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Construction of a system for the access, storage and exploitation of data and medical images generated in radiology information systems (RIS)

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Abstract. We present the analysis, design and implementation of a system that allows specialists at a medical centre to recuperate and manage information produced by computers that generate medical diagnosis images. The main objective of the system is to define an architecture that provides doctors with an easy and centralized access to any information they may need, and to allow users to access this information from the computers at the hospital itself as well as from remote locations, which then require telemedicine sessions. The architecture is built according to a layered and modular methodology, which provides high scalability and interoperability with other information systems (HIS, RIS, etc). All the information is stored in a database: not only the various image studies of the patient, but also all data concerning the diagnosis and any comments the specialist may have made. We have also incorporated tools that are not usually found in conventional systems (image segmentation, advanced visualization, etc), but that help the specialist with the decision-making process.

Keywords: Information systems; Relational database; Telemedicine; Medical image; Computer vision

1. Introduction

In recent years, the progress in computers that generate medical diagnosis images, such as Computerized Tomography (CT) or Nuclear Magnetic Resonance (NMR), has led to the development of systems that are able to manage this enormous amount of new information. These systems are called PACS: they store and communicate images and facilitate the access to and the visualization of the digital information generated by various image diagnosis techniques.

One of the main problems of the first PACS, in the early 1990s, was related to the compatibility of communication between computers and the storage method of the different medical image modalities. Each manufacturer produced a proprietary format, which was usually closed and not easily accessible to other systems (due to, for instance, the use of different syntax: little endian versus big endian). [1]

In 1982, the ACR (American College of Radiology) and the NEMA (National Electrical Manufacturers Association) developed a common standard to eliminate

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these incompatibility problems. After several revisions, the DICOM3 (Digital Imaging and COmmunications in Medicine) standard was published in 1998 [2]. Although it has certain deficiencies [3], and is regularly revised in order to correct these issues, the standard has proved to be essential for the integration of medical image-based information.

In recent years, the use of this standard and the continuous improvements and advances in the technology of these devices (i.e. the development of more efficient and inexpensive systems for massive storage, improvement of the communication lines, etc) [4] have boosted the installation of PACS in hospitalary centres all over the world [5].

These systems must also use security mechanisms that guaranty both the integrity and the confidentiality of the medical data they store and transmit. An increasing number of legal restrictions oblige organizations responsible for data to implement mechanisms that make the information inaccessible for unauthorized personnel but, at the same time, guarantee its availability [6, 7].

This work presents a system designed according to a layered and modular methodology, whose main objective is to allow specialists to access medical diagnosis image information easily and efficiently. It is designed to function in a network environment, but also provides a set of tools for analysis, processing and advanced visualization, which improve the decision-making process. For instance, when an x-ray is taken from a patient at an Intensive Care Unit, the doctor can consult this x-ray immediately, without having to wait for the development and physical transfer of the picture.

The system was developed with open standards, which allows incorporation of new modules and communication with other hospitalary systems (HIS) [8]. The result is a tool that allows specialists to recuperate patient information from HIS, and that assists in analysis of the diagnosis image.

The graphical user interface (GUI) of the system was developed with web technology: it is a user-friendly environment that allows specialists to access the system locally as well as remotely, without having to perform configuration tasks at each station (since the personalization of the environment is managed and stored in the server).

As indicated previously, the system presents a layered architecture, in which each layer consists of a module that defines its functions. The layers are: (a) acquisition and network; (b) storage; (c) analysis tools, study and exploitation; and (d) a support layer for the clinical decision-making, which shows filtered information of interest to the specialist.

We are at present carrying out implantation and system access tests in three hospitals of different sizes and communication infrastructures.

2. Architecture of the system

Figure 1 shows the layered structure of the system. The first level of the system, called 'Acquisition and networking', controls all the aspects of information gathering via communication with other systems.

We use DICOM to acquire the medical images and define their communications and storage format. Our communications protocol is TCP/IP, which is the basis of the Internet [9, 10] and is used by DICOM.

