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Faculty of Science

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GastrOS

**Open Standards Based Clinical Knowledge Modelling and
Development of an Endoscopic Information System Project**

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Software Requirements Specifications

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Preface

This document contains the Software Requirements Specification (SRS) of GastrOS Digestive Endoscopy Reporting Application to be developed within the context of the *Open Standards Based Clinical Knowledge Modelling and Development of an Endoscopic Information System Project* which is funded by a research grant from the University of Auckland Faculty Research Development Fund (Project No: 3624469/9843).

GastrOS SRS is prepared according to IEEE STD 830-1998, IEEE Recommended Practice for Software Requirements Specifications. This document includes scope, purpose, the product perspective, functions, user characteristics, system assumption, constraints and specific requirements such as functional requirements, performance requirements, and logical database requirements.

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1 INTRODUCTION

1.1 Purpose

This Software Requirements Specification (SRS) document provides a complete description of all the functions and constraints of GastrOS to be developed for the University of Auckland within the context of the *Open Standards Based Clinical Knowledge Modelling and Development of an Endoscopic Information System Project*.

The aim of this SRS is to formally define the software requirements for GastrOS, which would either match or exceed the functionality built into the former research prototype (aka GST). This is called Stage 1 development. After that Stage 2 development will commence where some change of requirements will be introduced. Formal software measurement for maintainability using standard metrics will be performed on both applications and finally results will be compared. Stage 2 is not defined in this SRS.

This SRS is prepared to establish a communication between the acquirer, users, and the software development team.

1.2 Scope

The intended software to be developed is GastrOS. The scope is:

- Stage 1 only; GastrOS shall have the same functionality with the GST at a minimum. These are given in 3.2 System Features section.
- The Detailed Search and System Operations functions shall be excluded as the focus of the study is the domain knowledge driven GUI, persistence and reposting aspects of software.
- GastrOS shall be a standalone Microsoft Windows Forms application.
- The intended number of users is one.
- It is not intended to be installed to a live clinical setting as a production system.
- GastrOS shall build upon openEHR formalism and use openEHR Reference Model (RM), Archetypes, Templates. It may also support Archetype Query Language (AQL).
- GastrOS shall use the Minimal Standard Terminology for Digestive Endoscopy (MST) version 2 by means of openEHR MST Archetypes developed previously.
- GastrOS shall not have application level security functionality.
- A simple wrapper application shall be provided which will enable recording of basic patient, visit and clinical information.

For its users GastrOS:

- Shall enable endoscopists to enter examination characteristics, findings, diagnoses, procedures of an endoscopic examination.
- Shall allow selection of signout endoscopists.
- Shall generate reports for viewing and printing.
- Shall let users to perform basic search operations (by Patient ID and Report ID).

In future if deployed in a clinical setting GastrOS will help to:

- Eliminate paper-based records.
- By means of structured data entry, it will reduce transcription errors, omissions, ambiguity; thus enhance safety.
- Boost productivity by reducing reporting time and effort.
- Improve physician training by providing a standardised reporting process and also large volumes of high quality and structured data.

The scope and purpose of this report:

To present first an overview of the project and then give detailed view of the project.

To present an analysis of the perceived problem from which a list of specific unambiguous requirements will be formulated from the user's point of view. This list will include functional, external interface, performance and other requirements as well as a summary of future expectations. Design constraints and attributes leading to the finished product will be specified.

To provide an overview of the interaction between the users and the system, the visual appearance of the former application's user interface will be provided. This will include a description of the interface between the user interface and GastrOS.

To provide an overview about persistence requirements and relationship with external information provided by means of software interfaces.

1.3 Definitions, Acronyms and Abbreviations

Definitions

Acquirer	: The individual or organization that specifies requirements for and accepts delivery of a new or modified SW product and its documentation.
Medical Warnings	: Indicators for chronic renal failure (CRF), Hepatitis B,C,D and HIV.
Dx Text	: The free text representation of user selected structured MST diagnoses plus free text entry using SDE to be used in reporting
Health Level 7	: An international multi-vendor standards body for interchange of medical data among different medical centres. It is an XML based message oriented standard.
Patient ID	: Patient's unique identifier (either national or provider specific).
Patient Information	: Patient ID and minimal demographics (Name, Age, Sex, Ethnicity/Origin).
Record ID	: A numeric unique identifier for each endoscopy examination. It may be system generated with auto increment.
SDE Text	: The text generated from the structured data entry forms after user selection. This includes data from MST based Examination Characteristics, Findings and Additional Diagnostic and Therapeutic Interventions Pages.
SDE Information	: The whole structured instance of SDE Information which contains user entered data or retrieved from database.
Exam Information	: Information about the endoscopy examination (at a minimum endoscopy type, device, premedication, notes, date of report)
Users	: Endoscopists, trainees, nurses, technicians and system administrators.
Visit	: Patient's each unique admission to a health care institution/doctor.
Visit Information	: Patient's information which is created for each unique visit to a health institution/doctor for a specific complaint; will contain at a minimum date/time of visit, social security/insurance information, physician and referring department.
Wrapper Application	: A FOSS .Net Windows Forms application which provides minimal information to GastrOS for creating a valid endoscopy report. Wrapper application and GastrOS component will be able to work as a standalone system with a local persistence solution.

Acronyms and Abbreviations:

API	Application Programming Interface
CIS	Clinical (usually departmental) Information Systems.
CPU	Central Processing Unit
DB	Database
FOSS	Free and Open Source Software
GPRS	General Packet Radio System
GUI	Graphical User Interface
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIS	Health Information System
HIV	Human Immunodeficiency Virus
HL7	Health Level 7
Hx	History
ID	Identifier
IEEE	The Institute of Electrical and Electronics Engineers
JAR	Java Archive
JDBC	Java Database Connectivity
LAN	Local Area Network
LOINC	Laboratory Observation Identifier Names and Codes
LIS	Laboratory Information System
Mbps	Megabit per Second
MB	Mega byte
MST	The Minimal Standard Terminology for Digestive Endoscopy
N/A	Not Applicable
ODBC	Open Database Connectivity
openEHR	openEHR specifications or the openEHR Foundation.
PAS	Patient Admission System
PC	Personal Computer
PDA	Personal Digital Assistant
PE	Physical Examination
PMH	Past Medical History
RAM	Random Access Memory
RIS	Radiology Information System
SDE	Structured Data Entry
SRS	Software Requirements Specification
SSL	Secure Sockets Layer
SNOMED	Systematized Nomenclature of Medicine
TCP/IP	Transfer Control Protocol/Internet Protocol
WLAN	Wireless Local Area Network
XHTML	Extensible Hyper Text Markup Language
XML	Extensible Markup Language

1.4 References

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1.5 Overview

This document is prepared in accordance with the IEEE Std 830-1998, IEEE Recommended Practice for Software Requirements Specifications and the other documents specified in Section 1.4.

