Integration of e-Health Systems with the Open Source Approach and O3 Example

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Abstract. The key technological challenges in e-Health, namely integration and interoperability of the e-Health information systems are derived from analysis of current situation in the European e-Health world.

The Open Source approach is proposed to face these challenges and the proposition is founded on the basis of the thorough investigation of the Open Source principles and practice considering the European specific situation in the field of e-Health.

A successful case study is presented with it’s domains, organization, community, costs and products in order to practically demonstrate a successful approach that can solve the key challenges of the e-Health technology and implementation in Europe.

Keywords. Ehealth, Open source, Information systems, Integration, Interoperability

1. Introduction

From the practical point of view the term E-health is often confused with the simple digitalization of documents and the partial data. In fact, in the last year we witnessed a very fast growth of stand-alone systems for the management of partial E-health information. The result of this approach is having “islands” of information that cannot share data and more communicate efficiently. This fragmented approach is the first and the simplest step of the process for moving to E-health. The more complex steps are related to the meaning of “sharing”: the information should be accessible not only inside those islands, but also from all systems around them. This is the critical challenge for health in our time and also for the E-health story in Europe. For this reason the most important and also the most common terms in today E-health technology are: integration and interoperability.

Integration means to have the capabilities to communicate and share data with other systems, typically using standard protocols and interfaces. Interoperability is a wider term than integration and extends its meaning. It means, for the systems, not only to communicate but to cooperate together in the most profitable way.

Realizing integration and interoperability on the implementation level and taking care also of privacy and security aspects, can take Europe towards the success in the E-health story.

In the enlistment of possible solutions for fostering the concept of integration and interoperability, the Open Source approach has a great role. In this paper we propose Open Source as an answer to those challenges.

2. Open Source

The highly cited and excellent source on OS philosophy "The Cathedral and the Bazaar" [1] reports that there are two models to develop software:

- The Cathedral model in which everything is well defined: project design, management and developers roles. There is no interaction with the end user, typically the clinicians. This approach is commonly associated to proprietary software.
- The Bazaar model in which the process follows the idea of “creative collaboration”. The roles are not clear as the previous model and there is a great integration between Users and developers. A continuous feedback from the users is crucial for the acceptance of the product and for their satisfaction. This approach is commonly associated to Open Source products.

Open Source development model follows the second method. In this way many companies and individuals can collaborate on a product that none of them could achieve alone. This means
higher development speed and lower overhead. Implementation process

It is proved (the references are listed at the mentioned OSI web page) that OS generally means higher security and higher reliability. The real-world evidence shows that OS also brings robustness, clear flexibility and higher quality if compared to closed software in general.

Open source software has had success in horizontal applications, or applications that are useful in many different industries. These applications include enterprise resource planning and customer relationship management. But open source has had less impact vertically, in applications specific to one single industry, such as health care. The potential market for vertical applications is smaller than that for horizontal applications. Furthermore, the health care industry historically has not made IT a top priority, so it lags behind other, more IT-intensive industries, such as financial services and Internet businesses in adopting OS.

2.2. Open Source in Health Care

When advocating OS in health care applications most of the readers will search for the benefits of having “customers” in the developing team. A continuous feedback from clinicians or technician in all the phases of the development procedure gives an high value to the system. The acceptance problems should decrease and even the switching between the “analogical” approaches to the “digital” ones (ore between two different system) should be easier.

But what is the main advantage that the OS applications bring to the hospitals or healthcare institutions? The advantage is that those organization don’t become prisoners of the vendors. The implementation of close information systems into their daily routine would impose limits to the customization, assistance and evolution of the systems! Open Source guarantees the freedom to decide the best partner for services on a system. The opportunity to have access to the source, guarantees that the health organizations can survive the collapse of their vendor. They are no longer at the mercy of unfixed bugs. And if the vendor's support fees become inflated, they can buy support from elsewhere. But this is not the only advantage.

