

Post-MAPS

AN INTERACTIVE ACQUISITION PLATFORM FOR GASTROENTEROLOGY

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*"The only way to do great work is to love what you do."
Steve Jobs*

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Abstract

Post-MAPS is a web platform that collects gastroenterological exam data from several european hospital centers, to be used in future clinical studies and was developed in partnership with experts from the gastroenterological area and information technology (IT) technicians. However, although functional, this platform has some issues that are crucial for its functioning, and can render user interaction unpleasant and exhaustive.

Accordingly, we proposed the development of a new web platform, in which we aimed for an improvement in terms of usability, data unification and interoperability. Therefore, it was necessary to identify and study different ways of acquiring clinical data and review some of the existing clinical databases in order to understand how they work and what type of data they store, as well as their impact and contribution to clinical knowledge. Closely linked to the data model is the ability to share data with other systems, so, we also studied the concept of interoperability and analyzed some of the most widely used international standards, such as DICOM, HL7 and openEHR. As one of the primary objectives of this project was to achieve a better level of usability, practices related to Human Computer-Interaction, such as requirement analysis, creation of conceptual models, prototyping, and evaluation were also studied. Before we began the development, we conducted an analysis of the previous platform, from a functional point of view, which allowed us to gather not only a list of architectural and interface issues, but also a list of improvement opportunities. It was also performed a small preliminary study in order to evaluate the platform's usability, where we were able to realize that perceived usability is different between users, and that, in some aspects, varies according to their location, age and years of experience.

Based on the information gathered during the platform's analysis and in the

conclusions of the preliminary study, a new platform was developed, prepared for all potential users, from the inexperienced to the most comfortable with technology. It presents major improvements in terms of usability, also providing several new features that simplify the users' work, improving their interaction with the system, making their experience more enjoyable.

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Abbreviations

| | |
|-------|--|
| ADL | Archetype Definition Language |
| ANSI | American National Standards Institute |
| ASGE | American Society for Gastrointestinal Endoscopy |
| CKM | Clinical Knowledge Manager |
| CNCDC | Centro Nacional de Coleção de Dados em Cardiologia |
| CORI | Clinical Outcomes Research Initiative |
| DICOM | Digital Imaging Communications in Medicine |
| EHR | Electronic Health Record |
| HCI | Human Computer Interaction |
| HIS | Health Information System |
| HL7 | Health Level Seven |
| IHE | Integrating Healthcare Enterprise |
| ISO | International Organization for Standardization |
| NCDB | National Center Database |
| NED | National Endoscopic Database |
| PACS | Picture Archiving and Communications in Medicine |
| SPC | Portuguese Society of Cardiology |
| STS | Society of Thoracic Surgeons |
| TAM | Technology Acceptance Model |
| TPB | Theory of Planned Behavior |
| TRA | Theory of Reasoned Action |
| UML | Universal Modelling Language |
| WHO | World Health Organization |

Introduction

Post-MAPS is a web platform developed to collect data from gastroenterological exams that, while functional, presents some problems that can compromise its functionality. Accordingly, the main goal of this project was to develop a new web platform, with several of its aspects improved.

There were four main work phases. The first step was to research and study some key concepts essential to the development of the new platform. The next step was to analyze the Post-MAPS platform and detect problems and malfunctioning, as well as its strengths and opportunities to improve. The third step was to make a preliminary study through a questionnaire sent to all users registered on the platform, to evaluate its usability. Finally, based on information collected during the other phases and on the conclusions drawn from the preliminary study, a new platform was developed, prepared for all potential users and presenting new features, as well as improvements in terms of usability.

The current chapter presents the context and motivation, the main goals, the approach followed in this thesis, and the thesis outline.

1.1 Context and Motivation

Post-MAPS is a web platform that consists of a form that only physicians chosen to participate in the study have access to. It enables filling it with data from gastroenterological exams. This platform was developed based on the "Prevalence, diagnosis and management of gastric pre-neoplastic and neoplastic lesions: An European Multicentre study" protocol, created in partnership with experts from gastroenterological and information technology (IT) area.

Its objectives are [6]:

- To determine the more accurate way for identifying individuals with advanced stages of gastric precancerous conditions;
- To estimate which is the incidence rate for dysplasia among individuals with advanced stages of gastric precancerous conditions;
- To estimate the true prevalence of gastric precancerous conditions and lesions in the European population;
- To determine if random biopsies increase the diagnostic yield for gastric preneoplastic lesions;
- To clarify the phenotype of risk for gastric dysplasia and cancer;
- To establish the most cost-effective surveillance schedule for individuals with gastric preneoplastic conditions.

Data collected electronically through the platform will later be used in a multi-center cohort study involving several gastroenterology centers of various European countries.

Although the Post-MAPS is a functional platform, it has interoperability, data consistency and usability issues, that affect its functioning and that can even make the user interaction unpleasant and exhaustive. If the platform use is simple and interactive, it increases the probability of being used more regularly, and so the greater will be the quantity and variety of gastroenterological exams data it gathers. Consequently, the greater will be the impact and contribution of the study in the gastroenterology area. These facts were the great motivation to research and study ways to create interactive web platforms that are simple and easy to use, and prepared for all types of potential users. Also, the challenge of developing a new platform from scratch, concerned with aspects of usability, data unification and interoperability also represents a major motivation.

1.2 Objectives

The main objective of this thesis is to develop a new platform for the acquisition of gastroenterological exams data, in which are intended improvements over the previously developed platform, including::

- improvements in terms of usability, with simple interfaces, organized and with well distributed and localized artifacts;
- alteration of data entry flow and thereby improving the amount of information presented to users in each screen;
- addition of new features such as: request access, manage request access, invite users, dashboard with metrics, exam visualization, manage entities and patient concept;
- data validation;
- design and construction of a database for storing data acquired through the platform;
- interoperability with other systems through the use of the main standards DICOM, HL7 and OpenEHR.

1.3 The approach followed in this dissertation

The developed platform we proposed addresses different areas, including: human computer interaction, software engineering and interoperability. Accordingly, beforehand, some key concepts were explored and studied:

- Clinical studies (since the platform collects data for future clinical studies) and means of clinical data acquisition;
- Currently existing clinical databases, in order to understand how they work, what type of data they store and their impact and contribution to clinical knowledge;
- Interoperability and international standards most often used to facilitate the exchange of clinical data between different systems, including DICOM, HL7 and openEHR;
- Human Computer Interaction and associated practices, such as the analysis and gathering of functional and nonfunctional requirements, creation of conceptual models, prototyping, evaluation of usability and the methodology used in each one.

Subsequently, an analysis of the Post-MAPS platform was carried out, from the non-clinical point of view, and a list of issues and problems that can compromise its proper functioning and make the users' tasks exhausting and frustrating was put together.

A small preliminary study was also performed, based on the Technology Acceptance Model 2 (TAM2) to evaluate the platform's usability through a survey sent to the users registered on the platform. Through this study, we verified that the usability perception can be different between users and, in some aspects, it may vary according to location, age and years of experience. All the information gathered was considered on the development of the new platform.

The platform development was divided into tasks that were performed in the following order:

- Definition of the actors and platform functionalities, as well as the design of the respective use cases diagram;
- Data model design, where all the database tables were defined, as well as the relations between them;
- Definition of the data insertion flow, where there is a clear separation between the different data types (patient data, observation data, biopsy data);
- Interface organization, which was based on the use of containers placed strategically by separating menus, shortcuts, forms, hidden information and flow buttons.

1.4 Outline of the dissertation

This dissertation is divided into six chapters, including this one:

- In the second chapter, we approach clinical studies, data collection methods, clinical databases, interoperability and developed standards, human computer interaction and some of the encompassed aspects;
- In the third chapter, a brief introduction to the Post-MAPS and its objectives is made, the data entry flow is shown and a survey of detected failures is also displayed;

- The fourth chapter presents the preliminary study conducted to evaluate the usability of the Post-MAPS platform;
- The fifth chapter describes all the development steps of the application proposal;
- The final chapter presents conclusions of the developed work, suggestions for improvement and features that can be added to the platform in a future work.

State of the art

This project aims to develop a data acquisition web platform from gastroenterological exams, in order to store them for later use in clinical studies. To build a database to store the acquired data, it was first necessary to study and analyse ways of acquiring clinical data, as well as to analyse some existing clinical databases, to understand its functioning, what kind of data they store and its impact on clinical knowledge. As one of the goals of this project was to achieve interoperability with other systems, this concept has also been studied, and the functioning of some of the standards commonly used in healthcare area, including DICOM, HL7 and openEHR were analysed. Finally, in order to get an improvement in terms of usability, the concept of Human Computer Interaction (HCI) has been studied and analysed, and some of the aspects that it includes, among which: requirements, prototyping, usability and methods for evaluating it.

2.1 Clinical Studies

All clinical studies involve clinical information and seek, in a patient sample, answers and clinically important outcomes that may be applied to patients with similar characteristics [7]. A clinical study can take place in many locations (e.g., hospitals, universities) that depends on who is conducting the study and involves research using:

- human volunteers (also called participants) that are intended to add to medical knowledge;
- a main researcher, who is often a medical doctor;

- a research team that may include doctors, nurses, social workers, and other healthcare professionals;
- a research plan known as the protocol.

A study protocol describes the plan for conducting the clinical study and explains the purpose and function of the study as well as how to carry it out. The reason for the study; the number of participants; eligibility and exclusion criteria; details of the intervention or therapy the participants will receive; what data will be gathered; what demographic information about the participants will be gathered; steps for clinical caregivers to carry out; and the study endpoints are some specific information included in the protocol.

There are two main types of clinical studies: interventional (also called clinical trials) and observational [8]. Interventional studies are experimental studies that test new treatments in humans and aim to find out if new treatments work better, the same, or not as well as standard treatments for the same disease. Observational studies are used to examine which risk factors are associated with an increased or decreased risk that an individual will develop a disease, like gastric cancer. Unlike interventional studies, researchers only observe the participants and do not interfere by providing a treatment. There are several different types of observational studies like case-control, cross-sectional surveys, routine-data-based studies and cohort studies [8].

The Post-MAPS platform was developed in order to collect gastroenterological exams data for later use in a cohort study. Thus, in this dissertation only observational studies will be discussed, specifically the cohort studies.

2.1.1 Cohort study

In a cohort study a study population is selected (the cohort) and information is collected to determine which subjects may have been exposed to etiological agents (e.g., smoking or drinking) or have a particular characteristic (e.g., blood group A) that is suspected of being related to the development of the disease under study [8]. This study involves the selection of two groups of individuals without the disease (cohorts): a group of individuals exposed to a risk factor and a comparison group of individuals not exposed to the same factor. The non exposed group must have exactly the same characteristics and both groups must not have the outcome at the time of exposure [9].

Usually, two types of cohort studies are distinguished: prospective and retrospective, Fig. 2.1 [1]. In retrospective cohort studies, both the exposure and the outcomes occurred in the past. In this case the researcher uses clinical records or interviews to determine the presence or otherwise of exposure and the consequent outcome. Most studies are prospective, studying the cohorts over time and waiting for the previously defined outcome and the researchers can eventually use the data to answer many questions about the associations between risk factors and disease outcomes.

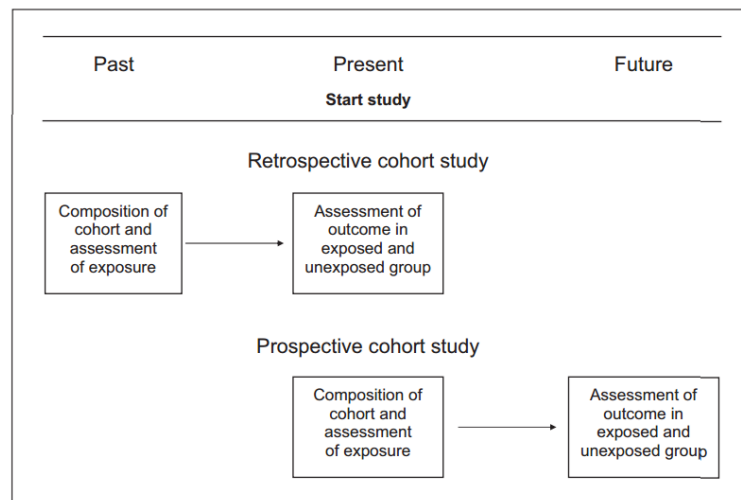


Fig. 2.1: Graphical representation of the timeline in a retrospective and prospective cohort study design [1].

A major advantage of cohort studies in general is the possibility to study multiple exposures and multiple outcomes in one cohort. It also allows the measurement of outcome incidence, the investigation of disease etiology (causality) and the identification of risk factors. It also presents several limitations: it is expensive and time consuming and requires a large sample size to obtain statistically significant results [9] [10].

Regardless of the study carried, data collection can be done on paper or electronically, using forms designed by researchers to reflect the data that must be collected. The clinical record on paper consists of recording clinical data in handwritten form. This record type has some advantages, such as the facilitation of data introduction, the fact that each professional can adapt the recording to its preferences, as well as versatility in data recording and no need for specific training for its use. On the other hand, it has inconveniences, such as record illegibility by other professionals, the inconsistencies with formats or information location, the loss and/or informa-

tion duplication and limited access. In the electronic clinical record, data is entered directly into a computer through an interaction interface, designed according to the forms projected by the researchers. This record type has advantages such as the ease of information access (allowing simultaneous access from different locations), readability and more organized clinical information (because the structure is imposed on data introduction), higher speed in information access, better data protection, constantly updated information, error prevention, while opening up the possibility to participate in medical research studies [11].

2.1.2 Discussion

The data collection for clinical studies is done through forms, on paper or electronically. Although it is not necessary training in data collection on paper, with this practice the following situations may happen: lost or duplicate data, illegibility by other professionals, limiting the type of data stored (images, videos, sounds) and difficulty in its query. On the other hand, on the electronic collection the data is directly entered into the computer, preventing errors and allowing greater readability, organization and data protection.

In prospective cohort studies the follow-up period is usually long (maybe years), since patients must be followed for sufficient time for the outcome to appear. This can make it difficult to maintain records of all the patients [9], which is another plus for electronic data collection methods.

2.2 Clinical Databases

A database is a collection of data which has been organised so that a computer program can quickly store, search and select desired items. The benefits of databases include:

- reducing the amount of time spent managing data;
- allow analyse data in variety of ways;
- improving the quality and consistency of information.

A clinical database stores clinical data, such as patient data and their medical conditions.

In this subchapter a discussion on general clinical databases will be presented, since it is difficult to find databases only focused on gastroenterological data. Thus, and as it is important to realize which are the existing clinical databases, as well as its mode of operation, some examples will be presented below.

2.2.1 The National Endoscopic Database (NED)

The National Endoscopic Database (NED) has been started by the Clinical Outcomes Research Initiative (CORI). The CORI was developed in 1995, under the support of the American Society for Gastrointestinal Endoscopy (ASGE), to study the results from GI endoscopic procedures in order to use the NED to acquire information that can improve the quality of clinical practice in gastroenterology. Experts of gastroenterological area participating in the consortium CORI electronically send their produced GI endoscopy reports to a central data repository where they are merged with data from other participants in the NED [12] [13]. The aggregated data from the NED can serve one of several purposes: clinical research, hypothesis testing, pilot research data, data for industry and site specific queries.

Currently, the NED contains millions of reports collected from various health institutions (hospitals, ambulatory care centers, private practices, universities and others) of 24 States [12].

CORI provides support for prospective research projects, including interventional or observational research. The recent prospective researches will be presented below:

- "Complications of Colonoscopy Performed on Asymptomatic Patients (Cynthia Ko, PI)", to estimate the overall risk of major complications of colonoscopy;
- "A Cross-Sectional Study of Acid Related Upper Endoscopy Findings in Subjects with Diabetes as Compared to Non-Diabetics (Astra Zeneca)" to investigate and estimate the prevalence of acid-related EGD findings for diabetic and non-diabetic subjects;
- "Use of the CORI Database to Determine Adverse Events Associated with Peri-Endoscopy Warfarin Management (Lauren Gerson, PI)" to determine the risk of adverse events in anticoagulated patients in the peri-endoscopic period;
- "Prospective Study of Endoscopy Outcomes in Patients with Chronic Constipation (Novartis)" to measure the prevalence of selected findings in patients with chronic constipation.

This clinical database collects gastroenterological endoscopy data procedures from 24 different States, comprising a wide variety of races, ethnicities, habits, location or even different climatic conditions, which enable the conducting of many studies in order to understand, for example, which of these variables lead to increase disease incidence.

2.2.2 National Center for Data Collection in Cardiology (CNCDC)

The National Center for Data Collection in Cardiology (CNCDC) was created by the Portuguese Society of Cardiology (SPC) and aims to facilitate the completion of studies (national regional studies, multicentric studies or epidemiological studies) in the context of cardiovascular disease involving several portuguese health structures (cardiology services, health centers, medical services, etc.).

The CNCDC encompasses multiple databases corresponding to its various National Registries (such as the National Register of Myocarditis, the National Register of Interventional Cardiology, National Register of Chronic Angina, among others). Currently, in all its records the data collection is done through electronic CFRs, and the oldest records (started in 2002) began with data collection on paper. To every investigator are assigned access credentials to the Register platforms so that only authorized persons have access to them.

Today, more than 75,000 patients were included in the database, more than seven million data were stored over all activity years and more than two hundred scientific works have been conducted, published and communicated in meetings in Portugal and abroad, based on the information gathered [14].

Because of the collected and stored data in CNCDC, it is possible to promote scientific research and get a better understanding of the reality in Portugal with regard to cardiovascular diseases. As this database only collects data from institutions located in Portugal, all studies resulting from the use of its data will only be referring to the portuguese population.

2.2.3 The Society of Thoracic Surgeons National Database (STS National Database)

The Society of Thoracic Surgeons National Database (STS National Database) was established in 1989 by the Society of Thoracic Surgeons (STS) and it is the premier clinical data registry for cardiothoracic surgery. The STS National Database is composed of three components, focused on different areas of cardiothoracic surgery: Adult Cardiac Surgery, Congenital Heart Surgery, General Thoracic Surgery.

The STS Adult Cardiac Surgery Database is the main clinical registry in the world for adult cardiac surgery, containing now more than 5.5 million surgical records; the STS Congenital Heart Surgery Database was launched in 2002 and is the biggest database in North America dealing with congenital cardiac malformations and the STS General Thoracic Surgery Database was also launched in 2002 and is the biggest clinical thoracic surgical database in the United States [15].

Administrative, demographic, risk factors, historical, cardiac preoperative status, operative informations, postoperative events, morbidity and mortality data are collected.

The STS National Database has grown to be the largest database of its kind in medicine and is one of the pioneers in the analysis and reporting of risk-adjusted outcomes in cardiothoracic surgery.

This database acquires a wide range of information and is divided into three components that, while related to thoracic surgery, focus on different branches (adult cardiac surgery, congenital heart surgery and general thoracic surgery). This data separation may allow better studies, with other detail, since the variables of interest in each branch can differ.

2.2.4 National Cancer Database (NCDB)

The National Cancer Database (NCDB) was established in 1989 on a joint program of the Commission on Cancer (CoC) of the American College of Surgeons (ACOS) and the American Cancer Society (ACS). It is a clinical oncology database whose data are collected from over 1500 accredited facilities in the United States and in Puerto Rico. The hospitals, treatment centers and other facilities need to be accredited by CoC Accreditation Program, in order to submit data to the system. All data are submitted electronically.

