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Design and Implementation Issues of an Information System Supporting Cervical Cancer Screening Programs

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Abstract

Cervical cancer is one of the most common women mortality reasons in the world. However it is a well studied disease with known natural history that can be prevented and treated if diagnosed in early stage. The key to prevention is the regular check of all women fulfilling specific criteria with test Papanikolaou, this process is called population based cervical cancer screening program. As the involved population is very large, critical to the success of the program is the organization and quality control and assurance. Unavoidable a computerized information system supporting the program must be in place. Aim of this article is to present aspects of the architecture, design and implementation of an information system supporting the Hellenic Cervical Cancer Screening Program. Within the framework of the Hellenic national program against cancer and especially for the

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branch related to the prevention of cervical cancer, it was designed and implemented a software system to support basic requirements. The requirements were captured from numerous sources, the basis was the European Guidelines and the users. The work flow design was produced and the system implementation was based on open source tools as the total cost had to be extremely low. The design and implementation of such systems has a lot off challenges; there are involved patients, specialists from numerous health disciplines, technical specialties and professionals from health authorities and management activities as well, the security requirements are very strict due to personal data and medical records, the system stability, availability and scalability requirements should be taken as well to account, finally user training and acceptance of the system especially as this is deployed for first time is crucial. The design and implementation of information systems supporting population based screening programs is feasible via open source tools and can be made available to the end users as a service via a web browser. Continuous support of the systems in terms of maintenance, expansions and user training is required especially if deployed for first time.

Keywords: Cervical Cancer Screening, Medical Software Systems, Health Information Systems, Information and Communications Technology, Software Design, Workflow management

1 Introduction

Cervical cancer is not a negligible hazard in the modern world; actually it is the second most common cancer worldwide among women between 14 and 44 years old and the third leading cause of cancer death after breast and lung cancer [1]. Human papillomavirus (HPV) infection is associated with cervical cancer; the virus is affecting millions of women worldwide. HPV is the most common

sexually transmitted infection worldwide and from the more than 100 HPV types, 13 are high-risk oncogenic and can cause cervical cancer [2-4]. The natural history of cervical cancer and its relation with HPV is well studied [5], HPV infection is very common in young people; approximately 70% of women have a HPV infection during their lifetime, is usually transient, however if a combination of high-risk HPV type and a compromised immune system persists then this is a fundamental factor with consequent progression to cervical intraepithelial neoplasia (CIN) and invasive carcinomas [6, 7]. It takes a number of years to develop precancerous lesions and cancer [8-10], thus there is adequate time to identify these and act before they develop to cancer.

Test Papanikolaou (Pap test) has been considered for 60 years; and is nowadays the most valuable tool in preventing cervical cancer [11-14]. The evaluation of cervical cytology smears is a task that requires effort and can be accomplished by well-trained cytopathologists. Despite the fact that the prevalence of cervical cancer decreased 75% between 1955 and 1992 as a result of the cervical cancer screening programs and methods introduced by George Papanikolaou, there are still many deaths from this reason. In Europe, more than 50,000 women develop cervical cancer each year and about 25,000 die from the disease. The American Cancer Society reported that 12200 new cervical cancer cases were expected in USA in 2010 and that there will be 4210 deaths [15]. Approximately 7-8% of the total population screened in the UK will have an abnormal smear [16, 17]; of those approximately1.5-2% will present with a high-grade and 5% with a low-grade lesion, the former requires medical treatment and the later frequent monitoring.

Obviously due to the nature of this disease, organized cervical cancer screening programs have a severe impact and can prevent the majority of cervical cancers [18]. This benefit can be achieved only if screening is well organized with quality control and assurance that can be achieved if the program is supported by an information technology system.

This article presents the concepts behind the design and implementation of a software system that supports organization and quality control of the Hellenic national cervical cancer screening program designed according to the European Guidelines [19].

According to the European Guidelines Population-based information systems are required for continuous monitoring of screening process indicators and a legal framework is required to support the registration of individual data and interconnections with databases holding population data, screening files, cancer registries and mortality records. The information system is essential for managing the screening program and for automatic computation of numerous indicators, for example: attendance, compliance, quality and impact; and for continuous provisioning of feedback to the involved professionals and the numerous health authorities.

The design and implementation of such systems has numerous challenges; there are involved patients, specialists from divergent health disciplines, technical specialties and professionals from health authorities and management activities, the security requirements are very strict as there are personal data and medical records, the system stability, availability and scalability requirements should be taken as well to account, user training and acceptance of the system especially as this is deployed for first time is crucial, and finally the total cost of implementation had to be extremely low. In addition Cervical cancer screening programs are nationwide applied, and affect the majority of the population. This study presents the architecture, design and initial experiences during the deployment of the software system supporting the Hellenic population based cervical cancer screening program.

