </ul>				
<ul style="list-style-type: none"> <li>▪ Availability of portable suction machine</li> </ul>				
<ul style="list-style-type: none"> <li>▪ Defibrillator/EKG monitor with external pacing capabilities or an automated external defibrillator</li> </ul>				

Does the surgical outreach cleft team have the following systems in place during the surgical outreach program:	Mandatory	Optional	Score	Notes
▪ Pediatric/adult electrode defibrillator pads				
▪ IV catheters (materials to start IV: catheters, tape, alcohol, tourniquet, and tongue blades)				
▪ Needles/syringes				
▪ Intraosseous infusion needle				
▪ Primary/piggyback IV tubing				
▪ Ringer's lactate or normal saline				
Crash cart have the following medications/fluids:				
▪ Adenosine				
▪ Albuterol Inhaler				
▪ Aspirin				
▪ Atropine				
▪ Calcium Chloride 10%				
▪ Diphenhydramine				
▪ Dextrose 50%				
▪ Dopamine				
▪ Epinephrine				
▪ Furosemide				
▪ Hydrocortisone				
▪ Lidocaine				
▪ Mag Sulfate 50%				
▪ Methylprednisolone				
▪ Morphine sulfate narcotic cabinet				
▪ Narcan				

Does the surgical outreach cleft team have the following systems in place during the surgical outreach program:	Mandatory	Optional	Score	Notes
▪ Nitroglycerine				
▪ Procainamide				
▪ Sodium Bicarb 8.4%				
▪ Sotalol				
▪ Sterile Water				
▪ 0.9% Na chloride				
▪ Vasopressin				

**TOTAL SCORE** \_\_\_\_\_

#### Requirement 6.4: High Dependency Care Provisions

Does the surgical outreach team have the following in place at the outreach hospital:	Mandatory	Optional	Score	Notes
High dependency care capabilities (ICU) or a current, functioning transfer agreement for Smile Train-sponsored patients with a nearby healthcare facility?				
Guidelines for safely transferring patients? (Only applicable to partners using another hospital's ICU facility).				
A Trained anesthesia provider, intensivist or pediatrician overseeing ICU management and care provided to patients?				
Trained nurses and technicians to care for and assist with ICU management and monitoring of patients?				(Ideally 1:2 nurse to patient ratio)
Protocols in place and implemented by the staff for				

<b>Does the surgical outreach team have the following in place at the outreach hospital:</b>	<b>Mandatory</b>	<b>Optional</b>	<b>Score</b>	<b>Notes</b>
emergency care, triage, CPR, and blood transfusions?				
ICU equipped with mechanical ventilators to assist breathing through an endotracheal tube or a tracheostomy tube?				
ICU with functioning cardiac monitors?				
ICU equipped for constant monitoring of SpO <sub>2</sub> , NIBP, ECG, EtCO <sub>2</sub> , temperature?				
ICU equipped with intravenous lines?				
ICU equipped with feeding tubes?				
ICU equipped with nasogastric tubes?				
ICU with Arterial Blood Gas capability?				

**TOTAL SCORE** \_\_\_\_\_

**HOSPITAL SAFETY AUDIT SCORE:** \_\_\_\_\_

- A total score of  $\geq 288$  ( $>90\%$ ) – Partner hospital has successfully completed the safety audit (Auditor Signatory Option 1 pg. 21).
- A total score of 216 -288 ( $>75\%$ ) – Partner hospital has completed the safety audit; however, they must meet any missed Mandatory requirements to successfully complete the safety audit. This must be further signed off by Smile Train regional staff to ensure that all requirements have been met. (Auditor Signatory Option 2 pg. 21)
- A total score of 144 – 216 (50 – 75%) – Partner hospital must work on meeting any of the Mandatory requirements that were missed during the safety audit. The cleft surgery program should be temporarily suspended until these requirements are met. The hospital will need to be re-evaluated to ensure that they are in compliance with the Safety and Quality Protocol.
- A total score  $< 144$  ( $< 50\%$ ) – Partner hospital is not in compliance with many of the Mandatory requirements in the Safety and Quality Protocol. The Partner hospital should be suspended effective immediately while the regional team decides how to proceed with the partnership.

## Auditor’s Summary Report

Key Areas for Safety and Quality Improvement:

**Infrastructure/Facility:**

**Medical Personnel:**

**Systems/Practices/Protocols**

**Please select one of the following signatory options:**

**OPTION 1:**

"(Partner Conducting Surgical Outreach Program)" at "(Outreach Hospital)" has completed the Safety Audit and is compliant with the required standards in Smile Train's Safety and Quality Protocol.

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Smile Train Auditor Signature

\_\_\_\_\_

Date of Audit

**OPTION 2:**

"(Partner Conducting Surgical Outreach Program)" at "(Outreach Hospital)" has completed the Safety Audit and has been instructed on the mandatory requirements that were missed and must be met in order for the surgical outreach program to be compliant with Smile Train's Safety and Quality Protocol. Programs at this outreach hospital will be temporarily suspended until these areas have been addressed and verified by a Smile Train Regional staff member.

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Smile Train Auditor Signature

\_\_\_\_\_

Date of Audit

"Regional Staff Name" has verified that the Partner conducting surgical outreach programs at the outreach hospital has met the mandatory requirements that were missed on the Safety Audit and is now ready to resume their outreach programs.

\_\_\_\_\_

Smile Train Staff Signature

\_\_\_\_\_

Date of Audit