In the United States, nearly 70% of all cases of diagnosed cancer are captured in an institutional level and forwarded to the NCDB, where they are tracked and analyzed. This includes patient informations and characteristics, cancer staging and histological tumor characteristics, type of first course treatment administered and outcomes information. The data contained in the NCDB are used to explore trends in cancer treatment, create regional and state benchmarks for the participating hospitals and also serve as a basis for quality improvement [16].

This database collects data related to all types of cancer, since its stage and histological characteristics until its treatment and results. Thus, taking into account the diversity of oncological diseases, it is necessary to have a wide range of variables within the same database, since each cancer type has different stages, characteristics and treatments. Accordingly, and in order to cover the greatest number of variables to be studied, it may be interesting to have a separation in small databases, focused on certain cancer types.

2.2.5 Discussion

Although there is a wide variety of clinical databases in diverse areas, in gastroenterology they are still scarce. Thus, an internet search was conducted in order to realize which clinical databases exist and how they work. The chosen databases have different sizes, operating in different countries and/or regions and focused on different areas, essentially, gastroenterology, cardiology, cardiothoracic surgery and finally oncology. Databases were chosen because these areas, according to the World Health Organization (WHO) are the ones where there is higher incidence of death.

We tried to contact the responsables for the databases to obtain more information about the data they collect, but they only sent us links of their websites that had little information. Data collection, in some databases, is restricted to accredited entities, with the necessary credentials, allowing greater control of accesses. Furthermore, the data collected access is, in many cases, only available to entities that participated in its collection.

All clinical databases presented were created in order to promote scientific research, a better understanding of reality regarding the areas where they are focused and, consequently, enhance the exploitation of new treatments. Consequently, the data access should also be available to research institutions or universities that focus their studies in the area of databases operation. In Table 2.1 is presented a summary

of the information obtained on the clinical databases analyzed.

Tab. 2.1: Summary of the clinical databases analyzed.

| | National Database | Endoscopic Database | National Center for Data Collection in Cardiology | Society of Thoracic Surgeons Database | National Cancer Database |
|--------------------------|---|---------------------|--|---|---|
| Area | Gastrointestinal disease | | Cardiovascular disease | Cardiothoracic surgery | Clinical oncology |
| Collection method | Electronically | | Paper-based or Electronically | Electronically | Electronically |
| Purposes | Clinical research, hypothesis testing, data for industry and others | | National regional studies, multicentric studies or epidemiological studies | Analysis and reporting of risk-adjusted outcomes in cardiothoracic surgery | Explore trends in cancer treatments and create regional and state benchmarks |
| Data collected | - | | - | Administrative, demographic, risk factors, historical; Prospective, operative and postoperative informations; Morbidity and mortality | Patient informations and characteristics; Cancer staging and characteristics; Treatments and outcomes |
| From | United States and abroad | Portugal | | United States | United States and Puerto Rico |

2.3 Interoperability Standards

The ability to handle health information electronically, consequently brought the need to establish a standard of health to allow the exchange of information. Ensuring that information can be shared efficiently and effectively and in a manner which protects the privacy and confidentiality of patients is critical. Thus, various organizations and research groups have been meeting in recent years to propose rules that enable the interoperability of health systems [17] [18]. There are two main levels of interoperability of information:

- Functional interoperability is the exchange of data between computer system A and computer system B, this is, the ability of two or more systems (devices, information systems, databases) to exchange information;
- Semantic interoperability ensures that the information exchanged between system A and system B are understood, interpreted and used in the same way by both systems, this is, the ability for information shared by systems to be understood at the level of formally defined domain concepts (so that information is computer processable by the receiving system).

The interoperability standards are not hardware neither software, but are used by technology developers for the development of health information systems that may

be compatible with other systems [18]. The main developed international standards to facilitate the exchange of health information are shown below.

2.3.1 DICOM

Digital Imaging and Communications in Medicine (DICOM), is the international standard for handling, storing, printing, and transmitting information in medical imaging and related information which was created to cover all functionalities of the digital medical imaging.

An important term associated to DICOM is the PACS - Picture Archiving and Communications in Medicine. PACS are medical systems that include digital devices of image acquisition (e.g., CT scanners, x-Ray or ultrasound), digital image files (where the acquired images are stored) and workstations (where the images are displayed) [18, 19]. The acquisition devices send the images to digital files only to be accessed by workstations, Fig. 2.2.

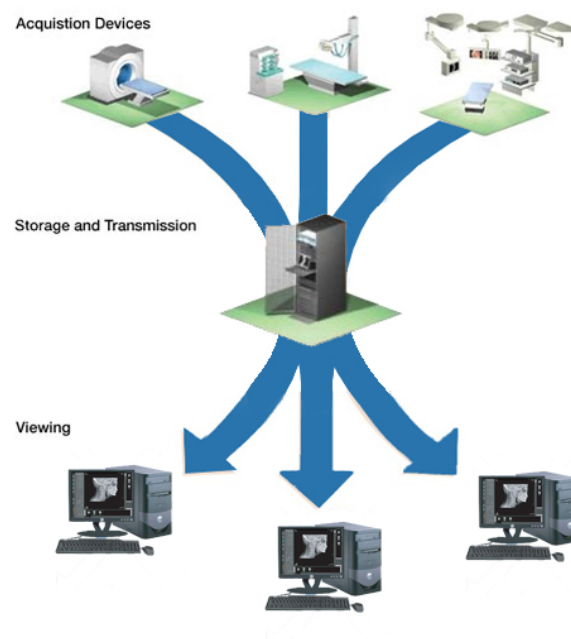


Fig. 2.2: Basic components of a PACS [2].

Functioning

All data related to patient, studies and medical devices are considered by DICOM as objects with different properties and attributes, which are defined according to a standard, DICOM Information Object Definition (IODs). For example, an IOD of a

patient can be described by: name, ID, gender, age, weight, and blood group. Thus, a patient, as any DICOM object, can be resumed in a set of attributes that define it. Attributes considered standard are used to form the DICOM data dictionary in order to keep consistency in the naming attributes and their processing. Once the data are collected, it can be transmitted through various DICOM devices (Application Entities). This process is interpreted by DICOM with the help of a service provider. As each service performs an exchange of information with one another, it is required an association for different types of services to the data they process. These associations are called Service Object Pairs (SOPs). In Fig. 2.3, an example of a medical image storage is displayed for a PACS, where it is made a requirement of mode (applicants) to the archive (supplier) which, in turn, provides the service. The DICOM standard, in order to distinguish the applicants for service providers, gives them the denomination of Service Class Users (SCU) and Service Class Providers (SCP), respectively. During the data transfer process, whenever there is a request by the applicant (mode), there must be a response from the supplier (archive) [3].

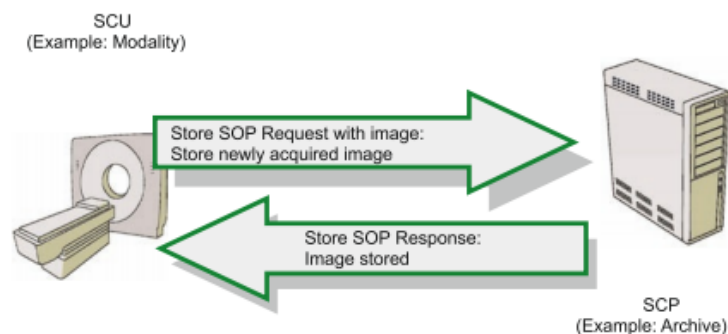


Fig. 2.3: Storage example of a medical image [3].

DICOM message

All information transmission between equipment is done through the IP network and using DICOM messages. A DICOM message consists of a command set and data set. The command set is used to indicate operations to perform on the data set and is defined as a set of command elements encoders of each field according to the DICOM Message Service Element protocol. These control elements appear in ascending order taking into account the label number assigned to them (Command Element Tag) that identifies the element in a single way and can only appear on a set of commands once. In turn, the data set comprises several data elements composed

by different fields: label, value representation, value size and also data field. These fields are also defined by a label and must be sorted in ascending order. In Fig. 2.4 it is presented a simplified schema of a DICOM message [3].

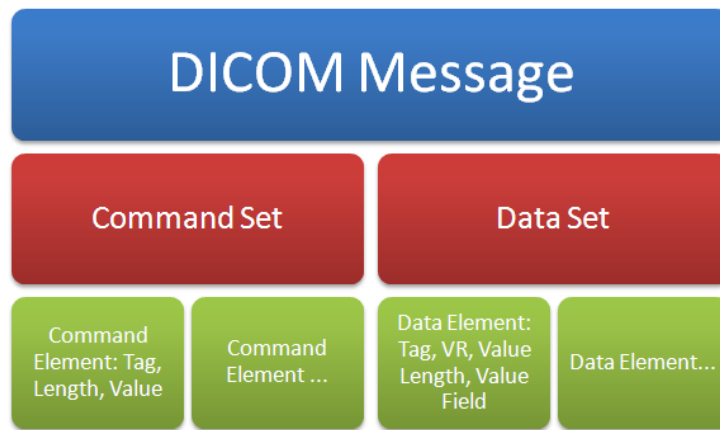


Fig. 2.4: DICOM message [3].

The IHE (Integrating Healthcare Enterprise) defines how DICOM messages are exchanged between systems. For endoscopy, the IHE defined the endoscopy workflow (EWF) which specifies a series of workflows from the order for endoscopy to the result that is returned to the system. The actors directly Involved in the EWF are [20]:

- Order Placer (OP), e.g. HIS, that places orders or cancel orders as necessary;
- Order Filler (OF), e.g. endoscopy system, that receives and processes orders and receives order cancellations;
- Execution Information Creator (EIC), that provides endoscopy execution information to the Execution Information Receiver (EIR).

The EWF can be separated into four major parts [20]:

- **Order endoscopy:** this transaction is used by the OP to place an order to prepare the endoscopy. The OP sends to OF a message type OMG (general clinical order message) composed of several segments. One of the segments, OBX, is used to transmit an observation or fragments of an observation and may have information encapsulated as a DICOM image. In response to the order of a new endoscopy, a message type ORG is sent to the OP.

- **Notify Patient Arrival:** this transaction is used by the OF to notify the examination status (patient arrival, examination start and finish, etc.) to the OP, that sends it a message type ORU.
- **Notify Endoscopy Execution Information:** upon the completion of the execution data entry, the EIC notifies the OP about the performed information and notifies the OF, that receives status information included in the information performed.
- **Fill Endoscopy Order:** The OF sends a message type OMI (Order Message Imaging) to the IEC, where there is a segment, the IPC, that contains information about tasks that need to be performed in order to fulfill the request for imaging service (such as location, type and instance identification of equipment, acquisition modality, stages and procedure steps). Then the OF identifies the exam end when it receives the task completion notification from the EIC .

2.3.2 Health Level Seven (HL7)

HL7 is a standard developed through a nonprofit organization called Health Level Seven, founded in 1987 and certified by ANSI (American National Standards Institute) to develop standards for the health sector since 1994. The level seven refers to the highest level - application level - the communications model for interconnection between systems of international standards organization (ISO - International Organization for Standardization) [21].

HL7 is an international protocol for exchanging electronic data in all healthcare environments, integrating information from clinical, administrative and demand [22]:

- Provide systems and related standards for the exchange, integration, sharing and retrieval of electronic information in health, allowing greater control of health services;
- Create methodologies, standards and guidelines that are flexible and that make interoperability and sharing of clinical information electronically store.

The standard HL7 presents an oriented architecture to the message, i.e., when a particular event occurs (for example, a new patient record), the applications send messages instead of invoking services and works with two different versions: 2.x and 3.

In versions 2.x, the HL7 messages are composed by two elements: segments and fields. The segments correspond to each data line and are terminated by carriage return delimiter. Each segment has a specific semantic purpose, i.e., represents data associated with a particular area (for example, ADT represents the administrative area and DFT the finance area). In Fig. 2.5 it is presented an example of a HL7 message. The MSH header always starts the first segment since it contains essential metadata, such as the name of the sender and receiver applications or the version. Concerning the fields, they are presented as the segments basic unit, being separated by a delimiter "|". They may still exist sub-components, enclosing the symbol "&".

```

MSH | ^~\& | ADT1 | MCM | LABADT | MCM | 198808181126 | SECURITY | ADT ^ A01 | MSG00001- | P | 2.4
EVN | A01 | 198808181123
PID | | | PATID1234 ^ 5 ^ M11 | | JONES ^ WILLIAM ^ A ^ III | | 19610615 | M- | | C
PV1 | 1 | I | 2000 ^ 2012 ^ 01 | | | 004777 ^ LEBAUER ^ SIDNEY ^ J. | | | SUR | | - | | ADM | AO
AL1 | 1 | | ^ PENICILLIN | | PRODUCES HIVES ~ RASH ~ LOSS OF APPETITE
DG1 | 001 | I9 | 1550 | MAL NEO LIVER, PRIMARY | 19880501103005 | F
PR1 | 2234 | M11 | 111 ^ CODE151 | COMMON PROCEDURES | 198809081123

```

Fig. 2.5: Example of a HL7 message.

In turn, version 3 is based on development formal methodology, being object-oriented (OO) and uses principles of Universal Modelling Language (UML). The Reference Information Model (RIM) and the HL7 Health Development Framework (HDF) are the foundation of the development process of message standards HL7 version 3, using the markup language called XML. The RIM specifies how the representation of clinical data should be made (domains) and the lifecycle of messages or message groups. In turn, the HDF is a project to specify the processes and methodology used by all standard-setting committees of the international organization HL7 for the start of the project, the requirements analysis, the standards conception, its implementation, the standard approval process, etc.

Overall, the standard enables all applications to communicate with each other intelligently and flexibly, and as it presents an open system architecture, also allows multiple systems to be connected (since using the appropriate protocol). On the other hand, it presents disadvantages as the study standard high time, the high cost of platform implementation and is not plug and play, i.e., it is necessary to adjust the HL7 parser for each new implementation.

According the IHE, the messages used in endoscopy workflow are the following

ones [20]:

- The general clinical order message (OMG) is used for endoscopy order;
- The general clinical order acknowledge message (ORG) is used for the response to OMG message;
- The ORU message transmits observations and results from the producing system/filler (endoscopy system) to the ordering system/placer (i.e., HIS);
- The imaging order message (OMI) notifies endoscopy/procedure information;
- The execution information notification message (ORI) is an event where a response to an endoscopy observation notification is provided.

2.3.3 OpenEHR

OpenEHR is an open standard specification that describes the management, storage, retrieval and exchange of data in Electronic Health Record (EHR). OpenEHR specifications have been developed to standardise the representation of an international EHR [23]. The goal of openEHR is to provide semantic interoperability between all medical specialities, reducing the needed of standards to a single one, in opposition to the several standards that are used nowadays. The openEHR standard follows the paradigm of multilevel modeling that consists basically in the separation of information and knowledge [24].

The openEHR architecture can be divided into two major parts - separates the technical knowledge (the IT professional), and the clinical knowledge (professional), respectively: Reference Model and Archetype Model [25].

The Reference Model (RM) contains the basic entities for representing any entry in an EHR. The Archetype Model is based on archetypes, which are formal definitions of clinical concepts in the form of structured and constrained combinations of the entities of a RM [26]. The separation of these two models significantly reduces the need for changing the software.

An archetype, defined using Archetype Definition Language (ADL), represents a clinical concept and it is used to constrain instances of the openEHR information model by defining a valid structure, data types and values. Thus, an electronic health record that has been archetyped will have the same meaning no matter where it appears [25] [24].

Due to the special sensitivity of medical data and the wide range of ethical and legal constraints, data exchange must be done in a meaningful way, avoiding all possibility of misunderstanding or misinterpretation [26].

The Clinical Knowledge Manager (CKM) is the largest and most used repository of clinical knowledge artefacts (openEHR archetypes and templates) and it supports the full life cycle management of openEHR archetypes through a review and publication process [27].

2.3.4 Discussion

Interoperability allows that different systems communicate with each other using a common language between them. Regarding health systems, interoperability allows to share clinical information of patients (such as history, symptoms, medication, exams and diagnostics) among health professionals, clinics, laboratories and health units, protecting the privacy and confidentiality of patients. Thus, clinical patient information becomes available in different health institutions for consultation, avoiding duplication of information and exams, and thus working the health in a more preventive way.

2.4 Human Computer Interaction

Human-computer interaction (HCI) is a discipline concerned with the design, evaluation and implementation of interactive computing systems for human use and with the study of major phenomena surrounding them [28]. HCI, also sometimes referred as Man Machine Interaction or MMI, is a design science concerned with understanding human beings and helping them to interact with and through technology [29]. It is the study of how people interact with computing technology and is a multi-disciplinary field in which psychology and other social sciences unite with computer science and related technical fields with the goal of making computing systems that are both useful and usable. The goal is to produce software and hardware that is useful, usable, and aesthetically pleasing [30]. The HCI professionals developed design principles, guidelines and standards that help programmers to obtain consistency, informative return, error prevention and shortcuts for experienced users.

2.4.1 The Evolution of Human-Computer Interaction

HCI emerged in the late 1970s and early 1980s, initially as an area in Computer Science. HCI has expanded rapidly and steadily for three decades, attracting professionals from many other disciplines and incorporating diverse concepts and approaches. Then will be presented a brief overview of the main landmarks of the HCI evolution [31] [32]:

- The rise of the Personal Computer (1970): The broad project of cognitive science, which incorporated cognitive psychology, artificial intelligence, linguistics, cognitive anthropology, and the philosophy of mind, had formed at the end of the 1970s.
- Graphical User Interface (1980): Graphical User Interface (GUI) is the interface that is designed for the easier understanding of the users of the computers. Before GUI, there was a command prompt by which command was given to the computers. GUI started the graphical interface which is easy to use, understand, visualize, and it improved the working environment.
- The Internet and Collaborative works (1990): The Internet started journey in 1990s. So, communications among people became easier. In the consequence of this, many new technologies arrived for better communication.
- Mobile Computing and Beyond (2000): Mobile phones, PDA (Personal Development Assistance), and Smart Phones are ruling the present world. They offer a wide range of services to the people such as sms, mms, multimedia, games, email, internet, chatting, video conference, GPS, among others.

2.4.2 Requirements

A requirement is a statement about an intended product that specifies what it should do or how it should perform. Establishing requirements it is an important phase of software engineer and is not simply writing a wish list of features. First it is necessary to understand as much as possible about the users, their work, and the context of that work, so that the system under development can support them in achieving their goals.

One of the aims of the requirements activity is to make the requirements as specific, unambiguous, and clear as possible. Unclear objectives and requirements are a major cause of failure. But otherwise, clear objectives and requirements, are

pointed out as critical success factors [31]. Requirements come in many different forms and at many different levels of abstraction, but it is important to make sure that the requirements are as clear as possible. In software engineering, two different kinds of requirements have traditionally been identified: functional requirements and non-functional requirements.

Functional requirements are related to functional aspect of software, what the system should do, this is, specify a behaviour or function. Non-function requirements define the overall qualities or attributes of the resulting system, for example, safety, security, usability, reliability and performance requirements. Basically, the difference is that non-functional requirements describe how the system works, while functional requirements describe what the system should do [33]. Within the non-functional requirements, there are some but here only requirements directly related to users will be described: environmental requirements, user requirements and usability requirements [31].

