



R-Bay
R-Bay; Creating an eMarketplace for the transfer of imaging related eHealth services in Europe.

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Author(s):	Ulf Andersson, Director of Marketing, North Europe, Carestream Health, Andrea Tacchino, Solution Architect, Carestream Health
Partner(s) contributing:	RSD, Mawell

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Project Co-ordinator

Company name: Region Syddanmark (RSD)
Name of representative: Claus Duedal Pedersen
Address: Rugaardsvej 15, 2
5000 Odense C, Denmark
Phone number: +45 65 43 20 30
Fax number: +45 65 43 20 50
E-mail: cdp@medcom.dk
Project WEB site address: www.r-bay.org

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1 Executive Summary

This report is describing the R-Bay project, which aims to enable an eMarketplace for image transferring and reading. The report reviews the harmonisation, interoperability and standards important to the success of the R-Bay project. Interoperability in healthcare is essential for meeting the current and future demands on the systems and the use of international standards will help ensure this interoperability.

R-Bay is a concept to apply modern Internet tools using existing communication standards to provide diagnostic services across a wide geographical area, sharing diagnostic skills in different countries with hospitals requiring specialist or extra diagnostic support.

The R-Bay is built on existing technology solutions:

- Carestream PACS
- Carestream RIS
- Carestream IMS
- Mawell eConsultation

The whole workflow process in R-Bay uses well established standards – HL7 & DICOM V3.0 with established web based tools to apply the facilitator concept for web sales for improved patient care across political and geographic boundaries.

Even though it is too early to draw any conclusions of the R-Bay project, it can be stated that standards and technology appears to support such eMarketplace for image transferring and reading in radiology. However, as stated in the Risk Assessment, system interoperability needs to be addressed by involved vendors. For any connection, it's essential that the involved parties are working together. R-Bay will use the IHE framework to secure this cooperation between the technical parties.

This report does not take into consideration any economical or political aspects this could imply, but focuses solely on the harmonisation, interoperability and standard aspects in the used technology.

2 Introduction

Each and every healthcare system faces the challenges of an aging population, more chronic diseases and an increasing number of exams per inhabitant. Additionally, new technology increases the interpretation time and the number of radiologists is not increasing with the same ratio. Therefore the need of high productivity, work balance and second opinion is increasing. The objective of R-Bay is to offer one solution in facing these challenges.

This report reviews the harmonisation, interoperability and standards important to the success of the R-Bay project and further deployment.

3 Harmonisation

R-Bay will validate the market for eHealth related services using modern Internet tools and existing communication standards to provide diagnostic services across a wide geographical area, sharing diagnostic skills in different countries with hospitals requiring specialist or extra diagnostic support.

R-Bay is a concept to apply acknowledged security solutions and modern Internet tools using existing communication standards to provide diagnostic services across a wide geographical area, sharing diagnostic skills in different countries with hospitals requiring specialist or extra diagnostic support.

The solution and platform permits:

- eInterpretation – eConsultation in first readings & second opinion
- eProcessing for image analysis and image processing
- eArchiving – storage capacity
- eTraining – guidance and learning tool for the use of R-Bay services

The establishment and running of the R-Bay platform requires harmonisation in many different processes. This report will deal with harmonisation in technology by addressing interoperability in healthcare and the use of standards.

Other processes requiring harmonisation are:

- Security – is addressed in WP4 and output available in report D4.2 (draft) and D4.4 (final).
- Legislation - is addressed in WP4 and output available in report D4.1 (draft) and D4.3 (final).
- Business approach – is addressed in WP2 and output available in report D2.3 (draft) and D2.5 (final).

4 Interoperability in Healthcare

The need of medical information technology interoperability is recognised as an important aspect in the improvement of the quality in healthcare. Interoperability is by the IEEE (a non-profit professional association for the advancement of technology) defined as follows:

In healthcare, interoperability is the ability of different information technology systems and software applications to communicate, to exchange data accurately, effectively, and consistently, and to use the information that has been exchanged.

Interoperability can be investigated in different categories in the healthcare domain, such as the interoperability of the messages exchanged between healthcare applications, the interoperability of electronic healthcare records (EHRs), the interoperability of patient identifiers, coding terms, clinical guidelines and healthcare business processes, etc.

