SmileTrain
Changing The World One Smile At A Time.

Safety and Quality Improvement Protocol

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/ anesthetist 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

World Health Organization

Surgical Safety Checklist (First Edition)

Before induction of anaesthesia ▸▸▸▸▸▸▸▸▸

SIGN IN

- ☐ **PATIENT HAS CONFIRMED**
  - IDENTITY
  - SITE
  - PROCEDURE
  - CONSENT
- ☐ **SITE MARKED/NOT APPLICABLE**
- ☐ **ANAESTHESIA SAFETY CHECK COMPLETED**
- ☐ **PULSE OXIMETER ON PATIENT AND FUNCTIONING**

DOES PATIENT HAVE A:

KNOWN ALLERGY?

- ☐ NO
- ☐ YES

DIFFICULT AIRWAY/ASPIRATION RISK?

- ☐ NO
- ☐ YES, AND EQUIPMENT/ASSISTANCE AVAILABLE

RISK OF >500ML BLOOD LOSS (7ML/KG IN CHILDREN)?

- ☐ NO
- ☐ YES, AND ADEQUATE INTRAVENOUS ACCESS AND FLUIDS PLANNED

Before skin incision ▸▸▸▸▸▸▸▸▸▸▸▸▸▸

TIME OUT

- ☐ **CONFIRM ALL TEAM MEMBERS HAVE INTRODUCED THEMSELVES BY NAME AND ROLE**
- ☐ **SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE VERBALLY CONFIRM**
  - PATIENT
  - SITE
  - PROCEDURE

ANTICIPATED CRITICAL EVENTS

- ☐ **SURGEON REVIEWS:** WHAT ARE THE CRITICAL OR UNEXPECTED STEPS, OPERATIVE DURATION, ANTICIPATED BLOOD LOSS?
- ☐ **ANAESTHESIA TEAM REVIEWS**: ARE THERE ANY PATIENT-SPECIFIC CONCERNS?
- ☐ **NURSING TEAM REVIEWS:** HAS STERILITY (INCLUDING INDICATOR RESULTS) BEEN CONFIRMED? ARE THERE EQUIPMENT ISSUES OR ANY CONCERNS?

HAS ANTIBIOTIC PROPHYLAXIS BEEN GIVEN WITHIN THE LAST 60 MINUTES?

- ☐ YES
- ☐ NOT APPLICABLE

IS ESSENTIAL IMAGING DISPLAYED?

- ☐ YES
- ☐ NOT APPLICABLE

Before patient leaves operating room

SIGN OUT

NURSE VERBALLY CONFIRMS WITH THE TEAM:

- ☐ **THE NAME OF THE PROCEDURE RECORDED**
- ☐ **THAT INSTRUMENT, SPONGE AND NEEDLE COUNTS ARE CORRECT** (OR NOT APPLICABLE)
- ☐ **HOW THE SPECIMEN IS LABELLED** (INCLUDING PATIENT NAME)
- ☐ **WHETHER THERE ARE ANY EQUIPMENT PROBLEMS TO BE ADDRESSED**
- ☐ **SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE REVIEW THE KEY CONCERNS FOR RECOVERY AND MANAGEMENT OF THIS PATIENT**

THIS CHECKLIST IS NOT INTENDED TO BE COMPREHENSIVE. ADDITIONS AND MODIFICATIONS TO FIT LOCAL PRACTICE ARE ENCOURAGED.

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Patient Medical Record

PATIENT RECORD CONSENT DOCUMENT

The surgery ______________________ (Name of Patient) is about to receive is supported by The Smile Train. The Smile Train is an international children's charity working with doctors and hospitals to eradicate the prevalence of cleft lips and cleft palates.

The Smile Train maintains medical records on the patients undergoing surgery. These records include information such as: the names and addresses of patients and their parents, clinical diagnosis, other relevant medical health information, surgical procedures, and results. The records also include pictures of all patients taken before and after surgery.

The Smile Train uses these records for reviews of surgical quality, education, evaluation, and public relations purposes and will update you if any additional uses of the information become known. The personal health information contained in the medical records will be maintained in The Smile Train's worldwide web-based cleft lip and palate database (www.smiletrainexpress.org). Only authorized persons, such as physicians and other medical personnel, will have access to the records and the database.