2 System design

This section presents the various aspects of the software system architecture and issues taken to account during design and implementation. The main semantics of the information system include: the case or patient (i.e. women that participate in the screening program) along with numerous contact details, the second semantic is the visit, being linked to invitations rendezvous and a multitude of information such as demographic data, medical history, biological samples and examinations such as cytological, colposcopical, histological and if required therapies. The third basic entity is the user linked with numerous other information such as roles, rights and work institute.

2.1 Requirements and workflow description

System requirements were captured from numerous sources, major source is the screening process itself that has a well defined work flow being outlined in Figure 1.

Specifically the basic parts of the work process include:

- Periodically and depending on the woman health status and age, every woman receives an invitation to have a Pap test, this invitation is expected to motivate the woman to book a rendezvous to a health center and finally visit this center for examination.
- When the woman arrives to the health center, she meets a specialist and provides her updated contact details (telephone numbers, emails, addresses etc, see section 2.3 for the patient or case model), demographic data and medical history, additionally the specialist gets a cervical sample, this sample is shipped to a specialized cytopathology laboratory.
- When the sample is received in the Cytopathology laboratory it is prepared and further assigned to specialized medical doctor for Papanikolaou examination.

The result of this examination is sent back to the health center that handles the woman.

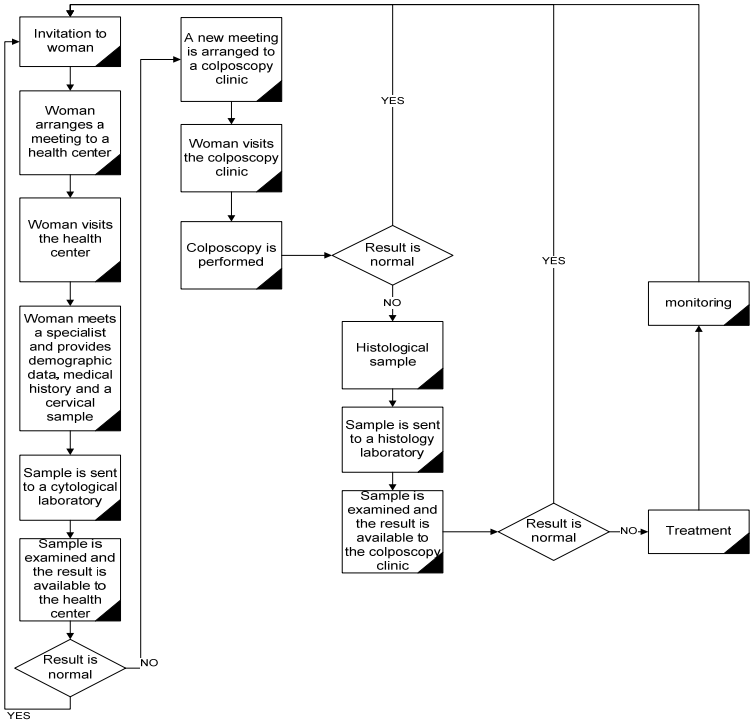

Figure 1: Process flow required for cervical cancer screening

- According to the Papanikolaou examination result, is decided the time that the next invitation will be send to the woman and additionally if it is required additional examination this time in a colposcopy clinic.
- If the result is abnormal the woman should be examined by a gynecologist certified to perform colposcopies. In this case a new meeting is arranged and the woman should visit a colposcopy clinic. According to the colposcopy result the woman may be released to the normal cycle of invitations (i.e. to perform another Paptest within a specific timeframe according to her medical status and

age) or in a case that the colposcopy result is abnormal a new histological sample should be taken to be further analyzed by a histology laboratory (biopsy). The histological sample is sent to a cooperating histopathology laboratory.

- The histological sample is received and after preparation is examined histologicaly. This result is made available both to the health center that treats the woman and to the colposcopy clinic.
- The colposcopy clinic is now responsible to handle the case, if the histopathology result is normal the woman may return to the standard cycle and wait for the next invitation for Pap test, otherwise it is required a new visit to the colposcopy clinic for treatment (therapy) and monitoring.

Another important source of requirements is the system users:

- Midwifes and gynecologists are responsible to fill the details related to demographic data and medical history, therefore their opinion is decisive for the forms design, level of details, obligatory or optional information as well as automatic checking of field correctness.
- Cytopathologists report the Pap test findings in a common language, this is the revised Bethesda classification system (TBS2001 system) [20-22], being proposed to be used as standard by the European Guidelines.
- Similarly histopathologists and gynecologists should report the histological diagnoses and colposcopical findings in a common format, therapies and women treatment is another aspect requiring standardization.
- Health authorities required to have control on the program results at various levels therefore the system design should allow extraction of statistics in predefined forms
- Biological samples, either cytological or histological should be sent to remote laboratories within specific timeframe, therefore sample tracking is important.

