Open Source: A Lever for Enhancing Opportunities of Healthcare Information Systems - An Italian Case Study

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Abstract. Open source is a still unexploited chance for healthcare organizations and technology providers to answer to a growing demand for innovation and to join economical benefits with reliability and a new form of managing hospital information systems. This article will present the case of the web enterprise clinical portal developed by the Niguarda hospital (Italy) with the support of Fondazione Politecnico di Milano, in order to enable a paperless environment for clinical and administrative activities in the ward. Niguarda's strong open source strategy, as well as organizational and technological matters will be described. This represents also one rare case of reuse in the healthcare sector, as the system's porting is now taking place in another hospital, with other institutions evaluating this option.

1 Introduction

Open source is a development method for software that harnesses the power of distributed peer review and transparency of the development process. The promises of open source are better quality, higher reliability (the source code can be consulted), more flexibility, easier application interoperability, lower cost (typically licenses and maintenance), spur of innovation, and an end to predatory vendor lock-in [1]. The use of open source tools in the healthcare sector is not so widespread. The role of open source benefits and the use of technical standards is well described and linked to the functional extension of the Hospital Information System (HIS) and its adherence to clinical users' needs. In Italy, for public administrations, the use of open source and the porting or reuse of successful open source solutions are strongly supported by national rules, but with low results.

The A.O. Ospedale Niguarda "Ca'Granda" is the leading public hospital in Milan since 1939 and a national centre of excellence. It is national reference hospital for emergency events and the only regional point of care qualified to perform any kind of tissue and organ transplant. It hosts 26 centres of high specialization. The Hospital employs 740 doctors and 1,540 nurses, performing 54,000 admissions (both ordinary and Day Hospital) and over 3 millions First Aid treatments per year.

The Clinical Portal solution developed by Niguarda's ICT Unit also with the support of Fondazione Politecnico di Milano, is one case of open source and reuse

of clinical information systems between healthcare organizations: this theme will be described by analyzing a real case of porting of a HIS between hospitals.

2 Open Source in the Healthcare Sector - A Chance for Growth?

Clinical care increasingly requires access to patient record information that may be distributed across multiple sites, and is a whole of free-text, structured, coded and multimedia entries. The challenge of providing clinicians with an integrated view of each patient's health history has so far proved difficult to meet: healthcare ICT (Information and Communication Technology) is often present usually in the diagnostic or administration area, in form of single-point isolated applications not exchanging data. Therefore, acquisition, integration and organization of data is a major challenge [2]. This is even more challenging in the Italian environment, where healthcare CIOs have to face a small number of specialist vendors supplying proprietary solutions, who may not be ready to deal effectively with such modern issues.

Given this situation, the opportunities of ICT [2, 3] and open source [4] in the healthcare sector are considerable. Open source solutions can offer a valid and valuable option to the slowness and difficulties related to information exchange between professionals and foster cooperation between providers, application interoperability, the independence from software vendors. Today, an healthcare provider which is interested in the use of open source can find in the market several kinds of applications, such as systems for radiology management (RIS-PACS), for the organization of the central booking service and for the realization of basic EPRs (Electronic Patient Record). Wikipedia and Apfelkraut.org [5, 6] provide a fairly comprehensive lists of open source software for the healthcare sector. But although the number and kind of such applications are constantly increasing, the reality is implementations is still not widespread in the industry, even if supported by national rules (e.g. in Italy). First, the healthcare sector has special needs: most of the systems are "mission critical" and thus it is absolutely necessary to ensure quality and reliability of the software, its compliance to regional standards, and continuity of service. Moreover, there is a strong need for healthcare organizations to support specific processes with vertical systems, with the use of single speciality solutions (e.g. for radiology's management), which often need further customization. Finally, a sort of "cultural issue" still to overcome, may also contribute.

3 A Real Case of Open Source - Niguarda's Clinical Portal

Since year 2000, Niguarda has been carrying out a new approach to healthcare informatics, completely revising the whole HIS and rethinking the traditional concept of patient record, conceiving it as a core instrument for supporting extensively clinical and management processes. According to this point of view, Niguarda has developed a web enterprise intranet portal (named Clinical Portal), used for operational support to primary processes in the hospital. The Portal is designed as a unique access point to the HIS, networking the other vertical subsystems and thus linking clinical and administrative processes crosswise the organization [7, 8].