The Smile Train will not share your health information with non-authorized outside third parties such as marketers or vendors. Additionally, The Smile Train will keep your health information private and confidential by implementing security standards that limit access to the database to only authorized personnel as determined by The Smile Train. The Smile Train also will allow you to view data contained in the medical record database and to remove your name and health information from the database upon request.

I understand the information written above. I give permission to send The Smile Train a completed Smile Train Medical Record Form for myself (if of the age of majority in proper jurisdiction)/my son/my daughter/other (*please circle one*).

I give The Smile Train permission to use this health information for quality assessment, education, evaluation and public relations purposes.

Signature of Patient/Parent/Guardian	**Date**	**Signature of Witness**	**Date**

PART ONE: PATIENT INFORMATION

General Information

Patient Record Number | **Did the parent/guardian sign the Guardian Consent form?** ☐ Yes ☐ No *Please proceed only if YES*

Surname/Last Name | **Middle Name** | **Given name/First Name** | **Date of Birth** *(dd/mm/yyyy)* ____ / ____ / ______

Gender ☐ Male ☐ Female ☐ Unknown **Race** ☐ Asian ☐ Caucasian (white) ☐ African (black) ☐ Asian (Indian) ☐ Mixed ☐ Other

Street Address | **Town/Village/City** | **Province**

Country | **Zip/Postal code** | **Telephone** | **Is this patient sponsored by Smile Train?** ☐ Yes ☐ No ☐ Unknown

Name of Partner/Organization | **Name of Hospital** | **Country**

Parent/Guardian Information

Surname/Last name | **Middle initial** | **Given name/First name**

Relationship with patient ☐ Mother ☐ Father ☐ Grandparent ☐ Brother ☐ Sister ☐ Aunt ☐ Uncle ☐ Cousin ☐ Friend ☐ Other

How did the patient hear about The Smile Train? ☐ Charity Organization ☐ Hospital/physicians ☐ Newspaper and TV ☐ Internet ☐ Friends and relatives ☐ Other

Family History

Length of pregnancy: ______ **months** ☐ Don't Know | **Did the mother have complications during pregnancy?** ☐ Yes ☐ No ☐ Don't Know

Were there any complications during birth? ☐ Yes ☐ No ☐ Don't Know | **Did the mother smoke during pregnancy?** ☐ Yes ☐ No ☐ Don't Know

Did the mother consume alcohol during pregnancy? ☐ Yes ☐ No ☐ Don't Know

Do any of the patient's parents and/or siblings brothers/sisters have a cleft lip, cleft palate, or cleft involving the face? ☐ Yes ☐ No ☐ Don't Know

Do any other relatives (cousins, aunts, uncles, grandparents) have a cleft lip, cleft palate, or cleft involving the face? ☐ Yes ☐ No ☐ Don't Know

Diagnosis

Patient Height | **Patient Weight** | **Did the Patient have any lip or palate surgery before this evaluation?** ☐ Yes ☐ No

If yes, pick the type of surgery the Patient had ☐ Cleft Lip Surgery ☐ Cleft Palate Surgery ☐ Cleft Lip and Palate Surgery

Diagnosis *(Description of Lip and Palate at birth or before any surgeries)*

Lip		**Patient's Left**	**Patient's Right**
Type of Cleft Lip:	1 – Not Cleft	☐	☐
	2 – Complete	☐	☐
	3 – Incomplete	☐	☐

Alveolus		**Patient's Left**	**Patient's Right**
Type of Cleft Lip:	1 – Not Cleft	☐	☐
	2 – Complete	☐	☐
	3 – Incomplete	☐	☐

Hard palate		**Patient's Left**	**Patient's Right**
Type of Cleft Palate:	1 – Not Cleft	☐	☐
	2 – Complete	☐	☐
	3 – Incomplete	☐	☐
	4 – Submucous	☐	☐

Soft palate		
Type of Cleft Palate:	1 – Not Cleft	☐
	2 – Complete cleft	☐
	3 – Incomplete cleft	☐
	4 – Submucous	☐

Are there additional craniofacial deformities? ☐ Yes ☐ No ☐ Don't Know

Does this patient have velopharyneal insufficiency following prior cleft palate repair? ☐ Yes ☐ No ☐ Don't Know