Section two of this document gives a general description of GastrOS. It also provides product perspectives, product functions, user characteristics, constraints, assumptions and dependencies of the system. It will also include what part of the system will be apportioned for future versions.

Section three contains all the details of GastrOS' external interface requirements, functional and performance requirements, logical database requirements, design constraints, software system attributes and other requirements. While organizing specific requirements, the fifth template of the IEEE Std 830-1998, IEEE Recommended Practice for Software Requirements Specifications (Organisation by Feature) is used in this document.

Last section contains supporting information like appendices.

2 OVERALL DESCRIPTION

In this section, the general factors that affect the product and its requirements will be described without stating specific requirements.

2.1 Product Perspective

In this subsection, the parts of the product will be put into perspective with each other. GastrOS consists of two distinct parts:

- 1) **The Wrapper Application ("Wrapper")**: the part of the application required to drive the other component so that it will function as a minimal desktop clinical information system; includes functions like patient and visit data entry, simple searching and sign-off/reporting.
- 2) **openEHR based Structured Data Entry Component ("SDE")**: will contain all data entry/validation/update functionality driven by underlying MST Archetypes & Templates. This part shall implement openEHR.

The combination of Wrapper and SDE will serve as a standalone system and act like a single application. Both parts are intended to be Free and Open Source (FOSS) however this depends on the FOSS availability of third party components if any. It is anticipated that possible uses of GastrOS by others will be through utilising the SDE component by means of method calls through a well defined service model.

2.1.1 System Interfaces

Wrapper will interact with SDE using standard method calls. The XML based data captured by SDE will be passed onto Wrapper and stored into MS Access 2003 Database. There will be no messaging between two systems at the application level; however in future this interface may be redesigned as a formal API so that other applications can easily consume SDE.

2.1.2 User Interfaces

There is only one type of user: *user*

User interfaces shall be Win Forms based conforming to .Net Framework.

The screen resolution shall be minimum 1024x768 pixels, with 16bit colour and this shall be the default form size for automatically generated SDE forms unless specified by GUI directives.

The general outline and flow of user interfaces of GastrOS is depicted below:

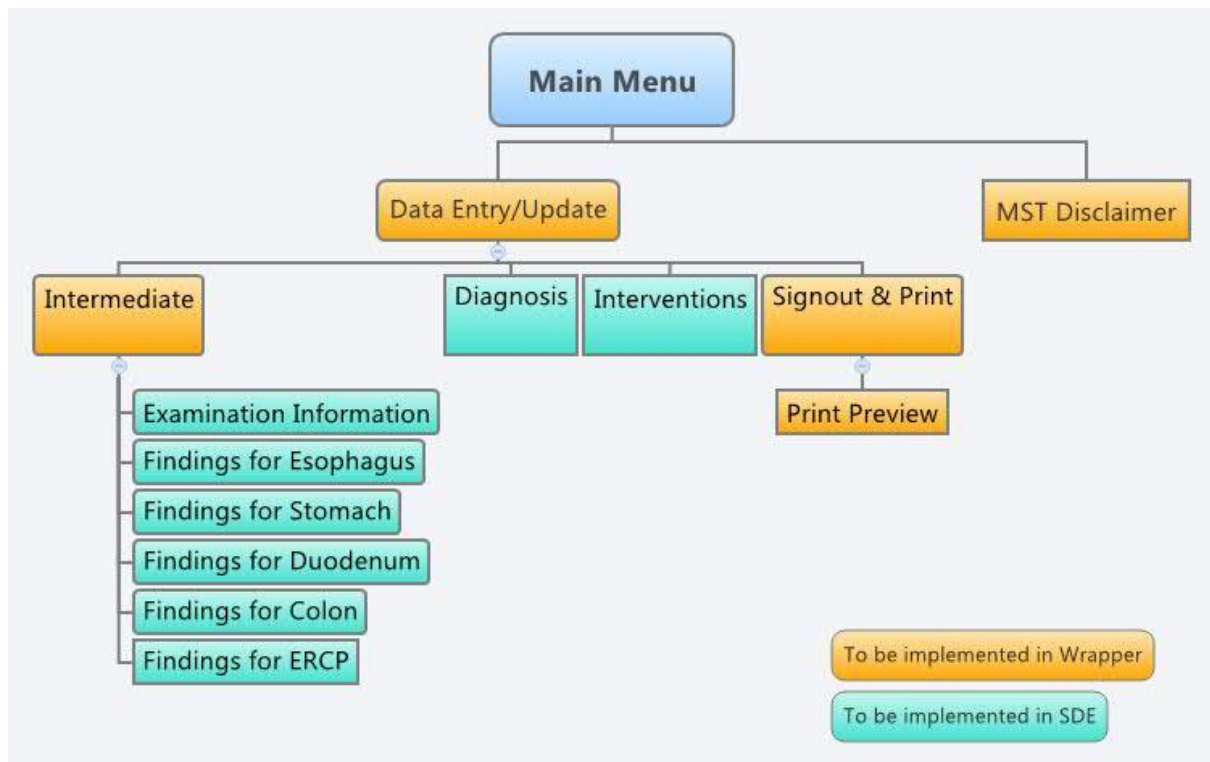


Figure 1 – GastrOS User Interface Diagram

2.1.3 Hardware Interfaces

Since GastrOS shall be a standalone application, there are no additional hardware interfaces other than provided by the host operating system.

2.1.4 Software Interfaces

Although behaves like a standalone system, GastrOS shall comprise two distinct components talking to each other through interfaces. This shall be in the form of a typical component usage; i.e. by method calls. The captured data by SDE shall also be passed to Wrapper to be stored in XML format in the MS Access 2003 database after going through processing by Hibernate.

Software interfaces that result from those requirements are listed below.

Name: Windows7 Operating System

Version Number: -

Source: Microsoft Corp.

Purpose: this software shall be the operating system of GastrOS.

Definition of the interface: refer to [X].

Name: MS .Net Framework

Version Number: -

Source: Microsoft Corp.

Purpose: this provides the CLR running on the host computer.

Definition of the interface: refer to [X]

Name: MS SQL Server 2005 Express

Version Number: -

Source: Microsoft Corp.

Purpose: this is the database software (RDMS) running on the host computer.

Definition of the interface: refer to [10]

Name: Hibernate

Version Number: -

Source: ??

Purpose: this is used for mapping and persisting Object data into RDMS.

Definition of the interface: refer to [X]

2.1.5 Communications Interfaces

GastrOS shall be a client application. The only communications foreseen shall be with the database through MS Native Client using Shared Memory [X].