Several requirements are captured from the European Guidelines [19]. According to these the information system should be designed to support all the aspects and the work flow of the screening program and enable monitoring and evaluation. The basic functionalities include:

- Identify the target population that should participate in the screening program, this database includes the entire target population.
- Identify individual women in the target population, that are unscreened or already screened, and identify women in specially target groups.
- Produce and store letters to be sent to the individual women in order to: i) invite/remind to visit a health center for test Papanikolaou, and to re-attend for screening at the appropriate interval ii) support early recall, if required due to specific woman characteristics; for example when being in a higher risk group.
- Record the screening findings and identify women that a further action is recommended.
- Monitor if the recommended action has been taken by the woman, and collect information on the further investigations and management.
- Provide long-term follow-up for patients that have been treated.
- Identify cancers and deaths in the whole population.
- Permit linkage of individual screening episodes, and cancers and pre-cancerous lesions for systematic quality assurance purposes and feed-back to laboratories and clinicians.

The role of Cytopathology and histopathology laboratories are crucial in the screening process; laboratories are equipped with their own information systems facilitating their internal workflow: Laboratory Information System (LIS). According to the European guidelines there must be an adequate computerized record-keeping system within the laboratories. It must be accurate, user friendly and easily accessible to all authorized laboratory personnel. The system should include at least the following:

- Patient identification data
- Name and address of the laboratory
- Laboratory ID number
- Date of arrival of the smear in the laboratory
- Indication for examination: screening, follow-up or clinical indication,
- Type of examination: cytological, histological or virological
- The results of the laboratory examination in accordance with the current standard classification system (the Bethesda System) and data format, including a judgment of the quality/adequacy of the preparation
- Advice for repeat sample or referral
- Date of the final report
- Name of the person or persons who evaluated the sample.
- Link multiple test results for the same patient
- Provide easy access to details about previous cervical cytology and histology of the patient
- Provide a mechanism for ascertaining and recording clinical outcome after cytology tests, including colposcopy findings, biopsies, reasons for biopsies not being taken
- Provide the data necessary for evaluation of the population screening program.

Despite that the LIS functionalities are not required to be supported within the framework of the software system supporting the screening process, it seems that all the required characteristics can be implemented in a common framework.

Finally due to stringent financial circumstances a basic requirement was that the system should have extremely low cost.

2.2 Institutes, actors and hierarchy

As depicted in Figure 1, there are many places involved in this process. In the terminology adopted for the implementation of the software system for these

places is “institutes”. This term includes all places that a system user may work, i.e. health centers, cytopathology laboratories, colposcopy clinics, histopathology laboratories etc.

Specifically invitations are sent by specific *municipality services* as these have available records of all the citizens, these records include all the required information to contact the women, and the woman birth date, indicating if a woman is eligible to participate to the screening program. Therefore *municipalities have actors that are responsible to send invitations* to women, proposing them to choose a health center from a list and perform a Pap test within a specific timeframe.

Health centers are the first level handling the women, a health center may serve citizens of many municipalities and additionally a woman may visit a health center in another municipality. A health center is a part of a larger structure, actually health centers in Greece are considered remote branches of hospitals and each health center is managed by a single hospital. Since health centers are places that women may book a rendezvous and additionally there are performed medical tasks, it is required to *have personnel for secretary support as well as medical and/or paramedical personnel*.

Similarly to health centers *colposcopy clinics* are the second level for women support, women visit colposcopy clinics for additional examinations and treatment (therapeutic measures) if required, a colposcopy clinic is located in a hospital that is responsible for its management and is stuffed by *personnel for secretary support as well as medical and/or paramedical personnel*.

Finally in the flow there are involved two types of cooperating laboratories, *cytopathology and histopathology laboratories*, performing test Papanikolaou examinations and biopsies (or histological examinations) respectively. Despite these places are not visited by women but operate in a business to business manner with the health centers and colposcopy clinics, it is required to have *secretary support* to handle bureaucratic procedures related to examination results,

specialized medical personnel for examination of the received samples and *medical technicians* for sample preparation.

In addition to the mentioned personnel defined for each individual institute, there is a need for a person responsible to manage the personnel and have control over the process and quality of work, therefore for each institute, it is required a *manager* or named alternatively head of clinic, health center or laboratory.

The hierarchical organization of institutes is depicted in Figure 2. Institutes belong to organizations; these organizations are hospitals that manage health centers and colposcopy clinics, and cytopathology and histopathology laboratories. In a higher hierarchy level is the management authority that is responsible for many hospitals in a specific geographic region, Greece is divided into seven management authorities called Directorates for Health Services. According to the European Guidelines [19] is important for a screening program to define catchment areas according to specific geographical borders and population limits, for the implementation of the Hellenic national screening program each Management Authority corresponds to a Directorate for Health Services and represents a catchment area fulfilling the criteria required by the European Guidelines.