Clinicians’ use of information systems and the ability of these systems to share patient data are two critical steps in the transformation of the health care. But these accomplishments also pose difficult IT challenges - among them, how to share patient information beyond the walls of individual institutions and clinics, how to bring health care providers into regional networks that can easily and securely exchange that information, and how to expand the use of electronic medical records.

Very good analysis of Open source in health care is a reference [3], where also actual solutions with some concrete software descriptions are suggested.

A. Interoperability and integration in relation to the OS health care history

The IT systems in health care are relatively complex and interdisciplinary – in a typical healthcare institution they are dealing with: information exchange and processing, knowledge management, process integration, research, collaboration, teaching, delivery, evaluation... It is not difficult to guess that the magic words here are “interoperability” and “integration”. In the closed source information systems you get interoperability rare and slow, while in the collaboration environment generated by critical mass of OS developers, interoperability (especially between OS solutions) is relatively easy to achieve. The guiding principle of OS development in health is collaboration in open, problem based, evidence guided manner.

There are several success stories of OS in health care. Early ones (till 2003) are well documented under the SPIRIT project funded by the European commission (http://www.euspirit.org/). Others are WorldVista (Integrated hospital EHR, multimedia patient record), PrimaCare, OSCAR, JEngine, OpenEMed, HAPI and others. In the same paragraph it has to be mentioned that several early (from 1998 to 2001) initiatives failed, mostly due to the premature state of technology and, at that time, low trustworthiness of OS for accomplishing critical missions.

B. Costs associated to the use of OS in health care

One of the most popular arguments for OS is “lower cost” and, while several studies and cases that prove this argument are publicly presented, there are few documented cases for health care environment and almost none for hospitals. As a good documented example from health care, we recommend the study from Beaumont hospital
published by Fitzgerald and Kenny in 2003 [4]. The conclusion of the study is that OS brings substantial savings to the hospital in several fields of IT solutions over 5 year period: Desktop applications by factor 8, Content management by factor 4, Digital imaging by factor 30 and Application server by factor 9.

C. Specifics of the OS development for health care

Health care organizations that develop their own applications using their own programming staff find open source software attractive for four main reasons:
- low cost and ease of acquiring the software,
- growing selection of OS projects results in the independence on supplier,
- wide support for open source standards,
- flexibility
- ability to view and modify the source code.

On the other hand, these organizations often must arrange their own project support. They face the risk that the community developing the open source software may become inactive and cease enhancing it. Small health care organizations, such as group practices, clinics, and most hospitals, do not develop any software themselves. They may engage consultants to customize standard, off-the-shelf applications. For them, the benefits of open source are the lower acquisition cost of the many pieces of software they need to build a complete IT environment. Also, by relying on open source solution gives them greater flexibility and more options in the future.

E. OS for medical devices: CE Marking

It is important to underline that the European legislation on medical devices is very severe. Above all the new versions of EU 92304 and ISO 14971, which are already active, narrow the range of systems utilization inside the hospital. Today the software is considered as medical device only if is a part of a medical device (e.g. the software installed inside a Electrocardiograph) or if the software runs in critical areas. From 1st January 2009 all the software used in the Healthcare is considered as Medical devices. This new definition of clinical software will limit the number of Open Source systems that can freely run inside health organizations. Only Open Source projects with a strong team that do all the tests and analysis required by CE marking process will continue to be available for Health environment.

3. Case study: The Open Three (O3) Consortium

O3 Consortium is a Worldwide project that aims to push a new vision of IT in the Healthcare, fostering the adoption of Open Source Technologies. The Project was born in 2004 after the successful meeting “EuroPACS-MIR 2004 in the enlarged Europe” held in Trieste (Italy). The conclusion of the meeting was that the adoption of open standards and open source solutions is becoming a strictly obligated path to facilitate a fast integration of health systems in Europe and worldwide. In fact, only well supported open source solutions can ensure a worldwide adoption of manager/archiver and cross-enterprise document sharing systems for medical data and images; furthermore, open source promotes the expandability and modularity of solutions, thus allowing collaboration among developers. Finally, open-source assures stability in the service use of the products, being the user – the health-care system in the general sense – able to use it with long-term continuity and also to improve, update, modify and integrate it as much as necessary for his scopes, even in case the developer or the vendor disappears from the market.

