Software Requirements Specification



for

Thousand Smiles Digital Charts – Surgery Report Application

Version 0.9.2

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Thousand Smiles Foundation

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Revision History

Name	Date	Reason For Changes	Version
Syd Logan	12/15/2019	Original	0.9
Syd Logan	12/27/2019	Add reference hyperlinks	0.9.1
Syd Logan	10/07/2020	Initial Anesthesiology edits	0.9.2

1. Introduction

1.1 Purpose

The purpose of this document is to outline the basic requirements associated with the Surgery Report Application. This document focuses specifically on requirements that were gathered via interviews with the primary stakeholders.

The surgeons and anesthesiologists to which this functionality is directed perform surgery and use the application described in this document to view details obtained during the screening of the patient prior to the surgery, and to report the occurrence and details of surgery performed.

The scope of this design is the data and interfaces related to the surgery reporting function only. The surgery screening portion of the Station application (described externally in *Thousand Smiles-Digital Charts – Surgery Screening Subsystem*) contains the same functionality as this application except:

- the ability to search for reports based on patient name or ID
 - in the Station application, the surgeries will be available only for the patient currently checked into surgery screening, no searching function is provided
- the ability to create and edit a new surgery report

1.2 Document Conventions

There are no specific conventions associated with this document.

1.3 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 reporting 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 implementing these requirements must follow to be considered valid.

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

1.4 Product Scope

The surgery report application is a standalone application that is used at the time of surgery (or at some point in time thereafter) to create a surgery report for a patient. It can also be used to view and edit past surgery reports.

Surgeons and anesthesiologists will be able to search for patient by name or ID in a manner similar to that employed in the patient registration application. Once located, the user can view prior surgery reports for that patient, or create a new one.

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

- Increased access to data by other specialists. We ultimately aim to make the data recorded by surgery teams 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.

1.5 References

This document makes reference to the following documents:

- Software Requirements Specification for Thousand Smiles Digital Charts Surgery Screening Subsystem https://github.com/slogan621/tscharts/blob/master/docs/requirements/pdf/surgeryscreening_requirements_0.9.pdf
- Standard Official Mexicana NOM-024-SSA3-2010 <u>Standard Official Mexicana NOM-024-SSA3-2010 https://github.com/slogan621/tscharts/blob/master/docs/nom/NOM-024-SSA3-2012 English.pdf</u>

2. Application Flow

The Surgery Report application has the following major components/functionality. Each will be described in detail in later sections of this document:

- 1. Login
- 2. Patient Search
- 3. Medical History
- 4. Diagnosis
- 5. Subsequent Diagnosis
- 6. Missing tooth chart
- 7. Treatment Plan
- 8. Notes
- 9. Past Surgery Reports
- 10. Create New Surgery Report
- 11. Logoff/Exit

Items 3 – 9 provide the same functionality as found in the Software Requirements Specification for Thousand Smiles Digital Charts – Surgery Screening Subsystem. Login (Item 1 above) and Logoff (Item 11 above) are the same as found in all existing applications. Patient Search (Item 2) is the same functionality and design as found in the patient registration application. What is new for this app, and described in detail by this specification, is Item 10, Create New Surgery Report.

3. Functional Requirements

3.1 Login

The user will login using the username and password that is used to login in and register for a clinic on the volunteer website.

3.2 Patient Search

In order to access patient data and view prior reports, medical history, or to create a surgery report, the patient must be identified. Only patients who have been registered and screened at a clinic prior to the surgery will be in the system, this application does not provide the means to create a new patient in the database.

Search for the patient will be identical to that found in the patient Registration application. Users-will be able to enter free form test consisting of some subset of the patient first, maternal last, paternal last, or middle name, date of birth, or patient ID (if known). The system will display a list of matching patients, each with name information, DOB, and a head shot taken of the patient at the last time he or she was registered. Selecting that patient will cause the display to provide access to the patient chart. That patients' chart data will be the only data available until the search function is invoked once again, and a new patient is selected.