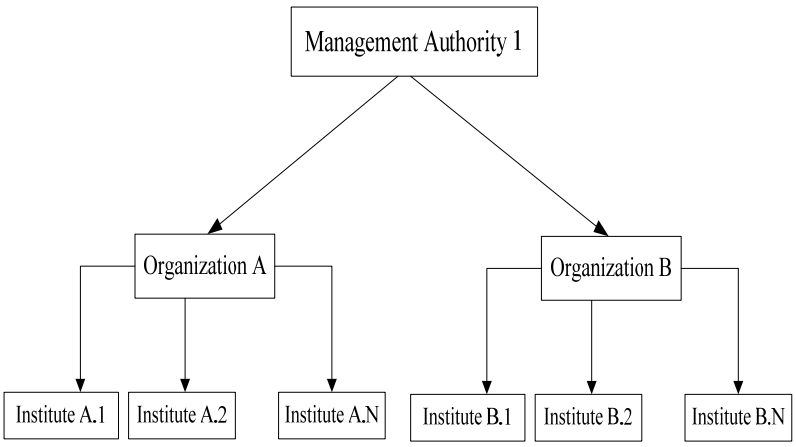

Figure 2: Hierarchy of organizational entities

Finally there are other actors that do not appear in the workflow diagram (Figure 1), specifically it is required personnel for technical support, mainly user management, i.e. user creation and assignment of rights and personnel that has access to specific indicators and statistics related either to a complete catchment area or in a national level.

2.3 Patient or case model

The patient model is depicted in Figure 3, a patient can have many telephones, addresses, e-mails, insurances and identification documents such as police ID card, passport etc, a patient many declare preferences especially for methods that prefers to be informed for invitations, forthcoming rendezvous or for availability of test Papanikolaou results. Finally each patient belongs to a single municipality being responsible to send personalized invitations calling women to book a time slot to a local health center and visit the health center for Papanikolaou examination.

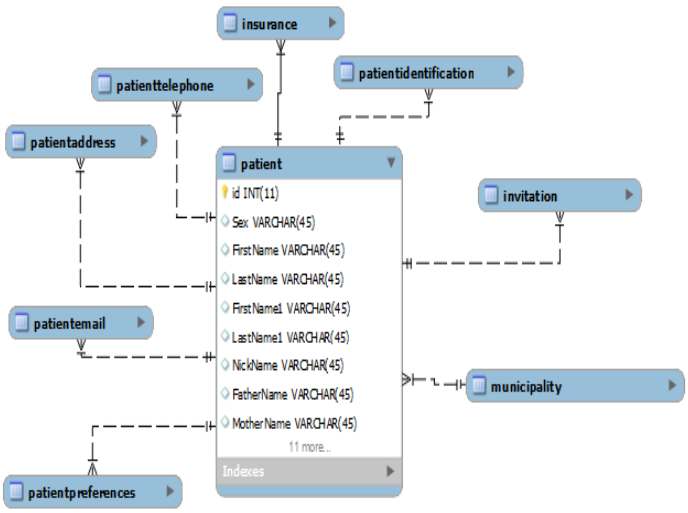

Figure 3: Patient model

2.4 Visit model

All information related to the medical record of the women, are created in relation to patient visits. To obtain quality measures of the system a visit is related to a rendezvous which may be triggered by an invitation (see Figure 4). Depending on the institute type (health center or colposcopy clinic) different entities can be related to each visit, colposcopy clinics have a superset of entities that can be obtained from health centers. In detail during a visit there can be obtained demographic information, patient history and the macroscopic view, additionally to perform the Pap test a sample should be taken. For the case of colposcopy clinics it may be performed a colposcopical examination and obtained two types of samples; cytological and histological. Furthermore therapeutic actions can take place. Finally a sample can be related to a histological or cytological examination result depending on its type.