For R-Bay the interoperability of systems is important in order to ensure as seamless a workflow as possible for the users and to create a secure environment for the service exchange. There is today technology available that on which to create unified solutions and platforms. A number of interoperability areas relevant to R-bay are identified.

Image transfer

Image transfers are today using DICOM (Digital Imaging and Communications in Medicine) (see chapter on Standards below), which facilitates the communication between entities. However, a validation between vendors needs to occur. The standard is well accepted and therefore integration normally goes very smooth. The R-Bay technology vendors have an extended experience and knowledge within DICOM and its usage.

Patient administration

Countries and even hospitals within the same country can have different patient index, which can create issues when the same patient is entering in different hospitals.

The R-Bay platform will ensure that each image, which reaches the R-Bay server, has its own identifier and will be stored that way. Hence, the problem with different patient index is managed. It is the eConsultation portal which uniquely references a series in the R-Bay archive and associates it to the proper referral. It will send report back to source with proper IDs will as well.

Network security

Network is the channel for information (images and reports). R-Bay services rely fully on network connections; if the network connections are not working properly, the services are not available. Networks in R-Bay base fully on existing networks and generic techniques.

Web based services eLearning, eProcessing and eInterpretation base on HTTPS, which is considered as a secure client-to-client connection. It is used for an example in web-banking. DICOM images cannot be send in HTTPS secured channel and DICOM images are not encrypted. Because of that, DICOM images are sent from hospitals to eArchive inside secure channel basing on VPN technique. Two implementations of VPN technologies are used in R-Bay: Stunnel open VPN and Baltic Health Network.

Baltic Health Network

The Baltic Health Network (BHN) is a secure Internet-based infrastructure which connects all hospitals and other healthcare institutions from Denmark, Norway and Sweden as well as East-Tallinn Central Hospital, Estonia and Vilnius University Hospital, Lithuania.

The Baltic Health network consists of a central node through which all traffic between stakeholders is routed. To be connected to the Baltic Health network, consortium members must establish a VPN connection from their own “secure” nets to the central node. Technical and security requirements for connecting to BHN can be viewed in Annex I.

Stunnel

Stunnel is a program that allows encrypted arbitrary connections inside Secure Socket Layer (SSL). Stunnel can allow secure non-SSL aware daemons and protocols (like POP, IMAP, LDAP, etc) by having Stunnel provide the encryption, requiring no changes to the daemon's code. The Stunnel source code is available under the GNU General Public License, meaning it is free to use in both commercial and non commercial applications.

In the same way Images are using the DICOM protocol, reports are managed through the HL7 (Health Level 7) protocol, see below in 2.4 Standards. Reports are written in e-Consultation portal and then sent via HL7 to requester, this transmission again should be accommodated into cross-country VPN. In order to set up the connection, vendors (sender and receiver) has to be working together to establish the connection.

The existing technology can bridge the mentioned issues. As standards supply the framework on which interoperability will develop, they should be open, public and non-proprietary. Standards specify many of the details necessary to ensure interoperability. However, some critical details are in the hands of the parties that actually implement the standards. Therefore it is essential for any connections that involved parties are working together.

5 Standards

The traditional healthcare systems are changing and a need and pressure to connect local and national systems and applications are emerging. Interoperability can create a unified

and standardised environment for the connections and communication in and between these systems and applications. But in order to achieve this various connectivity and communication standards should be followed. A standard is an agreement among parties within an area of technology. Interoperability is the result of an agreement between or among systems to share information.

Basically, standards in healthcare information technology can be categorised on data transmission standards and medical terminology interpretation standards. In the early stages of implementation, it is unlikely that every system is completely interoperable with each other. But there is a movement towards full interoperability, as interoperability of clinical information from a variety of sources is achieved through the usage of agreed-upon standards. Therefore, initial efforts at achieving interoperability should be focused on the clinical information that is already stored in a coded and structured format, and that would yield the highest clinical value if made interoperable.

IHE – Integrating the Healthcare Enterprise

IHE is an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information. IHE promotes the coordinates use of established standards such as DICOM and HL7 to address specific clinical need in support of optimal patient care.

