

# Integrating Medical Images and Clinical Information: InCor's Experience

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## ABSTRACT

The Heart Institute (InCor) of São Paulo has been committed to the goal of integrating all clinical information within the institution. In the last few years, InCor has successfully created a system for transmission, archiving, retrieval, processing and visualization of Medical Images and also a Hospital Information System that stores the administrative and clinical information. These integrated subsystems form InCor's Electronic Patient Record (EPR). Since InCor is one of the six institutes of the University of São Paulo Medical School and each institute has its own information system, exchanging information among the institutes is also a very important issue. This work describes the experience in the effort to develop a functional and comprehensive EPR, which includes access control, lab exams, images (static, dynamic and 3D), clinical reports, documents and even real-time vital signals. This paper addresses also the integration of distributed and heterogeneous EPR. Currently, more than 3.5TB of DICOM images, have been stored using the proposed architecture. The EPR stores more than 5 GB/day of integrated data and presents more than 1400 hits per day. The proposed storage subsystem allows six months of visibility for rapid retrieval and more than two years for automatic retrieval using a jukebox.

### keywords:

Electronic Patient Record, Interoperability, Medical Images, Modeling.

## I. INTRODUCTION

Electronic Patient Record (EPR) can be defined as a set of relevant patient information stored in digital format that allows adequate medical assistance delivered to the patient even in distinct places and scenarios [1]. The pursuit of an efficient and comprehensive EPR has stimulated several groups [2,3,4,5,6,7]. The potential advantages of an EPR over a traditional paper-based patient record involve distributed and simultaneous access, high availability, fast information retrieval, better quality, higher confidence. The capability to establish access control policy, including audit trail and digital signatures, assures higher level of privacy than conventional paper-based records. Furthermore, the inclusion of medical images and the integration of data from

different systems make possible a more comprehensive EPR.

The Heart Institute (InCor) of São Paulo has been committed to the goal of integrating all relevant information within the institution. In the last few years, InCor has successfully created a system for transmission, archiving, retrieval, processing and visualization of Medical Images and created also a Hospital Information System (HIS) that stores the institution administrative and clinical information. These integrated subsystems form InCor's Electronic Patient Record (EPR). InCor is also facing a challenge that is becoming very common in the healthcare field: the need of exchanging information among different institutions. Since InCor is one of the six institutes of the University of São Paulo Medical School Hospital (HC) and each institute has its own information system, exchanging information among the institutes is also a very important issue. This work describes the experience in the effort to develop a functional and comprehensive EPR, which includes lab exams, images (static dynamic and 3D), clinical reports, documents and even real-time vital signals. This paper addresses also the integration of distributed and heterogeneous EPR.

## II. MATERIAL AND METHODS

Beyond a simple interchange of data, we need to deal with a more complex level of integration. The desired level of interoperability can be achieved through the use of standards such as: UML - Unified Modeling Language [8]; DICOM - Digital Imaging and Communications in Medicine [9] for archiving and communication of medical images; CORBA - Common Object Request Broker Architecture [8] for heterogeneous and distributed objects; PIDS - Patient Identification Service [10]; COAS - Clinical Observation Access Service [11] and CIAS - Clinical Images Access Service [12].

A key point in the development is the modeling of patient data, including medical images as part of the global patient information. We developed an object-oriented representation of the whole clinical image domain and its integration to our HIS. Representation

of images is based on DICOM3 standard for communication and storage of medical images. This standard incorporates associated data such as identification of the patient, performed study, image acquisition context and image interpretation findings. DICOM3 standard describes a patient-oriented model that is well suited to follow all information related to a patient. However, as the main purpose of the project is to allow a higher level of complexity on searches, we expanded the model proposed on the standard in order to fulfill the requirement of retrieving medical images from any attribute. The new model allows the representation of different image modalities, integration of these modalities in a same study, investigation of similar images from different patients and contextual visualization and processing of clinical images [13].

Another important issue is that EPR is constantly evolving, therefore the architecture should be flexible enough to accommodate new functionalities and

technologies.

The implementation was based on client-server architecture via Web servers connected to several databases and subsystems: HIS, image (PACS) database, document database, signal monitors and resource access decision (RAD) subsystem (fig. 1).

#### A. Clinical and administrative data

The structured information of our HIS is formed from several clinical information sub-systems: lab exams; clinical reports; hospital procedures; diagnoses; prescriptions; patient evolutions; dismissals, etc. The general data model that integrates all these information is shown in figure 2 using the UML notation [13].