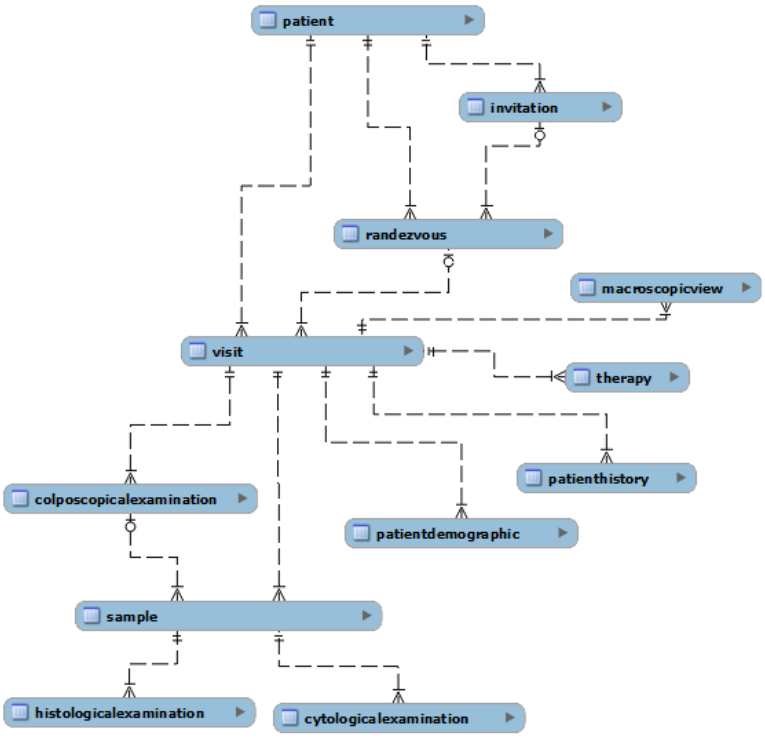

Figure 4: Visit model

2.5 User model and user roles

The user model is depicted in Figure 5, similarly to patients, users have several contact details such as telephone numbers and e-mail addresses. Each user belongs to an institute and can have one or more specialties that intent to be informative details available to other users. Concerning user rights, these are defined from the user roles, each user may have one or more roles according to the tasks that he/she performs. Each user has one or more managers, a manager is another system user that will be involved if the user requests to unlock a record due to mistakes in data entry and the user manager will have access to user performance metrics. The link to the table user preferences serves storing of preferred contact hours and is reserved for additional future use. Finally there is a link to a logging system of user actions, a table that stores actions taken by each user such as CRUD operations (Create, Read, Update, Delete) on patient and other system records as these are stored in the system database.