R-Bay will use the IHE framework to secure interoperability by using the recommended standards and by adhering to IHE's Four Step Process:

- I. Identify Interoperability Problems.** Clinicians and IT experts work to identify common interoperability problems with information access, clinical workflow, administration and the underlying infrastructure.
- II. Specify Integration Profiles.** Experienced healthcare IT professionals identify relevant standards and define how to apply them to address the problems, documenting them in the form of IHE integration profiles.
- III. Test Systems at the Connectathon.** Vendors implement IHE integration profiles in their products and test their systems for interoperability at the annual IHE Connectathon. This allows them to assess the maturity of their implementation and resolve issues of interoperability in a supervised testing environment.
- IV. Publish Integration Statements for use in RFPs.** Vendors publish IHE integration statements to document the IHE integration profiles their products support. Users can reference the IHE integration profiles in requests for proposals, greatly simplifying the systems acquisition process.

DICOM

Digital Imaging and Communications in Medicine (DICOM) is a standard for handling, storing, printing, and transmitting information in medical imaging. It includes a file format

definition and a network communication protocol. The communication protocol is an application protocol that uses TCP/IP to communicate between systems. DICOM files can be exchanged between two entities that are capable of receiving image and patient data in DICOM format. DICOM enables the integration of scanners, servers, workstations, printers and network hardware from multiple manufacturers into a picture archiving and communication system. The different devices come with DICOM conformance statements, which clearly state the DICOM classes they support.

The DICOM Standards Committee exists to create and maintain international standards for communication of biomedical diagnostic and therapeutic information in disciplines that use digital images and associated data. The goals of DICOM are to achieve compatibility and to improve workflow efficiency between imaging systems and other information systems in healthcare environments worldwide. The National Electrical Manufacturers Association (NEMA) holds the copyright to this standard. But DICOM is also a cooperative standard. Connectivity works because vendors cooperate in testing via either scheduled public demonstrations, over the Internet, or during private test sessions. Every major diagnostic medical imaging vendor in the world has incorporated the DICOM standard into its product design, and most are actively participating in the enhancement of it. Most of the professional societies throughout the world have supported and are participating in the enhancement of the standard as well.

DICOM is used by nearly every medical profession that utilizes images within the healthcare industry. These include cardiology, dentistry, endoscopy, mammography, ophthalmology, orthopedics, pathology, pediatrics, radiation therapy, radiology, surgery, etc. DICOM is even used in veterinary medical imaging applications and is making inroads in smaller applications like dentists' and doctors' offices.

HL7 Messages

Health Level Seven (HL7)¹ is an all-volunteer, not-for-profit organization involved in development of international healthcare standards. "HL7" is also used to refer to some of the specific standards created by the organization (i.e. HL7 v2.x, v3.0, HL7 RIM etc.). HL7 and its members provide a framework (and related standards) for the exchange, integration, sharing and retrieval of electronic health information. The standards, which support clinical practice and the management, delivery, and evaluation of health services, are the most commonly used in the world.

The HL7 version 2 standard has the aim to support hospital workflows. Originally created in 1987 it defines a series of electronic messages to support administrative, logistical, financial as well as clinical processes. Since 1987 the standard has been updated regularly, resulting in versions 2.1, 2.2, 2.3, 2.3.1, 2.4, 2.5, 2.5.1 and 2.6. Collectively these versions are known as version 2.x. The v2.x standards are backwards compatible, i.e. a message based on version 2.3 will be understood by an application that supports version 2.6.

HL7 v2.x mostly uses a proprietary (non-XML) encoding syntax based on delimiters. HL7 v2.x has allowed for the interoperability between electronic Patient Administration Systems (PAS), Electronic Practice Management (EPM) systems, Laboratory Information Systems (LIS), Dietary, Pharmacy and Billing systems as well as Electronic Medical Record (EMR) or Electronic Health Record (EHR) systems. Currently, every major medical information systems vendor in the United States supports HL7's v2.x messaging standard.

6 Technical Solution

The technical solution will be described based on the elements that provided clear benefits:

- Carestream PACS
- Carestream RIS
- Carestream IMS
- Mawell eConsultation

Carestream Health image and information management system is supporting the Diagnostic Solution of the R-Bay platform. The platform can accommodate unique workflow requirements throughout the enterprise and has expanded to support the evolution of PACS from a Radiology focused image management system to a mission critical, healthcare enterprise information management system.

The Carestream Client permits the management of requests and orders and then schedules the exams. This system then permits the report to be created electronically using open standards, HL7 which can be integrated at the back end for bi-directional data exchange with information systems. The Carestream RIS can also be integrated at the front end for virtual desktop application, which is fully validated for a Carestream PACS and can be tested for other PACS applications.

