Software Requirements Specification

for

Thousand Smiles Digital Charts – Surgery Screening Subsystem

Version 0.9

Prepared by Syd Logan, Dr. Earl Freymiller, and Dr. Nick Veaco

Thousand Smiles Foundation

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Revision History

Name	Date	Reason For Changes	Version
Syd Logan	11/16/2019	Original	0.9

1. Introduction

1.1 Purpose

The purpose of this document is to outline the basic requirements associated with the Surgery Screening portion of the Thousand Smiles Digital Chart. The overall requirements of the system are described in a separate document. This document focuses specifically on Surgery Screening requirements that were gathered via interviews with the primary stakeholders.

The surgeons to which this functionality is directed screen cleft patients for surgery at some future time. These surgeons work in collaboration with audiology and ENT, both which have separate portions of the digital chart dedicated to the data they record, and specified separately from this requirements document.

The scope of this design is the data and interfaces related to the screening function only, and the display of data obtained from prior surgeries performed on the child.

The collection of data at the time of the actual surgery or surgeries performed on the patient is covered in a separate requirements document.

1.2 Document Conventions

There are no specific conventions associated with this document.
Intended Audience and Reading Suggestions
The intended audience includes:

Thousand Smiles Board Members: Board members should read this document to become familiar with the overall overall scope of Surgery Screening in the digital charts project. This knowledge may prove helpful as background when evaluating logistics and expenditures associated with the implementation of the system, e.g., equipment purchases.

Implementation Team: This document spells out requirements which guide the implementation of the system. It is not intended to be a design document, rather it spells out the requirements that a design must follow to be considered valid.

Surgery Screening Specialist: This document must be read and approved by the end user(s) of the system, the surgeons who provide surgery screening at out clinics. This document will likely go through some number of revisions towards eventual approval. The surgeons involved in surgery screening should read this document critically and identify omissions, errors, and changes so that they can be dealt with.

1.3 Product Scope

The surgery screening portion of the digital chart is intended to provide the surgeons who perform the surgery screening function with the following capabilities:

- Ability to manage the data associated with the evaluation, diagnosis, and treatment of a child that the surgeon is tasked with at a Thousand Smiles clinic. The data collected here is

specific to the screening function that is performed ahead of a subsequent surgery (possibly to be performed at the same clinic as the screening, or perhaps at a later time).
- Ability to refer to a patient history that consists of evaluation, diagnosis, and treatment made at prior Thousand Smiles clinics.
- Surgeries occur in what are "ideal windows of time". It is important that the system support this by allowing the surgeons to manage/specify when a surgery that is a part of a treatment plan is to be performed. It is also desired that the software make it clear, via notifications or other means, that a given patient is nearing such a surgery such that it not be forgotten. This window is defined by patient age. Examples:
  - Procedure A must be performed exactly at age Y.
  - Procedure A must be performed no later than age Y.
- View other portions of the digital chart associated with a child.
- View data recorded as related to prior surgeries performed on the child. This data is gathered in a separate application, and is documented in a separate requirements document.
- Eliminate the need for paper charts to the extent possible.

The benefits we hope to realize by migrating surgery screening from paper charts to digital charts include:

- Increased access to data by other specialists. We aim to make the data recorded by surgery screening more easily located and viewed by other specialists involved with the care of the child during his or her visit at one of our clinics
- Increased reporting functionality. Migrating to a database-backed chart allows the organization to more readily generate reports; for example, number of children, types and numbers of procedures, incident counting (e.g., number of children seen with a specific condition). This data could be used for various purposes, both clinical and administrative in nature.

1.4 References

This document makes reference to the following documents

- *Software Requirements Specification for Thousand Smiles Digital Charts – Surgery Reports (XXX link here)*
- *Standard Official Mexicana NOM-024-SSA3-2010 (XXX link here)*

2. Chart Content

The surgery screening chart consists of the following components:

- Diagnosis
- Subsequent Diagnosis
- Missing tooth chart
- Treatment Plan
- Notes
- Past Surgery Reports

Each of these components is available to surgery screening personnel when the patient has been checked in to the tablet at a surgery screening station. A component (e.g., Diagnosis) can be selected from a menu available on the left hand portion of the tablet screen. When selected, an icon for each record of that component type (for that patient) which was created in the past will be

displayed. Each will be labeled by the date that the record was created. Clicking on any one of these icons will result in display of the data.

In addition, a button will be displayed which, when pressed, will allow the users to create a new record of that type for the current clinic/date.