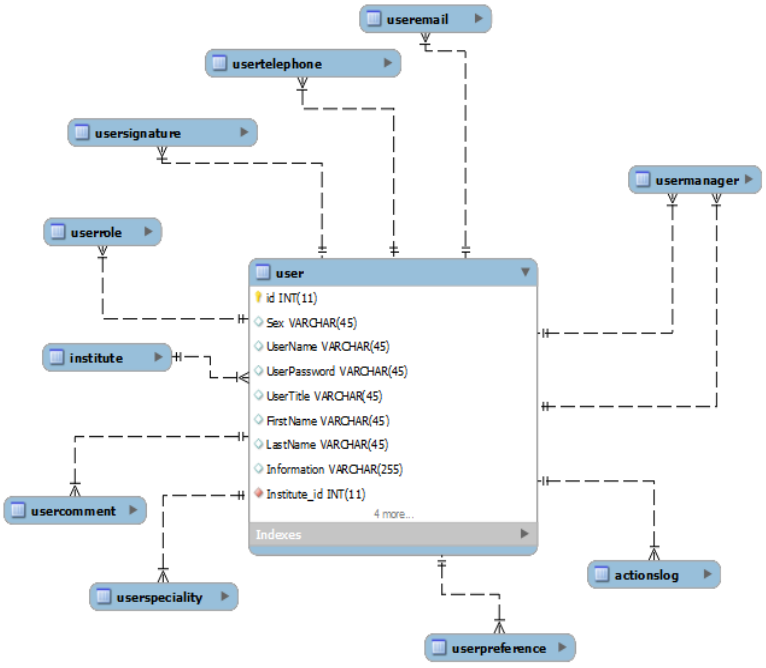

Figure 5: User model

Table 1:User roles, functionalities and access rights on the database entities

#	User role (terminology)	Responsibilities/Functionalities	Rights
1	Invitation Sender	Responsible to send invitations and reminders to eligible women, this type of user can add new women in the system and can modify personal data.	CRUD operations on user personal data and invitation data
2	Health Center Secretary	Can add new women in the system and modify personal data and handle rendezvous and visits	CRUD operations on user personal data, rendezvous for the associated institutes and visit details for the women that handles
3	Sample Taker	Can modify women personal data, and append to defined visits medical entities, specifically: medical history, demographic details, macroscopic view of vulva, vagina and cervix as well as cytological samples. Additionally this user is responsible to send the samples to the associated cytological laboratories and to denote to the system what samples were send to every institute and the date that were sent. This user has read access to the complete medical record and history of individual women that handles.	RUD operations on women personal details, CRUD operation on medical history, demographic details, macroscopic view, samples.
4	Director of Health Centre	Is the head of the health center responsible for Papanikolaou smear taking. This role acts as supervisor of the other personnel (roles 2 and 3). Has read access to the complete medical record and history of individual women that the institute handles and can view statistical details of the institute and the performance of the health center users.	Read operations on women personal details and medical records, unlock permissions to managing users and access to health center statistics and quality tables and user performance tables.
5	Director of Cytopathology Laboratory	Is the head of the Cytopathology laboratory, acts as supervisor of the other personnel (roles 6, 7 and 8). Has read access to the complete medical record and history of individual women that the lab handles and can view statistical details of the Cytopathology laboratory and the performance of the related users.	Access to specific menus producing reports for the performance of the personnel and the laboratory workload, flow and quality indices
6	Medical Doctor Specialized in Cytopathologist	Responsible to add the cytological diagnosis on a sample and to confirm the cytological examination form details.	Read operations on women personal details and medical records for the women that handles, CRUD operations on cytological examinations.
7	Cytotechnician	Responsible to receive the cytological samples from the cooperating health centers and to declare the reception date. After sample preparation declares the preparation date.	Specific Read and Write operations on specific samples
8	Secretary of Cytopathology Laboratory	Responsible to fill the form with the details of the cytological examination upon reception of the form from the responsible doctor. Subsequently the cytopathologist confirms the form and the results are available to the related health center	Specific CRUD operations on cytological examinations.
9	Director of Colposcopy Clinic	Is the head of the colposcopy clinic responsible for Papanikolaou smear taking, histological samples taking, colposcopical examinations and application of therapies. This role acts as supervisor of the other personnel (roles 10 and 11). Has read access to the complete medical record and history of individual women that the clinic handles and can view statistical details of the clinic and the performance of the users.	Read operations on women personal details and medical records, unlock permissions to managing users and access to colposcopy clinic statistics tables and user performance tables.

#	User role (terminology)	Responsibilities/Functionalities	Rights
10	Medical Doctor Certified in Colposcopy	Can modify women personal data, and append to defined visits medical entities, specifically: medical history, demographic details, macroscopic view of vulva, vagina and cervix, cytological and histological samples and applied therapies. Additionally this user is responsible to send the samples to the associated cytological and histological laboratories and to denote to the system what samples were send to every institute and the date that were sent. This user has read access to the complete medical record and history of individual women that handles.	RUD operations on women personal details, CRUD operation on medical history, demographic details, macroscopic view, samples and therapies.
11	Secretary of Colposcopy Clinic	Responsible to handle women that appear for colposcopical examination in the colposcopy clinic. Can modify women contact details and rendezvous of the clinic.	CRUD operations on specific women personal details. CRUD on the institute rendezvous
12	Director of Histopathology Laboratory	Is the head of the histopathology laboratory, acts as supervisor of the other personnel (roles 13, 14 and 15). Has read access to the complete medical record and history of individual women that the lab handles and can view statistical details of the Histological laboratory and the performance of the related users.	Access to specific menus producing reports for the performance of the personnel and the laboratory workload, flow and quality indices
13	Medical Doctor Specialized in Histopathology	Responsible to add the histological diagnosis on a sample and to confirm the examination form details.	Read operations on women personal details and medical records for the women that handles, CRUD operations on histological examinations.
14	Histopathology Laboratory Technician	Responsible to receive the histological samples from the cooperating health centers and to declare the reception date. After sample preparation declares the preparation date.	Specific Read and Write operations on specific samples
15	Secretary of Histopathology Laboratory	Responsible to fill the form with the details of the histological examination upon reception of the form from the responsible doctor. Subsequently the histopathologist confirms the form and the results are available to the related health center	Specific CRUD operations on histological examinations.
16	Health Authority Officer Managing the Screening Program in National Level	Has access to the complete statistical details of the screening program to assess performance indicators related to the success of the program.	Access to specific menus producing reports for the quality of the program in a national level
17	Health Authority Officer Managing the Screening Program in Catchment Area Level	As16 but for the specific region that handles (one of the 7 catchment areas)	Access to specific menus producing reports for the quality of the program in a catchment area level
20	User Manager	Responsible to create and manage users, assign them to institutes, assign institutes to municipalities and health organizations (i.e. hospitals) and assign organizations to management authorities (i.e. catchment areas), users have contact details such as telephones and e-mails, rights as these are reflected by their roles, preferences and belong to one institute.	CRUD operations on user, institute, organization and management authority entities. This type of user has no access to women personal or medical data

A variety of user roles (Table 1) is essential for the implementation of the work flow required to have a system capable to handle all required processes and ensuring that every person has all the rights required to perform his/her tasks without compromising security (actually by having non necessary rights on specific records). Specifically depending on the institute that a user may be a member and his/her specialty and work tasks there are defined various types of roles. Due to lack of personnel, a user may have to perform various tasks, for instance a nurse of midwife working in a decentralized health center may have to book rendezvous as well, thus she has to act as a health center secretary, for this reason a user may have more than one roles along with the related rights.

According to each individual role various system functionalities may be available, these appear in the system menu and in each individual screen holding patient data, in the later case records may be not be visible or locked for editing.

