Standardization, security and interoperability procedures for international certification of healthcare services

(Certification of Education Programs, R&D, Partnership)

1. Overview of Healthcare Information Management

The principal scope of Healthcare Informatics is to offer an optimal alternative to actual medical information communication systems mainly based on numerous physical documents. The new healthcare platform should be capable to follow patients moving from registration in the hospital to the recovery process outside the hospital, from both clinical and administrative service perspective. At each time moment the current situation and problems of a patient should be available for the authorized persons: clinical patient evolution, involved costs, assigned medical staff, medical equipment, etc.

Research departments of software companies defined four levels of healthcare informatics implementation from the perspective of *process integration as function of quality of medical services provided*: (1) stand-alone healthcare, (2) connected healthcare, (3) integrated healthcare, and (4) integrated health management (see diagram in Fig. 1) [1, 2, 3]:

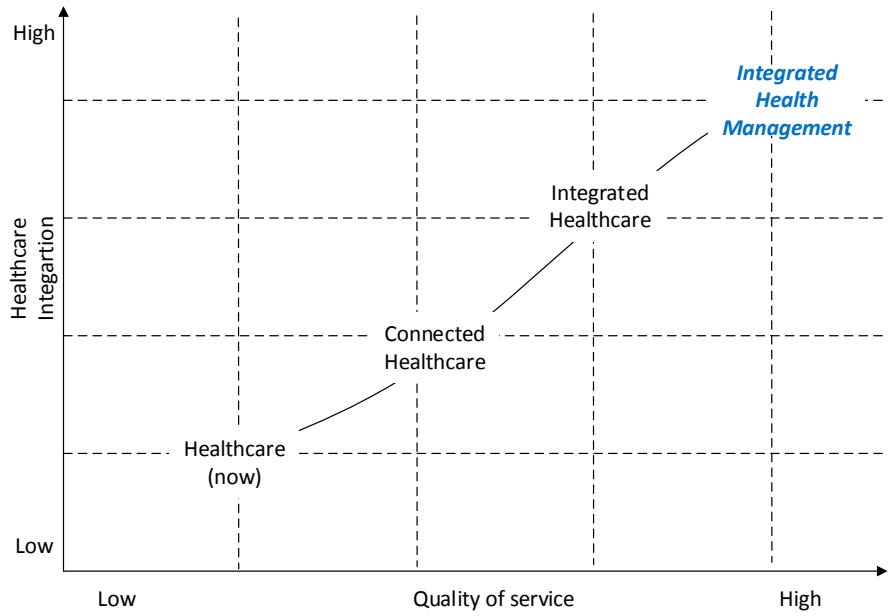

Fig. 1 Healthcare requirements in Integrated Health Management

- Stand-alone healthcare implementations (current state), presented as stand-alone institutions implementations, restricted to fragmented systems implemented at departmental or institutional level.

- Connected healthcare achieves primary care integration with processes from EMR, EHR, facility management and Imaging Centres building digital hospitals. Real time alerts and messages are functional locally.
- Integrated Healthcare achieves automation of manual processes from hospitals, clinics and physician offices, health information stored in different EHRs is exchanged, telemedicine and home care is integrated, patients and providers have access to data via health portals.
- Integrated Health Management (IHM) comes on top of Integrated Healthcare, cross EU health information exchanged is achieved, providers and payers are integrated via enterprise resource planning services, personalized, predictive and preventive process integrated based on personalized, evidenced base medicine.

2. System requirements

2.1. Integrating the Healthcare Enterprise requirements

IHE (*Integrating the Healthcare Enterprise*) is a healthcare organization that offers healthcare processes, profiles, technical frameworks in order to facilitate information systems connection. From the medical software application development point of view, the IHE specifications facilitate fast and safe releases of new products as well as simple mechanisms for implementing interfacing options with other, already existing ones [4].

IHE identifies a subset of functional components from a medical informatics system and describes its interactions using a set of transactions. The actors and the transactions described in the IHE specifications are abstractions of the medical system present in a hospital.

- *Actor* represents the role assumed by an entity of the system. The main actors defined according to the IHE specifications are: image acquisition devices, patient registration systems, cost calculation systems for billing the performed medical procedures, medical examination management systems, images, medical reports and associated information visualization systems, image storage management and archiving systems, medical reports management systems, medical reports visualization systems, medical images printing servers (DICOM Print Server) and the financial administration systems.
- *Transactions* are interactions between actors that transfer the required information through standards-based messages.

The reason behind introducing these actors and transactions is to be able to define the interactions between the entities forming a medical informatics system.