The R-Bay platform is being configured based on East-Tallinn Central Hospital installation, se figure 1 below.

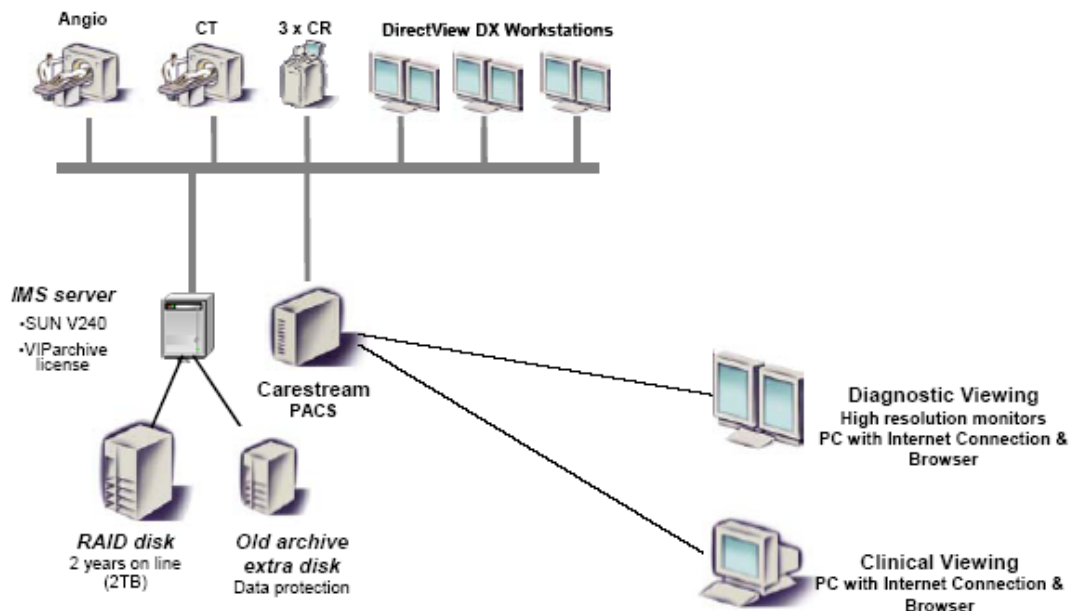


Figure 1 East-Tallinn Central Hospital configuration

eProcessing

The eProcessing service can be described as:

- A high degree of customization available to the workflow, providing the ability to handle the requirements of different institution types, specialty areas, departments, and individuals.
- Native, easy to use tools, including advanced 3D, help radiologists efficiently interpret an increasing number of studies that contain more and more images.
- A compelling suite of tools and capabilities to “reach out” beyond radiology to referring physicians, remote teleradiology and clinical areas of the healthcare enterprise through a number of options such as self playing CDs, distribution via auto-routing or via e-mail etc.
- Streaming technology provides improved dynamic streaming capabilities and is directly available to Carestream Client users. The technology offers fast and advanced visualization and 3D tools to physicians reading extremely large studies over a variety of network speeds.

eArchiving

The eArchiving service can be described as:

- A DICOM conformant, on-line storage and archive environment that can support clinical information lifecycle management to insure information access and preservation.
- Multi-Source, Open Archiving for Medical (e.g. DICOM or ‘ology’) or non-Medical (IT, office or video etc.) data sources. Standard Interfaces e.g. DICOM, FTP, FS interfaces etc and API support for 3rd Party device integration.
- Remote Disaster Recovery with HIPAA Conformance.
- Extreme scalability through state of the art architecture, from a single stand-alone workstation to a large multi-site distributed enterprise.
- Integration ease with modalities and information systems such as HIS, RIS, EMR, and other 3rd party application extensions based upon industry standards.
- Obsolescence Management with preservation data independent of storage or format obsolescence. External DICOM migration is slow and may require new hardware.
- Enhanced Data Lifecycle Management with business rules allow the archive storage versus performance to be optimized Data storage scheduling based on clinical needs e.g. pediatrics - 21 years, or Mammography - 10 years
- Scalability for Growth. Adaptable to various growth factors; sources, redundancy, performance, storage and incremental architecture changes instead of new systems

eLearning

The eLearning service can be described as:

- The Carestream Client is equipped with eLearning functionality to serve different

support relative to facilitate the operability of the system and communication to clients and referring entities, such as On-line help files, e-Report distribution and Virtual Teaching Library.

eConsultation

Mawell has developed an Internet based remote medical consultation solution as the front end of R-Bay, providing consultation and second opinion requests. This is implemented using normal Internet browser tools and requires that certain roles are clearly defined in the workflow; User roles, Request maker, Reporter, multilingual secretary and administrator.