2.1.6 Memory

The primary and secondary memory requirements of the necessary software that shall be installed on host computer are depicted below:

Product	Primary Memory	Secondary Memory
Windows 7 OS	Min 512 MB, recommended 1 GB	?? GB with a minimum of ?? GB free space
.Net Framework	?? MB	?? MB
Hibernate	?? MB	?? MB
SQL Server	512 MB	?? MB

The Operating System and other software memory requirements are sufficiently met by the current hardware specifications of the system (refer to section 3.1.2).

2.1.7 Operations

Refer to Appendix III – Use Case Diagrams

New Examination: *user* shall be able to create a new record. Patient, Visit and Medical Warnings shall be provided at a minimum. An automatic unique examination number shall be created. *user* shall be able to enter custom notes to the record which may or may not be visible on the printed report. At the end *user* shall have the option to either update the record or cancel new examination.

Modify Record: *user* shall be able to make changes and then either update record or cancel changes.

Delete Record: *user* shall be able to delete record when necessary.

Find Record: *user* shall be able to find the record of a particular examination either by the unique report number. *user* shall be able to find the records of studies by the unique patient identifier. The number of records found shall be prompted and also navigation among these records shall be provided.

Enter MST Structured Data: *user* shall select either of the examination types and navigate to SDE Pages.

- *user* may enter Reasons for Endoscopy, Examination Characteristics and Complications information.
- *user* may enter findings per organ using MST driven SDE forms. The organ(s) to be selected shall be determined by examination type.
- *user* may enter the diagnoses for each organ that was investigated in the examination. Both free text and MST based pick-list values can be entered.
- *user* may enter the Additional Diagnostic and Therapeutic Procedures as given in MST by using SDE forms.

Sign-off and Print Report: After selecting sign-out endoscopist, *user* shall be able to print a formal endoscopy report. *user* shall be able to generate a preview of endoscopy report. The option whether to print a header/footer, number of copies, printer setup dialog as well as printing report captions in a different language may also be present.

Display MST Disclaimer: *user* shall be able to display the original MST copyright as dictated by the governing organisation OMED.

Browse Project Website: *user* shall be able to browse the Project Website (<http://gastros.sourceforge.net>) by invoking a browser.

2.1.8 Site Adaptation Requirements

GastrOS needs no extra modifications/configurations at this stage for integration with any other system. However application parameters and sign-out endoscopist need to be maintained. The system administrator shall input all these information by using the DBMS management tools or front-end applications such as MS Access.

The hardware at the hardware interfaces (Section 2.1.3 part of this document) should be installed, running and configured as stated

The software at the software interfaces (Section 2.1.4 part of this document) should be installed, running and configured as stated.

2.2 Product Functions

Summary of the major functions that GastrOS shall perform are as follows:

Data Entry/Update: GastrOS shall let user to enter data for a new endoscopy examination or modify existing records. The MST based SDE forms will be used.

Sign-off and Reporting: GastrOS shall provide the means to select users who are responsible for the report (sign-off) and prepare a formal endoscopy report.

Search: GastrOS shall let the users to search for records based on Record ID and Patient ID.

2.3 User Characteristics

There is one type of user and this user should be computer literate and have general knowledge about computer applications - specifically windows applications.

2.4 Constraints

Regulatory policies of the University of Auckland: The terms and conditions of the research grant impose strict constraints on the schedule and budget of the project. Realistically the application development should end by mid March 2010 and then Stage 2 will commence where measurement and evaluation will be done. Whole project must end by 30 June 2010.

Resource limitations: The Department of Computer Science has assigned 0.4 FTE (2 days) of research programmer time for the development and 0.7 FTE of Dr. Atalag's time.

Project aims and scope: The research project aims to develop an application for the purpose of software measurement and evaluation; thus real world usability and consequent

requirements do not have to be met (i.e. security, availability, performance, multi-user access, etc.). However, scope of the software is strictly determined by what aspects of the software are going to be measured and how. One big issue is that scope of the software is limited mainly to domain specific aspects – i.e. dictated by underlying medical concepts.

openEHR specifications and tools: Since GastrOS shall use openEHR based clinical models (MST Archetypes and Templates), the modelling formalism and resulting artefacts put major constraints on software. The correctness and implementability of specifications together with libraries and tools is of utmost importance during implementation.

Free and Open Source Licensing: Since GastrOS shall be a FOSS application, the third party libraries and components used should comply with the licensing model to be chosen. Currently the openEhrV1 assembly which implements the openEHR RM and a few others by Ocean Informatics Pty. is not FOSS.

2.5 Assumptions and Dependencies

Since GastrOS is going to use openEHR formalism and that this is going to be the first implementation using C# in .Net environment, it is assumed that all software libraries, components and tools shall be available and running according to openEHR specifications.

Since this is an academic study, it is assumed that no change of requirements will take place other than defined by the researchers.

The educational and expertise levels of *users* are assumed to comply with User Characteristics in section 2.3.

2.6 Apportioning of Requirements

The below mentioned issues are to be implemented in future versions of GastrOS:

In Stage 2, a number of new requirements shall be introduced as well as changes to existing ones. These will be determined throughout the research. These will be both retrospective (i.e. ones that arose during usage of GST) and prospective (we will determine new requirements due to changes in the content or structure of MST and also resulting from changes to application functionality).

Searching capability where records can be searched using multiple criteria. This would include searching within the structured archetype based data.

Reporting capability for search results and also summary reports

Data analysis and clinical decision support based on existing data and external sources.

System maintenance functions

Application level security and multi user capability

A message-based application level interface (HL7 compliant) with other Health Information Systems like Patient Admission Systems (PAS), Radiology Information Systems (RIS), Laboratory Information Systems (LIS), Pathology Information System and etc. and use international standards like SNOMED, DICOM and LOINC.

3 SPECIFIC REQUIREMENTS

3.1 External Interface Requirements

User Interfaces, Hardware Interfaces, Software Interfaces and Communication Interfaces will be clearly defined. Necessary references will be given to other relevant sections.

3.1.1 User Interfaces

For the user interface details of GastrOS refer to Appendix I.

3.1.2 Hardware Interfaces

The hardware interfaces of GastrOS contain the following components:

Table 1 - Detailed Hardware Interfaces

Hardware Interfaces	Properties
Host Computer	RAM: 4 GB RAM HDD: 200 GB CPU: Inter Core 2 Duo 3 GHz Ethernet Adapter: Gbit Ethernet Display: 22" Wide LCD

Also refer to section 2.1.3

3.1.3 Software Interfaces

Refer to section 2.1.4

3.1.4 Communications Interfaces

Refer to section 2.1.5

3.2 System Features

3.2.1 Application Start

This feature contains the essential functionalities of GastrOS to be performed by Wrapper when starting the application.

It may also offer functionalities for basic patient management such as entry/update/delete patients and entry/update/delete of patient visits which will be passed to the Data Entry/Update functions.