Integrating profiles offer a common language that healthcare professionals and vendors that may be used in communicating requirements for the integration of products. Integration Profiles describe real-world scenarios or specific sets of capabilities of integrated systems. An Integration Profile applies to a specified set of actors and for each actor specifies the transactions necessary to support those capabilities. IHE promotes the coordinated use of established standards such as DICOM and HL7 to address specific clinical need in support of optimal patient care.

The DICOM and HL7 standards provide the necessary means and technology for the medical software applications development, while the IHE ensures the specifications needed for implementing these into the real-world. IHE specifications include the following equipment and medical software applications:

- Informatics systems that ensure patient and resource management for medical centres (HIS, RIS);
- Imaging and investigation equipment from the medical field (MR, CT, US, CR, DX, etc.);
- Software applications from the field of medical imaging (PACS, Review Stations, Reporting Systems);
- Other equipment from the medical field (Printers, Imagers, etc.).

Major requirements to design and implement a healthcare cloud environment for medical devices are given mainly by availability of resources:

- Application servers should always be available to process all arrival requests from multiple medical devices (registered or non-registered but entitle) and provide response within agreed timelines.
- Cloud entities must be designed to achieve higher degree of physical and virtual resource utilization than the agreed terms via Service Level Agreement contract except emergency cases.
- Mechanisms to automatically adjust computing resources need to be included in order to offer support for newly register medical devices or increase tasks from an already registered device.

2.2. Healthcare Security requirements

Information technology is increasingly used in healthcare in order to minimize costs and improve the quality of medical services. A high degree of security has been developed for designated medical information systems, degree that should be maintained also for sharing IT services over the Internet - a concept brought by cloud computing technology. Healthcare systems must have a proper security and privacy framework and mechanisms since disclosure of medical data may have severe consequences especially for patients, and could affect the overall quality of medical services.

Cloud Security Alliance has published a survey result in form of a cloud security threats top ranked in order of severity identifying: data breaches, data loss, account hijacking, insecure APIs, Denial of Service, malicious insiders, abuse of cloud services, insufficient due diligence and shared technology issues [5].

In [6] a requirements list is build up on a collection of representative research papers used for creation of a security pattern for healthcare hybrid cloud. Authors identify as security requirements for a healthcare electronic system: confidentiality, integrity, availability, non-repudiation, patient privacy, patient consent and authorization.

The research reported in [7] identified healthcare cloud computing security and privacy risks that need to be taken into consideration in the area of information technology in clinical environment: authentication and access control, virtualization, mobile access/access via internet, flexibility and changeability of services and service providers. Particularly for public clouds, shared usage of computing resources, outsourced and distributed computing are identified as risks.

Data transfer from local databases to large data centres involves a series of security challenges in terms of virtualization, accessibility, privacy, confidentiality and loss of data accessed from a third party. Data security in cloud computing analysis with focus on migrating from single cloud to a multi cloud environment, done in [8], concluded that data encryption and implementation of secure standards are not sufficient for securing a single cloud.

Based on papers results presented above, main security requirements in implementing a healthcare system have been identified in terms of security and privacy as: availability for assuring that data is available whenever it is requested, authentication for person/system identity confirmation, authorization for ensuring that data is available only for authorized

entities, integrity assurance that data is accurate and consistent, confidentiality grant that data is available only for authorized entities and data loss guarantee that data stored and processed in the cloud will not be lost.

3. Information Systems in Medicine

The healthcare sector has been adopting technologies and information systems to support diagnoses, treatment and patient care. One of the most important areas of healthcare is represented by the medical imaging due to the huge amount of information that is produced by new technologies in imaging diagnosis. Digital storage and visualization devices need to be introduced in order to improve physician's workflow, to speed it up and to reduce costs.

Significant changes have been registered in digital radiology modalities, e.g. X-Rays, Computed Tomography (CT), Magnetic Resonance Imaging (MRI), Ultrasounds (US), etc. Healthcare institutions have purchased new generation sensory devices with high resolution and large image data size. The amount of images produced by acquisition devices has increased and the medical image repository has to scale up in order to support the large volume of medical data.

Health Information Exchange related systems can be divided in three main categories:

1. Non-Clinical Information Systems deals with administrative flows: Enterprise Resource Planning (ERP);
2. Clinical Information Systems deals with the management of medical data: Radiology Information System (LIS), Operating Room Information Systems (ORIS), Pathology Information Systems (PIS), Radiology, Information Systems (RIS);
3. Health Information Systems acts as interface for database centres being used for storing, retrieving, and displaying of medical data: Electronic Medical Record (EMR), Electronic health Record (EHR), Patient portals, Picture Archiving and Communication Systems (PACS).