Environmental requirements, also sometimes referred as context of use, set out the environment in which the system will be used (technical and non-technical), this is, refer to the circumstances in which the interactive product will be expected to operate. User requirements define the user group, this is, capture the characteristics of the intended user group. For example, a novice or a casual user will require step-by-step instructions, such as series of menus. On the other hand, an frequent or expert user, will require a flexible interaction with some shortcuts. Usability requirements identify key usability issues, this is, capture the usability goals and associated measures for a particular product [33] [31]. The usability requirements also include learnability, flexibility and consistency. All these requirements can be collected using some techniques such as [31]:

- questionnaires, that are a series of questions designed to extract specific information;
- interviews, that involve asking someone a set of questions. However, interviews are time consuming and it may not be feasible to visit all the people of interest;
- focus groups and workshops, that are good at gaining a consensus view and/or highlighting areas of conflict and disagreement;
- naturalistic observation, that involves spending some time with the stakeholders, observing what is being done in the natural context of the activity, making notes and asking questions;

- studying documentation, that is good for understanding legislation and getting some background information on the work.

2.4.3 Conceptual models

A conceptual model is a description of the proposed system, which integrates a set of ideas and concepts about what it should do, how to behave and what should be its appearance. A key aspect in creating these models is to understand how users perform their tasks and which is the interaction mode that helps them in its implementation. Decisions about the interaction mode differ from the decisions of the style to adopt, which are focused on the selection of specific types of interface. Having identified the ways to interact with the system, the design of the conceptual model should be thought in terms of concrete real solutions, which involves drawing up the interface behavior, interaction styles that will be used and the interface aspect. At this stage, some ideas should be explored, in order to evaluate the advantages and disadvantages of each one [31].

As with any aspect of interaction design, the process of fleshing out conceptual models should be done iteratively, using a number of methods that include sketching out ideas, storyboarding, describing possible scenarios, and prototyping aspects of the proposed behavior of the system.

2.4.4 Prototyping

A prototype is associated with a system/model without intelligent functionalities (such as database access), and may contain only graphic functionalities, but can also be a paper scheme of an interface or set of interfaces. The prototypes are used for a variety of purposes, such as test the feasibility of an idea, clarify vague requirements and answer questions and support designers in choosing between alternatives. Thus, a prototype is a limited representation of a project and should always precede any writing code.

A prototype may arise as paper-based outline of a screen or set of screens, an electronic mockup, a video simulation of a task, a three-dimensional paper and cardboard mockup of a whole workstation, or a simple stack of hyperlinked screenshots, among other things [31].

2.4.5 Usability

One of the greatest challenges in developing computer systems used by people is to know how to make the transition between what can be done - functionality - and how it should be done - usability - in order to meet user needs [34].

Usability is a key term in HCI and concerns not only to the product, but also to the user. In general, usability is related to the ease a user has in using a certain tool to perform an action. Thus, with regard to HCI, usability refers to the interface simplicity, ease of interaction with the application, passing through the effectiveness, efficiency and satisfaction that the product allows the user to achieve its objectives [31] [35]. It is important that the usability should be comprehensive and embrace the aspects concerning with user [28]. More specifically, usability presents as goals: effectiveness (effective to use), efficiency (efficient to use), safety (safe to use), utility (have good utility), learnability (easy to learn) and memorability (easy to remember how to use) [31].

Another way of conceptualizing usability is in terms of design principles. When design principles are used in practice they are commonly referred to as heuristics. Below are the ten usability heuristics, developed by Jakob Nielsen and his colleagues [31] [36].

1. Visibility of system status: always keep users informed about what is going on, through appropriate feedback within reasonable time;
2. Match between system and the real world: speak the users' language, with words, phrases and concepts familiar to the user, rather than system-oriented terms;
3. User control and freedom: provide ways of allowing users to easily escape from places they unexpectedly found themselves, through clearly marked "emergency exit" and also support undo and redo;
4. Consistency and standards: avoid making users wonder whether different words, situations, or actions mean the same thing;
5. Error prevention: even better than good error messages is a careful design which prevents a problem from occurring in the first place. Either eliminate error-prone conditions or check for them and present users with a confirmation option before they commit to the action;

6. Recognition rather than recall: minimize the user's memory load by making objects, actions, and options visible. The user should not have to remember information from one part of the dialogue to another. Instructions for use of the system should be visible or easily retrievable whenever appropriate;
7. Flexibility and efficiency of use: provide accelerators, unseen by the novice user, but allow more experienced users to carry out tasks more quickly;
8. Aesthetic and minimalist design: avoid using information that is irrelevant or rarely needed;
9. Help users recognize, diagnose, and recover from errors: use plain language to describe the nature of the problem and suggest a way of solving it;
10. Help and documentation: provide information that can be easily searched and provides help in a set of concrete steps that can easily be followed.

These principles are ideal situation but hard to implement all of them in one system [28].

Assess the usability involves measuring the users performance whether in the interaction with the system, whether in performing tasks that it incorporates. The users performance is typically measured in terms of the errors number and the time it takes to perform a particular task. To evaluate the usability of a system, satisfaction questionnaires or interviews can be conducted.

2.4.6 Discussion

Before starting the development of a platform it is necessary to think about a whole serie of different issues such as: who will use the platform, what is the purpose, in which environment will be inserted, how to behave, what aspect should have, among others. This practice involves several design processes with different levels of detail: thinking through the problem design, understand the users' needs, coming up with possible conceptual models, prototyping them, evaluating them with respect to usability and user experience goals.

Thereby, and involving users at all stages, it is possible to create simple products, aesthetically pleasing and easy to use, that meet all users' needs and help them in carrying out their tasks.

An Analysis over the current Post-MAPS User Interface

In this chapter, a brief introduction to Post-MAPS and its objectives is made. In the following subsections it will be displayed both the form used to collect the necessary data to achieve the presented objectives, as well as the data insertion flow. Thereafter, it will be presented a survey of some issues detected in the data acquisition platform, mainly in terms of usability, highlighting some of its weaknesses and strengths, always from the non-clinical point of view. All information collected will be further considered during the design and development of a new proposal for the Post-MAPS platform. In the final part of this chapter, some suggestions for improvements will be presented.

3.1 Post-MAPS and its aims

The Post-MAPS is a web platform which aims to collect gastroenterological data from various medical centers from different European countries, and was developed based on the "Prevalence, diagnosis and management of gastric pre-neoplastic and neoplastic lesions: An European Multicentre study" protocol, put together by Pedro Pimentel-Nunes, Mário Dinis-Ribeiro and Miguel Coimbra, available in Annex [A](#). The study objectives are:

- To determine the accuracy of the identification of individuals with advanced stages of gastric precancerous conditions;
- To estimate which is the incidence rate for dysplasia among individuals with

advanced stages of gastric precancerous conditions;

- To estimate the true prevalence of gastric precancerous conditions and lesions in the European population;
- To determine if random biopsies of incisura increase the diagnostic yield for gastric preneoplastic lesions;
- To clarify the prevalence of a high-risk phenotype for gastric adenocarcinoma (extensive atrophy/intestinal metaplasia);
- To establish the most cost-effective surveillance schedule for individuals with gastric preneoplastic conditions.

3.2 Post-MAPS - Web form

To be able to achieve the objectives above, it is necessary to collect certain data. This is made through a form with two sections:

- Data concerning the patient, such as demographics, symptoms, family history and current medication;
- Data related to the observation, such as observational general description, and pre and post-biopsy data.

Patient Data

In the first section of the form, users are asked to enter patient's demographic data (e.g., gender and birth date) and to indicate what is the reason for the performed exam. It could be the existence of symptoms, or other indication that should be discriminated. In addition to these data, information related to family history is also requested, in order to understand if there is a record of relatives with gastric cancer or other related pathologies. Finally, it is still necessary to indicate if the patients are taking any kind of medication, and for how long.

Observation Data

At this stage of the form, users are asked to enter some data related to the exam, such as the date, duration, endoscope used, need for sedation, and also a short description of the exam results. According to the study objectives, samples from

three stomach locations are collected (antrum, corpus and incisura) and, for each of these locations, users must satisfy at least one of the proposed questions:

- "Did you suspect/diagnose any superficial lesion (e.g., suspicion of dysplasia/-carcinoma)?"
- "Did you perform any targeted biopsies according to endoscopic features other than suspicious of carcinoma?"
- "Did you perform any random biopsies?"

In response to these questions, users are asked to indicate the area from which the sample was removed, the description (e.g., normal, atrophy, metaplasia, carcinoma), the type of light used in the endoscope, the presence or not of *Helicobacter Pylori* gastritis (HP), while uploading images illustrating where they have taken the biopsy. The histology (analysis of tissue) section that also needs to be filled, refers to the biopsy results that come back from the lab. An example of the form for data entry regarding the observation is shown in Fig. 3.1.

B. Did you perform any targeted biopsies according to endoscopic features other than suspicious of carcinoma? Yes No


| Site | Type | Description | Images | Histology |
|------------------|--|---|---|---|
| Lesser Curvature | White-Light <input checked="" type="radio"/> Yes <input type="radio"/> No | Metaplasia HP: <input type="radio"/> Yes <input checked="" type="radio"/> No |  A: <input type="text"/> Nen...ado B: Escolher ficheiro Nen...ado C: Escolher ficheiro Nen...ado | Metaplasia Atrophy level: Select one ... HP: <input type="radio"/> Yes <input checked="" type="radio"/> No |
| | HRE <input type="radio"/> Yes <input checked="" type="radio"/> No | Select one ... HP: <input type="radio"/> Yes <input checked="" type="radio"/> No | A: Escolher ficheiro Nen...ado B: Escolher ficheiro Nen...ado C: Escolher ficheiro Nen...ado | Select one ... Atrophy level: Select one ... HP: <input type="radio"/> Yes <input checked="" type="radio"/> No |
| Add other site | | | | |

Fig. 3.1: Screenshot of an observation data questionnaire part.

In Fig. 3.2 is shown a schema where the required data is synthesized to complete the questionnaire: the first frame shows the data concerning the patient and the second shows the data related to the observation.

3.2.1 Insertion flow

This questionnaire is divided in two sections: creating a patient profile, where the user is requested to introduce information regarding the history of current patient

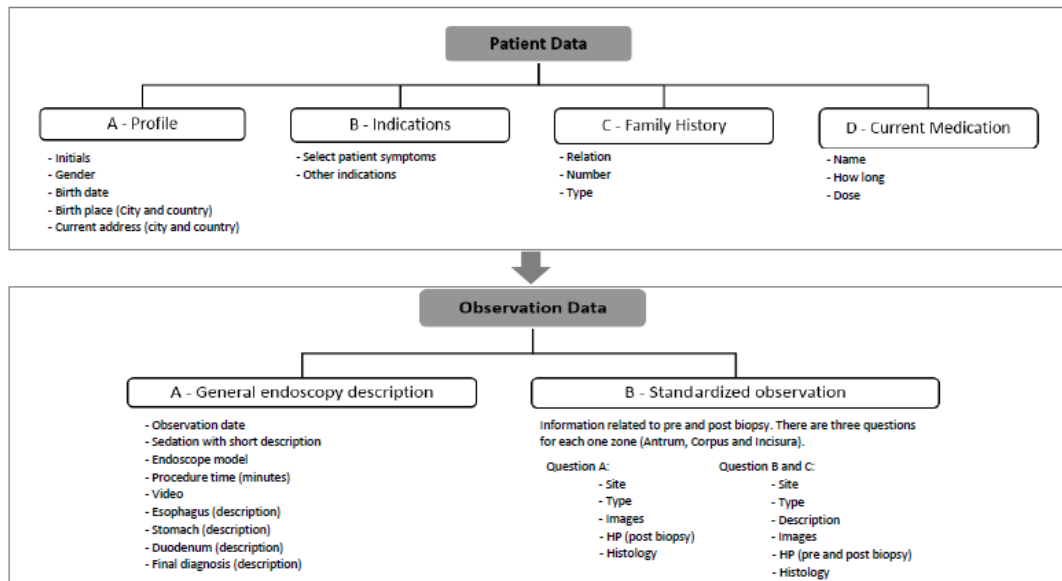


Fig. 3.2: Synthesis of the data required in the questionnaire and representation of data insertion flow.

status (symptoms and other indications), as well as relevant family clinical history and current medication being administered. Observation information, where the user can upload the video and images collected on the procedure, should also be added.

The insertion of all these data is made in only two web pages: one page with all the data related to the patient, and another page with all the data related to the observation. Through Fig. 3.2 it is possible to verify that the data insertion flow goes from patient data (first screen) to the observation data (second screen).

3.3 A Non Clinical Analysis over the UI

The developed platform has some problems that, from the non clinical point of view, are crucial to its good functioning. Then, some aspects that need to be improved are presented in order to:

- Optimize the users interaction and make their experience more enjoyable;
- Help users to focus on their tasks;
- Reduce the occurrence of errors during the data entry;

- Increase the validity of the data collected.

All information collected will be considered during the development of the proposal platform. Despite these points of improvement, the application has some advantages that make it functional and user-friendly.

3.3.1 Strengths

The online form interface was developed in collaboration with medical experts, having into account the potential user needs, and being adapted through their requests. If the interface has a familiar aspect to users, the interaction is facilitated, as the learning curve is shorter and the tasks are performed more quickly, also bringing a greater degree of satisfaction to the user.

A big advantage of the platform is to allow the user not to insert data all at once. For example, users can first enter the data related to the patient and pre-biopsy data, and return later to insert post-biopsy data, as that may take a while to come back from the lab.

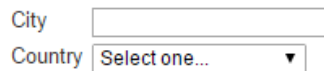
The application provides documentation to help less experienced users to fill out the form. E-mails are also available to come into direct contact with the Post-MAPS administrators, in case any questions arise or doubts remain after reading the manual.

Quick links that allow users to find the part of the form that they want to see or to fill are provided.

3.3.2 Weaknesses

All the aspects that could be improved follow below:

- Upon entering the application, the first screen is always an abstract that reminds users of the aims of Post-MAPS studies. This screen should only be displayed for a first use.
- Should the city be available for insertion, the user can insert existing cities, but can write them differently, Fig. 3.3. A city that does not belong to the chosen country can also be inserted, since any type of validation is not available.
- The date format does not follow the standard, YYYY-MM-DD, used in Europe (nothing that this study is used in some European countries).



The image shows two input fields. The first is a text box labeled 'City' with an empty rectangular input area. The second is a dropdown menu labeled 'Country' with the text 'Select one...' and a small downward-pointing triangle icon on the right side.

Fig. 3.3: Input text to insert cities.

- Symptom list is static and too long, occupying a considerable part of the questionnaire page, Fig. 3.4. The process of choosing the symptoms is also confusing and presents dubious options.

When choosing symptoms related to dyspepsia it is possible to choose the two symptoms (Ulcer-like with burning epigastric pain and dysmotility-like with bloating, early satiation). When "Both/Unspecified" is selected, data analysts will not be able to tell if the option was chosen because the patient presented both symptoms or because symptoms are not specified. Also, on symptoms related to "Suggestive of gastroesophageal reflux", it is only possible to choose two symptoms by clicking on "Both". It would be nice to let the user select all the symptoms, since they are only two, rather than being used more than one option.

- The family history form is also too long. It is presented with too many options and some repeated information, such as "specify relation", "specify number" and "specify type", as can be seen in Fig. 3.5. There is no data validation and, making it more prone to errors. The user can insert numbers in string fields and vice-versa.
- Regarding medication, Fig. 3.6, the user has to choose an option, even to provide the indication that no drug is currently being administered. For options PPI (Proton-pump inhibitor) and NSAIDs (Nonsteroidal anti-inflammatory drugs), all fields - active ingredient, dose, and for how long it has been taken - are mandatory. If the option "other" is used, no validation is done to the content.
- Each inserted exam represents a patient. If the user inserts two exams for the same patient, it counts as two separate patients with different IDs.
- The observation data insertion should be performed in two moments, as there should be a separation between pre and post biopsy data. This way there is too much concentrated information and the user does not know where to begin. In Fig. 3.7 it is presented a screenshot of a form section where it is possible to verify that there is too many options for users to consider.

B. Indications for upper GI endoscopy

Symptoms Yes No

Select symptoms

- Dyspepsia
 - Ulcer-like with burning epigastric pain
 - Dysmotility-like with bloating, early satiation
 - Both/Unspecified
- Suggestive of gastroesophageal reflux
 - Heartburn
 - Regurgitation
 - Both
 - Other
- Dysphagia
- Odynophagia
- Persistent Nausea/vomiting
- Hematemesis/melena
- Anemia
- Weigth loss with abdominal pain

Other indication Yes No

Which?

Fig. 3.4: Form to select symptoms or other indications to endoscopy.

C. Family history of gastric adenocarcinoma

Family history Yes No

| | | | |
|---|--|--|---|
| <input type="checkbox"/> First degree relatives | Specify relation <input type="checkbox"/> Parents <input type="checkbox"/> Offsprings <input type="checkbox"/> Full-sibs | Specify number <input type="text"/> <input type="text"/> <input type="text"/> | Specify type (eg. intestinal, diffuse) <input type="text"/> <input type="text"/> <input type="text"/> |
| <input type="checkbox"/> Second degree relatives | Specify relation <input type="checkbox"/> Grandparents mother lineage <input type="checkbox"/> Grandparents father lineage <input type="checkbox"/> Parents Full-sibs <input type="checkbox"/> Half-sibs <input type="checkbox"/> Grandchildren | Specify number <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | Specify type (eg. intestinal, diffuse) <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |
| <input type="checkbox"/> Third degree relatives or more (not included in first and second degree) | Specify relation <input type="text"/> | Specify number <input type="text"/> | Specify type (eg. intestinal, diffuse) <input type="text"/> |

Fig. 3.5: Family history form.

D. Current medication *

No medication

PPI Name How long (months)? Dose?

NSAIDs Name How long (months)? Dose?

Other

Fig. 3.6: Medication form.

- The users can only insert three images max, by site, and there is no validation for the type of files uploaded.
- By clicking in "Add other site", marked with the red number 1 in Fig. 3.7, a new form is added, but it is not possible to remove it.

A. Did you suspect/diagnose any superficial lesion (eg, suspicion of dysplasia/carcinoma)? Yes No

| Site | Type | Description | Images | Histology |
|-------------------------|--|-------------|---|---|
| | White-Light <input type="radio"/> Yes <input checked="" type="radio"/> No | | A: <input type="text"/> Nen...ado B: <input type="text"/> Nen...ado C: <input type="text"/> Nen...ado | Select one ... Atrophy level: Select one ... HP: <input type="radio"/> Yes <input checked="" type="radio"/> No |
| | HRE <input type="radio"/> Yes <input checked="" type="radio"/> No | | A: <input type="text"/> Nen...ado B: <input type="text"/> Nen...ado C: <input type="text"/> Nen...ado | Select one ... Atrophy level: Select one ... HP: <input type="radio"/> Yes <input checked="" type="radio"/> No |
| Add other site 1 | | | | |

Fig. 3.7: Observation data form.

- During the patient examination, the user is faced with a lot of information on-screen. This practice usually causes distractions and even tiredness. A scroll is needed to go through all the form, since shortcuts are not available to help the user to navigate through different sections. On the top of each page, quick links are available, but when the user reaches the end of a section or the page, there is no help to get back to the top of the page.
- When there is large amount of data, the tables can get to big dimensions and the users need to scroll the page to view the contents of the entire table.