Following these guidelines, the Bioingeneering and ICT Group of University of Trieste, under the support of the High Education of Clinical Engineering (HECE), together with the group of the Radiology Department of Padova, started the Open Three Consortium Projects, commonly called O3 Consortium.

O3 Consortium deals with the three domains of the tomorrow’s e-health, in the frame of the European e-health programs: hospital, territory and home-care / mobile-care /ambient assisted living (AAL).

![Fig. 1: The three domains of O3](image)

In the current vision in which at the center of all health services there is the citizen, anywhere he/she is and whatever he/she does, these three
domains should be very strictly interconnected and every actor involved should interoperate with the others. As mentioned above and in a lot of Scientific Articles and also in the real practice, only an Open Source Approach is the first “brick” for moving toward this vision. All O3 Solutions are completely Open Source, released under the GPL license, and freely downloadable from O3 Consortium Website (www.o3consortium.eu) and from SourceForge (sourceforge.net), the biggest and most famous Open Source repository. In 2005 the Faculty of Medicine of the University of Maribor, which is participating in the development and implementation, joined the O3 Consortium.

3.1. O3 Open Approach

The Open Source license is not the unique feature that characterizes the products of O3 Consortium. For a complete interoperability and integration of O3 products it is necessary to extend the meaning of “Open”. In fact all the benefits derived from an Open Source installation are ineffective if the systems use closed standards or proprietary ways to communicate. The Open Approach followed by O3 Consortium is intended in his widest meaning. Open Source of course, but even Open Standards and Open Interfaces. Furthermore O3 has chosen to adhere at the new worldwide interoperability initiative IHE (Integrating the Healthcare Enterprises) [5 and 6]. This initiative aims to solve real integration problems, that IHE calls Profile, by a set of communication rules (transactions) between systems (Actors). Since the development process of closed products is quite slow, in Europe most of the health IT vendors modified their software trying to reach the adherence to this Initiative. O3 Consortium, decided to adhere completely at IHE and it figured out that the only way to reach a complete interoperability was to develop the system as a collection of IHE Actors. The demonstration of the benefit of this new way of thinking the systems can be gathered from the results of the last Connectathons. The Connectathon is a Connectivity Marathon where all vendors test their system for the IHE aproval. The O3 products have been tested successfully at the IHE 2005 Connectathon in Amsterdam and at the IHE 2006 Connectathon in Barcelona, gaining compliance to 19 IHE actors and 15 IHE profiles, having passed more than 300 tests with most of the European market brands.

Another thing to consider when approaching an Open perspective is that an open Source System should use even Open sub layers. Sometimes a lot of Open Solutions uses proprietary libraries or other software as Databases or Application Servers. It is easy to understand that such an approach limit drastically the benefit to have the code freely available. O3 Product use only open sub layers and, when it is possible, they are independent from any software and hardware. The strong usage of Web and Java technology, which is interpreted and not only executed, helps O3 system to be installed in any environment. So O3 doesn’t force to buy license neither for Operative System or Commercial Database. O3 suggests a tested software configuration, completely made of Open Source systems (Linux, Mysql and so on) and, for specific requests, is able to easily adapt the product fitting perfectly to the environment in which they will operate.

Even for Hardware O3 is not bound to any particular hardware configuration or architecture. O3 systems are completely scalable and they can be successfully installed on a laptop, on a big server with secure storage, up to clusters of computers.

3.2. Community

As mention in the first chapters, the software development process can follow two different models: the Cathedral and the Bazaar:

An Open Source initiative, as the O3 one, should follow the bazaar model. Anyway this model shows its limit for a critical use, like inside a Hospital. A confused development process, without a head, can discourage IT specialists and clinicians to adopt the software inside their departments, even though it fits perfectly their needs [7]. To overcome this issue, O3 consortium is organized as follows:

a. The Steering Committee leads the development process of O3 Systems and solutions. It is made of the core team of the Project from University of Trieste together with high personalities in the field of the ICT applied to the healthcare. Those people are both from Academic and Private Area and they cover all the specialties in which O3 Consortium is active

b. The Scientific Committee is made of Clinicians, Technicians, Researchers and other high standing people interested in giving their feedback and their support to the project.
c. The Developer Community is made by all the people that work on O3 Systems. Some of them are employed at the University of Trieste. But the greatest contribute comes from the Open Source Community from all over the world.

d. The User Community is made by local teams where O3 systems are installed. O3 receives continuously feedbacks and suggestions in order to improve the developing process of the systems.