Further, *standard information systems* that are required by a healthcare organization based on medical imaging are described in detail.

Electronic Medical Record and **Electronic Health Record**

[HIPPA] defines the two terms as:

- *Electronic Medical Record* (EMR) is an electronic record that contains the standard medical and clinical data gathered by a healthcare provider. EMR is used for diagnosis and treatment containing all patient medical history from one practice.

  The information stored in EMRs is not easily shared with providers outside of a practice. A patient's record might even have to be printed out and delivered by mail to specialists and other members of the care team.

- *Electronic Health Record* (EHR) is an electronic record of health related information on an individual that is created, gathered, managed and consulted by authorizes health care clinicians and staff. EHR include a comprehensive patient history on top of data collected by a healthcare provider.

For example, EHRs are designed to contain and share information from all providers involved in a patient's care. EHR data can be created, managed, and consulted by authorized providers and staff from across more than one health care organization.

Picture Archiving and Communication Systems

The data volume generated in medical imaging laboratories by X-Ray, multi slice CT, high field MRI, and ultrasound needs to be efficient stored and permanent available. These labs need to consider several problems related to IT infrastructure including: solution scalability, fault tolerance, performance issues, hardware maintenance costs and migration.

The Picture Archiving and Communication System (PACS) solution approaches several hardware, communication networks and software technologies. PACS describes five main functions covered by the use of digital image technology: 1) acquisition, 2) communication (transfer), 3) storage (archiving), 4) display and 5) processing [4], [9]. These functions are used to communicate image data between modalities, workstations, remote storages and archive hardware, creating print jobs and exchange image studies on CD-ROM.

PACS's main components (image acquisition and scanning devices, storage archive units, display workstations and databases with patient record) communicate through the network with Radiology Information System (RIS) and Hospital Information System (HIS), building up a filmless radiology service. In order to provide doctors and departments with medical images, MRI and CT scans should be transferred from modality machines to the PACS server through the standardized DICOM communication protocol.

In [10] the author proposed three main solutions that describe general radiology workflows in an imagistic centre:

- *Stand-alone workflow* presents a multiple central repository that acts as local storage, medical imaging data being stored in a central archive from where it is send automatically to the workstations for interpretation. Workstations are able to query and retrieve data from the central archive server; the server automatically prepares data and sends it to the workstations.
- *Client-server workflow* presents a single central repository; the imaging data is sent to PACS Archive being available for download based on patient code. No local storage is implemented; images are automatically discarded after the review and the user has access to all PACS data without query/retrieve or prefetching.
- *Web-based solution* presents a web application deployed in the same data centre with the PACS Archive. The user can access medical data using Internet connection and the provided web browser.

PACS technology has been used for almost a decade to successfully manage the increasing volumes of radiology images. One of the main reason that PACS technology is developed by many researchers as a stand alone system (independent of the implemented solution) is given by DICOM (Digital Imaging and Communication in Medicine) standard that permits the transfer of medical images and capability to interface PACS with any information system environment [11].

Radiology Information Systems

The Radiology Information System (RIS) provides support to patient- and resource management, being a specialized ERP application in the area of radiology. RIS provides the following main functional workflows: (a) patient registration, (b) examination scheduling, (c) automated distribution of documents, (d) data base access management, (e) document scanning and storing, (f) management of the imaging centre's resource, (g) cost calculation, and (h) patient management (allergies, procedure incompatibles, etc.).

RIS acts as a component of an overall radiology systems along with PACS. Considering the functionality offered by RIS and the capabilities developed by ERP industry solutions, the RIS solution can be successfully be replaced by ERP Healthcare industry solution defined below.

Enterprise Resource Planning

During the last decades many healthcare institutions have introduced ERP (*Enterprise Resource Planning*) software. From the organizational view, a single instance of an ERP system can map one department of a hospital as well as worldwide institutions with a lot of departments and subsidiaries. First, the ERP systems were developed as systems that could create a strong integration of logistics and financial processes. In recent years the functionalities of an ERP-system have expanded drastically with *supply-chain management*, *workflow management*, human resources management, etc. An ERP-system is in principle a standard organization-information-system. By setting different parameters in the system, an ERP- system can be 'customized' so users experience it as a custom-made system.

ERP is defined as a software solution tailored to the specific standards, processes, activities and functions *creating an optimal integration of logistics and financial processes of an organization* [12], [19].