The search screen shall be the default screen displayed once the user logs into the application. A menu item or button will be available in all other screens to allow the user to return to the search screen.

3.3 Display of Medical History, Diagnosis, Subsequent Diagnosis, Missing Tooth Chart, Treatment Plan, Notes, and Past Surgery Reports

3.3.1 Medical History and Surgery-Related Data

All Medical History, Diagnosis, Subsequent Diagnosis, Missing Tooth Chart, Treatment Plan, and Notes for the patient for current and past clinics shall be available for review in the surgery reporting application. Surgery Reports for the patient for all past clinics shall be available for review in the surgery reporting application.

3.3.2 ENT and Audiology Data

All ENT and Audiology data for the patient for current and past clinics shall be available for review in the surgery reporting application.

There is no requirement for access to dental, orthodontic, or speech therapy data.

3.4 Printing

The application will allow for the printing of relevant patient data on a per-screen basis for all items described in Section 3.3, above. This is to support the case where surgeries are performed offsite 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, below, for more details on hospital/remote operation.

3.5 Surgery Reports

The main functionality of this application is to create and view surgery reports. Surgery reports created in this application will be available for viewing in the Station application for viewing by surgery screening in subsequent clinics when the patient returns and is checked into the surgery screening station.

A surgery report consists of data that includes the name and date of the surgery, the procedures performed, notes about the surgery, materials used, and so on. Section 4, below, goes into the detailed requirements for the creation, editing, and viewing of surgery reports.

3.6 Logoff

The user may logoff by exiting the application (swiping the application away). Restarting the application will present a screen by which the user can then login.

4. Surgery Reports

In this section, the functional requirements for a surgery report are presented.

4.1 Overview

The surgery report is used to:

- view and edit reports of prior surgeries performed for the currently selected patient
- create a surgery report for the currently selected patient

4.2 Prior Surgeries

The display will show a scrollable list of icons, one for each surgery report that exists for the selected patient. The list will be sorted so that the most recent surgery is first in the list. The date of the surgery will be displayed in this list. Clicking on any of the prior surgeries will cause the screen to display the corresponding surgery report. The user may edit this surgery report to correct errors, and save any changes made. If the user tries to return to the search screen with unsaved changes, a dialog will be displayed to notify the user that there are changes and prompting the user to either save or discard these changes. If changes are invalid in some way, and the user attempts to save changes, the user will be prompted to identify the errors so that they can be corrected.

The display of prior surgeries for the patient shall be the default display of the application once the patient has been selected.

4.3 New Surgeries

In addition to displaying a list of all prior surgeries, a button will be displayed which, when clicked, will allow the user to a create a new surgery report. Clicking this button will cause a form to be displayed which will allow the user to enter the details of the surgery.

The user can save changes by clicking a save button. If the user attempts to leave the form without saving unsaved changes, he or she will be prompted to save or discard the changes.

If changes are invalid in some way, and the user attempts to save changes, the user will be prompted to identify the errors so that they can be corrected.

4.4 Content

The surgery report shall contain the following content.

Name of the surgeon(s) performing the procedure (XXX is this just one person per report, or multiple surgeons? Do we need to record other names such as nurses, anesthesiologist, etc.)?

Date of the surgery

Whether the surgery was a repair or a procedure

If a repair, the material used if any (more than one material??)
If a procedure, the method used (presumably only one method per-procedure)
Free form notes

4.4.1 Repairs

The application shall present all repairs as a list from which the appropriate repair can be selected. The list of supported repairs includes:

XXX please provide list of possible repairs

In the case a repair is not listed, "other" shall be selected, and free form text shall be used to supply the name of the repair.

4.4.2 Materials

The application shall present all materials as a list from which the appropriate material can be selected. The list of supported materials includes:

XXX please provide list of possible materials

In the case a material is not listed, "other" shall be selected, and free form text shall be used to supply the name of the material.