In Subchapter 5.4, some suggestions to improve or eliminate the problems and failures mentioned above will be presented. In addition to the improvement points, there are some features that could make the use of the application more pleasant, but are not yet implemented:

- Allow registration and invitation of users through the platform. The users need to contact the post-MAPS administrator, via email or telephone, to obtain access to the platform or to invite colleagues to participate in the study, which makes this process entirely dependent on the availability of administrators.
- Allow account recovery through the platform. Currently, if the users lose their access credentials, they have to come into contact with the administrators.
- Allow completed exams visualization. Currently, after a completed exam submission, users no longer have access to the data inserted.

3.4 Discussion

After the detection of the application weaknesses, an analysis was accomplished in order to make the application easier to use, more organized and, therefore, less prone to entry errors.

All data entered through input text should be validated to reduce the probability of insertion errors. This validation should, preferably, be on the fly, so that the users receive immediate feedback. It should not be permitted to submit a form with errors and the user should be informed of what is incorrect. Therefore, problems such as entering numbers in text input would be avoided, for example.

The insertion of all the required information referred above is done in just two web pages, resulting in a large amount of information that is presented directly to the user. The form should be divided in more parts, even if it means more clicks to get to them. The higher the amount of information presented on screen, the more difficult it is to keep the users focused in carrying out their tasks. By reducing the amount of information by screen, the probability of the user introducing errors or give up on filling data may be lower.

The problem of the tables excessive size can be solved using datatables. There are numerous solutions that allow pagination, instant search and multi-column ordering. Thus, the need to scroll the page to view the contents of the entire table would be unnecessary.

As mentioned above, each inserted exam represents a patient. So if the user inserts two exams for the same patient, they would be interpreted as two separate patients. It would be interesting to create the "patient" concept in the application and, making it possible to display exams per patient. Data pertaining to that patient would not be required to insert, since this should remain unchanged.

Application of the TAM to assess the Post-MAPS usability

There are multiple theories that attempt to predict the impact of technology on human behavior in order to bring constant improvements and identify internal or external factors that may be involved in decisions, intentions and satisfaction of the individual regarding the acceptance and use of technologies [37]. Here, only three theories are discussed: Theory of Reasoned Action (TRA), the Theory of Planned Behavior (TPB) and, finally, the Technology Acceptance Model (TAM).

The Theory of Reasoned Action (TRA) was developed by Martin Fishbein and Icek Ajzen, between 1975 and 1980 and is a model for predicting the intention to perform a behavior, in which are defined relationships between beliefs, attitudes, norms, intentions and behavior. The TRA considers also that people behave rationally, evaluating what they have to lose or gain from the manifestation of attitudes. A scheme of this model is shown in Fig. 4.1. Beliefs refer to the information that an individual has in relation to a particular object and the subjective norms concern the perception of an external evaluation as to adopt, or not, certain behavior. According to this model, the intention determines the actual behavior, i.e. the observable actions. For example, the technology acceptance is the result of an intention to perform the behavior that is influenced by the individual attitudes who, in turn, are determined by beliefs and norms regarding behavior (use of technology).

A few years later came The Theory of Planned Behavior (TPB) and complemented the TRA by adding it another construct: perceived behavioral control. Perceived behavioral control refers to the individuals awareness about their ability to perform certain behavior and it is supposed to be determined by the set of beliefs.

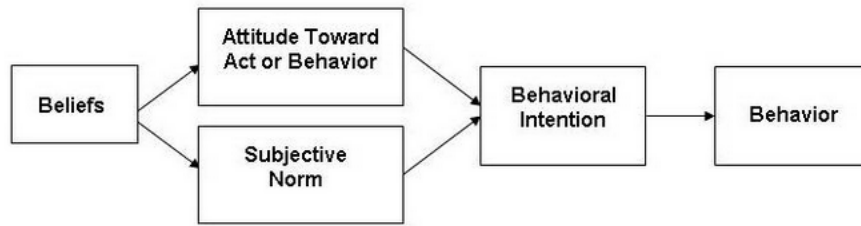


Fig. 4.1: The Theory of Reasoned Action (TRA). Source: Fishbein and Ajzen - 1975.

A scheme of this model is shown in Fig. 4.2. This theory defends that the attitude towards behavior, subjective norm and perceived behavioral control, shape attitudes and behavioral intentions of an individual.

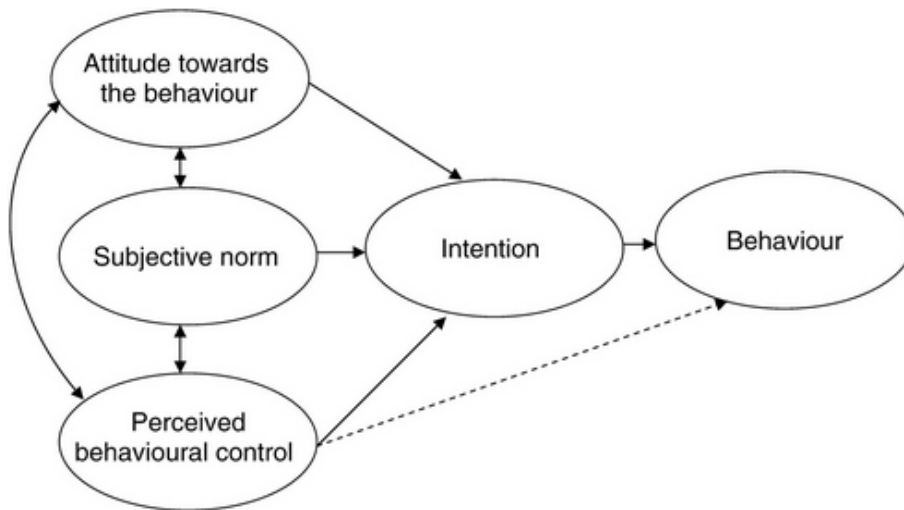


Fig. 4.2: Theory of Planned Behavior (TPB). Source: Ajzen - 1991.

Finally, the Technology Acceptance Model (TAM) was developed from the Theory of Reasoned Action (TRA), in order to create a model of information technology acceptance. As the best known and most widely used in the area of information systems, it was the method chosen for this study and thus will be explained with more detail in the following subchapter.

4.1 Technology Acceptance Model

The Technology Acceptance Model (TAM) is based on the Theory of Reasoned Action (TRA) and it was developed by Davis et. al (1986) [38]. Davis developed the TAM to explain the computer usage and acceptance of information technology.

The purpose of the TAM is to predict the acceptability of a certain tool and to identify changes to the system in order to make it acceptable to users. This model suggests that acceptability is determined by two factors: perceived usefulness and perceived ease of use [38]. The perceived usefulness is defined as the degree to which a person believes that the use of a system may increase its performance. In turn, the perceived ease of use is defined as the degree to which a person believes that it is not necessary effort in using a system. [39].

Venkatesh and Davis (2000) proposed a TAM extension, the TAM2, by identifying and theorizing about the general determinants of perceived usefulness: subjective norm, image, job relevance, output quality, result demonstrability and perceived ease of use, as well as two moderators: experience and voluntariness [40]. The first two determinants (subjective norm and image) fall into the category of social influence and the remaining determinants are system characteristics. The TAM2, Fig. 4.3, presents two theoretical processes, social influence and cognitive instrumental processes, to explain the effects of the various determinants on perceived usefulness and behavioral intention [40] [41].

- Subjective norm is defined as an individual's perception of whether people important to the individual think the behaviour should be performed;
- Image is defined as the degree to which an individual perceives that use of an innovation will enhance his or her status in his or her social system;
- Job relevance is defined as individual's perception regarding the degree to which the target system is relevant to his or her job;
- Output quality is defined as the degree to which an individual believes that the system performs his or her job tasks well;
- Result Demonstrability is defined as the degree to which an individual believes that the results of using a system are tangible, observable, and communicable;
- Voluntariness is defined as the extent to which potential adopters perceive the adoption decision to be non-mandatory.

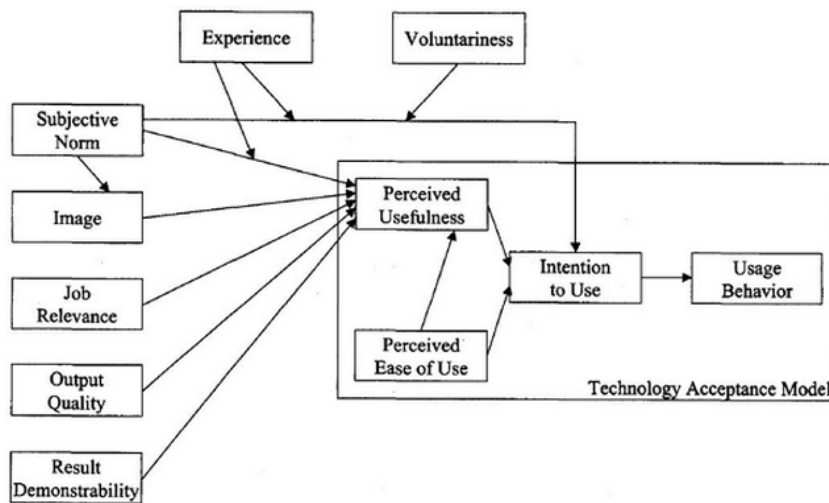


Fig. 4.3: Technology acceptance model 2 (TAM 2).

4.2 Preliminary Study

4.2.1 Methods

To evaluate the usability of the Post-MAPS platform a preliminary study was conducted. We opted to use a survey, because it is an information gathering tool that can be applied to all individuals the same way and with the same sequence. Also, it allows the description and comparison of individuals responses. This survey was developed using google forms, based on the above mentioned model TAM 2 (Subsection 4.1) and was shared with all users registered in the Post-MAPS. The survey was divided into different sections with closed questions:

- personal information;
- intention to use;
- perceived usefulness;
- perceived ease of use;
- subjective norm;
- voluntariness;
- image;
- job relevance;

- output quality;
- result demonstrability.

All items were measured through a 7-point Likert scale, where 1 = strongly disagree, 2 = moderately disagree, 3 = somewhat disagree, 4 = neutral (neither disagree nor agree), 5 = somewhat agree, 6 = moderately agree, and 7 = strongly agree. Thus resulting in an easy, intuitive and fast-fill form. There were initially requested some personal information to users in the personal information section, such as: age, nationality and years of experience, but exclusively for statistical purposes, as explained in a small introduction of the form. The survey is available in Annex B.

4.2.2 Dataset

The survey was sent to ten users of the Post-MAPS, but were only collected five responses in total, all of them considered for this study. The data were exported to an Excel sheet to carry out its analysis. Users who answered the survey are aged between 30 and 59 years old, having an experience between 3 to 35 years. In the sample, there are also users of different European countries: England, Italy and Romania, as can be seen in Table 4.1.

Tab. 4.1: Users that have answered the survey, according to their age and years of experience.

| City | Age | Years of experience |
|----------------------|-----|---------------------|
| Nottingham, England | 34 | 9 |
| Rome, Italy | 30 | 3 |
| Rome, Italy | 59 | 35 |
| Targu Mures, Romania | 35 | 5 |
| Targu Mures, Romania | 52 | 25 |

4.2.3 Results

In this subsection, the results obtained from the questionnaires will be presented and analyzed, and a simple descriptive analysis, which includes statistical data such as mean and standard deviation will be displayed.

Table 4.2 presents a summary of the constructs used in the survey, the related questions, as well as the mean and standard deviation of the values assigned by

users, being the mean value score set on a 1 to 7 scale. Thereafter the results of each construct are analyzed.

Intention to use

This question group is related with the intention of use of the Post-MAPS platform. By analyzing the data in Table 4.2, we verified that the average of 6 values (moderately agree) meant that all the surveyed users show an intention to use the platform.

Perceived usefulness

Regarding the perceived usefulness, the respondents consider that the Post-MAPS increases, in some ways, their productivity and improves their effectiveness in work, with an average of 5 values (somewhat agree). We also found that the respondents consider the platform useful and that using it can increase their performance at work, validate by the average of 6 values.

In this set of questions, as expected, users have recognized the platform usefulness (it is through it that data is inserted to be later used in the cohort study). On the other hand, regarding productivity and performance increasing, lower values were expected, since the platform use does not influence the way they carry out their duties in their work. The high values attributed on these points can possible be justified by the fact that users consider that the platform use is an activity that is part of their work and help them during data storage.

Perceived ease of use

The respondents consider the system easy to use and its interaction with it clear and understandable, assigning it an average of 6 values. They also consider there is no need of significant mental effort during the interaction with it, assigning it an average of 5 points. Thus, in general, the respondents found the Post-MAPS platform easy to use, after analyzing the data with more detail, we verified that two users from the same country require some mental effort to use the platform (assigning the question 3 and 4 values). At this point, it is necessary to take into account that the platform was developed by portuguese professionals and that the terminology may be different from that used in the country of the two respondents, which can be translated into some difficulties at the time of the exam insertion.

Tab. 4.2: Summary of constructs, questions, means and standard deviation.

| Construct | Question | Mean | STD |
|------------------------|--|------|------|
| Intention to use | Assuming that I have access to the system, I intend to use it. | 6.4 | 0.89 |
| | Given that I have access to the system, I predict that I would use it. | 6.2 | 0.84 |
| Perceived usefulness | Using the system improves my performance in my job. | 6 | 1.22 |
| | Using the system in my job increases my productivity. | 5 | 1.41 |
| | Using the system enhances my effectiveness in my job. | 5.2 | 1.30 |
| | I find the system to be useful in my job. | 6.4 | 0.89 |
| Perceived ease of use | My interaction with the system is clear and understandable. | 6.4 | 0.89 |
| | Interacting with the system does not require a lot of my mental effort. | 5 | 1.41 |
| | I find the system to be easy to use. | 6 | 0.71 |
| | I find it easy to get the system to do what I want it to do. | 6.2 | 0.45 |
| Subjective norm | People who influence my behavior think that I should use the system. | 5 | 2 |
| | People who are important to me think that I should use the system. | 4.8 | 1.92 |
| Voluntariness | My use of the system is voluntary. | 6.8 | 0.45 |
| | My supervisor does not require me to use the system. | 6.4 | 1.34 |
| | Although it might be helpful, using the system is certainly not compulsory in my job. | 5.2 | 1.72 |
| Image | People in my organization who use the system have more prestige than those who do not. | 5.4 | 0.89 |
| | People in my organization who use the system have a high profile. | 6.2 | 0.84 |
| | Having the system is a status symbol in my organization. | 4.4 | 2.04 |
| Job relevance | In my job, usage of the system is important. | 5.2 | 1.93 |
| | In my job, usage of the system is relevant. | 5.8 | 1.30 |
| Output quality | The quality of the output I get from the system is high. | 4.4 | 2.07 |
| | I have no problem with the quality of the system's output. | 5.2 | 1.92 |
| Result demonstrability | I have no difficulty telling others about the results of using the system. | 5.4 | 2.07 |
| | I believe I could communicate to others the consequences of using the system. | 4.6 | 1.82 |
| | The results of using the system are apparent to me. | 6.2 | 0.84 |

The Post-MAPS was developed in partnership with experts from the gastroenterology area. The fact that the platform meet users expectations and that they consider it easy to use reinforces the importance of cooperation between health specialists and information technology (IT) experts in the development of clinical studies.

Subjective norm

When asked about social influences, whether from people who influence its behavior or people that are important to respondents. An average of 5 values was assigned. By analyzing the data presented in Table 4.2, we verified that the standard deviation obtained is high, and we speculate that there is no agreement on these issues.

All users of the Post-MAPS platform are collaborating with a research study and may be surrounded by people who recognize the importance of this work, or people who just do not care or do not recognize its value. Thus, on these questions were expected extreme responses since users may or may not be influenced. However, one respondent attributed to this questions group an average of 4 values which may mean that it is not influenced, or is unaware of the people opinion around it in relation to its collaboration in the study.

Voluntariness

We verified that the respondents use the platform voluntarily, assigning it an average of 7 values (strongly agree). They consider that although the platform is useful, its use at work is not mandatory, assigning it an average of 5 values. As the standard deviation is high, there was no agreement among the respondents.

In this set of questions were expected low values, but the assigned values are understood, since users are volunteers in collaborating with the study and not with the platform use. Nevertheless, it is also important to mention that one of the respondents, when asked about the intention to use the platform, assigned 5 values, but when asked about the voluntary use of the platform, it assigned 7 values. So, do not show great intention to use the platform but is 100% volunteer in its use. This behavior may lie in the inherent altruism to the word "voluntary".

However, the fact that respondents use the platform voluntarily without being imposed by their superiors is very important, once it reinforces the idea that they are aware of the benefits and future impact of this study.

Image

The respondents consider that in their organization, the ones who use the platform have more prestige than those who do not use and have a higher profile, assigning it an average of 5 and 6 values, respectively. However, they assigned an average of 4 values to the question "Having the system is a status symbol in my organization", which resulted in a high standard deviation that gives the indication that, once again, there was no agreement among the respondents. In this question, one respondent fled the pattern of answers from other users by assigning an average of 1 value. By analyzing the pattern of answers of that user, we also found that in this question it assigned an outlier, which can somehow mean confidence in its answer.

Users, to be invited to participate in this study are generally considered to be of high profile and consequently have prestige in the area where they work. When asked about the prestige in the platform use, three of the respondents gave 6 values to the question, which may mean that they are aware that only prestigious people (where they are included) are invited to participate in this type of research studies. However, one of the users assigned only 4 values to the question and, when asked about the status symbol on the platform use it assigned 1 value, which could mean that, for this user, the fact that the platform does not make it more prestigious or superior concerning other professionals of the area.

Job relevance

On average, respondents have a score of 5 values to the question "In my job, usage of the system is important". When asked about the relevance of platform use in their work, respondents have given an average of 6 values. As the sample of respondents is reduced and the answers to these questions have a high standard deviation, once again there was no agreement among the respondents.

When asked about the importance of using the platform in its work, one of the users answered outside the patterns of all other users, by assigning it 2 values. This response may mean that this user is aware that currently the Post-MAPS brings no advantages in performing its functions, which does not mean that it is unaware of the impact of this study in the future.

If users consider the platform use for exams submission as part of its work, high responses would be expected, otherwise, the answers should be low. For example, one of the users, when asked about the importance of using the platform in its work, assigned 2 values, which may mean that this activity (of submitting exams on the

platform) is not included in performing its duties, but it's something that is beyond its work. The other users, who attributed values above 5 to this question, may consider important the use of the system in their work because they consider it a part of their duties.

Output quality

Regarding the output quality, we verified that the respondents have given an average of 4 values (neither agree nor disagree) to the question "The quality of the output I get from the system is high". Concerning the question "I have no problem with the quality of system's output" respondents have given an average of 5 values. As the standard deviation obtained for both issues was high and as the sample of respondents is small, there was no agreement.

On these questions were expected low values since after an analysis of the Post-MAPS platform (Chapter 3) there have been some problems, such as lack of feedback after users actions (such as saving data) or lack of data validation upon insertion. The fact that users have assigned high values on these questions means that in their interaction with the platform, their interest is to be able of submitting data and they are not concerned or aware of any flaws that it may present.

Result demonstrability

On average, the respondents considered having no difficulty in talking with others about the system use results and assigned to that question 5 values. The respondents consider to be able to communicate to others the consequences of system use, assigning to this question an average of 5 values. They also consider that the system use results are apparent to them, giving an average of 6 values to this question.