3.2.1.1 Associated functional requirements

3.2.1.1.1 Display Main Menu Page

Introduction: It displays the Main Menu page.

Inputs: N/A

Process: It shall display the Main Menu page on application start and prompt user options to navigate to Data Entry/Update Page and display MST Disclaimer Page.

Output: N/A

3.2.1.1.2 Display MST Disclaimer Page

Introduction: It displays the MST Disclaimer page.

Inputs: N/A

Process: It shall display the MST Disclaimer page and may provide a vertical scroll bar to allow use read all of the text. It shall close the page and return back to Main Menu page when user closes it.

Output: N/A

3.2.1.1.3 Browse Project Website

Introduction: It allows browsing the project Website.

Inputs: N/A

Process: It shall open the Web browser and navigates to the project Website (<http://gastros.sourceforge.net>).

Output: N/A

3.2.2 Data Entry/Update

This is feature holds the basic data entry functionalities of GastrOS to be performed by Wrapper. A new examination can be initiated or existing records can be modified or deleted. Basic search functions which find record(s) by Record ID and Patient ID are provided. The core of the feature lies in the Data Entry/Update Page where:

- Patient Information,
- Visit Information,
- Medical Warnings,
- Exam Information,
- SDE Text,
- Notes

Information is handled. Other pages related with this feature are also accessible from Data Entry/Update page which are:

- Intermediary Page
- Examination Information Page
- Findings Page
- Diagnosis Page
- Interventions Page

To prevent accidental alteration or deletion of user entered data the controls which hold Patient Information, Visit Information, Medical Warnings, Exam Information, SDE Text and Notes shall be locked and unlocked as necessary. This group of controls shall be called as “Data Entry Controls”.

3.2.2.1 Associated functional requirements

3.2.2.1.1 Display Data Entry/Update Page

Introduction: It displays the Data Entry/Update Page.

Inputs: Record ID

Process: When user selects to go to the Data Entry/Update page from the Main Menu page, GastrOS shall display the Data Entry/Update page. It may provide a separate page for patient centred handling of patient demographics and visit information, and also for finding records by Patient ID and Record ID.

In the Data Entry/Update page all text fields shall be locked to prevent accidental changes and deletion of record. However the following functions shall be available:

- Modifying or deleting current record
- Signout and reporting
- Display Intermediate Page
- Display Diagnosis Page
- Display Interventions Page

The following functions may also be provided:

- Quick finding records by Record ID
- Quick finding records by Patient ID
- Starting a new examination

The values of pick lists for: referring department, social security/insurance information, examination type and device shall be populated from database (these information may be managed by using database administration tools).

Output: Patient Information, Visit Information, Medical Warnings, Exam Information, SDE Text and Notes.

3.2.2.1.2 Search by Record ID

Introduction: It searches for a record with a specific Record ID.

Inputs: Record ID

Process: The user shall be promoted for Record ID and then it shall seek the particular record. If found it shall display this record. If not found a message shall be displayed.

Output: Patient Information, Visit Information, Medical Warnings, Exam Information, SDE Text, Notes and record not found message.

3.2.2.1.3 Search by Patient ID

Introduction: It searches for records with a specific Patient ID.

Inputs: Patient ID

Process: The user shall be prompted for Patient ID and then it shall retrieve all records with that particular Patient ID. Use shall be informed about the result of the search; it may display a message which shall state either no record is found or the number of records found. If one or more records are found it shall enable navigation among found records.

Output: Patient Information, Visit Information, Medical Warnings, Exam Information, SDE Text, Notes and search results message.

3.2.2.1.4 New Study

Introduction: It enables starting a new examination for endoscopy reporting.

Inputs: N/A

Process: It shall unlock Data Entry Controls if they have been locked before. Record ID for the newly created record may be automatically assigned by GastrOS. Then user may enter information. Order of fields during data entry shall be organised so as to move from one field to the next one with the keyboard. The user shall also be given the option to cancel the operation and asked for confirmation when cancelling.

Output: Patient Information, Visit Information, Medical Warnings, Exam Information, SDE Text, Notes and Cancel New Record Confirmation Message.

3.2.2.1.5 Modify Record

Introduction: It enables making changes to the current record.

Inputs: Record ID

Process: It shall unlock Data Entry Controls if they have been locked before. The user may then modify information. Once finished it shall save changes to the current record and then lock Data Entry Controls to prevent accidental change of the current record.

It is important to note that SDE Text, if present, may be edited by endoscopist to correct grammar and/or for adding additional findings and comments. Once SDE Text is created, it has no link to the underlying structured data unless it is recreated again.

Output: Patient Information, Visit Information, Medical Warnings, Exam Information, SDE Text, Notes.

3.2.2.1.6 Delete Record

Introduction: It deletes the current record.

Inputs: Record ID

Process: When enabled it shall prompt the user to confirm the operation and then delete the current record.

Output: Delete Record Confirmation Message.

3.2.2.1.7 Display Intermediary Page

Introduction: It displays the Intermediary Page which presents user to call SDE forms based on examination type. There are two classes of MST based SDE forms here: 1) Findings and 2) Examination Information which contains examination characteristics, reasons for endoscopy and complications as per MST. The endoscopic findings are different for each organ which is then determined by examination type. Refer to MST document for details. So MST based Findings forms are given for each organ. Also other examination information such as examination characteristics and reasons for endoscopy are different depending on examination type. Upper and lower GIS endoscopy examinations share the same Examination Characteristics information and ERCP has a different set. All three examination types have separate Reasons for Endoscopy information. Complications contain a simple list which applies to all examination types.

Inputs: Examination type.

Process: Intermediary Page shall be displayed and made active.

The page shall present the organ(s) involved in endoscopy which allow navigating to MST Findings SDE Forms. For upper GIS endoscopy esophagus, stomach and duodenum shall be presented. For lower GIS endoscopy colon shall be presented. For ERCP duodenum and either as a group or individually papilla major, papilla minor, pancreas and biliary system shall be presented.

The page shall also let user to display Examination Information Page.

The option to convert selected information into narrative text (SDE Text) shall also be presented. If there is existing text (either entered manually or previously using SDE Forms) it shall display a message to confirm overwriting.

It shall also let use to close form and return to Data Entry/Update Page.

Outputs: SDE Text, Overwrite Existing SDE Text Message

3.2.2.1.8 Create SDE Text

Introduction: It is used to create human readable textual text corresponding to a narrated report based on user selection in associated SDE Forms.

Inputs: Examination type, SDE Information.

Process: It will scan through user selection in SDE Forms and concatenate MST items based on the general hierarchy HEADING>TERM>ATTRIBUTE>ATTRIBUTE VALUE and SITE(S).