The use of Internet technology overcomes many issues of interoperability also being addressed by the IHE (Integrating the Healthcare Enterprise) with its XDS Profile (Cross Enterprise Document Sharing) to allow integration of other medical data systems across the organizations in R-Bay. The eConsultation uses open standards to communicate with the workflow tools of the RIS, PACS, patient report databases (DICOM, HL7, CDA, IHE). The solution also provides a stand alone function for requests and responses are made and delivered within the solution.

7 R-Bay workflow

R-Bay provides a web interface accessible through normal web browsers, with hospitals requiring a diagnosis for a clinical study, requesting diagnostic support on the R-Bay Portal. The R-Bay Administrator assigns the image to the most appropriate diagnostic support, who receives an email and SMS providing details about the patient and a URL link to the image set requiring diagnosis. The diagnosis is done in the portal and then signed off by the referring physician. The diagnosis is then passed back the requesting hospital via a HL7 message. When the hospital has reviewed the diagnosis, it authorises payment to the R-Bay centre that forwards the payment to the referring physician.

The whole process uses well established standards – HL7 & DICOM V3.0 with established web based tools to apply the eBay concept for web sales for improved patient care across political and geographic boundaries. The system is independent of the local PACS/RIS system and ensures that communication maintains the independence of the local system while enhancing the local teams support for diagnosing images when resources or short or extra skills are needed rapidly.

This whole process is quick, uses simple, available tools and operates over open standards, see figure 1 below.

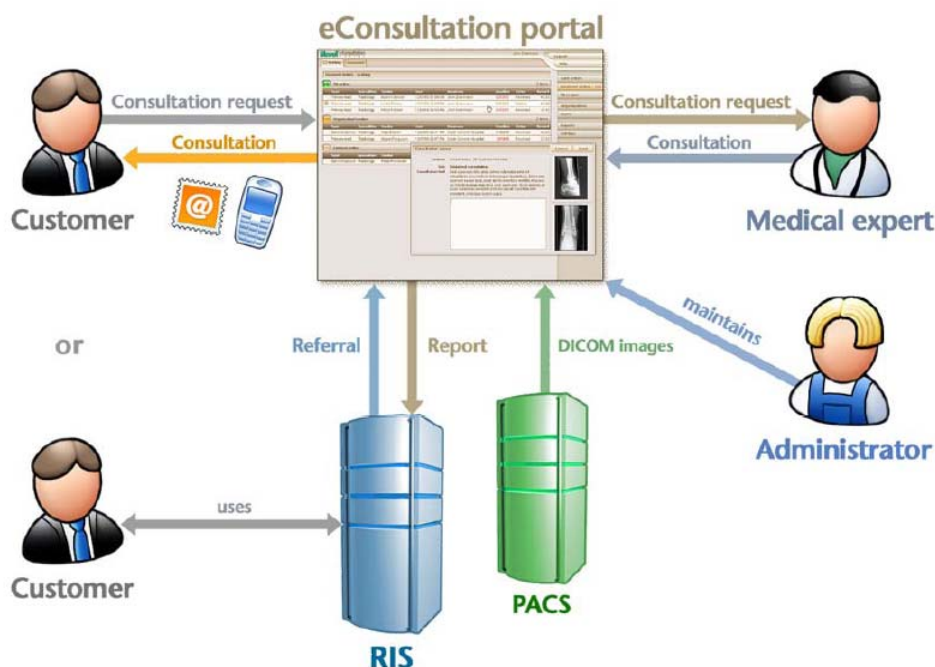


Figure 2, R-Bay workflow

The image review is done across the web and the actual location of the image is transparent to the reviewer.