Different ERP industry solutions have been offered by providers, for example ERP for healthcare is a portfolio of state-of-the-art software solutions customized for healthcare industries to allow integration with clinical systems providing content, tools and methodologies.

An ERP system is based on the Client/Server architecture with three layers:

- Database layer: stores application programs and data;
- Application layer: runs business application program in client/server concept. Application modules access database in order to read/write data based on input/output data required from the presentation layer;
- Presentation layer: accesses a GUI (*Graphical User Interface* or *Web Portal*) from a local user PC. The presentation layer allows connection from mobile devices such as: PDA, laptops, external PCs, mobile phones through the Internet.

In order to conduct a case study on standardization, security and interoperability required to certify at international level healthcare services and systems, world-wide commercial software packages on Enterprise Information and Management, available on the market are further presented. One such leading package is SAP, standing for "Systems, Applications, and Products in Data Processing". The use of this package makes it possible to track and manage in real-time sales, production, finance accounting and human resources in an

enterprise, independent of her business domain. SAP software was developed to be modular, scalable, open and flexible, allowing institutions to tailor it specifically to their needs. SAP calls this approach to implement software "configure to order" because each implementation will be different according to each customer's needs. SAP provides integration tools and methods for linking legacy and distributed systems as well as a host of third party software solutions, to get information into the right hands, internally and externally.

SAP for Healthcare is built up on SAP ERP and is designed to integrate all basic functions of any healthcare organization: financials, human resources, procurement and logistics execution, sales and distributions and industry specific solutions for healthcare.

SAP healthcare solution offers three applications: IS-H (Industry Solution - Healthcare), Patient Management and Collaborative E-Care Management covering analytics, mobile (Sybase Unwired Platform), cloud (SAP Business ByDesign), database and technologies categories (SAP HANA).

SAP offers four levels of data interchange:

[1] **EDI** (*Electronic Data Interchange*) messages are used for exchanging business data between SAP and non-SAP systems. This architecture requires a so called Intermediate Document (IDoc) Interface following the definition of a data structure and the processing logic of this data structure. The data structure used as exchange format of the communicating systems using different methods: RFC or as a file.

[2] **RFC** (*Remote Function Call*) interface is a protocol used by SAP for communications between remote independent systems: independent SAP systems or SAP and non-SAP systems.

There are several methods of implementing an RFC interface:

- Using RFCs into the ABAP programming environment acting as either the client or the server to a SAP system.
- Using Business APIs (BAPIs) to access and work with SAP business objects which make up an object-oriented representation of real-world business objects. SAP system contains Business Application Programming Interfaces (also called Business APIs, or BAPIs), which provide a programming interface to business objects. BAPIs feature a set of methods for working with and manipulating SAP business objects.

[3] *Web Service* is an interface implementing the industry standards of SOAP and WSDL (and usually HTTP) to expose functionality to a web service consumer. It is a technical implementation to expose functionality through a standards based protocol. In case of SAP applications, SAP RFC, BAPI, IDOC are proprietary methods of integration that require middleware adapters. Web services allow a direct integration between non-SAP applications with the SAP business suite.

[4] *Enterprise Service SOA toolsets* provided by SAP to manage the usage of web services in the enterprise. A SAP enterprise service is technically a web service, based on SAP global data types and that has been modelled within SAP ESR using business objects, process components and the SAP enterprise model.

SAP for Healthcare offers a method to integrate customers' and partners' systems using the web services technology. Standards-based integration offered by SAP is done with fields of the interface that are more oriented towards healthcare standards than towards SAP terminology. SAP implementation in the field of healthcare requires an IAH (*Integration Adapter for Healthcare*) HL7 Adapter based on IHE compliance and HL7 standard.

SAP integration with partner and customer systems is considered on a common reference model based on IHE specifications and HL7 standard containing: use cases, roles, business objects, enterprise process components and enterprise services (Fig. 2) [4], [13].

