Software Requirements Specification

for

Thousand Smiles Digital Charts – ENT Subsystem

Version 1.3.1

Prepared by Syd Logan, Dr. Marc Lebovits, and Dr. Mike Nussbaum

Thousand Smiles Foundation

12/27/2019

Table of Contents

Revision History

Name	Date	Reason For Changes	Version
Syd Logan	12/29/2013	Original	1.0
Syd Logan	01/06/2014	Incorporated review comments from Dr. Lebovits	1.1
Syd Logan	01/09/2014	Minor edits suggested by Dr. Lebovits	1.2
Syd Logan	01/15/2014	Factored out data in general requirements	1.3
Syd Logan	12/27/2019	Add external reference to NOM English translation	1.3.1

1. Introduction

1.1 Purpose

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

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 ENT 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.

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

1.4 Product Scope

The ENT portion of the digital chart is intended to provide the ENT specialist with the following:

- Ability to manage the data associated with the evaluation, diagnosis, and treatment of a child that the ENT specialist is tasked with at a Thousand Smiles clinic
- Ability to refer to a patient history that consists of evaluation, diagnosis, and treatment made at prior Thousand Smiles clinics
- View other portions of the digital chart associated with a child.
- Eliminate the need for paper charts

The benefits we hope to realize by migrating ENT from paper charts to digital charts includes:

- Increased access to data by other specialists. We aim to make ENT 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 administratively.

1.5 References

This document makes reference to the following documents:

- *Standard Official Mexicana NOM-024-SSA3-2010* *https://github.com/slogan621/tscharts/blob/master/docs/nom/NOM-024-SSA3-2012_English.pdf*

2. Clinical Note

The ENT-related data for a child is organized as a "clinical note". The order in which the sections should appear when writing and reading our clinical note should be:

- History
- Exam
- Audiogram(s)
- Diagnosis
- Treatment Plan

2.1 History

The ENT specialist needs to be able to record the following extensions to the medical history for the patient relevant to ENT:

[] No problems
Hearing Loss
R [] Days [] Wks [] Mos [] Intermittent
L [] Days [] Wks [] Mos [] Intermittent
Drainage
R [] Days [] Wks [] Mos [] Intermittent
L [] Days [] Wks [] Mos [] Intermittent
Pain
R [] Days [] Wks [] Mos [] Intermittent
L [] Days [] Wks [] Mos [] Intermittent

The ENT specialist must be able to modify the medical history during the course of the examination.

In addition to the above, there may be one or more additional history items gathered from the patient which must be recorded. For each, ENT should be able to record the name of the condition

and add it to the examination record. For each history item, the specialist must be able to specify the following:

R [] Days [] Wks [] Mos [] Intermittent
L [] Days [] Wks [] Mos [] Intermittent

There is no limit to the additional history items that can be added to the patients' history.

A free form text area is to be provided for additional history-related text to be entered by the specialist. The ENT specialist should be able to add, modify or remove any data in the free form text area.

The ENT specialist must be able to record the date the diagnosis was made, and the name of the person who made the diagnosis.

The ENT specialist should be able to select and view the history items from a previous examination performed on the patient.

2.2 Examination

2.2.1 General

The ENT specialist must be able to create a new examination record pertaining to the current date of examination, and the patient being seen. This examination record is referred to in this document as the "current" examination.

The examination (clinic visit) consists of the history, exam, diagnosis, and plan.

Each section allows for free form notes to be added. In addition, general notes can be added for the examination for items not falling into one of the above sections.

The ENT specialist should be able to view all items in the current examination.

The ENT specialist should be able to modify items in the current examination.

The ENT specialist should be able to remove items from the current examination.

2.2.2 Examination Notes

The ENT specialist needs to be able to record the following examination notes:

Normal [] R [] L
Microtia [] R [] L
Wax [] R [] L
Drainage [] R [] L
External otitis [] R [] L
FB [] R [] L

Tube
R [] in place [] extruding [] in canal
L [] in place [] extruding [] in canal

Tympanosclerosis
R [] anterior [] posterior [] < 25% [] < 50% [] <75% [] total
L [] anterior [] posterior [] < 25% [] < 50% [] <75% [] total
TM Granulations [] R [] L
TM retraction [] R [] L
TM atelectasis []R [] L
Perf
R [] anterior [] posterior [] marginal [] < 25% [] < 50%
[] <75% [] total
L [] anterior [] posterior [] marginal [] < 25% [] < 50%
[] <75% [] total

Hearing loss by voice testing [] normal [] abnormal
Hearing loss by tuning forks AD [] A>B [] B>A [] A=B
AS [] A>B [] B>A [] A=B

BC: [] AD [] AS lateralizes to [] AD [] AS

Fork [] 256 [] 512

A free form text area is to be provided for additional exam-related text to be entered by the ENT specialist. The specialist should be able to add, modify or remove any data in the free form text area.