The MedicalRecord class represents the set documents that composes the medical record of patient and it is capable of representing any medical

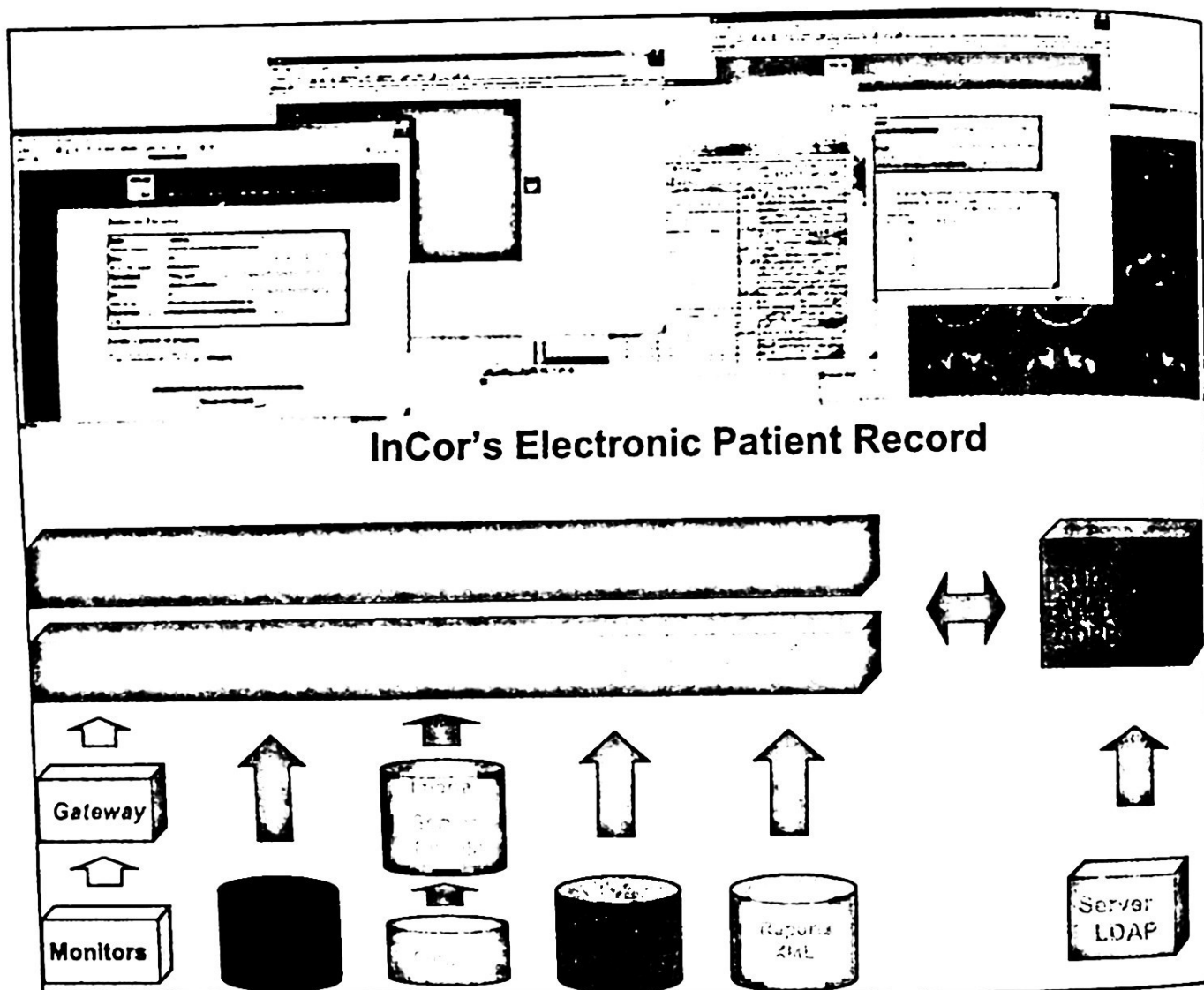


Figure 1. Overview of proposed integrated Electronic Patient Record

document. Each **MedicalRecord** instance has an association with one and only one patient. Each instance of **MedicalRecord** has an association with zero or more medical documents, represented by the **Document** class. The **Document** class represents all medical documents in a patient record. Subclasses of this class represent a specific document, such as x-ray report, ECG report, and so on. This class has two attributes, the document identifier (*docId*) and timestamp of the document creation (*reportTimeStamp*). Each document has also a list of other documents that support the creation of the document. For example, a physician could use information in previous reports to create a new document. These documents should be included in the supporting document list. The **PatientEvents** class represents the list of events that occurred in the life of a patient, such as admission, exams, surgeries, etc. Each instance of this class has an association with one and only one instance of the **Patient** class and with one or more instances of the **Event** class. Through the **PatientEvents** class it is possible to retrieve all the patient history. Instances of the **Event** class represent events that happened to the patient. The *eventId* attribute is the event identifier and the *eventTime* attribute is the event timestamp. Each instance of the **Event** class has an instance of the **PatientEvents** class associated to it. The **PatientEvents** class represent all the events for a patient, while the **Event** class represents only one

event. The **Patient** class stores demographic information of a patient. More detailed description of the classes and sub-classes can be found in [13].

## B. Medical Image data

The proposed image data model is a specialization of the Clinical Information Model, for the particular case in which the events involve the generation or manipulation of medical images. It is also described in details in [13].

Our PACS (Picture Archiving and Communication System) is based on DICOM3 standard and all image generators send their images to our institutional DICOM servers. The DICOM servers archive the images in the storage subsystem and update the image database and HIS database. Currently, the institution has the following medical scanners, most of them are DICOM compliant:

- Five (5) CATH labs (hemodynamic): 3 of them are ACRNEMA, whose data are converted to DICOM;
- Two (2) Magnetic Resonance
- Two (2) spiral CT;
- Nine (9) Nuclear Medicine scanners, including 1 PET

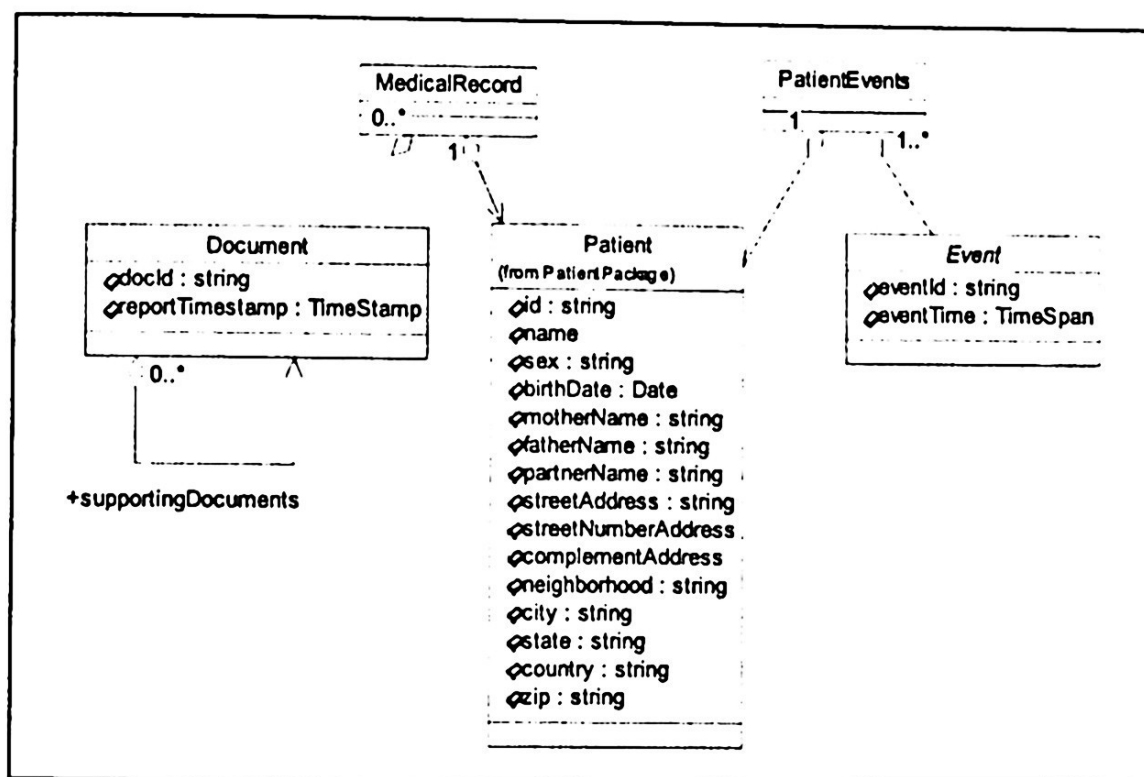


Figure 2. Proposed general Clinical Information Model

- Seventeen (17) ultra-sound/echocardiographs, whose video data are acquired and converted to DICOM.