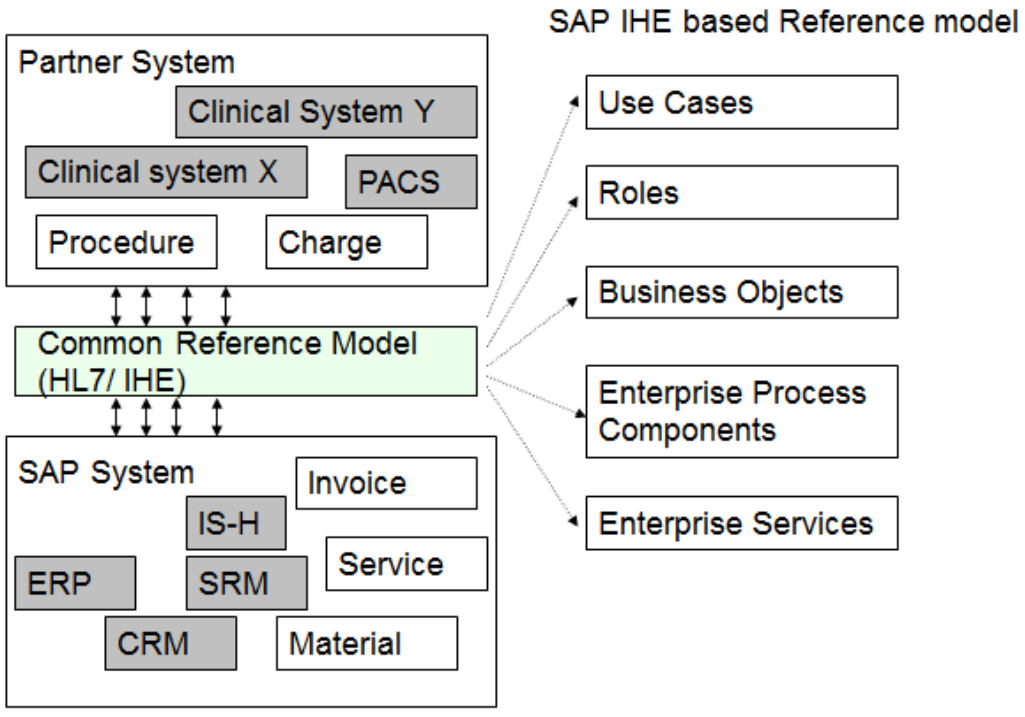

Fig. 2 SAP IHE Integration Reference Model

A common reference model is used to configure middleware application between a SAP system and a non-SAP system in order to facilitate legacy system integration. SAP Healthcare solutions presents integration with PACS systems and other clinical systems using procedure and billing (charges) that must be transferred in SAP as invoices and services based on predefined materials.

- **Use Cases:** a textual and graphical depiction of the actors and operations that addresses information exchange in the context of a set of specific tasks performed by different systems or devices;

  Example: A hospital scheduling clerk receives calls from patients asking for outpatient appointments. The clerk asks each patient whether he or she has previously been a patient at the hospital. If yes, the clerk searches for the existing patient record by name and birth date (Find Patient by Basic Data operation). If not, the clerk creates a temporary patient entry for the patient, and enters the patient's name, date of birth, and insurance status (Create Patient operation).

- **Roles:** actors are information systems or components of information systems that produce, manage, or act on information associated with operational activities in the enterprise;

  Example: Patient - is any person who potentially receives medical attention, care or treatment. The person is most often ill or injured and in need of treatment by a healthcare professional.

- **Business Objects (BO)** are entities of the real world that the different systems of a given system landscape want to communicate with like a patient, an invoice or an encounter.

  Example: A Patient Business Object is used to access and manage patients. It is a healthcare-specific projection of the Business Partner business object and functions in the same way. The Patient Business Object is located within the Healthcare Business Partner Data Management process component, which is a central process component of all hospital information systems. This process component provides service operations to create, maintain, and read instances of patient business object.

- **Enterprise Process Components** are logical components that provide a product independent view on the IT landscape. Examples are: Patient Financials or Patient Encounter Management.

Example: Healthcare Business Partner Data Management provides a unique identifier for every patient in the enterprise or in a collaborative healthcare network. This would include the medical centre, outpatient clinics, practice offices and rehabilitation facilities. All registration systems would look to this component to obtain patient information based upon several identifiers.

- **Enterprise Services (ES)** are offered at a business level of abstraction upon the defined BO's. ES represents a standards-based way of encapsulating enterprise functionality and exposing it as a reusable business service that can be combined with other services to meet new requirements. Enterprise services, defined by SAP and its partners and customers, can be assembled together to compose new applications or enable new business processes [13].

  Example: Create patient service is used when a new patient is being admitted. Create Patient inbound operation creates a new instance of the Patient business object to store the information. Example of input data for this operation: patient's name and birth date are entered; if required, more details can be entered later, using the Maintain Patient or Update Patient operation.

Based on the reference model presented above, SAP provides several available bundles (Table 1), business objects and enterprise services, as well as additional resources that may be useful for the configuration of the system and the deployment of integration scenarios, for example the IAH HL7 adapter from SAP [13].