Required operations on all system data involve Creation, Reading, Update and Deletion (CRUD) of records related to specific database entities. The term personal data is related to women contact and identification details including social security data, personal data do not include any medical or demographic information, thus the system holds two types of data related to each individual woman: 1. Personal data as mentioned above and 2. Medical records being much more sensitive.

In Table 1 are presented the various roles that the software system should have in order to support the operation of the screening program and the security requirements.

2.6 Reporting

The information system should create reports at various levels to produce quality measures of the program:

- Coverage statistic (see Table 2)

Table 2: Report indicating the coverage of the program (adapted from the EU guidelines [19])

Age	women living in the area	Invited women			women eligible to participate in the program	women eligible to participate to the program
		Number of women	Number of women Invited in	Percentage of invited		
<20						
20-24						
25-29						
30-34						
35-39						
40-44						
45-49						
50-54						
55-59						
60-64						
65+						
Total						

- Cytological examinations statistics
- Tabulation of women requiring to repeat the cytological examination
- Tabulation of women referred to colposcopy along with their cytological diagnosis
- Compliance of women referred to colposcopy (i.e. if the women performed the examination)
- Cross tabulation of the cytological vs. the histological examination results (this servers as a metric of the quality of the cytological examination)

- Tabulation of women that have been found with neoplasia, i.e. women age group v.s. neoplasia type.
- Cross tabulation of the treatment type and the related histological result from the sample received during treatment (indicates if the treatment was required).
- Tabulation of the cytological examination after the treatment (indicates if the treatment was successful).

3 Implementation

The described software system is partially implemented and is operational in order to support the screening program and the majority of involved users, additionally it is under continuous testing and refinements in respect to the user comments and requirements.

It is a multi-tier web based system implemented with open source tools. The first tier is the web browser located on the user side, the second tier is the Apache Tomcat application server [23] and finally the third tier is MySQL database server [24]. The user interface is generated on the server side and is based on the Java programming language, thus all required changes are performed on a single side and system updates and maintenance is facilitated and immediately available.

3.1 Security considerations

Security of systems maintaining personal and especially medical records is essential, furthermore if these systems are operated by a multitude of users that need to have access on specific patients that may roam to different health centers or colposcopy clinics and especially if these are remotely operated make the system security design requirement more stringent. For the specific system there

have been taken security measures related to the physical access to the hardware and to the usage of the software.

a) Physical security: Access to the servers and related devices such as routers, switches and firewalls, is restricted only for authorized technical personnel that have no access to the patient data and software. The role of these technicians is related only to system maintenance, troubleshooting and smooth operation of backup procedures.

b) Data storage and transmission: Data security is related to information storage and transmission. Sensitive data should be stored in encrypted form in the database, therefore all information that may link specific persons with personal data and medical history are stored in encrypted form. For information transmission is employed a secured channel using Secure Socket Layer (SSL).

c) Data access: accessing patient data is essential for the smooth operation of the program, at the personal data level a user may access personal data only if he/she has adequate rights. The rights are granted only if the patient is treated by the specific health center of colposcopy clinic or if the patient is handled by a specific laboratory.

For an individual health center or colposcopy clinic user to access patient personal details if the patient is not handled by the specific institute, it is essential that the patient books a rendezvous or appear in this institute.

- in the case that a rendezvous is booked then automatically the specific institute is listed in the institutes that handle the specific patient data and all user details become available to this institute as well
- in the case that a woman appears in the institute and is already recorded in the system then she should provide a correct first name, last name, father name, birth date and additionally an identification number (police ID card, passport number, emigrant card number, social security number etc) that is already registered in the system, based on these data the institute user can find the

specific patient and his/her institute will be listed in the institutes that handle this woman.

Except of health centers and colposcopy clinics, Cytopathology and histopathology laboratories should have access to the patient details, these rights are granted when a patient sample is sent to the specific laboratory, especially when a cytotechnician of histopathology lab technician confirms the reception of a patient sample sent from a health center of colposcopy clinic, automatically this lab is listed in the institutes that have access to the patient records.

d) Data exchange: despite no implementation of data exchange mechanisms are available the screening system should be capable to send and receive patient details to and from other systems, this should be performed using a standardized format such as DICOM or XML and via a secured information channel. Secure web services signed via valid SSL certificates seem to be adequate for this type of application as the data exchange is between a limited number of pairs of well known servers as there is a centralized system implementation and medical records become available to the users via the central server system.

3.2 Availability

Availability refers to the ability to cope with, and if necessary recover from failures of the host server either due to hardware reasons or due to failure of the operating system and the application software, and to cope with hardware and maintenance activities that may cause downtime. The system availability is crucial for the program smooth operation, if the system is not operational the consequences range from missing rendezvous to canceled treatments. To improve the availability the system, it is hosted in a high availability server system with more than one Internet connections. However printouts of the various entities should be possible and given to women for their personal record. An alternative

plan to operate the program without the information system for a short time period should be made and be known to the users in advance.