In the first questions, one respondent fled the pattern of responses from other users, by assigning them 2 values. Analyzing this user pattern of responses, we found that it answered "Strongly" in 50% of the questions, which shows certainty in its responses. The fact that in these two issues it has assigned a lower value may mean that it really finds difficult to transmit some system information. Finally, with an average of 2 values, respondents consider having no difficulty in explain why the platform use may or may not be beneficial. Also in this question, another user answered outside the pattern, assigning it 5 values, which may mean that this user is not aware or that the platform use benefits were not transmitted to it.

By analyzing Table 4.3 some conclusions may be taken. It is verified that when

Tab. 4.3: Summary of not regarding positive/negative answer percentage according to 7-point Likert scale, by user.

| City | Age | Years | %Neutral | %Strongly | %Moderate | %Somewhat |
|----------------------|-----|-------|----------|-----------|-----------|-----------|
| Nottingham, England | 34 | 9 | 15.38% | 11.54% | 30.77% | 42.31% |
| Rome, Italy | 30 | 3 | 26.92% | 11.54% | 50.00% | 11.54% |
| Rome, Italy | 59 | 35 | 15.38% | 23.08% | 34.62% | 26.92% |
| Targu Mures, Romania | 35 | 5 | 0.00% | 80.77% | 15.38% | 3.85% |
| Targu Mures, Romania | 52 | 25 | 0.00% | 50.00% | 46.15% | 3.85% |

filling out the questionnaire people from the same country/city had the same kind of behavior, for example, respondents from Romania always showed safety in their responses, never opting for neutral responses and rarely by somewhat answers; respondents from Italy were more moderate in their decisions, but still with some percentage of neutral and strongly answers and, finally, the respondent in England has opted for a higher percentage of moderate and somewhat type of answers.

Concerning the years of experience, we found that the more experienced user is the one with a wider range of answers. This behavior can give us an indication that this user did not just read the questions and assign a value, but also thought about them and assigned them values consciously, a typical behavior of more experienced people.

4.3 Discussion

It was verified by analyzing the data presented above that respondents have intention to use the platform, recognizing its usefulness as a means to enter the required data for the study. In turn, also consider that the platform use contributes to productivity and performance increasing, which can be valid if they consider the platform use as part of their work and recognize that is designed to allow them a faster and effective data insertion (which was not verified in Chapter 3, where the platform is analyzed).

Respondents generally consider that the interaction with the platform is clear and understandable, not requiring great mental effort and being easy to use, which reinforces the joint work between health specialists and experts from the IT area in the development of clinical studies. Regarding the social influence, respondents may be surrounded by people who understand and value their work while participants in a

research study, or people who do not recognize its usefulness and value. Respondents consider the platform use as voluntary and with no obligation by their supervisors. But in reality, users are only voluntary in the study participation for which they were invited and not on the platform use (that as already mentioned, is the mean used for required data entry).

It is also verified that, in general, those who use the platform consider having greater visibility and prestige than people who do not use it, even considering that, in carrying out its duties, the platform use is important and relevant (if the platform use is part of the tasks associated with its work). Chapter 3 presents an analysis of the functional point of view to the Post-MAPS platform and where some failures were detected. However, users consider to have no problem with the system output. This reinforces the idea that in their interaction with the platform, users only want to enter the exams data and are not aware or do not care for any failure the platform may present, as long as their data is stored.

With respect to results statement, the respondents consider to be not difficult to pass on to others the consequences of the platform use as well as the results of using it, they consider to be obvious.

Along this study the biggest limitation was the number of responses obtained, which reduced the sample of respondents and consequently, an average was obtained that does not reflect the reality in many of the constructs used.

A New User Interface for Post-MAPS

After identification and analysis of the Post-MAPS platform in use (Chapter 3), the next step in this thesis was the development of a new platform with new features, while keeping and enhancing basic functionalities. During the platform development we always took into account usability principles, in order to make the user interaction more pleasant, quick and effective, as well as less propitious to errors and consequent frustrations. This chapter describes all the development steps of the platform proposal. It is divided in four sections: Analysis and design, Interface organization, Development, and Discussion. In the first section, Analysis and design, use cases and features to the platform are defined. It is also explained the defined data model and all data insertion flow. All interface organization is defined and explained in the second section. The Development section describes the development environment, the technologies we used and the platform architecture.

5.1 Analysis and Design

5.1.1 Use cases

The use cases diagram documents what the system does from the user's point of view, as it describes the main features of the system and the interaction of these features with system users. It is composed by actors, which represent the system users, and by use cases, which define the system actions [42]. In Fig. 5.1 is depicted the Post-MAPS's use cases diagram in which the actors and their actions are represented. There are only three types of actors: the Post-MAPS administrator, the entity administrator and the entity collaborator.

- The administrator is the user with highest level permissions in this platform and is responsible for all management related to requests for access to the platform, entities, users and validation of master files content.
- The entity administrator can invite people from his organization to participate in the study and have access to the platform. He is also responsible for managing all users from his entity and can edit their data or even eliminate them. He can insert his own patient exams, and can consult or edit them.
- The entity collaborator is the user with the most basic permission sets. He is able to insert patients and exams of his own, as well as view or edit their data.

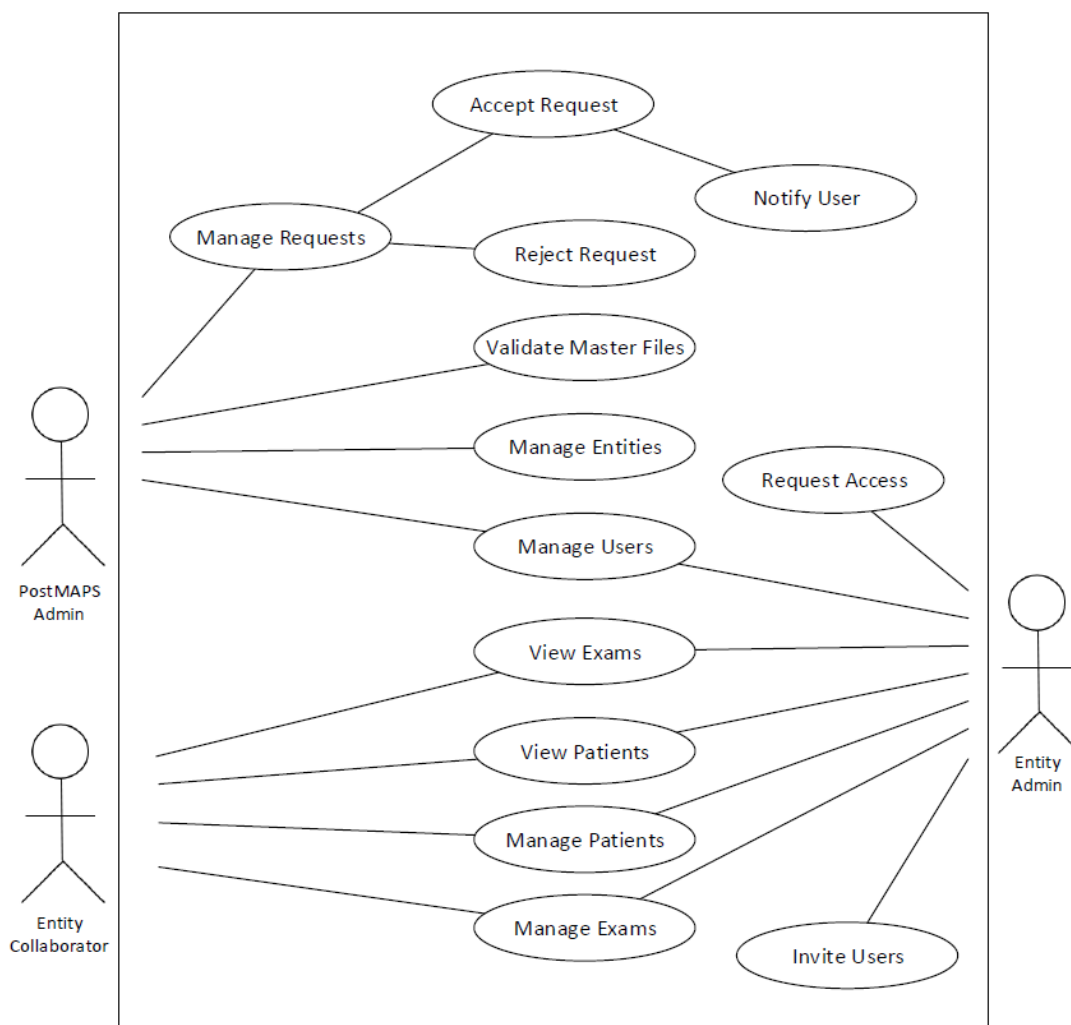


Fig. 5.1: Use case diagram of the Post-MAPS platform proposal.

As mentioned above, in the Post-MAPS platform proposal, the basic functionalities are not only maintained, but improved. Some features that we would consider as a plus were also added:

Request Access: the request access is made through the login page and should always be accomplished by entity administrator. By clicking in "Request Access" a dialog arises with a small form where the user is prompted to insert some information. After the form submission, the Post-MAPS administrator is notified by email of the existence of a new request access.

Manage requests: as mentioned above, the Post-MAPS administrator is responsible for managing access requests. Through this feature, the administrator has the ability to:

- **Accept Request:** if all information are correct. The user is notified by e-mail, with a link of a page where he can edit or complete the profile and also invite users of his entity, if he wishes to do so.
- **Reject Request:** if wrong or faulty information is detected;
- **Request Info:** if there is any inconsistencies or some data is lacking. The user is also notified by e-mail where those fields are indicated.

Invite users: this feature is accessible through the menu and only for entity administrators. It allows to invite new users for the platform, where information such as name and email is requested. These users are then notified by mail, where they are asked to complete the data.

Manage users: this feature allows the access to all user records of an entity - in the case of entity administrator -, or to all users of the platform in the case of Post-MAPS administrator. It also allows to edit associated data and user deletion.

Manage entities: this feature is of the responsibility of the Post-MAPS administrator only. Through this, he has access to the listing of all information associated to an entity, can edit its data and, may it be necessary, remove/disable one.

View patients: this feature provides access to a listing of all registered patients, according to user permissions, where information as gender, initials, place and date of birth are available.

Manage patients: this feature allows users to edit data related to the patient, such as initials, current address or daily habits (like smoking or drinking). The user can also delete its patients.

Insert exam: all Post-MAPS users, excluding the administrator, have the possibility to insert exams. This feature consists in inserting data related to the patient at the time of observation (like symptoms, family history and medication), data related to observation (like endoscope, sedation), pre-biopsy data (by different zones) and also data pos-biopsy (also for different zones). The user has the possibility to complete data insertion at a later time instead of finishing it right away.

Manage exams: as mentioned above, the user can leave the exam informations incomplete. The exams management gives the user the possibility to return to a point left incomplete, and supplement the missing information or edit what already is there. After an exam is closed, the user no longer has the ability to make any kind of edit.

View exams: the visualization of exams allows users to access the list of all inserted exams according to their permissions, completed or incompleted. The visualization of completed exams allows the user access its data.

Validate master files: this is a feature that allows the Post-MAPS administrator to validate all information that is being added to the master files, during exam insertion.

5.1.2 Data Model

After the use cases and all features are defined, we need to design the database and create the data model. The data model represents the set of tables where data will be stored, as well as the associations between them. This is a fundamental part of the application development, since a good database design also allows to develop applications that are stable and work well from the beginning [43].

During the modeling of the database, the following rules were established:

- the table name is always in lowercase and in the singular;
- all primary keys (PK) have the same nomenclature, ID;
- all foreign keys (FK) are composed of the table name followed by the word ID (e.g., if we want to refer the country table in the table users, the FK in that table will be countryID).

The whole database structure has been designed to allow its growth. So, the concept of master files was introduced, which consists in database tables where

permanent information is stored, cannot be eliminated, and will be updated periodically. A master file can be composed of different fields, but the most common are the following:

- ID, which is the PK of the table;
- name, which is a description (e.g., Portugal);
- label, which is the abbreviation (e.g., PT);
- deprecated, boolean indicating if the country is deprecated;
- deprecatedDate, that indicates the date on which the country became deprecated;
- validated, column used when users, through the platform, insert content in the master files. This column remains FALSE until the Post-MAPS administrator validates the added data.

All the tables related to the master files have "mf" at the beginning of its name (e.g., mf_city). In Fig. 5.2 is depicted the data model of Post-MAPS, where the tables related to master files are not shown for better viewing.

5.1.3 Data insertion flow

The first strong need felt in the development of the insertion flow was related to the dimension of the presented forms to the users. There was a lot of information in each screen in a disposition that could cause confusion in users. Consequently, there was a bigger probability of errors occurring at the moment of data insertion.

After debating the data model, the presence of master files, and taking into account the features available, we decided to create a simple flow of insertion, where there is a clear separation between patient data, observation data, pre and post biopsy data.

This first division helps the user to identify in how many stages data insertion is divided, since there is a clear separation between content that is not directly related. As described in Chapter 2, the more complex a task is, in more steps should it be divided so that it could be easier to perform [44]. So, within this initial separation there is another one, performed in order to minimize the amount of information that is shown to the user by screen and, again, separating whatever is not related.

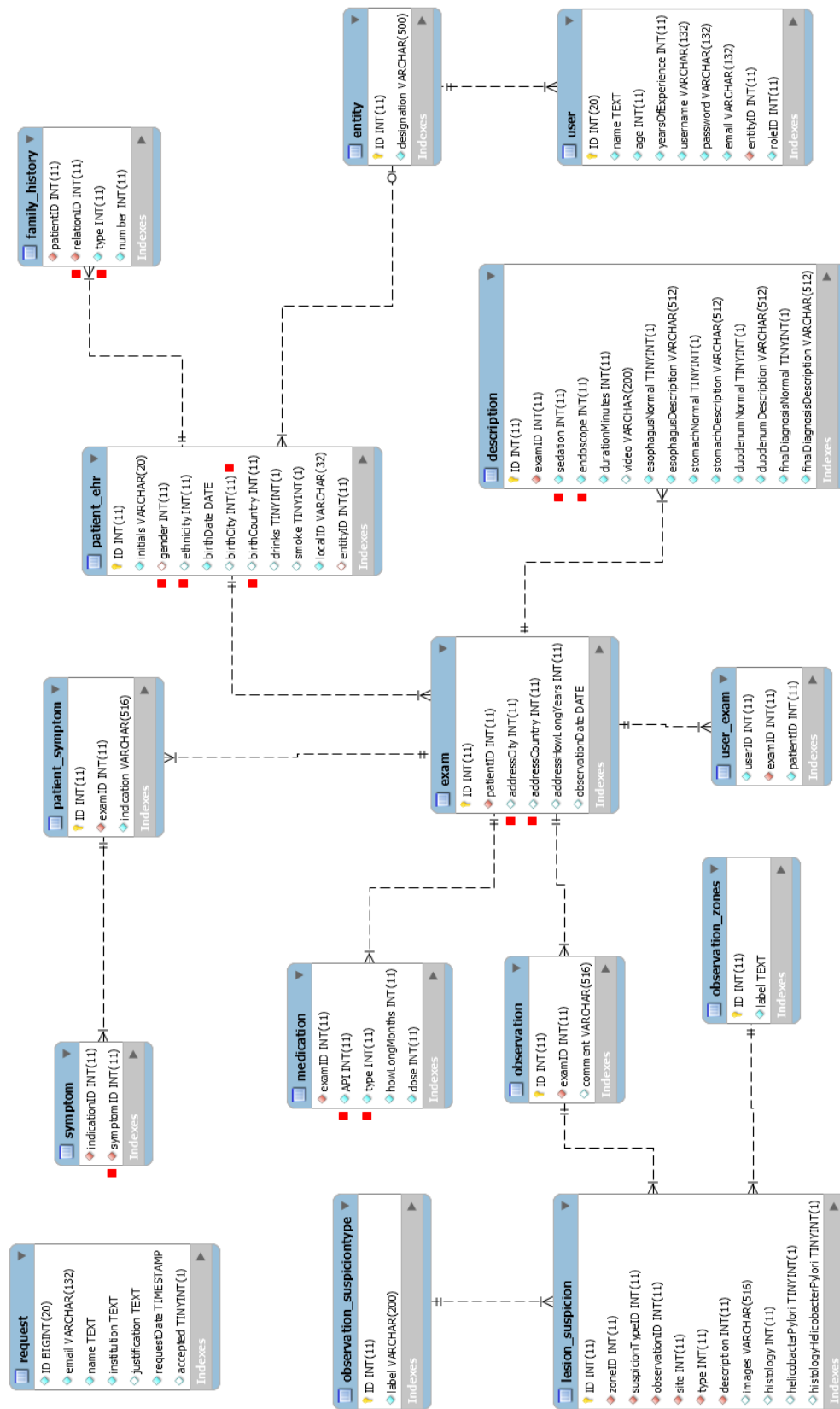


Fig. 5.2: Data Model of the platform without master files. Note: the red squares represent links to master files.

For example, regarding patient data, a division is made between personal data, symptoms, family history and medication. Although these data are related to the patient, they are not related themselves. This way, when accessing a page form, the user perceives that all the information it needs is fully visible and there is no need to scroll to proceed with the insertion, focusing on what it sees and having no expectations about what might be hiding in the remaining page. This data separation, resulting in the flow shown in Fig. 5.3, guides the user at the insertion time, leaving no doubts on what should the next step be. This flow represents only the ideal way of data insertion (first the patient related data, followed by the observation data, finishing with pre and post-biopsy data). However, the user has the possibility to enter data by the order that is more suitable, since some shortcuts are provided along the insertion. In Fig. 5.3, each square represents a screen.

5.2 The interface

Before we start the development of the interface, we need to do some research work, in order to understand which are the main aspects to be considered to improve the interaction of the user with the platform, avoiding doubts and incorrect interpretations of data. The aesthetics and the elements' organization are fundamental, and one should always seek to combine beauty, simplicity and functionality in order to create an excellent and comfortable experience to the user. It must have a good presentation with all artifacts well distributed and positioned, always trying to reduce the user cognitive effort in his tasks, while making itself an emotionally satisfactory experience [44]. The style of an interface, in terms of the shapes, fonts, colors, and graphical elements that are used, and the way they are combined, influences how pleasurable it is to interact with [31].

5.2.1 Organization

So, the first step was to understand a better way to organize the information in each screen, in order to help the user during the interaction, as it is crucial in factors as usability and acceptability of the application. This interface organization consists of grouping similar items and separate different or independent items. The grouping can be achieved in several ways, such as placing the elements together, using color, or using containers to indicate the relation between the elements [31].