R-Bay has investigated two options to optimise response times and consider the legal status of PHI in different countries. The first option concerns countries that will not permit PHI e.g. images to be stored outside of the country of origin. In this case, the request contains a URL to the local PACS web server. In the second scenario, where national rules permit images to be stored in a central consolidated archive, and so offering the eArchive option, uses the Carestream IMS solution to offer cost effective intelligent archiving across the appropriate media for the clinical exam. When the study is retrieved by the URL link, the images are viewed in the Web Viewer and can permit diagnostic tools from the PACS to support any diagnostic manipulation that is needed.

Figure 3 is schematic of the information flow and use of open standards for the R-Bay workflow.

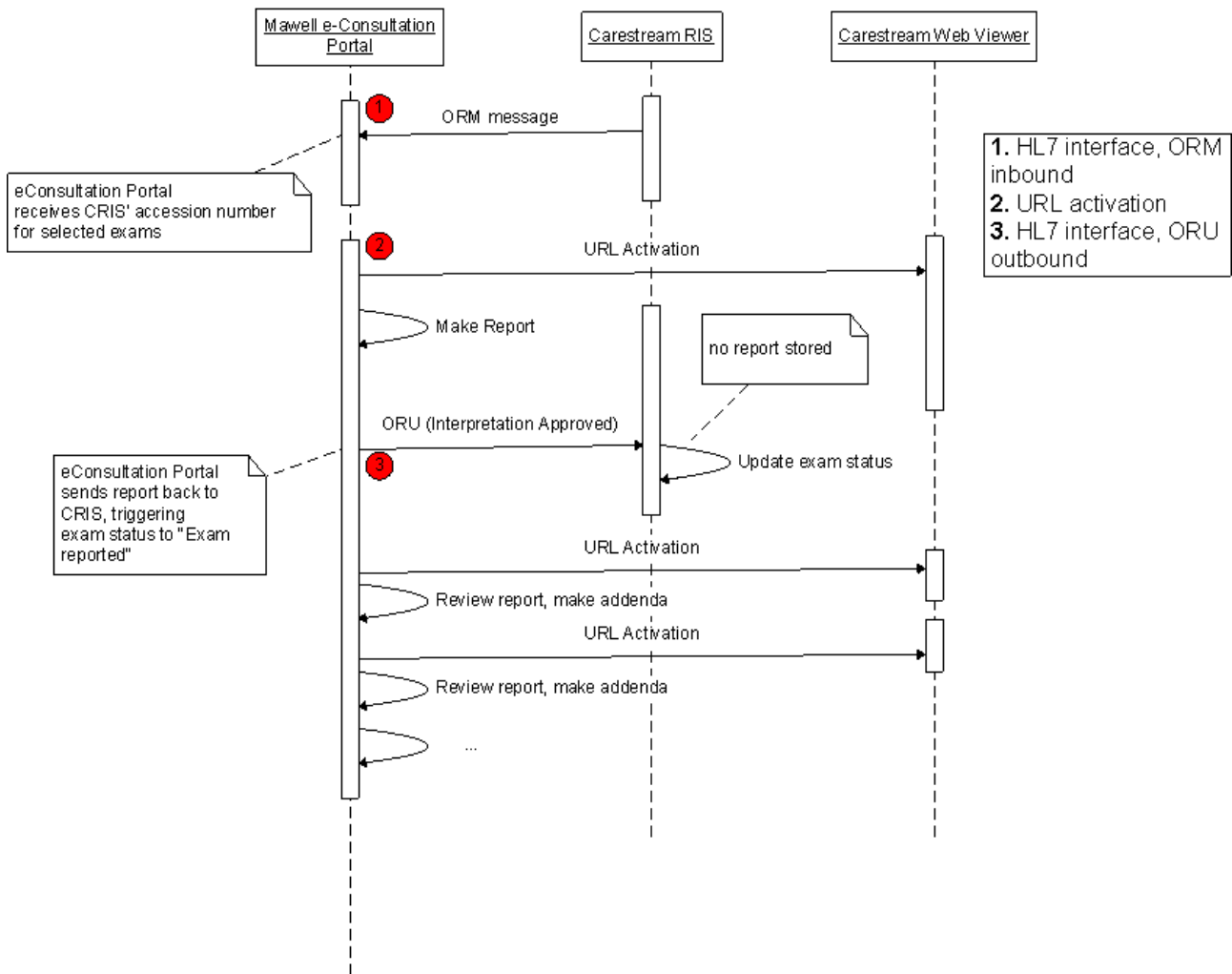


Figure 3, Information flow

The workflow starts in the RIS. The RIS user decides whether to manage (report) current study internally in the hospital or ask for help through R-Bay. In that case, an ORM message (with patient and exam details) is automatically sent to the R-Bay web portal and creates a new order request.