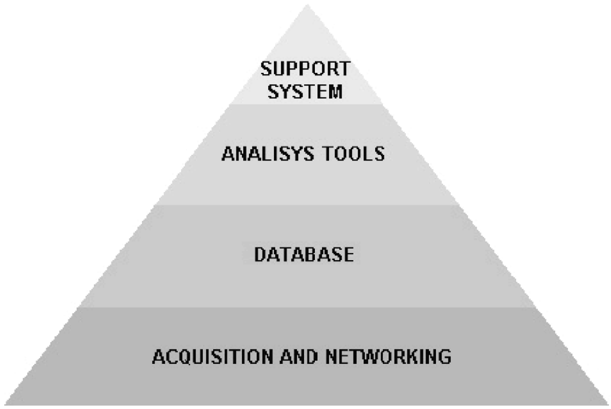

Figure 1. System architecture.

Once acquired, the data pass to the storage layer. At this point, the information is integrated in a relational database management system (RDBMS). The current implementation of the system uses MySql [11], a relational open source database able to store great amounts of binary data (such as diagnosis images) and which reduces the access times. At present however we are migrating to Oracle, because of its greater functionality and robustness.

To model the data, we created a scheme based on the Entity-Relation model (E-R). To define the entities and their relation, we use the objects structure proposed by DICOM. To recuperate the stored information, we use the standard query language SQL embedded in the pages implemented in PHP [12].

Furthermore, we provide the system with a set of exploitation tools that allow an expert to extract significant information from the data in the RDBMS, and whose results are much more elaborate than those obtained with conventional tools. At the same time, we can visualize data from a patient's clinical records. Our system gathers the Minimal Basic Data Set (MBDS), which contains the information necessary to identify the patient as a unique entity, the patient's pathology, the study's images and the results of the analysis tools. It is possible to extract the subjective information, gathered by an expert during years of visual analysis, parameterize it objectively and register it in the information system where it can be consulted by other experts. To this end, the expert is asked to give an opinion on the obtained result: the best results will be used later on for images with similar characteristics.

Finally, the last layer, called Support System for Clinical Decision-Making (SSCDM), shows the results and serves as an interface with the user.

The information exchange takes place at the layer level, using the different implemented standards which are open and can be found in most current platforms. Figure 2 shows how the layers communicate. On a network level, the information exchange uses the communications protocol TCP/IP; the information storage uses a RDBMS; the recuperation uses SQL; the communication between the analysis tools and the other layers uses JAVA; and we use HTTPS and XML to show the information to the user and exchange it with other systems.

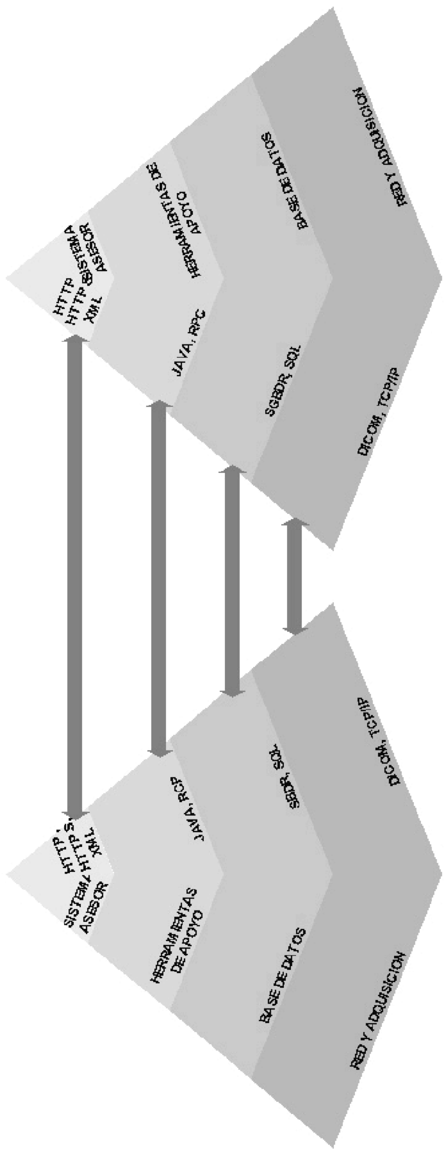

Figure 2. Diagram of the communications between information systems.