In the Post-MAPS platform proposal, we decided to separate the interface in five

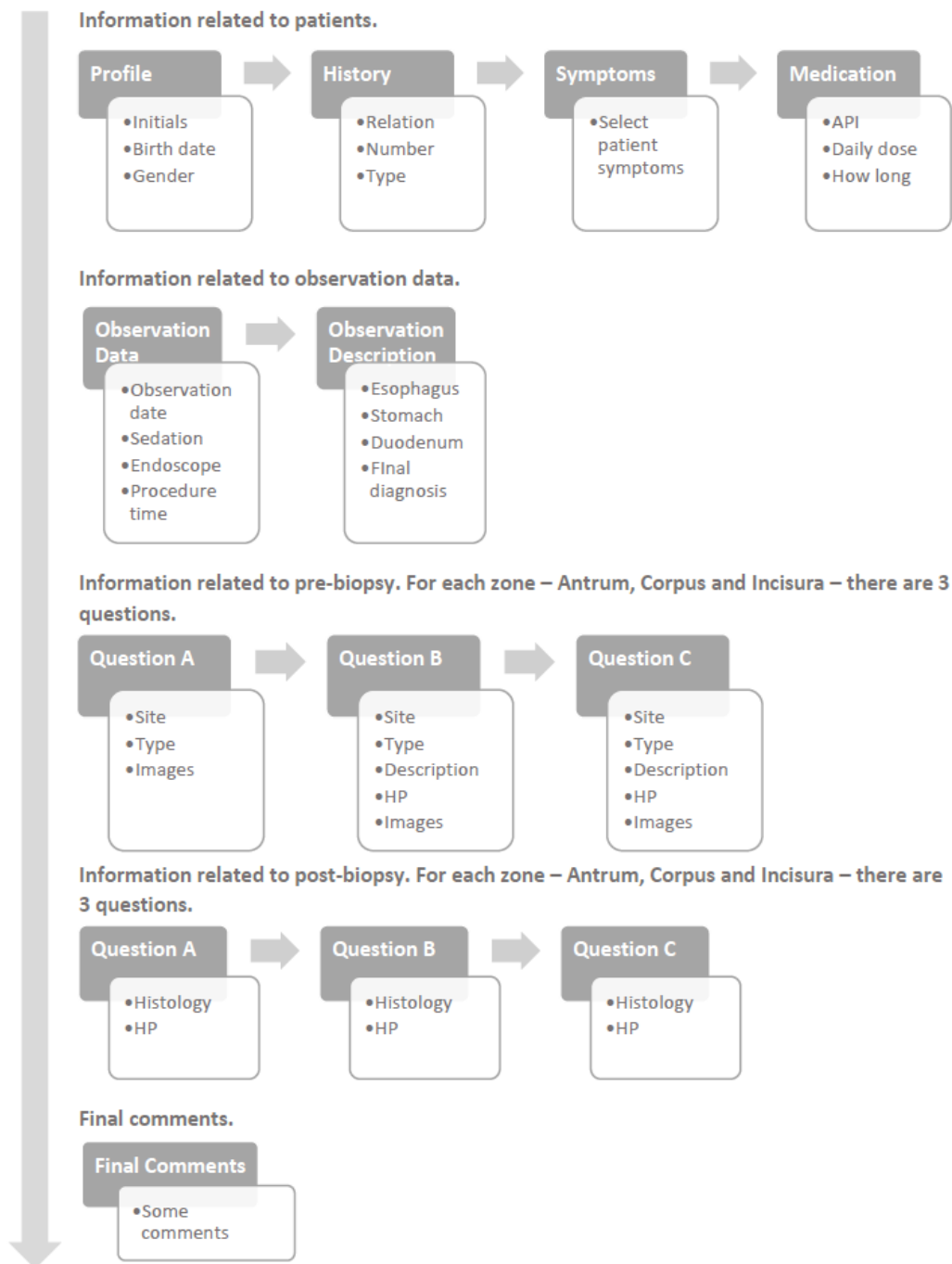


Fig. 5.3: Data insertion flow that begins with patient data insertion and ends with final comments. Each square represents a screen.

containers, as shown in Fig. 5.4.

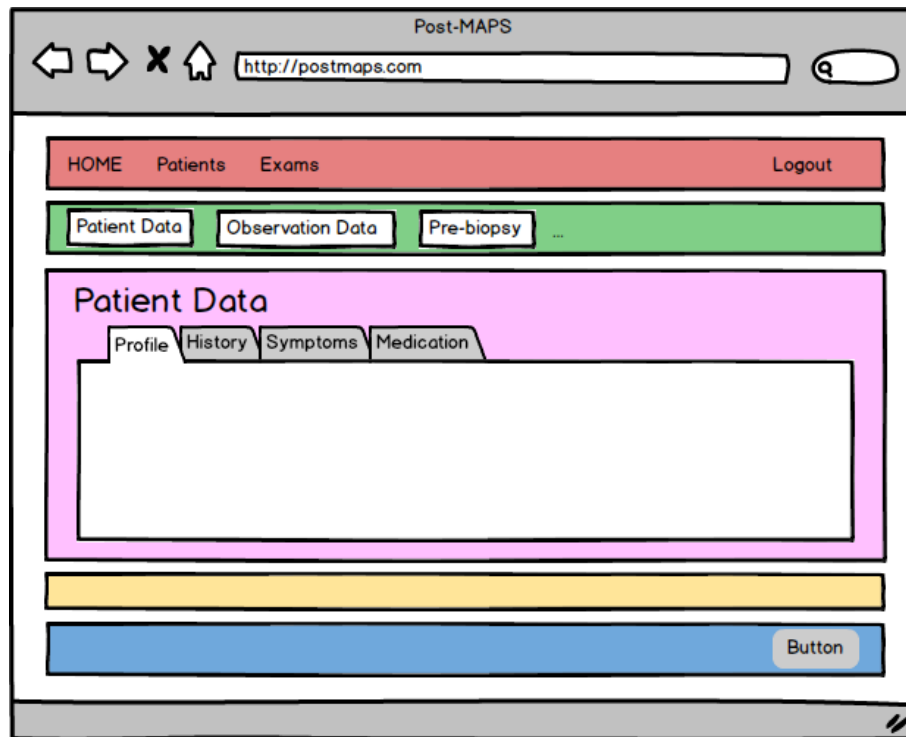


Fig. 5.4: Interface organization mockup, which are presented the different containers (with different colors).

A brief description of each container follows, highlighting its role in the platform:

- Red container: related to the menu, in which the user can navigate to the different platform's options.
- Green container: where the shortcuts are, which allow the more experienced users to navigate through the platform faster.
- Pink container: where all forms are presented and where the data are shown to the user. It is through this container, using labels, that the user has the perception of where he currently is in the platform.
- Yellow container: this whole interface is based on the principle that only necessary and essential informations must be kept on the screen. Therefore, there is a container where no essential information is placed, which helps the user to focus on his tasks.
- Blue container: where the buttons are, which guide the user along the data insertion.

Throughout the application there is always consistency in the disposition of these containers, and the user easily can recognize them, separating what is related from what is not [31].

5.2.2 Interface improvements

Notifications

Each time an user requests access to the platform, the Post-MAPS admin is notified by e-mail. Thus, when a user logs into the platform, it can immediately see if there are any pending requests through the existence of notifications on the menu, represented by the red container of Fig. 5.4. The notifications are an increasingly common practice in web applications, since they allow the immediate perception that something is happening. In Fig. 5.5 are displayed some examples of well-known applications where notifications are used. As the users are increasingly familiar with this practice, we decided to implement this feature in Post-MAPS, Fig. 5.5 c). These notifications only disappear when the user carries out some action (accepts, rejects or ask for informations) about the requests, otherwise the notifications remain visible.

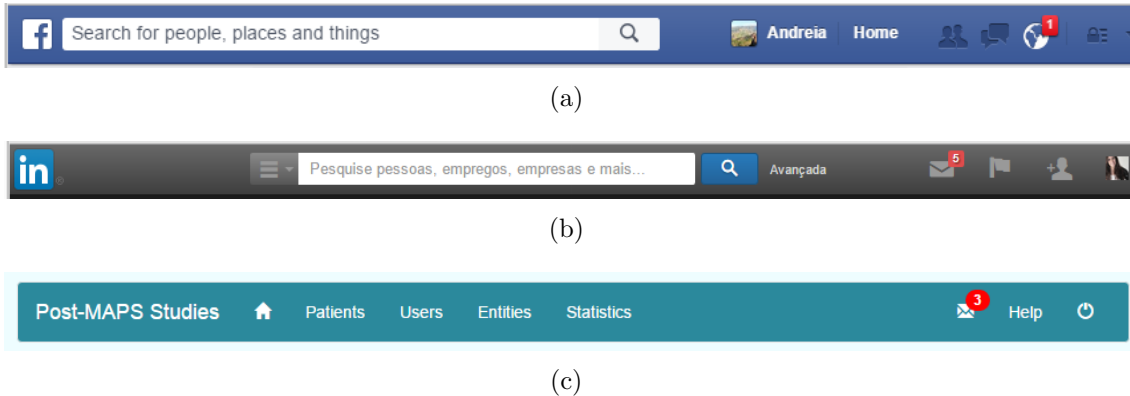


Fig. 5.5: Examples of well-known applications where notifications are used: a) Facebook notifications [4]; b) LinkedIn notifications [5]; c) Post-MAPS notifications.

Shortcuts

Apart from the insertion flow mentioned above, the user also has the possibility to enter data the way it find most convenient. In the red container some shortcuts are available that let user freely navigate through the various forms, Fig. 5.6. This is a valuable feature for more experienced users who have no need of help at the

insertion moment. On the other hand, users may not have at their disposal any information or may not want to follow the suggested flow. These shortcuts make the user experience more pleasant as they can speed up the interaction for more experienced users, allowing them to not get tired over the application use. The shortcuts must be always visible and let the user follow other paths if he wishes or needs to do so [45].

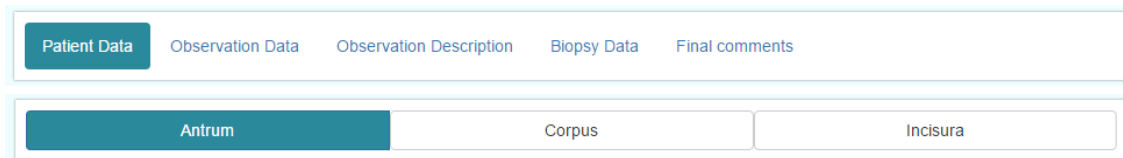


Fig. 5.6: Example of some shortcuts available in the application.

Colors and buttons

When developing an application, consistency and standards are fundamental, since the user should not have doubts whether actions, words or even colors are associated with different events [44]. Thus, throughout the interface, consistency is maintained in the colors allocated to certain actions:

- Green: associated to acceptance/confirmation actions. For example, the validation of an access request. This color is also used for validation on the fly, indicating that the data are correct.
- Red: associated to rejection/error actions, such as rejecting a request access to the application. This color is also used in data validation to indicate that something is wrong.
- Blue: blue buttons always perform a submission or insertion operation.
- White: buttons that cancel operations or close windows are always white.
- Yellow: it is not widely used over the interface. It is only used on access requests management, when the administrator does not have enough information to accept a request. It is used because this color is associated to warnings, representing lower risk than red but higher than green.

Drag and drop

- Select symptoms:

Several options were analyzed in order to display a list of symptoms. The major concern was not to make the screen size dependent on the symptoms list, since it may be enhanced in the future. Thus, options as checkboxes were excluded because they can grow indefinitely. The possibility to use a dropdown select was considered, but once again, the usability was conditioned by the number of symptoms.

After this analysis, it was decided to use a small container where some symptoms are visible (to see the rest, the user must scroll in this container). sTwo different ways were defined to choose the associated symptoms within the patient: to drag a symptom and drop it in the patient's symptoms container (drag and drop) or select symptoms and click on the arrow pointing to the patient's symptoms container. In Fig. 5.7 is presented a screenshot of the patient symptom insertion, where it can be seen the container with a list of symptoms and the container where they can be put.

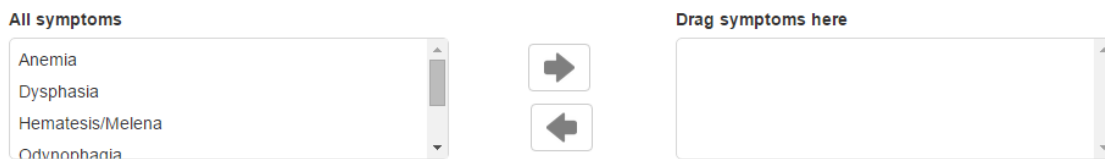


Fig. 5.7: Selection of the patient's symptoms.

The Drag and drop is an interactive and widely used feature, in which the user "grabs" an item that he wants and drags it to the desired location. In the example, the user takes the symptom and drags it to the patient symptoms container. Selecting the symptoms and clicking on the arrow is a more traditional feature and leaves less experienced users more comfortable during symptom choice.

- Select images:

In the image selection interface there are also two distinct features available to the user: one more traditional, which is to click the "Select files" button and let the user choose the images that he want to upload to the application; other directed at experienced users, where it is possible to drag the images from computer directories for a container. The selected or blurred images are immediately available for viewing, as shown in Fig. 5.8.

It is very important that an interface is designed for all potential users, including the

most experienced, so that they can perform certain tasks more quickly and efficiently as possible [36].

Images

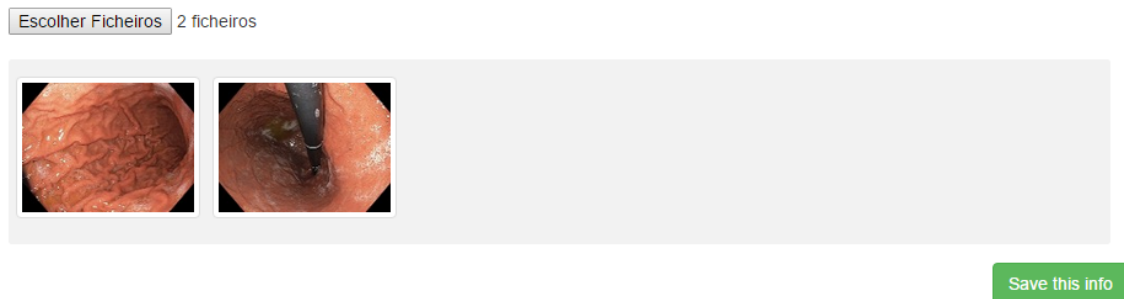


Fig. 5.8: Image upload interface through which it is possible to upload images by two different ways: by clicking the "upload files" button and select images; drag images from the directory and drop it into the grey container.

Validation on the fly

The validation on the fly ensures that input errors may be easily avoided. This feature lets the user see if the data is correct, even before submitting the data. For example, if on a birth date the user attempts to enter a name, he immediately realizes that something is wrong. When the data is incorrect, the validation on the fly aspect is displayed in Fig. 5.9 b). The red color and a cross are used as they are associated with danger/error. If the data is correct, feedback is also given to the user, as Fig. 5.9 a) shows. The green color and a tick are used, since they are associated with success.

This feature will make the user more comfortable when inserting data, as it will receive feedback as it goes. Thus, it avoids the frustration feeling that most users experiment when after submitting a form with incorrect data, they have to re-enter it all [31]. Better than an error message, is an interface that prevents its occurrence [36].

Autocomplete with dropdown select

Another major concern of this interface was making data input dynamic, i.e., by always providing an option to insert information that the user thinks might be missing or not available in a dropdown select. Therefore, we decided to conjugate two different features:

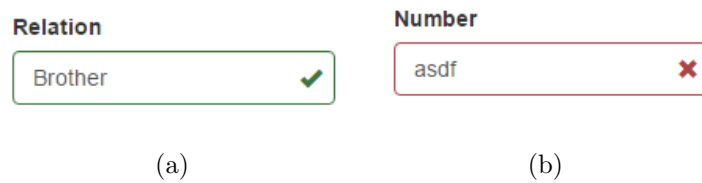


Fig. 5.9: Validation on the fly examples: a) aspect in the case of correct data; b) aspect in the case of wrong data.

- Dropdown select, where the user can select the option from a list.
- Autocomplete, which enables users to quickly find and select from a pre-populated list of values as they type, leveraging searching and filtering.

In Fig. 5.10 it is possible to see an example of an autocomplete input with dropdown select.

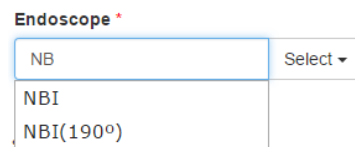


Fig. 5.10: Autocomplete intup with dropdown select.

If the user does not find the information that he needs in the dropdown list or in the autocomplete, he will have the possibility to enter the missing data. As already mentioned above, it is the responsibility of the Post-MAPS administrator to validate the new data that will be entered into the master files. This flexibility facilitates the task of data insertion, since simplicity is maintained for less experienced users and at the same time accelerates the interaction for experienced users, which accounts for a more practical and satisfactory experience.

Feedback

When the user finishes filling out the form, there is an option to allow him to close the exam if all the required fields are filled. If the user tries to close an incomplete exam, in addition to receiving an immediate error message, the shortcuts will show a reddish color. In Fig. 5.11 there is an example in which is shown an attempt of closing an exam without filling the required information related to the patient and the observation description. The shortcuts related to the missing information present a reddish color in order to alert the user where is the lack of information. This feature helps the users to not have to look all over the form.

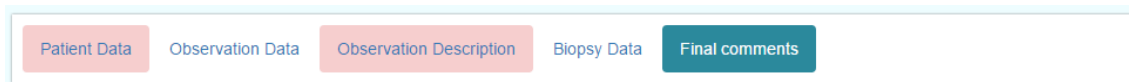


Fig. 5.11: Aspect of the shortcuts when a user tries to close an exam with patient informations and description of the missing observation.

Hide information

All the information that is presented to the user should be relevant and necessary, otherwise it may be cause for distraction. If this is not relevant, it eventually changes the focus from the important information. To help user to focus on the main task, an area has been created (depicted in the yellow container of Fig. 5.4), where related information, but unnecessary at the moment, is stored. For example, during the pre-biopsy data insertion, the user's main task is data entry. As he goes about submitting the data, it will be partially hidden in the container shown in Fig. 5.12 a). So, on the same screen, the user has at its disposal all the information it needs, but in an organized fashion to keep the focus only on its task. To view the entered data, the user simply has to click on the container, Fig. 5.12 b).

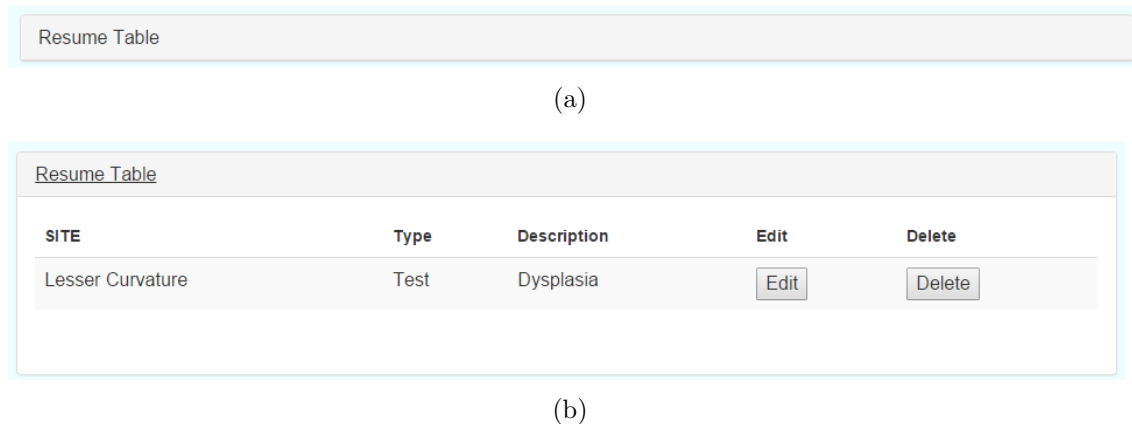


Fig. 5.12: Yellow container: a) with hidden information; b) with extended information.