The rule for creating the SDE Text for Findings and Procedures is as follows:

ORGAN: Normal + “ (“ + Site1 + “ , “ + Site2 ... + “)”
--

Term1 + “,” + Attribute1 + “:” + Attribute Value1 + “,” + Attribute2 + “:” + Attribute Value2 + + “ observed at “ + Site1, + “,” + Site2 +

Term2 + (New line for each term)

If user entered no data on an organ based findings form then nothing will be displayed; not even the organ's name.

It is important to depict that normal can be used in two ways:

- 1) Only Normal is selected (i.e. without sites or any other item on form). This means that the organ has been found entirely normal during examination and no further information is necessary.
- 2) However when Normal is selected with associated sites and/or other findings then it means only those sites have been found normal but other findings may be present. In that case the reporting will continue normally (i.e. according to above rule).

It should also be noted that it is currently not possible to depict negative findings; i.e. to report if a particular lesion is not present which is also important clinically.

For Examination Information: only Examination Characteristics have such functionality. Generally terms are not used but the attributes, attribute values and site (only one site is allowed in GST). Also there are exceptions and extended concepts (which does not occur in MST).

Term (Extent of examination) + “:” + Site

Attribute (Quality) + “:” + Attribute value

“ Site: “ + Site (Preparation>Site)

Attribute (TBD: Inspection and Rectal Examination>Inspection) + “:” + Attribute value

Attribute value (TBD: Inspection and Rectal Examination>Inspection description)

Attribute (TBD: Inspection and Rectal Examination>Digital rectam exam) + “:” + Attribute value

Outputs: SDE Text

NOTE: a related function exists (Prepare Report) in Signoff and Reporting which prepares the free text representation of diagnoses (Dx Text) entered using SDE.

3.2.3 MST based Structured Data Entry

This is feature contains the core functionalities of GastrOS to be performed by SDE when called by Wrapper. It is in fact provided by a generic openEHR compliant GUI generator, data entry and validator component consuming MST Archetypes. When a particular Archetype ID is provided by the Wrapper based on Examination Type and option selected, it contains the means to manage SDE functionalities.

3.2.3.1 Associated functional requirements

3.2.3.1.1 Display Diagnosis Page

Introduction: It displays the Diagnosis Page where diagnoses for each organ can be entered from MST pick lists and free text. MST defines a list of diagnoses for each organ. Different organs are involved in each examination type and the final report presents diagnoses by each organ.

Inputs: Archetype ID, Edit Status

Process: Diagnosis Page shall be displayed and made active. The page shall contain four MST diagnoses pick lists and one free text field for each organ. Three organs shall be visible at a minimum. Depending on Examination type, MST based pick lists shall contain the list of diagnoses for particular organs involved in that examination type. In the case that current record has previously entered diagnoses then the pick list and text fields will be populated with these values. If this is a new examination all the fields shall be blank. If the record is allowed to be edited (either new examination or modification in progress) all controls shall be unlocked. Otherwise the controls shall be locked to prevent accidental changes.

Outputs: Diagnoses

3.2.3.1.2 Save Diagnoses

Introduction: It saves the diagnoses selected by user and closes the page.

Inputs: Edit Status.

Process: It shall save the user selected diagnoses if the record is editable and close the Diagnosis Page and return to Data Entry/Update Page.

Outputs: Diagnoses.

3.2.3.1.3 Display Findings Page

Introduction: It displays the appropriate Findings Page and lets user to quickly enter endoscopic findings using point & click selections.

Inputs: Organ/Group selected, Edit Status.

Process: Depending on the organ/group selected in Intermediary Page, the corresponding MST Findings Form shall be instantiated, displayed and made active. The following pages shall be displayed:

Upper GIS Endoscopy

- MST Findings for Esophagus Page
- MST Findings for Stomach Page
- MST Findings for Duodenum Page

Lower GIS Endoscopy

- MST Findings for Colon Page

ERCP

- MST Findings for Duodenum Page
 - MST Findings for ERCP Page (which includes MST Findings for Papilla Major, Papilla Minor, Pancreas and Biliary System).
- A) If this is a new entry the form will be blank; otherwise the form shall display previously selected information. If the record is allowed to be edited (new examination or modification in progress) then all controls shall be unlocked. Otherwise the controls shall be locked to prevent accidental changes.
- B) The form shall let user to delete all entries on the form, save information or cancel operation.
- C) The form may have tabs to better present elements. Its organisation shall follow the design principles as defined by Koray Atalag's Ph.D. Thesis. For details of this form refer to Section 5.
- D) Based on MST organisation and content, the form shall present terms, attributes and values in a consistent and user-friendly manner and let user to make selection by point & click operations. To avoid confusion, if this is a new entry (i.e. the form does not contain previously entered information), only the terms shall be visible. If there is any previously entered information then the page shall display it (by making visible attributes, values and the means to display anatomic sites).
- E) The GUI shall not be required to allow for multiple selection of same terms (with a different set of attributes and/or values and sites).
- F) The list of Site(s) on each form shall be limited to the MST Site(s) defined for each organ; i.e. if Stomach is selected then the Site(s) will have only stomach sites for selection.

Outputs: Delete Entries Confirmation Message, MST Findings.

3.2.3.1.4 Display Interventions Page

Introduction: It displays the appropriate Interventions Page and lets user to quickly enter additional diagnostic and therapeutic procedures using point & click selections.

Inputs: Examination type, Edit Status.

Process: Depending on the examination type MST Interventions Form shall be instantiated, displayed and made active. For all examination types the same form will be used.

The list of Site(s) shall be limited to the MST Site(s) defined for organ(s) for that particular examination type; i.e. if Upper GIS Examination is selected then the Site(s) will have only sites for Esophagus, Stomach and Duodenum.

It shall also provide the user to create textual representation of selected procedures and append to SDE Text.

- A) If this is a new entry the form will be blank; otherwise the form shall display previously selected information. If the record is allowed to be edited (new examination or modification in progress) then all controls shall be unlocked. Otherwise the controls shall be locked to prevent accidental changes.
- B) The form shall let user to delete all entries on the form, save information or cancel operation.
- C) The form may have tabs to better present elements. Its organisation shall follow the design principles as defined by Koray Atalag's Ph.D. Thesis. For details of this form refer to Section 5.
- D) Based on MST organisation and content, the form shall present terms, attributes and values in a consistent and user-friendly manner and let user to make selection by point & click operations. To avoid confusion, if this is a new entry (i.e. the form does not contain previously entered information), only the terms shall be visible. If there is any previously entered information then the page shall display it (by making visible attributes, values and the means to display anatomic sites).
- E) The GUI shall not be required to allow for multiple selection of same terms (with a different set of attributes and/or values and sites).
- F) The list of Site(s) shall be limited to the MST Site(s) defined for organ(s) involved in the Examination type; i.e. if Upper GIS endoscopy is selected then the Site(s) will have Esophagus, Stomach and Duodenum sites for selection.