4.4.3 Procedures

The application shall present all procedures as a list from which the appropriate procedure can be selected. The list of supported procedures includes:

XXX please provide list of possible procedures

In the case a procedure is not listed, "other" shall be selected, and free form text shall be used to supply the name of the procedure.

4.4.4 Methods

The application shall present all methods as a list from which the appropriate method can be selected. The list of supported methods includes:

XXX please provide list of possible methods

In the case a method is not listed, "other" shall be selected, and free form text shall be used to supply the name of the method.

5. Anesthesiology Reports

In this section, the functional requirements for an anesthesiology report are presented.

5.1 Overview

The surgery report is used to:

- view and edit anesthesiology reports of prior surgeries performed for the currently selected patient
- create an anesthesiology report for the currently selected patient

5.2 Prior reports

The display will show a scrollable list of icons, one for each anesthesiology report that exists for the selected patient. The list will be sorted so that the most recent surgery is first in the list. The date of the surgery will be displayed in this list. Clicking on any of the prior surgeries will cause the screen to display the corresponding anesthesiology report. The user may edit this anesthesiology report to correct errors, and save any changes made. If the user tries to return to the search screen with unsaved changes, a dialog will be displayed to notify the user that there are changes and prompt the user to either save or discard these changes. If changes are invalid in some way, and the user attempts to save changes, the user will be prompted to identify the errors so that they can be corrected.

The display of prior anesthesiology reports for the patient shall be the default display of the application once the patient has been selected.

5.3 New Anesthesiology Report

In addition to displaying a list of all prior surgeries, a button will be displayed which, when clicked, will allow the user to a create a new anesthesiology report. Clicking this button will cause a form to be displayed which will allow the user to enter the details of the surgery as related to the data gather specific to anesthesiology.

The user can save changes by clicking a save button. If the user attempts to leave the form without saving unsaved changes, he or she will be prompted to save or discard the changes.

If changes are invalid in some way, and the user attempts to save changes, the user will be prompted to identify the errors so that they can be corrected.

5.4 Content

The anesthesiology report shall contain the following content.

5.4.1 Item 1

TBD

5.4.2 Item 2

TBD

5.4.3 Item 3

TBD

5.4.4 Item 4

TBD

5.4.5 Item **5**

TBD

6. Availability

The surgery report application will be available at the time of surgery only when surgeries are performed within our clinic building. In this environment, we have full access to our database of patients and the digital chart data for these patients, making it possible to meet the requirements for patient search and data access. The Thousand Smiles digital charts system runs on a local network with the main clinic building, and requires a backend/server containing the patient data to be located on that local network. No access to the server or patient data is available on the Internet.

Surgeries which are not performed in our clinic present a challenge, in that we may not have access to a network and our servers. Similarly, the tablets need infrastructure to connect to this server, mainly a private wireless network and router able to assign addresses, Access points may also be required to ensure connectivity depending upon the environment and distances involved between the tablets and the wireless infrastructure.

In all likelihood, remote surgeries will need to be recorded on paper, to be later transcribed into the system using this application when running on the main clinic network. To support this eventuality,

both this app, and the Station app, will need to support the ability to print chart data needed at the time of surgery, such as medical history, screenings from ENT, Audiology, and surgery screening made prior to the time of surgery, past surgery reports, treatment plans, etc.. as applicable. It is via printed copies that we will make such data available at the remote location at the time of surgery.

The system must also support the printing of forms that can be used to adequately record the surgery performed, corresponding to the requirements set forth in Section 4, above.

7. Other Nonfunctional Requirements

7.1 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.

7.2 Safety Requirements

There are no specific safety requirements associated with this subsystem.

7.3 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. Please see References, above, for a link to an English translation of this document.

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 usernames 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 encryted on the system, and logging will be used to track account creation, login, and logoff activity.

7.4 Software Quality Attributes

There are no specific SQA attributes associated with this subsystem.

7.5 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.

8. 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.>