The specialist needs to be able to record the date of the examination, and the name of the person who performed the examination.

The specialist should be able to view the examination notes associated with a previous examination.

2.2.3 Free Form Notes

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

The intent of this requirement is to provide the ENT specialist a place to record data which might not be directly attributable to the sections described earlier in this section. Each of these requirements allows for free form notes to be attached as well.

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

The ENT specialist should be able to delete the text associated with the current examination.

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

The specialist should be able to view the free form notes associated with a previous examination.

2.3 Audiograms

ENT needs to be able to view audiograms that were obtained by audiology at the current clinic.
ENT needs to be able to view audiograms that were obtained by audiology at past clinics.

2.4 Diagnosis

The ENT specialist needs to be able to record the following diagnosis.

(In the following, AD = right ear, AS= left ear, AU = both, HL = hearing loss)

Hearing Loss
Conductive HL [] AD [] AS [] AU
Hearing Loss [] AD [] AS [] AU
Mixed HL [] AD [] AS [] AU
Sensory HL [] AD [] AS [] AU

External Ear
Cerumen Impaction [] AD [] AS [] AU
Ear Canal FB (FB = foreign body) [] AD [] AS [] AU
Microtia [] AD [] AS [] AU

Tympanic Membrane
Atelectasis [] AD [] AS [] AU
Granuloma [] AD [] AS [] AU
Monomer [] AD [] AS [] AU
Tube [] AD [] AS [] AU
Tympanic Perf [] AD [] AS [] AU

Middle Ear
Cholesteatoma [] AD [] AS [] AU
Eustachian Tube Dysfunction with TM Retraction [] AD [] AS [] AU
Otitis Media [] AD [] AS [] AU
Serous Otitis Media [] AD [] AS [] AU

Oral Cavity
[] Ankyloglossia
[] Airway obstruction due to tonsil enlargement
[] Cleft lip repair deformity
Cleft lip [] unilateral [] bilateral [] unrepaired [] repaired
Cleft palate [] unilateral [] bilateral [] unrepaired [] repaired
[] Speech Problem

Nose
Nasal obstruction [] Deviated Septum [] Turbinate Hypertrophy
[] Nasal Deformity secondary to Cleft Palate

Syndrome
Hemifacial Microsomia [] R [] L
Pierre Robin Syndrome [] R [] L

Other

In addition to the above, there may be one or more additional diagnoses that are observed and must be recorded. For each, ENT should be able to record the name of the diagnosis and add it to the examination record. There is no limit to the additional diagnosis that are entered. For each diagnosis, the ENT specialist should be able to add a line of free form text to further describe the diagnosis.

The ENT specialist must be able to add, remove, or modify any diagnosis that is made to the current examination.

The ENT specialist must be able to record the date of the diagnosis, and the name of the person who made the diagnosis.

A free form text area is to be provided for additional diagnosis-related text to be entered by the specialist. The specialist should be able to add, modify or remove any data in the free form text area.

Each diagnosis may be designated by the ENT specialist as "active" or "past". An active diagnosis pertains to a currently observed condition. A past diagnosis pertains to a diagnosis that was previously active but is no longer applicable to the patient.

A new diagnosis that is attributed to the patient in the current examination is defaulted to the "active" state.

The current examination will automatically include diagnoses made during previous examinations, if such diagnoses exist. The ENT specialist will be able to choose the visibility of previously made diagnoses using the following:

[] Show all diagnoses
[] Show only past diagnoses
[] Show only active diagnoses

The default is to show only active diagnoses.

The ENT specialist can view, for each previous diagnosis, its modification history. This history includes the date of creation, and the dates that it transitioned from active to past, or from past to active state. This will aid the specialist in identifying patterns of recurrence associated with a particular diagnosis.

2.5 Treatment Plan

2.5.1 General

A section named "Plan" is used to list treatments that have been recommended for a child. The common plan would consist of the following options:

Ear cleaned [] AD [] AS

Audiogram [] AD [] AS [] AU
[] Right away and return to see me right afterwards. May need surgery tomorrow.

Tympanogram [] AD [] AS [] AU
[] Right away and return to see me right afterwards. May need surgery tomorrow.