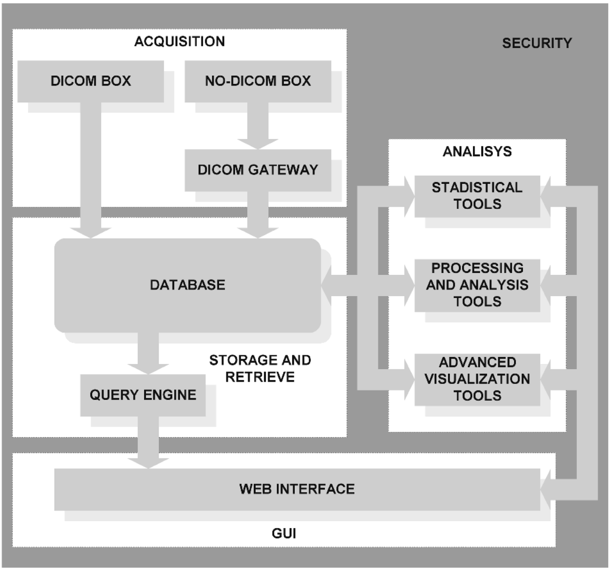

Figure 3. Functional modules of the system.

The functional modules that currently make up the layers of our system are:

(a) the acquisition module, associated with the first layer;
(b) the storage module, associated with the layer with the same name;
(c) the support module, which uses the system's tools to generate new data based on existing data;
(d) the interface module, which interacts with the medical expert and presents in an integrated manner all the data that are necessary for a correct diagnosis; and
(e) the security module, which intervenes in each of the layers and guarantees the integrity and confidentiality of the data during the acquisition and consulting transmissions (layer 1), the stability, availability and databases access controls (layer 2), the execution of the analysis tools for the generation of new data (layer 3), and the access control for authorized personnel and monitoring of the system's activity (layer 4).

The following sections describe in detail the implementation and problems of each module.

2.1. *Acquisition*

This module consists of the data and medical images acquisition services and communications with superior levels and with other systems of the intra-and extra-hospitalary network.

Medical image generation equipment can be classified according to the image technology they generate: analogous devices (mainly conventional radiology and echography) and digital devices (RC, TC, ASD, RMN, PET, SPECT). The digital devices consist of DICOM-compatible computers and others that use proprietary communications and storage formats. Even though more and more digital devices use DICOM, or incorporate the possibility of adding a DICOM interface, it is still true that most hospitals make use of all three kinds of equipment. At present, our system integrates images only from digital devices (DICOM or not DICOM-compatible).

The images are acquired directly from the device, if it supports DICOM. We developed a JAVA application that implements the Query/Retrieve and Storage services as defined in part 3 of the DICOM standard.

Those devices that do not support DICOM use a *pasarela* that converts the images to DICOM format. These black boxes also have the Query/Retrieve and Storage services implemented, but in this case they function as SCPs (Service Class Providers). The no-DICOM devices and the standardization gateway connect via a periodically programmed FTP service (File Transfer Protocol).

The programming frequency of the acquisition FTP depends on the data volume generated by the devices and their storage capacity. The FTP service does not control the data flow, which means that it guarantees neither the transmission nor the integrity of the data (integrity meaning that the data have not been altered). To solve this problem, we have implemented a transmission system with a double connection: one connection assures the standard FTP transmission, the other is used to send an information file that specifies the size of the data. Naturally, this redundancy file must be generated by the device that emits the data (see figure 4).

This layer also consults the HIS of the hospitalary system to obtain the MBDS of the patient's clinical records, which is not integrated into the image acquisition process. There are two types of HIS:

(a) HL7-compatible HIS: we obtain the data through protocol messages; and
(b) non-compatible HIS: we develop client applications based on the proprietary connectors (for instance: AS/400 Client).

As mentioned above, the communications system was developed to function with various communication lines (RTC, RDSI, ADSL, ATM, etc). Several studies, such as the EU's Bonaparte project [13], have shown that, according to the available bandwidth, the user uses response outputs that may or may not be found acceptable. Based on these studies, we have carried out our own research, which shows that functionalities are operative according to the available bandwidth (see Results).

2.2. *Storage of the information*

Storing information means taking into account all the different types of data with which the system works: DICOM messages (bitmap + basic identification information); demographic data (obtained from the HIS); clinical information (provided by the specialists) and information generated by the system itself (as a result of the analyses, processing and statistical studies). Another important factor is the temporary character of the stored information: data may lose their validity while they are in the database and provoke inconsistencies in the stored information.