Outputs: Delete Entries Confirmation Message, MST Interventions.

3.2.3.1.5 Select Terms, Attributes and Values

Introduction: During entry of findings on a MST Findings Page this function defines how terms (i.e. ulcer), attributes (i.e. size) and values (diameter in mm.) will be entered by user.

Inputs: MST Findings.

Process: It shall allow user to select terms by using simple point & click operation. The attributes and values shall be made visible only after a term is selected. They shall be unselected and hidden again when the associated term is unselected. It shall also provide the means to let use select anatomic sites for each term, provided that this has been defined in MST.

Outputs: Selected MST Findings.

3.2.3.1.6 Display and Select Anatomic Sites

Introduction: MST provides the list of anatomic sites for each observation (called Term) per organ. So when user selects findings (Terms) on any MST Findings Page, if MST defined anatomic sites for that particular term and user decides to enter this information then this function will provide the means to allow user to easily select multiple anatomic sites. If this information has been previously entered then this will be presented and user will be able to modify if editing is allowed.

Inputs: Organ/Group and Term selected, MST Sites, Edit Status.

Process: When user decides to specify anatomic sites associated with a particular term during data entry in any MST Findings Page, if MST has defined entry of this information for a particular term, then the user shall be provided with a list of anatomic sites for the organ being specified. A pop-up or splash form/dialogue may best be presented where user can make multiple selections using simple point & click operations if editing is allowed for record. Otherwise selection shall not be possible. After selection user shall be able to return back to MST Findings Page. If any selection has been made previously then this selection shall be presented to user and if editing is allowed modification shall be made possible.

Outputs: Selected MST Sites.

3.2.3.1.7 Display Examination Information Page

Introduction: It displays the appropriate MST Findings Page and lets user to quickly enter MST Examination Characteristics, Reasons for Endoscopy and Complications information using point & click selections.

Inputs: Examination Type, Edit Status.

Process: Depending on the Examination Type, the corresponding Examination Information Form shall be instantiated, displayed and made active. If this is a new entry the form will be blank; otherwise the form shall display previously selected information. If the record is allowed to be edited (new examination or modification in progress) then all controls shall be unlocked. Otherwise the controls shall be locked to prevent accidental changes.

The form may have tabs to better present elements. Its organisation shall follow the design principles as defined by Koray Atalag's Ph.D. Thesis. For details of this form refer to Section 5.

The form shall let user to delete all entries on the form, save information or cancel operation.

Outputs: Delete Entries Confirmation Message, MST Findings.

3.2.4 Sign-off and Reporting

3.2.4.1 Introduction/Purpose of feature

This is feature contains the functions for signing off and printing endoscopy reports. Any formal medical report has to have at least one physician who is responsible (and liable) to sign-off. GastrOS allows up to four individuals to sign-off; which may be assisting endoscopists, trainees or attending nurses depending on organisational preferences. But one of these will be designated as the main one based either on the appearance of signatures on the report (i.e. usually the right or left most one is the main physician; or in some cases this may explicitly be labelled in the report).

Print function displays the final report to be printed. For printing, GastrOS expects to have at least one sign-off name selected and saves all selected names together with current date and time for as sign-off history. By this way, it is possible to trace multiple prints of reports (possible modifications or reprints).

Two pages are involved with this feature – the Signoff and Print Page and Print Preview Page.

3.2.4.2 Associated functional requirements

3.2.4.2.1 Display Sign-off and Printing Page

Introduction: It displays the Sign-off and Printing Page where the individual(s) signing-off (i.e. responsible) the endoscopy report can be selected.

Inputs: Sign-off List, Sign-off ID 1 to 4.

Process: Sign-off and Printing Page shall be displayed and made active. If the report has been previously signed-off and printed then the page shall show these names; but the user may change for the particular sign-off (i.e. if has been wrongly selected). If it is a new examination, user shall be able to select up to four sign-off names (one being the principal) from an existing list (configured with external database administration tools). Each of the four sign-off selections shall be labelled from 1 to 4 - 1 being the principal endoscopist. However if the report has been signed-off previously any name which is inactive shall be displayed.

It shall also let user to close the page and return back to Data Entry/Update Page.

Outputs: Sign-off ID 1 to 4, Signed-off Report Message.

3.2.4.2.2 Prepare Report

Introduction: It prepares the content for the report. Refer to APPENDIX V – Sample Endoscopy Report to view a sample report.

Inputs: Patient Information, Visit Information, Medical Warnings, Exam Information, SDE Text, Dx Text and Notes, Sign-off ID 1 to 4

Process: It shall gather all parts of current record's data to prepare an endoscopy report. The general layout is given in the sample report. However it is worth describing the following process:

Diagnosis: it shall lookup the four structured diagnoses per organ, write the name of the involved organ(s), and then concatenate the text separated by comma and display in the same line. The free diagnosis, if any, will be placed under this in a new line. The rule is as follows:

Organ1 + ": " + Dx1 + ", " + Dx2 + ", " + Dx3 + ", " + Dx4
Free Text Dx
Organ2

Outputs: The Report content

3.2.4.2.3 Sign-off and Print

Introduction: It allows user to select the name(s) signing-off report and print.

Inputs: Sign-off ID 1 to 4

Process: It shall allow user to select up to four sign-off names from Sign-off List. It shall not allow for signing-off and printing report unless at least one endoscopist is selected;

otherwise it shall display a message to use to select at least one name if any attempt is made for signing-off and printing. It shall not allow for selection of same endoscopist twice and display a warning message to user.

After sign-off and initiating printing, a print preview of final report may be allowed.

On successful signout and printing it shall update the record to save the ID of names so that when the record is reopened it can prompt user with this information. It shall also save the ID of names together with date to database which will serve as record history.

It shall close the page and return to Data Entry/Update Page.

Outputs: Duplicate Sign-off Message, Select a Name Message, Report Preview, Report.

3.3 Performance Requirements

Users will use the system via desktop PCs and a high speed LAN for connecting with peripherals and to the Net. Since this is a standalone application and that only one user can run the application at a time the load is expected to be low. Nevertheless performance of the system should match old apps'. At the minimum GastrOS should respond to 100% of Data Entry/Update requests in less than 1 second. The performance during Search (i.e. Finding records by Record ID and Patient ID) is not critical and may extend up to 5 seconds (but shall not exceed 5 seconds).

3.4 Persistence Requirements

GastrOS shall store collected data into a RDMS – which in this case MS SQL Server 2005 Express. The Wrapper Application shall use this persistence solution for its own data using classical normalised tables with keys and indexes. The output structured data from SDE shall also be stored in XML format within this database.