3.3. Cost and services

Since there are no licenses for O3 Products, a healthcare facility that needs to use O3 solutions will pay only the real work for installation, maintenance, customization and assistance. O3 Team is well structured for offering those kinds of services. Each installation has its Project Manager and a Call Center for the first assistance is already available [8].

For the European market the O3 products are marked with the CE Mark. This guarantee that the system is secure and can be installed in critical environment [9].

3.4. Main products

a. O3-DPACS

O3-DPACS is a Java J2EE (Java 2 Enterprise Edition) application. It has been realized as a modular collection of services, as summarized in Fig. 3. As communication protocols, DICOM is used mainly for clinical data, signals and images and HL7 (Health Level 7) for administrative data.

- Storage: to store DICOM objects. The server allows the storage of: 1) images (as all the PACS systems), 2) data, such as reports, in the form of DICOM Structured Reports, Presentation States, and 3) waveforms, such as ECG, EMG, EEG etc., as DICOM Waveform;
- Query/Retrieve of DICOM Objects: to execute query and retrieval of the stored objects via DICOM protocol;
- Modality Performed Procedure Step: to receive messages about the exam completion status and link them to the stored data;
- DICOM Storage Commitment: to verify that data are properly stored and to confirm this to modalities;
- HL7 message interpretation: to manage administrative data, as identifying information exchange, or check for re-alignment of not consistent patient information, i.e., due to a first-aid procedure.

b. The RWS Image-Data Display

The RWS Workstation has the functionalities of a display manager with many additional services. RWS fully supports authentication. Three different authentication systems are provided: the smart card authentication, a basic username/password authentication or a network authentication; the last one provides a fully-traceable sub-system for the management of the use of RWS.

Its object-oriented design offers a common base of essential services for the correct management of different types of data for different source types: it is possible to open medical files from a remote image/data manager (from a PACS) or from the local disk; the file can contain images, signals or pure SR (Structured Reporting) data.

Once the clinical data are taken by one of the different sources as a PACS, a DICOMDIR (a
unique and mandatory DICOM File within a File Set which contains the Media Storage Directory SOP Class) or a local disk, they can be viewed using one the appropriate viewers:

- Image Viewer (also for multi-slice images);
- DICOM Structured Reporting (SR) viewer;
- Waveform Viewer.

It is possible to work on these types of data using also other modules:

- Print Module, allowing a DICOM and non-DICOM print procedures;
- Study Move Module, letting the user moving the selected data to from a PACS server to another one;
- Patient CD module, providing a simple way to burn exams on removable devices, like CDs or DVDs, also creating an html tree model with all the images on jpeg format.

DICOM SR is used both to present numerical data as those related to the Clinical Chemistry Laboratory, as well as to offer a new type of presentation of medical reports, based on structuring the report contents. This approach has been started with radiological reports, and it is under test and evaluation within an international multi-centric group of radiologists.

RWS supports many add-on modules. One of the most claimed modules is O3-TEBAM which actually performs, using an 8-16 CPUs computing system, the 3D electrical brain activity reconstruction.

Fig. 3: An example of multiple image visualization on the O3-RWS workstation

O3-RWS is fully internationalized, allowing its use even in a multi-language hospital or territorial body, and therefore the simple exchange of images and reports between hospitals of different countries using in each country the own language and character set. This is a feature particularly important in multi-lingual regions and countries, as Friuli Venezia Giulia in Italy or Switzerland, which both have four official languages: Italian, German and Ladin/Friulian, plus Slovenian in the first one and French in the second one.

4. References