By integrating the different vertical subsystems, the Portal provides authorized operators all clinical patient's data, including those relating to previous care events. Thus, thanks to the Portal, each department can access or contribute to the creation of an EPR in order to facilitate the process of care. This is done in compliance with requirements of security, traceability and user's profiling according to Joint Commission standards [9]. The system also supports digital signature entries validation. This can be made in two ways: by the use of username and password ('weak' signature) or by the use of the Regional Healthcare SmartCard ('strong' signature). With the latter, documents and information generated by the Portal can be shared within the SISS network (Sistema Informativo Socio-Sanitario Regionale), enabling hence the feed of an Electronic Health Record at local level in the Lombardy Region (health informatics users usually assign the term EPR to a discrete record, and EHR referred to comprehensive digital patient folders with his whole history).

3.1 The Features of the Clinical Portal

The Portal takes its place "above" the other components of the HIS. In fact, the Portal can be considered as an unique access point to all vertical subsystems, networking them and thus linking clinical processes not communicating before, allowing new information flows sharing patient data, standardizing communication and process interaction between different hospital departments, also introducing automated workflows [8].

Niguarda's Portal allows clinical and administrative management both of inpatients and outpatients. For inpatients, the physician can find several features for the management of patients and units. The Portal allows each ward e.g. to manage directly its logistic, the pharmacy's inventory, and so on. As far as concerns patient's management, the Portal offers several features dealing with administrative data (e.g. DRG list and discharge summary for reimbursement by the NHS) and clinical activities related to hospitalization. During hospitalization, the Portal interface also allows the physician to request speciality exams or consult the repository of the patients' medical reports, both generated by internal function of the Portal (resignation's letter, echocardiography, chest and digestive endoscopy, stress tests,...) or issued by other vertical subsystems (RIS, LIS, pathological anatomy). The reports can be text (in .pdf format) or images (based on a PACS). Recently the Portal has been redesigned by introducing a new functional module, the Clinical Dossier, conceived with a dual purpose: first, to experience a service of EHR that could enable the creation of completely paperless environment, and second, to allow the EHR's management also in mobility within the units through TabletPCs connected to the wireless network. Starting from these two objectives, this module has been tested in distinct environments. Where a high need of mobility was needed, the Clinical Dossier has been implemented so as to provide a more intuitive and rapid interface, allowing the view of medical reports split up by type and date, with the possibility to maintain active the visualization's window while editing e.g. the patient's clinical diary (Portal's tools automatically support free-hand writing digitalization as a text).

The complete EHR is being implemented in an Intensive Care Unit with the support of Fondazione Politecnico di Milano, a research institute connected to the Politecnico di Milano technical university. ICUs are a very data-rich environment, where needs of integration of structured information flows from the biomedical

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instrumentation and LISs, as well as data handling needs are quite demanding. This version of the Dossier implements almost all sheets of the actual paper record, from administrative reports, to daily instructions, to clinical sheets, to transfer/discharge final reports. Also nurses are supported in nursing needs planning, body functions and vital signs monitoring, and so on. To avoid commonplace paper digitalization [10], documents were revised, split into functionalities and organized on daily/weekly views. The ultimate goal is to make this model general and to extend it to all wards.

For outpatients, the Clinical Portal allows the computerized workflow management of the appointments, guiding staff through job planning, appointments management, nurses' reception, examination and reports issuing. Reception can be carried out either by a desktop pc or by Personal Digital Assistant (PDA). Moreover, the physician can access the electronic prescription-book, to request additional services, and view previous reports from the hospital's central repository. At the end of each visit, the physician proceeds to the guided creation of a structured report, and to its digital signature. Since the hospital adheres to the Regional SISS network, physicians have to mark if the report can be consulted online by the patient through the hospital's service of telemedicine, Niguarda OnLine.

Finally, thanks to his open architecture, the Clinical Portal is today one of the few HIS networked within the Regional (SISS) and national (NSIS) health systems as well as integrated with the Regional network of pathologies (oncology, epilepsy, rare diseases). The implementation of open source technologies like RIA (Rich Internet Applications) has been done also for other subsystems, which are now getting integrated into the Portal under a unique user experience. The new PACS is an example of this. This will allow on one hand the seamless support of new processes by the Portal, and on the other hand the extension of videoimagery also to the enhancement of excellence clinical units of Niguarda like Psychiatry (where the system is being now implemented).