For example, clicking the Diagnosis icon will display a screen of all previous diagnosis for this patient, one per patient visit, labeled (and sorted) by date. In addition, a button that can be used to create a new diagnosis corresponding to the current date is prominently displayed.

The following subsections describe the data collected and displayed in each of the above listed components, as well as any specific requirements of each.

2.1 Diagnosis

The surgery screening specialist must be able to create a new patient diagnosis during the course of the examination.

The diagnosis for all visits by this patient to surgery screening should be available for review at subsequent clinics. Each diagnosis will be identified by the date it was initially created. Clicking on a diagnosis will cause it to be displayed on the screen. A previously obtained diagnosis can be modified, but will retain the date of its first creation if so. Once created and saved, it is not expected that it will be modified except to correct errors.

2.1.1 Content

Cleft Lip [] Left Complete [] Left Incomplete [] Right Complete [] Right Incomplete
Cleft Palate [] Complete [] Soft Palate Only [] Sub-mucous
Cleft Aveolus [] Left [] Right
Residual Fistula [] Yes [] No
VPI [] Yes [] No
Missing Teeth (see missing tooth chart if “Yes”) [] Yes [] No
Orthognathic Surgery Needed [] Yes No []

2.2 Subsequent Diagnosis

A subsequent diagnosis is nothing more than a diagnosis that is created at a clinic other than the clinic during which the initial diagnosis was made.

2.2.1 Content

The content in this section is the same as described in Section 2.1.1, above.

2.3 Missing Tooth Chart

The surgery screening specialist must be able to create and edit a missing tooth chart during the course of the examination.

The missing tooth chart for all visits by this patient to surgery screening should be available for review at subsequent clinics. Each missing tooth chart will be identified by the date it was initially created. Clicking on a missing tooth chart will cause it to be displayed on the screen. A previously edited missing tooth chart can be modified, but in doing so the chart will retain the date of its first creation. Once created and saved, it is not expected that the missing tooth chart will be modified except to correct errors.

2.3.1 Content

The missing tooth chart will be graphical in nature. The specialist must be able to select the type of mouth (child or adult). The default selection will be child. The selection maybe be toggled as desired. Making a selection will cause the corresponding tooth chart (either child or adult) to be displayed. When toggling, the display will not lose any teeth previously selected as missing.

2.4 Treatment Plan and History

The surgery screening specialist must be able to create and maintain a patient treatment plan for the patient. The treatment plan and history is available as a single screen that shows all of the past treatments/surgeries performed on the patient, as well as a list of the planned treatments/surgeries to be performed on the patient in the future.

In some cases, a treatment listed in the plan will need to be performed by a specific patient age, for various reasons including the difficulty associated with the procedure, or its lack of effectiveness, should the treatment be performed later than the specified patient age. Thus, each treatment may be assigned an completion age. The system shall display this age along with those treatment items to which it is associated, and highlight the treatments that are due both in the next and current year in a way that makes it clear to the surgery screening specialist that the treatment, for this patient, is due and should be considered a priority.

There shall be a single treatment plan for the patient.

2.4.1 Content

In the following, the term “treatment” refers to either a “repair” or “procedure”.

For each item in the treatment history/plan, the following data must be displayed and be editable:

- Name of surgeon who added the treatment to the plan and the date it was added.
- If already performed:
  - an indication that the procedure or repair has been completed
  - the name of the surgeon(s) who performed the procedure or repair
  - the date that it was performed.

    - a button which can be clicked to view a summary of the procedure in a dialog. That dialog will display any materials/methods and notes that were added to the surgery report.
- The name of the procedure/repair. The procedure/repairs are known a-priori and must be selectable from a list. If the procedure/repair is not among those listed, selecting "other" will enable a text field which can be used to enter a short procedure or repair name. However, this is an exceptional case and the need to use "other" should be reported as a defect in the software so that the missing repair or procedure name can be added to the list of selectable repairs/procedures.
- The age at which the treatment must be performed, if any. When the procedure or repair is added to the treatment plan, should the selected procedure or repair have such a date, it will automatically be assigned to this field. The specialist may then change the value as necessary. If the age of the patient is the same as the recommended age, this will be highlighted as "due this year" in some way. Furthermore, if the age of the patient is greater than the due age of a yet to be performed treatment or repair, this will be highlighted as well.
- For newly added treatments, and for treatments which have a due date, an indication as to whether the treatment must be performed this clinic.
- Free-form text notes.

