



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: Health care facilities performing surgeries for The Smile Train will 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: Health care facilities performing surgeries for The Smile Train will 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: Health care facilities performing surgeries for The Smile Train will 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 with the purpose of understanding the cause of the event and, if appropriate, developing system changes to prevent such an event's occurring again. 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 (with accompanying narrative, if the facility desires) 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 report.

Part 2: The Selection of Patients for Cleft Surgery

Requirement 2.1: Health care facilities performing surgeries for The Smile Train will 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, urinary tract infection and, in underweight children, parasites.

Part 3: The Surgery

Requirement 3.1: Health care facilities performing surgery for The Smile Train will 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.
- 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: Health care facilities performing surgery for The Smile Train will 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: Health care facilities performing surgery for The Smile Train will 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: Health care facilities performing surgery for The Smile Train will provide a safe surgical environment, *BY*:

- Having experienced operating room personnel.
- Having staff familiar with sterile technique and working sterilizing machines; and
- 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: Health care facilities performing surgery for The Smile Train will provide safe post-anesthesia care, *BY*:

- Having a designated unit for post-anesthesia care.
- Having a clearly delineated medical responsibility for care of children in the first 24 hours after cleft surgery.
- 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.
- Having sufficient numbers of skilled post-anesthesia staff that individualized observation is possible the first night after surgery.

Requirement 4.2: Health care facilities performing surgery for The Smile Train will 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 drugs, an oxygen delivery system and oxygen supply, an EKG and a crash cart.
- 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.

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Email: dgreenwood@smiletrain.org

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
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PART ONE: PATIENT INFORMATION

General Information

Patient Record Number		Did the parent/guardian sign the Guardian Consent form? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>Please proceed only if YES</i>		
Surname/Last Name		Middle Name	Given name/First Name	Date of Birth (<i>dd/mm/yyyy</i>) ____/____/____
Gender <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown	Race <input type="checkbox"/> Asian <input type="checkbox"/> Caucasian (white) <input type="checkbox"/> African (black) <input type="checkbox"/> Asian (Indian) <input type="checkbox"/> Mixed <input type="checkbox"/> Other			
Street Address		Town/Village/City		Province
Country	Zip/Postal code	Telephone	Is this patient sponsored by Smile Train? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
Name of Partner/Organization		Name of Hospital		Country

Parent/Guardian Information

Surname/Last name		Middle initial	Given name/First name
Relationship with patient <input type="checkbox"/> Mother <input type="checkbox"/> Father <input type="checkbox"/> Grandparent <input type="checkbox"/> Brother <input type="checkbox"/> Sister <input type="checkbox"/> Aunt <input type="checkbox"/> Uncle <input type="checkbox"/> Cousin <input type="checkbox"/> Friend <input type="checkbox"/> Other			
How did the patient hear about The Smile Train? <input type="checkbox"/> Charity Organization <input type="checkbox"/> Hospital/physicians <input type="checkbox"/> Newspaper and TV <input type="checkbox"/> Internet <input type="checkbox"/> Friends and relatives <input type="checkbox"/> Other			

Family History

Length of pregnancy: _____ months <input type="checkbox"/> Don't Know	Did the mother have complications during pregnancy? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know
Were there any complications during birth? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know	Did the mother smoke during pregnancy? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know
Did the mother consume alcohol during pregnancy? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know	
Do any other relatives (cousins, aunts, uncles, grandparents) have a cleft lip, cleft palate, or cleft involving the face? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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	<input type="checkbox"/>	<input type="checkbox"/>
2 – Complete	<input type="checkbox"/>	<input type="checkbox"/>
3 – Incomplete	<input type="checkbox"/>	<input type="checkbox"/>

Hard palate	Patient's Left	Patient's Right
Type of Cleft Palate:		
1 – Not Cleft	<input type="checkbox"/>	<input type="checkbox"/>
2 – Complete	<input type="checkbox"/>	<input type="checkbox"/>
3 – Incomplete	<input type="checkbox"/>	<input type="checkbox"/>
4 – Submucous	<input type="checkbox"/>	<input type="checkbox"/>