3.2 The Architecture of the Clinical Portal

Niguarda's Clinical Portal is a pure web application, developed internally by staff of the IT unit, based entirely on open source technologies and Oracle database, integrated with plug-ins acting as interfaces with external subsystems and rich clients.

Niguarda started in early 2000 with a two-levels web architecture based on JSP (Java Server Pages) including presentation, application logic and data access (deployed on Apache/Tomcat) and Oracle DBMS for data management. This solution had clear leaks regarding: maintainability and performance of applications, complexity and costs of integration of external software components. Now, the architecture of the Clinical Portal is a three-level-architecture deployed as JBoss Web Application, and characterized by a logical division of the three layers:

- 1. Presentation Layer: JSF (Java Server Faces), AJAX, and others;
- 2. Business Logic: Java objects (POJO Plain Old Java Object) for Business delegate and Model layer;
- 3. Data: DAO (Data Access Object) interface, implemented by Hibernate persistence layer, supported by Oracle 9i DBMS for data management.

At the highest level, the user is provided with an advanced and capable interface, based on HTML, JSF and AJAX technology. Some modules of the Portal even belong to the RIA class of web applications: the Clinical Dossier itself is such. At this point, users, interacting with the presentation layer, handle a series of objects, managed by the Front Controller, which is also responsible for displaying proper feedback to users' actions. The Controller then passes objects instances to the layer of business delegate. This one is responsible for all the business logic. Here objects are handled and changed according to the logic of each single application module, by two components: business delegate and model layer. After this, object are passed to the DAO layer, which is responsible for data storage. DAO implements a layer of interfaces, which is responsible for abstracting the interaction with the database, allowing to define standard methods. These can be implemented using different technologies; here we use a Persistence Manager like Hibernate [11]. Finally, data management is done by Oracle 9i DBMS. The advantage of this type of architecture is that it can be easily integrated with external components, both at business level, using the HL7 (Health Level Seven) messaging standard for the communication, and at data level, extending the methods implemented within the Persistence Manager. Today the Portal manages via HL7 also integration procedures like: ADT flows, patient list synchronization, acquisition within the Clinical Dossier of structured data and files from medical reports - e.g. LIS, order transmission to the whole HIS and so on.



Fig. 1. The target J2EE architecture being implemented by Niguarda's Portal [12].

The final step in the evolution path of the Portal will be the transition within 2009 to a fully compliant J2EE architecture [12], as shown above in Figure 1. The target Niguarda is moving towards is an enterprise web architecture, in which the business logic is implemented by Enterprise Java Bean (EJB) on a JBoss application server. This kind of architecture, besides having all the advantages of a 3-levels architecture, has additional features which are very useful for the design and the implementation of Enterprise-class systems. All software components are implemented inside an application server (JBoss) that, as such, contains a series of integrated services including a logger (to track all transactions enforced by the various components), a persistence manager and a web server. But above all J2EE also has important advantages in terms of performance and scalability of the developed system because ensures, through clustering services, the execution on N different nodes. Moreover, an application server adherent to the J2EE patterns allows the use of connection pooling, load balancing and caching services.

The adoption of such an architectural model, leads a deep change also in the organization of the IT Unit at Niguarda. People working on the Portal were organized in a separate unit, divided into different areas dealing each one with a specific architectural layer. Moreover, new patterns were implemented for software development: Unified Process has become a standard, but some teams also experimented AGILE methodologies [13]. Moreover, an internal roadmap has been developed to guide new releases of the system, each new package gets tagged and its code commented before being allowed for release.

3.3 Discussion: The Advantages of Open Source as Experienced at Niguarda

The choice to use open source technologies instead of proprietary technologies for the realization of individual functional blocks allowed to obtain real benefits. First, the adherence to standard open languages, also for application servers and communication protocols, allows easy Portal's integration with external components. The HL7 interoperability layer reduces the amount of problems which has to be faced while configuring the right communication between the components of the HIS. This advantage is even stronger in the healthcare sector, where the HIS consists of many vertical (proprietary) subsystems that must be integrated.

