wHospital: a web-based application with digital signature for drugs dispensing management

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Abstract— **wHospital is the result of an information technology research project, based on the utilization of a web based application for managing the hospital drugs dispensing. Part of wHospital back bone and its key distinguishing characteristic is the adoption of the digital signature system, initially deployed by the Government of Lombardia, a Northern Italy Region, throughout the distribution of smart cards to all the healthcare and hospital staffs. The developed system is a web-based application with a proposed Health Records Digital Signature (HReDS) handshake to comply with the national law and with the Joint Commission International Standards. The prototype application, for a single hospital Operative Unit (OU), has focused on data and process management, related to drug therapy. Following a multi-faceted selection process, the Infective Disease OU of the Hospital in Busto Arsizio, Lombardia, was chosen for the development and prototype implementation. The project lead time, from user requirement analysis to training and deployment was approximately 8 months. This paper highlights the applied project methodology, the system architecture, and the achieved preliminary results.**

I. Introduction

WHOSPITAL is initiated as a research project financed by the Directorate for Health of Regione Lombardia, the largest Northern Italy Region. In 2002 the Directorate decided to join the European Community NETC@RDS project [1] in order to deliver smart-cards, and to store personal clinical data for all of the Region citizens and potential patients, about 10 million individuals. This project is classified as CRS-SISS (SISS: Sistema Informativo Socio-Sanitario; Social-Health Information System). At the same time, individual smart-cards were distributed to healthcare and hospital staffs, both medical doctors and nurses/assistants, to provide signature certifications. The CIRS-SISS project goal was to facilitate the progressive distribution of healthcare informatic services across the entire Country territory.

wHospital project was conceived as a stream of the CRS-SISS project, with the objective to add value to the framework designed by the distribution to the hospital staffs of digital signature certification smart cards.

For the prototype digital signature wHospital application, as prime key objective it was decided to reduce the clinical risk, so thinking about patients first. As a consequence, the core of the development work was around the definition of an informatic system focused on drugs delivering management. Indeed, drug delivering processes, managed manually and with paperwork, produces many dispensing errors, above all caused by transcriptions errors [2].

Many automatic dispensing systems have been proposed and some commercial solutions are now available. The main difficulties encountered with the implementing of commercial solutions are linked to the integration with existing ERP systems in the hospital structure and with the costs implied [3]. Moreover the main target for a hospital administration of a public healthcare system, like the Italian one, is the reduction of cost without making significant investments. So, the key point carried out from the above considerations and the storyline behind wHospital, was to have a hospital information system that could be developed and deployed through a sequence of modular steps, Operative Unit by Operative Unit of one or of multiple hospitals, starting from a core application to which specific customizations can be added.

With these specific requirements a web-based system is the natural architecture for easily distributing software application. The main advantage of a web-based application is indeed the easiness of delivering applications through a hospital pre-existent information system: only a *web* browser is needed by the client host. The disadvantage of web architecture is the difficulty in the software programming and implementation of client procedures, such for example the one implied with the digital signature.

Another critical decision was where to develop and test the prototype application. Considering that Busto Arsizio Hospital was the first, in the Lombardia region, that developed a management system compliant with the Joint Commission International JCI Standards [4], its reliable and effective quality management and process flow control procedures became the key decision factor in the selection process. The JCI standards guarantee indeed the appropriate conditions to establish accurate system requirements analysis and to define a core solution largely representative of other OU's needs. In addition, having set the goal of reducing clinical risks and therefore the need to select an Operative Unit where the drug delivery is critical, the Infective Disease

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Operative Unit in Busto Arsizio Hospital was selected as the most appropriate environment for developing and testing the application.

II. User Requirements Analysis and Staff Training Methods

For the specific project it was decided to combine the user requirements analysis with the staff training.

The first 12 hours, divided in 6 sessions, were spent on interviewing the chief medical doctor and the chief nurse about their working processes and the patient's data management as currently done on paper.