Considering all this, the exploitation is oriented towards the level of the data we wish to recuperate. The fact that the information gathering is linked to the functionality of the system conditions the set of predefined SQL queries, which allow us to recuperate all the information corresponding to that level (i.e. the

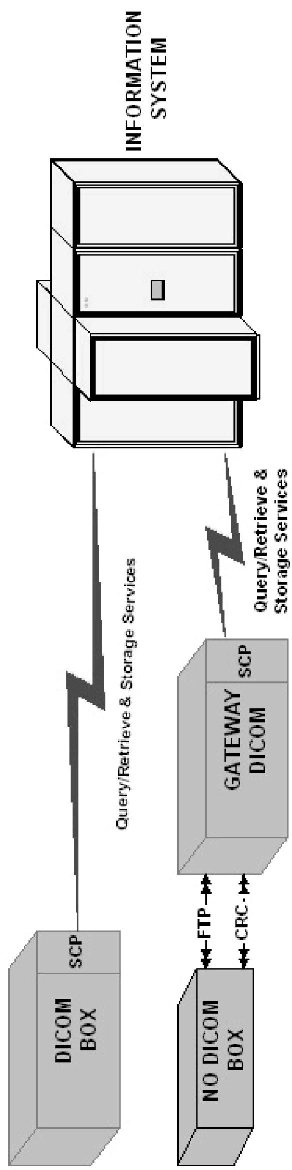

Figure 4. Image acquisition mechanisms.

basic information plus the information that may have been added at each separate stage). Various profiles are defined according to the user of the system. Figure 5 shows how the information evolves as we go through the different stages.

The system also incorporates information coming from the exploitation of the database, such as that generated by the analysis algorithms applied to the images. This allows us to provide the users with more elaborate results.

As can be seen in figure 6, the design of the database is based on the Entity-Relation model. In this model, the main entities are represented by the patient, who may have undergone one or various studies. A study consists of various series; each series consists of one or various images; and each image has its corresponding preview (icon).

The DICOM files consist not only of the study performed, but also of the patient's demographic and personal data, which are stored as data of the BLOB type (Binary Large OBject). The demographic data however (number of clinical record, name, gender, date of study, medical expert, etc) are also stored in separate tables. Although this measure implies a replication of the information, it is indispensable if we wish to maintain an efficient access to the data, have a DICOM study as a unity without modifications (maintenance of the standard) and guarantee more data integrity (normalization).

In order to optimize access to the database, especially from remote points where not only the speed of the RDBMS counts but also the connection speed, we created a fast visualization icon (around 50 Kb) for each image in the database. This 'preview' is also used by the expert to select the study to be returned: first a rapid image of the study is received, after which a detailed image can be selected for further analysis.

2.3. *Support tools for the clinical decision-making process*

The development of this module is still in its testing phase. We have created a set of algorithms that help the medical expert to segment and visualize an image (figure 7), and thus reach a diagnosis and set out a therapy more easily. In its current state, this module focuses mainly on the development of tools for the analysis of patients with a prosthesis implant [14]. The same tools are being applied to analyse the TACs of patients with mouth and tongue tumours [15].

Our objectives are the following: automatic segmentation of the medical images, measurement of distances and angles, visual improvement of the image, and calculation of areas and volumes. We have divided this layer into three modules: measurement tools, processing tools, and analysis of the images and of advanced visualization. Even today, the segmentation of anatomical structures remains a great challenge, due to the complexity and variability of the images on the one hand, and the great amount of data that must be handled by the researcher, on the other. Nevertheless, the included tools and their combination seek to automate this process.

Since these tools are part of the system's exploitation, they have been developed as much as possible in JAVA; however, the algorithms whose performance would be diminished by the use of this technology were programmed in C and are invoked from within the JAVA applications. The information associated with the use of each algorithm (parameters, applied algorithm, etc) is stored in the database, where it generates feedback information that allows the specialist to improve results and optimize use of the system (using a more adequate