In general, compliance to standards is an important aspect also in assuring application maintainability. The open source software used in the project are designed and maintained by internet virtual communities (often with the support of organizations like the Apache Software Foundation) where continuous testing activities lead to timely release of patches and updates, allows the hospital to access technologies that are evolving faster than proprietary, and that often prove being more stabile, efficient, flexible. Another advantage is that the collaborative development model based on knowledge's sharing makes large amounts of information and support to developers available on the Net. The use of open source languages also provides more opportunities for system customization and system enrichment, thanks to the possibility to enter the code of the program used for the creation of a single functional block of the whole architecture and to personalize it. The availability of the code allows also to move the application on a new architecture, as has been done for example by adapting the Portal to work on multiple devices, including PDAs. Consequently, flexibility and range of program's applications are increasing; this possibility of customization of individuals elements of the architecture would not be possible using proprietary technologies. Finally, the fact that the architecture is made up of individual blocks, rather than a monolithic proprietary solution, allows easily interchangeability of components and their reuse, thus lowering license costs.

Thanks to the use of open source technologies, Niguarda has hence developed the Portal in a safe manner, based on updated and reliable technologies and ensuring interoperability of the different vertical subsystem existing inside the structure and is able to develop quickly and independently from suppliers new features, updating and personalization in order to accommodate the changing needs of the physicians working within the hospital.

3.4 Reuse of the Clinical Portal

The excellent results gained in Niguarda have soon became recognised as a best practice in the region: other hospitals have soon started to consider the Portal as a possible solution for their own realities. One of this hospitals is the "Fondazione IRCCS Istituto Neurologico Carlo Besta" in Milan, a national and international centre of excellence for care and research on neurological diseases, that has chosen the Portal to implement its own clinical information system [14]. The whole project of reuse is based on a porting operation, which, by the definition, is "the process of adapting software so that it can be created for a computing environment that is different from the one for which it was originally designed" [15, 16]. Reusing an application means not merely "recycling" it, but involves complex design activities aiming at making the solution available to be used in different environments. Business analysts and developers from Niguarda and Fondazione Politecnico tried to provide their solution with all the features that should be required by a solution to be considered adequate to be chosen by organizations looking for this kind of applications. A special attention was given to quality level, with open source technologies making it possible to reach compliance to standards, maintainability, reliability, usability and portability. Compliance to standard is essential in ensuring interoperability with existing information systems: this has an impact on strategic decisions, since not communicating systems could affect the decision of installing them, since much more expensive actions should be taken in order to substitute already working systems.

Maintainability is an aspect of real interest for both developers and users, since applications built with standard technologies are expected to require standard actions to be maintained; on Niguarda's point of view, this aspect is reinforced by the fact that maintenance made for one Portal will help preventing bugs also on the other application.

Compliance to standards and open source technologies are also the basis to ensure reliability to the application; the possibility to make a reusable solution fitting different environments makes it probable that the excellent results originally gained could be replied.

Usability and portability are embedded in the definition of the act of porting the application: open source technologies are used to develop a solution that could easily evolve in answer to user feedbacks and requirements.

For Besta, after the first roll-out of the outpatients module in October 2008, benefits that were just potential began to turn out to be authentic: the use of a standard

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language to make possible the communication with other applications revealed efficient, providing the physicians with an updated working list of patients to be visited each day. The continuous monitoring of the process, held by Fondazione Politecnico di Milano, assured an uninterrupted flow of feedbacks from the users to the developers, in order to quickly analyse and solve "infancy problems" of the solution and also to capitalize on flexibility provided by open source technologies, beginning to work in order to improve the solution with current users' requirements.

The benefits gained by Besta are essentially linked to lower costs of the application than those of market packages, in addition to all those linked to the solution's quality and process support, which can be translated in satisfaction expressed by clinicians and future savings on ordinary and evolutionary maintenance costs. On the other side, Niguarda can face lower costs by using open source standards and then, by selling the application already developed, it could cover the costs sustained to build a solution and its extensions working not only for Besta but also for Niguarda itself. The choice of open source technologies allowed Niguarda to find the basic advantages provided by the absence of license costs for acquiring their own portal (reusing products developed on open platform may be more convenient than using solutions based on proprietary components), but also great advantages in the reuse of it, when just small expenses have been required to make the solution fit the environment in which it has been installed.