Dialogs

The dialogs are used during insertion of post biopsy data, since the amount of information that is requested does not justify the submission in a new page. So, by clicking on the icon below "Add results", Fig. 5.13 a), a dialog will open with the form to insert the remaining data. Behind the dialog, the user continues to view all data, Fig. 5.13 b), in the background.

Once the user submits it, the dialog is closed, and the user returns to the starting page, where he can immediately understand what were the changes he just made. This way, the probability of the user getting overwhelmed or navigating to a screen that he does not want, is reduced.

Did you suspect/diagnose any superficial lesion (eg, suspicion of dysplasia/carcinoma)?

| SITE | Type | Description | Histology | HP | Add results |
|------------------|------|-------------|-----------|----|-------------|
| Lesser Curvature | Test | Dysplasia | | | |

(a)

(b)

Fig. 5.13: Post-biopsy data insertion: a) incomplete data; b) dialog with the short post-biopsy form where, behind, it can see the other information.

5.2.3 New features

Request access

Unregistered users that wish access to Post-MAPS can require it through the login page, clicking on "Request Access". A dialog with a short form that they have to fill will appear. After data submission, the Post-MAPS administrator is immediately notified by e-mail that there is a new request for access, as it is his responsibility to manage these requests. This feature allows users to request access to the platform without the need to communicate with the Post-MAPS administrator.

Manage request access

As mentioned above, it is the responsibility of the Post-MAPS administrator to manage and make all decisions regarding access requests. There are two distinct

ways to access the requests management: through the menu (Users - Requests) or by clicking in the notifications present in the menu.

In the requests management page, the Post-MAPS administrator can accept, reject or request information from users. He should accept a request when all the informations are correct; reject it when there is no consistency in the data; request informations when there is dubious information or when already exists an entity administrator with access. In any type of , the user is always notified via e-mail. That the Post-MAPS administrator only manages requests coming from entities administrators. Fig. 5.14 depicts the appearance of access request management page.

| Name | Email | Institution | Request Date | Accept |
|-----------------|----------------------------|-------------|--------------|-------------|
| Andreia Moreira | andreiamoreira05@gmail.com | HSJ | 2015/07/28 | Yes Info No |
| Joana Almeida | andreiapgmoreira@gmail.com | Julio Dinis | 2015/07/17 | Yes Info No |

Total: 2

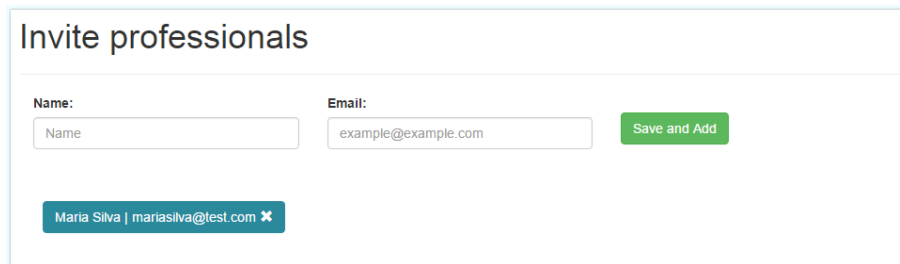
Fig. 5.14: Request management interface.

Invite users

The entity administrators registered in Post-MAPS can invite users to participate in the study through the platform (Menu - Invite users), by only needing to write the name and the email of the person. The invited users are also notified by e-mail, where there is a link with access to a short form which they should fill with the remaining missing data, if they accept the invitation. Fig. 5.15 depicts the appearance of the page to invite the users. This feature speeds up the whole user registration process in the application, since it is made without any kind of intermediate user.

Dashboards with metrics

In the dashboard there are some metrics available that provide relevant information to users and are not always of immediate perception. Upon entering the application, the user has at its disposal the sum of all incomplete exams, the sum of complete



The screenshot shows a web interface titled "Invite professionals". It contains a form with two input fields: "Name" and "Email". The "Email" field contains the text "example@example.com". To the right of the "Email" field is a green button labeled "Save and Add". Below the form, there is a list of added users, with one entry visible: "Maria Silva | mariasilva@test.com" followed by a close icon (✕).

Fig. 5.15: Invite users interface.

exams and also his patient totals, Fig. 5.16. The incomplete exams are shown in red, to draw the user's attention, giving him the indication that there is missing information. In this way, the user can better organize all tasks in the applications. In addition to the presented metrics it is possible to add other according to user requirements.

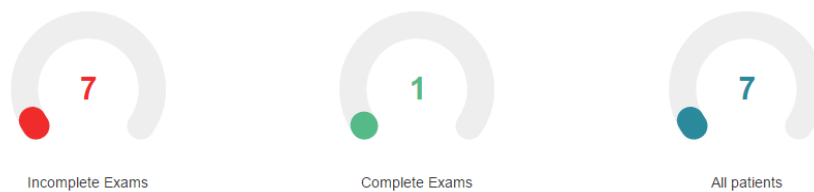
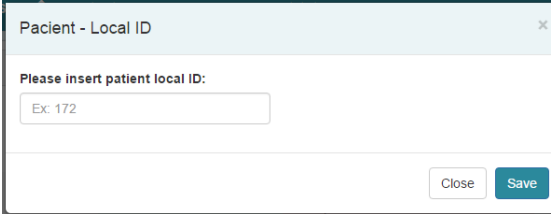


Fig. 5.16: Example of some metrics present in the dashboard.

Patient local ID

When inserting a new observation, it is always requested to the user to indicate the patient local id, through which is possible to check if a record already exists. Some data associated to a patient remains static, such as, the date and place of birth. If there are already records for the inserted local id, all personal data of this patient will be provided. This practice assists and simplifies the user's work since it is no longer necessary to insert data repeatedly, not removing the ability to edit them, if necessary.

A dialog is used, since the requested information from the user (only the patient local id) is not too much to be displayed in a web page. When the user clicks on "Insert exam", the dialog shown in Fig. 5.17 pops up. After submitting the form, the user is forwarded to the patient profile page.



A dialog box titled "Patient - Local ID" with a close button in the top right corner. The main content area contains the text "Please insert patient local ID:" followed by a text input field with the placeholder text "Ex: 172". At the bottom right of the dialog, there are two buttons: "Close" and "Save".

Fig. 5.17: Dialog with a short form where the user must indicate the patient local ID.

Exam visualization

Exam visualization is only possible when its data is complete, allowing users to have access to all stored information. The user can visualize a complete examination through different ways: through the dashboard, by clicking in "Complete exams"; through the menu (Exams - Complete); through the users (Patient - Exams).

Manage entities

The Post-MAPS administrator is the only user able to manage all information related to the entities, consulting and editing related information as necessary. Fig. 5.18 shows the entities listing, from which the administrator also has access to all registered users.



The "Entities Listing" interface shows a table with columns for ID, Designation, Nr of users, and Actions. There are two rows of data: one for "IPO" with 2 users, and one for "Postmaps" with 1 user. Each row has "Edit" and "View Users" buttons. The interface also includes a search bar, a display count of 10, and pagination controls.

| ID | Designation | Nr of users | Actions |
|----|-------------|-------------|-----------------|
| 8 | IPO | 2 | Edit View Users |
| 9 | Postmaps | 1 | Edit View Users |

Fig. 5.18: Listing entities interface through which it is possible to edit its information and access to its users.

5.3 Development

5.3.1 Technologies

During the development of the application we used WampServer. WampServer is a free web development environment for Windows that allows the creation of web

applications with Apache 2, PHP and MySQL database. It offers a tool, phpMyAdmin, that allows easy management of the MySQL database. Web languages have been chosen (described below), due to the previous knowledge of these languages and for being compatible with almost all servers in use today. Additionally, they are free [46].

PHP

PHP (Hypertext Preprocessor) is a server-side language. It is a widely-used, open source scripting language specially suited for web development and can be embedded into HTML [47]. PHP code is usually processed by a PHP interpreter which is usually implemented as a web server's native module. After the PHP code is interpreted and executed, the web server sends the response to its client, usually in form of a part of the generated web page.

Apache HTTP Server

The Apache HTTP server is a software (or program) that runs in the background under an appropriate operating system. The web server Apache receives the client's requisition (browser) and answers it in HTML code. The Apache neither comprehend HTML code nor understand the PHP code. When it receives a request .php, the server set the PHP interpreter which process the PHP request (for example, database access, email server access) and returns it in HTML format to the Apache that sends it to the browser. The browser reads the HTML code and creates the web page for the user [48].

MySQL

MySQL is an opensource relational database management system (RDBMS).

phpMyAdmin

During the application's development it was used a web tool, free and open-source, for a better management of the MySQL database, the phpMyAdmin. The phpMyAdmin is written in PHP intended to handle the administration of MySQL with the use of a web browser. It can perform various tasks such as creating, modifying or deleting databases, tables, fields or rows; executing SQL statements; or managing users and permissions [49].

HTML and CSS

The HTML (Hypertext Markup Language) is a markup language used to create web documents (web pages) [50]. It is written in the form of HTML elements, called tags, that are used to create a document that will be displayed using a browser. HTML elements form the building blocks of all websites and allow images and objects to be embedded and can be used to create interactive forms. The HTML is an independent language of platforms that can be used in any one (such as Linux, Windows or other).

The CSS (Cascade Style Sheets) is a style sheet language used for describing the look or formatting of a document written in a markup language. So, the CSS defines how HTML elements are to be displayed. For example, CSS covers fonts, colors, margins, lines, width, height, positions and many other things [51].

JavaScript

JavaScript is an object-oriented programming language used to develop interactive webpages and create web applications. Client-side JavaScript programs, or scripts, can be embedded directly in HTML source of Web pages. The language supports several built-in objects, and programmers can create or delete their own objects. It is widely supported and it is available in most browsers [52].

JQuery and JQuery UI

JQuery is a fast, small, and feature-rich JavaScript library. It makes things like HTML document traversal and manipulation, event handling, animation, and Ajax much simpler with an easy-to-use API that works across a multitude of browsers [53].

JQuery UI is a curated set of user interface interactions, effects, widgets, and themes built on top of the jQuery JavaScript Library [54].

Bootstrap

Bootstrap is the most popular HTML, CSS, and JavaScript framework for developing responsive, mobile-first web sites. It is a free front-end framework for faster and easier web development that includes HTML and CSS based design templates for typography, forms, buttons, tables, navigation, modals, image carousels and many other, as well as optional JavaScript plugins. Bootstrap also gives you the ability to easily create responsive designs [55].

5.3.2 Architecture

The architecture of this application is based on client-server model. The client is usually a browser (Chrome, Firefox, Internet Explorer, or other), and the server is an application in the form of a service, hosted remotely. This application uses the Apache HTTP Server. The user accessing the Post-MAPS through a browser makes a request to the server. The server processes the request and generates a response that the browser receives and interprets, build a web page.

In a web application there are always two types of programming: client-side and server-side programming. The client-side programming (HTML, Bootstrap, CSS, JavaScript, JQuery) generates the content rendered by the browser and displayed to the user. The server-side programming (PHP) includes access to data (MySQL), calculations and all the algorithms that must be performed on the server side (DAL and php scripts). In the Fig. 5.20 is represented an application architecture scheme. All pages presented to the user are created in HTML. The Bootstrap is used in the creation of all forms, dialogs, menus, buttons and shortcuts, and because it allows the development of responsive design, enabling the platform's use in mobile devices. CSS is used for formatting styles of some artifacts, to change its dimension, position, color, size and font. The JQuery UI is used to create the datatables and widgets displayed in the dashboard, for example, the Knobs, which presents the metrics. The JQuery is used to create animations, make ajax requests and for event handlings, such as clicking a button and dialog arise, or clicking a "delete" button and delete a row of a table.

Mirth Connect (MC) is an open source healthcare data integration engine and allows to transport healthcare informations between data sources and destinations in a quick and easy way. The MC supports a wide variety of message types such HL7 (v2 and v3), DICOM, XML, Delimited Text and others, and uses a channel-based architecture to connect health systems and allow messages to be filtered, transformed and routed based on rules defined by users [56].

In this platform, the MC receives an HL7 message from an endoscopy equipment, Fig. 5.20. Then, it makes the mapping of the message fields for the databases tables columns according to defined rules, i.e., as defined correspondence between the segments fields and columns databases columns.

For example, it was defined that the second field of PID segment (shown in

```
MSH|^~\&|ENDO LAB|ELAB-3|ENDO OE|BLDG4|201509150930||ORU^R01|CNTRL-3456|P|2.4
PID|1|00001234|00001234||PHILIPS^JOHN^E^IJR.||19580704|M||WH|17628 AVOCADO
AV^^TUSTIN^CA^92780|OC|(206)3345232|(206)752-121||||||||||
```

Fig. 5.19: Extract of an HL7 message (version 2.4).

red in the extract of an HL7 message, Fig. 5.19), corresponds to *localID* column of *patient_ehr* table. In this way, it will result the following query that makes the *localID* insert of a patient in *patient_ehr* table:

```
INSERT INTO patient_ehr (localID) VALUES ($localID);
```

Then, the MC receives a DICOM message, also from the endoscopy equipment, and transforms it into a XML file. A DICOM message is communicated in two parts: the metadata of the image and the image. The Mirth analyses the metadata and searches the identifiers of the patient and of the exam, that are used for searching in the database to obtain the *observationID* to which the image will be associated. The Mirth sends the image to a directory reserved only for DICOM images, as configured, and makes an update to the *images* pointer of *lesion_suspicion* table:

```
UPDATE lesion_suspicion SET images = "directory of DICOM images"
WHERE observationID = "observationID obtained";
```

5.4 Discussion

In the platform development there was special care with the amount of information submitted to users by screen. Accordingly, a new data entry flow was defined, in which there is a clear separation between the patient data, the observation data and before and after biopsy data. This new flow helps users to focus on their tasks, since all the information they need is on the screen without need to scroll the page to access the rest of form. Although the defined flow is the ideal for data entry, there were available some shortcuts for experienced users to freely navigate through the different forms.

In the design and construction of the platform's interfaces there was also special care with its organization, with its aspect, with the layout and location of the artifacts. All interfaces have a new aspect, simpler, more aesthetically appealing and

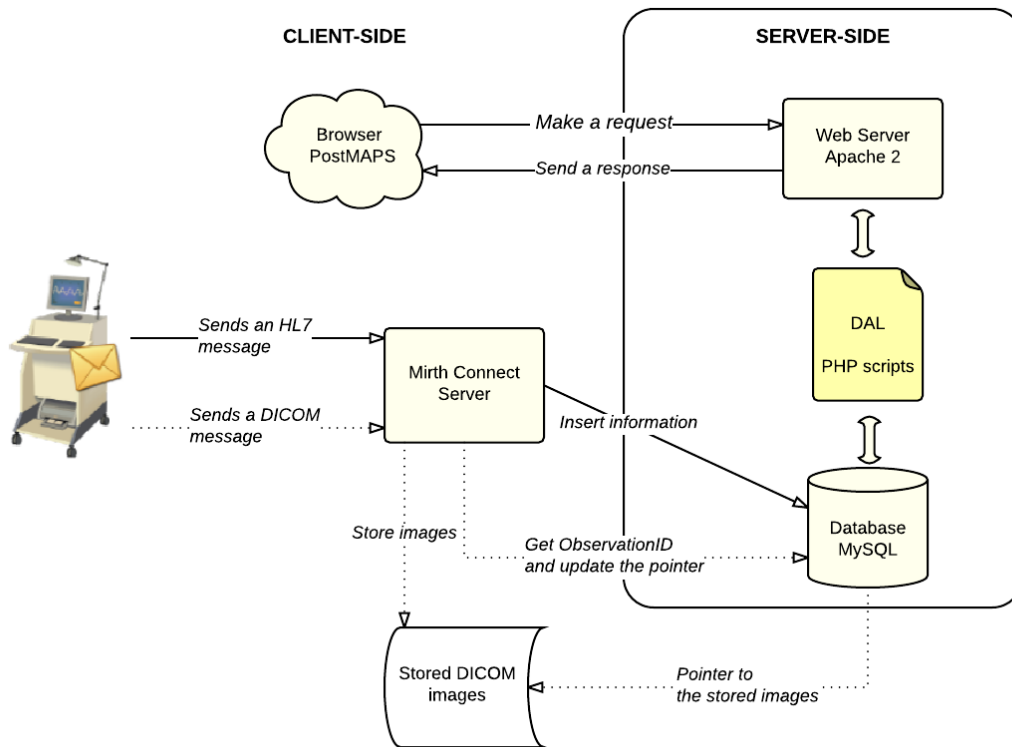


Fig. 5.20: Post-MAPS architecture.

easy to use. Basic features have been retained and enhanced and added new, having already been available tools to help users during their interaction with the platform, preventing errors during data entry and allowing greater speed in performing tasks.

Furthermore, the database was designed to allow its growth and to facilitate statistical analysis performing on the stored data.

Chapter 6

Conclusion

The main objective of this project, which was the development of a data acquisition platform from gastroenterological exams, was achieved.

An analysis of the Post-MAPS application revealed usability issues and lack of crucial features, which could condition the users' tasks and make their experience somewhat frustrating and a bit exhausting. A preliminary study was also conducted in order to evaluate the platform's usability. A survey was sent to all registered users on the platform, and, regardless of the small sample used, it was possible to take some conclusions that helped us understand what were the needs of users and which variables can affect their perceived usability.

A major challenge during the development of the platform was the interface organization and the definition of data insertion flow. So we decided to divide the interface into five different containers that separate the menu, shortcuts, forms, non relevant information and insertion flow buttons. This way we help users recognize them easily, separating what is related to what it is not. Regarding the entry flow, there is a clear separation between patient data, observation data, and pre and post biopsy data, providing all the information a user needs on the screen, without the need of scrolling. Tools were also made available, allowing more experienced users to navigate freely through the different forms. Other improvements were also added such as:

- Notifications, which provide the administrator the immediate perception that it has pending access requests;
- Validation on the fly, which helps users understand if the data they are entering are incorrect, before submitting the form;

- Autocomplete with dropdown select, which makes data entry dynamic, not limiting the options to users;
- Feedback, allowing users to realize immediately where incomplete information is, without having to go through all the forms;
- Hide information that helps users to focus on their tasks and in relevant and necessary data;
- Dialogs, used to give feedback to users after entering, editing, or deleting data, but also for small forms.

In addition we added new features, non existent on the previously developed platform:

- Request access and invite colleagues from the same organization to access the platform;
- Manage access requests, where the administrator can accept, reject or ask for informations;
- Dashboard with metrics that enable users to have immediate perception of the number of patients, as well as incomplete and complete exams;
- Patient concept, in which it is no longer necessary to re-enter information if the patient is already registered;
- View completed exams, i.e., data display from a gastroenterological exam inserted into the platform;
- Manage entities, which allows the administrator to edit informations of entities and also has access to all registered users.

With this construction the consistency and the standards are also well distributed and positioned on the interface. Also, we always tried to combine beauty, simplicity and functionality to create an excellent and comfortable user experience. There was also attention in creating a platform with a responsive design that easily adapts to all types of screens, including mobile devices.

We were able to integrate the platform with Mirth Connect, which receives and filters HL7 messages from an endoscopic equipment. It then maps message fields for the database columns, as it was previously configured, and executes the query for

data insertion in the database. However, for lack of time, the data entry visualization through Mirth Connect has not been developed. It was not possible to use the openEHR standard to achieve platform semantic interoperability with other health systems since there are no defined archetypes for the gastroenterological area in the CKM repository.