Mastoid debrided [] AD [] AS
[] Hearing aid evaluation

Antibiotic [] drops [] orally [] for acute infection [] for after water exposure infection prevention
Boric acid powder [] instilled today [] dispensed for home use
Tube removed [] AD [] AS
Foreign body removed [] AD []AS
Return [] 3 mos [] 6 mos [] prn
[] Referred to pvt ENT in Ensenada
[] Referred to Children's Hospital in Tijuana

[] Surgery Tomorrow

Tubes [] AD [] AS [] AU
T-plasty [] AD [] AS [] AU
EUA (Examination under anesthesia) [] AD [] AS [] AU
FB (foreign body) removal [] AD [] AS [] AU
Middle Ear Exploration via myringotomy [] AD [] AS [] AU
Cerumen removal [] AD [] AS [] AU
Granuloma removal [] AD [] AS [] AU
[] Septorhinoplasty
[] Scar revision cleft lip
[] Frenulectomy

[] Surgery in Future

Tubes [] AD [] AS [] AU
T-plasty [] AD [] AS [] AU
EUA (Examination under anesthesia) [] AD [] AS [] AU
FB (foreign body) removal [] AD [] AS [] AU
Middle Ear Exploration via myringotomy [] AD [] AS [] AU
Cerumen removal [] AD [] AS [] AU
Granuloma removal [] AD [] AS [] AU
[] Septorhinoplasty
[] Scar revision cleft lip
[] Frenulectomy

Free form text corresponding to each option is required to allow a more detailed description, if desired.

Free form text at the beginning or end of the plan section is required, to fill in treatment options that are not accounted for in the available choices.

2.5.2 Prior Treatment Plans

Treatment plans from prior clinics should be viewable at the discretion of the ENT specialist. The treatment plan should be selectable by clinic date.

A new treatment plan should be pre-filled with the union of all treatments that were previously assigned to the child and have not be marked as complete.

2.5.3 Other

The specialist should be able to edit an existing treatment plan, adding or removing items. Items marked as complete can not be removed from a treatment plan.

The specialist should be able to mark items on a treatment plan as complete. The user interface shall make it clear which items have and have not been completed.

Specialist from one specialty, (for example ENT), should not be able to edit data in another specialist's, (for example speech therapy or audiology or dental), subsection.

2.6 Surgical History

A portion of the surgical history of the patient is to be maintained by the ENT specialist. The surgical history data which is attributable to ENT consists of the following (AD = right ear, AS = left ear, AU = both ears):

Tubes [] AD [] AS [] AU
T-plasty [] AD [] AS [] AU
EUA (Examination under anesthesia) [] AD [] AS [] AU
FB (foreign body) removal [] AD [] AS [] AU
Middle Ear Exploration via myringotomy [] AD [] AS [] AU
Cerumen removal [] AD [] AS [] AU
Granuloma removal [] AD [] AS [] AU
[] Septorhinoplasty
[] Scar revision cleft lip
[] Frenulectomy

Each of the above surgeries must have free form space to describe any pertinent surgical findings. In addition, each surgery must have a date associated with it.

The ENT specialist must be able to add a surgery to the list of surgeries performed upon the patient. The specialist must be able to select the type of surgery, the date of the surgery, the ear or ears that the surgery was performed upon, and add notes specific to the surgery.

The specialist must be able to record the name of the surgeon, assistants, and nurses who performed the surgery.

The specialist must be able to view a list of all surgeries. The specialist should be able to select a surgery and view its details and associated notes.

2.7 Other Requirements

The ENT specialist should have access to the general medical history for the patient that was obtained when the patient was received at the clinic.

The ENT specialist should be able to modify the general medical history for the patient.

The ENT Specialist should be able to view all data recorded in the digital chart for this patient, in addition to data that is specific to ENT.

Each exam, history, etc. recorded at a clinic shall be stored in the database as a separate entity, independent of the same stored during a past clinic or at a future clinic. The ENT specialist should be able to page through the data recorded in past clinics for a child. This data from previous clinics is read only, and cannot be modified or deleted post-clinic.

The initial data for a new exam, history, etc. shall be initialized with the data taken from the most recent clinic for which the data was recorded for the child, should that data exist in the database.

Data that is saved to the database shall be notated such that one can determine the name of the specialist that recorded the data, and the date and time at which the data was writen to the database.

3. Other Nonfunctional Requirements

3.1 Performance Requirements

- The system should provide 99.9999% uptime during the clinical
- Search and access to the database should occur with a latency of no more than 5 seconds.

3.2 Safety Requirements

There are no specific safety requirements associated with this subsystem.

3.3 Security Requirements

We assume that the patient digital chart, and the ENT sub-system in particular, does not need to adhere to HIPAA requirements, and does not require HIPAA certification. We assume there are no regulatory requirements of the state of Baja, or of the Mexican government, to which this system must conform, or which governs how it is designed, implemented, or used by Thousand Smiles and its volunteers.

The system communication on the day of the clinic will occur over a subnet that has no routes to the Internet.

Users of the system will have accounts and must authenticate prior to using the digital chart. The usernames and password 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.

3.4 Software Quality Attributes

There are no specific SQA attributes associated with this subsystem.

3.5 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.

4. 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.>