Alveolus	Patient's Left	Patient's Right
Type of Cleft Lip:		
1 – Not Cleft	<input type="checkbox"/>	<input type="checkbox"/>
2 – Complete	<input type="checkbox"/>	<input type="checkbox"/>
3 – Incomplete	<input type="checkbox"/>	<input type="checkbox"/>

Soft palate	Patient's Left	Patient's Right
Type of Cleft Palate:		
1 – Not Cleft	<input type="checkbox"/>	<input type="checkbox"/>
2 – Complete cleft	<input type="checkbox"/>	<input type="checkbox"/>
3 – Incomplete cleft	<input type="checkbox"/>	<input type="checkbox"/>
4 – Submucous	<input type="checkbox"/>	<input type="checkbox"/>

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

Does this patient have velopharyngeal 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 <input type="checkbox"/> Yes <input type="checkbox"/> No	Nose <input type="checkbox"/> Yes <input type="checkbox"/> No	Fingers or toes <input type="checkbox"/> Yes <input type="checkbox"/> No	Skull <input type="checkbox"/> Yes <input type="checkbox"/> No	Retarded Growth <input type="checkbox"/> Yes <input type="checkbox"/> No
Urinary system <input type="checkbox"/> Yes <input type="checkbox"/> No	Ears <input type="checkbox"/> Yes <input type="checkbox"/> No	Skin <input type="checkbox"/> Yes <input type="checkbox"/> No	Mandible <input type="checkbox"/> Yes <input type="checkbox"/> No	Mental Retardation <input type="checkbox"/> Yes <input type="checkbox"/> No
Eyes <input type="checkbox"/> Yes <input type="checkbox"/> No	Limbs (arms/legs) <input type="checkbox"/> Yes <input type="checkbox"/> No	Tongue <input type="checkbox"/> Yes <input type="checkbox"/> No	Speech <input type="checkbox"/> Yes <input type="checkbox"/> No	

Does the patient have allergies? Yes No Don't Know

Medication allergies

Other allergies

Other Health Problems

Name of Evaluator

Title of Evaluator

Date of Evaluation: (dd/mm/yyyy) ____/____/____

Clerk Surgeon Nurse Other

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)

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 <input type="checkbox"/> Patient Death <input type="checkbox"/> Patient Injury <input type="checkbox"/> Serious Complication	
Name of Patient		Patient's date of birth (dd/mm/yyyy) ____ / ____ / ____	
Type of Operation (Pick the one that applies)			
<input type="checkbox"/> Primary Lip Repair <input type="checkbox"/> Primary Cleft Palate Repair <input type="checkbox"/> Lip/Nose Revision <input type="checkbox"/> Secondary Cleft Palate (Velopharyngeal) Repair <input type="checkbox"/> Alveolar Bone Graft			
<input type="checkbox"/> Primary Lip / Nose Repair <input type="checkbox"/> Fistula Repair <input type="checkbox"/> 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
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Name of person filing report	Title of person filing report <input type="checkbox"/> Surgeon <input type="checkbox"/> Anesthesiologist <input type="checkbox"/> Other
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Nature of event <input type="checkbox"/> Patient Death <input type="checkbox"/> Patient Injury <input type="checkbox"/> Serious Complication	Name of Patient
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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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dehiscence	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fistula	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Medication Problem	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Excessive Bleeding	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Aspiration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Respiratory Arrest	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pneumonia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sepsis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Stroke	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cardiac Arrest	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Death	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Others	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

Physical Assessment Process	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Communication with Patient/Family	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Patient Observation Procedures	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Adequacy of Technological Support	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Staffing Levels	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Equipment Maintenance/Management	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Training of Staff	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Physical Environment	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Competency Assessment/Credentialing of Staff	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Labeling or dispensing of Medications	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Supervision of Staff	<input type="checkbox"/> Yes	<input type="checkbox"/> 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?
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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?
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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?
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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 Medical Record with this form. Please feel free to attach a narrative if desired.
Please fax, email, or mail to The Smile Train Office.

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