The proposed architecture for storage combines online, nearline and offline modes in an asynchronous flow of data [14]. The flow is controlled by a manager software based on information archived in a database. The online storage is based on a RAID-5 magnetic disk system with 700GB of capacity. The access time is clinically adequate (less than 3s) using fast networking (fast Ethernet and Gigabit Ethernet.) For the nearline storage we have used a jukebox of DLT (Digital Linear Tapes) with 48 slots and 4 drives with 3.5 TB of storage capacity. The offline storage is simply the tapes on the shelves.

We have also developed DICOM viewer in java that is able to handle dynamic images at 30 frames per second.

### C. Scanned Document data

Some important patient information are still in paper format, such as patient consent. Since the EPR should provide all relevant context, we decided to include this kind of data as scanned documents. The process of document inclusion has three main phases [15]:

- Microfilming and scanning: these processes are carried out by an external service provider, that first produces a microfilm of the documents of a dismissed patient, and then digitizes the film content. The digital images are then indexed and stored as TIFF files in a CD-ROM.
- Loading data into EPR: the contents of CD-ROM are automatically loaded and integrated to the image database and HIS.
- Visualization: since the data are stored as multi-frame TIFF files, the documents are visualized by a TIFF viewer (web browser plug-in) in an integrated way from the patient folder (Fig. 1).

### D. Real-Time Signals data

Real-time vital signals, such as EKG and respiration, of patients in surgery and intensive care are obtained via special patient monitors (Siemens, models SC7000 and SC6002XL) that are able to communicate with other computerized systems via HL7 protocol (Health Level Seven) [16]. All communication between the network of monitors and the hospital network is carried out through an implemented HL7 server (Fig.1) that integrates this type of data with the HIS.

### E. Integrating distributed and heterogeneous EPR

A single person produces a huge amount of information during his/her life. Having this information available in a way that it could be easily retrieved is important not only for the patient, but also for research purposes. Since each Medical Institution usually has its own information system, which uses a particular combination of database management system, programming language, operational system, data structure and hardware platform, the task of retrieving the complete medical record for a single patient is highly complex. Even inside a single healthcare institution, information is commonly distributed over different departmental systems, which also have a particular combination of software and hardware platforms. This inherently heterogeneous environment makes the task of integrating healthcare information a challenge to meet.

The integration of distributed and heterogeneous systems can be attained with the use of middleware objects that work as interfaces between different systems. We have utilized middleware based CORBA [8], since it allows integration of a large variety of heterogeneous environments and it is also an open international standard. However, CORBA is not enough to deal with clinical information exchange. OMG has defined some services for Healthcare area. Specifically, we are using three of them: PIDS, COAS and CIAS.

The proposed architecture is composed by four basic services (middleware), as shown in figure 3. Patient Identification Service (PIDS) retrieves patient demographic information. This service provides a standard method for locating person identifiers and their associated records across facilities and enterprises. The Clinical Observation Access Service

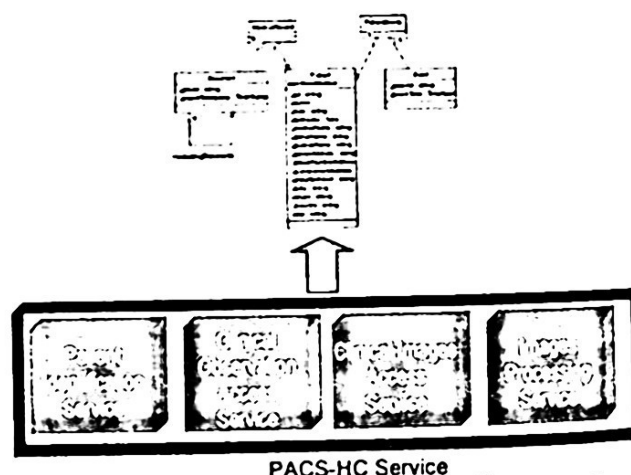


Figure 3. Services for interoperability among heterogeneous systems.