3.3 Scalability

Scalability refers to the ability to spread both the system software and the load of application queries across multiple machines. In early stages of system operation the number of users is kept low as this period serves for testing purposes. In this stage a single machine hosting both the Tomcat Application server and the MySQL database server is adequate. However in a full system operation the server load may become very high thus countermeasures should be available. The escalation plan for future use has two steps:

a) Initially a split of the application server and the database server into two machines will take place.

b) If the load of one of the two servers is in high levels then a further split either *of the application server or/and the database server may follow*

Tomcat application server is designed to support load balancing, clustering and failover mechanisms [25-27], therefore is feasible the creation of a server farm composed of many computers, this will not only distribute the load caused by the user requests but additionally will be possible to cope with hardware of software failure of one or more computers.

On the database server tier, the MySQL database has already being deployed into many applications demanding high availability and scalability, the MySQL system may support database replication and geographically redundant, multi-server solutions, according to the MySQL 5.0 user guide the uptime can be up to 99.999% [28].

3.4 Deployment: user training and problem resolution

Parts of the system deployment are user training and initial problems resolution. For training purposes it was selected a hierarchical method: initially there are trained information technology specialists of the seven catchment areas that the Hellenic national health system is composed, training involves all software aspects, subsequently end user training within each area is performed by trained specialists (Train The Trainer (TTT) model).

To resolve initial problems and additionally to collect user requirements and ideas for the system optimization there was implemented an electronic reporting mechanism, i.e. each user has a available a menu option that enables reporting of problems and additionally to send proposals and ideas for system enhancements, these user “comments” (see entity relation in Fig. 5) are collected by the system and may be used for the bug fixes and continuous improvements of the functionalities.

4 Discussion

In practice open source tools were successfully applied to build the information system for the population based cervical cancer screening program. The system is web based and thus easily deployed at nationwide level. The installed system was tested with 300,000 artificial cases with excellent response times [29] (less than 5 seconds seek time in the database and appearance of patient data on screen).

The proposed hierarchical system deployment and user training strategy has numerous advantages. User training is performed by professionals that are already in contact with the end users and are aware of user capabilities and the hardware and networking limitations at workplaces (institutes). The reporting mechanism proved to be a useful tool not only for bug detection but for further system

development according to the everyday user needs. Deploying Cervical Cancer Prevention IT systems in a nationwide level is not a simple task; the proposed hierarchical method provides centralized control and simultaneously decentralized user training and support, thus reduces the workload of central offices and provides more personalized support to system users.

However the described system is far for being perfect, as it is isolated and there are no interactions with other systems. Specifically a more automated system should be interconnected with a multitude of other systems: 1. systems keeping birth records or municipality systems keeping citizen's records as these are the sources of new women that should be involved in the screening program 2. mortality registries, to avoid sending invitations or contacting women not being alive 3. cancer registries to send automatically histological results of malignant cases and additionally get information of screened women concerning their cancer history 4. Laboratory Information Systems (LISs) to receive automatically cytological and histological examination results, without any human interventions and in order to avoid duplicated data entry 5. centralized Hospital Information Systems (HISs) to get complete patient history records. 6. Interconnection with social security systems for cross validation of women details to avoid entry of the same woman with two different names and finally 7. interconnection with national system for rendezvous.

Support for research activities within the framework of the information system is another aspect that is encouraged by the European Guidelines [19], nowadays there is a multitude of biological markers available; to name a few: HPV arrays allows simultaneous detection of different HPV genotypes by PCR amplification of a fragment within the highly conserved L1 region of the virus[30], NASBA assays[31] are used for the identification of E6/E7 mRNA of the HPV types, flow cytometry allows the identification of E6/E7 mRNA expression of high-risk HPV [32] and finally is possible to identify the immunocytochemical expression of p16 [33]. All these tests produce results that can be used not only to estimate the risk

of danger of an individual woman but additionally allow the determination of the triage method that may follow [34-44]. Additionally new biomarkers and techniques may become available, therefore it is expected that in information system should be easily adaptable to support new examination types and research protocols in order to evaluate the accuracy of new or existing techniques; especially on specific and targeted parts of the population, of course informed consent forms should be signed by all women participating in these protocols.

Additionally multiple biomarkers can be combined and provide a better estimation of the risk of danger of specific parts of the population, in this area statistical classifiers and more modern techniques such as artificial neural networks have already been reported [45-53], most of these system have already produced excellent results in relatively small datasets, an information system embedding modern decision support methods and “business” logic perhaps could be of the benefit not only of the screened women but for the health professional as well.

5 Conclusion

Design and implementation of information systems supporting population based screening programs is feasible via open source tools and can be made available to the end users as a service via a web browser. Continuous support of the systems in terms of maintenance, expansions and user training is required especially if these are deployed for first time.

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