With this new platform we hope to help users accomplish their tasks by providing tools that help them focus, carrying them out more quickly and reducing the incidence of errors. So, we hope users will find the experience more pleasant, submitting data more frequently and with less incidence of errors, thus contributing to new clinical knowledge in gastroenterology area.

6.1 Future work

Although the developed platform is functional, it is still necessary to carry out several tests to detect and solve small failures, and to add small improvements or features, concerning the needs. It is also necessary its deployment, so it can be used in different institutions, by people who really need to interact with the platform. After some time using the platform, it would also be interesting to conduct a new preliminary study to evaluate the platform usability in order to realize where there may still be improvement points. It would also be interesting to conduct a preliminary study, after some time of use, to assess the platform usability and understand where there may be improvement points.

There are still some features that can be added to the platform, in a future work, which were not developed for lack of time. We can highlight:

- Statistical module, where users could be able to do some statistical analysis over the data they submitted on the platform;
- Image annotation, where users could highlight the focus area to the image uploaded to the platform, subsequently facilitating the interest area to display;
- Automatic and filtered data export, where users could extract data according to their needs, i.e., by custom settings to, for example, import them in other software or to perform other analysis.

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Appendix **A**

Post-MAPS Protocol

Protocol:

**Prevalence, diagnosis and management of gastric
pre-neoplastic and neoplastic lesions: An European
Multicentre study**

Protocol Code: "Pos-MAPS study"

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SUMMARY

Introduction: Gastric atrophy and intestinal metaplasia are considered the principal precursors for gastric cancer. Although current guidelines recommend surveillance of individuals with these conditions, the best method for its identification and the best time schedule for follow-up are still controversial.

Aims: To determine the more accurate way for identifying individuals with advance stages of gastric precancerous conditions (HR-NBI and targeted biopsies vs. random biopsies with conventional endoscopy); To estimate which is the incidence rate for dysplasia among individuals with advance stages of gastric precancerous conditions.

Methods: A multicenter cohort study involving various gastroenterology centres from several European countries. In the first study (study A) consecutive patients performing upper endoscopy will be evaluated by HR-NBI and by conventional endoscopy in order to determine if HR-NBI with targeted biopsies can replace the common/standard random biopsies. In the second study (study B), patients with advanced stages of gastric preneoplastic lesions will be randomized to a schedule of annual endoscopy or to a 3 and 5 year follow-up endoscopy in order to establish the incidence rate of dysplasia and the best surveillance schedule for patients with these conditions.

Expected results: Gastroscopy using HR-NBI may obviate the need of biopsies in gastric mucosa in order to identify those individuals to be followed-up due to their high-risk for gastric cancer. A precise incidence rate of dysplasia among patients with gastric preneoplastic lesions will be established. Furthermore, an improvement of the definitions and current guidelines can be expected.

INTRODUCTION

Correa was the first one to describe a multistep pathway for the intestinal-type gastric adenocarcinoma, where *Helicobacter pylori* is considered the initiator of the so-called Correa cascade of gastric carcinogenesis that involves chronic gastritis, atrophic gastritis, intestinal metaplasia, gastric dysplasia and, finally, intestinal-type gastric adenocarcinoma. However, less than 1% of patients colonized by this bacterium appear to evolve into gastric adenocarcinoma. Moreover, among patients with atrophic changes in gastric mucosa, only those with advanced stages of atrophy and/or intestinal metaplasia seem to be at higher risk to develop neoplastic changes and therefore will benefit of a different management. A follow-up endoscopy every 3 years, if no dysplasia is observed, was recommended for these patients (Dinis-Ribeiro M et al. 2012) even though based on sparse evidence and mostly based on expert opinion.

Nevertheless, it is noticeable that:

- the yield of conventional endoscopy to identify these lesions is not optimal;
- the 'morphological assessment' solely based on the histopathological assessment of biopsies in antrum and in corpus was still recommended as the "gold-standard" to identify those individuals at a higher risk for gastric carcinoma but problems were also noted as the inter-observer agreement in the histopathological assessment is concerned;
- a "serological 'biopsy'" could also be relevant but this was seldom addressed in Western countries.

Recently, a classification of endoscopic features with high-resolution and NBI was described as reliable and accurate for the diagnosis of gastric mucosal changes such as intestinal metaplasia and dysplasia (Pimentel-Nunes P et al. 2012). Indeed, NBI seems to increase the detection of dysplasia lesions during the surveillance of patients with atrophy and intestinal metaplasia (Capelle LG et al 2010).

We believe that a "large cohort data" could improve estimates of current guidelines and potentially redefine the "gold-standard" of 'a at risk profile'.

AIMS

Primary aims:

1. To determine the accuracy of HR-NBI and targeted biopsies vs. random biopsies with conventional endoscopy to identify individuals with advance stages of gastric precancerous conditions;
2. To estimate which is the incidence rate for dysplasia among individuals with advance stages of gastric precancerous conditions;

Secondary aims:

1. To estimate the true prevalence of gastric precancerous conditions and lesions in the European population;
2. To determine if random biopsies of incisura increase the diagnostic yield for gastric preneoplastic lesions;
3. To clarify the phenotype of risk for gastric dysplasia and cancer;
4. To establish the most cost-effective surveillance schedule for individuals with gastric preneoplastic conditions.

METHODS

In order to answer to the two primary aims of this project, two studies were delineated:

Study A

Accuracy of high-resolution endoscopy with NBI for the diagnosis of gastric preneoplastic lesions

Research question

Can the endoscopic assessment of gastric mucosa with HR-NBI replace random biopsies to identify individuals with gastric preneoplastic and neoplastic lesions?

Patients' selection and Study design

- A multicenter cohort study;
- Individuals older than 45 years submitted to upper GI endoscopy;
- The majority of patients will be submitted to HR-NBI and conventional assessment on the same day (day 1);
- A subset of patients will be submitted only to conventional endoscopy (in the centres that do not have scopes with HR-NBI);
- Exclusion criteria for participation on the study will be: known gastric pathology; history of previous gastric surgery; serious co-morbidities (hepatic, renal, pulmonary or cardiac failure); medication with anticoagulants.

Procedures

- Endoscopists will be included according to their experience with HR-NBI;
- "HR-NBI endoscopy and targeted biopsies": using Olympus endoscopes, GIF-H 180 or 190 (preferably), gastroscopy will be performed and targeted biopsies will be performed in antrum, incisura and corpus if changes are observed suggestive of precancerous conditions and/or

lesions (atrophy, intestinal metaplasia or dysplasia) (Pimentel-Nunes P (2012)) **(educational video will be provided to participants)**;

- “Conventional assessment and random biopsies”: If no changes were determined by HR-NBI (or in the centres without HR-NBI scopes), random biopsies will be performed in antrum, incisura and corpus according to Sydney-Houston protocol (Dixon 1994)
- All endoscopic procedures will be recorded for further quality assessment and reliability evaluation;
- Endoscopic images will be taken from all the sites of biopsy samples;
- All specimens collected are sent to histopathological assessment in separate jars;
- Both OLGA (Operative Link for Gastritis Assessment) and OLGIM (operative link on intestinal metaplasia assessment) will be used and individuals classified accordingly (Rugge 2007, Capelle 2010);
- Blood collection will be performed for further analysis.

Outcomes

- Proportion of individuals with OLGIM III/IV (Main outcome);
- Proportion of individuals with OLGA III/IV;
- Proportion of individuals with dysplasia;
- Proportion of changes in incisura angularis.

Sample size and Planned Statistical analysis

- OLGIM assessment seems to be more reliable than OLGA (Capelle LG 2010).
- We consider that: the proportion of individuals with main outcome may vary between 10 and 20% (Capelle LG 2010, Lomba-Viana R 2012, Dinis-Ribeiro M 2004);
- Assuming random biopsies as the current "gold-standard" (identifying per definition all cases, i.e., all individuals with a risk profile are defined according to histology), the sensitivity for “Conventional assessment and random biopsies” may be considered higher than 95%;
- In conclusion, number of patients needed to detect no more than a 10% difference in the sensitivity and the specificity of the two procedures (“HR-

NBI endoscopy and targeted biopsies” vs. “Conventional endoscopy and random biopsies”) with a power of 90% and a type I error rate of 0.05 is 1065;

- Per centre will have to include no more than 100 patients with more than 45 years old, perform NBI in all of them with biopsies, store all videos of all endoscopies (with a standard protocol), collect blood from all patients; follow-up approximately 40 patients; and 10 on an yearly basis and 30 at 3 years.

Expected results

- Gastroscopy using HR-NBI may obviate the need of biopsies in gastric mucosa to identify those individuals to be followed-up due to their high-risk for gastric cancer;
- We would like also to consider this cohort of individuals for follow-up. All individuals will be followed-up and assessed at least in 3 and 5 years; and a refinement of the definitions and current guidelines can be expected (STUDY B).

Study B

Risk of dysplasia among patients with advanced gastric atrophy: a multicenter cohort and randomized study

Research question

Which is the incidence rate for dysplasia among individuals with advanced stages of gastric precancerous conditions?

Patients' selection and Study design

- A multicenter randomized controlled study of individuals from study A:
 - o 'Exposed' individuals will be considered those with OLGIM III/IV or those with endoscopic changes and no intestinal metaplasia in the corpus (or those with positivity for pepsinogen if performed);
 - o 'Unexposed' individuals will be considered as those without these phenotype matched for age (+/- 5 years, gender and H. pylori status after eradication).

- Individuals will be randomized on a 1:1 to:
 - o A – Follow-up at 3 years and 5 years (approximately n= 200);
 - o B – Follow-up every 1 year to 5 years (approximately n=200).

Procedures

- All individuals will be followed-up and submitted to "HR-NBI endoscopy and targeted biopsies": using Olympus endoscopes, GIF-H 180 or 190 (preferably), gastroscopy will be performed and targeted biopsies will be performed in antrum, incisura and corpus if changes are observed suggestive of precancerous conditions and/or lesions (atrophy, intestinal metaplasia or dysplasia) according to Pimentel-Nunes P (2012);
- Histopathology assessment according to OLGA and OLGIM classification (Rugge 2007, Capelle 2010);
- All endoscopies will be recorded for further assessment;
- Blood collection will be performed for further analysis.

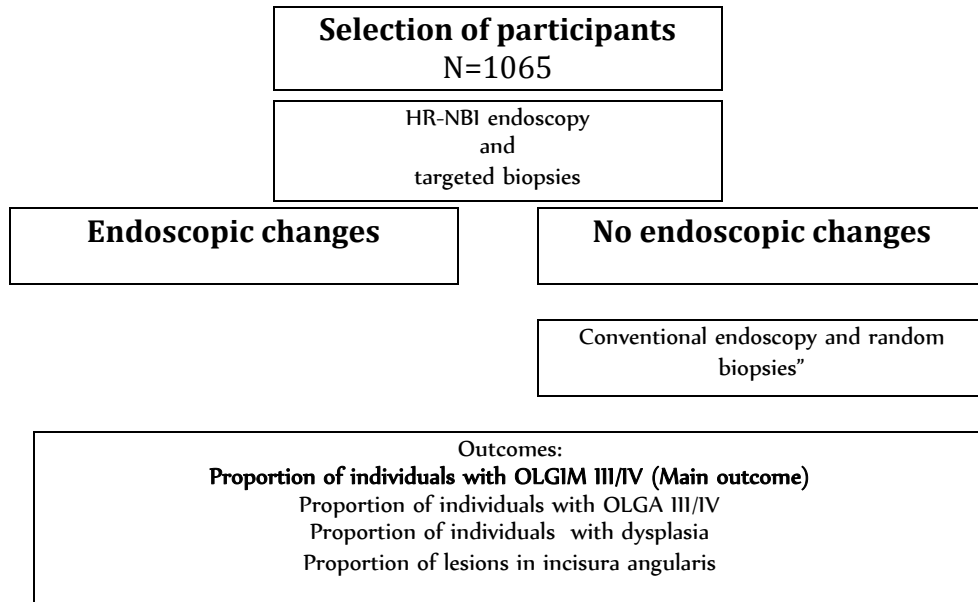
Outcomes

- Proportion of individuals with dysplasia;
- If HR-NBI does provides an alternative for current "gold-standard";
- Taxonomies for Improving the recognition of suggestive precancerous conditions and/or lesions;

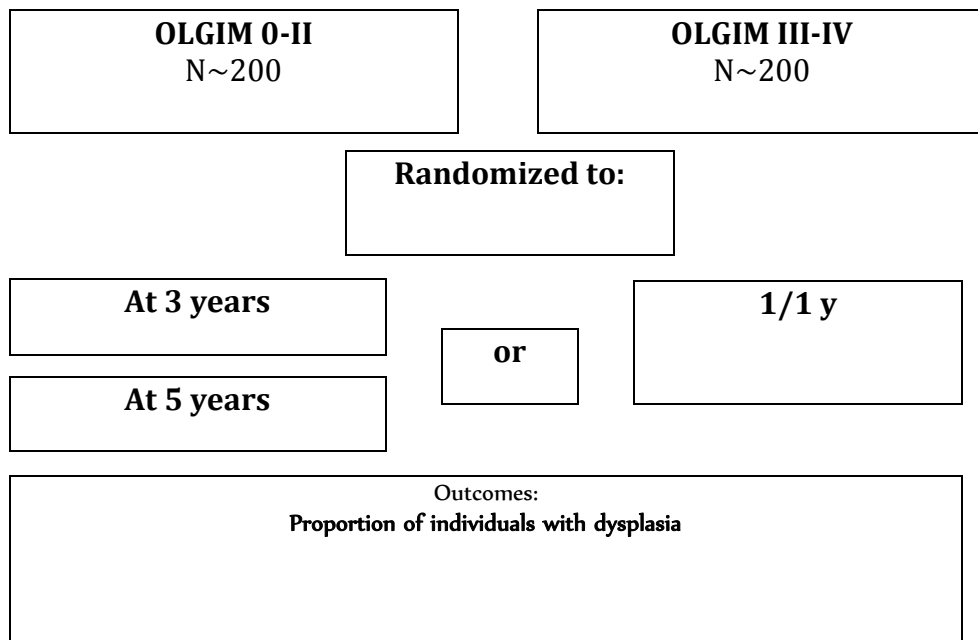
Expected results

- Refinement of the definitions and current guidelines can be expected.
- Moreover, this data will be used for accuracy assessment (follow-up studies C...Z, A1...).

Study A



Study B



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Appendix B

Usability Evaluation Survey


Post-MAPS - Usability Evaluation

This evaluation relates to the usage of the Post-MAPS platform. Please, take in consideration that you are evaluating the insertion of new cases in the platform and not administrative functions of the same. We estimate that this evaluation will take you around 15 minutes to conclude.

You will be asked about some personal information, that will be used for statistics, but will never be used for user evaluation.

All questions will be measured on a 7-point Likert scale, where 1 = strongly disagree, 2 = moderately disagree, 3 = somewhat disagree, 4 = neutral (neither disagree nor agree), 5 = somewhat agree, 6 = moderately agree, and 7 = strongly agree.

[Continuar »](#)

 9% concluido

Personal information

Name *

Email used in the Post-MAPS as login *


City *

Age *

Years of experience *

[« Anterior](#)

[Continuar »](#)

 18% concluido

Intention to Use

Assuming I have access to the system, I intend to use it. *

1 2 3 4 5 6 7

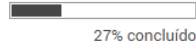
strongly disagree strongly agree

Given that I have access to the system, I predict that I would use it. *

1 2 3 4 5 6 7

strongly disagree strongly agree

[« Anterior](#) [Continuar »](#)



Perceived Usefulness

Using the system improves my performance in my job. *

1 2 3 4 5 6 7

strongly disagree strongly agree

Using the system in my job increases my productivity. *

1 2 3 4 5 6 7

strongly disagree strongly agree

Using the system enhances my effectiveness in my job. *

1 2 3 4 5 6 7

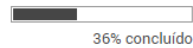
strongly disagree strongly agree

I find the system to be useful in my job. *

1 2 3 4 5 6 7

strongly disagree strongly agree

[« Anterior](#) [Continuar »](#)



Perceived Ease of Use

My interaction with the system is clear and understandable. *

1 2 3 4 5 6 7

strongly disagree strongly agree

Interacting with the system does not require a lot of my mental effort. *

1 2 3 4 5 6 7

strongly disagree strongly agree

I find the system to be easy to use. *

1 2 3 4 5 6 7

strongly disagree strongly agree


I find it easy to get the system to do what I want it to do. *

1 2 3 4 5 6 7

strongly disagree strongly agree

« Anterior

Continuar »

 45% concluído

Subjective Norm

People who influence my behavior think that I should use the system. *

1 2 3 4 5 6 7

strongly disagree strongly agree

People who are important to me think that I should use the system. *

1 2 3 4 5 6 7

strongly disagree strongly agree

« Anterior

Continuar »

 54% concluído

Voluntariness

My use of the system is voluntary. *

1 2 3 4 5 6 7
strongly disagree ○ ○ ○ ○ ○ ○ ○ strongly agree

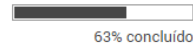
My supervisor does not require me to use the system. *

1 2 3 4 5 6 7
strongly disagree ○ ○ ○ ○ ○ ○ ○ strongly agree

Although it might be helpful, using the system is certainly not compulsory in my job. *

1 2 3 4 5 6 7
strongly disagree ○ ○ ○ ○ ○ ○ ○ strongly agree

« Anterior Continuar »



Image

People in my organization who use the system have more prestige than those who do not. *

1 2 3 4 5 6 7
strongly disagree ○ ○ ○ ○ ○ ○ ○ strongly agree

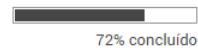
People in my organization who use the system have a high profile. *

1 2 3 4 5 6 7
strongly disagree ○ ○ ○ ○ ○ ○ ○ strongly agree

Having the system is a status symbol in my organization. *

1 2 3 4 5 6 7
strongly disagree ○ ○ ○ ○ ○ ○ ○ strongly agree

« Anterior Continuar »



Job Relevance

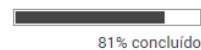
In my job, usage of the system is important. *

1 2 3 4 5 6 7
strongly disagree ○ ○ ○ ○ ○ ○ ○ strongly agree

In my job, usage of the system is relevant. *

1 2 3 4 5 6 7
strongly disagree ○ ○ ○ ○ ○ ○ ○ strongly agree

« Anterior Continuar »



Output Quality

The quality of the output I get from the system is high. *

1 2 3 4 5 6 7

strongly disagree strongly agree


I have no problem with the quality of the system's output. *

1 2 3 4 5 6 7

strongly disagree strongly agree

« Anterior

Continuar »

 90% concluído

Result Demonstrability

I have no difficulty telling others about the results of using the system. *

1 2 3 4 5 6 7

strongly disagree strongly agree

I believe I could communicate to others the consequences of using the system. *

1 2 3 4 5 6 7

strongly disagree strongly agree

The results of using the system are apparent to me. *

1 2 3 4 5 6 7

strongly disagree strongly agree


I would have difficulty explaining why using the system may or may not be beneficial. *

1 2 3 4 5 6 7

strongly disagree strongly agree

« Anterior

Enviar

 100%: terminou.

Nunca envie palavras-passe através dos Formulários do Google.