This enables the rather quick development of a prototype, not yet with a solid data management system, but appropriate and usable for the staff training purpose. The training was firstly dedicated to the nurses, about 12 persons, divided in group of three, with two hour sessions. The outcome of this training session was the understanding and the usability requirements of the software. Simultaneously the application was re-engineered and additional shadowed analysis (a passive and discrete observing of the working process and practice) were carried out, to map and evaluate doctors and nurses routine activities during the three different working shifts: morning, afternoon and night. Initially, the shadowed analysis was conducted without any software support, then, once the prototype software was developed and locally installed on a Tablet PC, data and working activities were tracked and stored electronically. This second shadowing session was utilized also to test the application and to estimate parameters, such as the lead times or transcription error, of same activities, such as managing the patient vital data patients, when traditionally done on paper versus when performed with the inserting of data in the software application.

After having tested the application, a parallel data management process was put in place, with the hospital staff engaged in tracking vital data and assisting three selected patients over a period of two months, using simultaneously the traditional paper work and the wHospital prototype.

The analysis requirements, the application development and testing and the staff training phases were completed within eight months (Table 1).

TABLE I
Requirements Analysis and Training Phases

Phase	Duration	Activity
1	12 hours	Medical and nurse chief interview
2	8 hours	Staff training on the application prototype
2	8 hours	Usability user requirements analysis
3	16 hours	Shadowing sessions
4	58 hours	Shadowing sessions using software
4	58 hours	Software testing
5	2 months	Staff uses software for 3 patients

Simultaneous phases have an equal's number. The software develop were completed within eight months.

III. System Architecture

In order to utilize the developed web-application near the patient's bed with a Tablet PC, a wireless LAN network was installed. A meshed wireless network (FluidMesh Network, Boston, USA) was preferred to a classical wireless LAN to minimize the time and cost spent for the network installation.

The meshed wireless LAN installed utilizes a layer 3 backbone made by two radio channels of different frequencies 2.4GHz and 5GHz.

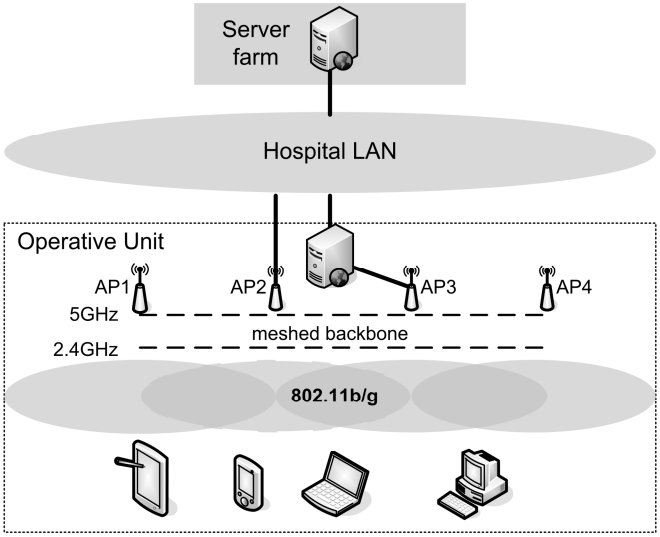

Fig. 1. wHospital network topology. The AP is meshed access point. The elliptical areas represent the layer 2 wireless LAN. The dashed lines represent a layer 3 meshed backbones. The line represents 802.3 LAN connection to the hospital's LAN.

The wireless backbone complies the necessary European Radio Standards [5],[6] whereas the data are managed and encrypted by a proprietary protocol.

The layer 2 network access was provided by the 802.11b/g physical layer standards. In order to cover the UO area and to provide redundant network for any possible breakdown, four meshed access points (APs) were sufficient (Fig. 1).

The Radius/802.1x for the network authentication/access joined with the AES for encrypt the wireless transmission was utilized for implementing a reliable security schema. The security was moreover improved by the use of a local network domain, based on a Windows Active Directory and *https* data protocol for encrypting the web page transmission.

A Windows Server 2003 with IIS Web-Server was placed directly on the OU area, closed in a locked metal chassis, and a backup server was placed in hospital server farm.

The web-based application technology was ASP.Net using the 2.0 .Net Framework, and the software was developed utilizing Visual Studio 2005 by Microsoft. The data base management system was the SQL 2005 by Microsoft.