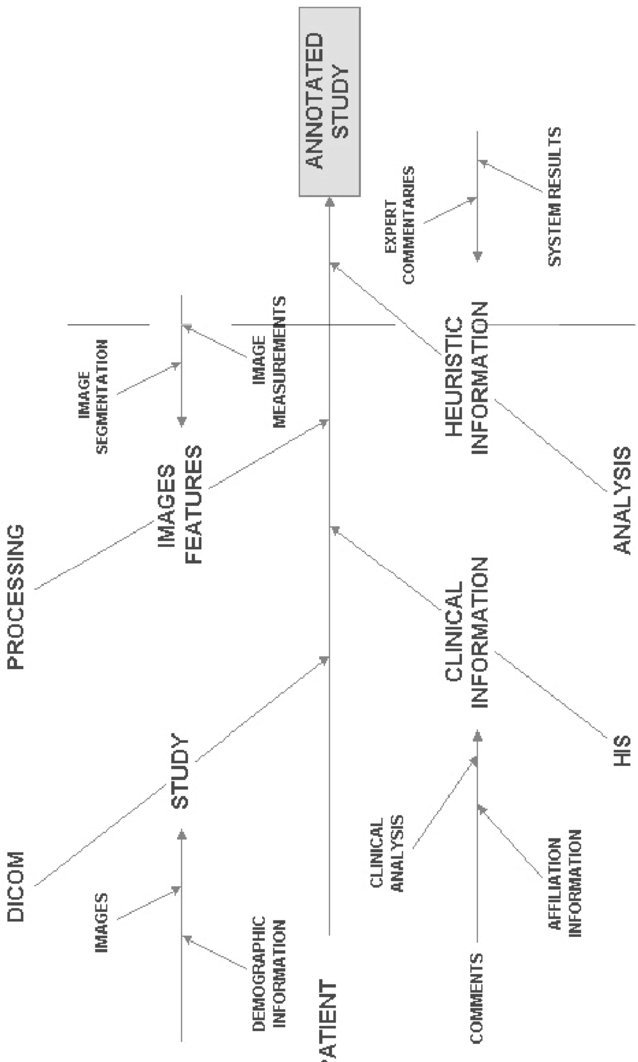

Figure 5. Information flow.

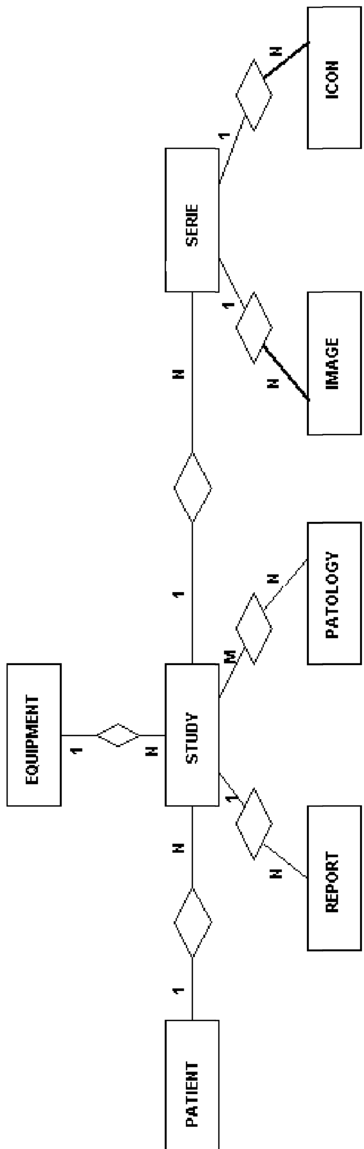

Figure 6. E-R representation of data modelling.