GastrOS may also use an openEHR compliant persistence layer where available and may then have the ability to run Archetype Query Language (AQL) based queries. EHR Bank solution of Ocean may be used.

3.5 Design Constraints

This implementation of GastrOS is aimed for measurement of software maintainability and comparative evaluation using GST Therefore only design constraints are all described in this document. This SRS will serve as the main reference material for software verification.

Since the SDE is driven dynamically in the run-time by the underlying MST Archetype model and the openEHR RM expressed in openEhrV1 assembly, it will be constrained by these which are subject to change frequently.

The user interface will also be affected by the capabilities offered by the development environment; in this case MS Visual Studio 2008 and Win Forms.

3.6 Software System Attributes

3.6.1 Reliability

GastrOS shall be operational for XX% of time after reaching version 1.0.

3.6.2 Availability

GastrOS shall be available at all times except during the administrator performs his operations as depicted in Section 0 System Operations.

3.6.3 Security

GastrOS shall not have application level authentication mechanism but depend on operating system and network security. For future security features refer to 2.6 Apportioning of Requirements section of this document.

3.6.4 Maintainability

GastrOS shall be designed using object-oriented methodology and openEHR Archetype based Multi-Level Modelling and Development (A-MLM/D) formalism. Any additional requirements or future changes in existing requirements shall not require exhaustive redesign, coding, testing and deployment tasks. However parts of software where functionality is not delivered by using A-MLM/D may affect some classes.

3.6.5 Portability

GastrOS shall be developed using .Net technology and C# language. Although GastrOS is a Microsoft Windows Forms application to be developed by Microsoft Visual Studio 2005, considering that both .Net and C# is an international ECMA standard, it should be possible to port to other environments such as UNIX, Solaris and Mac Operating Systems.

Also since the software interface with PAS shall be based on HL7 v2.x standard, data and information level (or semantic) integration/interoperability problems are unlikely.

4 APPENDIX I – USER INTERFACES

4.1 Main Menu

4.2 Data Entry/Update Page

5 APPENDIX II – MST BASED SDE FORMS DESIGN PRINCIPLES

The most crucial part of the application is the design of these forms; this is where openEHR formalism is expected to make the biggest difference in terms of robustness of GUI and the maintainability of the overall system.

MST gives this set of minimum structure, syntax and semantics which is envisaged to be present in all endoscopy reports. It prescribes a strict hierarchy consisting of terms, attributes, attribute values and associated anatomic sites which is given in Figure 2 - The MST Hierarchy. It is this aspect of MST that affects the GUI design.

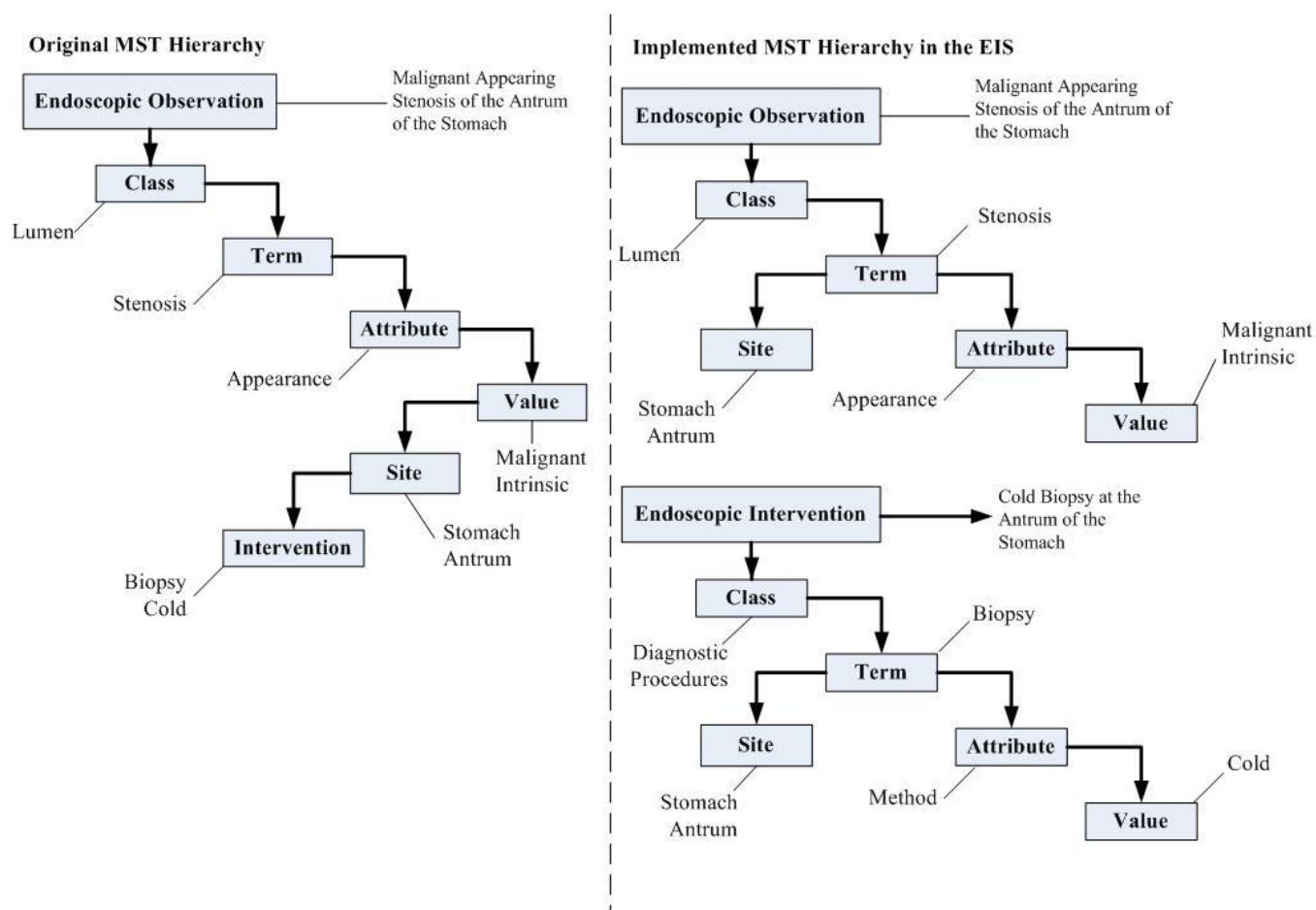


Figure 2 - The MST Hierarchy

Note that while the original hierarchy is given on the left side of the figure, the ones on the right proved to be usable and have been implemented in the former research prototype.

According to this, any endoscopic finding is first associated with an organ. So we have one MST Findings Form per organ. In each form the findings shall be organised using data elements with different levels in the hierarchy as follows:

1st Level → Class (or Heading): an abstract classification to group individual findings according to certain properties. It may correspond to a frame/container in GUI for its terms.