Table 1 SAP Healthcare Enterprise Services Bundles

Bundle	Description
Hospital Communication Module (IS-HCM)	This bundle offers *application-to-application services* (A2A) whose intention is to provide a functional equivalent to the widely-used hospital internal communication capabilities of SAP Patient Management (usually known as IS-HCM or simply HCM), in order to overcome its current technological restrictions (see below) and allow for stronger support of Industry Standards and initiatives such as HL7 and IHE, respectively.
Patient Administration	This bundle uses application-to-application (A2A) services to seamlessly integrate SAP Patient Management with the many third-party systems typically deployed in today's healthcare facilities in the areas of Patient Identification and

	ADT (Admission, Discharge, Transfer).
Medical Activities, Patient Billing and Invoicing	This bundle is intended to support the processes of documentation of medical activities, of patient invoicing and of payment handling.
Medical Documentation and Coding	Medical documentation is normally created in clinical systems, but is also needed in SAP Patient Management for administrative, billing and reporting purposes. This ES Bundle offers asynchronous services for the reception of this documentation.
Resource Planning and Scheduling	This bundle supports a range of processes in the healthcare area - shift planning, occupancy management, and appointment scheduling - by service enabling the SAP Patient Management and SAP Human Capital Management solutions in order to provide connectivity to partner solutions for resource planning and scheduling.
Resource and Supply Chain Planning for Healthcare Providers	This bundle handles two key functions: it enables healthcare professionals to requisition medical supplies on the one hand and assess human and material resource schedules on the other.

4. Standards in Medical Informatics

The main objective of *medical informatics standards* is to produce a set of specifications that allows free communication and exchange of data between medical software applications in order to eliminate or reduce incompatibility among different applications.

DICOM and HL7 standards provide the necessary means and technology for developing software applications, while IHE supervises their adoption into real-life medical world. IHE provides support for the medical software applications users by ensuring a better access to information and eliminating, as much as possible, confusions or misunderstanding when acquiring such applications.

4.1. Health Informatics

4.1.1 *Health Level 7*

Non-profit organization Health Level 7 (HL7) developed a series of standards dedicated to process and management of administrative in the area of clinical data communication split into message protocols, conceptual (HL7 RIM), document (HL7 CDA) and application standards (HL7 CCOW) [14]. HL7 standard addresses to software developers and medical

equipment manufactures with the declared goal of unifying the way the information present in medical units and institutions is transmitted, exchanged and/or stored, based on a common format, agreed by all the parties involved.

HL7 provides a set of specifications that allow communication and exchange of data between medical software applications in order to eliminate or reduce incompatibility among different applications. HL7 offers specifications corresponding to the following fields/domains:

- Patient management – admit, discharge, transfer patient (ADT);
- Queries, resources (rooms, beds, devices, etc.), patient scheduling;
- Scheduling of medical procedures, results, clinical trials;
- Financial administration;
- Medical documents;
- Medical records;
- Medical treatments;

ISO/HL7 10781 Electronic Health Record: System Functional Model describes the content and means of functioning of the electronic health record system independent if it is a system or a system of systems. This standard refers to healthcare specific applications that manage electronic healthcare information along with middleware or other infrastructure components.

ISO/HL7 27932 Data Exchange Standards: HL7 Clinical Document Architecture (HL7 CDA) is a document mark-up standard that specifies the structure and semantics of clinical documents for the purpose of exchange between healthcare providers and patients. HL7 CDA provides a model for clinical document interchanging and makes possible the integration of information technology in the medical field. CDA allows for the clinical documents to be compatible to the informatics field by using XML, HL7 RIM (Reference Information Model) and medical informatics codes but also tries to maintain a high degree of understanding and assimilation by the medical staff.

The CDA standard is based on the following concepts:

- CDA documents are based on the XML standard (Extensible Mark-up Language) and can be viewed using web browsers;
- The structure of the CDA documents is based on the HL7 Reference Information Model (HL7 RIM) and the HL7 data types (ISO/HL7 21090);

- The CDA specifications are very flexible and are structured on 3 levels: document level, section level and entity level;
- CDA document is a completely defined object and can include text, images, sound recording and other multimedia components.

HL7 CDA clinical documents contain observations and services and have the following characteristics/attributes:

- *Persistency*: continues to exist in an unaltered state for a well-defined period of time;
- *Organization*: maintained by an organization entrusted with this task;
- *Possibility to certify*: contains a set of information that can be certified;
- *Context*: sets a predefined value;
- *Integrity*: the authentication of a clinical document is made as a whole and is not applied to parts of the document without taking into account the whole context;
- *Readability*: the possibility of being read. Guaranties that the obtained CDA document can be easily viewed using a web-browser.