The process which drove to the choice by the Besta institute of porting Niguarda's application has followed several steps. The first step has been the definition of Besta's requirements, through the evaluation of the procedures followed by physicians of Besta and the definition of the needed functionalities, the evaluation of flexibility and adaptability to changes of current technologies and that of the management's commitment. A detailed analysis over required functionalities was paramount: the more fundamental features are covered by the application, the less is the cost of personalization of the original solution. Besta is a more specialized clinical structure then Niguarda, and so Niguarda's solution covered most of the features required by Besta, but the Portal needed anyway some extensions and customizations (e.g. to feed scientific research databases). A great effort for adequacy verification was dedicated to technological analysis, that is to say the evaluation of software, to evaluate possible technical incompatibilities, as well as the interoperability with already existent solutions. A further analysis was conducted to evaluate the compliance to some quality levels: compliance to standards, maintainability, reliability, usability, support's quality, portability. The use of standard open source languages, as highlighted in the previous paragraph, ensures interoperability and has important impact in assuring maintainability of application. Concerning reliability, it is linked to the reason that a reuse experience is based to success of previous uses. Usability is guaranteed also by a structured training program that Niguarda will hold to Besta's users, by the functionality of eLearning provided inside the Portal and is improved by constant monitoring of functionalities, based on users' feedback, together with a perceptual interface.

The collaboration model realized with Besta allowed to gain other relevant benefits. The solution has been installed on customers' servers and data are stored in their own databases. In this way customers are forced to manage the solution by themselves, even if a continuous monitoring by Niguarda is required, at least in the first stage of the roll-out. This methodology allows Niguarda to gather feedbacks from users of a different environment and, by analyzing data, to understand which criticalities and suggestions could be faced also in the original environment. A virtual private network has been built in order to let developers correct Besta's bugs without the necessity of physically going there; furthermore, each action made on the application is included into a release which modifies both solutions. In addition it is important to remember that open source technologies give the possibility to enlarge the application's features quite easily, then some aspects not presented in the original solution had to be developed "ad hoc"; given to the collaboration model, these new features could be easily transferred back to the original solution.

The challenges in the future are on the organization of the IT structure that will support the evolution of the system. The management of the system and the support of the users are organized in each single hospital, but the evolution of the software should follow a coherent strategy. The governance of this strategy will be a challenge for the actual IT group. The analysis of the processes of application management of the open source world can propose a solution to this problem. In this area the competences and support of Fondazione Politecnico di Milano will play an important role. Moreover, spreading the acknowledgement of the solution among the Region, with positive feedbacks from users, is a unique opportunity to position itself as a reference product, to offer wider features to customers and to gain the attention of public Institutions, which could turn to more chances to get involved in funded research projects.

4 Conclusions

We present the experience of Niguarda as an example of how an open source project could lead, even in the field of public healthcare, to an approach that supports in an effective and efficient way clinical and administrative processes, providing healthcare professionals with useful services and promoting even the redesign of processes. The case of Clinical Portal in Niguarda hospital is a clear case of use of open source technologies to deliver a standard, open and flexible Information System which uses state of the art solutions and reaches top levels of performance and adherence to users' needs. Niguarda's Portal is conceived as a powerful tool to manage clinical and administrative processes in the hospital, experienced by the user as a unique interface also to vertical subsystems in the HIS. It integrates ambulatory and ward management functionalities, workflow capabilities, a modular and flexible EPR accessible through different devices (e.g tablet PCs, PDAs..) depending on the actions to be performed.

The past development of the Portal and its recent migration to a new HL7-J2EE compliant architecture were the chance to implement also new lean procedures and a new organization within the ICT Unit in Niguarda. A detailed view of this new architecture has been provided, highlighting benefits of Niguarda's open source strategy and challenges for developers and management.

Moreover, Niguarda is also an example of another important issue related to open source, that is the reuse of software. In fact, Niguarda, the Istituto Besta in Milan and Fondazione Politecnico di Milano developed an agreement defining a model to manage organizational and technological matters related to the porting and the evolution management of Niguarda's Portal. Thus, the Besta system leverages the benefits of the standard solution of Niguarda in a logic of reuse. The benefits, at economical and intangible level, are also enhanced with a common strategy of technical and functional evolution of the Clinical Portal, shared by the two healthcare organizations. In this context future enhancement projects - as integration with the regional system of Personal Health Record, information management in the neurophysiology units or support of new decision support and data management functionalities for medical researchers - will be developed by the two hospitals using the synergies in an optimized way [14]. This proved reuse being a practice with an increasingly strategic role in public administration and healthcare, as an instrument to achieve significant savings, to have recourse of process's models and solutions already consolidated and share and capitalize experiences. Thus, players of these areas can focus on projects that have already borne real benefits, avoiding to start ad hoc projects or programs, motive of wastes and costs.

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