The developed web-based software implements various sections of patient folder files: patients physiologic initial valuation, clinical daily notices, physiological parameters notation and visualization, but the key point of the system was the prescription and delivering of drugs.

During the daily patient visit, the doctor prescribes the therapy plan that is composed by a list of drugs, with their respective dosages, modality of assumption and frequency of delivery. For every new drug prescribed the doctor or the nurse plans the deliver times, divided in working shifts: morning, afternoon and night. During the daily doctor patient visit the therapies of the day before have to be confirmed or suspended and the new therapies could be prescribed. The new therapies and the confirmed ones have validity until the daily time for the patient visit; this is a specific time for an OU and has to be setup in the system. During the validity time an active therapy could be suppressed, this implies the erase of that therapy from the drug delivery working sheets.

All the above described activities required the implementation of the digital signature procedure, to comply with the national law and with the Joint Commission Standards. The digital signature implementation over client oriented software consists in the application of signature algorithm using the private key stored in the hardware medium, the smart-card, and the PIN code provided by the user. In order to implement such procedures to a web-based application, a client-side signature procedure and a server-side dada validation step are required and summarized here below.

Essentially the proposed data handshake for Health Record Digital Signature (HReDS), is composed by seven main steps.

When the user clicks on the signature link then the *HRe_module* is sent to the web-server. The web-server receives the *HRe_module* and creates an object, dependent from the specific *HRe_module* that implements the *ISignable* interface.

The *ISignable* interface requires 3 methods:

- *GetTextToSign()*, that returns a string composed by the health data attribute in the *HRe_module* that have to be digital signed;
- *SaveOnDb()* that commits the saving data on the management and law databases;
- *ValidateTextSigned() that* implements the control risk procedures checking the health record before saving on the databases.

After the object creation the web-server immediately calls the *GetTextToSign()* method and send back to the client a *web* page containing a formatted *html 3.2* string to be signed, a empty text box, and the "*save signature*" button. The client browser shows the *web* page on browser window and automatic calls the developed digital signature ActiveX.

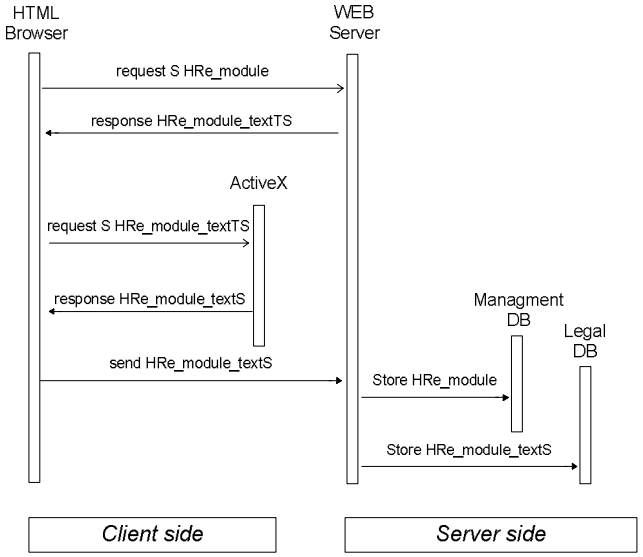

Fig 2. HReDS handshake sequence diagram. *HRe_module* is the generic html page. The dictum "*request S*" indicates the user signature request. *HRe_module_textTS* is the text to be signed whereas the *HRe_module_testS* is text signed.

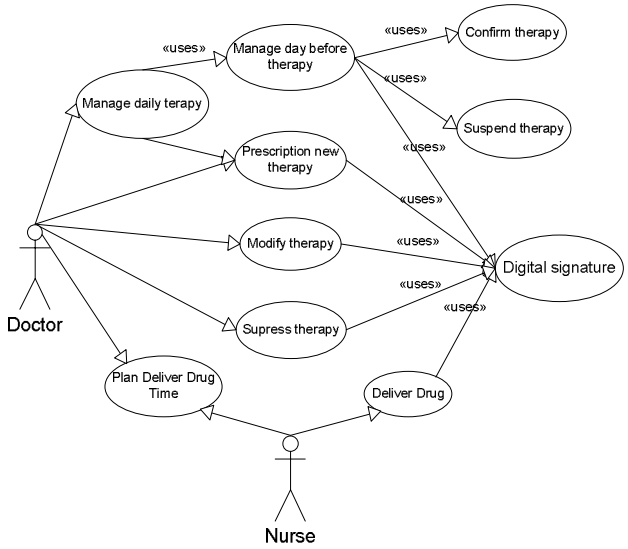

Fig 3. UML use cases diagram for the drug therapy management.