(COAS) is a mechanism for retrieving clinical observations data from information repositories and applications. The Clinical Images Access Service (CIAS) retrieves medical images. This service permits search of images of a single patient or based on images characteristics, as body part, equipment, modality, and so on. The Image Processing Service contains several image processing methods, as blurring, zooming, segmentation, etc. Clients of the distributed system, that could be running in any software and hardware platform, can access these services through CORBA interfaces. The four basic services are used by the proposed system, as shown in figure 3.

#### F. Access Control

Designing proper models for authorization and access control for the electronic patient record is essential to wide scale use of the EPR in large health organizations. We have proposed a contextual role-based access control (RBAC) authorization model for EPR [17]. The implemented RBAC regulates user's access to computers resources based on organizational roles [18] and extends the proposed National Institute of Standards and Technology (NIST, USA) RBAC reference model. A contextual authorization uses environmental information available at access time, like user/patient relationship, in order to decide whether a user is allowed to access an EPR resource. This model was implemented using Lightweight Directory Access Protocol (LDAP), Java programming language and the CORBA Security Service and Resource Access Decision Facility. With these open and distributed standards, heterogeneous EPR components can request user authentication and access authorization services in a unified way across multiple platforms.

The proposed model is consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) recommendation to regulate access to patient health information. The run-time components of contextual RBAC authorization model is formed by a set of administrative tools, a contextual RBAC authorization server and the implementations of context interfaces.

The authorization model representation was stored in a hierarchical directory service, with access and data scheme description standardized by LDAP protocol [19]. Administrative tools allow privileged users to manage the EPR authorization policies stored at LDAP server. The contextual RBAC authorization implementation was integrated into a Java/CORBA server. It is in charge of user authentication, session management and access authorization decision. Authentication and session management are done through implementations of *PrincipalAuthenticator* and *Credentials* standard interfaces of the CORBA

Security Service [20]. Access authorization decision service is available through an implementation of *PolicyEvaluator* standard interface of the Resource Access Decision Facility [21] from Object Management Group. Contexts are implemented in Java as dynamic libraries loaded at run-time using the Java Extension Mechanism.

### III. RESULTS

Currently, user authentication and access decision services has been used daily at InCor. The process for deployment of our solution was based on the following steps: definition of roles; load of user's profiles from personnel software into LDAP server and assignment of respective roles; creation and use of authorizations by the applications that compose the EPR. So far 1900 users have been registered and assigned to some of 51 professional roles. Furthermore, complex access control logic can stay outside the application, though considering the necessary context to grant or deny permission. Thus, changes in authorization logic do not imply changes in application code. Another benefit is the conflict policy resolution that considers the need to know principle. Conflicts can be determined according to the authority and responsibility defined to each role via associated authorizations. Only the actions that configure real conflicts of interests are forbidden to a user with conflicting roles assigned. Finally, automatic role activation leaves the user free from explicit selection of a role, making RBAC transparent to final users.

In terms of volume, since mid of 2000, more than 3.5TB of DICOM images have been stored and integrated using the proposed architecture. The EPR stores more than 5 GB/day of data and presents more than 1400 hits per day. The proposed storage subsystem allows six months of visibility for rapid retrieval (online mode) and more than two years for automatic retrieval using the DLT jukebox.

The distributed access of all integrated data is carried out via web browsers through our network with around 1000 terminal clients. The clients can be conventional microcomputers or linux thin-client terminals configured with 128 MB or more of memory space.

### IV. DISCUSSION

Implementing a comprehensive EPR is a huge challenge that several centers in the world are pursuing. We described our experience and our vision about EPR. It includes several important and relevant pieces of information, but it is not comprehensive enough yet. Some features have not been integrated such as material control. However,

the proposed model allows the representation of any medical document, as well as procedures, guidelines and clinical observations.

Realistically, a common patient has records in several EPRs. It is clear the importance of interoperability among distributed and heterogeneous EPR to collect distributed information about a specific patient. This is a very complex issue that we are also addressing. We are proposing CORBA services such as COAS and CIAS for integration of heterogeneous and distributed systems. We strongly believe that the use of non-proprietary standards is the path that will make a comprehensive Electronic Patient Record a reality. The proposed approach is based on standards such as CORBAMED specifications, DICOM and XML.

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