Does this patient have abnormalities in any of the following areas? *(check all that may apply)*

Heart ☐ Yes ☐ No	**Nose** ☐ Yes ☐ No	**Fingers or toes** ☐ Yes ☐ No
Urinary system ☐ Yes ☐ No	**Ears** ☐ Yes ☐ No	**Skin** ☐ Yes ☐ No
Eyes ☐ Yes ☐ No	**Limbs** (arms/legs) ☐ Yes ☐ No	**Tongue** ☐ Yes ☐ No

Skull ☐ Yes ☐ No	**Retarded Growth** ☐ Yes ☐ No
Mandible ☐ Yes ☐ No	**Mental Retardation** ☐ Yes ☐ No
Speech ☐ Yes ☐ No	

Does the patient have allergies? ☐ Yes ☐ No ☐ Don't Know | **Medication allergies**

Other allergies | **Other Health Problems**

Name of Evaluator | **Title of Evaluator** ☐ Clerk ☐ Surgeon ☐ Nurse ☐ Other | **Date of Evaluation:** *(dd/mm/yyyy)* ____ / ____ / ______

PART TWO: INTERVENTION INFORMATION

Surgical Treatment

Date of admission: *(dd/mm/yyyy)* ____ / ____ / _____ | **Date of the Surgical treatment:** *(dd/mm/yyyy)* ____ / ____ / _____ | **Date of Discharge:** *(dd/mm/yyyy)* ____ / ____ / _____

Name of the Surgeon | **Name of the Anesthesiologist** | **Anesthesia Method** ☐ General ☐ Local

Type of Operation *(Check all surgical procedures that were conducted at the time of this hospitalization)*

☐ Primary Lip / Nose Unilateral Repair (partial or complete) ☐ Primary Lip / Nose Bilateral Repair (partial or complete) ☐ Primary Cleft Palate Repair

☐ Fistula Repair ☐ Secondary Cleft Palate (Velopharyngeal) Repair ☐ Lip/Nose Revision ☐ Alveolar Bone Graft ☐ Other: ______________________________

–

Type of Repairs		
	Unilateral Lip	☐ Rotation-Advancement Variant ☐ Triangular Variant ☐ Others
	Bilateral Lip	☐ Straight Line ☐ Forked Flap ☐ Others
	Palate	☐ Langenbeck Variant ☐ Pushback Variant ☐ Others

Were there any complications, injury, or patient mortality? ☐ Yes ☐ No *If no, please go directly to Additional Comments on Intervention below.*

If yes, did these complications result in patient death or serious physical or psychological injury to the patient? ☐ Yes ☐ No *If yes, please complete the Sentinel Event Report*

If no, please indicate type of complication: ☐ Blood transfusion ☐ Breathing problems ☐ Dehiscence ☐ Delayed oral feeding ☐ Fistula ☐ Return to OR

Additional Comments On Intervention *(Optional)*:

Photographic Records

Pre-operative Photo *(please check one)* ☐ **Frontal** ☐ **Intra-oral**

Date of Photo: _____ / _____ / _______ *(dd/mm/yyyy)*

Place photo here

Lip Repair (Frontal)/Palate Repair (Intra-oral)

Post-operative Photo *(please check one)* ☐ **Frontal** ☐ **Intra-oral**

Date of Photo: _____ / _____ / _______ *(dd/mm/yyyy)*

Place photo here—wound should be cleansed and free of blood

Lip Repair (Frontal)/Palate Repair (Intra-oral)

Post-operative Photo (Frontal Smiling)

Date of Photo: _____ / _____ / _______ *(dd/mm/yyyy)*

Place photo here—wound should be cleansed and free of blood

Frontal Smiling

(Optional) Please attach any other optional photos of this patient here

Please check all that apply ☐ **pre worm's eye view** ☐ **post worm's eye view** ☐ **pre cleft side lateral** ☐ **post cleft side lateral**

Date of Photos: _____ / _____ / _______ *(dd/mm/yyyy)*

Date of Event: *(dd/mm/yyyy)* _____ / _____ / _______ **Name of Hospital**

Optional

Sentinel Event Report

In case of mortality, injury, or complication

PART ONE: INITIAL EVENT FORM

The Smile Train must receive verbal or email notification of the event within 24 to 48 hours. Local partners will be responsible for obtaining confirmation from The Smile Train that this notification has been received. This form must be received by The Smile Train within 5 business days.