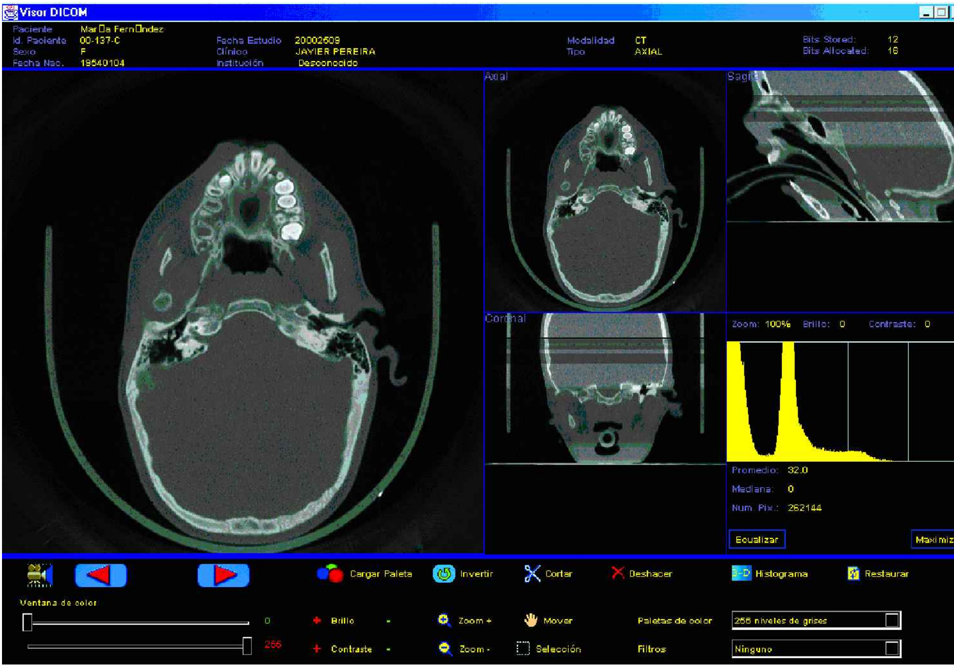

Figure 7. Interface of the advanced visualization of medical images. The reconstruction of the sagittal and coronal perspective is based on a series of axially generated images.

algorithm, adjusting the parameters, etc). The system also offers the possibility to make comments on the medical images, which stimulates the knowledge exchange with other specialist and the training of new experts.

The techniques that are currently implemented in the system can be divided into two large groups: analysis by region and analysis by detection of discontinuities. Table 1 shows the algorithms and their parameters.

In the first group, several diffuse clustering algorithms were implemented: FCM (Fuzzy C-Means) [16], FKNN (Fuzzy K-Nearest Neighbour) [17] and AFCM (Adaptive Fuzzy C-Means) [18]. These techniques classify the image in regions (clusters), and determine which pixel belongs to which cluster by means of a fuzzy membership function. Thanks to this function, a pixel is assigned to a cluster at the end of the process, which increases the searching time and therefore improves the classification; also, we can be more or less sure that that a pixel belongs to a cluster.

The second group of algorithms allows us to delimit the zones that separate the diverse elements of the image (e.g. bone and prosthesis metal). We selected algorithms that apply various strategies to detect the points that supposedly make up an edge: Canny [19], Heitger [20] and Bezdek's diffuse detector [21]. Canny for instance analyses the gradient of the image, whereas Heitger studies the energy of the points, and Bezdek focuses on the geometric characteristics an edge should have, using a fuzzy function based on the Takagi-Sugeno model [22] to select the candidate points.

Table 1. Parameters for various algorithms

Algorithm	Entry parameter
FCM	Number of clusters
	Sample of each cluster
FKNN	Number of clusters
	Sample of each cluster
AFCM	Number of clusters
	Sample of each cluster
Canny	Smoothing factor
	Minimal hysteresis threshold
Heitger	Maximal hysteresis threshold
	Image improvement factor
Bezdek	Thresholding value
	Control parameter of the fuzzy system
	Threshold value

We have also included a number of classic digital image processing algorithms that may be useful to the expert: histogram equalization, Sobel masks, homomorphic filters, etc.

As mentioned above, we know that these techniques do not provide a perfect segmentation. The results vary according to the quality of the entry image, the initial selection of the parameters (e.g. chosen samples) or the noise that may appear on the output image. To solve these problems, new techniques are being tested (e.g. T-snakes [23]), and new algorithms are being developed, which combine the results of the existing techniques with knowledge-based methods such as artificial neuron networks applied to medical images processing [24].

2.4. *Web interface*

The interface was designed to be easily accessible: the specialist uses a simple web browser, i.e. an environment that is familiar, user-friendly, and does not require specific configurations for client equipment.

We used the W3C norms to build the HTML pages [25]. Via PHP, these pages are linked to the databases; the algorithms are executed with JAVA applets.

In order to comply with the security norms, the design of an information system requires the definition of public access areas and restricted access areas. In this case, the public access area proposes an 'image gallery' built by experts for educational purposes: the user can consult the images that radiologists consider of public interest (teletraining). Various criteria guide the user through this gallery: modalities, pathologies or anatomical areas.

The restricted access area, on the other hand, establishes an authentication session for each user access. The information of each user is stored in a profiles database. The system assigns a series of privileges to the open session in which it defines the functionalities a particular user may access. The access to this area takes place over safe connections that use the SSL v2.

Table 2 shows the levels and types of access to the system.