The list of supported procedures and repairs may be found in *Software Requirements Specification for Thousand Smiles Digital Charts – Surgery Reports.*

2.5 Surgery Report

The surgery screening specialist must be able to view and edit the details of any prior performed surgery during subsequent screenings. The surgery report itself is entered/edited in a separate surgery report application, which is detailed in a separate document/specification. Please refer to that specification (*Software Requirements Specification for Thousand Smiles Digital Charts – Surgery Reports* see References) for the details of the content of the surgery report, and how it is entered, edited and viewed.

- A summary of the surgery report is available for view in the treatment history/plan portion of the chart.
- The user, from this application, can obtain a list of all prior surgeries and view and edit their content. Again, for the details of what is displayed and how it is edited, please refer to the *Software Requirements Specification for Thousand Smiles Digital Charts – Surgery Reports*.

As with the diagnosis and tooth chart, past surgery reports should be available for review at subsequent clinics. Each surgery report will be identified by the date it was initially created. Clicking on a listed surgery report will cause it to be displayed on the screen. A previously edited surgery report can be modified, but in doing so the surgery report will retain the date of its first creation. Once created and saved, it is not expected that the surgery report will be modified except to correct errors.

2.5.1 Content

For content, please refer to the specification for the *Software Requirements Specification for Thousand Smiles Digital Charts – Surgery Reports*.

2.6 Free Form Notes

The examination should provide a single "free form" text area where notes may be added by the surgery screening specialist.

The intent of this requirement is to provide the surgery screening specialist a place to record data which might not be directly attributable to the sections described earlier in this section.

The surgery specialists should be able to edit text previously entered in the free form area during the current examination.

The name of the person entering or editing a note, and the date, should be recorded along with the note.

Past free form notes should be available for review at subsequent clinics. Each free form note will be identified by the date it was initially created. Clicking on a listed free form note will cause it to be displayed on the screen. A previously edited free form note can be modified, but in doing so the free form note will retain the date of its first creation. Once created and saved, it is not expected that the free form note will be modified except to correct errors.

3. Printing

The application will allow for the printing of relevant patient data on a per-screen basis for all items described above. This is to support the case where surgeries are performed off site and recording of the surgery is done on paper for later transcription, where access to the patient database is not available. Printing will only be available in the main clinic, not at a remote site such as a hospital.

All printed copies should be watermarked, or at best notated, on a per-page basis, to indicate the following

- this document contains sensitive, patient medical data
- disclosure of the content of this document is in violation of **Standard Official Mexicana NOM-024-SSA3-2010**
- this document should not be photocopied or duplicated in any form
- if found, please notify Thousand Smiles (include e-mail address and phone number)
- this document should be shredded immediately after use

The above disclaimer must be provided on each page of the document, in both Spanish and English language.

See the section on Availability in the *Software Requirements Specification for Thousand Smiles Digital Charts – Surgery Report***s** for more details on hospital/remote operation.

4. Other Nonfunctional Requirements

4.1 Performance Requirements

- The system should provide 99.9999% uptime during the clinic

- Search and access to the database should occur with a latency of no more than 5 seconds.

4.2 Safety Requirements

There are no specific safety requirements associated with this subsystem.

4.3 Security Requirements

We assume that the patient digital chart, and the surgery screening sub-system in particular, does not need to adhere to HIPAA requirements, and does not require HIPAA certification. **Standard Official Mexicana NOM-024-SSA3-2010, which establishes the functional objectives and functions, must observe the products of Systems of Electronic Filing to ensure the interoperability, processing, interpretation, confidentiality, safety and use of standards and catalogues of the electronic records health information. An English translation of this standard is available, see References, above, for a link.**

The system communication on the day of the clinic will occur locally and not leave the local network.

Users of the system will have accounts and must authenticate prior to using the digital chart. The user names and their passwords are unique to this system and are not the same used by the volunteer system; only a subset of our volunteers should be granted access to patient data. The database itself is physically and administratively separate from the volunteer database. Passwords will be encrypted on the system, and logging will be used to track account creation, login, and logoff activity.

4.4 Software Quality Attributes

There are no specific SQA attributes associated with this subsystem.

4.5 Business Rules

Access to the system during the clinic will be limited to authenticated users. There are no specific rules associated with who can authenticate.

Between clinics, database access will be restricted to the administrator of the system for purposes of backup and maintenance only. The patient data, and user account information, will not be accessible on the Internet except for purposes of backup and maintenance.

5. Other Requirements

No additional requirements have been identified for this subsystem as of now.

Appendix A: To Be Determined List

<Collect a numbered list of the TBD (to be determined) references that remain in the SRS so they can be tracked to closure.>