Date of Event: *(dd/mm/yyyy)* ____ / ____ / _____

Name of Hospital

Name of Partner/Organization

Nature of event ☐ Patient Death ☐ Patient Injury ☐ Serious Complication

Name of Patient

Patient's date of birth *(dd/mm/yyyy)* ____ / ____ / _____

Type of Operation *(Pick the one that applies)*

☐ Primary Lip Repair ☐ Primary Cleft Palate Repair ☐ Lip/Nose Revision ☐ Secondary Cleft Palate (Velopharyngeal) Repair ☐ Alveolar Bone Graft

☐ Primary Lip / Nose Repair ☐ Fistula Repair ☐ Other: ______________________________

Name of surgeon

Name of anesthesiologist

Initial explanation of what happened to the patient:

The Smile Train Safety and Quality Improvement Protocol requires facilities to submit a detailed report of its review of this event within 30 days of the event.

What is the expected date that the hospital will complete its investigation and submit Part Two of the Sentinel Event Report (Event Analysis Form)? : ___/___/____ *(dd/mm/yyyy)*

All of The Smile Train's funding of surgeries at your facility may, at The Smile Train's discretion, be temporarily suspended until The Smile Train has received and conducted its review of the Sentinel Event Report for this event.

Name of person filing report

Signature of person filing report

Title

Date : *(dd/mm/yyyy)* ____ / ____ / _____

Please fax or email to The Smile Train Office.

Phone: 212-689-9199 Fax: 212.689.9299
Email: dgreenwood@smiletrain.org

PART TWO: EVENT ANALYSIS FORM *(This form must be received by The Smile Train within 30 days of the event)*

Date of event: *(dd/mm/yyyy)* ____ / ____ / ______

Name of Hospital

Name of Partner/Organization

Name of person filing report

Title of person filing report ☐ Surgeon ☐ Anesthesiologist ☐ Other

Nature of event ☐ Patient Death ☐ Patient Injury ☐ Serious Complication

Name of Patient

What happened and when did this event occur *(Check all that may apply)*

Event	Pre-surgery	During surgery	Post-surgery	After leaving hospital
Incisional Infection	☐	☐	☐	☐
Dehiscence	☐	☐	☐	☐
Fistula	☐	☐	☐	☐
Medication Problem	☐	☐	☐	☐
Excessive Bleeding	☐	☐	☐	☐
Aspiration	☐	☐	☐	☐
Respiratory Arrest	☐	☐	☐	☐
Pneumonia	☐	☐	☐	☐
Sepsis	☐	☐	☐	☐
Stroke	☐	☐	☐	☐
Cardiac Arrest	☐	☐	☐	☐
Death	☐	☐	☐	☐
Others	☐	☐	☐	☐

In your opinion, were these events related to (Check all that may apply)

Physical Assessment Process	☐ Yes	☐ No
Patient Observation Procedures	☐ Yes	☐ No
Staffing Levels	☐ Yes	☐ No
Training of Staff	☐ Yes	☐ No
Competency Assessment/Credentialing of Staff	☐ Yes	☐ No
Supervision of Staff	☐ Yes	☐ No
Communication with Patient/Family	☐ Yes	☐ No
Adequacy of Technological Support	☐ Yes	☐ No
Equipment Maintenance/Management	☐ Yes	☐ No
Physical Environment	☐ Yes	☐ No
Labeling or dispensing of Medications	☐ Yes	☐ No

Was there equipment needed that was not available? If so, what kind?

Was there particular medical expertise that was needed that was not available? If so, what kind?

Did the staff know the procedures to follow in cases like this? If no, what types of procedural information would have been helpful?

What actions are your organization taking as a result of this event?

How will you measure whether these actions have helped to prevent further problems from occurring?

What process did you use to collect the information required for this report?

Please tell us what you think happened to the patient and why. What could have been done to have prevented the untoward event?

Please attach a copy of the patient's medical chart that contains 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, to this form.

The Smile Train
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