ISO/HL7 21731 Health informatics: The reference information model is an object model created as a representation of HL7 clinical data domains and identifies the life cycle that a message or groups of related messages will carry. HL7 RIM standard defines a number of messages that cover all activities specific to medical units. A message is made up of segments, fields, components and sub-components and is characterized by the message type (a 3 character code) organized by different domains/fields (e.g. admit, discharge, transfer, clinical trials scheduling, etc.).

According to HL7 RIM, a medical application that uses HL7 standard sends to another application a “HL7 type” message generated as a result of some medical event occurring in the current activity: admit patient - A01, transfer patient - A02, discharge patient - A03, etc. If the application receiving the messages also complies with HL7 regulations, then it can be certain that there will be no missing information, all information received will be interpreted in the right way and a proper response will be issued back. Thus, the exchange of information made is coherent and efficient.

ISO/HL7 27931 Data Exchange Standards establish an application protocol for electronic data exchange in healthcare environments.

ISO/HL7 21090 Health informatics: Harmonized data types for information interchange provide a set of data types definitions for representing and exchanging basic concepts that are commonly encountered in healthcare environments in support of information exchange in the healthcare environment. The standard also specifies a representation of the data types based on XML along with UML definitions of data types. This data type standard is intended to be used for external interfaces and message based communication design.

4.1.2. *DICOM*

ISO 12052 also known as DICOM (**D**igital **I**maging and **C**ommunications in **M**edicine) is an industry standard for handling, storing, printing and transmitting information in medical imaging [15]. This standard addresses the exchange of digital images and information related to production and management of those images beetween bmedical imaging equipment and management information systems facilitating interoperability. DICOM defines two basic themes: *data models of real world objects* representing medical imaging exams and *communication protocols* for exchange and inquiry of these objects [16].

The DICOM standard was developed with the purpose of helping the distribution, display and storage of medical images (CT, MRI, US). The standard is more than just a file/image format, being in fact a set of standards that describe the way digital data used in medicine can be transferred, stored and displayed.

The DICOM standard has a series of advantages:

- It is a universal standard. Generally, all medical equipment acquiring medical images supports this standard and communicate among them using it;
- Images are stored at a higher quality. DICOM supports:
    - *JPEG compressed images*: lossless JPEG compression for 8, 10, 12, 16 bits grey levels, or 24 bit colour images, or loss JPEG compression for 8, 12 bits grey levels or 24 bits colour images;
    - *JPEG 2000 compressed images*: lossless or loss JPEG 2000 image compression for 8-16 bits grey level or 24 bits colour images
    - *RL (run-length) compressed images*
    - *Uncompressed images* (bitmap)
- Allows the storage of additional information related to the image acquisition parameters. DICOM can store besides the actual 2D image additional information,

such as: the patients 3D position, physical size of the objects present in the image, slice thickness, exposure parameters, and others. These are used for a better later processing and interpretation.

- Support for full storage of medical data. The DICOM files and messages support more than 2000 standardized attributes that maintain patient's medical data and images

Images are acquired and stored using parameters that are device independent. Likewise, DICOM images can be processed without taking into account the actual device used in the acquisition process

4.2. Security standards

Ethical, legal and technical support of security analysis is based on the international standards for e-health infrastructure documented by *International Organization for Standardization* (ISO) [15]. The main standards identified in the area of healthcare security are listed in continuation [18]:

- ISO 27000 family of standards (ISO 27001 through ISO 27006) addresses general information security;
- ISO 27799 information security management in healthcare using ISO/IEC 27002;
- ISO 18308 Health Informatics requirements for an electronic health record architecture.

ISO/IEC 27000 Information technology: Security techniques overview - provides general terms and definitions commonly used in information security management system family of standards being applicable for all types and sizes of organization.

European Union Agency for Network and Information Security (ENISA) adopts ISO 27001 and ISO 27002 controls for cloud computing offering a security analysis for governmental clouds based on 21 EU countries case studies [2], [6].

ISO/IEC 27001 Information security management: Provides requirements for an information security management system. It is an approach to manage sensitive company information based on risk management process in a way that information remains secure, including people, processes and IT systems. The standard is applicable for small, medium and large business implementations in any sector.

ISO/IEC 27002 Information technology: Security techniques act as a guideline for organizational information security standards and management practices from the perspective of selection, implementation and controls considering organization risk environment.