The ActiveX loads a windows form for user's PIN inserting then calls a specific smart-card driver application program interface (API) to sign the *html 3.2* string displayed on the web page. After received the signature from the smart-card driver, the ActiveX inserts the signature and the string signed in the web page text box. At this point the user checks if the signature procedure is terminated correctly and then clicks on "*save signature*" button for sending the filled text box to the web server. The web server, once received the text and the digital signature, calls the *ValidateTextSigned*() method.

In order to validate the health records received the ValidateTextSigned() method implements three operations:

- controls if the string corresponds to the string sent, previously store in the server session side;
- checks if the signature received is related to the string received;
- checks the validity of the signature public key received.

If the *ValidateTextSigned()* method returns a true boolean value then the *SaveOnDb()* method is called. This method stores the data received by the *HRe_Module* in the management database and the string signed and the respective signature to the legal database.

The HReDS handshake implies 3 user actions: the signature request on the *HRe_module*, the PIN insertion, and the final "*save signature*" command (Fig. 2). During the daily patient visit many therapies are confirmed or suppressed, the average number of drugs managed, as observed in the infective disease OU studied, is about 10 for each patient. To increase the speed of the prescription process the *Manage Day Before Therapy* use case, that uses the *Confirm Therapy* and *Suspend Therapy* use cases, sends only one H*Re_module* to the *Digital Signature* use case that implements the HReDS handshake (Fig. 3). The only case that does not utilize the digital signature procedure is the *Time Deliver Drug Planning,* since not required legally and from a quality assurance perspective. In any event, the author and the time of every single planning activity are stored and tracked by the system.

IV. Results and Discussion

Amongst the most challenging project activity was the staff training, especially in using the TabletPC and PDA. The choice to develop a prototype of the system in order to carry out the staff training, helps both for training and user requirements analysis. Every new developed software modules was indeed viewed and approved by the OU staff. With this approach, even the first initial application utilized by the staff had minor impacts on the working process. Moreover, during the shadowing sessions, was immediately possible to estimate a work reduction of about 30 minutes per nurse in the time dedicated to the transcription from the therapies plan sheet to the working sheet. Qualitatively when this activity is automated with wHospital, the related clinical risk will reduce. Other clinical risks, such as the one related to drug dispensing errors, i.e.: from incorrect preparations of the drug dosage, can only be minimized and overcome through the implementation of an automatic dispensing system. A complete quantitative and qualitative analysis of the benefits that wHospital delivers, considering the clinical risk reduction, the working process optimization, as well as the consequently increased care and attention provided to the patient, requires a wider sample of cases.

A main and key aspect, although not deeply analyzed in this report, is related to systems and data security and to its implementation strategy, which could be obtained applying different schemes and approaches [8]. Indeed the presence of many clients in a network domain increases the network management procedures. Whereas this specific aspect has not been critical for the Busto Arsizio solution, with only few "*clients*" of a single OU, for the upcoming wHospital implementations to other OU's and Hospitals further analysis and solutions have been undertaken and are under evaluation.

The use of a digital signature handshake, as the proposed HReDS, shows advantages compared to a digital signature procedure that directly sign the displayed *web* page. A web page could indeed contains data code that has to be interpreted by the browser. The use of a handshake that build an *html 3.2,* a simple ASCII strings, ensures that the data signed is independent from software. The HReDS handshake moreover implements two important control of the health record signed:

- the user can re-control the signed data before saving in the database;
- the server implements a validation of the health records and the public key before storing them in the data base and making them no longer modifiable.

The proposed HReDS handshake is used by each of the wHospital modules and could be implemented on different technology for a generic web based application providing digital signature. The only clients software needed are the device driver of the smart card reader and the digital signature ActiveX that can be provided by a web page and auto installed on a client host.

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