At this point the R-Bay users will assign the new exam to proper provider (specialist, hospital, clinic, or single radiologist) and ask for a report (first reporting or second opinion). Selected provider will be alerted about the new exam available for reporting and will make RIS side (exam status will be sent to "Final answer" in the RIS).

This workflow can apply to Carestream Health's RIS, which is tested and proven functional, and to whatever other RIS systems that can manage the integration described above.

8 Risk Assessment

The R-Bay platform and its solution face some challenging aspects.

- Images are transferred from originating hospital to R-Bay server, most of the times cross boundary. Encryption is key for security and need to be monitored and maintained
- Images are coming from several, inconsistent, different environments. Different hospitals, different countries, etc. this means that it is crucial to manage identifiers properly. Proper Patient identification is a very sensitive aspect.
- Image retention policy inside R-bay server should be very well expressed and clear to all parties. We are storing something we do not own.
- R-Bay technical solution has to maintain high uptime
- Due to the interoperability issues it is essential that vendors representing new R-Bay clients are willing to work closely with the R-Bay team to ensure connections

9 Conclusions

Interoperability can be investigated in different categories in the healthcare domain, such as the interoperability of the messages exchanged between healthcare applications, the interoperability of electronic healthcare records (EHRs), the interoperability of patient identifiers, coding terms, clinical guidelines and healthcare business processes, etc.

For R-Bay the interoperability of systems is important in order to ensure as seamless a workflow as possible for the users and to create a secure environment for the service exchange. There is today technology available that on which to create unified solutions and platforms. A number of interoperability areas relevant to R-bay are identified:

- Image transfer
- Patient administration
- Network security

The traditional healthcare systems are changing and a need and pressure to connect local and national systems and applications are emerging. Interoperability can create a unified and standardised environment for the connections and communication in and between these systems and applications. But in order to achieve this various connectivity and communication standards should be followed.

Key standards for the R-Bay Projects are identified as:

IHE – Integrating the Healthcare Enterprise

IHE is an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information. IHE promotes the coordinates use of established standards such as DICOM and HL7 to address specific clinical need in support of optimal patient care.

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Even though it is too early to draw any conclusions of the R-Bay project, it can be stated that standards and technology appears to support such eMarketplace for image transferring and reading in radiology. However, as stated in the Risk Assessment, system interoperability needs to be addressed by involved vendors. For any connection, it's essential that the involved parties are working together. R-Bay will use the IHE framework to secure this cooperation between the technical parties.

This report does not take into consideration any economical or political aspects this could imply, but focuses solely on the harmonisation, interoperability and standard aspects in the used technology.

Terminology

Terminology	Description
CS	Abbreviation for Carestream Health
DICOM	(see above)
HL7	(see above)
IMS	Information Management System
ORM	Order Entry messages contain the Patient and Order identifiers. It defines the important details of the study/procedure to be done.
ORU	This message type is used to convey the report information (Preliminary or Final) from the RIS to the PACS or other HL7-based destination.
PACS	In medical imaging, picture archiving and communication systems (PACS) are computers or networks dedicated to the storage, retrieval, distribution and presentation of images. The medical images are stored in an independent format. The most common format for image storage is DICOM
RIS	Radiology Information System - used to store, manage and distribute patient radiological data and images.
URL activation	Uniform Resource Locator. Strictly, the idea of a uniform syntax for global identifiers of network-retrievable documents was the core idea of the World Wide Web. In the early times, these identifiers were variously called "document names", "Web addresses" and "Uniform Resource Locators". In this specific case, URL activation means calling a URL against Carestream Health's image viewer (eProcessing) in order to see pictures related to selected study.

References and biography

References

¹ Definition by Wikipedia: <http://en.wikipedia.org/wiki/HL7>

Biography

- R-Bay Description of Work – Technical Annex version 4
- Mawell corporate material on eConsultation
- <http://medical.nema.org/>
- <http://www.ihe.net/>

List of Annex

Annex I – 1_The Internet-based Health Data Net
Annex II - 2_Security and Responsibility