2nd Level → Term: this is the descriptive term used for finding (i.e. name of lesion). Users shall be able to select terms using simple point & click operation (or by touching in a tablet PC) in GUI.

3rd Level → Attribute: qualifiers for a term; labels of the attributes shall be displayed in this level.

4th Level → Attribute values: the leaf nodes – or deepest element in hierarchy. These shall be located in GUI according to data type of the attribute and suitable widget.

The anatomic site associated with a term can be thought of an attribute with always same values in a given form; but has to be located on GUI in a consistent way to enable easy selection with other elements.

Refer to Figure 3 - MST Based SDE Form for Stomach for a screenshot which was implemented in former research prototype.

UPPER GIS ENDOSCOPY FORM - Stomach

PAGE-1

☐ **NORMAL**

☒ Urease (+) ☐ Urease (-)

LUMEN

☒ Stenosis Appearance: Site(s):
Traversed:

☐ Deformity

☐ Extrinsic Impression

☒ Evidence of previous surgery Anastomosis:
Suture material visible: Site(s):

☐ Gastrostomy

CONTENTS

☒ Blood Kind of blood: Site(s):

☐ Food(residue)

☐ Fluid

☐ Foreign body

☐ Stent

PAGE-2

MUCOSA

☒ Erythematous (Hyperemic) Extent: Site(s):
Bleeding:

☐ Congested (Edematous)

☐ Granular

☐ Friable

☐ Nodular

☐ Atrophic

☐ Hemorrhagic

☒ Petechia Number: Site(s):
Extent:

Delete **Edit** **OK**

Figure 3 - MST Based SDE Form for Stomach

One big drawback of the former research prototype was the inability to select the same term more than once. This turned out to be a significant requirement during research. However this functionality shall not be implemented in GastrOS; but shall appear as a change request which we will compare the effort required to add this functionality to both applications.

6 APPENDIX III – THE ARCHETYPE MODEL

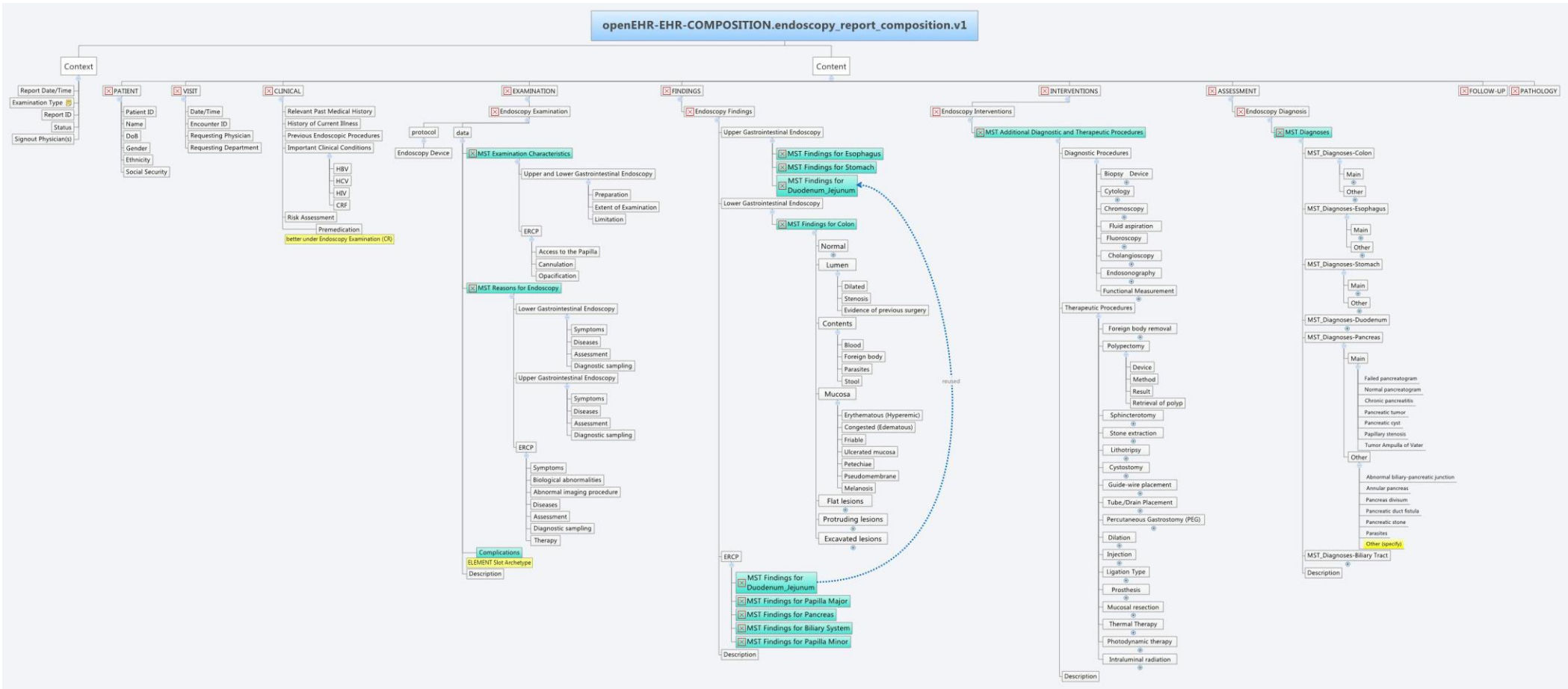


Figure 4 - openEHR Archetype Model

7 APPENDIX IV - USE CASE DIAGRAMS

7.1 Use Case Diagram for GastrOS User



Figure 5 - Use Case Diagram for GastrOS User

8 APPENDIX V – SAMPLE ENDOSCOPY REPORT



**SOME
UNIVERSITY
HOSPITAL**

ENDOSCOPY REPORT

Name	: Koray Atalag	Date	: 1/04/2010
Age	: 39	Gender	: m
Doctor	: Dr. Stone	Report No	: 2
Device	: Device 1	Patient No	: 1
Premedication	: Dormicum		

PROCEDURE

Colon:
Few diverticula, narrow-mouthed in the sigmoid colon.

Lesion 1: pedunculated polyp (type Ip), size 15 mm, without active bleeding but with stigmata of bleeding in the sigmoid colon.

Lesion 2: nonpolypoid, slightly elevated (type IIa), size 8, without active bleeding and without stigmata of bleeding in the ascending colon.

Polypectomy was performed using a snare. The polyp was completely removed in one piece. The polyp was retrieved. Endoscopic submucosal dissection was performed. The lesion was completely removed in one piece. The lesion was retrieved.

Ileum: Not examined.

DIAGNOSIS

Colon: Poliposis Coli

Prof.Dr. Sedat BOYACIOĞLU