ISO 27799 Health Informatics: Information security management in health using ISO/IEC 27002 defines guidelines to support the interpretation and implementation in health informatics and can be seen as an extension of ISO/IEC 27002 applied in health informatics domain. ISO 27799 provide a set of controls and best practices for managing health information security that helps organizations to achieve minimum level of security in terms of confidentiality integrity and availability of health information.

ISO 18308 Health Informatics: Requirements for an electronic health record architecture; defines a set of requirements for healthcare system architectures detailing security and privacy issues including communication between systems as follows:

- *Authentication* as the need of verifying the identity of a person / system that claims to be;
- *Authorization* as a framework of personal access rights and authorizations role;
- *Integrity* as the data property to preserve the accuracy and consistency of data regardless of changes made;
- *Non-repudiation* as the property of data to confirm the integrity and origin of a data item;
- *Confidentiality* as the data property that indicates the extent to which affected data have not been made available or disclosed to unauthorized individuals, processes or other entities [20].

References

[1] ***, NIST Special Publication 800-165, Computer Security Division: 2012 Annual Report. Accessed on January 2014 http://csrc.nist.gov/publications/PubsSPs.html

[2] ***, Practice Guide for securely deploying Governmental Clouds, ENISA 2013. Accessed on April 2014, http://www.enisa.europa.eu/

[3] ***, Healthcare Information and Management Systems Society, 2014 HIMSS Analitics Cloud Survey, http://www.himssanalytics.org/home/index.aspx, Accessed on December 2014

[4] ***, Integrating the Healthcare Enterprise, IHE Radiology Technical Framework Integration Profiles, Available at http://www.ihe.net/Technical_Framework/index.cfm#radiology, Last accesed on July 2012

[5] ***, Cloud Security Alliance–Cloud Computing Top Threats in 2013, Retrieved from https://downloads.cloudsecurityalliance.org/initiatives/top_threats/The_Notorious_Nine_Cloud_Computing_Top_Threats_in2013.pdf, Last accessed on June 2013

[6] Y.-Y. Chen, J.-C. Lu, J.-K. Jan, A Secure HER System Based on Hybrid Clouds, in Journal of Medical Systems, vol. 36, no.5, October 2012, pp.3375-3384

[7] Knut Haufe, Srdan Dzombeta, Knud Brandis, Proposal for a Security Management in Cloud Computing for Healthcare, The Scientific Publishing Corporation, Hindawi Publishing Corporation, Vol 2014, Article ID 146970

[8] M. AlZain, E. Pardede, B. Soh, J. Thom, Cloud Computing Security: From Single to Multi Clouds, 45th Hawaii International Conference on System Sciences, 2012

[9] Siegel, E.L., Kolodner, R.M., Filmless Radiology, Springer, 1998

[10] Huang, H., K., PACS and Imaging Informatics Basic Principles and Applications, John Wiley & Sons, Inc., 2004

[11] Moreno, R., A., Iversen, T.P.N., Nielsen, K.,S., Furuie, S.,S., Gutierreza, M.,A., Tachinardic, U., Mini-WEBPACS – A Compact System for Storage and Retrieval of Medical Images, Computer Methods and Programs in Biomedicine XX, p1-p2, Elsevier Science, 2005

[12] Chang Won Lee, Kwak, N. K., Strategic Enterprise Resource Planning in a Health-Care System Using a Multicriteria Decision-Making Model, Journal of Medical Systems 35:265–275, Springer Science, 2011

[13] ***, SAP Documentation, SAP Radiology solutions, available at http://help.sap.com/saphelp_erp60_sp/helpdata/en/4d/b0f8b436fe0b59e10000000a42189c/frameset.htm, Last access on October 2012

[14] *** Health Level Seven International (HL7), http://www.hl7.org, Last accessed on October 2014

[15] Khoury, I., Wu, C. S., Chang, C., Cebeci, S., e-Healthcare Web Service Broker Infrastructure for Medical Data Exchange, Oakland University Research Paper, USA, 2011

[16] Anzbock, R., Dustdar, S., Modeling and implementing medical Web services, Data and Knowledge Engineering, 2005

[17] ***, International Organization for Standardization (ISO). ISO/IEC 27000 Information security management http://www.iso.org/iso/home/standards/management-standards.htm, Last accessed on October 2013

[18] Vic (J.R.) Winkler, Securing the Cloud, Cloud Computer Security Techniques and Tactics, Syngress, 2011

[19] ***, Advancing Open Standards for the Information Society, Available at https://www.oasis-open.org/, Last accessed on November 2014

[20] David S. Linthicum, Cloud Computing and SOA Convergence in Your Enterprise – A Step-by-Step Guide, Addison-Wesley Information Technology Series, 2009