3. Results and discussion

The output and system validation tests were performed at three medium-sized hospitalary centres with diverse communication infrastructures: the Hospital

Table 2. IS scheme

Public access: gallery of images	
Search by modality	
Search by pathology	
Search by anatomic zone	
Images list	
Usual images	
Pathological images	Diagnosis consult
Restricted access: medical assistance	
Search by CHN	
Search by patient name	
Search by doctor and date	
Search by modality	
Own images	
Advanced search	
Reports consult	
Reports edition	
Management	
Users and profiles management	
Access log consult	
Table management	
Work statistics	
Web server management	

Modelo de La Coruña (HM), the Instituto Médico Quirúrgico San Rafael (IMQSR) and the Hospital Fundación Pública Virxe da Xunqueira (HFPVX). Table 3 shows the characteristics of each hospital:

All three hospitals use similar RISs, based on DR, TAC, NMR and telecommand equipment. The HIS of the FPVX hospital is the HP-HIS2 in a HP server, the other two hospitals use SAP on an IBM AS/400. This heterogeneity of equipment and communication infrastructure has allowed us to test the capacity and flexibility of our system in very diverse situations.

Table 4 shows the time needed to access information according to the load supported by the system. These tests were carried out in the hospitalary intranet (fast-ethernet connections); the secure webpages (SSL) were consulted using the Internet Explorer 5.5 browser on an Intel computer with Windows 98. Once the images were downloaded, 10 studies were consulted, all with acceptable response times. Table 4 shows the results of these tests.

We have also carried out a series of tests to find out to what degree the interface is accepted and appreciated by the users. Figure 6 shows a fragment of a questionnaire that registers the user's opinion on matters like access speed, selection of options, clarity of results, etc. The results of this validation process are mostly positive, especially concerning choice of environment and user-friendliness. Users ask for a better integration with other hospitalary systems (e.g. more clinical record data) and more tools to analyse images.

There were two possibilities for the storage of information:

(a) store the DICOM files in the database (chosen option); or
(b) store the files' path in the tables (option of most PACS).

Table 3. Characterization of the hospitals

	Beds	Internal communications	External communications
HM	90	FastEthernet	ADSL (2 Mb)
IMQSR	110	Ethernet	RDSI (128 Kb)
HFPVX	75	Ethernet-FastEthernet	Dedicated line (512 Kb)

Table 4. System performance

N images	Response
100	—
1.000	1 sec
5.000	4 sec
20.000	10 sec
40.000	16 sec

Our system opted for the first possibility, because it offers more security:

- Once the integrity mechanisms and RDBMS backup are configured, they cover all the data (including the DICOM files). This is impossible if the files are saved outside the database.
- Unauthorized personnel are double-checked: once when accessing the computer, once when accessing the database. If the files reside in system folders, anybody with access to the computer, but not authorized to view the database, could consult the information.
- The information is monitored exhaustively: each and every user must connect to the RDBMS, which records the activity of the database. Spanish law demands this type of monitoring.

This solution has one major drawback: the increased size of the database. The table that contains the DICOM files is a considerable size, and as mentioned before, we want to avoid unnecessary access to this table to optimize the performance of the system. We therefore use previews, small-sized images that reside in another table and do not overload the RDBMS.

4. Conclusions

One of the main advantages of this system is the reduction of the time needed for a diagnosis. The specialist uses a consulting tool that allows access to all clinical information on a patient: patients can therefore be attended more quickly and expenses reduced.

Patients residing in regions with a largely dispersed population, mountainous orography and harsh climate benefit directly from a system that offers telemedicine sessions, as there is no unnecessary travelling, no gathering at large hospitals, but better medical assistance and an improved standard of living.

We should not see PACS as the sum of interconnected equipment, but rather as a means: a concept for the exchange of information based on images and data between doctors, services and hospitals. It is a concept that integrates hospitalary information, and opens it to worldwide communication [26]. In most installations, the demand for information, be it from internal or external sources, takes places once the PACS is implanted. The answer to all these demands is the use of Web technology in an information system that integrates all the services of a PACS and a set of analysis and information processing tools.

Most PACSs are proprietary systems, developed for one hospital by one single company. They are closed systems for which no applications can be developed. Although the DICOM standardization is becoming more popular, many compatibility problems still remain. Our system, on the contrary, is entirely modular and scalable. Each of its components can be changed individually (the RDBMS, the Web server or the web-DB gateway) without any danger to the other components; this facilitates the incorporation of new standards (e.g. standards proposed and approved by CEN/TC 251) and the communication with proprietary technologies.

An expert can now access studies of interest from any computer connected to the Internet. A doctor can be on duty without being present in person. With the new generation of cellular phones (UMTS) it will even be possible to consult the stored information without having to be connected to a computer.

Finally, we have configured several security levels for access to the information, and a communications protocol that guarantees secure data transmission that is compliant with Spanish law [27, 28].

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